All redactions on this page are withheld under (b)(6).

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF 19

1. CONTRACT/PURCH. ORDER/ AGREEMENT NO.	2. DELIVERY ORDER/ CALL NO.	3. DATE OF ORDER/CALL (YYYYMMMDD)	4. REQ./ PURCH. REQUEST NO.	5. PRIORITY
SP0700-00-D-3180	0747	2012 May 16	HJ47012132B286K	

6. ISSUED BY CODE FA8075
ESG/PKS
DEFENSE TECHNICAL INFORMATION CENTER
101 WASHINGTON SQUARE, BUILDING 40
OFFUTT AFB NE 68113

7. ADMINISTERED BY *(if other than 6)* CODE S3605A
DCMA DAYTON/ACOD
1725 VAN PATTON DRIVE,
AREA C, BUILDING 30
WRIGHT PATTERSON AFB OH 45433-5302

8. DELIVERY FOB
[X] DESTINATION
[ ] OTHER
(See Schedule if other)

9. CONTRACTOR CODE 79986 FACILITY
NAME AND ADDRESS
BATTELLE MEMORIAL INSTITUTE
505 KING AVENUE
COLUMBUS OH 43201-2696

10. DELIVER TO FOB POINT BY (Date) *(YYYYMMMDD)*
SEE SCHEDULE

11. MARK IF BUSINESS IS
[ ] SMALL
[ ] SMALL DISADVANTAGED
[ ] WOMEN-OWNED

12. DISCOUNT TERMS
10 Days - 00%; 20 Days - 00%; 30 Days - 00%; 0 Days - 00%; Net 30 Days

13. MAIL INVOICES TO THE ADDRESS IN BLOCK
See Item 15

14. SHIP TO CODE HJ4701
DEFENSE TECHNICAL INFORMATION CENTER
DTIC - I
8725 JOHN J. KINGMAN ROAD, STE. 0944
FT BELVOIR VA 22060-6218

15. PAYMENT WILL BE MADE BY CODE HQ0337
DFAS-COLUMBUS-HQ0337
DFAS COLUMBUS/NORTH ENTITLEMENT
P.O.BOX 182317
COLUMBUS OH 43218-2266

MARK ALL PACKAGES AND PAPERS WITH IDENTIFICATION NUMBERS IN BLOCKS 1 AND 2.

16. TYPE OF ORDER			
	DELIVERY/ CALL	X	This delivery order/call is issued on another Government agency or in accordance with and subject to terms and conditions of above numbered contract.
	PURCHASE		Reference your quote dated Furnish the following on terms specified herein. REF:

ACCEPTANCE. THE CONTRACTOR HEREBY ACCEPTS THE OFFER REPRESENTED BY THE NUMBERED PURCHASE ORDER AS IT MAY PREVIOUSLY HAVE BEEN OR IS NOW MODIFIED, SUBJECT TO ALL OF THE TERMS AND CONDITIONS SET FORTH, AND AGREES TO PERFORM THE SAME.

Battelle Memorial Institute — Digitally signed by [redacted] DN: cn[redacted] Date: [redacted] E — Contracts Manager — 16 May 2012

NAME OF CONTRACTOR — TYPED NAME AND TITLE — DATE SIGNED (YYYYMMMDD)

[X] If this box is marked, supplier must sign Acceptance and return the following number of copies: 1

17. ACCOUNTING AND APPROPRIATION DATA/ LOCAL USE
See Schedule

18. ITEM NO.	19. SCHEDULE OF SUPPLIES/ SERVICES	20. QUANTITY ORDERED/ ACCEPTED*	21. UNIT	22. UNIT PRICE	23. AMOUNT
	SEE SCHEDULE				

* *If quantity accepted by the Government is same as quantity ordered, indicate by X. If different, enter actual quantity accepted below quantity ordered and encircle.*

24. UNITED STATES OF AMERICA
TEL: 402-232-8658
EMAIL: alvin.butler@us.af.mil
BY: Alvin Butler
CONTRACTING / ORDERING OFFICER

25. TOTAL $534,260.00
26. DIFFERENCES

27a. QUANTITY IN COLUMN 20 HAS BEEN
[ ] INSPECTED [ ] RECEIVED [ ] ACCEPTED, AND CONFORMS TO THE CONTRACT EXCEPT AS NOTED

b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE — c. DATE (YYYYMMMDD) — d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

f. TELEPHONE NUMBER — g. E-MAIL ADDRESS

36. I certify this account is correct and proper for payment.
a. DATE (YYYYMMMDD) — b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

28. SHIP NO. — 29. DO VOUCHER NO. — 30. INITIALS

[ ] PARTIAL [ ] FINAL

31. PAYMENT
[ ] COMPLETE [ ] PARTIAL [ ] FINAL

32. PAID BY

33. AMOUNT VERIFIED CORRECT FOR

34. CHECK NUMBER

35. BILL OF LADING NO.

37. RECEIVED AT	38. RECEIVED BY	39. DATE RECEIVED (YYYYMMMDD)	40. TOTAL CONTAINERS	41. S/R ACCOUNT NO.	42. S/R VOUCHER NO.

DD Form 1155, DEC 2001 — PREVIOUS EDITION IS OBSOLETE.

Section A - Solicitation/Contract Form

a. Work shall be accomplished in accordance with the Department of Defense (DoD) Information Analysis Center (IAC) Technical Area Task (TAT) Statement of Work entitled, "FDA Food Defense Planning, Identification of Mitigation Strategies, and Training" for CB 12-0341.

b. The total estimated cost of this effort, including Base and Option Period(s), is (b)(4) consisting of (b)(4) estimated cost and (b)(4) fixed fee. This task is partially funded.

c. CLIN 0200, O&M Funding, is supported by the following MIPR(s):

Food and Drug Administration – OFDCER
5100 Paint Branch
College Park, MD 20740

MIPR # 224122010 Basic, Dated: 2 May 2012 Reimbursement/Cat I (b)(4)

d. The amount obligated is (b)(4) consisting of (b)(4) estimated cost and (b)(4) fixed fee. The current funding is estimated to support contractor performance for months of the award period(s). The total period of performance for this task is 36 months, including Base and all Option Periods.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	EST. QUANTITY	UNIT	UNIT PRICE	AMOUNT
0100			Lot		

Other than O&M Funding
CPFF
Perform Technical Area Tasks in accordance with Statement of Work.
FOB: Destination
PURCHASE REQUEST NUMBER: HJ47012132B286K

ESTIMATED COST
FIXED FEE
TOTAL EST COST + FEE $285,998.00

ITEM NO	SUPPLIES/SERVICES	EST. QUANTITY	UNIT	UNIT PRICE	AMOUNT
0200			Lot		

O&M Funding
CPFF
Perform Technical Area Tasks in accordance with Statement of Work.
FOB: Destination
PURCHASE REQUEST NUMBER: HJ47012132B286K

ESTIMATED COST
FIXED FEE
TOTAL EST COST + FEE

ACRN AA
CIN: HJ47012132B286K0000AA

ITEM NO	SUPPLIES/SERVICES	EST. QUANTITY	UNIT	UNIT PRICE	AMOUNT
1100 OPTION	Other than O&M; Option 1 CPFF Perform Technical Area Tasks in accordance with Statement of Work. FOB: Destination PURCHASE REQUEST NUMBER: HJ47012132B286K		Lot		

ESTIMATED COST	
FIXED FEE	
TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	EST. QUANTITY	UNIT	UNIT PRICE	AMOUNT
2100 OPTION	Other than O&M: Option 2 CPFF Perform Technical Area Tasks in accordance with Statement of Work. FOB: Destination PURCHASE REQUEST NUMBER: HJ47012132B286K		Lot		

ESTIMATED COST	
FIXED FEE	
TOTAL EST COST + FEE	

Section C - Descriptions and Specifications

STATEMENT OF WORK

TAT Statement of Work Authorization Page

IAC: CBRNIAC (SP0700-00-D-3180)

TAT Number: CB-12-0341

Estimated Duration: 36 months

TAT Title: FDA Food Defense Planning, Identification of Mitigation Strategies, and Training

IAC POC (Contractor):	**IAC Technical POC (Contractor):**

Requiring Activity (RA) (government):	**RA Technical POC (government) - *optional*:**
Directorate: US Food and Drug Administration	Directorate:
Office Symbol: FDA/CFSAN/FDOT	Office Symbol:
Attention Line: Julia Guenther	Attention Line:
5100 Paint Branch Parkway HFS-007, Room 2A017	Street Address
College Park, MD 20740	City, State, Zip
office: 240-402-1637 mobile: 240-753-4023	Phone:
Fax:	Fax:
Email: Julia.guenther@fda.hhs.gov	Email:
DUNS#: 927645523	DUNS#:

1.0 BACKGROUND: The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 to enable the Food and Drug Administration (FDA) to better protect public health by strengthening the food defense system against intentional and unintentional contamination. FSMA gave FDA a number of new authorities, including setting requirements for the protection against intentional contamination. In support of this effort, FDA's Food Defense Oversight Team (FDA/FDOT) has identified the need to further develop and evaluate a number of food defense tools and resources to better align with the agency's current thinking and the FSMA requirements.

Specifically, the FDA FDOT has identified the need to 1) further develop and test the Food Defense Plan Builder tool to facilitate implementation of the regulation to prevent intentional contamination and review the results of merged vulnerability assessment software and Mitigation Strategy Database (MSD) to confirm that appropriate mitigation strategies are assigned to vulnerability assessment software results, 2) perform a detailed review of the existing mitigation strategies database, provide content updates where applicable, 3) perform a detailed review of existing and new vulnerability assessment software modules, 4) conduct vulnerability assessments of key areas within a food system that are susceptible to intentional contamination. These key areas include identifying means for prevention and protection of food systems, and 5) perform studies and analyses for the FDA/FDOT to analyze food defense related issues, capabilities, and tools to identify technological or policy gaps and constraints that may limit the execution of FDA's food defense mission.

Other IAC TATs for this Requiring Activity (RA):

IAC	Delivery Order #	TAT Title	Follow-on (Y/N)
	None		N

2.0 OBJECTIVE: The objective of this TAT are to deliver a Food Defense Plan Builder Software tool, perform a detailed review of the existing FDA Mitigation Strategies Database (MSD), provide content updates where applicable, and review the results of merged vulnerability assessment (VA) software and MSD to confirm that appropriate mitigation strategies are assigned to VA software results, perform a detailed review of existing and new vulnerability assessment software modules, perform vulnerability assessments of up to thirty (30) food systems, and perform studies and analyses for the FDA/FDOT to analyze food defense related issues, capabilities, and tools to identify technological or policy gaps and constraints that may limit the execution of FDA's food defense mission.

3.0 TASKS:

3.1 (Task 1) – Post Award Orientation Conference

The post-award orientation conference will be held within 30 days of award. The CBRNIAC will schedule and conduct this meeting, in coordination with the RA, Contract Officer's Representative (COR), IAC Program Management Analyst (PMA), and Procuring Contracting Officer (PCO). Participation may be in person or via telephone; attendance by the COR, PMA, and CO is optional. Within 5 business days, the CBRNIAC will provide the RA with meeting minutes and a copy of the slides; a courtesy copy of these, including a list of attendees, shall be provided to the COR, PMA, and CO.

The purpose of the post-award conference is to: 1) explain unique characteristics of the IAC model; 2) identify stakeholders' roles and responsibilities; and 3) establish a common understanding of cost, schedule, and performance expectations.

CBRNIAC will create the following deliverables in support of this task:
Post-Award Brief and Minutes (Deliverable 4.1)

3.2 (Task 2) – STI Relevance Assessment and Gap Analysis

CBRNIAC TAT POCs shall maintain close coordination with Basic Center of Operations (BCO) personnel/resources, to ensure TAT performance builds on the breadth of the BCO knowledge base. TAT performance provides an opportunity to validate BCO research/scientific technical information (STI) in a specific, operational context. Further, TAT operational requirements provide real-time assessment of areas where STI is most needed. The intent of this task is to explore and documents the relevance of BCO STI resources in supporting TAT requirements, as well as to identify potential gaps in the BCO knowledge base based on TAT requirements.

The STI relevance assessment and gap analysis performed annually, builds on the STI literature search performed as a part of SOW development. It identifies, by SOW task, how much STI (gathered from DTIC databases, IAC Quad Charts in DoDTechipedia, and other sources) has been actually used to inform the work performed under the current TAT. The IAC shall provide the number of relevant STI search results (from the literature search, or subsequent post-award searches) that was actually employed in executing the SOW task. For each search term, highlight noteworthy examples of how STI significantly contributed to the performance of that particular task. For each task, identify any perceived gaps in the knowledge base (e.g., the task required information on XYZ, but the literature search did not turn up STI in XYZ). These "STI Gaps" serve as a signal for the BCO that they may need to build knowledge in XYZ (i.e., establish focused STI collection for "XYZ"), especially as the BCO notices trends where similar entries are made in this column across multiple TATs.

CBRNIAC will create the following deliverables in support of this task:

3.3 (Task 3) – Food Defense Plan Builder Software Tool Development and Content Review

The CBRNIAC shall further the development of a software application, the Food Defense Plan Builder Tool. The "Tool" will be utilized by companies and users authorized by the FDA. The tool will be a stand-alone desktop application that can be downloaded and installed by the end user on their own computer without any requirement to access additional data from the FDA or the sending of any data to the FDA from the application after installation. The Tool will allow the end user to create a basic Food Defense Plan by way of the Tool as a stand-alone desktop application. The Tool will be developed in multiple phases and will meet the FDA IT Standards and the IT Investment Management (ITIM) Process for the Tool. This includes following the agency's Enterprise Performance Life Cycle (EPLC) management process. The CBRNIAC shall share information and provide full access to code, constructs, databases, and documentation while delivering integrated, cohesive business and technology services and products.

3.3.1 **Administration and Guidance Resources.** The contractor shall update the existing Administration and Guidance resources within the existing FDPB with requested improvements.

3.3.2 The CBRNIAC shall integrate the Tool with the FDA VA Tool. This integration will allow the Plan Builder Tool to access VA data so that relative risk to intentional contamination and production process data will be available to the Plan Builder Tool. The VA Tool calculates the relative risk of individual production nodes to intentional contamination to identify nodes where risk of a potentially successful terrorist attack is greatest.

3.3.3 The CBRNIAC shall review the tool to ensure proper integration of the MSD and VA Tool. Resulting findings will be compiled into a report for FDA review. The CBRNIAC will incorporate any changes requested by the FDA

3.3.4 The CBRNIAC shall develop a self assessment audit tool for the Food Defense Plan Builder Tool that will allow users to create a self-assessment check list based on the Food Defense Plan created in order to perform regular internal audit type activities against a given food defense plan.

3.3.5 The CBRNIAC shall develop basic "help" information for the Food Defense Plan Builder Tool to be included in the Tool.

3.3.6 The CBRNIAC shall follow Health and Human Services (HHS's) Enterprise Performance Life Cycle (EPLC) management process and the FDA Information Technology Investment Management (ITIM) process. EPLC is a process-driven IT life cycle management approach emphasizing enterprise integration based on development of sound business and technical requirements. ITIM ensures that products in support of the FDA mission are produced using standard technologies that have been through a specialized review and approval process. To realize the benefits of the life cycle methodology, and achieve the success of the services model, FDA will depend on the adherence to its information technology standards. CBRNIAC shall share information and provide full access to code, constructs, databases, and documentation while delivering integrated, cohesive business and technology services and products. The expected level of required cooperation in the system or software development and testing processes is unprecedented in FDA's experience and is central to the success of the endeavor. Products developed under this contract shall be considered to be owned by the Government and shall not be labeled 'copyright' or 'proprietary' or anything similar that might obstruct the desired environment of fluid sharing and partnership.

3.3.7 The CBRNIAC shall be familiar with Section 508 requirements as described at http://www.section508.gov/ in order to ensure that documents generated as part of the tasks are fully Section 508-accessible using the available COTS tools. All Electronic Information Technology (EIT) products and services proposed shall fully comply with Section 508 of the Rehabilitation Act of 1973, per the 1998 Amendments, and the Architectural and Transportation Barriers Compliance Board's Electronic and Information Technology Accessibility Standards at 36 CFR 1194. CBRNIAC shall identify all EIT products and services proposed, identify the technical standards applicable to all products and services proposed and state the degree of compliance with the applicable standards. Additionally, the CBRNIAC must clearly indicate where the information pertaining to Section 508 compliance can be found (e.g., Vendor's or other exact web page

location). CBRNIAC must ensure that the list is easily accessible by typical users beginning at time of award. CBRNIAC must ensure that all EIT products and services proposed that are less than fully compliant, are offered pursuant to extensive market research, which ensures that they are the most compliant products available to satisfy the task order's requirements. If any such EIT product or service proposed is not fully compliant with all of the standards, the CBRNIAC shall specify each specific standard that is not met; provide a detailed description as to how the EIT product or service does not comply with the identified standard(s); and shall also indicate the degree of compliance.

3.3.8 The CBRNIAC shall conduct up to three (3) focus groups and/or user testing workshops with the intended users to assess the usability of the Food Defense Plan Builder Tool. The CBRNIAC shall compile the resulting feedback from the focus groups/user testing workshops into a report for FDA review.

3.3.9 The CBRNIAC shall provide technical support, subject matter expertise, and final upgrades/modifications to the FDPB Tool to support the launch and rollout of the Food Defense Plan Builder Tool. This includes providing the technical support necessary to launch the tool on FDA.gov.

CBRNIAC will create the following deliverables in support of this task:
Food Defense Plan Builder Software Tool and Report (Deliverable 4.5)

3.4 (Task 4) – FDA Mitigation Strategies Database (MSD) Content Review

The CBRNIAC shall research and identify food defense mitigation strategies, in consultation with FDOT, in support of the FDA's Food Defense Regulation/Guidance document development process under the FSMA

3.4.1 The CBRNIAC shall review the existing MSD. The review will focus on database content and data gaps; but will also include review of database layout, information presentation, and general user friendliness. Resulting recommendations will be compiled into a draft report for FDA review. The CBRNIAC will incorporate any changes requested by the FDA. The draft report will be used for further development of the MSD during a face-to face workshop with the FDA (Task 3.4.2)

3.4.2 The CBRNIAC shall prepare for and a hold face-to-face meeting to review the draft report from Task 3.4.1 with the FDA. The CBRNIAC shall prepare a final report based on the review of the existing database and results of the face-to face meeting for delivery to the FDA

3.4.3 The CBRNIAC shall research existing FDA VA results and other sources to include DTIC databases, to identify additional appropriate mitigation strategies for critical nodes common to the food industry and to fill data gaps identified in Tasks 3.4.1 and 3.4.2. The CBRNIAC shall consult with industry and trade organization subject matter experts that participated in previous FDA VAs for input.

3.4.4 The CBRNIAC shall identify recommended mitigation strategies to be considered by the FDA for inclusion in the MSD and other guidance documents.

CBRNIAC will create the following deliverables in support of this task:
FDA Mitigation Strategies Database (MSD) Content Report (Deliverable 4.6)

3.5 (Task 5) –Vulnerability Assessment Software Module Review

3.5.1 The CBRNIAC shall perform a detailed review of existing and new VA software modules developed by the FDA's Software contractor. The review will focus on software design and functionality, content and examples for help screens, and proper integration of the MSD. In addition, for previously reviewed modules, the CBRNIAC shall follow-up on the successful incorporation of previously recommended changes. Finally, for the Retail VA module, the CBRNIAC shall evaluate the technical aspects of each question for content, appropriateness of the question, flexibility for various industries within the retail sector, and availability of appropriate pre-populated answers.

3.5.2 The CBRNIAC shall compile resulting recommendations into a draft report for FDA review. The CBRNIAC will incorporate any changes requested by the FDA. The draft report will be used for further development of the VA software modules during a face-to face workshop with the FDA) (Task 3.5.3)

3.5.3 The CBRNIAC shall prepare for and hold a face-to-face meeting to review the draft report from Task 3.5.2 with the FDA.

3.5.4 The CBRNIAC shall prepare a final report based on the review of the existing database and results of the face-to face meeting for delivery to the FDA

CBRNIAC will create the following deliverables in support of this task:
Vulnerability Assessment Software Module Report (Deliverable 4.7)

3.6 (Task 6) –Vulnerability Assessments (VA) on Food Products

The CBRNIAC shall conduct up to 30 assessments of food products over 3 years as identified by the FDA/FDOT. The intent of these assessments will be to identify security gaps, increase awareness and coordination between the food and agriculture sector and the United States Government (USG), develop processes to reduce identified vulnerabilities, and identify/define research needs.

3.6.1 The CBRNIAC shall identify subject matter experts (SMEs) from the food industry, academia, trade groups, and local, state, and federal regulators to participate in distinct focus groups (2-4 members) for each assessment.

3.6.2 The CBRNIAC shall provide the focus group participants with project background information and expectations of participation, and will establish/agree on the process flow to be used in the assessment.

3.6.3 The CBRNIAC shall use the most appropriate vulnerability assessment tool at the assessment to evaluate the food process/system.

3.6.4 The CBRNIAC shall submit a VA report that includes the data collected and analyzed at each of the assessment meetings. These reports will be portion marked as unclassified, confidential or SECRET as outlined in the security guidance manual that FDA/CFSAN/OFDCER will provide. PowerPoint slides are to accompany each report (CFSAN/OFDCER to provide a template). FDA anticipates the final presentations to be classified SECRET. Each report shall contain:

3.6.4.1 Overview and flow diagram with associated process description of each food process/system evaluated.

3.6.4.2 Discussion of vulnerabilities of process nodes and identification of critical nodes.

3.6.4.3 Discussion of mitigation strategies to reduce the threat/prevent an attack. Strategies may include actions that either industry or government may take to reduce vulnerabilities with emphasis on critical nodes.

3.6.4.4 Description of allocation/sourcing of ingredients used to produce the product evaluated (including country(s) of origin).

3.6.4.5 Discussion of research needs potentially drawing from the following areas that have been identified previously as needs.

3.6.4.5.1 Threat-agent and agent/matrix research including prioritization of threat agents for specific foods, physical/chemical/ environmental characteristics of threat agents and their sensitivity to such factors, and toxicity and accessibility of such agents.

3.6.4.5.2 Incident detection including available methods, accessibility of such methods to industry, and ease/speed of use.

3.6.4.5.3 Incident magnitude and response including modeling of economic consequences, recovery of consumer confidence, and decontamination/disposal procedures.

3.6.4.5.4 Improved communication channels with emphasis on facilitated/simplified means for sharing information and determining point-of-contact.

3.6.4.6 For update assessments the CBRNIAC shall conduct an independent comparison of the update meeting outcomes to the original VA outcomes. The VA report will include 1) a summary of the process review discussion with emphasis on changes as compared to the original VA 2) a summary of vulnerability discussion with emphasis on changes as compared to the original VA, and 3) a summary of the likely reasons a particular vulnerability was raised or lowered compared to the original VA, what process changes directly resulted in the vulnerability change, and what prompted the food process change.

3.6.5 The CBRNIAC shall provide unclassified working notes to all VA participants.

CBRNIAC will create the following deliverables in support of this task:
Vulnerability Assessments (VA) on Food Products (Deliverable 4.8)

3.7 (Task 7) – Food Defense Studies and Analyses

Upon review and approval by the FDA/FDOT of a plan to conduct an analysis, the CBRNIAC shall analyze food defense related issues, capabilities, and tools to identify technological or policy gaps and constraints that may limit the execution of FDA's food defense mission. These analyses will identify potential courses of action to address identified gaps and constraints, and make recommendations to decision makers to improve food defense capabilities. The CBRNIAC shall perform up to six (6) analyses. Each analysis will be documented in a report of mutually agreed format.

CBRNIAC will create the following deliverables in support of this task:
Food Defense Studies and Analyses (Deliverable 4.9)

4.0 DELIVERABLES/REPORTING REQUIREMENTS:

Not all deliverables required by this SOW are STI. Examples of deliverables that are typically **not** considered to be STI are monthly progress reports, trip reports, financial status reports, workload and staffing plans and reports, cover/transmittal letters, plans of action and milestones (POA&Ms), etc. **An SF298 Report Documentation Page is a required submission for STI deliverables only.**

4.1 Post-award brief and minutes. Post-award orientation meeting to discuss cost, schedule, performance (including RA requirements and IAC approach, with specific focus on IAC model of building on BCO knowledge base and producing STI for future reuse).

4.2 STI Relevance Assessment and Gap Analysis. Annual summary of STI used in performance of tat, including value of that STI and feedback on its usefulness in the context of the tat. Also includes summary of tat needs for STI unmet by the existing BCO knowledge base (i.e., areas where additional BCO STI would have been useful in performance of the tat).

4.3 Monthly Status Report. Includes, at a minimum, task expenditures versus planned expenditures, technical progress made, schedule status, travel conducted, meetings attended, PCO approved equipment/materials procured and excessed, issues and recommendations. The monthly status report is intended to report on cost, schedule, and performance against sow requirements, providing information at the tat task level. As such, it will identify funding compared to ceiling, planned versus actual expenditures, deliverables funded and date they were funded, technical progress made and schedule status per deliverable, deliverables completed within the previous reporting period, identifying them by title and number, and will indicate what deliverables are scheduled to be delivered during the upcoming reporting period. Specific format and content shall be mutually agreed upon by the IAC and RA, per the guidance contained herein; status report format should be established no later than the post-award conference. The monthly status report shall be in pdf format, and e-mailed to the RA and the CBRNIAC. The CBRNIAC will make all monthly reports available to the contract COR, PMA, and PCO.

4.4 Final detailed written Technical Report (TR). (as defined by http://www.dtic.mil/dtic/stresources/techreports/index.html). Shall include task background, objective, assumptions, specific data collected, conclusions analyses conducted and recommendations. Each report shall be delivered to the RA and COR, prior to expiration of the period of performance. Under authority of the RA, with approval by the COR, each TR (whether unclassified or classified) shall have a Distribution Statement. **Every effort will be made to avoid utilizing Distribution F (Further Distribution Only As Directed by…).** However, if sensitive internal information is contained in the TR, every attempt shall be made to produce a sanitized (redacted) version of the TR for distribution within DoD (Distribution D) and inclusion in the DTIC database. For classified reports to be included in DTIC classified databases, and unclassified SF298 will be produced and signed by the government TAT RA; this document shall serve as the basis for creating unclassified metadata, which the IAC will add to the DTIC unclassified database, in accordance with established policy and procedures.

4.5 Food Defense Plan Builder Software Tool and Report. The CBRNIAC shall provide the updated tool and report on the integration of the Food Defense Plan Builder Tool with the VA Tool, resulting changes, development of self-assessment audit and help tools, user testing, incorporated changes, and results and recommendations.

4.6 FDA Mitigation Strategies Database (MSD) Report. The CBRNIAC shall recommended mitigation strategies to be considered by the FDA for inclusion in the MSD and other guidance documents.

4.7 Vulnerability Assessment Software Module Report. The CBRNIAC shall perform a detailed review of existing and new VA software modules developed by the FDA's Software contractor and prepare a final report based on the review of the existing database and results of the face-to face meeting for delivery to the FDA.

4.8 Vulnerability Assessment (VA) on Food Products. The CBRNIAC shall conduct up to 30 assessments on food products as identified by the FDA/FDOT and submit a VA report that includes the data collected and analyzed at each of the assessment meetings.

4.9 Food Defense Studies and Analyses. The CBRNIAC shall analyze food defense related issues, capabilities, and tools to identify technological or policy gaps and constraints that may limit the execution of FDA's food defense mission. These analyses will identify potential courses of action to address identified gaps and constraints, and make recommendations to decision makers to improve food defense capabilities.

Deliverable Number	TAT SOW Reference	Deliverable Title	Number of Deliverables	# of STI - subset of # deliverables	Due by (## Days After Funding)
4.1	3.1	Post-Award Brief and Minutes	1	0	35
4.2	3.2	STI Relevance and Gap Analysis	3	3	Annually
4.3	All	Monthly Status Report	36	0	45, 15th of month
4.4	All	Final Technical Report	1	1	1095
4.5	3.3	Food Defense Plan Builder Software Tool and Report	1	0	365
4.6	3.4	FDA Mitigation Strategies Database (MSD) Report	1	1	1035
4.7	3.5	Vulnerability Assessment Software Module Report	1	1	1035
4.8	3.6	Vulnerability Assessment (VA) on Food Products	30	30	365, 730, 1095
4.9	3.7	Food Defense Studies and Analyses	6	6	365, 730, 1095

5.0 GOVERNMENT FURNISHED EQUIPMENT, PROPERTY, AND/OR DATA:

The Government agrees to provide the CBRNIAC with all documents and information necessary to perform the tasks outlined in the SOW. Government NISPOM computers will be provided.

6.0 SECURITY REQUIREMENTS:

This TAT requires that CBRNIAC personnel possess a DoD SECRET security clearance. This TAT will require access, receipt, generation, and storage of classified information up to and including the SECRET level. The current overarching SECRET DD254 for the CBRNIAC contract is adequate for performing the work on this technical task.

6.1 Classified information generated in the performance of this task shall be classified in accordance with the appropriate security classification guidance, which will be provided to the CBRNIAC. Extracted or summarized classified information will be marked in accordance with the classification markings from the source document.

6.2 The CBRNIAC shall comply with all security requirements outlined in the National Industrial Security Program Operating Manual (NISPOM) and the NISPOM supplement, and CFSAN Standard Operating Procedures – National Security Classification of Vulnerability Assessments dated April 2007, regarding the protection, safeguarding, dissemination, and processing of all classified and unclassified information developed, generated and handled under this contract.

6.3 The CBRNIAC shall use a non-networked, dedicated laptop designated for "Controlled Unclassified Information" to record meeting proceedings, generate working documents, and create a draft of unclassified reports.

7.0 BENEFITS TO THE IAC AND TO THE GOVERNMENT:

This TAT effort shall benefit from the knowledge base of the CBRNIAC BCO. The information resources of the BCO are a necessary part of the work effort required under this TAT SIW, and shall be used to eliminate any duplication, reuse existing STI, and guild on that STI as if is applied in the operational context of this SOW.

The FDA will benefit by existing STI in the DTIC database which may be relevant. TATs performed for other organizations touched on prevention of intentional contamination of food systems, and safe combat rations manufacturing technologies.

This effort shall directly benefit the core capabilities of CBRNIAC and its broader technical community. The IAC database shall be expanded and enhanced through the identification, acquisition, and development of relevant data, use of that data to address new technical challenges identified under this TAT, and the development of new STI.

8.0 CONTRACT SOW PARAGRAPH REFERENCE:

6.1.s (Domestic Preparedness), 6.1.t (Counterterrorism)

9.0 TRAVEL REQUIREMENTS:

CONUS and OCONUS travel is anticipated. All travel will be approved by the government technical POC and conducted in accordance with joint federal travel regulations.

10.0 PLACE OF PERFORMANCE.

The CBRNIAC shall perform the work at government and CBRNIAC locations.

11.0 ESTIMATED PERIOD OF PERFORMANCE:

Total of 36 months: 12 month base period with two (2) 12 month options. Activity conducted during each period will include:

11.1 Base Period: In accordance with the statement of work, the CBRNIAC shall coordinate with the FDA to continue development of food defense tools under development including the Food Defense Plan Builder (FDPB) tool and the Mitigation Strategies Database (MSD). The CBRNIAC shall advance FDA's mission of reviewing the content of the mitigation strategies MSD for accuracy and relevance. The CBRNIAC shall conduct vulnerability assessments on food products as identified by the FDA to support the FDA in satisfying its assessment responsibilities. The CBRNIAC shall also support the FDA's food defense mission by conducting studies and analyses as identified by the FDA.

11.2 Option Year 1: In accordance with the statement of work, the CBRNIAC shall coordinate with the FDA to advance the development of the FDPB and the MSD by developing relevant "help" information, user assistance information and conducting usability and focus group testing and feedback sessions, face-to-face meetings, and other collaborative activities to refine and enhance the capabilities and functionality of these valuable tools. The CBRNIAC shall coordinate with the FDA to develop content and guidance documents related to potential mitigation strategies the food and agriculture industry may find beneficial for inclusion to the MSD. The CBRNIAC shall advance FDA's mission of identifying mitigation strategies for inclusion in the MSD and continue to conduct vulnerability assessments on food products as identified by the FDA. The CBRNIAC shall also support the FDA's food defense mission by conducting studies and analyses as identified by the FDA.

11.3 Option Year 2: In accordance with the statement of work, the CBRNIAC shall coordinate with the FDA to continue the development, refinement and upgrades of the FDPB and the MSD by conducting usability and focus group testing and feedback sessions, face-to-face meetings, and other collaborative activities to refine and enhance the capabilities and functionality of these valuable tools. The CBRNIAC shall advance FDA's mission of identifying mitigation strategies for inclusion in the MSD and conduct vulnerability assessments on food products as identified by the FDA. The CBRNIAC shall also support the FDA's food defense mission by conducting studies and analyses as identified by the FDA

12.0 GOVERNMENT POC:

Julia Guenther
U.S. Food and Drug Administration
5100 Paint Branch Parkway
HFS-007, Room 2A017
College Park, MD 20740
Phone: (240) 402-1637
Mobile: (240) 753-4023
Fax: (301) 436-2633
E-mail: julia.guenther@fda.hhs.gov

Alternate Government POC:
Jon Woody
U.S. Food and Drug Administration
5100 Paint Branch Parkway
HFS-007, Room 2A01
College Park, MD 20740
Phone: (240) 402-2171
Fax: (301) 436-2633
E-mail: jon.woody@fda.hhs.gov

Government Security POC:
Al Gillis
10903 New Hampshire Ave.

WO1 Rm 1232
Silver Spring, MD
Phone: (301) 796-4607
Fax: (301) 847-8102
E-mail: Alexander.Gillis@fda.hhs.gov

DTIC POC:
Elliott Brick
DTIC PMA
Acuity Consulting, Inc.
Defense Technical Information Center, DTIC-I
Fort Belvoir, Virginia
Phone: (703) 767-9108
Email: ebrick.ctr@dtic.mil

CONTRACT ADVISORY AND ASSISTANCE SERVICES DO NOT APPLY.
THIS SOW IS FOR NON-PERSONAL SERVICES.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0100	N/A	N/A	N/A	Government
0200	N/A	N/A	N/A	Government
1100	N/A	N/A	N/A	Government
2100	N/A	N/A	N/A	Government

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0100	POP 16-MAY-2012 TO 15-MAY-2013	N/A	DEFENSE TECHNICAL INFORMATION CENTER DTIC - I 8725 JOHN J. KINGMAN ROAD, STE. 0944 FT BELVOIR VA 22060-6218 703-767-9171 FOB: Destination	HJ4701
0200	POP 16-MAY-2012 TO 15-MAY-2013	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	HJ4701
1100	POP 16-MAY-2013 TO 15-MAY-2014	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	HJ4701
2100	POP 16-MAY-2014 TO 15-MAY-2015	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	HJ4701

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 97 201220130400R 7967 224122010-FY12 CB-12-0341/DO-DD74-255-HJ470226687 044450
AMOUNT:
CIN HJ47012132B286K0000AA:

Section H - Special Contract Requirements

RATES

The Government reserves the right to negotiate an adjustment to this Order based on resolution of the issues identified by DCAA and DCMA.

As part of the terms and conditions of this contract (or delivery order) the contractor shall not bill in excess of the following capped rates and shall not request additional funds solely to cover higher final Overhead and General & Administrative (G&A) rates.

Capped Rates:

Any costs incurred by the contractor in excess of the above capped rates are determined unallowable by the Contracting Officer under this contract (or delivery order). All directly associated costs are also unallowable. In accordance with FAR 31.201-6, these costs shall be excluded from any billing, claim, or proposal applicable to this contract (or delivery order).

Section I - Contract Clauses

CLAUSES INCORPORATED BY FULL TEXT

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 5 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 10 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36 months.
(End of clause)

DATE: 2-25-2013

FAX To: Ms. Elizabeth Dickinson, Esq.

Chief Counsel
Rm. 4536
Food and Drug Administration
Silver Spring, MD 20993-0002
(T) 301-796-8540
(F) 301-847-8637
E-mail: Elizabeth.Dickinson@fda.hhs.gov

SUBJECT: YOUR LETTER OF FEBRUARY 22, 2013, TO MR. JOHN HNATIO AT FOODQUEST TQ, LLC

NOTE:

Dear Ms. Dickinson:

We received your letter of February 22, 2013, asking for a response to your letter of January 28, 2013. On February 12, 2013, we faxed our response directly to your office. I have made direct contact with your office to make certain that you receive the attached copy of our original response. Thank you very much for your willingness to look into this matter. If you have any questions, please feel free to contact me at 240-439-4476 x-11. You can also reach me at e-mail: jhnatio@thoughtquest.com Best regards, John.

FROM:

John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702
240-439-4476 X-11
E-mail: jhnatio@thoughtquest.com

COPY

DATE: 2-12-2013

FAX TO:

Ms. Elizabeth Dickinson, Esq.
Chief Counsel
Rm. 4536
Food and Drug Administration
Silver Spring MD 20993-0002
(T) 301-796-8540
(F) 301-847-8637
E-mail: Elizabeth.Dickinson@fda.hhs.gov

SUBJECT: RESPONSE TO YOUR LETTER OF JANUARY 28, 2013 TO MR. JOHN HNATIO, FOODQUESTTQ, LLC

FROM:

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702
240-439-4476 x-11
E-mail: jhnatio@thoughtquest.com

COPY

ORIGINAL SENT ON: 2-12-21013 COPY PROVIDED ON 2-25-2013

Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

February 12, 2013

Dear Ms. Dickinson:

Thank-you very much for your letter of January 28, 2013. In your letter you refer to the letter that we wrote to Senator Barbara Mikulski on December 19, 2012. We truly appreciate your help and we are looking forward to working with you as we move forward together to fairly resolve this matter.

In the Fall of 2012, our company became concerned that the Food and Drug Administration (FDA) Food Defense Team may be improperly using FoodQuestTQ LLC generated trade secrets and other business proprietary information to duplicate several of our products.

We have since learned that members of the FDA's Food Defense Team have taken our FoodQuestTQ LLC product descriptions and our proprietary commercial and trade secret information and duplicated three of our products. Other new products that duplicate our pre-existing commercial offerings may also be in development by the FDA that we are not yet aware of at this time.

1. The new ***FDA Food Defense Plan Builder*** tool takes our pre-existing **Food DefenseTQ** tool, which is used to build food defense plans (just recently upgraded to become **Food Defense Architect**) and duplicates it.

2. The new ***FDA FREE-B*** tool takes elements of our pre-existing **FREE** and **FEAST** computer software tools, which are used to simulate and manage food emergencies, and duplicates them.

In your letter you refer to our December 19, 2012, letter to Senator Mikulski and you ask us to "identify the patents to which you are referring in your letter and the FDA software system which you allege uses your ideas." The patent upon which the entire FoodQuestTQ integrated Food Protection computer software tool suite is based is:

- USPTO Patent No.: US 8,103,601 B2, DOI: January 24, 2012.

The patent describes methods and techniques that are an expression of the Complexity Systems Management Method or CSM Method®. The CSM Method® is a registered trademark business process and data transformation patent for dealing with complex and evolving risks and risk countermeasures across all critical infrastructures including food and agriculture. It consists of 92 objects of invention that are integrally tied to each of the 20 claims granted by USPTO under the patent.

It is important to note, however, that our company's concerns go well beyond the possibility that the FDA may have infringed on our patent to include the more immediate concern that the Food Defense

ORIGINAL SENT ON: 2-12-21013 COPY PROVIDED ON 2-25-2013

Team has improperly taken FoodQuestTQ LLC product information and company proprietary commercial and trade secret information to duplicate our products.

Attached please find a brief description of some specific topics that you may wish to discuss directly with the FDA Food Defense Team. We wanted to provide this information to you now in order to make our upcoming meeting as productive as possible.

Again, thank you very much for looking into our concerns. We are still very interested in building a cooperative relationship with the FDA so that we can work together to make the food we all eat safer. We very much look forward to meeting with you personally to lay out a plan on how we can work together to fairly resolve this issue in a mutually beneficial way.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,

John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

COPY OF ORIGINAL DATED 2/12/201 FOR YOUR EYES ONLY

Informal Note for: Elizabeth Dickinson

From: John Hnatio J. H.

Date: 2/12/2013

For many years prior to my retirement from government service, I had the great privilege of serving in senior positions in both the Executive and Legislative Branches of our government where I dealt directly with technology transfer issues and the vital relationship between the government and industry in achieving national objectives. For example, I was the leader of the technology transfer program for the nuclear weapons program that included all ten of the national laboratories where I oversaw billions of dollars of cooperative work between the government and the private sector. I also served as a loaned Executive from the White House to the Senate to spearhead efforts to strengthen the defense industrial base and promote greater cooperation between government and industry. Suffice it to say that I have "lived and breathed this stuff" for well over 30 years.

Based on my significant expertise in this area, there may be several specific aspects of this situation that you may wish to explore directly with the FDA Food Defense Team before we have the opportunity to meet.

First and foremost, is the requirement that federal employees protect and keep as confidential proprietary commercial information provided to them by the private sector. In all of our interactions with the FDA Food Defense Team we clearly advised them whenever we were sharing proprietary commercial information. In addition, all of the proprietary commercial information we provided to the FDA Food Defense Team was clearly marked as containing proprietary information. The FDA Food Defense Team used this proprietary information and other publicly available descriptions of our product to duplicate three of our products.

Second, are the numerous laws and statutes that dictate when the government can and cannot internally "build" products. Here the rules are very clear. Among these important rules is a documented "build-no build" determination by a government agency based on the notion that the activity involved is an "inherently government function." While the authority to regulate the food industry certainly is an inherently government function, food defense and food safety undertakings to assist the food industry implement and comply with those regulations are not. Rather, they represent a shared responsibility between the government and the private sector. The FDA Food Defense Team did not make a good faith "build-no build" determination before they decided to duplicate our products.

Another important government determination requires that no government agency or its subcontractors, including Battelle Memorial Institute in this case, be permitted to compete with the private sector. Here the rules are also very clear. Before and as part of any funding decision by a federal agency to contract with a Federally Funded Research and Development Center (FFRDC) the agency must make a "compete-no compete" determination. This requires that each federal agency systematically consider and reach a considered determination that the activity they are funding will not compete with the same, similar or better product offering that is already available in industry. In many federal

COPY OF ORIGINAL DATED 2/12/201 FOR YOUR EYES ONLY

agencies this responsibility is shared by the Head Contracting Official and is basis to the procurement process. The FDA Food Defense Team did not make a good faith "compete-no compete" determination before they decided to duplicate our products.

There are several other issues that raise serious concerns about the integrity of the FDA Food Defense Team's actions that are disturbing that their supervisors should be made aware of.

On October 6, 2012, we briefed the FDA Food Defense Team. During that briefing we attempted to discourage them from pursuing a course of action that would only result in a waste of taxpayer dollars to duplicate pre-existing commercial products. At that meeting, we offered the FDA Food Defense Team a one dollar a year license to use our tools for all FDA personnel across the Food and Agricultural industry vertical. The FDA Food Defense Team never responded to our offer. But they did tell us that our company's products were far better than the ones that the FDA was developing under their contract with Battelle Memorial Institute.

In December 2012, we were invited by the Grocery Manufacturer's Association (GMA) to attend an FDA Food Defense Team sponsored workshop. Before the meeting we were told by the FDA Food Defense Team that the principal purpose of the workshop was to discuss the use of a food defense targeting tool originally developed by the military Special Forces that has been converted by the FDA Food Defense Team for use by food facilities. After speaking personally with a member of the FDA Food Defense Team about the "true purpose" of the meeting, FoodQuestTQ created a web based survey to reach out to industry to obtain their inputs on the usefulness of the FDA targeting tool.

Just days before the scheduled Food Defense Team sponsored workshop at GMA, we published an article giving the preliminary results of the industry survey. The results of the survey raised serious questions about the utility of the FDA targeting tool by industry. This article received very significant notoriety within the FDA Food Defense Team as evidenced by the fact that the FoodQuestTQ article was "opened" for reading and further distribution by the leader of the FDA Food Defense Team more than 40 times.

A few days before the FDA Food Defense Team sponsored workshop was scheduled to take place on December 12, 2012, we were provided with a copy of the FDA Food Defense Team agenda for the workshop by GMA. We realized at this time that the Food Defense Team intentionally misled us about the true purpose of the workshop. The agenda made it clear that the real purpose of the workshop was for the FDA Food Defense Team to demonstrate and receive inputs from the food industry on the FDA's new Food Defense Plan Builder tool. A representative of Battelle Memorial Institute wrote the company an e-mail stating that the FDA Food Defense Team industry workshop to demonstrate their new Food Defense Plan Builder tool could only be attended by food processing companies.

Late in the evening of December 11, 2012, we were informed by GMA that the FDA had prohibited our company from attending the following day's workshop to demonstrate our FoodQuestTQ food defense plan builder tool (known as Food Defense Architect). The GMA advised us that the FDA Food Defense Team prohibited us from attending the workshop because they (the FDA Food Defense Team) did not want to give our company any unfair competitive advantage. After the workshop, we were able to

verify that we were again misled by the FDA Food Defense Team when we found that attendees at the workshop included many other non-food processing companies including competing software companies.

COPY

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Senator Barbara Mikulski
Washington, DC
503 Hart Senate Office Building
Washington, D.C. 20510

February 12, 2013

Dear Senator Mikulski:

We would like to thank-you very much for your help in arranging a meeting with Ms. Dickinson at the Food and Drug Administration. We would like to extend our particular thanks to Mr. Barton Kennedy of your staff for his diligent efforts working through the federal bureaucracy on our behalf. We express our personal thanks to Bart.

We recently received a letter from Ms. Dickinson asking for background information on our concerns. We have responded to her request and hope to meet with her very soon to resolve the matter. We feel confident that when Ms. Dickinson gets the opportunity to review the materials she will take the appropriate actions necessary to resolve our concerns.

With your permission, we will keep you apprised of our progress in working with the Food and Drug Administration to resolve our concerns. Again, thanks to you and your staff.

Sincerely,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC

cc: Elizabeth Dickinson, FDA-OGC

COPY

Representative John Delaney
1632 Longworth House Office Building
Washington, DC 20515

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

February 12, 2013

Dear Representative Delaney:

We wanted to thank-you for your assistance in obtaining the opportunity to meet with Ms. Elizabeth Dickinson at the Food and Drug Administration. We realize that without your help such a meeting would never have been possible.

There is one particular person on your staff who worked diligently on our behalf. Kevin Mack deserves our special thanks. You must be proud to have him as a member of your staff.

We recently received a letter from Ms. Dickinson asking for background information on our concerns. We have responded to her request and hope to meet with her very soon to resolve the matter. We feel confident that when Ms. Dickinson gets the opportunity to review the materials she will take the appropriate actions necessary to resolve our concerns.

With your permission, we will keep you apprised of our progress in working with the Food and Drug Administration to resolve our concerns. Again, thank-you for all of your help.

Sincerely,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC

cc: Elizabeth Dickinson, FDA-OGC

CONFIDENTIALITY AGREEMENT

This agreement is entered into between FoodQuestTQ LLC, hereinafter referred to as "FQTQ", doing business at 7420 Hayward Road, Suite 102, Frederick, Maryland 21702 and the Food and Drug Administration, hereinafter referred to as the "FDA", doing business at 10903 New Hampshire Avenue Silver Spring, MD 20993.

WHEREAS, and in connection with anticipated communications between the two named parties to this Agreement concerning allegations by FQTQ that the FDA has taken FQTQ proprietary and trade secret information to duplicate FQTQ commercial products in violation of laws, government policies and required federal procedures. It is expected that FQTQ will disclose to the FDA Confidential Information including but not limited to a patent called the Complexity Systems Management Method (CSM®), Patent No.: US 8,103,601 B2 and proprietary and trade secret information on how Patent No.: US 8,103,601 B2 was reduced to practice in a suite of FQTQ commercial computer automated food defense, food safety and food risk management tools. It is also anticipated that the parties to this Agreement will share Confidential FQTQ Information as they work together to develop a detailed technical crosswalk between the FQTQ suite of tools and FDA-Battelle Memorial Laboratory developed tools listed below.

FQTQ Commercial Tools	FDA-Batelle Developed Tools	Purpose of Tool
Food Defense Architect	Food Defense Plan Builder	Build Food Defense Plans
Food DefenseTQ		
Food Mapper	iRisk	Computer search and risk management tool
FREE Tool	FREE-B	Emergency response mapping and simulation tool
FEAST		

NOW THEREFORE, in assurance of a full and good faith review by the Chief Counsel of the FDA as to the FQTQ allegations that FDA has infringed on Patent No.: US 8,103,601 B2 and taken FQTQ proprietary and trade secret information to duplicate FQTQ commercial products in violation of laws, government policies and required federal procedures, the parties agree as follows:

1. The FDA shall protect and keep confidential and shall not use for other purposes than those established in this Agreement, publish or otherwise disclose to third parties any and all Confidential Information of FQTQ. The obligation of confidentiality and restriction on use under this Agreement shall survive any termination of this Agreement.

2. By way of illustration, but not limitation, Confidential Information includes improvements, inventions, concepts, structures, formulas, techniques, processes, apparatus, know-how, and related data, clinical plans, business records, business or sales forecasts, past or current proposals, financial information, patent applications or legal opinions and documents which are disclosed to the FDA under this Agreement. Confidential Information may be supplied in written or oral form and may be identified as "confidential" but the lack of such explicit label or designation shall not preclude information from being treated as confidential under this Agreement.

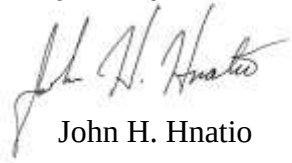
3. To assist in protecting Confidential Information, the FDA agrees (a) not to disclose any Confidential Information of FQTQ to anyone except government employees of the FDA who are specifically bound by the terms of this Agreement and directly involved in conducting a good faith review of the FQTQ allegations and; (b) not to copy any FQTQ Confidential Information except for the purpose of doing a good faith review of FQTQ allegations; (c) to take all reasonable steps necessary to prevent the unauthorized disclosure, copying or use of any FQTQ Confidential Information, and (d) to use at least the same degree of care it uses to protect its own Confidential Information.

4. The FDA agrees that upon a written request by FQTQ that all Confidential Information, all tangible expressions of the Confidential Information, together with all copies thereof shall be promptly destroyed or returned to FQTQ.

5. This Agreement shall be binding upon the parties hereto and their respective heirs, successors or assigns, from the date of signing and none of the benefits of this Agreement shall be assigned by the FDA without the written consent of FQTQ.

6. This Agreement shall be governed by the laws of Maryland. If any one or more of the provisions of this Agreement shall be held invalid or unenforceable, such provision shall be modified to the minimum extent necessary to make it valid and enforceable, and the validity of enforceability of all other provisions hereof shall not be affected thereby.

IN WITNESS WHEREOF, the parties have executed this Agreement.

For FoodQuestTQ LLC	For the Food and Drug Administration
By: 	By: _____
John H. Hnatio	Elizabeth Dickinson
Title: Chief Science Officer, TQ	Title: Chief Counsel
Date: March 2, 2013	Date: _____

Date: March 2, 2013

Note for: Ariel Seeley, FDA Counsel

From: John Hnatio, FoodQuestTQ LLC

Subject: More information on FoodQuestTQ tools and yesterday's E-mail

Hi Ariel,

Please call me John. It's good to meet you. We really want to thank you and Ms. Dickinson for your response and your good faith efforts to review the situation. Please say thank-you to her for me too.

I wanted to let you know that we have shared the nuts and bolts of literally everything we've developed with the Food Defense Team, JIFSAN, and CIFSAN over the past three or so years. This includes proprietary briefings and proposals including detailed information on our tools for building food defense plans, searching food standards and regulations, developing food emergency simulations, responses to food emergencies and much more. This is the same information that was used to duplicate our products.

But, if this information is not available to you from the FDA Food Defense Team, or if you want to have an independent read from us on the nuts and bolts of our technology, then we'd be happy to set up a demonstration for the folks in your office so that we can walk you through our Food Defense Architect, Food DefenseTQ, FEAST and FREE tools. The similarities between the tools duplicated by the Food Defense Team using our confidential information and ideas are quite obvious.

Also, the opportunity to get more specific information from you on the nuts and bolts of the operation of FDA's Food Defense Plan Builder and FREE-B would allow us to prepare a detailed "technical crosswalk" between the FDA Food Defense Team's and Battelle's Food Defense Plan Builder, FREE-B and our FoodQuestTQ tools. The "technical crosswalk" can put the entire issue of infringement and the use of our trade secret and proprietary information by the Food Defense team "to bed" very quickly.

As you do your good faith review, we hope that you will focus on all of the issues raised in the letter we sent Ms. Dickinson. The issue of patent infringement, while certainly of great importance, is only one of several critical issues that were raised in our letter. All of the issues we identified in our letter require careful consideration because they involve violations of specific statutes and violations of clearly established government-wide policies that specifically limit FDA's authority to build the same or similar products already available in the private sector.

Thus, we are really looking forward to working with you and Ms. Dickinson to fully explore the issues created by the Food Defense Team when they intentionally took our confidential information and used it to duplicate our tools in order to improperly compete with us. These highly significant issues go well beyond any specific patent infringements that have occurred in this case.

Please find a copy of a FoodQuestTQ LLC and FDA non-disclosure agreement (NDA). We would like to go ahead and execute an NDA with you at this time since we are uncertain of FDA's position with respect to adhering to the provisions of Title 18, as they relate to the protection of industry proprietary information. Our concern is based on the actions taken by the Food Defense Team to take our trade secrets and other proprietary ideas and information in order to duplicate our products.

As soon as we get an NDA in place, then I will call you to arrange a demonstration of our tools for you and other members of the FDA counsel's office and simultaneously make arrangements for you to share with us the information we will use to prepare the detailed "technical crosswalk" of the FDA/Battelle Food Defense Plan Builder and FREE-B tools against our Food Defense Architect, Food DefenseTQ and FREE tools.

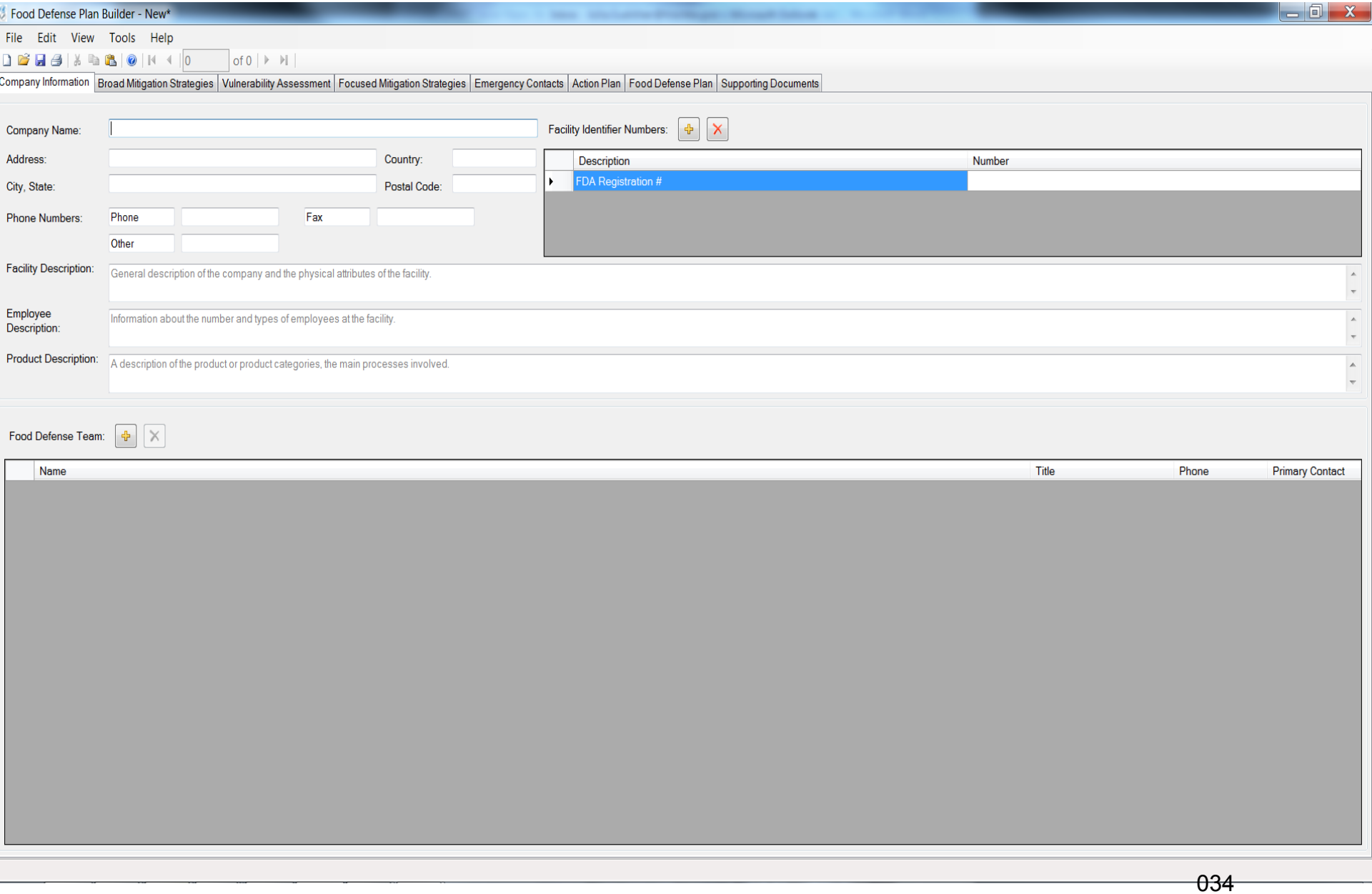
We really look forward to working with you Ariel. If you have any questions please don't hesitate to call me. My best number is 240-439-4476. I'm at extension 11. Hope to meet you in person very soon. All the best.

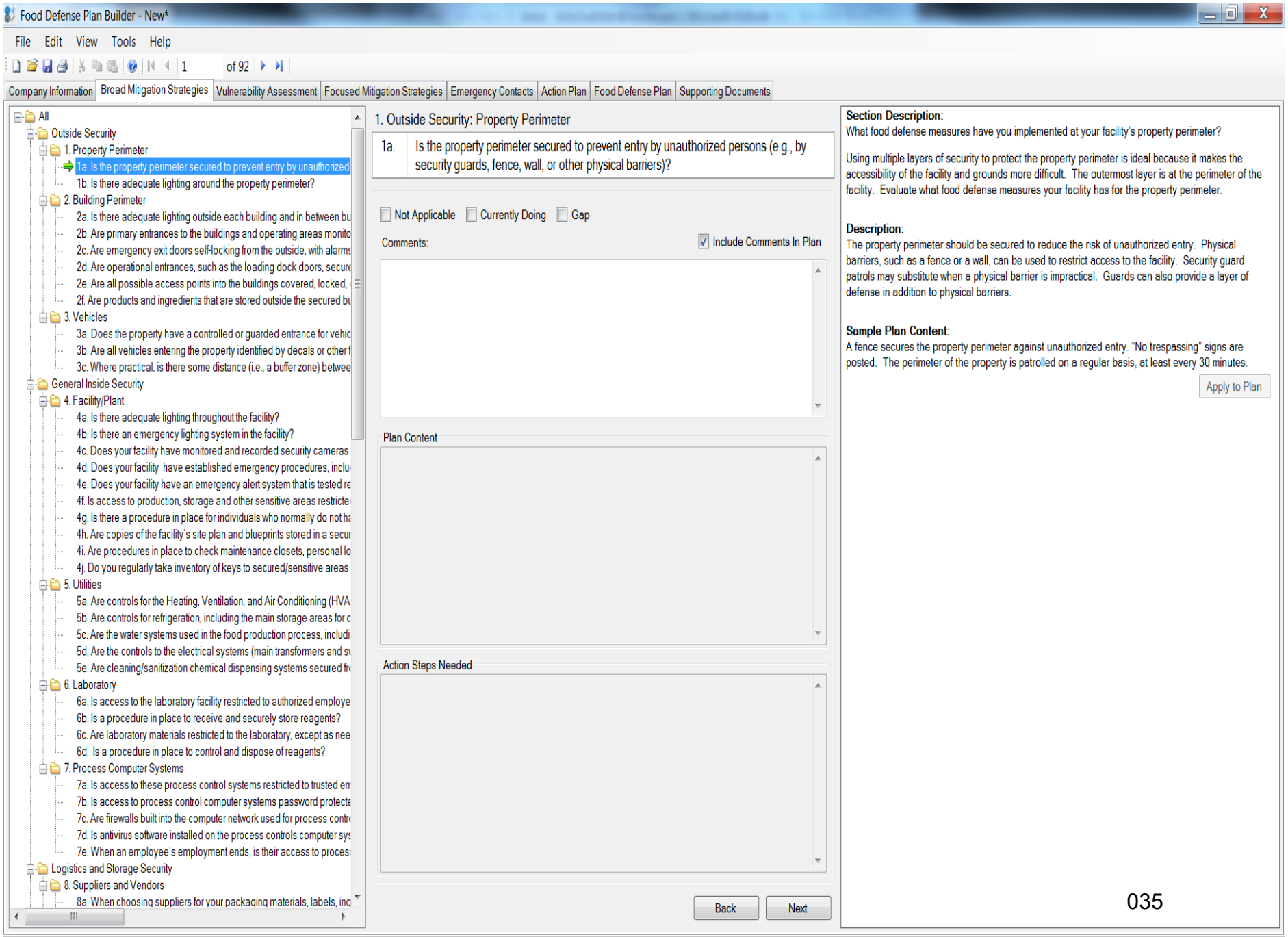
PS!

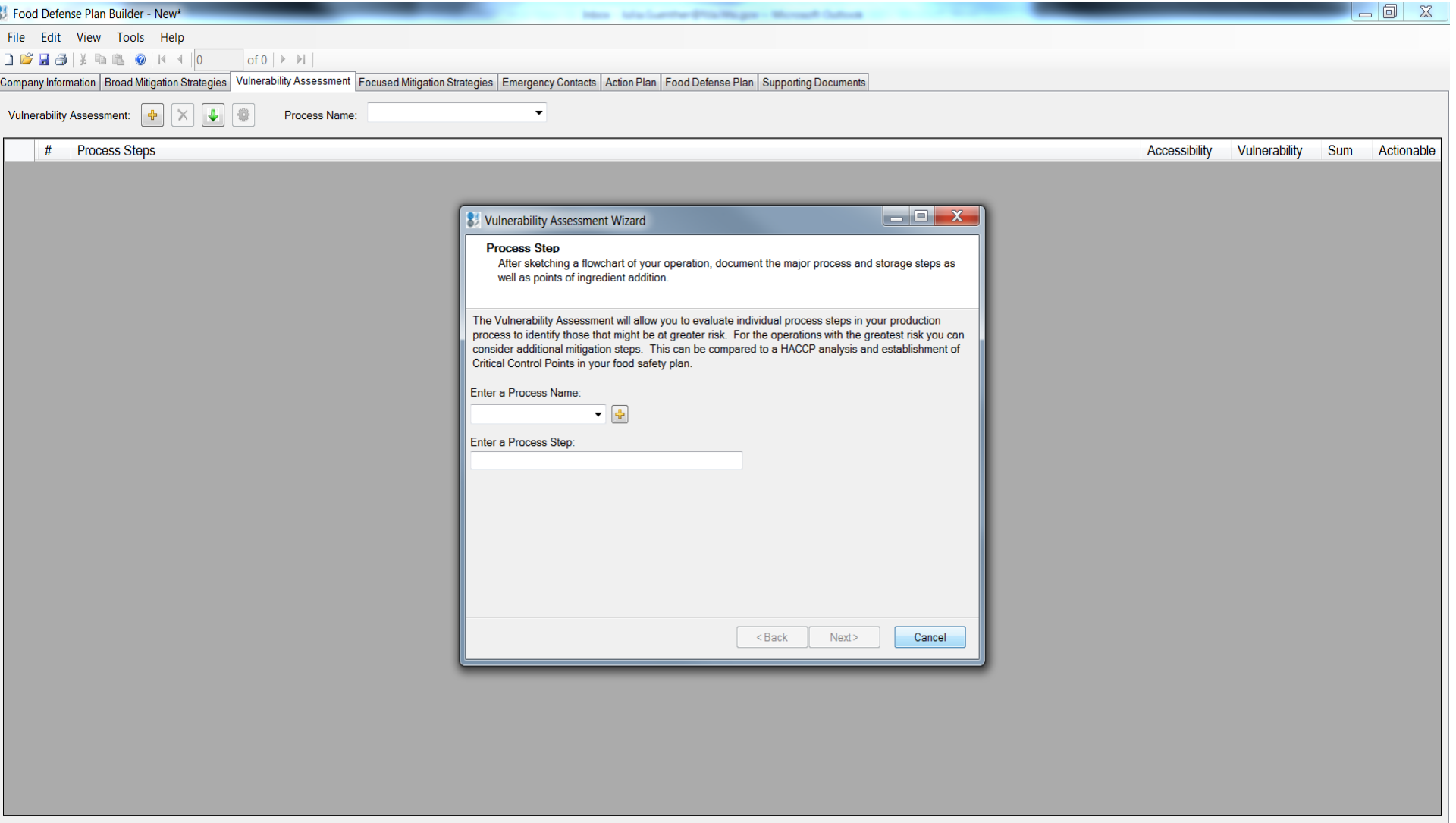
Ariel we've got another serious problem. When it rains it pours. We just came across FDA's new iRisk tool this morning. You can take a look at the new FDA offering at: http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/ . The new iRisk tool duplicates our Food Mapper tool and is based on proprietary information that we provided to the Food Defense Team and JIFSAN. We'll need to include the FDA iRisk tool as part of the above technical crosswalk against our Food Mapper tool.

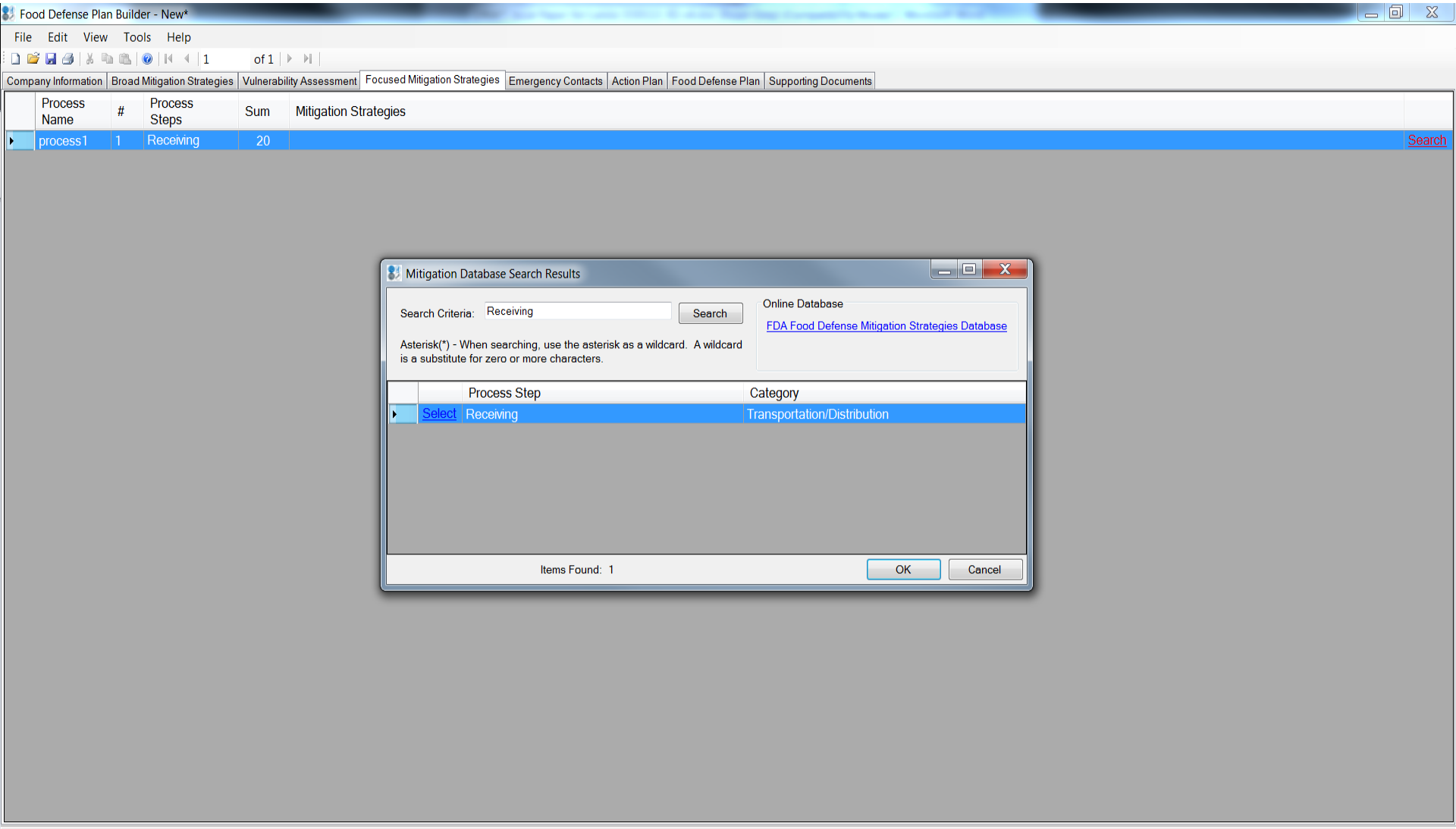
Food Defense Plan Builder v1.0 Screenshots

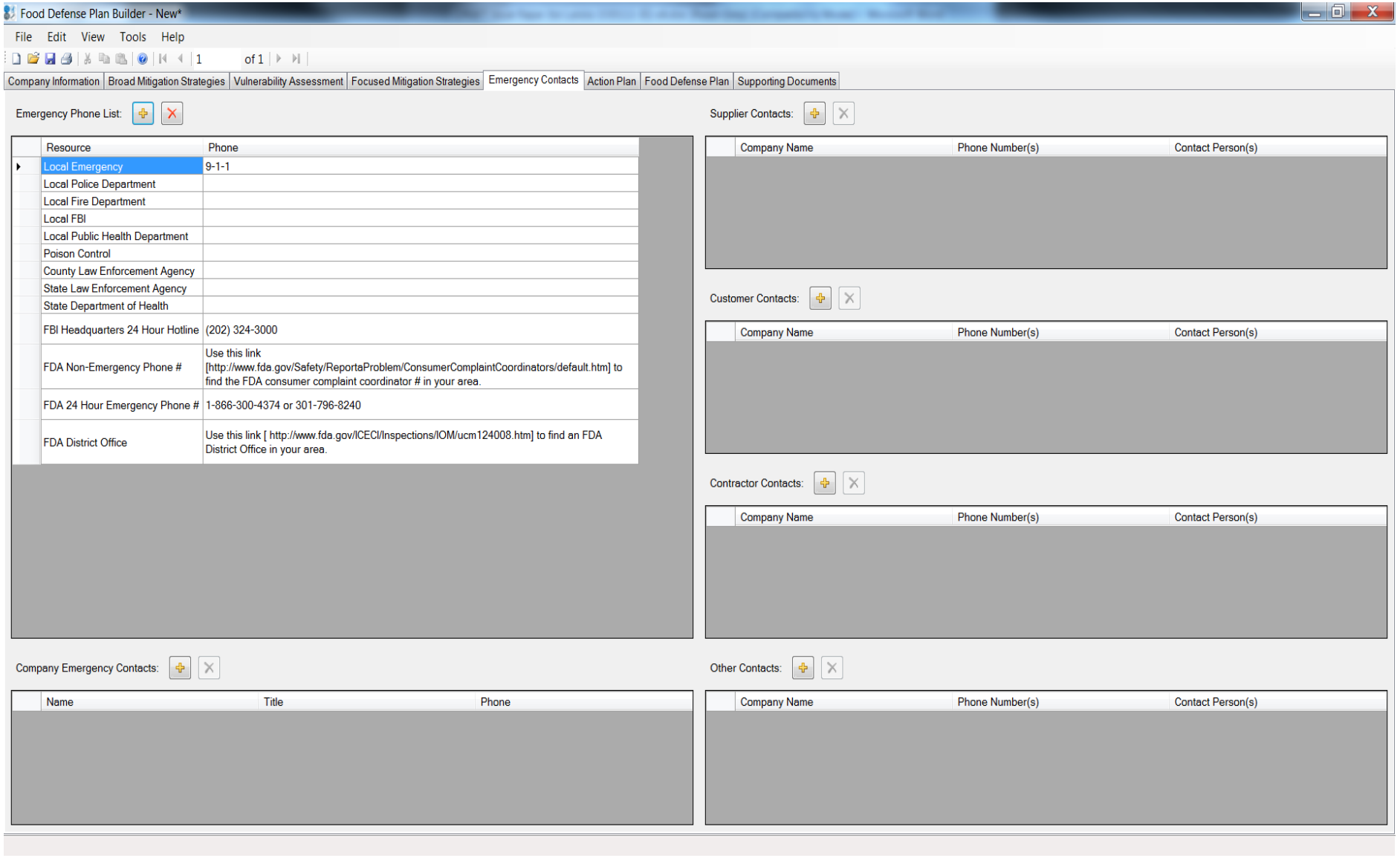
03/04/2013

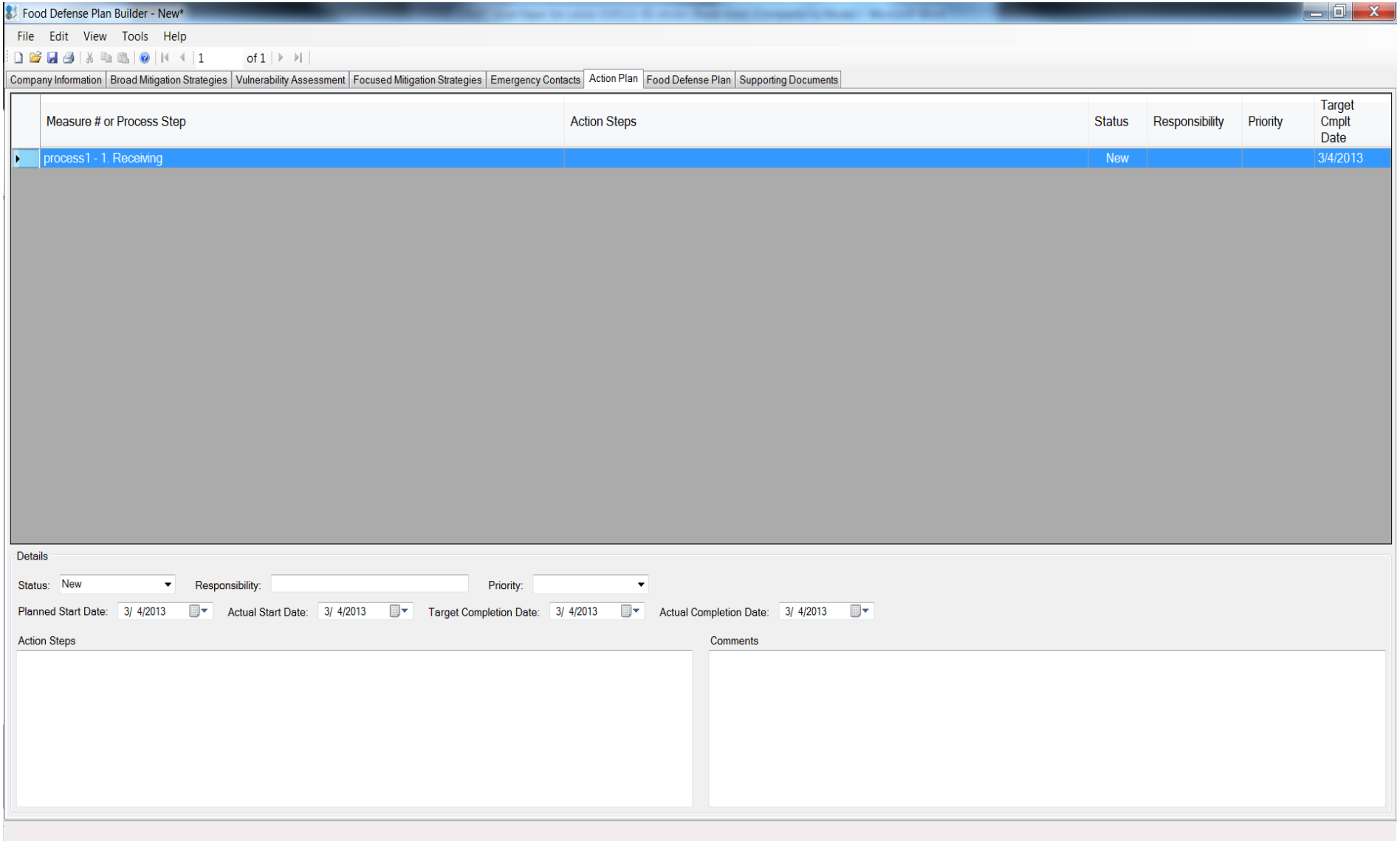

Food Defense Plan Builder - New*
File
Edit
View
Tools
Help
0
of 0
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Company Name:
Address:
Country:
City, State:
Postal Code:
Phone Numbers:
Phone
Fax
Other
Facility Identifier Numbers:
Description
Number
FDA Registration #
Facility Description:
General description of the company and the physical attributes of the facility.
Employee Description:
Information about the number and types of employees at the facility.
Product Description:
A description of the product or product categories, the main processes involved.
Food Defense Team:
Name
Title
Phone
Primary Contact

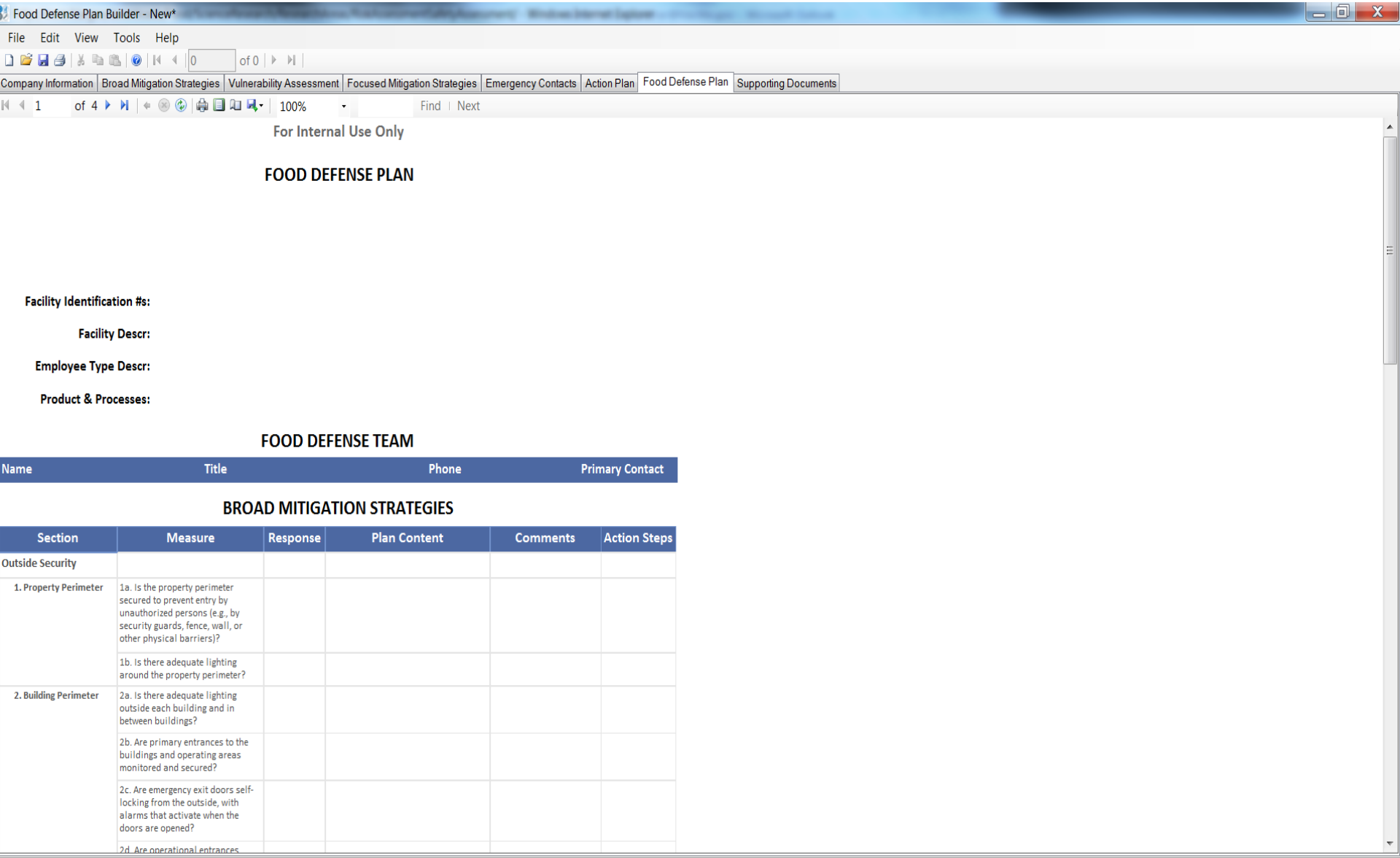

Food Defense Plan Builder - New*
File Edit View Tools Help
1 of 92
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
All
Outside Security
1. Property Perimeter
1a. Is the property perimeter secured to prevent entry by unauthorized
1b. Is there adequate lighting around the property perimeter?
2. Building Perimeter
2a. Is there adequate lighting outside each building and in between bu
2b. Are primary entrances to the buildings and operating areas monito
2c. Are emergency exit doors self-locking from the outside, with alarms
2d. Are operational entrances, such as the loading dock doors, secure
2e. Are all possible access points into the buildings covered, locked,
2f. Are products and ingredients that are stored outside the secured bu
3. Vehicles
3a. Does the property have a controlled or guarded entrance for vehic
3b. Are all vehicles entering the property identified by decals or other f
3c. Where practical, is there some distance (i.e., a buffer zone) betwee
General Inside Security
4. Facility/Plant
4a. Is there adequate lighting throughout the facility?
4b. Is there an emergency lighting system in the facility?
4c. Does your facility have monitored and recorded security cameras
4d. Does your facility have established emergency procedures, inclu
4e. Does your facility have an emergency alert system that is tested re
4f. Is access to production, storage and other sensitive areas restricte
4g. Is there a procedure in place for individuals who normally do not ha
4h. Are copies of the facility's site plan and blueprints stored in a secur
4i. Are procedures in place to check maintenance closets, personal lo
4j. Do you regularly take inventory of keys to secured/sensitive areas
5. Utilities
5a. Are controls for the Heating, Ventilation, and Air Conditioning (HVA
5b. Are controls for refrigeration, including the main storage areas for c
5c. Are the water systems used in the food production process, includi
5d. Are the controls to the electrical systems (main transformers and sv
5e. Are cleaning/sanitization chemical dispensing systems secured fr
6. Laboratory
6a. Is access to the laboratory facility restricted to authorized employe
6b. Is a procedure in place to receive and securely store reagents?
6c. Are laboratory materials restricted to the laboratory, except as nee
6d. Is a procedure in place to control and dispose of reagents?
7. Process Computer Systems
7a. Is access to these process control systems restricted to trusted en
7b. Is access to process control computer systems password protecte
7c. Are firewalls built into the computer network used for process contr
7d. Is antivirus software installed on the process controls computer sys
7e. When an employee's employment ends, is their access to proces
Logistics and Storage Security
8. Suppliers and Vendors
8a. When choosing suppliers for your packaging materials, labels, inq
1. Outside Security: Property Perimeter
1a. Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?
Not Applicable
Currently Doing
Gap
Comments:
Include Comments In Plan
Plan Content
Action Steps Needed
Back
Next
Section Description:
What food defense measures have you implemented at your facility's property perimeter?
Using multiple layers of security to protect the property perimeter is ideal because it makes the accessibility of the facility and grounds more difficult. The outermost layer is at the perimeter of the facility. Evaluate what food defense measures your facility has for the property perimeter.
Description:
The property perimeter should be secured to reduce the risk of unauthorized entry. Physical barriers, such as a fence or a wall, can be used to restrict access to the facility. Security guard patrols may substitute when a physical barrier is impractical. Guards can also provide a layer of defense in addition to physical barriers.
Sample Plan Content:
A fence secures the property perimeter against unauthorized entry. "No trespassing" signs are posted. The perimeter of the property is patrolled on a regular basis, at least every 30 minutes.
Apply to Plan

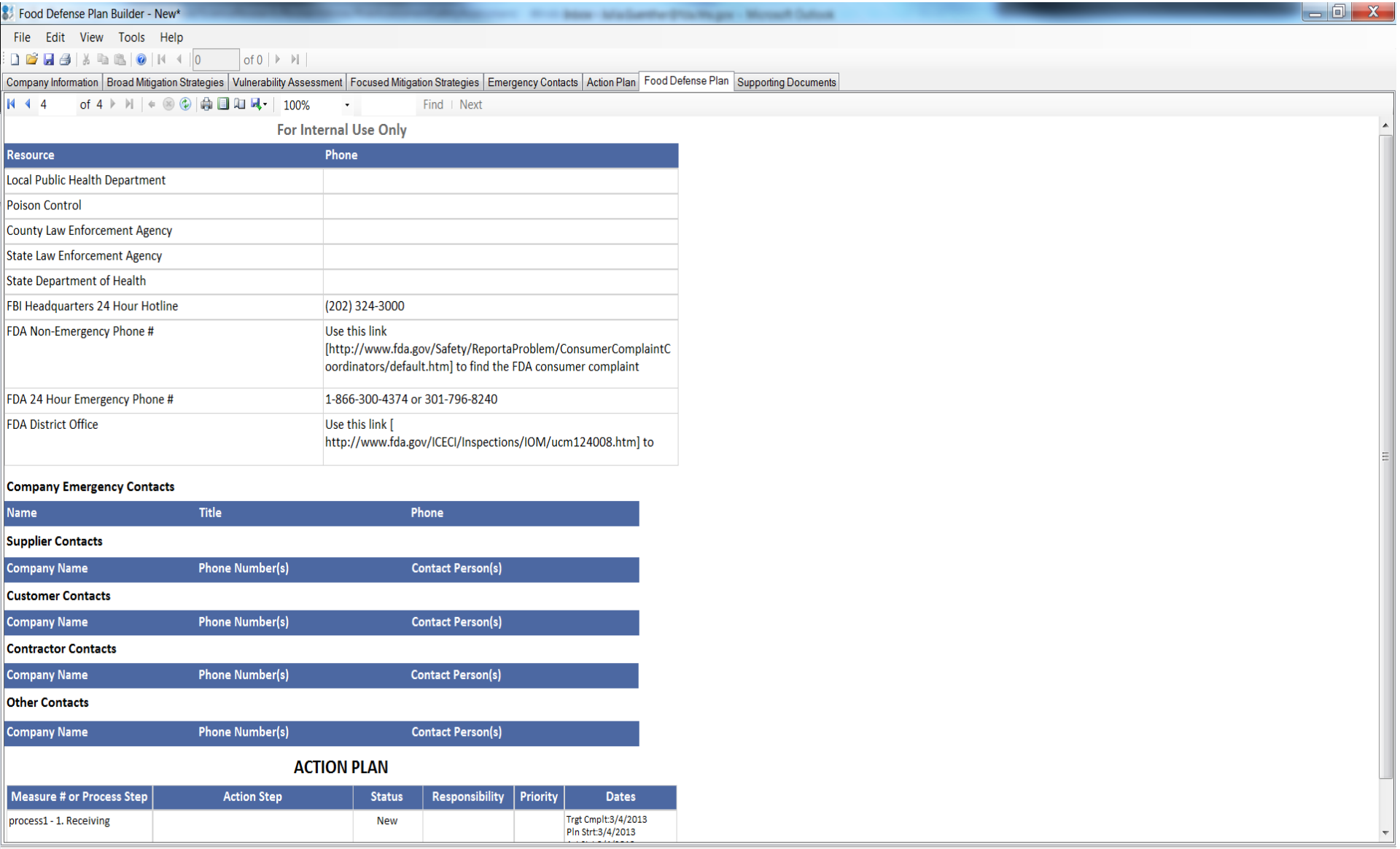

Food Defense Plan Builder - New*
File
Edit
View
Tools
Help
0
of 0
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Vulnerability Assessment:
Process Name:
#
Process Steps
Accessibility
Vulnerability
Sum
Actionable
Vulnerability Assessment Wizard
Process Step
After sketching a flowchart of your operation, document the major process and storage steps as well as points of ingredient addition.
The Vulnerability Assessment will allow you to evaluate individual process steps in your production process to identify those that might be at greater risk. For the operations with the greatest risk you can consider additional mitigation steps. This can be compared to a HACCP analysis and establishment of Critical Control Points in your food safety plan.
Enter a Process Name:
Enter a Process Step:
< Back
Next >
Cancel

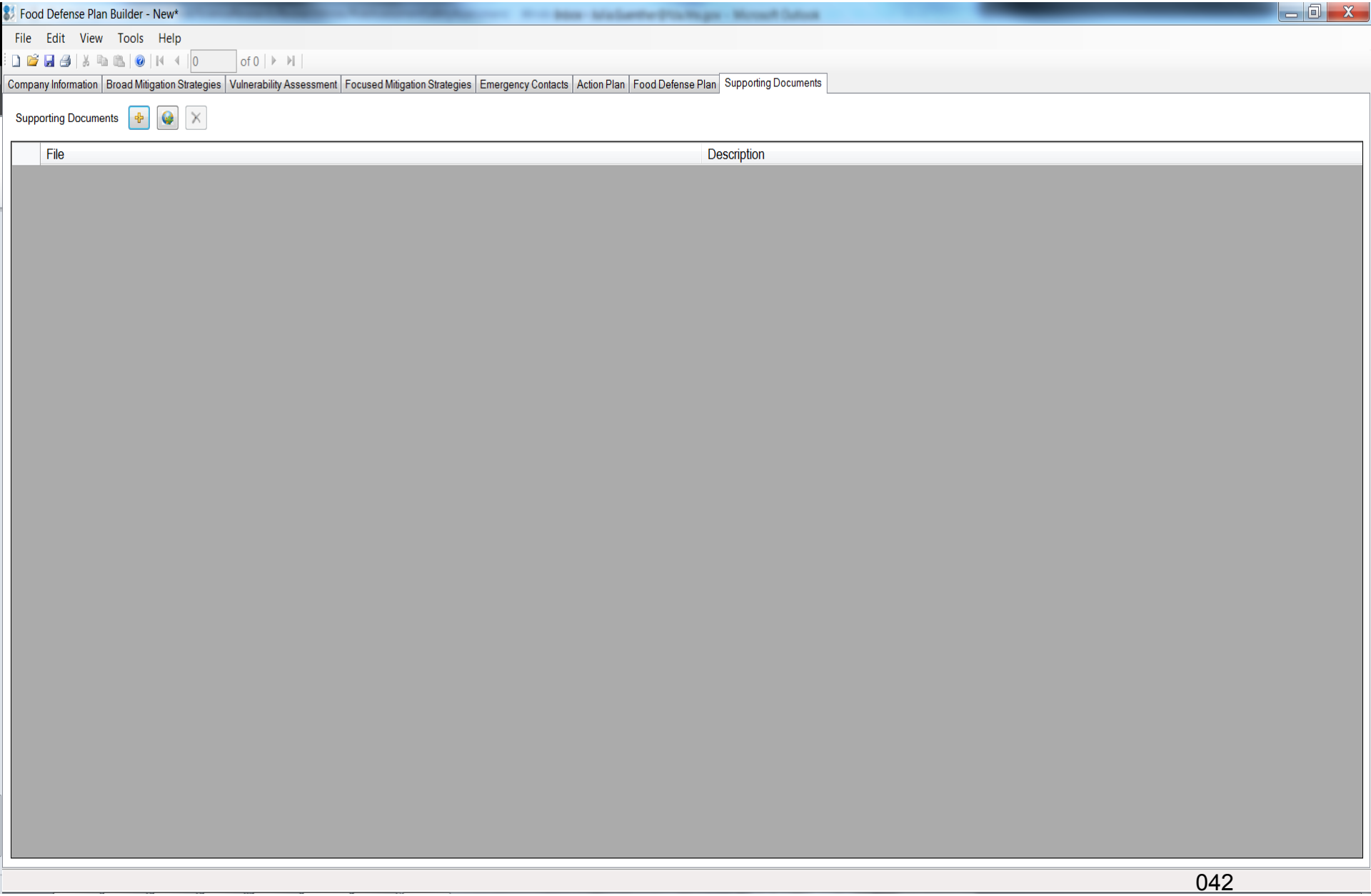

Food Defense Plan Builder - New*
File
Edit
View
Tools
Help
1
of 1
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Process Name
#
Process Steps
Sum
Mitigation Strategies
process1
1
Receiving
20
Search
Mitigation Database Search Results
Search Criteria:
Receiving
Search
Online Database
FDA Food Defense Mitigation Strategies Database
Asterisk(*) - When searching, use the asterisk as a wildcard. A wildcard is a substitute for zero or more characters.
Process Step
Category
Select
Receiving
Transportation/Distribution
Items Found: 1
OK
Cancel


Food Defense Plan Builder - New*
File Edit View Tools Help
1 of 1
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Emergency Phone List:
Resource
Phone
Local Emergency
9-1-1
Local Police Department
Local Fire Department
Local FBI
Local Public Health Department
Poison Control
County Law Enforcement Agency
State Law Enforcement Agency
State Department of Health
FBI Headquarters 24 Hour Hotline
(202) 324-3000
FDA Non-Emergency Phone #
Use this link [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm] to find the FDA consumer complaint coordinator # in your area.
FDA 24 Hour Emergency Phone #
1-866-300-4374 or 301-796-8240
FDA District Office
Use this link [http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm] to find an FDA District Office in your area.
Supplier Contacts:
Company Name
Phone Number(s)
Contact Person(s)
Customer Contacts:
Company Name
Phone Number(s)
Contact Person(s)
Contractor Contacts:
Company Name
Phone Number(s)
Contact Person(s)
Company Emergency Contacts:
Name
Title
Phone
Other Contacts:
Company Name
Phone Number(s)
Contact Person(s)


Food Defense Plan Builder - New*
File
Edit
View
Tools
Help
1
of 1
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Measure # or Process Step
Action Steps
Status
Responsibility
Priority
Target Cmplt Date
process1 - 1. Receiving
New
3/4/2013
Details
Status:
New
Responsibility:
Priority:
Planned Start Date:
3/ 4/2013
Actual Start Date:
3/ 4/2013
Target Completion Date:
3/ 4/2013
Actual Completion Date:
3/ 4/2013
Action Steps
Comments


Food Defense Plan Builder - New*
File Edit View Tools Help
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
100%
Find | Next
For Internal Use Only
FOOD DEFENSE PLAN
Facility Identification #s:
Facility Descr:
Employee Type Descr:
Product & Processes:
FOOD DEFENSE TEAM
Name
Title
Phone
Primary Contact
BROAD MITIGATION STRATEGIES
Section
Measure
Response
Plan Content
Comments
Action Steps
Outside Security
1. Property Perimeter
1a. Is the property perimeter secured to prevent entry by unauthorized persons (e.g., by security guards, fence, wall, or other physical barriers)?
1b. Is there adequate lighting around the property perimeter?
2. Building Perimeter
2a. Is there adequate lighting outside each building and in between buildings?
2b. Are primary entrances to the buildings and operating areas monitored and secured?
2c. Are emergency exit doors self-locking from the outside, with alarms that activate when the doors are opened?


Food Defense Plan Builder - New*
File Edit View Tools Help
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Find Next
For Internal Use Only
Resource
Phone
Local Public Health Department
Poison Control
County Law Enforcement Agency
State Law Enforcement Agency
State Department of Health
FBI Headquarters 24 Hour Hotline
(202) 324-3000
FDA Non-Emergency Phone #
Use this link [http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm] to find the FDA consumer complaint
FDA 24 Hour Emergency Phone #
1-866-300-4374 or 301-796-8240
FDA District Office
Use this link [http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm] to
Company Emergency Contacts
Name
Title
Phone
Supplier Contacts
Company Name
Phone Number(s)
Contact Person(s)
Customer Contacts
Company Name
Phone Number(s)
Contact Person(s)
Contractor Contacts
Company Name
Phone Number(s)
Contact Person(s)
Other Contacts
Company Name
Phone Number(s)
Contact Person(s)
ACTION PLAN
Measure # or Process Step
Action Step
Status
Responsibility
Priority
Dates
process1 - 1. Receiving
New
Trgt Cmplt:3/4/2013
Pln Strt:3/4/2013


Food Defense Plan Builder - New*
File
Edit
View
Tools
Help
0
of 0
Company Information
Broad Mitigation Strategies
Vulnerability Assessment
Focused Mitigation Strategies
Emergency Contacts
Action Plan
Food Defense Plan
Supporting Documents
Supporting Documents
File
Description

Journal of Food Protection, Vol. 76, No. 3, 2013, Pages 376–385
doi:10.4315/0362-028X.JFP-12-372

FDA-iRISK—A Comparative Risk Assessment System for Evaluating and Ranking Food-Hazard Pairs: Case Studies on Microbial Hazards

YUHUAN CHEN,[1] SHERRI B. DENNIS,[1]* EMMA HARTNETT,[2] GREG PAOLI,[2] RÉGIS POUILLOT,[1] TODD RUTHMAN,[2] AND MARGARET WILSON[2]

[1]*U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, Maryland 20740, USA; and* [2]*Risk Sciences International, Inc., 325 Dalhousie Street, Ottawa, Ontario, Canada K1N 7G2*

MS 12-372: Received 22 August 2012/Accepted 31 October 2012

ABSTRACT

Stakeholders in the system of food safety, in particular federal agencies, need evidence-based, transparent, and rigorous approaches to estimate and compare the risk of foodborne illness from microbial and chemical hazards and the public health impact of interventions. FDA-iRISK (referred to here as iRISK), a Web-based quantitative risk assessment system, was developed to meet this need. The modeling tool enables users to assess, compare, and rank the risks posed by multiple food-hazard pairs at all stages of the food supply system, from primary production, through manufacturing and processing, to retail distribution and, ultimately, to the consumer. Using standard data entry templates, built-in mathematical functions, and Monte Carlo simulation techniques, iRISK integrates data and assumptions from seven components: the food, the hazard, the population of consumers, process models describing the introduction and fate of the hazard up to the point of consumption, consumption patterns, dose-response curves, and health effects. Beyond risk ranking, iRISK enables users to estimate and compare the impact of interventions and control measures on public health risk. iRISK provides estimates of the impact of proposed interventions in various ways, including changes in the mean risk of illness and burden of disease metrics, such as losses in disability-adjusted life years. Case studies for *Listeria monocytogenes* and *Salmonella* were developed to demonstrate the application of iRISK for the estimation of risks and the impact of interventions for microbial hazards. iRISK was made available to the public at http://irisk.foodrisk.org in October 2012.

All stakeholders in the system of food safety would benefit from the availability of a tool that enables rapid, transparent, and rigorous evaluation of risks from foodborne hazards. The numerous combinations of foods and hazards make risk assessment across a broad mandate extremely challenging. In particular, federal agencies require evidence-based and transparent approaches to assess, compare, and evaluate the risk of foodborne illness from microbial and chemical hazards and the public health impact of interventions. Comparative risk assessment, sometimes called risk ranking, is integral to food safety decision making *(26)*. Given the multitude of potential foodborne hazards, limited resources should be focused on the greatest risks (and ideally, the greatest opportunities for risk reduction) among the many hazards, commodities, and farm-to-table stages in the food supply system. Assessing food safety risk over the product life cycle and over a large mandate requires the integration of science and state-of-the-art information technology to identify the food-hazard combinations posing the highest risks, to explore interventions to prevent harm, and to respond immediately when contamination and illness occur.

* Author for correspondence. Tel: 240-402-1914; Fax: 301-436-2641; E-mail: sherri.dennis@fda.hhs.gov.

As further evidence of the need for comparative risk assessment tools, an expert committee convened by the National Academy of Sciences *(26)* recommended that the U.S. Food and Drug Administration (FDA) develop tools for public health risk ranking as part of the iterative steps in a risk-based system for enhancing food safety decision making. The Academy panel recommended that the FDA create a model that is fit for purpose and ''scientifically credible, balanced, easy to use, and flexible'' *(26)* to conduct public health risk ranking in a systematic manner.

The FDA Food Safety Modernization Act, enacted in 2011 *(43),* emphasized the need for risk determination, including low versus high public health risk with regard to food products, production activities, and food facilities. For example, the designation of foods as high risk through risk assessment is needed for promulgating regulations pertaining to a product tracing system. In setting standards for produce safety, assessment is required to compare differences in risk associated with fruits and vegetables that are raw agricultural commodities. Risk analysis of on-farm manufacturing, processing, packing, or holding activities is needed for exempting from mandatory preventive controls certain facilities that engage in activities determined to be low risk and involving specific foods determined to be low risk. Implicit in each of these requirements is the need to

compare risks for many foods and hazards in parallel rather than evaluating one combination at a time.

Assessing the risk associated with various hazards and products can be challenging because of the complex and global nature of the food supply. Foods can be contaminated with microbial pathogens, microbial toxins, and chemical hazards at one or more points in the food supply system. Food safety hazards may be introduced from primary production on the farm, during processing, manufacturing, and retail distribution, and during food preparation at retail establishments or in homes. Control measures and interventions can also be identified and applied at various points in the system. A comparative risk assessment tool is needed to allow a systematic analysis of data for contamination, consumption, dose-response relationships, and health effects to identify the most significant risks and risk reduction opportunities based on public health metrics.

Identifying, comparing, and in some cases prioritizing food safety risks can involve a range of qualitative, semiquantitative, and quantitative methods. Various methods and their applications have been published. Qualitative decision trees or risk rules, such as a likelihood-severity grid for qualitative risk ranking *(4),* are examples of qualitative methods. Semiquantitative risk scoring includes the pathogen-produce pair attribution risk ranking model *(1),* the Risk Ranger *(32)* for determining relative risks for different product-pathogen-processing combinations, and the Food Safety Universe Database *(6, 26)* for ranking risks from food-hazard-location combinations in the food supply.

Many examples of quantitative risk assessment models have been published, notably the FDA and the Food Safety and Inspection Service (FSIS) risk assessments of *Listeria monocytogenes* in ready-to-eat foods *(41)* and *Vibrio parahaemolyticus* in raw oysters *(38).* The FDA and FSIS *L. monocytogenes* risk assessment included the development of a complex mathematical model with inputs of available exposure data for 23 ready-to-eat food categories and three dose-response models. The model predicted relative risk rankings among the 23 food categories based on outputs for two public health metrics (cases per serving and cases per year).

Both quantitative and qualitative methods of risk ranking can be useful for informing policy decisions, depending on the problem, the time frame, the specific risk management questions to be addressed, the availability and quality of the data, and the availability of resources. A readily accessible and structured system is desirable as both a risk assessment tool and a knowledge repository to inform food safety decision making, which often takes place in real time. Here, we describe the development and application of the FDA-iRISK (referred to in this article as iRISK) system, a Web-based database and quantitative risk assessment tool for storing evidence in a structured fashion and then assessing and comparing the health impact of microbial and chemical hazards in foods. To illustrate the capacity of iRISK, we present case studies for *L. monocytogenes* and *Salmonella* from an existing FDA library, including risk estimates for multiple food-hazard combinations and the impact of interventions.

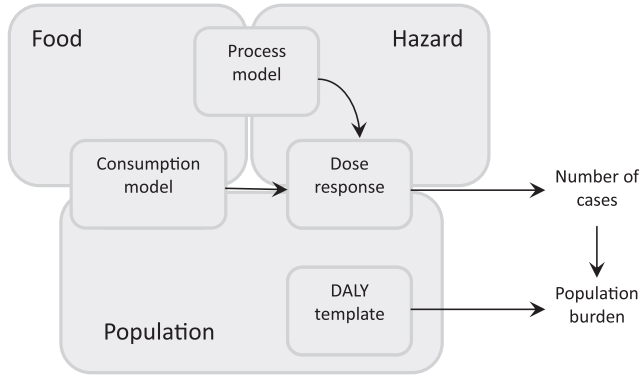


FIGURE 1. *Seven elements of a generic risk scenario in iRISK and their relationships.*

MATERIALS AND METHODS

iRISK development and peer review. The iRISK system was developed through partnership and collaboration with experts within and outside the government. iRISK originated from and built upon a risk ranking prototype developed through a cooperative agreement (grant) between the FDA and the Institute of Food Technologists (IFT). An expert panel with expertise in the food supply system, food safety, risk assessment and management, microbiology, toxicology, and other related areas was convened to develop the framework for the prototype *(29).* The FDA also commissioned a study conducted by RTI International (Durham, NC) to evaluate food safety risk ranking and prioritization models (at a later time RTI International also assisted with proof-of-concept testing of an earlier version of iRISK). Some of the models evaluated were published, but others were not available in the public domain. Based on the evaluation of the scope, strengths, and limitations of the available models, the FDA selected the IFT framework for further development. The IFT framework was operationalized into a series of quantitative risk assessment model elements by Risk Sciences International. The risk assessment model elements are combined with a relational database, a user interface, and report generation capabilities to form a Web-based program, designated iRISK. iRISK has undergone an external peer review for underlying algorithms and mathematical equations and the usability of the interactive Web interface, with a focus on microbial hazards. The FDA published a peer reviewed report describing efforts to expand the capacity of iRISK and enhance the user interface as suggested by the peer review panel *(39).*

iRISK model elements and their relationships. A risk scenario developed in iRISK is a quantitative risk assessment for a food-hazard pair to estimate the risk it poses to a population. The Web interface enables users to define the food and the hazard of interest, edit inputs, update references and assumptions, and store, view, and share data, information, and risk scenarios. Figure 1 illustrates the seven elements of a generic risk scenario: the food, the hazard, the population of consumers, a process model (i.e., food production, processing, and handling practices), consumption patterns in the population, dose-response relationships, and burden of disease measures associated with health effects (e.g., losses in disability-adjusted life years [DALYs]).

The iRISK model is consistent with the Codex risk assessment paradigm *(10, 11)*; hence, data inputs fall into two domains: exposure assessment and hazard characterization. Inputs in the exposure assessment domain focus on consumption patterns in the population, introduction of the hazard, and changes to the level and prevalence of the hazard through the farm-to-fork chain.

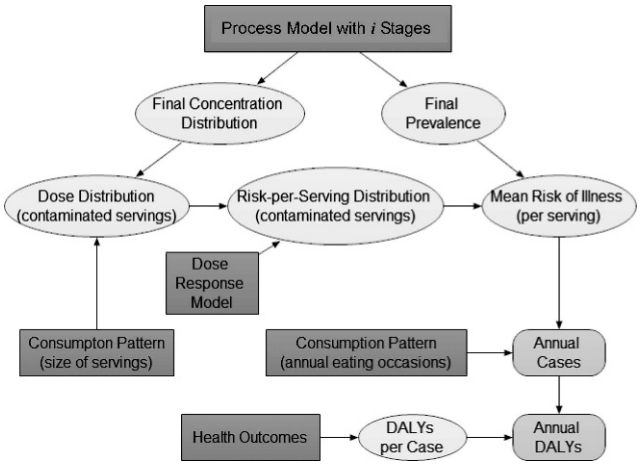


FIGURE 2. *iRISK model inputs and outputs for a food-hazard risk scenario (microbial hazards). User inputs are indicated by square nodes. Model outputs are indicated by oval nodes, with the ultimate risk output being the Annual DALYs for a food-hazard pair under evaluation. The data inputs as shown apply to a risk scenario in which the food is contaminated with a microbial hazard or a chemical hazard that causes acute effects. A risk scenario involving a chronic hazard includes the same inputs and outputs, except that consumption inputs are the amount consumed per day and the number of consumers.*

Inputs in the hazard characterization domain focus on the hazard pathogenicity or toxicity (expressed as a dose-response relationship) and the public health burden associated with infection or toxic effects of the hazard.

Structure of a generic model for microbial and chemical hazards. iRISK is designed to estimate risk associated with both microbial and chemical hazards. Figure 2 illustrates the inputs and outputs of a generic model for a food-hazard pair with a microbial hazard. This generic model also applies to a scenario in which the hazard is a chemical agent that causes an acute health effect. For a food-hazard pair in which the hazard is a chemical agent that causes chronic health effects, the overall underlying model structure is similar, but consumption patterns and doses are defined and measured differently. In this study, we focused on microbial hazards. The process model with multiple stages (Fig. 2) starts with the initial conditions of a pathogen in a food, i.e., the proportion of contaminated units (prevalence) and the distribution of the contamination in the contaminated units. The changes in contamination prevalence and levels as a result of food production, processing, and handling practices are modeled to estimate the final prevalence and concentration distribution of the hazard in contaminated units at the point of consumption. iRISK integrates the user-provided evidence inputs based on built-in templates and mathematical equations according to the biological and handling processes specified by the user. The outputs are generated by Monte Carlo simulations. The computations, including the Monte Carlo simulations, are conducted using the Analytica Decision Engine (Lumina Decision Systems, Los Gatos, CA). The mathematical architecture of iRISK has been peer reviewed *(39)*. Technical details on the models and equations employed are described in the technical documentation *(19)* available on-line with the iRISK tool.

Input elements for a food safety risk scenario. The user begins by specifying hazards, foods, and populations of interest and inputs data corresponding to the exposure assessment and hazard characterization domains. iRISK provides the model framework and templates, and the user chooses the template appropriate for a risk scenario and provides evidence (including the opportunity for providing a rationale for the selection of the evidence) for the seven elements (Fig. 1) within the framework.

Element I: foods. The definition of food affects the process model (e.g., the process model for peanut butter is different from that for soft ripened cheese). The granularity of the food classification (e.g., soft ripened cheese versus brie) depends on the specific purposes of the evaluation.

Element II: hazards. The type of hazard affects process model options (see description of process types below) and dose-response options provided within iRISK for the hazard. Risk ranking is done on the basis of the health burden for a food-hazard pair.

Element III: population groups. The choice of population group is linked to the choice of the dose-response model, specific patterns of health effects, and the consumption model. Depending on the risk scenario, one or more population groups (e.g., perinatal population or adults 60 years or older) and life stages of interest (e.g., early childhood or a duration of 5 years) can be defined.

Element IV: process models. The process model describes the impact of food production, processing, and handling on the level and prevalence of the hazard. The outputs from the process model are the probability distribution of the level of the hazard in the food at the time of consumption and the prevalence of contaminated servings; these data are used to predict ingested dose and the number of cases of illness. The data requirements for a process model include the initial conditions (i.e., initial prevalence, initial distribution of the hazard, and the unit mass), followed by process stages from farm to table (or a smaller scope) of the food supply chain up to the point of consumption.

Process models are defined as a succession of process stages, events, or steps along the farm-to-fork continuum. Each process stage is defined by a process type that describes the impact of the stage on the hazard and the unit size of the food. The process type describes what happens in an individual process stage, expressed as a fixed value or as a probability distribution representing variability. A process type may be selected from a menu of built-in process types that have been customized for this application. The process types and the associated mathematical equations describe the major process mechanisms that affect the prevalence, level, and spatial distribution of a microorganism. Mathematical equations describing the process types have been peer reviewed *(39)* and are similar to those previously published *(18, 27, 28)*. The process types and their data inputs are further described in Table 1.

Element V: consumption models. The consumption model is defined in relation to the specified population group. For microbial hazards, the distribution of the amount of food eaten (i.e., serving size) during each eating occasion and the number of eating occasions (i.e., number of servings) annually are required inputs. For chemical hazards, the distribution of the average amount of the food eaten daily (over a period of time or a lifetime) and the number of consumers are required.

Element VI: dose-response models. The dose-response relationship predicts the probability of a specific biological effect (response) at various levels of ingestion (doses) of a hazard. The

TABLE 1. *Process types and data inputs describing the impact of a process stage on microbial and/or chemical hazards*

Process type	Description of data inputs[a]
Increase by growth	This process type is applied to microbial hazards only. It describes the increase in level (a distribution or a fixed value on a log scale such as log CFU) due to growth of the bacterial pathogen, while prevalence is assumed to be unaffected.
Increase by addition	This process type represents the addition of the hazard in the amount of the specified addition to a unit of the food[b] (a distribution or a fixed value on a log scale such as log CFU or log PFU of a microbial hazard to a unit, or grams of a chemical hazard to a unit). The likelihood of such an addition occurring is also required (a fixed value from 0 to 1). This process type may be used to describe an increase in prevalence and/or concn or level as a consequence of cross-contamination, e.g., from the processing environment.
Decrease	This process type describes the removal or inactivation of some fraction of the hazard. For chemical hazards, the decrease is defined by a fixed value or a distribution that ranges from 0 (no decrease at all) to <1, because total elimination is assumed to be impossible. For microbial hazards, the decrease is defined usually by a distribution or by a fixed value of the log reduction in the level of contamination within the contaminated units. A reduction in prevalence is possible when the microbial hazard decreases because the individual microbes are discrete units. In contrast, chemical contamination is assumed to be continuous (i.e., distributed homogeneously throughout contaminated units); this process type leads to a diminution of the concn in contaminated units without change in the prevalence.
Pooling	When units of food are combined into larger units, some contaminated units may be mixed with some uncontaminated units, resulting in an increase in prevalence and a decrease in the concn or level of the hazard in each contaminated unit. Pooling reflects the simultaneous impact of cross-contamination and dilution. The input is the new unit mass (grams) of the food, and the iRISK model computes the associated changes to prevalence and concn or level of the hazard.
Partitioning	When units of food are subdivided, the result depends on the nature of the hazard. For chemical hazards, neither concn nor prevalence would be affected because the chemical is assumed to be spread sufficiently uniformly throughout the food that it would be expected to be in all partitions of the food. Microbial hazards exist as discrete units such as individual bacterial cells (at levels typically much lower than discrete molecules of chemicals) that cannot be divided among more units of food than their own number. The input is the new unit mass (grams) of the food as a fixed value, and the iRISK model computes the associated changes to prevalence and concn or level of the hazard.
Evaporation or dilution	This process type represents the proportional increase or decrease in hazard concn or level that results from varying the mass of the contaminated unit. Inputs fall between 0 and 1 for dilution and 0 and >1 for evaporation. For example, 2 would represent a doubling of the concn or level associated with a halving of the mass (such as in evaporation), and 0.25 would represent a fourfold decrease in the concn or level that results from increasing the mass by the same factor (such as in dilution).
Redistribution (partial)	This parameter describes the factor by which prevalence increases as a consequence of cross-contamination among food units; iRISK reduces the concn or level accordingly. Therefore, the input is a multiplier (≥ 1), either a distribution of values or a fixed value, to be applied to the current prevalence level. Using the number 1 implies no change in prevalence or no cross-contamination. This process type describes cross-contamination among food units but not from the processing environment.
Redistribution (total)	Selection of this process type automatically redistributes contamination evenly among all units. For chemical hazards, prevalence is set to 1.0. For microbial hazards, prevalence is set to 1.0 when there is a high enough level of organisms to redistribute to all units or is set to the maximum value possible when the level is not high enough. In both cases, the concn or level of the hazard for each unit is reduced accordingly by iRISK, keeping the total hazard load in the system (across all units) constant. No data input is needed. This process type describes cross-contamination among food units but not from the processing environment.
No change	The process does not affect prevalence, concn or level, or unit mass; no data input is needed. This designation is useful for describing the full processing system and for explicitly noting that no effect is expected at that stage. A ''placeholder'' process type is also available to be used in the initial stages of developing a process model before specific data are available.

[a] Usually the data input is defined by a distribution of values rather than a point value to represent the variability, such as in the levels of a hazard in food or in the growth, increase, and decline of a hazard in food over the product life cycle from production to consumption.

[b] A unit is a fixed quantity of food, which is key to maintaining a clear definition of prevalence because prevalence is described as the fraction of units that have one or more pathogens or any chemical contamination. Various processes in food production will change the functional unit of food because of, for example, pooling of milk from a farm tank into a bulk tank or partitioning milk from a processing plant to individual packages of milk. The change in the functional unit must be taken into account to adjust the estimates of prevalence and level or concentration of a hazard in response to these changes.

dose-response relationship is specific to the hazard type, either microbial or chemical (further broken down by acute versus chronic hazard). Dose-response relationships specific to population groups or foods can also be developed when data are available. One of the case studies (case study 2) provides population-specific dose-response models for *L. monocytogenes,* such as for the perinatal population and for adults 60 years of age or older. Currently, sufficient data are not available to develop dose-response relationships specific to the food matrix.

Element VII: health outcomes. Foodborne illness caused by a pathogen may have more than one health outcome among different individuals in the population *(2, 17, 21, 33).* For example, infection with *Salmonella* may result in mild diarrhea, severe

diarrhea requiring hospitalization, reactive arthritis, or death *(40)*. Different hazards will cause different frequencies of health outcomes, such as the proportion of illness cases resulting in hospitalization or death *(33)*. To compare the population health burden across different hazards, it is necessary to specify health endpoints of the illness in association with the hazard and translate the endpoints into a common metric. The DALY is one of several commonly used health impact metrics that integrate information on the severity and duration of illness to estimate disease burden *(2, 17, 21)*. A DALYs-per-case value (Fig. 2) is used as a measure of the averaged burden of disease per case of illness, taking into account the relative frequency of each potential health impact. Each health endpoint is defined in terms of its duration and severity, with the burden of disease being the product of these two factors. In the case of death, duration is expressed as years of life lost based on the age of the person affected, and severity is set to the maximum value of 1.0. Users can enter different health endpoints in iRISK to create a new DALY template. Through an expert elicitation *(39)*, the FDA has developed DALY templates for a number of hazards.

Case study data inputs. Case study 1 is a risk scenario for *Salmonella* (nontyphoidal) in peanut butter to illustrate the use of iRISK to estimate the population health burden for a single food-hazard pair. Through the use of built-in templates, inputs were entered for the elements of the *Salmonella* in peanut butter risk scenario (Table 2). Table 2 describes the iRISK template used for the various input parameters for the process model, the process type selected, and the input data, either as a fixed value (e.g., initial prevalence and unit mass) or as a distribution (e.g., initial level and log reduction during storage). For illustration purposes, the process model for peanut butter production was simplified, starting at the end of processing and including two stages: packaging and storage before consumption. At the end of processing, some units are contaminated, and the levels of *Salmonella* in the contaminated units are assumed to decline during storage before consumption. Data from the literature were used to estimate the initial contamination and log reduction during storage through the process model. Specific data inputs for the consumption model, dose-response model, and health effects are also shown Table 2. The iRISK templates provide the capacity to enter evidence that is required for the risk scenario in a consistent fashion and to document assumptions and sources of the data and references. These templates are described in greater detail in supplemental Tables IA, IB, and IC *(19)*. Having defined the food-hazard risk scenario by entering the evidence captured in Table 2, the scenario is available in a risk scenarios library within the individual user's iRISK database. The risk scenario is then selected for computation and reporting. iRISK constructs the model based on the evidence in the database and runs a Monte Carlo simulation while checking continuously for converging statistics of the output distribution. A report is generated as a portable document format file (Adobe Systems, San Jose, CA). The report includes a summary of the model outputs and risk scenario details, including all the input data, descriptions, and references, i.e., all the data and rationale entered by the user.

The second case study consists of risk scenarios for *L. monocytogenes* in soft ripened cheese for three population groups: the perinatal population, adults 60 years of age or older (adults 60+), and the general population (intermediate age). The perinatal population is defined as fetuses and neonates from 16 weeks after fertilization to 30 days after birth, the same definition used by the FDA and FSIS in the 2003 *L. monocytogenes* risk assessment *(41)*. Data and information inputs were the same for the hazard, the food, and the process model, whereas the three population groups were defined and the inputs were different for the dose-response model, consumption model, and DALY templates (Table 2). A more detailed description of the data, references, and rationale is provided in supplemental Tables IIA, IIB, and IIC *(19)*. The risk scenarios for the three population groups have different consumption patterns, dose-response relationships, and health effects. The model inputs for case studies 1 and 2 illustrate that although the food, hazard, and population of interest are different for the *Salmonella* risk scenario and the *L. monocytogenes* risk scenarios, the underlying model structure (Fig. 2) and the nature of the evidence required as inputs (Table 2) are the same for both pathogens. Case studies 3 and 4 included the evidence from case studies 1 and 2 to rank risks from multiple food-hazard pairs and to evaluate the effectiveness of interventions. Additional data were obtained from published studies *(23, 24, 30, 31)* and from an ongoing market basket survey to develop case study 3 on a risk scenario for *L. monocytogenes* in cantaloupes for adults 60+. The data inputs are shown in supplemental Tables IIIA, IIIB, and IIIC *(19)*.

Integration of model inputs through Monte Carlo simulations to estimate population health burden. The evidence entered for the seven elements of a risk scenario determine the level of exposure and the health impact of that exposure (Fig. 2). A risk-per-serving distribution (among contaminated servings) is generated taking into account the variability in the final distribution of the contamination (process model), the serving size distribution (consumption model), and the dose-response relationship (dose-response model). The mean risk of illness per contaminated serving is calculated from the distribution of risk (describing variability derived from any of the probabilistic inputs) generated through Monte Carlo simulation. The mean risk of illness per serving is the product of this mean and the prevalence of contaminated units at the time of consumption. The expected annual number of illness cases is calculated by multiplying the mean risk of illness per serving by the number of servings per year. The annual DALYs are calculated by multiplying the annual number of cases by the DALYs-per-case value. The iRISK Monte Carlo simulation is designed to address variability, and uncertainty can be explored by scenario analysis (e.g., changing parameters or changing distributions and comparing results).

The final result is the annual health burden, measured in DALYs lost per year, expected to result from the food-hazard combination given the assumptions for contamination, dose-response, health effects, and consumption pattern in the population in each scenario. Integration of data and information on duration and severity allow the comparison of different microbial pathogens associated with qualitatively different illness symptoms, severities, and health outcomes, including variations in the case complication (e.g., case fatality) rates among pathogens.

RESULTS AND DISCUSSION

iRISK 1.0 was used to develop the case studies reported here. These case studies are provided exclusively for illustrative purposes. The actual implementations of several of the case studies are available to users in the publicly released version of iRISK *(19)*.

Case study 1: a single food-hazard pair in one population group. The model results (Table 3) include final pathogen level (the mean of the distribution is reported), final prevalence, total illnesses, mean risk of

TABLE 2. *Examples of model inputs for food-hazard scenarios in iRISK*

Element of risk scenario	*Salmonella* in peanut butter, total population			*L. monocytogenes* in soft ripened cheese, three population groups		
	Input parameter, iRISK template	Model input	Reference(s)[a]	Input parameter, iRISK template	Model input	Reference(s)[a]
Food	Peanut butter	Description	*42*	Soft ripened cheese	Description	*41*
Hazard	*Salmonella*	Description	*34, 40*	*L. monocytogenes*	Description	*41*
Process model	Initial prevalence (manufacturing)	5.50E−06	*7–9, 36*	Initial prevalence (retail)	0.0104	*15*
	Initial concn	Uniform (−1.52, 2.55) log CFU/g	*5, 22, 34, 44*	Initial concn	Triangular (−1.39, −1.15, 0.699) log CFU/g	*15*
	Initial unit mass	6.85E+06 g		Initial unit mass	227 g	*15*
	Process stage 1: packaging, partitioning	Unit mass 250 g		Process stage 1: consumer storage, increase[b]	Triangular (0, 0.03, 5.79) (log CFU)	*12, 41*
	Process stage 2: storage, decrease	Uniform (0.49, 3.47) log CFU	*5*	NA		
Consumption model	Grams per eating occasion	30 g	*20, 37*	Grams per eating occasion[c]	(i) Triangular (10, 28, 85); (ii) Triangular (10, 28, 85); (iii) Triangular (10, 28, 168)	*41*
	Eating occasions per year	1.7E+10		Eating occasions per year[c]	(i) 1.2E+07; (ii) 1.8E+08; (iii) 1.7E+09	*41*
Dose-response model	Beta-Poisson model	$\alpha = 0.1324$; $\beta = 51.45$	*13*	Exponential[c]	(i) 4.51E−11; (ii) 8.39E−12; (iii) 5.34E−14	*14*
Health effects	DALY template (salmonellosis general population)	0.019 DALYs per case	*2, 33, 40*	DALY templates (listeriosis)[c]	(i) 14 DALYs per case; (ii) 2.6 DALYs per case; (iii) 5.0 DALYs per case	*21, 25*

[a] Detail description of rationale can be found in the supplemental Tables IA, IB, IC, IIA, IIB, and IIC *(19),* including assumptions made in using data and information from the listed references to derive the model inputs for the risk scenarios.

[b] The ComBase Predictor (http://www.combase.cc) was used to determine growth based on times and temperatures during consumer storage. See details in supplemental Table IIB *(19).*

[c] Inputs are defined separately for consumption, dose-response, and health effects for the three *L. monocytogenes* risk scenarios: (i) the perinatal population, (ii) adults 60 years of age and older, and (iii) the intermediate-age population (5 to 59 years of age). The three risk scenarios have the same food, hazard, and process model.

TABLE 3. *iRISK output example: summary results for a single food-hazard pair*

Scenario	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Salmonella in peanut butter, total population	0.273	4.18E−06	3,380	1.99E−07	1.70E+10	63.5	3.74E−9

illness, total eating occasions, annual DALYs, and DALYs per eating occasion. The detailed report generated for each scenario contributes to the documentation, knowledge base development, transparency, and consistency that is key to the application of comparative risk assessment.

The mean risk of illness is the average probability of illness from one serving or eating occasion and was generated through Monte Carlo simulations from the mean of the risk-per-serving distribution among contaminated servings (an intermediate result not shown) and the final prevalence of contamination in the food. The results shown in Table 3 accounted for variability of all inputs for a food-hazard pair. When the final prevalence of the pathogen contamination in food is low (e.g., less than 1%), as is often the case, the majority (e.g., >99%) of the servings are not contaminated. The risk per serving for these noncontaminated servings is 0. The 5th, 95th, and 99th percentiles of the risk per serving (among all servings) is then 0. The mean risk of illness per serving (among all servings) will likely also be very low; nevertheless, it is not 0 because the risk for the <1% of contaminated products is not 0. This was the case for the risk scenario *Salmonella* in peanut butter (Table 3), where the final prevalence was approximately 4E−6 (approximately 4 in 1 million) and the mean risk of illness per serving was approximately 2E−7 (or 2 cases per 10 million servings). The Monte Carlo approach applied in iRISK, which focuses computation resources on only contaminated units, is much more efficient than simulation of both contaminated and noncontaminated units, given the low prevalence expected in the final servings for many food-hazard pairs.

Case study 2: a single food-hazard pair in three population groups. Based on the data inputs for *L. monocytogenes* in soft ripened cheese and the population groups, iRISK generated risk estimates through Monte Carlo simulations for each of the three risk scenarios (Table 4). The mean risk of illness was 7.1E−8 for the perinatal population, 1.3E−8 for adults 60+, and 1.4E−10 for the intermediate-age population. The difference was primarily driven by the difference in the assumed *L. monocytogenes* dose-response relationship among the three population groups (Table 2), given that the same process model was used, which resulted in the same final mean level and the same final prevalence of *L. monocytogenes* in the soft ripened cheese at the point of consumption. Combining the mean risk of illness output with the number of servings per year, the expected annual number of cases was determined (results not shown) and subsequently translated into annual DALYs loss of 11.7, 6.12, and 1.20 for the perinatal, adults 60+, and intermediate-age populations, respectively. The health metric (e.g., annual DALYs lost) formed the basis for risk ranking for multiple risk scenarios.

iRISK was further employed to characterize uncertainty about the annual DALYs, using the intermediate-age population as an example. The uncertainty analysis for the predicted annual DALYs was obtained through sensitivity analysis focused on the dose-response relationship. The inputs for the dose-response model were different r values (the single parameter of an exponential dose-response model) representing the 5th percentile (r = 1.42E−14), median (r = 5.34E−14), and 95th percentile (r = 1.02E−13) of the r value uncertainty distribution from the Food and Agriculture Organization of the United Nations and the World Health Organization *(14)*. The resulted annual DALYs were 0.320 (5th percentile), 1.20 (median), and 2.30 (95th percentile) for the uncertainty estimates. The median DALYs result was used in risk ranking.

Case study 3: risk ranking for multiple food-hazard pairs. From the FDA iRISK library, we selected five risk scenarios for ranking, including the food-hazard pairs developed in case studies 1 and 2 and a risk scenario for *L. monocytogenes* in cantaloupes for adults 60+. The case studies illustrate that iRISK allows risk ranking of population health burden across many different dimensions: multiple population groups (Table 4), multiple foods (Table 5), and multiple food-hazard combinations (Table 6). Table 4 shows risk ranking among three population groups: *L. monocytogenes* in soft ripened cheese for the perinatal population, intermediate-age population, and adults 60+. Table 5 shows an example of risk ranking for two different foods, soft ripened cheese and cantaloupe, for the same populations in a baseline nonoutbreak situation. All five risk scenarios can be

TABLE 4. *iRISK output example: risk ranking across multiple population groups*

Scenario of *L. monocytogenes* in soft ripened cheese	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Perinatal population	3.55	0.0104	0.850	7.08E−8	1.20E+07	11.7	9.77E−7
Adults 60 yr and older	3.55	0.0104	2.37	1.32E−8	1.80E+08	6.12	3.40E−8
Intermediate-age population	3.55	0.0104	0.242	1.42E−10	1.70E+09	1.20	7.08E−10

TABLE 5. *iRISK output example: risk ranking across multiple foods*

Scenario of *L. monocytogenes* in adults 60+	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Cantaloupe	2.32	0.0130	2.39	2.22E−9	1.08E+9	6.18	5.72E−9
Soft ripened cheese	3.55	0.0104	2.37	1.32E−8	1.80E+08	6.12	3.40E−8

selected for ranking (Table 6), although the food-hazard pairs are being compared for different population groups. In some cases, it may be important and more informative to make comparisons based on the same population. The health burden associated with *L. monocytogenes* in soft ripened cheese for the total U.S. population is the sum of that from the perinatal and intermediate-age populations and adults 60+. We used a risk scenario grouping option in iRISK to aggregate the total DALYs from the three population groups and compared the aggregate DALYs for *L. monocytogenes* with the annual DALYs for *Salmonella* in peanut butter in the total U.S. population (Table 6). These examples illustrate the flexibility of the iRISK system, which can be used to address different questions to meet different risk management decision-support needs.

Case study 4: evaluation of interventions. The predictive multistage process model is the means by which iRISK enables evaluation of control measures and potential interventions. For case study 2, the baseline risk scenario for *L. monocytogenes* in soft ripened cheese for the perinatal population included the amount of growth as having a Triangular probability distribution (minimum = 0, mode = 0.03, maximum = 5.79), with units of log CFU. The maximum growth of 5.79 log CFU was based on the assumption of 15 days of storage at 13.0°C (see supplemental Table IIB *(19)*). We conducted sensitivity analyses using iRISK to evaluate the impact of reduced storage temperature through interventions such as consumer education. When the maximum storage temperature is reduced from 13.0°C (supplemental Table IIB, mean temperature + 4 SD) to 10.6°C (mean + 3 SD) or 8.2°C (mean + 2 SD), the growth of *L. monocytogenes* (maximum level) during consumer storage would be reduced from 5.79 to 3.42 and 1.64 log CFU, respectively. The corresponding predicted annual loss in DALYs would decrease from 11.7 to 0.128 and 0.00817, respectively, keeping all other inputs in the model unchanged.

iRISK can be used to evaluate interventions at any of the stages in the process model. Using the *Salmonella* in peanut butter risk scenario, we evaluated the impact of interventions in the processing environment on predicted health burden in the total population. For example, food producers may implement measures such as controlling personnel and material movements, applying hygienic equipment design principles, and minimizing or eliminating moisture in the peanut postroasting area *(16)* to reduce the levels of *Salmonella* contamination in the postroasting stages of production. If such control measures decrease contamination from the baseline (uniformly distributed on the log scale between 1.52 and 2.55) for the initial level by reducing the maximum level by 1 or 2 log CFU, the predicted annual loss in DALYs would be reduced by 67 and 93%, respectively (Fig. 3).

The results presented in these case studies were based on the data inputs and assumptions made; the predicted mean risk of illness and annual DALYs will change as different inputs are used. The risk scenarios, risk estimates, and risk rankings presented in this study are primarily for illustration purposes. Because the data are stored in each user's unique registry within iRISK, the risk scenarios can be easily retrieved and updated with new data and updated assumptions.

Future considerations. Ongoing efforts are being made to further improve and validate the iRISK model, including further testing, adding functionalities such as more probability distribution options, and improving the capacity of iRISK to predict health burden of microbial toxins. iRISK is flexible; in addition to the DALY metric, other health impact metrics such as cost of illness *(3, 35)* may be added to the system. Ongoing efforts include increasing the library of food-hazard pairs. Like any quantitative risk assessment, development of a risk scenario in iRISK is data intensive. Data are needed from multiple sources, including the scientific literature, government

TABLE 6. *iRISK output example: risk ranking of population health burden across multiple hazards, foods, and population groups*

Scenario	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Group 1: *Salmonella* in peanut butter, total population	0.273	4.18E−06	3,380	1.99E−07	1.70E+10	63.5	3.74E−9
Group 2: *L. monocytogenes* in soft ripened cheeses							
Total population						19.0	
Perinatal population	3.55	0.0104	0.850	7.08E−8	1.20E+07	11.7	9.77E−7
Adults 60 yr and older	3.55	0.0104	2.37	1.32E−8	1.80E+08	6.12	3.40E−8
Intermediate age population	3.55	0.0104	0.242	1.42E−10	1.70E+09	1.20	7.08E−10

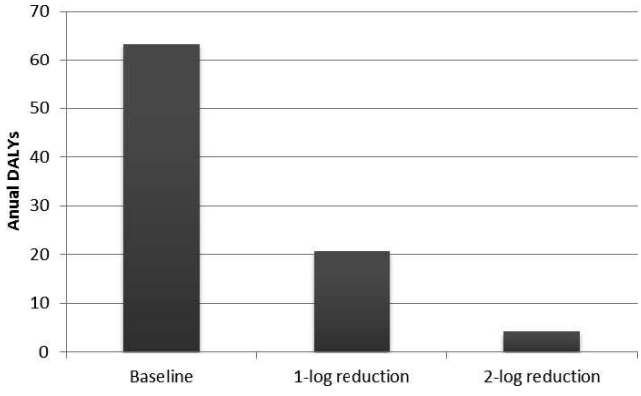


FIGURE 3. *iRISK output example: evaluation of intervention for the* Salmonella *in peanut butter risk scenario. Assuming improved control measures in the processing environment that reduces the maximum level of* Salmonella *contamination postroasting, the impact of the intervention on the annual DALYs was conducted using sensitivity analysis in iRISK. The inputs for the scenarios for the baseline and 1-log and 2-log reductions in the maximum level were distributions Uniform (−1.52, 2.55), Uniform (−1.52, 1.55), and Uniform (−1.52, 0.55), respectively.*

surveys (e.g., the National Health and Nutrition Examination Survey for consumption), publicly accessible databases (e.g., ComBase), expert elicitation and judgment (e.g., DALY-per-case estimates), and regulatory sampling and commissioned studies, as was shown in the case studies. Targeted data collection of prevalence and enumeration data for specific hazards in specific commodities at specific points throughout the food supply chain would help expand the library of food-hazard pairs. iRISK can be used to understand what takes place in a normal baseline situation and to explore an outbreak situation.

In conclusion, iRISK is an interactive, Web-based system that enables rapid, structured, quantitative risk assessment and serves as a knowledge repository due to the underlying relational database and reporting capability. iRISK has been designed to provide breadth and flexibility of calculations and computational features to simultaneously analyze data and estimate health burden in a manner that allows comparison across many dimensions with regard to hazards, foods and food commodities, food production, processing, and handling practices, and populations and the evaluation of interventions. iRISK calculates, through Monte Carlo simulation, the number of illness cases expected based on the contamination of the food by the hazard in question, the typical consumption pattern, and the dose-response relationship and then translates the number of cases into a public health metric to permit comparison of the public health burden across multiple food-hazard pairs. The FDA anticipates further enhancing the capacity and expanding the application of iRISK to support decision making to ensure food safety. iRISK version 1.0 was made available to the public in October 2012 *(19)*.

ACKNOWLEDGMENTS

The authors thank the many experts who provided invaluable input and critiques to assist the development of the iRISK system, including members of the IFT expert panel, RTI, and external peer reviewers. This work was supported in part by appointments (R. Pouillot) to the Research Participation Program at the Center for Food Safety and Applied Nutrition, administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the U.S. Food and Drug Administration.

REFERENCES

1. Anderson, M., L.-A. Jaykus, S. Beaulieu, and S. Dennis. 2011. Pathogen-produce pair attribution risk ranking tool to prioritize fresh produce commodity and pathogen combinations for further evaluation (P^3ARRT). *Food Control* 22:1865–1872.
2. Australian Institute of Health and Welfare. 2001. The burden of disease and injury in Australia 1996. Available at: http://www.aihw.gov.au/bod/bod_yld_by_disease/index.cf. Accessed 7 May 2012.
3. Batz, M. B., S. Hoffmann, and J. G. Morris, Jr. 2011. Ranking the risks: the 10 pathogen-food combinations with the greatest burden on public health. Emerging Pathogens Institute, University of Florida. Available at: http://www.epi.ufl.edu/sites/www.epi.ufl.edu/files/RankingTheRisksREPORT.pdf. Model available at: http://www.thefsrc.org/firrm.htm. Accessed 5 April 2012.
4. Bernard, D. T., K. E. Stevenson, and V. N. Scott. 2006. Hazard analysis, appendix 8-B, p. 57–68. *In* V. N. Scott and K. E. Stevenson (ed.), HACCP: a systematic approach to food safety, 4th ed. Food Products Association, Washington, DC.
5. Burnett, S. L., E. R. Gehm, W. R. Weissinger, and L. R. Beuchat. 2000. Survival of *Salmonella* in peanut butter and peanut butter spread. *J. Appl. Microbiol.* 89:472–477.
6. Cassidy, M. 2003. The food safety universe database: a risk assessment and risk ranking tool. Available at: http://www.aic.ca/conferences/pdf/Mike_Cassidy3.pdf. Accessed 27 July 2012.
7. Centers for Disease Control and Prevention. 2007. Multistate outbreak of *Salmonella* serotype Tennessee infections associated with peanut butter—United States, 2006–2007. *Morb. Mortal. Wkly. Rep.* 56: 521–524.
8. Centers for Disease Control and Prevention. 2009. Multistate outbreak of *Salmonella* infections associated with peanut butter and peanut butter–containing products—United States, 2008–2009. *Morb. Mortal. Wkly. Rep.* 58:1–6.
9. Chen, Y., V. N. Scott, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A. Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of *Salmonella* in low-moisture foods. II. Hygiene practices to minimize *Salmonella* contamination and growth. *Food Prot. Trends* 29:435–445.
10. Codex Alimentarius Commission. 1999. Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL-30. Available at: http://www.codexalimentarius.net/web/more_info.jsp?id_sta=357. Accessed 18 May 2011.
11. Codex Alimentarius Commission. 2007. Working principles for risk analysis for food safety for application by governments. CAC/GL-62. Available at: http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10751. Accessed 18 May 2011.
12. EcoSure. 2008. EcoSure 2007 cold temperature database. 2007 U.S. cold temperature evaluation design and summary pages. Available at: http://foodrisk.org/exclusives/EcoSure/. Accessed 24 October 2010.
13. Food and Agriculture Organization of the United Nations and World Health Organization. 2002. Risk assessments of *Salmonella* in eggs and broiler chickens. Technical report. Microbiological risk assessment series 2. Food and Agriculture Organization of the United Nations and World Health Organization, Rome. Available at: http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/salmonella0/en/. Accessed 7 May 2012.
14. Food and Agriculture Organization of the United Nations and World Health Organization. 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. Technical report. Microbiological risk assessment series 5. Food and Agriculture Organization of the United Nations and World Health Organization, Rome. Available at: http://www.fao.org/docrep/010/y5394e/y5394e00.htm. Accessed 9 May 2011.

15. Gombas, D. E., Y. Chen, R. S. Clavero, and V. N. Scott. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *J. Food Prot.* 66:559–569.
16. Grocery Manufacturers Association. 2009. Control of *Salmonella* in low-moisture foods. Available at: http://www.gmaonline.org/downloads/technical-guidance-and-tools/SalmonellaControlGuidance.pdf. Accessed 5 April 2012.
17. Havelaar, A. H., J. A. Haagsma, M.-J. Mangen, J. M. Kemmeren, L. P. B. Verhoef, S. M. C. Vijgen, M. Wilson, I. H. M. Friesema, L. M. Kortbeek, Y. T. H. P. van Duynhoven, and W. van Pelt. 2012. Disease burden of foodborne pathogens in the Netherlands, 2009. *Int. J. Food Microbiol.* doi:10.1016/j.ijfoodmicro.2012.03.029.
18. International Life Sciences Institute. 2010. Impact of microbial distributions of food safety. ILSI Europe report series. International Life Sciences Institute, Brussels. Available at: http://www.ilsi.org/Europe/Publications/Microbial%20Distribution%202010.pdf. Accessed 17 May 2011.
19. iRISK. 2012. iRISK, version 1.0. Technical documentation. Available at: http://irisk.foodrisk.org/SupportingDocumentation.aspx. Accessed 2 November 2012.
20. Jiang, R., J. E. Manson, M. J. Stampfer, S. Liu, W. C. Willett, and F. B. Hu. 2002. Nut and peanut butter consumption and risk of type 2 diabetes in women. *JAMA (J. Am. Med. Assoc.)* 288:2554–2560.
21. Kemmeren, J. M., M.-J. J. Mangen, Y. T. H. P. van Duynhoven, and A. H. Havelaar. 2006. Priority setting of foodborne pathogens. RIVM report 330080001/2006. Severity (Table 3) and duration (Table 18). Available at: http://rivm.openrepository.com/rivm/bitstream/10029/7316/1/330080001.pdf. Accessed 7 May 2012.
22. Kirk, M. D., C. L. Little, M. Lem, M. Fyfe, D. Genobile, A. Tan, J. Threlfall, A. Paccagnella, D. Lightfoot, H. Lyi, L. McIntyre, L. Ward, D. J. Brown, S. Surnam, and I. S. T. Fisher. 2004. An outbreak due to peanuts in their shell caused by *Salmonella enterica* serotypes Stanley and Newport—sharing molecular information to solve international outbreaks. *Epidemiol. Infect.* 132:571–577.
23. Leverentz, B., W. S. Conway, M. J. Camp, W. J. Janisiewicz, T. Abuladze, M. Yang, R. Saftner, and A. Sulakvelidze. 2003. Biocontrol of *Listeria monocytogenes* on fresh-cut produce by treatment with lytic bacteriophages and a bacteriocin. *Appl. Environ. Microbiol.* 69:4519–4526.
24. Leverentz, B., W. S. Conway, W. Janisiewicz, and M. J. Camp. 2004. Optimizing concentration and timing of a phage spray application to reduce *Listeria monocytogenes* on honeydew melon tissue. *J. Food Prot.* 67:1682–1686.
25. McLauchlin, J., R. T. Mitchell, W. J. Smerdon, and K. Jewell. 2004. *Listeria monocytogenes* and listeriosis: a review of hazard characterisation for use in microbiological risk assessment of foods. *Int. J. Food Microbiol.* 92:15–33.
26. National Academies of Sciences. 2010. Enhancing food safety: the role of the Food and Drug Administration. Committee on the Review of Food and Drug Administration's Role in Ensuring Food Safety, National Research Council. Available at: http://www.nap.edu/catalog/12892.html. Accessed March 2012.
27. Nauta, M. J. 2005. Risk assessment modelling of the food handling processes mixing and partitioning. *Int. J. Food Microbiol.* 100:311–322.
28. Nauta, M. J. 2008. The modular process risk model (MPRM): a structured approach for food chain exposure assessment, p. 99–136. *In* D. W. Schaffner (ed.), Microbial risk analysis of foods. ASM Press, Washington, DC.
29. Newsome, R., N. Tran, G. M. Paoli, L. A. Jaykus, B. Tompkin, M. Miliotis, T. Ruthman, E. Hartnett, F. F. Busta, B. Petersen, F. Shank, J. McEntire, J. Hotchkiss, M. Wagner, and D. W. Schaffner. 2009. Development of a risk-ranking framework to evaluate potential high-threat microorganisms, toxins, and chemicals in food. *J. Food Sci.* 74: R39–R45.
30. Penteado, A. L., and M. F. F. Leitao. 2004. Growth of *Listeria monocytogenes* in melon, watermelon and papaya pulps. *Int. J. Food Microbiol.* 92:89–94.
31. Pouillot, R., K. Hoelzer, Y. Chen, and S. Dennis. 2003. Estimating probability distributions of bacterial concentrations in food based on data generated using the most probable number (MPN) method for use in risk assessment. *Food Control* 29:350–357.
32. Ross, T., and J. Sumner. 2002. A simple, spreadsheet-based, food safety risk assessment tool. *Int. J. Food Microbiol.* 77:39–53.
33. Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M.-A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis.* 17:7–15. Available at: http://wwwnc.cdc.gov/eid/article/17/1/pdfs/p1-1101.pdf. Accessed 5 April 2012.
34. Scott, V. N., Y. Chen, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A. Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of *Salmonella* in low-moisture foods. I. Minimizing entry of *Salmonella* into a processing facility. *Food Prot. Trends* 29:342–353.
35. U.S. Department of Agriculture, Economic Research Service. 2010. Foodborne illness cost calculator. Updated date 28 December 2010. Available at: http://www.ers.usda.gov/Data/FoodborneIllness/. Accessed 27 May 2011.
36. U.S. Department of Agriculture, Economic Research Service. 2010. Peanut outlook. Impacts of the 2008–09 foodborne illness outbreak linked to *Salmonella* in peanuts. Available at: http://www.ers.usda.gov/Publications/OCS/2010/02Feb/OCS10A01/ocs10a01.pdf. Accessed 7 May 2012.
37. U.S. Department of Agriculture, Economic Research Service. 2010. Loss-adjusted food availability: spreadsheets. Available at: http://www.ers.usda.gov/Data/FoodConsumption/FoodGuideSpreadsheets.htm#fat. Accessed 7 May 2012.
38. U.S. Food and Drug Administration. 2005. Quantitative risk assessment on the public health impact of pathogenic *Vibrio parahaemolyticus* in raw oysters. Available at: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm050421.htm. Accessed 5 April 2012.
39. U.S. Food and Drug Administration. 2011. iRISK—a comparative risk assessment tool: peer review comment report. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD. Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm. Accessed 5 April 2012.
40. U.S. Food and Drug Administration. 2012. *Salmonella* species, p. 12–14; *Listeria monocytogenes*, p. 99–102. *In* Bad bug book—foodborne pathogenic microorganisms and natural toxins, 2nd ed. Available at: http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm. Accessed 7 May 2012.
41. U.S. Food and Drug Administration, and U.S. Food Safety and Inspection Service. 2003. Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. Available at: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm. Accessed 27 December 2010.
42. U.S. Government. 1998. Code of Federal Regulations. Title 21. Food and drugs. Part 164. Tree nut and peanut products. Subpart B. Requirements for specific standardized tree nut and peanut products. Sect. 164.150. Peanut butter. Available at: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1972408731c5160cccff411f08afb2c9&rgn=div8&view=text&node=21:2.0.1.1.37.2.1.3&idno=21. Accessed 7 May 2012.
43. U.S. Government. 2011. An act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply. Public Law 111-353. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/content-detail.html. Accessed March 2012.
44. Zink, D. 2008. Environmental investigation and regulatory response: *Salmonella* Tennessee in peanut butter in the United States, 2007. IAFP Symposium S1, 2008 Foodborne disease update: *Salmonella* in processed foods. Presented at the Annual Meeting of the IAFP, Columbus, OH, 3 to 6 August 2008.

THE Society for Food Science & Technology

Journal of Food Science

A Publication of the Institute of Food Technologists

Development of a Risk-Ranking Framework to Evaluate Potential High-Threat Microorganisms, Toxins, and Chemicals in Food

R. Newsome, N. Tran, G.M. Paoli, L.A. Jaykus, B. Tompkin, M. Miliotis, T. Ruthman, E. Hartnett, F.F. Busta, B. Petersen, F. Shank, J. McEntire, J. Hotchkiss, M. Wagner, and D.W. Schaffner

ABSTRACT: Through a cooperative agreement with the U.S. Food and Drug Administration, the Institute of Food Technologists developed a risk-ranking framework prototype to enable comparison of microbiological and chemical hazards in foods and to assist policy makers, risk managers, risk analysts, and others in determining the relative public health impact of specific hazard–food combinations. The prototype is a bottom-up system based on assumptions that incorporate expert opinion/insight with a number of exposure and hazard-related risk criteria variables, which are propagated forward with food intake data to produce risk-ranking determinations. The prototype produces a semi-quantitative comparative assessment of food safety hazards and the impacts of hazard control measures. For a specific hazard–food combination the prototype can produce a single metric: a final risk value expressed as annual pseudo-disability adjusted life years (pDALY). The pDALY is a harmonization of the very different dose–response relationships observed for chemicals and microbes. The prototype was developed on 2 platforms, a web-based user interface and an Analytica® model (Lumina Decision Systems, Los Gatos, Calif., U.S.A.). Comprising visual basic language, the web-based platform facilitates data input and allows use concurrently from multiple locations. The Analytica model facilitates visualization of the logic flow, interrelationship of input and output variables, and calculations/algorithms comprising the prototype. A variety of sortable risk-ranking reports and summary information can be generated for hazard–food pairs, showing hazard and dose–response assumptions and data, per capita consumption by population group, and annual p-DALY.

Keywords: food safety, risk, risk ranking

Introduction

Risk analysis is an essential part of science-based policies for food safety and public health protection today (Jaykus and others 2006). Food safety risk assessments completed to date typically focus on a single food product-pathogen pair such as *Salmonella* in eggs (USDA-FSIS 1998), a single agent such as mercury (Carrington and Bolger 2002), or a pathogen such as *Listeria monocytogenes* (FDA-CFSAN and others 2003) in one or a few specific food products. Food safety risk assessments today are not typically designed to quantitatively compare and rank risks of different food safety hazards (for example, microbiological hazards compared with chemical ones) because of the complexity of the calculations and comparisons required. A well-conceived strategic approach to public health protection that quickly and accurately identifies different types of hazards, ranks them by level of importance, and identifies approaches with the greatest potential to reduce hazards is critically needed (IFT 2002).

Risk ranking has been applied previously in a variety of settings, but very little activity has been applied to rank different types of risks in food systems. Havelaar and Melse (2003) maintained that to reduce the risk of foodborne illness, the relative risk across the different types of hazards should be compared. The U.S. Food and Drug Administration (FDA) awarded the Institute of Food Technologists (IFT) a 2-year cooperative agreement grant that supported development and implementation of a risk-ranking framework to evaluate potential high-threat microbiological agents, toxins, and chemicals in food. The framework was to include a model for quantitatively or semi-quantitatively comparing and determining potential threats and the ability to evaluate interventions or control points (for example, manufacturing/processing, warehouses, transport, retail) at various places in the farm-to-fork chain. Implementation of the framework would include use of existing and newly developed lists of hazardous agents for systematic ranking. Further, the FDA desired use of criteria in the risk ranking that at a minimum pertained to compatibility of a hazard with food as a vehicle, toxicity (or dose necessary to result in disease), accessibility, and likelihood of effect (illness). While many risk-ranking approaches are possible, the approaches fall into 2 main groups: surveillance-based "top-down" approaches and prediction-based "bottom-up" approaches.

Top-down and bottom-up approaches to risk ranking

With respect to microbial hazards, surveillance-based approaches attempt to infer the level of risk due to foods, hazards,

Authors Newsome and McEntire are with the Inst. of Food Technologists, Chicago, IL 60607, U.S.A. Authors Tran and Petersen are with Exponent, Inc., Washington, DC 20036, U.S.A. Authors Paoli, Ruthman, and Hartnett are with Decisionalysis Risk Consultants, Inc., Ottawa, Ontario, Canada K1H653. Author Jaykus is with North Carolina State Univ., Raleigh, NC 27695, U.S.A. Author Tompkin is retired from ConAgra, La Grange, IL 60525, U.S.A. Author Miliotis is with the Food and Drug Administration/Center for Food Safety and Applied Nutrition College Park, MD 20740, U.S.A. Author Busta is with the Natl. Center for Food Protection and Defense and Univ. of Minnesota, Minneapolis, MN 55455, U.S.A. Author Shank is retired from the Inst. of Food Technologists, Washington, DC 20036, U.S.A. Author Hotchkiss is with Cornell Univ., Ithaca, NY 14853, U.S.A. Author Wagner is with Mars Symbioscience, Rockville, MD 20850, U.S.A. Author Schaffner is with Rutgers Univ., New Brunswick, NJ 08901, U.S.A. Direct inquiries to author Newsome (E-mail: rlnewsome@ift.org).

doi: 10.1111/j.1750-3841.2008.01042.x

or their combinations based on information gathered by various observation systems such as active or passive disease reporting systems, outbreak databases, and a variety of other observations such as prevalence of pathogens in various commodities. Such information sources may be best for overall ranking of pathogens, but quantitative linkages to particular foods are often very difficult to justify from these sources alone and are typically estimated only for foods that might be attributed to a relatively high percentage of the attributable risk. The Foodborne Illness Risk Ranking Model (FIRRM), initiated in 2003 by the Food Safety Research Consortium, is an example of such top-down approaches to risk ranking (FSRC 2005). The FIRRM integrates data on foodborne illness surveillance; food–pathogen combinations; medical symptoms, complications, and outcomes; economic impact; and social values relevant to judging the significance of a potential hazard to population health.

In most cases, there is no systematic capacity to observe the effects of food-associated chemical exposures in the human population. This is because of a number of challenges, including the many potential causes of symptoms, the sheer number of chemicals that have common outcomes, and the long latency between exposure and outcomes. In addition, many chemical exposures occurring as a consequence of food consumption are at levels believed to be so low that there may not be any readily observable effects for a vast majority of exposed consumers.

The other main group of ranking approaches is based on predictive modeling of the fate of microbes and chemicals in the food supply together with their virulence or toxicity. The FDA's charge to the IFT panel included the capability to deal with a variety of microbial and chemical hazards. Given this and the inherent difficulties associated with top-down approaches for both microbial and chemical hazards noted previously, a bottom-up or predictive model of risk was used as the underlying framework for the ranking application described here. This requires the application of data and expert judgment to assemble sufficient information to predict the fate of the hazards in the food supply, together with their virulence and toxicity characteristics, to generate a prediction (which may be, of necessity, quite crude) of their relative level of risk to human health and the potential for changes to level of risk associated with possible interventions throughout the farm-to-fork chain.

The Process

IFT convened a panel of individuals with expertise in the farm-to-fork food system, food safety, risk assessment and management, microbiology, chemistry, toxicology, predictive microbiology, and computer modeling to develop the risk-ranking framework prototype. IFT staff experts in food safety and project management helped support the initiative. IFT supplemented the panel's expertise and efforts with additional developmental assistance by experts affiliated with risk, food, and chemical consultancies with expertise in food safety, biochemistry, environmental health science, public health, risk analysis, computer programming, and Web technology. The initial concept for the framework, which contributed to deliberations and subsequent prototype development, included an expert elicitation framework, tools, and envisioned information from several sources: expert panel judgment, evidence databases, value models, assessment assumptions, and policy options. This concept would feed into methodological research summary reports that were envisioned to aid the risk-ranking activities of the FDA and other possible users.

Model Components

The panel developed 2 main risk criteria modules: exposure (farm-to-fork) and hazard characterization (health impacts). The exposure module contained questions grouped into 3 food system stages: primary production; processing; and distribution, storage, retail, foodservice, and home. Questions comprising the hazard characterization module addressed agent pathogenicity or toxicity and potential public health burden. Formats for the answers to the explicit questions were qualitative (for example, high, medium, low, likely/not likely), quantitative (metric/scale), objective (available data), subjective (expertise), and rationale based.

Metrics (values assigned to individual risk input criteria) for the factors in the 2 modules were systematically developed. Metrics for levels of consumption of the identified food types of primary concern were compiled using the U.S. Dept. of Agriculture's 1994–1998 CSFII food intake database. The risk criteria comprising the 2 modules were integrated via an algorithm approach.

User inputs

Prototype users are prompted by specific questions for pertinent details on hazard prevalence, concentration, and changes in concentration at each of the 3 food system stages. Monte Carlo simulation computes mean final log concentrations from triangular distributions (minimum, most likely, or maximum log concentration value). To address health impacts, users are prompted to describe and assign importance to health impacts through pseudo-disability adjusted life years (pDALY). The pDALY concept is modified slightly from the general use of DALY (IOM 2005) to allow for a semiquantitative characterization of the disease burden of health impacts. The usual approach to measuring DALY is to assign a severity weight and duration weight to discrete relatively well-characterized health outcomes. The pDALY approach allows for the characterization of a standard health outcome (such as mild illness) without further definition of the exact impact. This was developed primarily to facilitate risk ranking of chemical substances that may present a risk of diverse, poorly characterized outcomes (for example, noncancer toxicity), which may not be easily assigned individual weights and durations.

Users create pDALY templates by assigning a fraction of cases to appropriate health impacts, such as mild, moderate, or severe pathogen, and short-term, adult, elderly, or childhood mortality. Some questions have predefined answers connected with predefined weights for risk-ranking calculations. Guidance exists in the form of help files that facilitate user responses to questions. Users can assign one or more dose–response functions to hazard outcome types, such as cancer or chronic noncancer. Users select the functional form of the dose–response relationship and record appropriate parameters for the chosen dose–response function.

Hazard–food pairs

IFT identified and incorporated into the prototype a number of hazard–food pairs (Table 1) to test the questions developed for the modules and the respective decision logic and to evaluate the metrics, ranking processes, and outcomes. The hazards for the pairs were chosen on the basis of participant knowledge of the hazard. To ensure that the prototype could address the full range of possible outcomes of varying severity and uncertainties, the chemical hazards were also chosen on the basis of conveniently available residue data, comparability to selected microbial hazards, and presence of multiple potential toxic endpoints. The prototype can accommodate additional pathogens and chemical toxicants and other hazard–food pairs, such as combinations involving food

canning and post-lethality processing of ready-to-eat (RTE) product or scenarios involving home food storage or preparation (for example, *L. monocytogenes* and temperature-abused RTE luncheon meat).

Prototype characteristics and functionality platforms

The prototype exists on 2 platforms: a web-based user interface, implemented in Visual Basic language and an Analytica® model. The web-based platform was developed to provide a user-friendly input/output user interface that facilitates concurrent use and data sharing without significant time delay. More specifically, the web-based platform (Figure 1) allows users to explore the complex ranking hierarchy, view the current evidence, edit evidence, and update assumptions. Calculations are performed in the web-based implementation using Visual Basic. Microsoft Access, a relational database, stores the relationships between variables (foods, hazards, processes, and evidence) that apply to each individually and their many combinations.

The Analytica model (Figure 2), which complements the web-based prototype application, facilitates visualization of the logic flow and interrelationship of input and output variables. It also allows inspection and auditing of the calculations comprising the prototype. Appropriate consumption measures with census-based population size estimates pulled from the database serve as the basis for risk calculations. Although the Analytica model reproduces the web-based calculations exactly, it allows only calculations based on a single hazard–food pair and does not allow relative risk rankings of different hazard–food pairs. The Analytica model was designed for the initial development of the calculations, given the visualization and computational features of the software, to facilitate further development, discussion, and review of the algorithms. The web-based implementation was then compared with the Analytica-based calculations to ensure that the implementation was sound.

Table 1 — Hazard–food pairs used for prototype testing.

Arsenic and smoked salmon
Bacillus cereus and liquid, extended-shelf-life coffee creamer in individual serving units
Benomyl and apple juice
Clostridium perfringens and beef broth-based gravy prepared in a restaurant
Cyclospora cayetanensis and fresh raspberries
Dioxin and lettuce
Dioxin and fresh green onions
Dioxin and cheddar cheese
Dioxin and whole milk
Escherichia coli O157:H7 and apple juice
E. coli O157:H7 and sprouts
Enterobacter sakazakii and powdered infant formula
Fumonisin and canned corn
Hepatitis A virus and fresh strawberries
Hepatitis A virus and raw oysters
Listeria monocytogenes and whole milk
Methyl mercury and smoked salmon
Nitrate and smoked salmon
Nitrite and smoked salmon
Norovirus and raw oysters
Salmonella spp. and powdered milk
Salmonella spp. and raw oysters
Shigella dysenteriae and fresh green onions
Staphylococcus aureus enterotoxin and natural cheddar cheese

Characteristics and functionality

Two main components make up the key conceptual features of the risk-ranking prototype: computer programming code integrating exposure and hazard characterization modules and risk information data. The framework characterizes the burden of disease for health impacts associated with hazards through illness duration and severity. It also links health impact categories to hazards through the pDALY, a simplified way of addressing burden of

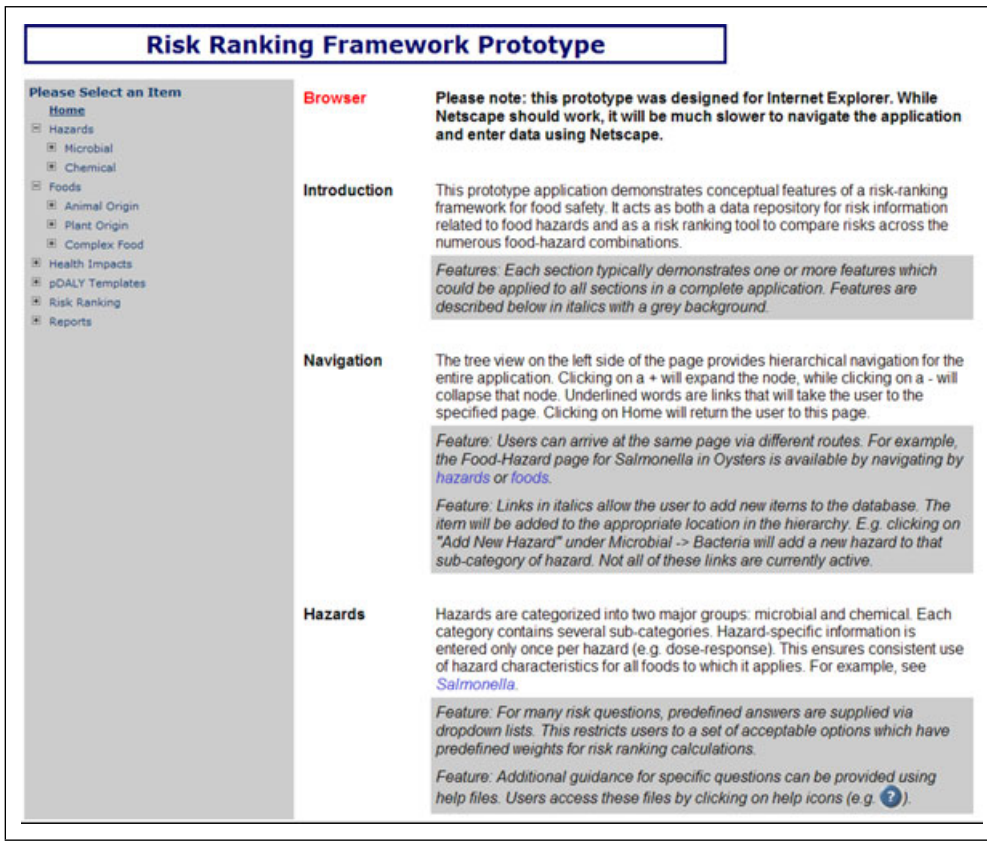


Figure 1 — Initial view: main page of web-based prototype implementation.

disease. CSFII 1994–1998 data were used to estimate the proportion of the population(s) potentially exposed to the hazard and the amount of food eaten.

The prototype generally incorporates empirical evidence (CSFII food intake data, dose response data, and residue data), expert rationale, and module integration algorithms (via Visual Basic language) and provides output in the form of risk-related evidence, assumptions, and risk-ranking reports. Thus, while the product is a prototype for a risk-ranking framework, there is inherent value in the knowledge comprising the prototype.

The framework is not intended to replace or substitute for more complex single hazard–food pair risk assessments since the level of detail is limited in the interest of allowing comprehensive and rapid ranking of many hazard–food pairs. Instead, the framework can provide a comparative risk rank for hazard–food pairs, expressed as annual pDALY. The risk-ranking section of the web-based version uses Monte Carlo simulation to compute a range of doses based on the concentration of the hazard in the food and the average serving size. The doses are used in conjunction with the dose–response model(s) for the hazard to compute a mean probability of illness for each population group. Prevalence values are then used to determine the number of contaminated servings. Triangular distributions were chosen for simplicity and ease of change; other distributions could readily be utilized in future iterations of the model. Combining the number of contaminated servings with the probability of illness and the pDALY template value for the hazard generates a final risk measure (annual pDALY). For chemical hazards, risks that are inferred based on lifetime exposures are prorated to an annual risk estimate by dividing by an arbitrary lifetime value of 70 y (consistent with the value used by the FDA and the Environmental Protection Agency) to allow for compatible timeframes for ranking. Alternatively, acute hazards (primarily microbial hazards) can be multiplied by the same factor to estimate compatible lifetime burden of disease measures. Tables 2 and 3 show the input and output variables of the prototype.

Another advantage of the prototype is its flexibility. For example, one could consider seasonal and geographic impacts on hazard prevalence, contaminated servings, and subsequent risk rank by addressing the appropriate number of suitably defined hazard–food pairs in the web-based implementation. An example of this would be *Vibrio vulnificus* in raw oysters harvested from the Gulf Coast during summer compared with winter. Similarly, the risk rank of a hypothetical intentional contamination event could be considered by incorporating the hypothetical hazard prevalence, concentration, and locations within the food chain in which contamination occurs.

Exposure module

The panel chose the 3 main food system stages—primary production (includes harvesting); processing (includes post processing); and distribution, storage, retail, foodservice, and home—to enable representation of key points at which hazard prevalence and concentration could change throughout the food system. In the future, the capability exists to address transport of source materials or animals prior to processing or food product subsequent to processing at any of the food system stages. Within each of these 3 food system stages, hazard presence is considered on a bulk lot or truckload type basis rather than by individual consumer or retail units.

The prototype addresses hazard concentration via initial concentration, in log units/g for microbes and g/g for chemicals, at the earliest point of primary production before any known production, processing, distribution/storage-related changes might occur. Subsequent concentration as a result of any increases or decreases or additions (introduction of contamination) occurring during the 3 food system stages is also addressed. The simulation engine examines each possible pathway of contamination explicitly, and the resulting concentrations are weighted by their respective probability of occurrence calculated in concentration weights. As a result, 16 pathways track probabilities for concentration throughout each of the 3 food system stages.

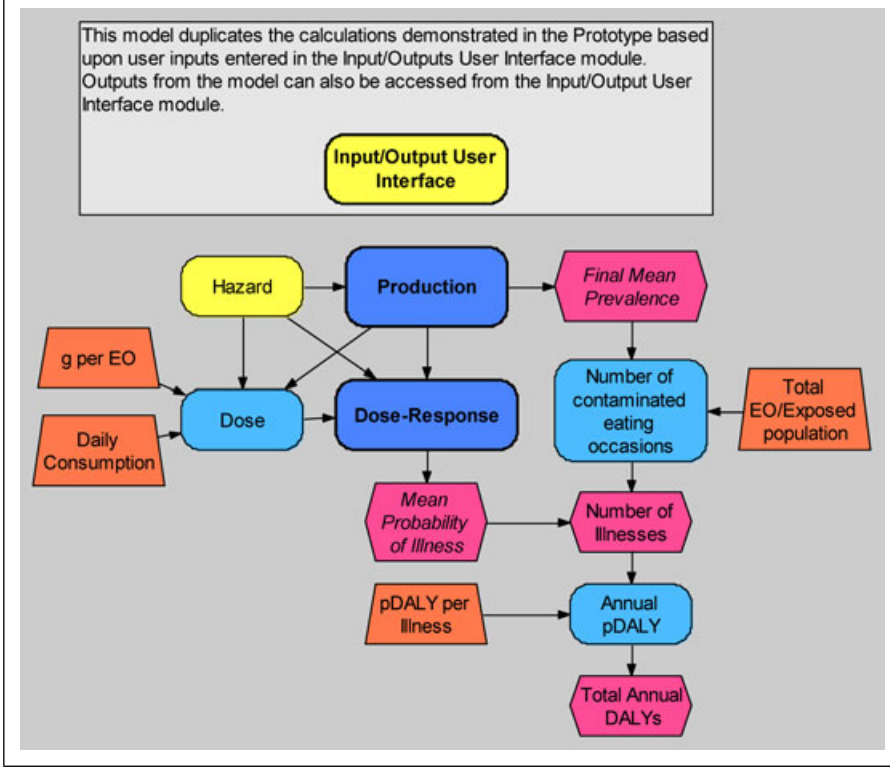


Figure 2—Initial view of Analytica model.

The prototype addresses hazard prevalence more simply by estimating the likelihood of hazard introduction at each of the 3 stages, changes in hazard prevalence during each stage, prevalence at the end of each stage, and final prevalence at the end of the continuum. The calculations for prevalence estimate the concentration of the agent at the end of the farm-to-fork chain based upon the changes in concentration (increases or decreases) and additions that occur throughout the food system as defined by the user. Initial prevalence is expressed on the basis of percentage of total units in which the hazard is present (contaminated units/total units, 0% to 100%). Change in prevalence (occurring independently of initial concentration), change in concentration, or introduced concentration within each of the 3 food system stages is addressed with values between 0 and 1 reducing the prevalence by that factor, values greater than 1 increasing the prevalence by that factor, and a value of 1 leaving the prevalence unchanged.

In allowing the user to address likelihood for introduction or addition of a hazard during each of the stages, the prototype has placeholders for future developmental efforts to address controllability efficacy and controllability compliance. This is based on the understanding that the existence of guidance or regulation to describe how a hazard enters the food chain and the ability to control a hazard is a relevant consideration in risk ranking. For example, if a hazard were controllable, then a risk-rank metric could be used for mitigation, or if not controllable, then the rank could be used in considering the need for research. These considerations, which are managerial in nature, do not currently lend themselves to an obvious numeric or ranking, but this may change with future iterations of the prototype.

Table 2—Risk-ranking prototype input variables.[a]

Initial prevalence
Initial concentration before processing
Change in concentration at primary production
Likelihood of introduction at primary production
Introduced concentration at primary production
Change in prevalence during primary production
Change in concentration at processing
Likelihood of introduction at processing
Introduced concentration at processing
Change in prevalence (processing)
Change in concentration at distribution, storage, retail, foodservice, and in the home
Likelihood of introduction at distribution, storage, retail, foodservice, and in the home
Introduced concentration at distribution, storage, retail, foodservice, and in the home
Change in prevalence at distribution, storage, retail, foodservice, and in the home
Total eating occasions/exposed population
Grams per eating occasions
pDALY per illness
Daily consumption
Dose–response model
Beta-Poisson
Exponential
Linear
Chemical cancer
Chemical noncancer
Noncancer method
Threshold
Linear model threshold
Linear model nonthreshold
Hazard
Microbial or chemical/toxin
Dose
RfD
Threshold

[a]As shown in the input/output user interface Analytica node.

Table 3—Risk-ranking output variables.[a]

Final mean concentration in positive lots
Final mean prevalence
Mean probability of illness
Number of illnesses
Annual pDALY

[a]As shown in the input/output user interface Analytica node.

Consumption (food intake) submodule

The consumption/food intake submodule addresses the proportion of the population that is exposed to the hazard and the amount of a given food that is eaten. Due to the large number of as-eaten foods in the U.S. Dept. of Agriculture's 1994–1998 CSFII 8-digit food-code database, expert panel members determined that an aggregate approach based on 3- and 5-digit levels of food intake data would be sufficient and effective for developing quantitative metrics for risk-ranking purposes. CSFII data are based on 4 population groups: the entire United States, women 16 y to 49 y of age, children 1 y to 6 y of age, and individuals 65 y of age and older. Users may also specify what percentage of a given population is at risk.

Chemical risks are computed using the mg/kg bw/day consumption measure (in which bw = body weight). Population size based on census estimates for each population group is in the database to compute population risk for chemicals. Microbial risk is calculated using mean serving size and total number of servings. For chemical hazards, risk (probability of illness) is calculated on the basis of 90th percentile for consumption.

Hazard characterization (health impacts) module

Multiple dose responses can be assigned to hazard outcome types (for example, cancer, acute or chronic noncancer [for chemicals] and infectious or toxigenic [for microorganisms]). Each dose response option subcategory offers a subset of appropriate dose–response models. When users address a hazard and corresponding dose–response models, they will encounter the question "What is the strength of judgment that this hazard causes adverse health effects?" for which there are 4 possible responses: no studies available, not well established, moderate evidence, or well established. Because the responses to the question do not readily lend themselves to numeric expression, they are not currently factored into the risk ranks. Nevertheless, the information is pertinent and provides justification which, at some future time, may lead to a more quantitative expression of strength of supporting evidence.

For toxicological dose–response relationships (chemical and toxin-producing microbial hazards), 5 models are available: step threshold, threshold linear, nonthreshold linear, beta-Poisson, and exponential. For infectious dose responses, 4 models are available: beta-Poisson, exponential, threshold linear, and nonthreshold linear. The dose–response templates cannot be changed by users. The dose–response section of the prototype shows appropriate parameters for the selected model; changing the model changes the parameters for the options provided. All dose–response pages allow consideration of probability of illness given response, addressing the question of what proportion of infections would result in illness. All dose–response curves are incorporated into the risk calculations. Users may choose from any number of health impacts, which basically represent a DALY approach (Table 4) and then link them with one or more of the pDALY templates (Table 5).

The pDALY template allows the impact of the hazard to be placed on a relative scale. The results of exposure are captured semi-quantitatively in 2 dimensions: impact severity (mild, moderate, severe, or death) and duration (short, medium, or long), allowing up to 12 ways to describe a health impact. In addition, when selecting a specific health impact, users may indicate and provide support for their choice of health impact, duration, and severity.

Other prototype characteristics

The prototype addresses microbial risk as represented by colony forming units at the point of consumption and does not track toxin production occurring throughout the food chain (for example, staphylococcal enterotoxin formation). Strain-to-strain differences in virulence of microorganisms are not included nor are differences in immunity among individuals because of innate or acquired immunity, such as resistance to certain pathogens (such as norovirus and hepatitis A virus).

Additionally, the model is very sensitive to situations where a microbial hazard has a toxigenic response characterized by a threshold linear model, as observed for *C. perfringens* and beef gravy. This sensitivity exists because the dose–response model contains a threshold below which a response does not occur and above which it does. Thus, when the predicted concentration of the pathogen is close to the threshold, very slight increases in the concentration of the pathogen can result in very large changes in health effects. The prototype has the capability of accommodating a number of possible modifications:

- Inserting additional scientific documentation;
- Allowing assignment of a relative estimate of data quality;
- Adding more inputs for multiple hazard reductions;
- Considering factors that contribute to a decrease or increase of a food hazard (as might occur during in-home preparation or storage);
- Integrating the web-based implementation with the Analytica model (allowing users to view and address more than one hazard–food pair at the same time);
- Allowing answers to the strength of judgment and hazard controllability questions to be factored into the risk-ranking output to address uncertainty associated with these factors;
- Accommodating the input of confidence intervals for input and output estimates;
- Considering the benchmark dose lower confidence limit as a risk measure rather than the reference dose;
- Standardizing the dose–response modeling for different categories of chemical hazards;
- Incorporating consumption data (for example, data from the National Health and Nutrition Examination Survey data); and
- Including additional data that would enhance the strength of the exposure and hazard characterization modules (for example, data pertaining to dose response).

Table 4—Health impacts.

Mild, short-term impacts
Mild, medium-duration impacts
Mild, long-term impacts
Moderate, short-term impacts
Moderate, medium-duration impacts
Moderate, long-term impacts
Severe, short-term impacts
Severe, medium-duration impacts
Severe, long-term impacts
Childhood mortality
Adult mortality
Elderly mortality
Hemorrhagic colitis
Hemolytic uremic syndrome
Enteric fever
Reactive arthritis/Reiter's syndrome
New health impact

Table 5—pDALY templates.

Acute (chemicals)
Blood target organ (chemical)
Cancer (chemical)
Escherichia coli O157:H7
Gastroenteritis only (rare fatality)
Hepatitis A virus
Neural tube defect
Neuro-developmental (chemical—below BmD)
Reproductive (chemical)
Salmonella
Severe pathogen
New pseudo DALY template

Risk-Ranking Output

The prototype provides a basic reporting mechanism that reports selected contents of the database (the evidence) according to foods, hazards, processes, and their combinations. A risk-ranking summary report can be generated, grouped by hazard or food; ordered by total risk or name; and produced in ascending or descending order. Total risk (pDALY) is aggregated by hazard or food depending on the grouping selected. The application sums the pDALY measures as a total risk for a particular food or hazard, depending on the grouping selected. In addition, users have the option to specify foods, hazards, or hazard–food combinations that are to be excluded from rankings due to incompleteness of data or development of assumptions. Checking the pertinent box on the food, hazard, and hazard–food pages determines whether they are included in the ranking. The individual food and hazard settings take priority over the combination of settings.

For the dose–response relationship, the risk-ranking summary report summarizes the type, model, and parameters of the dose–response; grams per eating occasion; total number of eating occasions; mean hazard prevalence; number of contaminated servings from once contaminated lots; mean concentration in food; mean dose; mean probability of illness; number of illnesses; pDALY per illness; and annual pDALY. By default, the risk-ranking summary report prints the 1st dose–response chart, but other charts are included. The "print summary" function produces a summary of the evidence entered and is distributable for discussion and holistic consideration.

Conclusions

In cooperation with the FDA, IFT participants in this study developed a functional semi-quantitative risk-ranking framework prototype—a flexible tool that enables relative comparison and ranking of microbial food-related risks with chemical risks via a single metric: annual pDALY. Specific approaches taken in developing the prototype enabled resolution of some broad challenges faced in risk-ranking efforts. The successful production of this risk-ranking prototype holds tremendous potential as a unique tool capable of comparing microbial hazards and chemical hazards not only separately but also comparatively by using a common metric.

Acknowledgments

This study was supported under FDA cooperative agreement grant number FD-U-002255-01 and by additional funding from the Food Risk Analysis Initiative of Rutgers Univ.

References

Carrington CD, Bolger MP. 2002. An exposure assessment for methylmercury from seafood for consumers in the United States. College Park, Md.: U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition: Available from: http://www. cfsan.fda.gov/~acrobat/mehgra2.pdf. Accessed Sept 4, 2008.

FDA-CFSAN, USDA-FSIS, CDC. 2003. Quantitative assessment of relative risk to public health from foodborne Listeria monocytogenes among selected categories of ready-to-eat foods. U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition, U.S. Dept. of Agriculture/Food Safety and Inspection Service, Centers for Disease Control and Prevention. Available from: http://www.foodsafety.gov/~dms/lmr2-toc.html. Accessed Sept 4, 2008.

[FSRC] Food Safety Research Consortium. 2005. Prioritizing opportunities to reduce the risk of foodborne illness: a conceptual framework. Available from: http://www.card.iastate.edu/food_safety/national_conference/FSRC_Conceptual_Framework_final.pdf. Accessed Sept 4, 2008.

Havelaar AH, Melse JM. 2003. Quantifying public health risk in the WHO guidelines for drinking-water quality. RIVM report nr 734301022/2003. Available from: http://www.who.int/water_sanitation_health/dwq/rivmrep.pdf. Accessed Dec 1, 2008.

[IFT] Institute of Food Technologists. 2002. Emerging microbiological food safety issues: implications for control in the 21st century. An expert report. Chicago, Ill.: Institute of Food Technologists. Available from: http://www.ift.org/cms/?pid=1000379. Accessed Nov 20, 2008.

[IOM] Institute of Medicine. 2005. Estimating the contributions of lifestyle-related factors to preventable death: a workshop summary. Washington, D.C.: National Academies Press, 80 p.

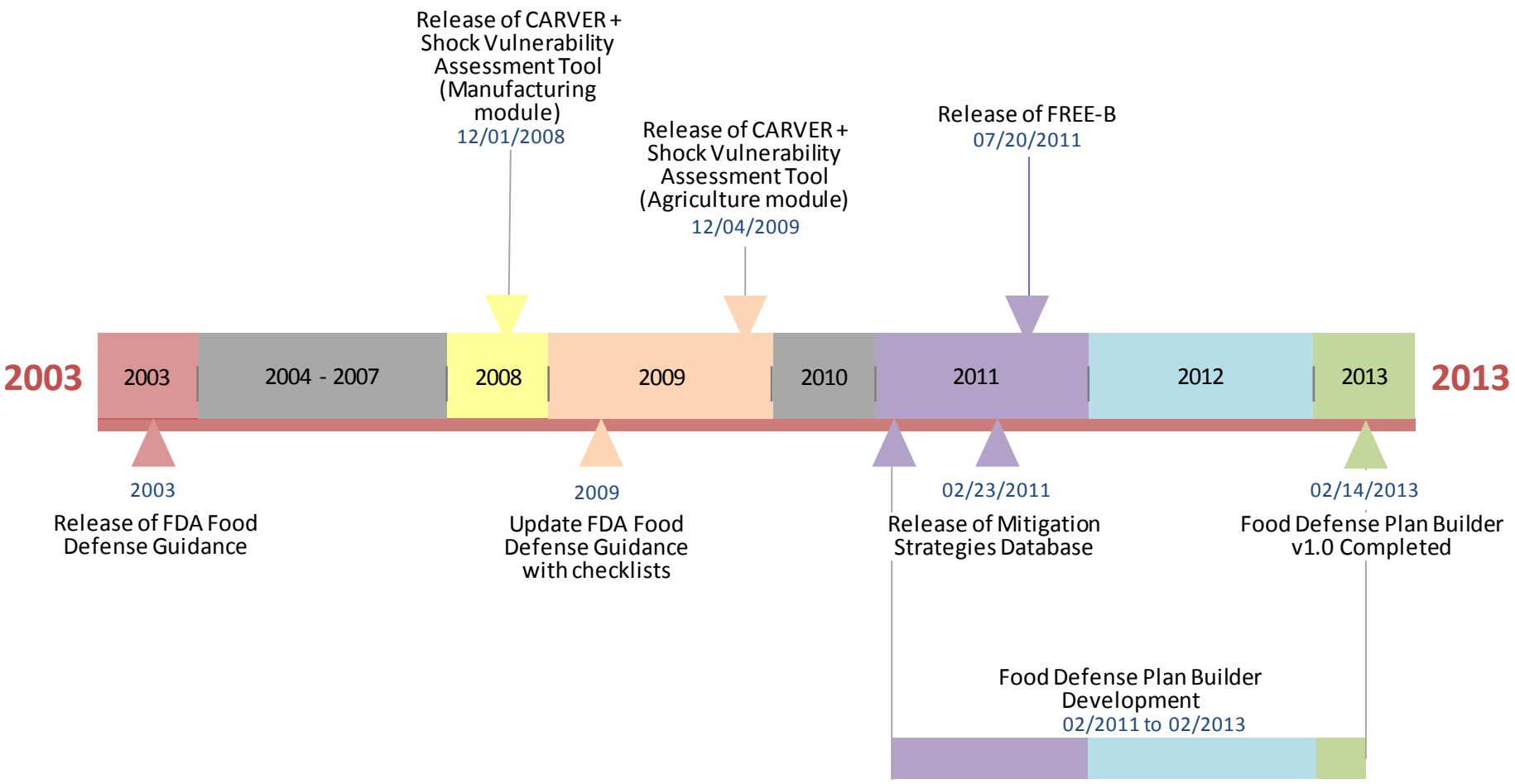
Jaykus L, Dennis S, Bernard D, Claycamp HG, Gallagher D, Miller AJ, Potter M, Powell M, Schaffner D, Smith MA, Ten Eyck T. 2006. Using risk analysis to inform microbial food safety decisions. Issue paper nr 31. Ames, Iowa: Council for Agricultural Science and Technology.

Murray CJL, Lopez AD, Mathers CD, Stein C. 2001. The global burden of disease 2000 project: aims, methods and data sources. Global programme on evidence for health policy discussion paper nr 36. Geneva, Switzerland: World Health Organization. Available from: http://www.who.int/healthinfo/paper36.pdf. Accessed Nov 8, 2007.

[USDA-FSIS] U.S. Dept. of Agriculture, Food Safety and Inspection Service. 1998. Salmonella Enteritidis risk assessment: shell eggs and egg products. Final report. Washington, D.C.: U.S. Dept. of Agriculture, Food Safety and Inspection Service. Available from: http://www.fsis.usda.gov/ophs/risk/. Accessed Sept 4, 2008.

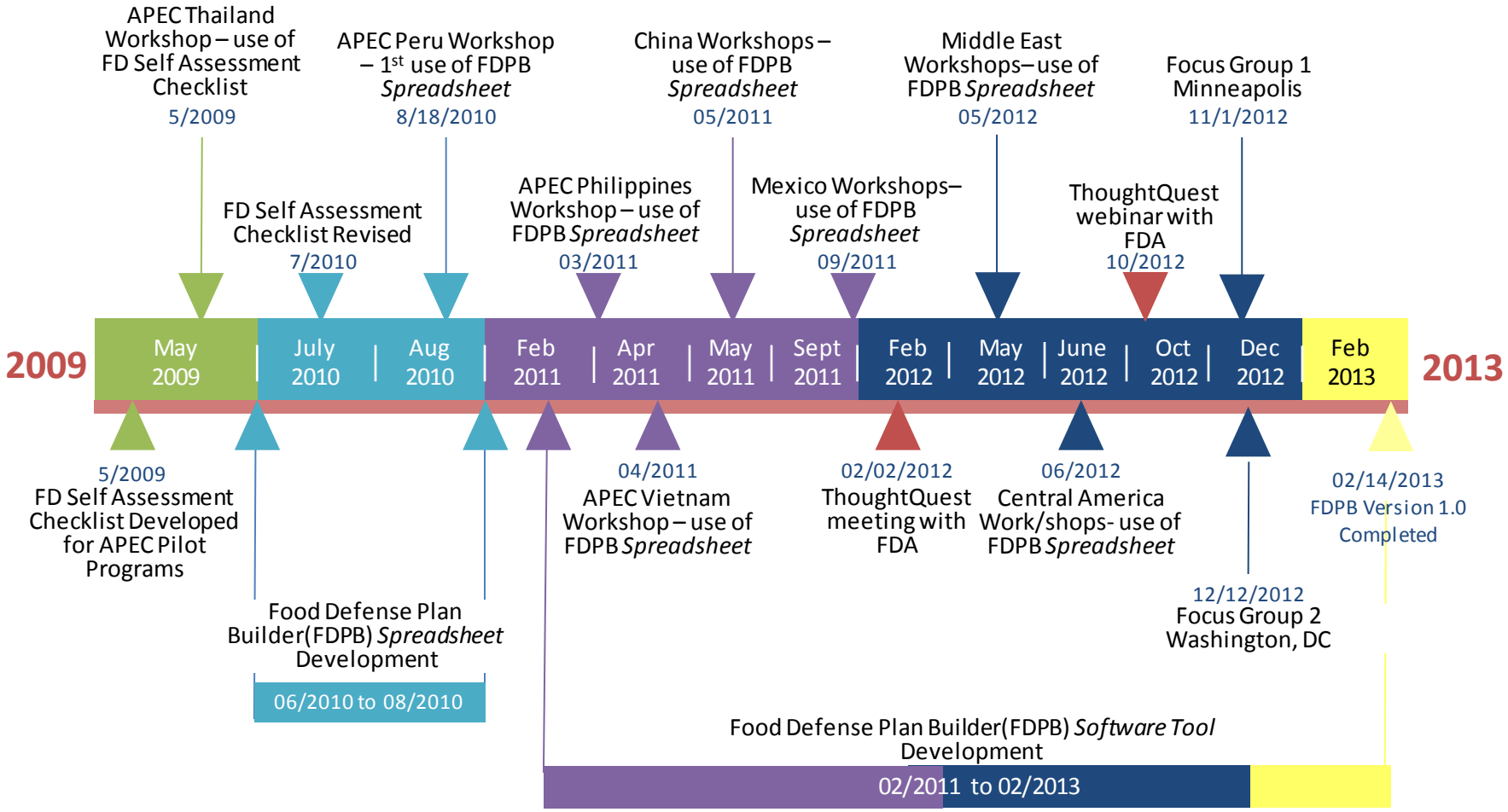
FDA FOOD DEFENSE TOOLS

TIMELINE



Revised 03/04/2013

FOOD DEFENSE PLAN BUILDER
GENERAL TIMELINE



Revised 03/04/2013

Battelle Memorial Institute
Catherine (Cate) Hart, PMP
Program Manager
Battelle Crystal City
1550 Crystal Drive, Suite 600
Arlington, VA 22205
HartC@Battelle.org
703-416-5823 (O)
703-850-0225 (C)
703-413-7826 (F)

Valbrea Technologies
Jeff Hooper
President
Valbrea Technologies, Inc.
972-661-2268
972-661-2298 (f)
214-906-3135
Jeff.hooper@valbrea.com
www.valbrea.com

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

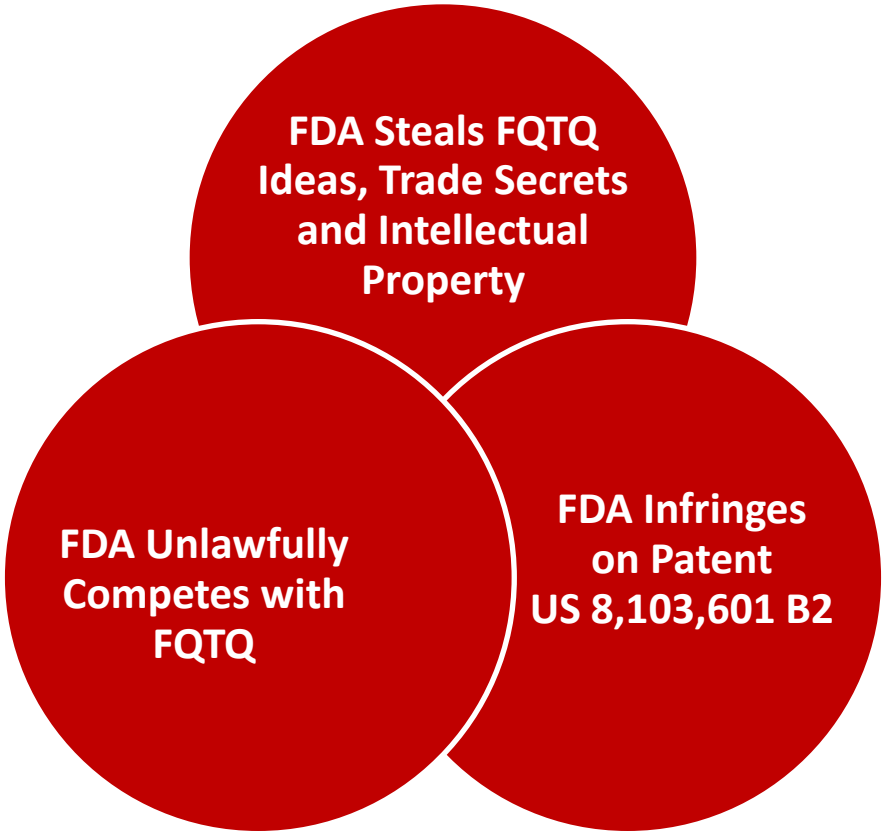
FoodQuestTQ LLC

March 19, 2013

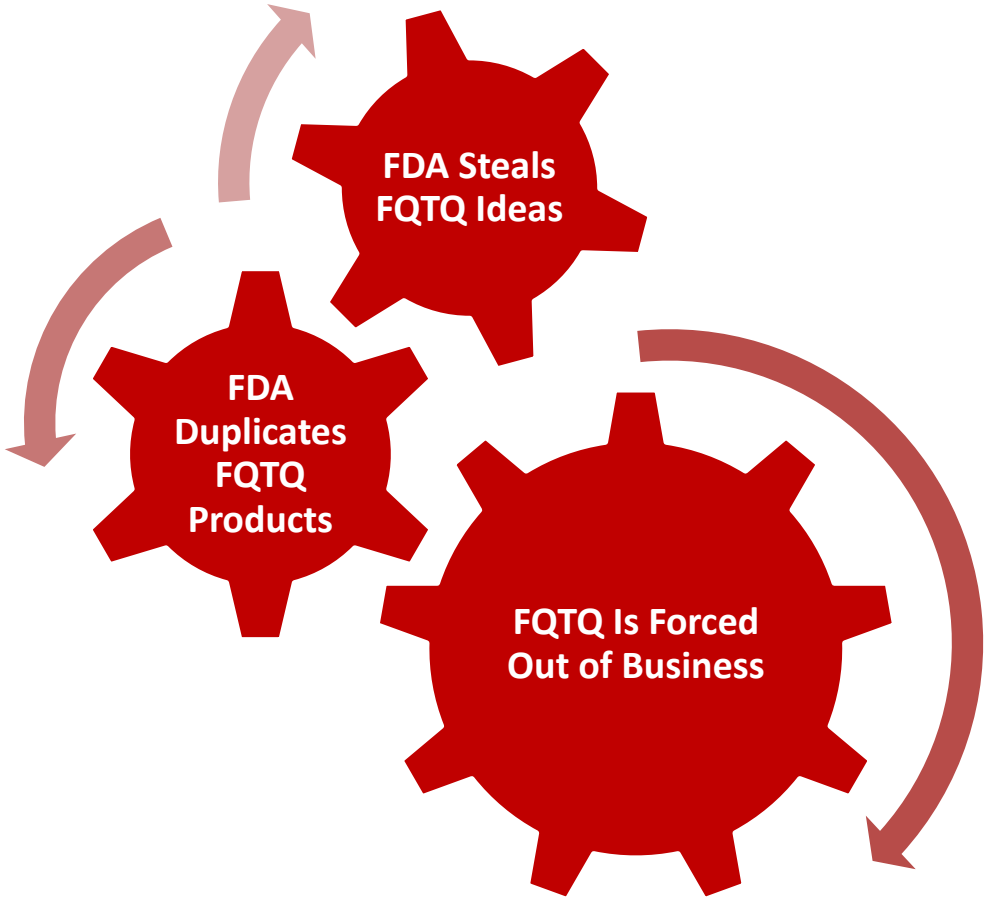
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- **The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.**

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- **The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.**

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- **The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.**

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- **The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."**

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- **The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."**

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- **The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.**

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- **The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.**

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- **The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.**

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed.

- **The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.**

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- **The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.**

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.**

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- **The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.**

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- **The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.**

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.**

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- **The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.**

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- **The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.**

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- **The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.**

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- **The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.**

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- **The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.**

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- **The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.**

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- **The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.**

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- **The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.**

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- **The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectiviity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.**

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

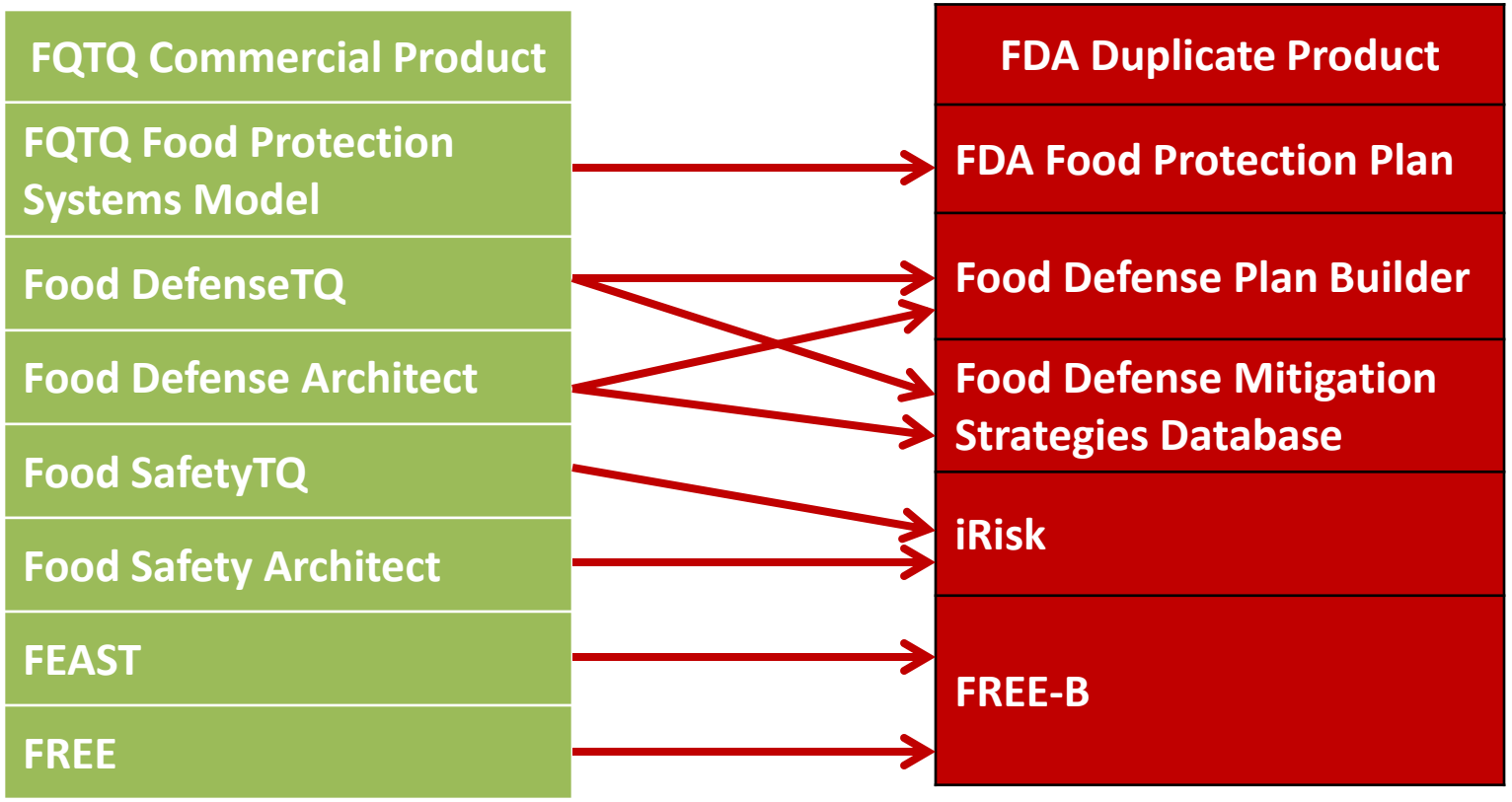
- **The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.**
- **The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.**

25. FQTQ Enhanced Risk Communications

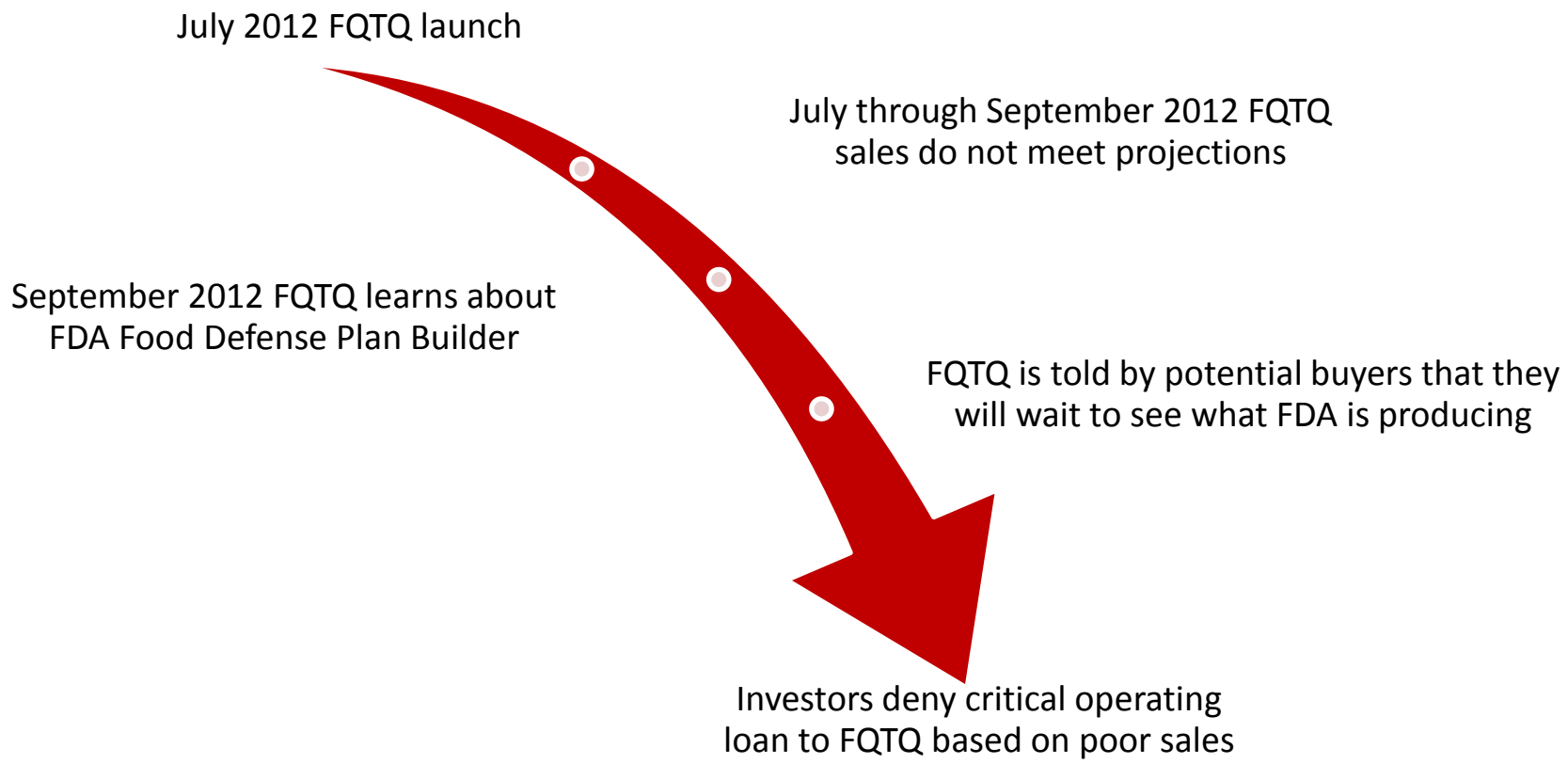
The FQTQ systems model for food protection improves risk communications.

- **The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.**

FDA Duplicates FQTQ Products



FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2

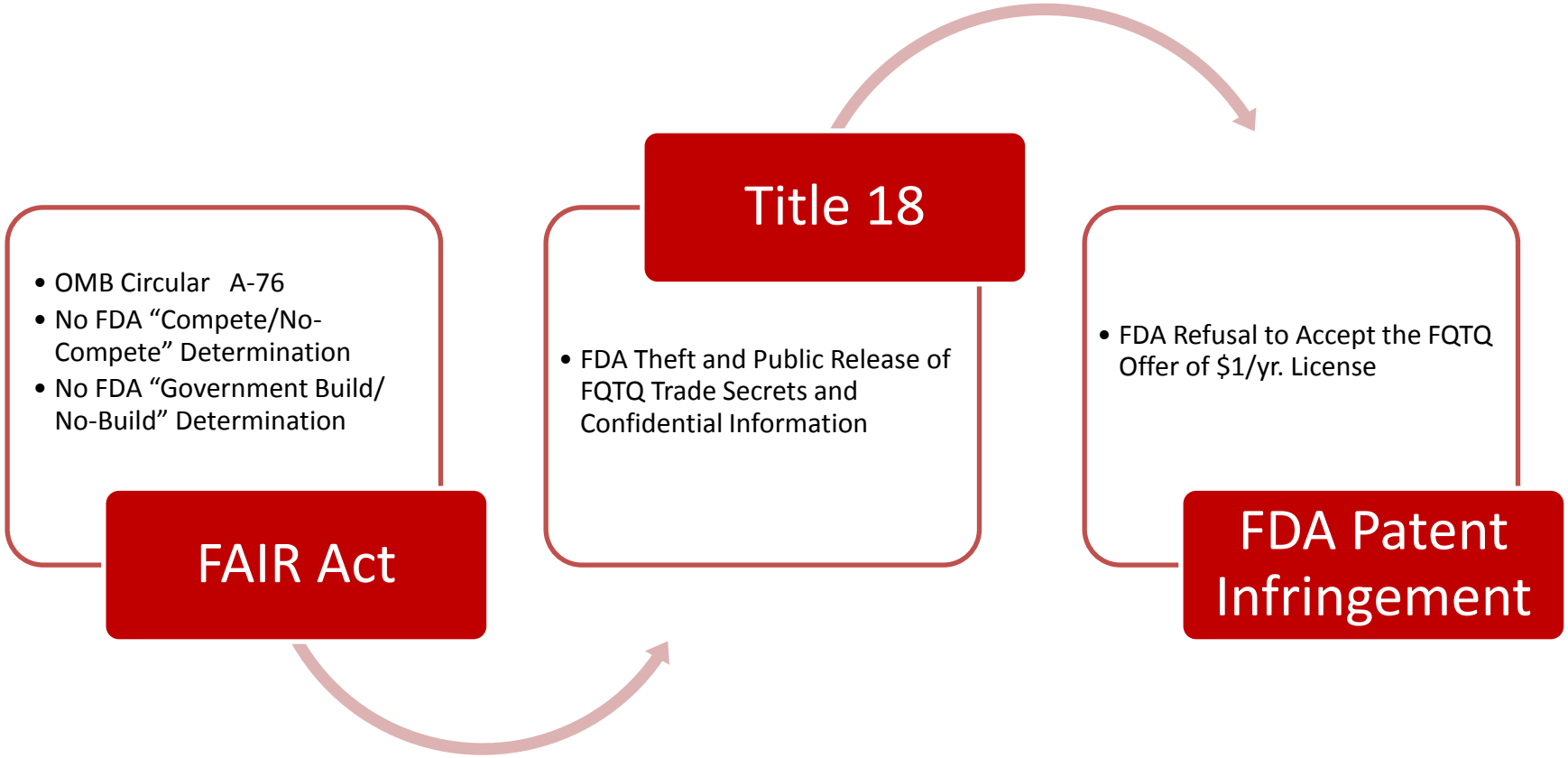
The patent has 20 claims and 101 associated objects of the invention

How FQTQ reduced the patent to use for food was FQTQ trade secret information until it was revealed by FDA in the FQTQ tools they duplicated and released to the public

FQTQ has prepared an extensive technical crosswalk that demonstrates flagrant infringement by the FDA on patent US 8,103,601 B2

FQTQ is prepared to share the results of the crosswalk with the National Small Business Ombudsman if it will assist in the timely resolution of this matter

FDA Unlawfully Competes with FQTQ



Pages 76 through 79 redacted for the following reasons:
- -
ENTIRE PAGES WITHHELD UNDER EXEMPTION (B)(5)
Entire page withheld under (b)(5).

Federal Agency Comment Form

Small Business Administration – Office of the National Ombudsman

OMB Control #3245-0313

Exp. date 5/31/2013

Purpose: Small business owners may use this form to submit comments on Federal enforcement/compliance actions that they consider excessive or unfair. The National Ombudsman will use the form to contact the Federal agency for a review of the action.

Case #: 1303150001

Instructions

1. Complete, sign and date this form. (Signature not required if completed at www.sba.gov/ombudsman).
2. Provide a brief written statement on the reverse side regarding the specific enforcement or compliance action taken against your organization by the federal agency.
3. Submit copies of substantiating documentation, such as correspondence, citation, or notice (Note: Can be submitted separately from this form by fax or mail. Make sure to reference your name or company's name with this information).
4. If your comments concern the IRS, you must also submit a completed IRS Tax Information Authorization Form 8821, available at http://www.irs.gov/forms (Can be sent by fax or mail).
5. Fax, e-mail or send this form and requested information to: (1) Fax: (202) 481-5719; (2) E-mail: Ombudsman@sba.gov; (3) Address: SBA, Office of the National Ombudsman, 409 Third Street, SW, Washington, DC 20024. Telephone : (202) 205-2417.

Please Print

Organization/Company Name: FoodQuestTQ LLC

Address: 7420 Hayward Drive, Suite 102

City: FREDERICK **State:** MD **Zip:** 21702

Phone: 240-439-4476 **Fax :** **E-mail:** jhnatio@thoughtquest.com

Contact Name: Mr. ☑ Ms. ☐ John Hnatio **Title:** Chief Science Officer

Please indicate your organization type:

✓ Small Business ____ Not-for-Profit, Representing ____ Members

____ Small Government (population of less than 50,000)

List the federal agency with which you are having a problem:

Federal Agency Name: Food and Drug Administration

Agency Contact person: Dr. Margaret Hamburg

Agency Office/Division: Office of Chief Counsel

√ Did the federal agency listed above inform you of your right to contact the SBA Office of the National Ombudsman?

☐ Yes ☑ No If not, how did you learn about this office?

On my own via web search

Confidentiality / Disclosure

The Small Business Regulatory Enforcement Fairness Act (SBREFA), allows you to keep your identity and other information private, and limit its access only to the SBA's (See 15 U.S.C. 657 (b) (2) (B)). However, by requesting confidentiality the federal agency may not have sufficient information to investigate your specific problem, possibly delaying or preventing any potential resolution of your situation.

I request that my information be kept confidential. ☐ Yes ☑ No (If yes, results may be limited.)

Signature: John Hnatio **Date:** 11/15/2013

Your signature authorizes the SBA Ombudsman to proceed on your behalf.

Pursue all legal options you believe are in your company's best interest.
This process is not a substitute for legal action.

SBA FORM 1993 (3-10) Previous Editions Obsolete

Please Note: The estimated burden for completing this form is 45 minutes. You will not be required to respond to this information collection if a valid OMB approval number is not displayed. If you have any questions or comments concerning this estimate or other aspects of this information collection, please contact the U. S. Small Business Administration, Chief, Administrative Information Branch, Washington, D.C. 20416 and/or Office of Management and Budget, Clearance Officer, Paperwork Reduction Project (3245-0313), Washington, D.C. 20503. PLEASE DO NOT SEND FORMS TO OMB.

Type or (print) your comments below:

We have been in contact with Ms. Ellie Zahirieh of the Office of National Ombudsman and provided her with a detailed report describing our concerns. In summary, the FDA has duplicated several of our commercial products under contract with Battelle Memorial Institute and, by so doing, undercut our sales and forced us out of business. FDA officials stole our trade secret and intellectual property information to duplicate our tools, infringed on our patent and entered into unfair competition with us in violation of the FAIR Act (OMB Circular A-76) and other statutes. We are a small company with no resources to pay for a protracted legal battle with the lawyers at the FDA and they are aware of our status as a small business that cannot afford to pay for a team of lawyers to fight for our rights. All principals of our small company have been laid off without pay since November of 2012 and are currently on unemployment. Our business has been ruined and our families have been left to suffer. We are in desperate need of relief from the actions taken against us by the FDA. We have been working with the FDA since January 2013 but the matter is being treated by legal maneuvering on the part of FDA to avoid seeking the truth and trying to fairly resolve the matter. That is why we are now forced to file a complaint with the Office of National Ombudsman.

SBA Ombudsman Case No. 1303150001

COMPETITION BY THE FOOD AND DRUG ADMINISTRATION WITH SMALL BUSINESS

The parties: FoodQuestTQ LLC, a small business with offices situated at 4720 Hayward Drive, Frederick, Maryland, 21702, and the Food and Drug Administration (FDA) with offices situated 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993.

FOODQUESTTQ LLC CONTACT INFORMATION

Dr. John Hnatio
Chief Science Officer
(o) 240.439.4476 x-11
(c) 301.606.9403
E-mail: jhnatio@thoughtquest.com

BACKGROUND

Projectioneering LLC is a small Frederick, Maryland-based company working with two other Frederick Maryland-based companies, ThoughtQuest LLC and FoodQuest LLC. Projectioneering LLC owns the intellectual property used by both ThoughtQuest LLC and FoodQuest LLC. ThoughtQuest LLC was created in 2008 for the purpose of supporting the start-up of companies across different industry verticals using the intellectual property owned by Projectioneering LLC. From 2008 to 2012, ThoughtQuest LLC reduced the Projectioneering LLC owned patent to practice for the food and agricultural fields of use. In early 2012, FoodQuestTQ LLC was established to commercially sell a suite of computer software tools across the food industry vertical that are based on the Projectioneering LLC patent.

SUMMARY

FoodQuestTQ LLC has filed a complaint with the Office of Small Business Advocacy and the Small Business Ombudsman. The complaint is based on three inextricably intertwined prohibited actions that the company alleges have been taken against them by the Food and Drug Administration, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, in violation of Title 18 U.S.C. and other statutes, and;

3. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in violation of Title 18 U.S.C. and other statutes.

Until December 2012, the FoodQuestTQ LLC employed five people. In January 2013, faced with the continuing prospect of direct government competition that interfered with their commercial sales, FoodQuestTQ was unable to obtain an essential operating loan it required to stay in business. In December 2012, the company was forced to lay off all of its employees because of lagging sales resulting from the public release of similar products by the FDA.

This document describes the events leading up to and surrounding the actions allegedly taken by the Food and Drug Administration (FDA) to duplicate products that were already developed and for commercial sale by FoodQuestTQ LLC.

CASE DESCRIPTION

Over the period of the past three years representatives of ThoughtQuest LLC and FoodQuestTQ LLC have met extensively with FDA employees and shared with them information regarding the reduction of their patented technology for commercial use/sale to the food industry.

The information provided to FDA personnel was clearly marked as containing industry proprietary information. In addition, ThoughtQuest LLC and FoodQuestTQ LLC principals state that FDA employees they spoke with were verbally advised that the information being shared with them was proprietary and contained ThoughtQuest LLC and FoodQuestTQ LLC business proprietary and trade secret information.

In September 2012, FoodQuestTQ LLC principals became concerned that the FDA was, unbeknownst to them, taking their business proprietary and trade secret information to duplicate their products, under a contract with Battelle Memorial Institute.

In late October 2012, under pressure to avoid direct competition with the FDA that would put them out of business, FoodQuestTQ LLC, with the permission of their Board of Directors, offered the FDA a $1/yr. license to use their technology. FDA officials did not respond to the FoodQuestTQ LLC offer.

FDA and their contractor, Battelle Memorial Institute, continue to deploy products free of charge to the food industry that duplicate the products that were already developed and being commercially sold by FoodQuestTQ LLC.

The FDA actions have severely impacted FoodQuestTQ LLC sales. In early December 2012 when they were no longer able to meet payroll FoodQuestTQ LLC was forced to lay off all of their company's employees.

In January 2013, based on continuing competition by the FDA resulting in poor sales of their products, FoodQuestTQ LLC was denied a critical operating loan they needed to stay in business.

TIMELINE OF EVENTS LEADING TO THE LAYOFF OF FOODQUESTTQ PRINCIPALS AND EMPLOYEES

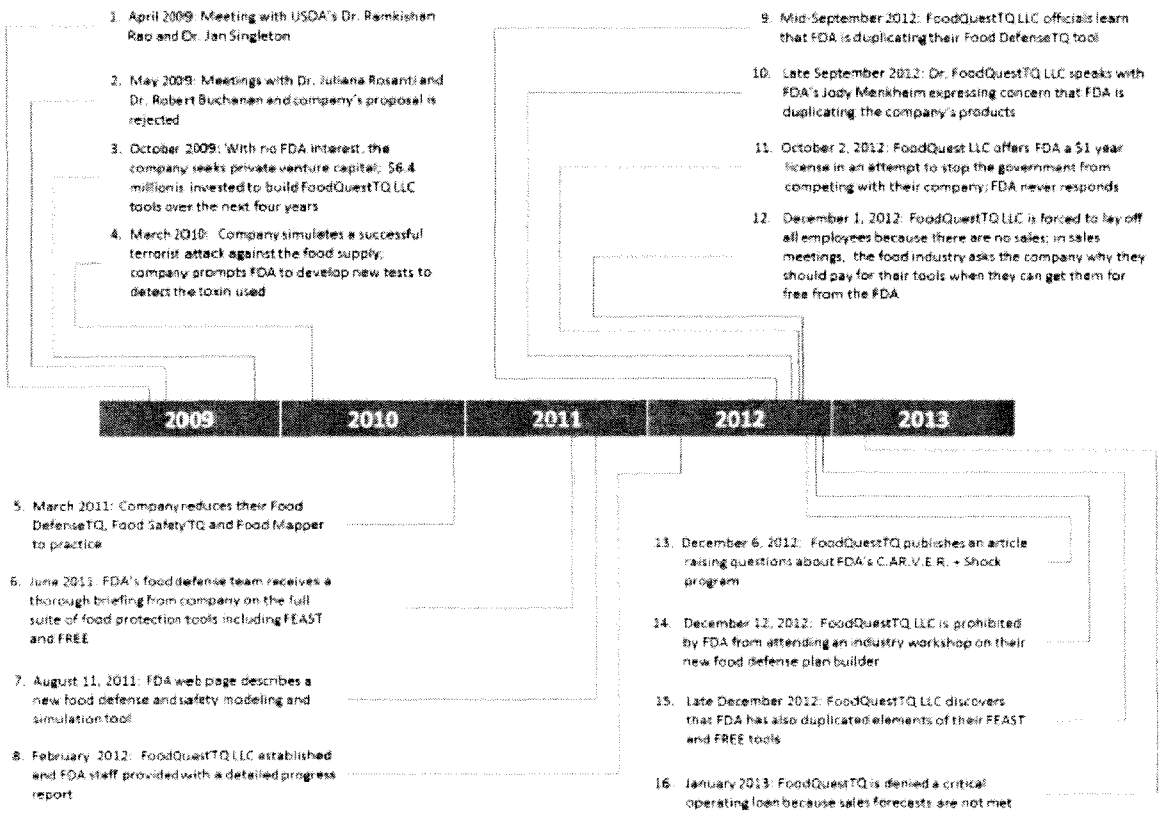


Figure 1: Timeline of FoodQuestTQ LLC and FDA Activities

1. In April 2009, representatives of ThoughtQuest LLC first contacted the U.S. Department of Agriculture (USDA). They met with Drs. Ramkishan Rao and Jan Singleton who were senior leaders at the U.S. Department of Agriculture's, National Institute of Food and Agriculture (NIFA). The purpose of the meeting was to forge a public-private partnership to make the food supply safer. ThoughtQuest LLC representatives shared their scientific breakthroughs, proprietary technology, and business plans for creating a safer food supply. Drs. Rao and Singleton were highly supportive of ThoughtQuest LLC's efforts. After the meeting, the company had follow-on meetings with Dr. Jeannette Thurston and other members of the USDA staff at NIFA to share their progress.

2. In May 2009, ThoughtQuest LLC representatives had their first contact with FDA when they met with Dr. Juliana Rosanti at the Joint Institute for Safety and Nutrition (JIFSAN). Their objective was to explore the possibility of a joint project with JIFSAN using their patent to make the food supply safer; this lead to a second meeting with Dr. Robert Buchanan, the head of the University of Maryland's Center for Food Safety and Nutrition (CIFSAN). Dr. Buchanan was a retired FDA senior food safety official and still serves as a senior scientific advisor to the FDA. At that time, Dr. Leanne Jackson, current head of the FDA's Food Defense Team was on the staff of CIFSAN.[i] As a result of these meetings, ThoughtQuest LLC representatives were asked to submit a detailed proposal to Dr. Buchanan describing their patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply. The proposal was clearly marked as containing proprietary information. The proposal was subsequently rejected by Dr. Buchanan.

   Note: Over the next three and a half years, the company continued to maintain very close contacts with both the USDA and FDA as they developed their products. The company briefed USDA and FDA officials on every step of their scientific and technological progress. They hoped that, at some point, USDA and FDA would join them in the public-private partnership they originally envisioned to improve the safety of the food supply based on the company's new science and technology innovations.

3. In October 2009, when the FDA showed no apparent interest in their patent and supporting technology, ThoughtQuest LLC sought venture capital. In addition to the $3.5 million invested by the two principals of ThoughtQuest LLC, the company received an additional $2.9 million in venture capital over the next four years to build and commercially deploy their suite of computer software tools to help the food industry prevent and improve responses to accidental and intentional food poisonings.

4. In 2010, ThoughtQuest LLC was asked by a large global food manufacturer to use their patent and technology to simulate a worst case terrorist attack using a biological agent against one of their major food product lines. The goal was to "bring down the company." Based on this tasking, ThoughtQuest LLC was able to scientifically simulate the successful take down of the company as a result of terrorists introducing a particular toxic agent into their product. The simulation was highly successful because no effective laboratory test existed at that time for detecting the presence of the agent that was used to poison the particular product. With the permission of the company involved, ThoughtQuest LLC representatives closely coordinated the results of the simulation and the methodology they used with Dr. Reginald Bennet and other officials at the FDA in

order to prompt the development of specific laboratory and field tests that would detect the deadly agent.

5. By early 2011, ThoughtQuest TQ LLC personnel reduced three of their products to practice and began commercial sales of their Food DefenseTQ, Food SafetyTQ and Food Mapper tools.

6. In June 2011, Mr. Menkhiem, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim to give him periodic updates on their progress.

7. On August 11, 2012, Mr. David Park, then Principal Scientist of FoodQuestTQ LLC came across an official FDA website that described a new FDA tool for modeling and simulating food defense and food safety scenarios.

   Note: As further discussed below, in late December 2012, Dr. Hnatio conducted a detailed review of the FDA website to discover that the FDA had duplicated the elements of two of FoodQuestTQ tools-the Food Event and Analysis Simulation Tool (FEAST) and the Food Response and Emergency Evaluation (FREE) tool. The FDA slightly modified the name of their new tool from the original FoodQuestTQ commercial name of FREE to the new FDA name "FREE-B."

8. In early February 2012, Projectioneering LLC and ThoughtQuest LLC stood up a new company called FoodQuestTQ LLC that would assume responsibility for the further development and sales of their computer software tools across the food industry.

   Also, Mr. Menkheim and his staff were provided with a detailed progress briefing and proprietary documents that included both business confidential and trade secret information describing the industry uses of the FoodQuestTQ LLC tools, the system architecture and the algorithms supporting the FoodQuestTQ tools. All this information was clearly marked as containing company proprietary information.

9. In mid-September 2012, FoodQuestTQ LLC officials learned for the first time, that the FDA had been working with Battelle Memorial Institute to build their own food defense

plan builder to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ, to call Mr. Menkheim to express his concerns that FDA was developing a product that already existed. Mr. Menkheim explained that FDA was not competing with FoodQuestTQ LLC had because the food defense plan builder tool being built by the FDA was not nearly as sophisticated as the FoodQuestTQ tools.

10. In late September 2012, Dr. Hnatio had another telephone another conversation with Mr. Menkheim and asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012. Mr. Menkheim told Dr. Hnatio that the principal purpose of the upcoming meeting was to discuss a terrorist targeting tool known as C.A.R.V.E.R. + Shock. He advised that FDA's food defense planner was being developed in order to make it easier for industry to use C.A.R.V.E.R. + Shock.[ii]

11. The next interaction between FoodQuestTQ LLC and the FDA took place on October 2, 2012, when a "go-to-meeting" webinar was held. During the webinar, FoodQuestTQ LLC FDA staff updated Dr. Menkheim and his staff on the company's continued progress to upgrade their suite of computer software tools. Particular attention was given to the use of the company's Food DefenseTQ tool as the way to build food defense plan. A more advanced tool known as Food Defense Architect that would make it even easier for food companies to develop their own food defense plans was also demonstrated.

    During the webinar, FoodQuestTQ again raised their concerns that FDA was building a food defense planner tool to compete with FoodQuestTQ LLC's existing Food DefenseTQ and Food Architect products. To avoid any potential conflict with FDA that could adversely impact their business, FoodQuestTQ LLC offered the FDA a license to use their technology across the food vertical for $1/yr. Prior to the webinar, FoodQuestTQ officials met with a member of their Board of Directors, Mr. Joe Welty, to discuss the FDA's actions and received permission to offer the $1/yr. license in order to avoid direct competition by the FDA. During the webinar, Mr. Menkheim advised that he could not make such a decision but would take the matter to his FDA bosses. FDA never responded to FoodQuestTQ LLC on the matter.

12. On December 1, 2012, when sales failed to materialize for FoodQuestTQ LLC's Food DefenseTQ and Food Defense Architect line of food defense tools, the company was forced to lay off all of their employees including the two founders of the company. Without pay, FoodQuestTQ LLC principals continued to prepare for the December 12,

2012, industry workshop on C.A.R.V.E.R. + Shock and the FDA's new food defense builder tool. The company developed an internet survey to ask the food industry how effective the FDA's C.A.R.V.E.R. + Shock approach was to them in protecting the food supply.

13. On December 6, 2012, Dr. Hnatio of FoodQuestTQ LLC published an article on the potential dangers of using C.A.R.V.E.R. + Shock as a counter-terrorist assessment tool. The article shared the preliminary results of the FoodQuestTQ survey. The results were mixed with a majority of respondents raising questions about the utility of C.A.R.V.E.R. + Shock. The C.A.R.V.E.R. + Shock article written by Dr. Hnatio was a matter of very significant interest throughout the FDA. For example, the web based software used to conduct the survey indicates that Dr. Leanne Jackson, (the former CIFSAN official referenced in entry 2. Above) who is now in charge of FDA's Food Defense Oversight Team, opened the article for review and/or further distribution over 40 times. It is noted that C.A.R.V.E.R. + Shock is a major $13 million funding line item for Dr. Jackson's office.

14. The December 12th 2012, FDA sponsored industry workshop was hosted by the Grocery Manufacturer's Association (GMA) at their Headquarters building in Washington, D.C. Mr. Warren Stone, Senior Director of Science Policy coordinated the meeting. At FoodQuestTQ's request, Mr. Stone allowed for a 20 minute slot on the workshop agenda for FoodQuestTQ to demonstrate their food defense plan builder tool that was already commercially available to the food industry.

    From e-mails sent to us by Mr. Stone as he coordinated the FDA workshop, we first learned that FDA was working under a multi-million dollar contract to help the FDA develop their food defense plan builder. We found the name of Mr. Colin Barthel, who is the Battelle Memorial technical manager for FDA's food defense mission. FoodQuestTQ LLC tried repeatedly to reach Mr. Barthel to discuss our concerns that Battelle Memorial Institute may be using the company's intellectual property to duplicate their products for use by the FDA. After repeated attempts to reach Mr. Barthel by e-mail and telephone to discuss the situation, FoodQuestTQ LLC finally received an abrupt e-mail from him stating he would not speak with them and that the FDA sponsored workshop on December 12th 2012 was strictly limited to food processors. Mr. Barthel referred FoodQuestTQ LLC back to the FDA's Food Defense Oversight Team to discuss any concerns.

    On the evening December 11, 2012, FoodQuestTQ LLC principals were notified by Mr. Stone that FDA had specifically disinvited any ThoughtQuest LLC (now FoodQuestTQ

LLC) personnel from participating in the FDA industry workshop to be held at GMA Headquarters the following day. Mr. Stone was told by the FDA that they did not want to give any preference or any endorsement to one commercial product over any other. FoodQuestTQ LLC was prohibited by the FDA from attending the workshop.

FoodQuestTQ LLC did, however, independently brief a few of the remaining food industry participants late in the day after the FDA sponsored workshop for industry was over and FDA officials had left the building. When FoodQuestTQ LLC officials signed into the conference room where they were going to demonstrate their products, they saw the attendee list of companies that participated in the earlier FDA sponsored industry workshop. The list included numerous companies that were not food processors but, in fact, competitors of FoodQuestTQ LLC, such as Tyco Integrated Systems.

15. In late December 2012, FoodQuestTQ LLC's concerns about the FDA action to prohibit their attendance at the FDA industry workshop caused them to go back and conduct a review of their work with FDA. It was at this time Dr. Hnatio took a closer look at Mr. Park's earlier reference (August 2011) to an FDA web site on modeling, simulation and responses to food defense and food safety emergencies. When Dr. Hnatio fully explored the FDA web page he discovered that the FDA had duplicated elements of their FEAST and FREE tools. Unbeknownst to FoodQuestTQ LLC, the FDA had slightly modified the name of the FDA tool from the FoodQuestTQ LLC's commercial name of FREE to the new government FDA name of "FREE-B."

    Note: During the preceding months, prior to learning about the actions of the FDA to compete with them, company officials were befuddled as to why their sales projections were not being met. They could not figure out why their products were not selling. It was not until after the FDA industry workshop that they began to receive direct feedback from food processing companies. In these sales meetings, industry asked FoodQuestTQ LLC why they should buy their products when the FDA was providing the same thing for free.

16. In January 2013, FoodQuestTQ LLC was denied a vital investor loan to continue operations. During the period from September 2012 through January 2013, FoodQuestTQ LLC was in critical negotiations to obtain an operating loan from their investors. In early October 2012, as the evidence mounted that FDA and Battelle Memorial Institute were duplicating their products and as sales were failing to materialize, FoodQuestTQ LLC principals were left with no option but to inform their Board of Directors of the situation. The news that FDA was spending millions of dollars under a contract with Battelle Memorial Institute to duplicate FoodQuestTQ's products

and poor sales raised the risk of future investment by their investors to an unacceptably high level. In early January 2013, their request for an operating loan was denied.

CURRENT STATUS

In January 2013, representatives of FoodQuestTQ LLC contacted members of Congress to request their assistance in obtaining a meeting with Ms. Elizabeth Dickinson, Chief Counsel at the Food and Drug Administration. Company officials felt that if Ms. Dickinson was made personally aware of the circumstances she would quickly act to correct the situation. At this time, the matter has become tied up in legal maneuvering by the FDA. Company officials still have not been allowed to personally meet with Ms. Dickinson. This is a matter of great concern to FoodQuestTQ LLC since the owners of the business and all employees had to be laid off without pay several months ago and the company cannot afford to pay the attorney's fees required to fight a long protracted legal battle with the FDA.

In February and March 2013, the inventor of the Projectioneering LLC owned patent undertook a comprehensive review of the FDA web site to identify any possible activities where the FDA had infringed on the Projectioneering LLC patent (The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.) The inventor identified five FDA products that accomplished the same or similar functions as the Projectioneering LLC patent and FoodQuestTQ software tools that were already or were in the final process of being made ready for commercial sale before they were duplicated by the FDA. A subsequent technical crosswalk of the five duplicate FDA products against each of the 20 claims and 101 objects of the Projectioneering LLC patent demonstrates flagrant infringement by the FDA.

PRINCIPAL ISSUES

1. FOOD AND DRUG ADMINISTRATION USE OF CONFIDENTIAL FOODQUESTTQ LLC BUSINESS AND PRODUCT INFORMATION

   Over a period of approximately three years FoodQuestTQ LLC met extensively with FDA employees and provided them with detailed briefings which included the proprietary and trade secret information relating to the reduction of their patent for commercial sale to the food industry. All proprietary information shared with FDA employees was clearly marked as containing industry proprietary information. In addition, FoodQuestTQ principals verbally advised the FDA employees they shared any proprietary information with that the information they were sharing required protection pursuant to the Code of Federal Regulations (48 CFR 27.402) and other government statutes.

Note: Title 18 USC 1905 applies to disclosure by a government employee of any information provided to the government by a company or other nongovernment organization, if the provider of the information identified it as proprietary or as being provided to the government in confidence. The penalty is mandatory removal from office (termination of employment), and the offender may be fined not more than $1,000 and imprisoned not more than one year.

Specific legal statutes and portions of the Federal Acquisition Regulations that pertain to the protection of commercially owned proprietary information include:

- Title 18 USC 1831–39 - Protection of Trade Secrets [Chapter 90].
- Title 18 USC 1905 – Disclosure of Confidential Information.
- Title 41 USC 423 – Procurement Integrity.
- Title 5 CFR 734 – Employee Responsibilities and Conduct.
- FAR 3.104-1 – Procurement Integrity, General (48 CFR).
- FAR 27.4 – Rights in Data and Copyrights (48 CFR).
- FAR 52.215-12 – Restriction on Disclosure and Use of Data (48 CFR).
- FAR 52.227-14 – Rights in Data (48 CFR).[iii]

2. FOOD AND DRUG ADMINISTRATION COMPETETITION WITH FOODQUESTQ LLC

The government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry. FQTQ offered the FDA Food Defense Team a $1/yr. license to use FoodQuestTQ LLC technology in order to avoid unfair competition by the government. FDA never responded to the offer. Based on proprietary business information provided to them, FDA was fully aware that the products they were developing with Battelle Memorial Institute were already developed and being commercially sold by FoodQuestTQ LLC.

Efforts to make the food supply safer are a shared responsibility between the government and the private sector and non-regulatory activities have never been considered an inherently government function. A simple Google search of food safety and food defense, identifies literally hundreds of "hits" with private sector companies doing everything from consulting, risk assessments, third party audits in support of FDA's governmental regulatory compliance responsibilities. The FDA itself promotes the use third party private sector companies to assure the quality of food safety and food defense at food operations all across the food supply.

The FDA actions in this case also raise questions regarding the Agency's compliance with OMB Circular A-76. This document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector.

3. THE IMPACT OF THE FOOD AND DRUG ADMINISTRATION POLICY AND ACTIONS ON SMALL BUSINESSES GENERALLY

FoodQuestTQ LLC is only one of millions of small businesses in America that provide the innovation required to solve national challenges. The nation depends on small businesses and the entrepreneurs who risk everything to create them. The jobs the nation must create to keep people employed are generated by small businesses like FoodQuestTQ LLC. Much of the innovation that the nation and our government must have to solve national problems comes from small businesses like FoodQuestTQ LLC. By competing with small businesses like FoodQuestTQ LLC and forcing them out of business, the FDA risks losing the genius and innovation the nation desperately needs to solve the country's food protection and food safety problems.

---

[i] See: http://www.linkedin.com/pub/leeanne-jackson/19/920/718

[ii] Note: C.A.R.V.E.R. + Shock was developed by the military special forces to plan attacks against the critical infrastructures of the enemy. In the aftermath of 9-11, FDA attempted to convert the tool for civilian use by the food industry with mixed results. Currently, the pursuit of C.A.R.V.E.R. + Shock is a continuing $13 million dollar FDA budget line item.

[iii] http://www.wrc.noaa.gov/wrso/security_guide/propriet.htm

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

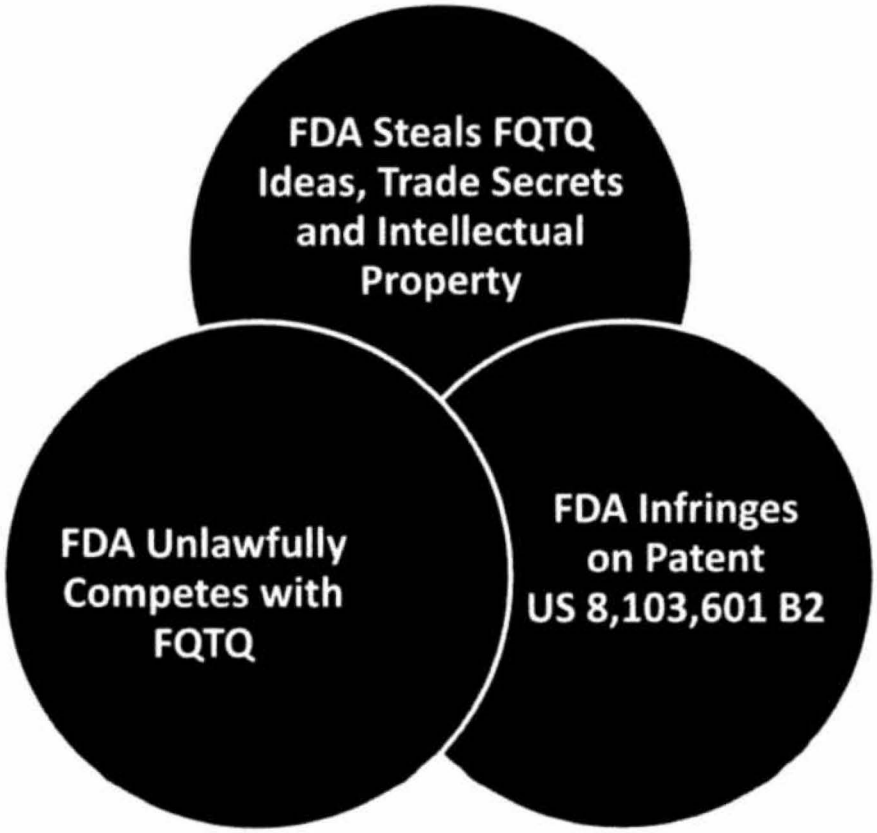
FoodQuestTQ LLC

March 19, 2013

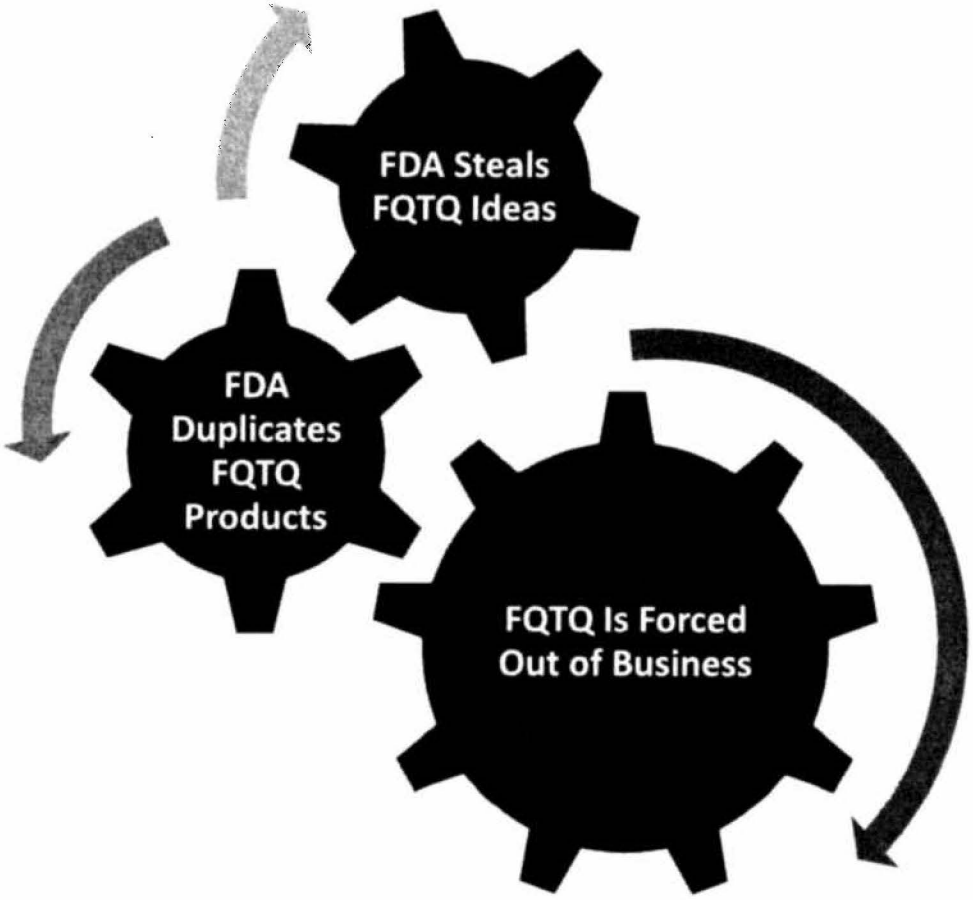
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed.

- The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectiviity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

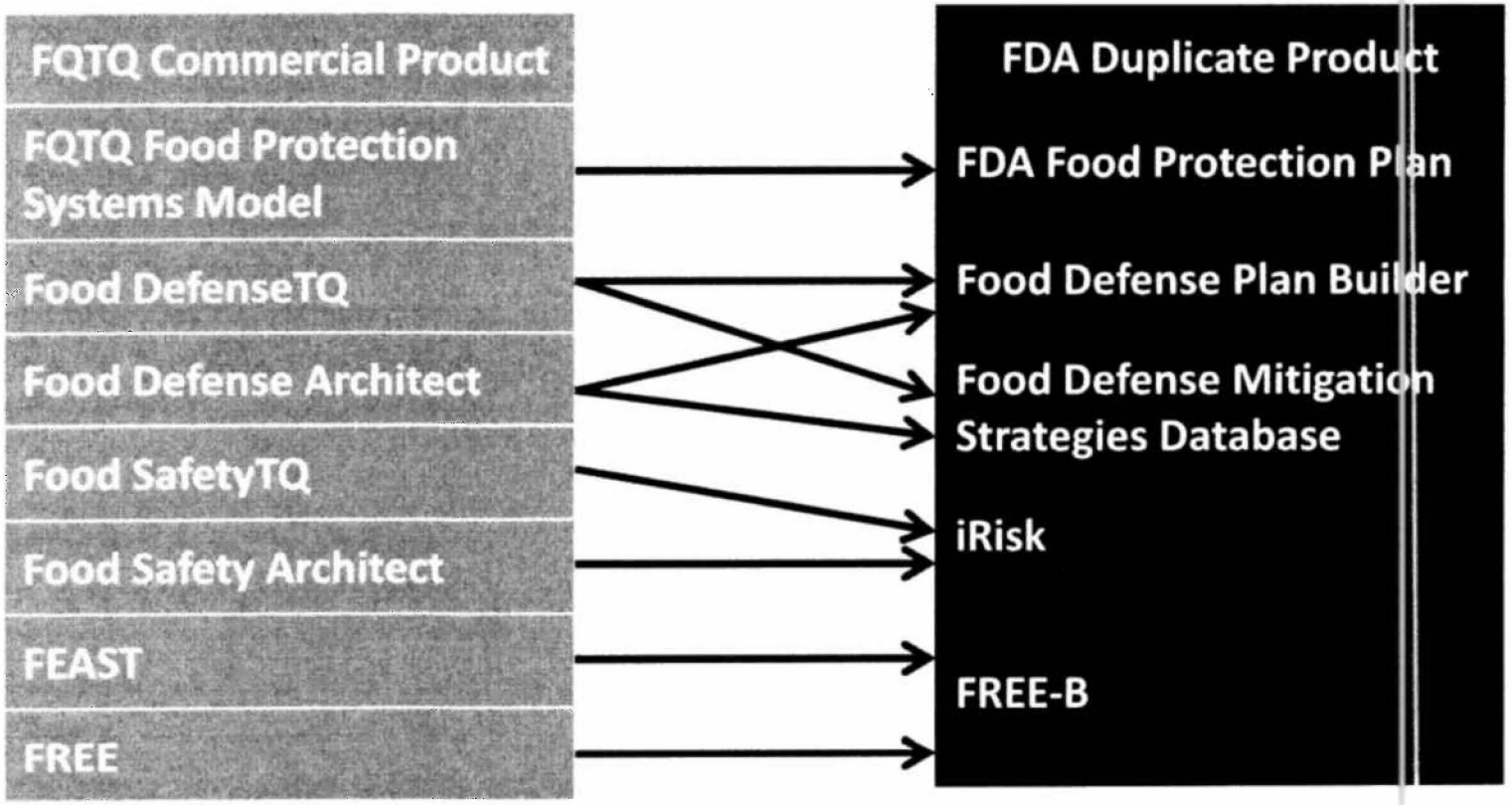
- The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.
- The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.

25. FQTQ Enhanced Risk Communications

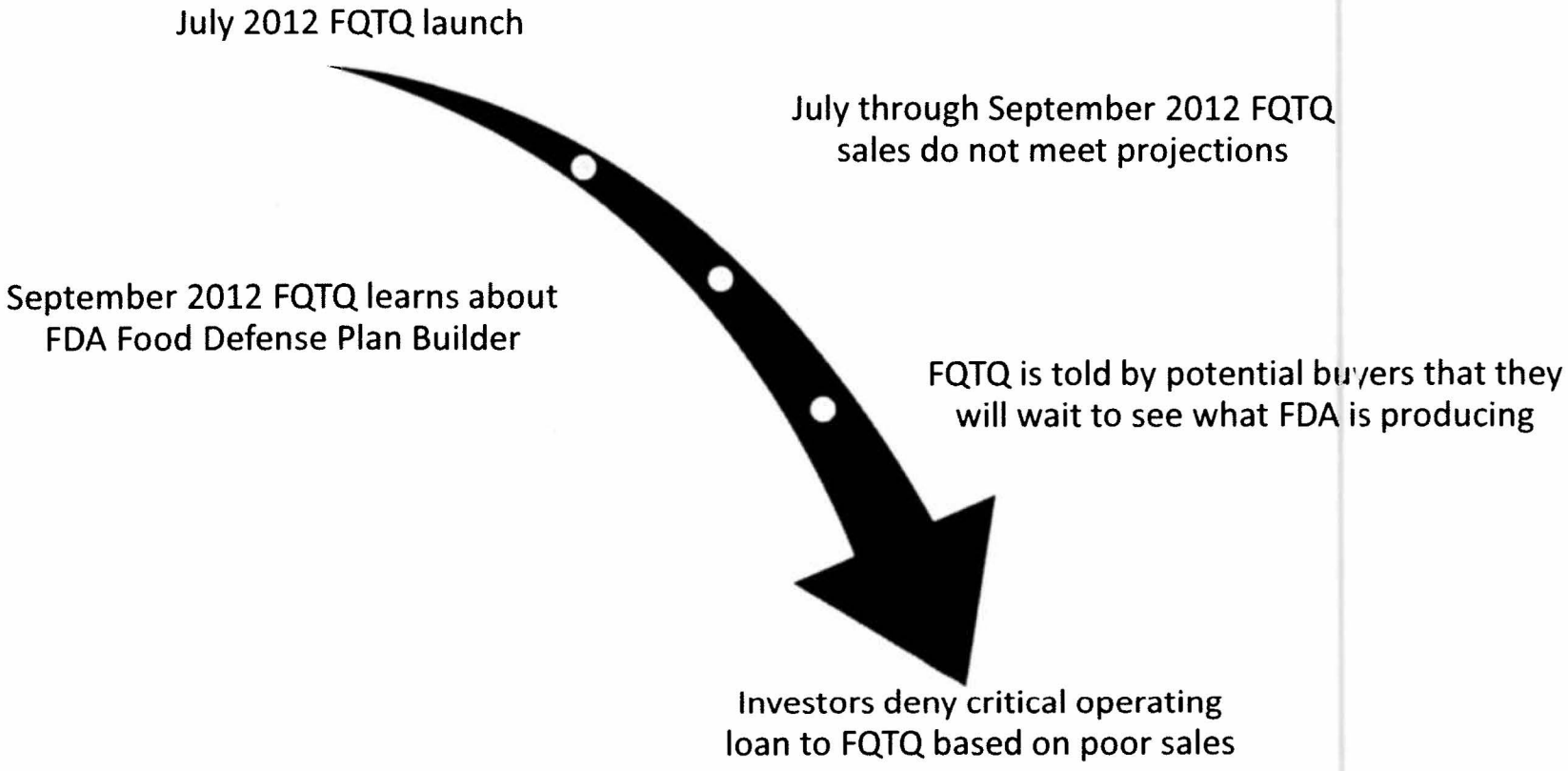
The FQTQ systems model for food protection improves risk communications.

- The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.

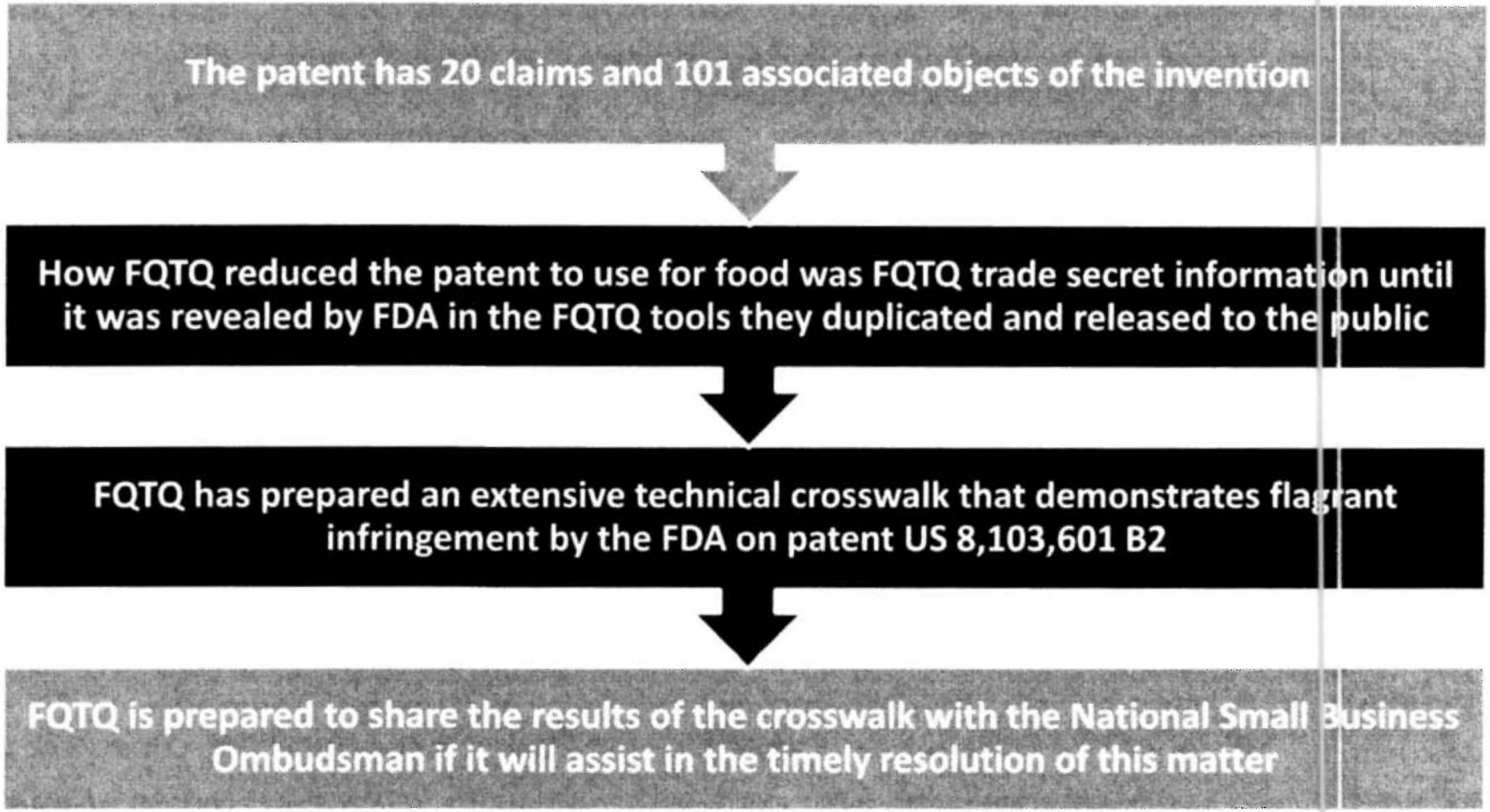
FDA Duplicates FQTQ Products



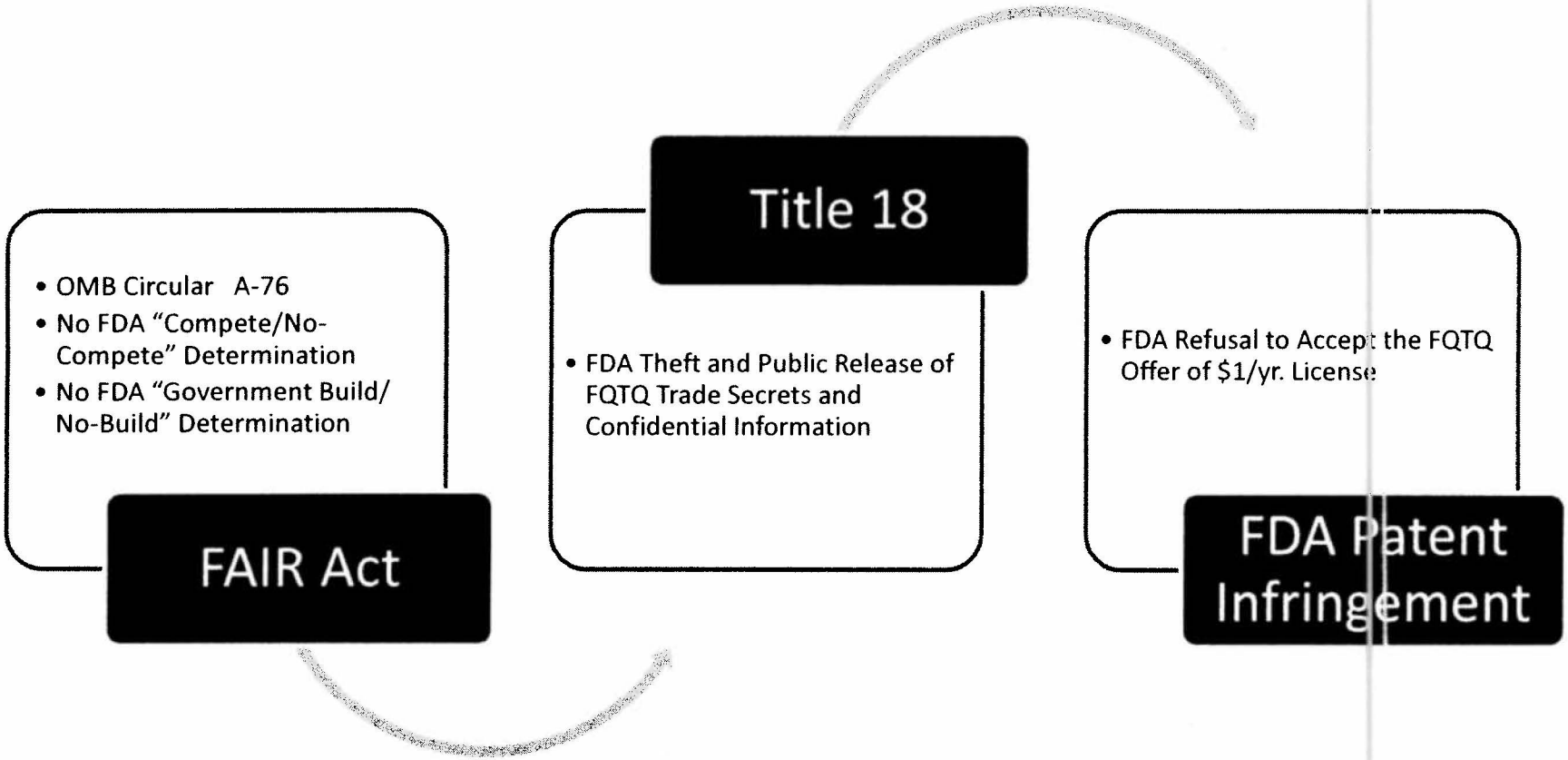
FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2



FDA Unlawfully Competes with FQTQ



Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 16, 2013

Dear Ms. Dickinson:

First, we want to thank-you very much for the hard work of Ariel Seeley of your staff. She has worked very diligently on this matter and we appreciate her efforts very much. You must be proud to have her as a member of your staff. We recognize the extremely difficult situation she is in trying, on the one hand, to defend the actions of the Food and Drug Administration while, at the same time, attempting to conduct an honest and good faith review of the situation. We can appreciate the terrible conflict this must create for her. Please extend our thanks to her.

When we first asked to meet with you I was sincerely hoping that we could simply sit down together, talk honestly to one another as people of mutual integrity and quickly move forward to fairly resolve our concerns. But instead the train of justice has fallen off the tracks. It has now been over three months since we first asked to meet with you and we still are not even able to agree that any wrong has actually happened here. As I shared with Ariel earlier, I am a simple man who is not an attorney and I cannot afford to hire one to advocate on my behalf in an adversary legal setting. But it does seem to me, as a layman, that while there is way too much FDA legal jockeying going on, there is way too little effort to resolve the real issues a play here. In the meantime, however, the lives of real people are being destroyed.

Our company, just when we were in the position to make the food supply safer for all Americans, has been forced out of business by the FDA; on our side of the equation we are now in the unemployment lines, we can no longer pay our bills, the credit ratings that we have worked to a lifetime to preserve have been destroyed and all of our families have suffered terribly as the result of the actions taken against us by the FDA. The extended order effects of improper actions have had devastating consequences in this case.

For example, did you know that one of my company's employees is an 80% disabled military veteran who has an extended family that relies on him as the principal breadwinner? Can you possibly imagine what that must be like for him and his family? In another case, a member of the FoodQuestTQ family of employees has worked, scrimped and sacrificed literally everything he owns including his house, his retirement and his entire life savings to make our business a success. He too is the principal breadwinner for an extended family whose elderly in-laws live with his family. There are many other stories of anguish too. It is much too easy to forget that the actions we take can hurt real people.

This is why I am again pleading for your help and understanding to resolve this matter as quickly as possible. What is happening here is not some far away abstraction of reality. It is the real thing. People's lives and futures depend on our integrity, honesty and willingness to come together in a responsible way to resolve this matter quickly and fairly. That is why I am asking for the opportunity to meet with you personally to get the train of justice back on the tracks here. In the meeting, we would like to simply share with you the honest story of exactly what has happened here. I am sure that once you hear the true and complete story you will be appalled and take whatever actions are necessary to immediately turn this bizarre situation around.

It is true that we are at the mercy of the FDA and our own government because we simply cannot afford a long and expensive legal battle to achieve justice for ourselves. In my case, I am a 62 year old white male with few prospects for any possibility of future employment who would likely die before receiving any relief for my family as the result of this terrible situation. I do not like to think about leaving my wife impoverished as the result of the risks I have taken to create a small business. Thus, we have no choice but to rely on you and our own government to act with integrity to fairly protect our interests.

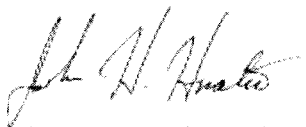
But time is definitely running out for us. This is why we have reached out to the Small Business Administration Office of Small Business Advocacy and the National Ombudsman for Small Business to help the FDA and FoodQuestTQ LLC come together. Our hope is that the SBA Ombudsman will carefully watch what is going on as an objective third party to help the FDA and FoodQuestTQ balance the need for FDA legal propriety against the real world needs of FoodQuestTQ to fairly resolve the situation as soon as possible. We believe that this approach will help both the FDA and FoodQuestTQ work through the issues fairly and objectively. The wonderful added advantage of this approach

is the requirement that we must complete our work within 30 days and file a full report to the Small Business Administration. Of course, this is critically important if FoodQuestTQ is to have any hope of surviving the actions that have been taken against us by the FDA.

Thank-you very much for your help in working with us. It is truly appreciated. We know how busy you are. If the personal meeting I suggest is agreeable to you please let me know and I will work our schedules to meet at any time that is convenient for you and your staff.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,



John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

cc: Ms. Ellie Zahirieh, Office of the SBA Ombudsman

FoodQuestTQ

The TQ stands for threat quotient

MANAGING FOOD DEFENSE RISK

This paper provides an overview of the application of the CSM Method® to determine the specific food defense: 1) threats to the food supply; 2) vulnerabilities to the food supply, and; 3) countermeasures that can reduce the risk exposure of food companies to each of the identified threats and vulnerabilities. The CSM Method® is a patented process used for the protection of critical infrastructures including food and agriculture. The results of the analysis of a large data repository of all hazards events affecting the food supply and open source intelligence are presented. The results of the data analysis are used to determine what needs to be protected, why it needs to be protected and what it needs to be protected against. The clustering of events most commonly affecting the food supply and the characteristics of the potential perpetrators of food defense events are identified along with the seven essential elements of a comprehensive food defense threat statement. The five essential elements of an effective food defense program are presented. The paper concludes with a brief description of technology advances that can help the food industry balance the costs of operations with the right combination of food defense prevention and response risk countermeasures to maintain their economic viability while simultaneously reducing and maintaining their food defense risk exposure at manageable levels.

Food DefenseTQ Technical Paper No. 5

December 2012

0109

MANAGING FOOD DEFENSE RISK: Technical Paper No. 5

By John Hnatio, Chief Science Officer, FoodQuestTQ LLC

Executive Summary

The food supply is one of the most exposed of all industry verticals to risk. From fires and arson, explosions, natural disasters, workplace violence, food safety, cyber-threats, food fraud, equipment malfunction, industrial accidents, tampering and many others, the list of threats and vulnerabilities is long.

When we looked across the available literature on threats and vulnerabilities to the food supply we found that it was almost exclusively anecdotal. Since 9-11, the principal focus of government efforts appears to be directed to the low probability, high consequence threat posed by terrorist cells using intelligence tradecraft. The principal threat of concern is the undetected placement of a biological agent in large batches of food at large food processing facilities resulting in mass deaths. But the reality is that the food defense threat and vulnerability spectrum is much broader and includes arson, facility sabotage, cyber-attack, bombings, workplace violence as well as many other serious threats that can affect the economic viability of a food company, curtail production and result in severe disruption.

Since no comprehensive industry or government statement of the food defense threat to the food supply exists in the open literature, we undertook a systematic process to develop one.[i] A comprehensive threat statement tells you what needs to be protected, why it needs to be protected, and what it needs to be protected against. A clear and unambiguous statement of the threat is an essential first step before you can conduct any meaningful assessment of your vulnerabilities. Using a large food event data repository called POISON™ in combination with an extensive open source intelligence review of food events we identified the three threats and the seven essential elements that must be addressed by a comprehensive food defense threat statement.

Under the threat posed by intentional poisoning we identified the intentional poisoning of food and water by introducing physical hazards, chemical toxins, biological agents or nuclear materials into food and water and the intentional distribution, sale or use of adulterated, mishandled, and/or mislabeled food and water product. Under the threat posed by the loss of production capacity we identified fixed site facility and cyber sabotage. Under the threat posed by disruption we identified inconvenience, economic losses and fear of the population to consume food.

A comprehensive threat statement must also include a description of the capabilities of potential adversaries. This is essential in order to determine the adequacy of food defense risk countermeasures against different threats and the vulnerabilities they pose. Our analysis of food defense events in the POISON food event data repository in combination with open source intelligence analysis indicates that high consequence food defense events will be motivated by disruption. ***The following spectrum of adversary characteristics and capabilities were identified: 1) an employee insider with access, opportunity and knowledge; 2) one or more outsiders that may, or may not, have insider assistance, and; 3) organized terrorist cells using intelligence tradecraft.***

Using this statement of the threat to the food supply, a vulnerability assessment of the food supply chain was conducted. All segments of the food supply chain were found to have significant food defense vulnerabilities across one of more of the following six areas of concern: 1) the intentional introduction of harmful materials into food; 2) the intentional distribution, sale or use of spoiled, adulterated or mishandled food product; 3) intentionally mislabeled food product and other forms of food fraud; 4) the sabotage of fixed site facilities; 5) cyber-sabotage, and; 6) attacks against food operations personnel including walk-in retail customers.

Based on the results of the vulnerability assessment, specific risk reduction countermeasures were identified. This was done by reviewing the open literature and extracting global, U.S. Government and industry standards, i.e., food safety and

defense schemas, related the food defense vulnerability identified. The review identified a total of 1,574 food defense related risk countermeasures.

Each of the 1,574 food defense risk countermeasures was then statistically weighted by teams of scientists, engineers and food defense experts in order to determine its risk reduction value in: 1) deterring the human actions leading to a food defense event; 2) detecting the actions of a perpetrator soon enough to prevent the food defense event; 3) preventing the event before it occurs; 4) responding to a food defense event after it has happened, and; 5) mitigating the consequences of the event. Each countermeasure was weighted in this way to determine the risk reduction value of any given food defense risk countermeasure in relation to others. ***This allows for the selection of the most effective countermeasure(s) to reduce the risk posed by a specific vulnerability.***

Finally, the 1,574 food defense countermeasures were grouped into individual areas of concern across the following five categories of food defense interest. ***The following five categories of food defense interest represent the basic components of any robust food defense plan: 1) preventing the destruction and sabotage of critical facilities and equipment; 2) protecting facility personnel; 3) preventing the intentional poisoning of food and water; 4) responding to food and facility emergencies, and; 5) building a continuity of operations plan.***

With a fundamental understanding of: 1) the threats to the food supply chain (including the characteristics of potential adversaries); 2 the vulnerabilities associated with the threats, and; 3) the value of food defense risk reduction countermeasures, an advanced computer software tool known commercially as ***Food Defense Architect^{TM} was developed to reduce food defense risk and increase cost efficiency by identifying the right combination of low cost prevention and response risk reduction measures.***

Introduction

In this paper, we treat risk management holistically as a portfolio of different risk factors that can result in untoward events. The term “all-hazards events” is used to describe the portfolio of risk factors that can impact a food company. All-hazards events include fires, explosions; site, facility and product sabotage; cyber sabotage; the intentional poisoning of food and water, the protection of facility personnel, including retail customers, and natural hazards emergencies.

The different risk factors that can impact food businesses along the supply chain are considered in the context of all-hazards events because all of the risks faced by the food industry are interconnected and interdependent. For example, you can never have a robust food defense program unless you already have an effective food safety program upon which to build it. Likewise, any robust food safety program must contain elements of food defense. We all know that fires can certainly affect food safety. But arson is the number one cause of fires in the United States. The result is that the very same investments we make to protect our facilities and equipment from industrial fires is also used to protect us from intentional arson.

This “interconnectedness” of risk factors means that the investments a food company makes in updating things like their HACCP plans should have appreciable value in strengthening their food defense plan. Likewise, a food defense vulnerability assessment should have appreciable value in strengthening a company’s HACCP plan. The evacuation drills we conduct to protect our workers from fire should also have value in protecting personnel from bomb threats and explosions and natural disasters and so on. ***The premise of this paper is that significant cost efficiencies can be achieved by leveraging this “interconnectedness” among different risk reduction factors.***

A Three Step Process: Step 1

To approach the challenge of food defense, we did three things in sequential order. First, we determined the threats to the food supply. There is a great deal of information out there but most of it is spread among a huge variety of sources and is almost exclusively anecdotal. We found that much of the threat information at the government level is focused on the notion of low probability-high consequence events based on concerns about what terrorists might do. At the food industry level, we found a more traditional approach to risk management that was focused on the types of food defense risks that food related operations have to manage every day. Things like disgruntled employees who contaminate food, steal company property and misuse computers, unreliable suppliers, hijacked trucks, tampering and a host of other problems that range from medium to high probability and medium to high consequence food defense events.

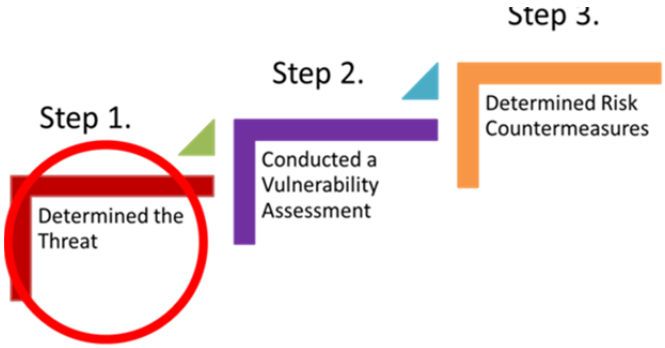


Figure1: Determining the Threat

To determine in a non-subjective way the threat to the food supply, we gathered information about the different types of events that occur at food facilities and created a large data repository known as POISON™. POISON covers intentional and accidental food poisonings, sabotage against food facilities and equipment, arson, fires, explosions, workplace violence, natural disasters and other all-hazards events that have disrupted the food supply. After pulling the events together from POISON and open source intelligence harvesting and analysis, we found five clusters where the events involving food facilities were concentrated: 1) arson and fires; 2) sabotage; 3) poisonings; 4) transport security, and; 5) personnel security.[ii]

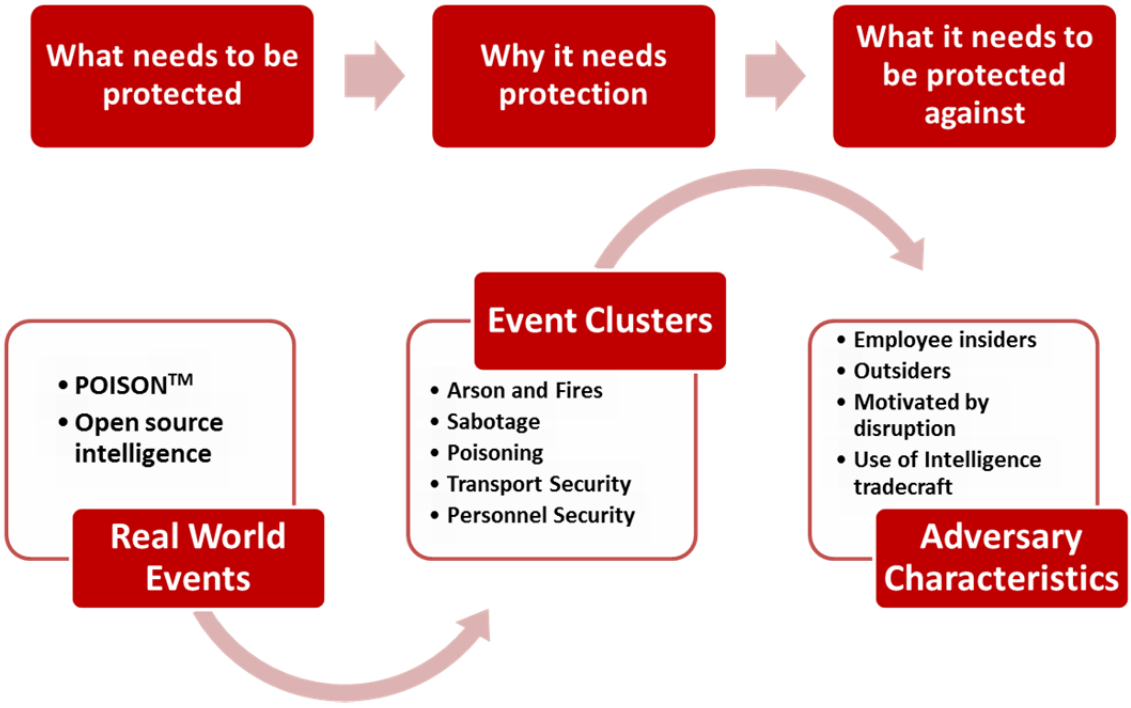


Figure 2: Defining the Food Defense Threat

A comprehensive threat statement must also include a description of the capabilities of potential adversaries. This is essential in order to determine the adequacy of food defense countermeasures against different threats and the vulnerabilities they pose. Our analysis of food defense events in the POISON food event data repository in combination with open source intelligence analysis indicates that high consequence food defense events will be motivated by disruption. The following spectrum of adversary characteristics and capabilities were identified: 1) an employee insider with access, opportunity and knowledge 2) one or more outsiders that may, or may not, have insider assistance; 3) organized terrorist cells using intelligence tradecraft.

The next step we took was to come up with the elements of a threat statement that would apply across all of the potential threats to the food industry that we found as we analyzed the events in POISON and open source intelligence. The challenge was to unambiguously state what needs to be protected, why it needs to be protected, and what it needs to be protected against.[iii]

Based on our analysis, we identified seven critical elements that should be included in a comprehensive food defense threat statement. To address the potential of intentional food poisoning, we identified the first two critical elements. The first element addresses the intentional poisoning of food by introducing physical hazards or toxic chemicals, biological agents or nuclear materials into food. The second element involves the intentional distribution, sale or use of adulterated, mishandled, and/or mislabeled food product. To address the threat of loss of production capacity, the analysis demonstrates that the third element that must be included in any comprehensive threat statement is fixed site facility sabotage. The fourth element addresses the possibility of cyber-sabotage.

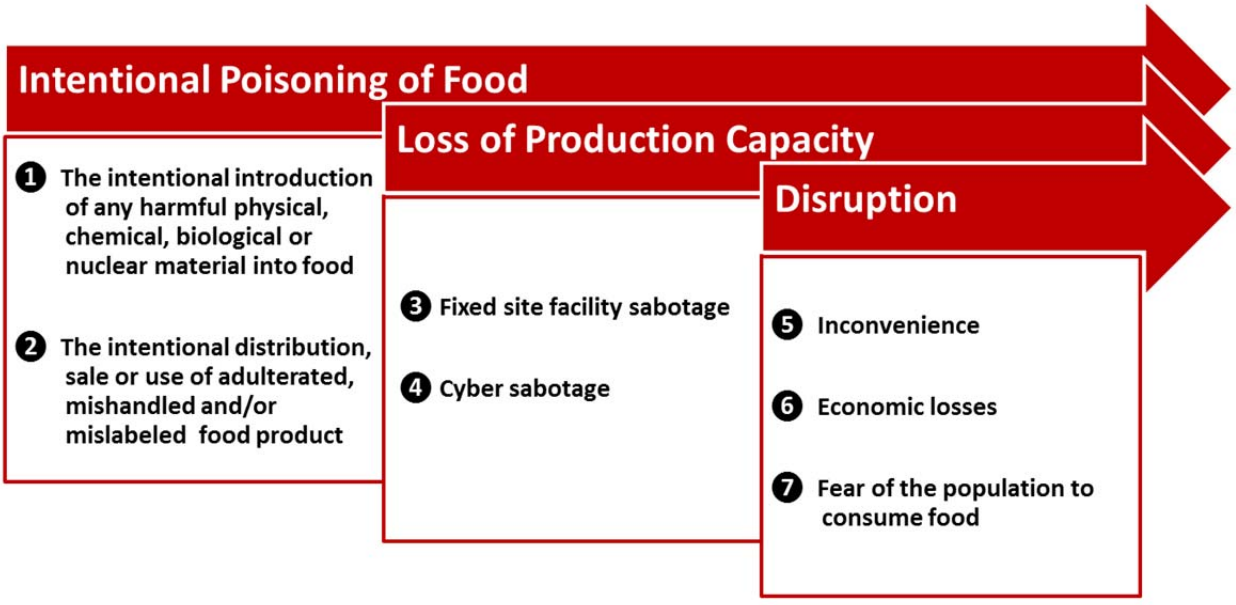


Figure 3: The Seven Elements of the Food Defense Threat

To address the types of disruption that would occur based on the intentional poisoning of food and loss of production capacity, the analysis shows that inconvenience, economic losses, and fear of the population to consume food must also be included as part of a comprehensive statement of the food defense threat.

A Three Step Process: Step 2.

Figure 4: Conducting the Vulnerability Assessment

After we determined the threat to the food supply, we were ready to move to the second step of the process. We needed to conduct a vulnerability assessment of the food supply against the design threat we developed in Step 1. We knew that without a design threat that tells you what you need to protect, why you need to protect it, and what you need to protect it against, you cannot possibly conduct a vulnerability assessment. This is because any effective vulnerability assessment must address each of the threat elements identified in Figure 3 (see page 7) and must consider the capabilities of the different types of adversaries who may attempt to take advantage of them.[iv]

After we defined what needs to be protected, why it needs to be protected, and what it needs to be protected against in a comprehensive statement of the threat to the food supply, we determined the vulnerabilities within the types of different food operations along the food supply chain. We looked across food growers (G), processors (P), transporters (T), warehouses (W), retail distributors (RD), grocery stores (GS), food service (FS), convenience stores (CS) and restaurants (R). The five clusters of events we found during our analysis of food events in POISON and from the open source intelligence review appearing in Figure 2 (see page 6) were used as threat categories. Based on the growing incidence and seriousness of computer-attacks that were found in conducting the open source intelligence analysis we identified and added the sixth cluster of cyber sabotage.

Threat		Location on Food Supply Chain								
		G	P	T	W	RD	GS	FS	CS	R
Intentional introduction of harmful materials into food	Probability	LP	MP	MP	MP	HP	HP	HP	HP	HP
	Consequence	HC	HC	MC	MC	MC	MC	MC	MC	MC
	Difficulty	L	M	L	M	L	L	L	L	L
The intentional distribution, sale or use of spoiled, adulterated or mishandled product	Probability	MP	LP	HP	MP	MP	MP	HP	HP	HP
	Consequence	HC	HC	MC	MC	MC	MC	MC	MC	MC
	Difficulty	L	L	L	L	L	L	L	L	L
Intentionally mislabeled product and other forms of food fraud	Probability	MP	MP	MP	MP	MP	MP	HP	HP	HP
	Consequence	MC	MC	MC	MC	MC	MC	MC	MC	MC
	Difficulty	L	L	L	L	L	L	L	L	L
The sabotage of fixed-site food facilities	Probability	LP	MP	LP	MP	MP	MP	MP	LP	LP
	Consequence	LC	HC	LC	MC	MC	MC	MC	MC	MC
	Difficulty	L	M	L	L	M	M	L	L	L
Cyber-sabotage	Probability	MP	MP	LP	LP	MP	LP	MP	LP	LP
	Consequence	MC	HC	MC	MC	MC	MC	MC	LC	LC
	Difficulty	L	M	L	M	M	L	M	L	L
Attacks against food operations personnel	Probability	LP	HP	HP	HP	HP	HP	HP	HP	MP
	Consequence	LC	MC	MC	MC	MC	MC	MC	HC	HC
	Difficulty	L	L	L	L	L	L	L	L	L

Figure 5: Threat Probability, Consequence and Difficulty Rankings

A traffic light approach of red to represent high, yellow to represent medium and green to represent low is used to signify the probability, consequence and difficulty associated with the different clusters of events across each segment of the food supply chain. Difficulty means the motivation, access to the materials necessary to mount a successful attack, and the know-how to plan and execute a successful attack. The probability of the event occurring is based on data in POISON and the analysis of open source intelligence including financial losses resulting to the food industry.[v] Past events of a similar nature in POISON and the analysis of open source intelligence (including economic losses) were used to estimate consequence.[vi] Knowledge of adversary motivation, access to the materials to carry out an attack and know-how to estimate the difficulty of attacking the different segments along the supply chain were drawn from open source intelligence analysis and used to assign a “difficulty” benchmark.

As part of the vulnerability assessment, events from the POISON database and from open source intelligence were analyzed and used to assign probability of occurrence and consequence rankings for the introduction of harmful materials, the distribution and sale of spoiled, adulterated and mishandled product, intentional mislabeling and other forms of food fraud, the sabotage of fixed site facilities, cyber-sabotage and the protection of food operations personnel including retail customers.

A traffic light approach was used to signify levels of concern. Red indicates the highest level of concern. All threat events with a high consequence, regardless of their probability of occurrence are marked in red. For example, even though the probability of someone intentionally introducing foot and mouth disease at several U.S. beef farms is low, the consequences could have a devastating impact on the beef industry and U.S. agricultural exports. In another example, even though the probability that a terrorist group could successfully introduce enough of the right toxin or biological agent into a large enough food batch to result in a catastrophic outcome is low, the consequences of a successful attack could have devastating consequences. In a final example, although the probability that an act of violence will occur at a retail distributor, grocery store, convenience store and a restaurant ranges from low to medium probability of occurring, the results have proven to be devastating in terms of loss of life and brand name risk exposure for many of the companies involved, so they appear in red. In similar fashion, yellow represents a very serious level of concern. All medium consequence events appear in yellow. Yellow signifies that while the impact of such an event would have very serious consequences on the company involved the outcome is still manageable. Green signifies that the event is manageable. All low consequence events appear in green. Green signifies that while such an event will adversely impact the company involved, the outcome is manageable.

In the following series of figures we show, in rank order, the specific threats of concern to food growers (G), processors (P), transporters (T), warehouses (W), retail distributors

(RD), grocery stores (GS), food service (FS), convenience stores (CS) and restaurants (R) and the associated risk countermeasures that should be emphasized.

Location	Priority	Required Risk Countermeasures
G	1. Spoiled, Adulterated and Mishandled Product (MP-HC)	Spoiled, adulterated and mishandled product risk countermeasures
	2. Harmful Materials (LP-HC)	Biological risk countermeasures for crops and livestock
	3. Food Fraud (MP-MC)	Food fraud risk countermeasures
	4. Cyber Sabotage (MP-MC)	Cyber-sabotage risk countermeasures
	5. Sabotage of Fixed Site Facilities (LP-LC)	Sabotage of fixed sites risk countermeasures
	6. Food Personnel (LP-LC)	Workplace violence and other risk countermeasures
P	1. Harmful Materials (MP-HC)	Nuclear, biological, chemical and physical risk countermeasures
	2. Spoiled, Adulterated and Mishandled Product (LP-HC)	Spoiled, adulterated and mishandled product risk countermeasures
	3. Sabotage of Fixed Sites (MP-HC)	Sabotage of fixed sites risk countermeasures
	4. Cyber-Sabotage (MP-HC)	Cyber-sabotage risk countermeasures
	5. Food Fraud (MP-MC)	Food fraud risk countermeasures
	6. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures

Figure 6: Rank Order of Threat Concerns for Growers and Processors

The occurrence of major food poisoning incidents and the introduction of spoiled, adulterated or mishandled product leading to criminal indictments and civil litigation for negligence have become major concerns for growers. In a growing number of cases, serious poisoning incidents have forced these companies into bankruptcy. For growers, the introduction of the right type of undetected toxin or biological agent into a large batch of food product could also have devastating consequences. The possibility of food fraud and cyber-sabotage (medium and large growers for traceability) would have medium consequences. The sabotage of building structures and violence against farms and farmers is considered to be a low probability and low consequence event.

Food processors have the greatest risk exposure of any single segment along the food supply chain. Although the probability is low, if the right toxin or biological agent were successfully introduced into a large batch the consequences could be devastating. In complex supply chains that allow for the fast and broad distribution of food both spoiled, adulterated and/or mishandled product and food fraud could have devastating impact on brand name. Processors are the most vulnerable to the sabotage of fixed sites with potentially devastating consequences. Cyber-sabotage could threaten food production, distribution and traceability to result in devastating consequences. Finally, the consequences of violence involving food personnel is considered as a medium consequence event due to the high cost of reparations and negative effects on employee morale and resulting decreases in production.

Location	Priority	Required Countermeasures
T	1. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	2. Harmful Materials (MP-MC)	Nuclear, biological, chemical and physical risk countermeasures
	3. Food Fraud (MP-MC)	Food fraud risk countermeasures
	4. Food Personnel (MP-MC)	Workplace violence and other risk countermeasures
	5. Cyber-Sabotage (LP-MC)	Cyber-sabotage risk countermeasures
	6. Sabotage of Fixed Site Facilities (LP-LC)	Sabotage of fixed sites risk countermeasures
W	1. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	2. Food Fraud (MP-MC)	Food fraud risk countermeasures
	3. Harmful Materials (MP-MC)	Chemical and biological risk countermeasures for crops and livestock
	4. Spoiled, Adulterated and Mishandled Product (MP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	5. Sabotage of Fixed Sites (MP-MC)	Sabotage of fixed sites risk countermeasures
	6. Cyber Sabotage (LP-MC)	Cyber-sabotage risk countermeasures

Figure 7: Rank Order of Threat Concerns for Transporters and Warehouse Facilities

For transporters the threats posed by the introduction of harmful materials, the distribution of spoiled, adulterated and mishandled product, food fraud, cyber sabotage and driver safety issues associated with the frequency of truck hijackings are all medium consequence events. As would be expected, the probability of occurrence and consequences associated with the sabotage of fixed site facilities are low for transporters.

Warehouses face medium consequences across all six threat areas.

Location	Priorities	Required Countermeasures
RD	1. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Chemical and biological risk countermeasures for crops and livestock
	3. Spoiled, Adulterated and Mishandled Product (MP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Cyber-Sabotage (MP-MC)	Cyber-sabotage risk countermeasures
	5. Food Fraud (MP-MC)	Food fraud risk countermeasures
	6. Sabotage of Fixed Site Facilities (MP-MC)	Sabotage of fixed sites risk countermeasures
GS	1. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Nuclear, biological, chemical and physical risk countermeasures
	3. Spoiled, Adulterated and Mishandled Product (MP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Cyber-Sabotage (LP-MC)	Cyber-sabotage risk countermeasures
	5. Food Fraud (MP-MC)	Food fraud risk countermeasures
	6. Sabotage of Fixed Site Facilities (MP-MC)	Sabotage of fixed sites risk countermeasures

Figure 8: Rank Order of Threat Concerns for Retail Distributors and Grocery Stores

For retail distributors the priority concern is violence affecting retail establishments of all kinds.[vii] The violence may be among employees or by outsiders. The consequences of violence, especially shootings, make retail food stores extremely vulnerable to after the

fact adverse brand name exposure. The introduction of harmful materials, spoiled and mishandled product, cyber-sabotage, food fraud and sabotage to fixed facilities are all considered to be medium consequence events.

Grocery stores are assigned the same ranking as retail distributors for the same reasons.

Location	Priorities	Required Countermeasures
FS	1. Harmful Materials (HP-MC)	Chemical and biological risk countermeasures for crops and livestock
	2. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	3. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	5. Food Fraud (HP-MC)	Food fraud risk countermeasures
	4. Cyber Sabotage (MP-MC)	Cyber-sabotage risk countermeasures
	6. Sabotage of Fixed Site Facilities (MP-MC)	Sabotage of fixed sites risk countermeasures
CS	1. Food Personnel (LP-HC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Chemical and biological risk countermeasures for crops and livestock
	3. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Food Fraud (HP-MC)	Food fraud risk countermeasures
	5. Sabotage of Fixed Site Facilities (LP-MC)	Sabotage of fixed sites risk countermeasures
	6. Cyber-Sabotage (LP-LC)	Cyber-sabotage risk countermeasures

Figure 9: Rank Order of Threat Concerns for Food Service and Convenience Stores

Like warehouses, food service establishments face medium consequences across all six threat areas.

Convenience stores, like other food retailers, face the threat of violence against personnel. The violence is usually instigated by outsiders and robbery attempts. The consequences of violence, especially shootings, make convenience stores extremely

vulnerable to after the fact adverse brand name exposure. The introduction of harmful materials, spoiled and mishandled product, food fraud and fixed site facility sabotage (not involving workplace violence) are considered to be medium consequence events for convenience stores. The probability and consequences of cyber-sabotage are considered low.

Location	Priorities	Required Countermeasures
R	1. Food Personnel (MP-HC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Nuclear, biological, chemical and physical risk countermeasures
	3. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Food Fraud (HP-MC)	Food fraud risk countermeasures
	5. Sabotage of Fixed Site Facilities (LP-MC)	Sabotage of fixed sites risk countermeasures
	6. Cyber-Sabotage (LP-LC)	Cyber-sabotage risk countermeasures

Figure 10: Rank Order of Threat Concerns for Restaurants

Finally, restaurants like other food retailers face the threat of violence against personnel and their customers. The violence is frequently instigated by outsiders and may involve mass shootings. The consequences of violence, especially shootings, make restaurants extremely vulnerable to after the fact adverse brand name exposure. The introduction of harmful materials, spoiled, adulterated and mishandled product, cyber-sabotage and food fraud are considered to be medium consequence events for restaurants. The consequences of fixed site facility sabotage (not involving workplace violence) are considered low.

As the final step in completing the vulnerability assessment of the food supply we identified five categories of interest that must be part of a comprehensive food defense plan based on the vulnerability assessment. First, a food defense program must address the sabotage of critical equipment and facilities.

Figure 11: Five Food Defense Categories

Second, it must protect facility personnel and walk-in retail customers from intentional attacks such as shootings, bombings, arson and other threats. Third, it must prevent the intentional poisoning of food and water. Fourth, there needs to be an effective command and control system in place to respond to food facility emergencies. Fifth, food operations must be prepared to deal with the loss of production and delivery capacity by having plans in place to shorten the curtailment of their operations.

A Three Step Process: Step 3.

In the third and final phase of the CSM Method® we turned our attention to determining the most effective risk countermeasures that should be employed to address each of the threats and vulnerabilities that were identified in steps 1 and 2.

Figure 12: Determining Risk Countermeasures

We started at the global level and extracted every food defense related benchmark and audit standard associated with the five categories food defense interest of: 1) the sabotage of critical equipment and facilities including cyber-sabotage; 2) the protection of facility personnel and retail customers from intentional attacks such as shootings,

bombings, arson and other threats; 3) the intentional poisoning of food and water; 4) an effective command and control system must be in place to respond to food facility emergencies, and; 5) the presence of continuity of operations plans to deal with the loss of production capacity by having plans in place to shorten the curtailment of their operations. In similar fashion, every food defense and site security related standard across the U.S. Government and the seven principal industry food safety and food defense schemas were also extracted.

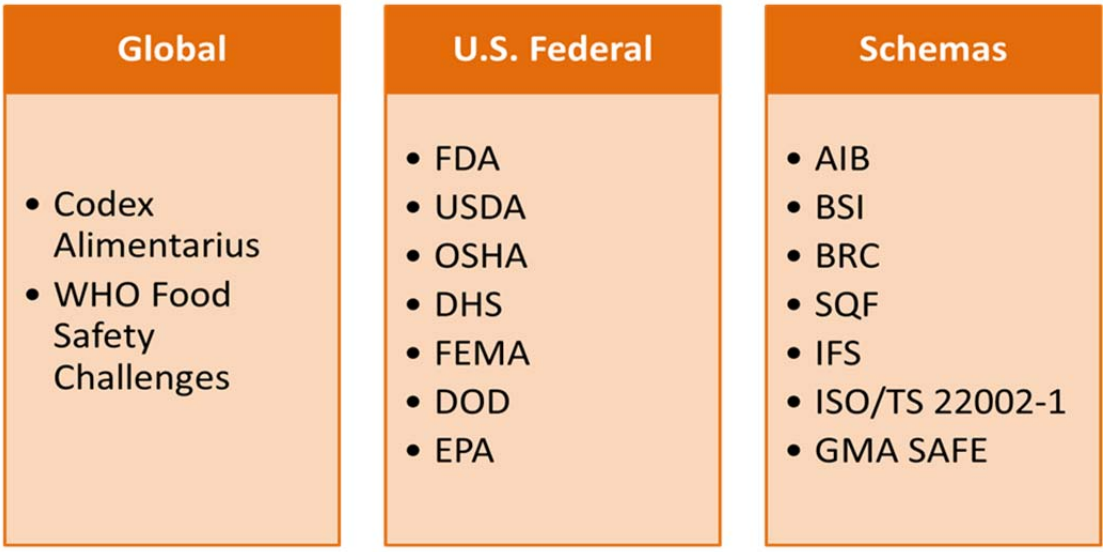


Figure 13: Sources of Food Defense Related Risk Countermeasures

A total of 1,574 food defense and site security related countermeasures were identified. The countermeasures were grouped into the five food defense categories of interest that were identified as the result of the vulnerability assessment (see Figure 11). Scientists and subject matter experts used similar events in the POISON™ food defense data repository and from open source intelligence to weight the value of each countermeasure in: 1) deterring the human actions leading to a particular type of food defense event; 2) detecting the actions of a perpetrator soon enough to prevent the event; 3) actually preventing the event; 4) improving the response to the event, and; 5) mitigating the consequences of the event. To do this, the scientists and food defense subject matter experts used a 5 point graduated Likert scale with their scores validated

by independent peer review. In this way, the value of each food defense risk countermeasure (and combinations of countermeasures) in addressing specified threats was determined. The countermeasures with the highest scores were flagged and represent the best investments a food company can make to prevent and respond food defense threats and their associated vulnerabilities.

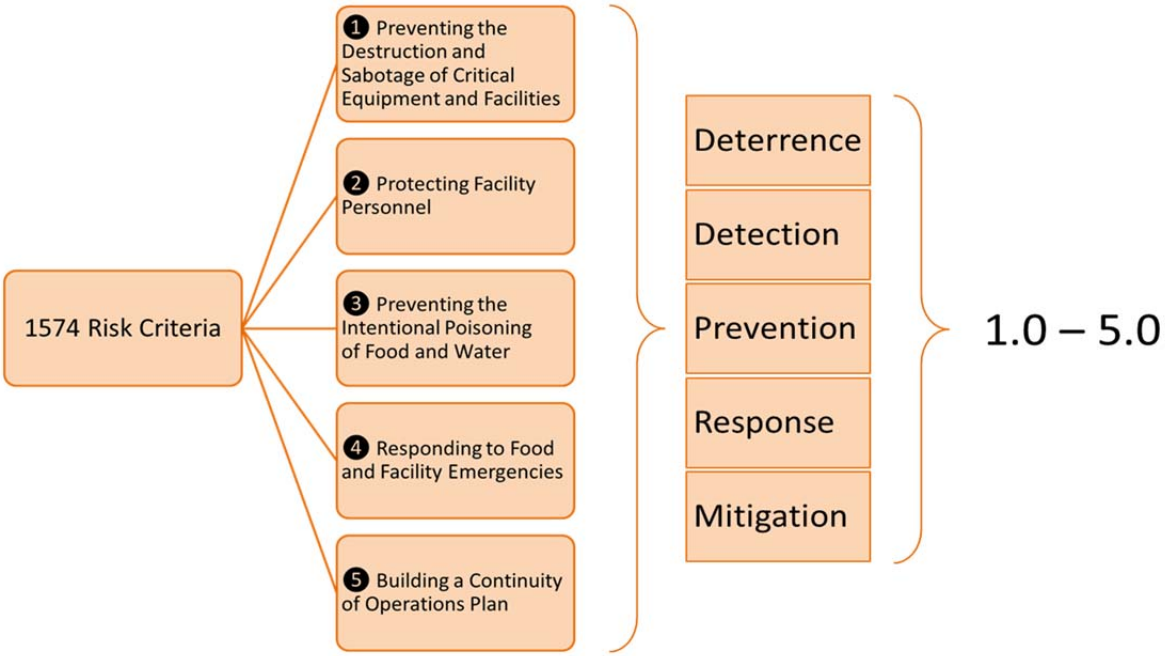


Figure 14: Identification, Grouping and Weighting of Food Defense Risk Countermeasures

Leveraging Technology to Achieve Food Defense Cost Efficiencies and Reduce Losses

With a fundamental understanding of: 1) the threats to the food supply chain that includes the characteristics of potential adversaries; 2) the vulnerabilities associated with the threats, and; 3) the value of food defense risk reduction countermeasures, a computer software program was developed to reduce food defense risk and increase cost efficiency by identifying the right combination of low cost prevention and response risk reduction measures that should be employed to address each vulnerability.

The software tool, which is based on the patented CSM Method®[viii], is called Food Defense Artchitect™. Food Defense Architect is a secure, cloud-based software platform that allows small, medium and large food growers, processors, transporters, warehouses, retail distributors, grocery stores, and food service companies (including caterers) to develop (and strengthen) their food defense programs to reflect their business size and location on the supply chain. The software reduces personnel time on task while simultaneously encouraging multi-disciplinary problem solving through the use of a workflow management protocol where food managers can assign different categories of questions to different operating personnel. The software is also full spectrum enabled to function on workstations, lap top computers, tablet and cell phone technology. This increases personnel cost efficiencies by allowing for both "in-the-office" and "on-the-floor" data inputs.

The software tool looks across each of the five categories of food defense interest: 1) the sabotage of critical equipment and facilities including cyber-sabotage; 2) the protection of facility personnel including retail customers from intentional attacks such as shootings, bombings, arson and other threats; 3) the intentional poisoning of food and water; 4) an effective command and control system to respond to food facility emergencies, and; 5) continuity of operations plans to deal with the loss of production capacity. It uses a questions accompanied by several steps and a "yes" or "no" format. By selecting the steps that are in place, the software generates a threat quotient. A threat quotient is the average of the deterrence, detection, prevention, response and mitigation scores for the food defense risk countermeasures, i.e., steps, which are selected.[ix]

The software also reduces the costs associated with assessments and audits through perpetual assessment. Perpetual assessment means that once the desired combination of prevention and response risk countermeasures are in place their implementation is continuously monitored by real-time feedback from operating personnel using personal digital assistants (PDA's). A cost factor analysis of food safety

and food defense assessments and audits indicates that the costs associated with assessment and audits can be reduced by up to 60% through the application of perpetual assessment methods.[x]

Conclusion

The goal of risk management is to help food companies balance the cost of their operations with the right combinations of prevention and response measures that keep losses low and profits high. Thus, the cost and effectiveness of food defense risk reduction measures in preventing and responding to food defense threats and vulnerabilities must be at the heart of any successful food protection strategy.

Recent advances in science and information technology now make it possible, for the first time, to quantitatively determine the value of risk countermeasures and combinations of risk countermeasures in preventing and, when necessary, mounting the most effective responses to all-hazards risk events that can affect a food company.[xi] Using these new advances, food companies can select and put into place the most cost effective combinations of prevention and response risk countermeasures that can keep their losses low and profits high.

End Notes

[i] Complexity Systems Management Method, Patent No.: US 8,103,601 B2. Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

[ii] Note: The POISON food event data repository contains 1500 selected all hazards events impacting the food supply to include accidental and intentional poisonings of food and water, fires, arson and sabotage, industrial accidents, equipment malfunction, workplace violence and natural disasters. FoodQuestTQ LLC does not publicly share our analysis of intentionally motivated attacks to avoid assisting terrorists and criminals. Read more about POISON at: http://www.nfpcportal.com/FQTools/POISON/tabid/197/Default.aspx

[iii] Jech, Ronald. (April 2010). NATO Science for Peace and Security Programme. NATO Advanced Technology Workshop: Advances in food security and safety against terrorist threats and natural disasters. Presentation, Risk management as it relates to food. Cairo, Egypt. Read more at: http://agtechint.com/uploads/Risk_Management_as_it_Relates_to_Food.pdf

[iv] Note: The public availability of a clear statement of the threats to the food supply that includes a description of the capabilities and characteristics of potential adversaries is an essential first step before the food industry can conduct effective food defense vulnerability assessments. The use of tools such as C.A.R.V.E.R. plus SHOCK in the absence of an unambiguous design basis threat can yield serious false positives with respect to the detection, prevention and effective responses to low probability-high consequence terrorist events.

[v] ThoughtQuest LLC (May 2011). Food: Market analysis and worksheets for the costing of assessments and audits and food industry losses as the result of all hazards events. ThoughtQuest LLC: Frederick, MD

[vi] ThoughtQuest LLC (May 2011). Food: Market analysis and worksheets for the costing of assessments and audits and food industry losses as the result of all hazards events. ThoughtQuest LLC: Frederick, MD

[vii] Northwood, Joyce (December 2011). Assaults and Violent Acts in the Private Retail Trade Sector, 2003—2008. Bureau of Labor Statistics, Department of Labor: Washington D.C., as retrieved from the World Wide Web at: http://www.bls.gov/opub/cwc/sh20111202ar01p1.htm

[viii] Complexity Systems Management Method, Patent No.: US 8,103,601 B2, Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

[ix] Note: Read more about Food Defense Architect™ at: http://nfpcportal.com/FQTools/FoodDefenseArchitect/tabid/282/Default.aspx

[x] ThoughtQuest LLC (May 2011). Food: Market analysis and worksheets for the costing of assessments and audits and food industry losses as the result of all hazards events. ThoughtQuest LLC: Frederick, MD

[xi] Complexity Systems Management Method, Patent No.: US 8,103,601 B2, Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

About the Author

John Hnatio is the Chief Science Officer at FoodQuestTQ. His career with the U.S. Government and industry spans a period of over 35 years where he has been involved in risk management. His service to the government includes threat analysis, vulnerability assessments and the implementation of risk countermeasures at U.S. nuclear weapons and other sensitive facilities, nuclear transportation systems and nuclear reactors worldwide. He also served as a loaned executive to the United States Senate from the Administration of President Ronald W. Reagan where he advised on risk matters involving the nuclear and biological programs of the former Soviet Union. In 2004, John retired from the U.S. government and is now an owner of several companies where he works with industry to reduce risk and enhance the resiliency of the nation's critical infrastructures including food and agriculture. He established FoodQuestTQ in 2011. John is the author of several patents and holds a doctorate degree from the George Washington University. He also holds a doctorate degree awarded honoris causa from the Urals Branch of the Russian Academy of Sciences.

FoodQuestTQ

The TQ stands for threat quotient

2012 REPORT CARD FOR FOOD PROTECTION: IS PERFORMANCE MEETING EXPECTATIONS?

The purpose of the paper is to set forth a possible framework and specific benchmarks against which quantitative data can be collected and analyzed to determine the true performance of industry and government in creating a safer food supply. This paper uses anecdotal information to assess U.S. Government and industry performance in creating a safer food supply across seven benchmarks of performance: 1) deterring the incidence of food borne poisoning; 2) detecting contaminated foods; 3) communicating possible threats of contaminated food; 4) delaying the potential for the ingestion of contaminated foods until an effective response is mustered; 5) the timeliness of responses to potential food poisonings; 6) the quality of those responses, and; 7) mitigating actions taken by industry and the government to ameliorate the future incidence of food poisonings. The 2012 levels of government and industry performance across the seven performance factors are graded on a scale from A to F. The paper concludes with several recommendations on how to strengthen government and food industry performance in making the food supply safer.

Food DefenseTQ Technical Paper No. 6

February 2013

0132

FoodQuestTQ LLC is located at 4720 Hayward Road, Suite 104, Frederick, Maryland 21702. Please contact us at 240-439-4476 for permission to reproduce or copy this document.

2012 Report Card for Food Protection: Is Performance Meeting Expectations?

Technical Paper No. 6

By John Hnatio, Chief Science Officer, FoodQuestTQ LLC

Executive Summary

Much of the information used in this paper to grade U.S. government and industry performance in creating a safer food supply is anecdotal since it does not represent up-to-date confirmed scientific data collected against specific performance benchmarks. ***The lack of current reporting requirements against specifically defined performance benchmarks represents a significant limitation in quantitatively deriving levels of industry and government performance in creating a safer food supply.***

The performance of government and industry to create a safer food supply were benchmarked across the 7 categories of performance and 23 associated criteria set forth in Figure 1, below. Levels of government and industry performance in each of the seven categories and associated criteria were graded on a scale from A to F. In the absence of current quantitative performance data provided by government and industry, we used government reports, media reporting of high profile incidents, professional articles and food industry media reporting to gauge levels of performance. ***For 2012, industry and government efforts to create a safer food supply received an average overall grade of a C on a scale of A to F based on available data and information.***

Category of Interest	Grade	Areas of Concern	Grade
1. Deterring the incidence of food borne poisoning	C	a) Shift to science and risk based standards	C-
		b) Timeliness and quality of government inspection	D
		c) Efforts to educate consumers	B+
2. Detecting contaminated foods	C	a) Identification of contaminated food products	C-
		b) Reduce the risk of consumption	C+
		c) Interdict consumption	C-
3. Communicating possible threats of contaminated food	C-	a) Timely notification of consumers	D
		b) Timely downstream notification of customers	C
		c) Timely upstream notification of suppliers	C
		d) Timely notification of government authorities	B
4. Delay to give responders the time they need to effectively respond	C	a) Inform the Consumer	C
		b) Make a "Recall" No Recall" Decision	C
		c) Determine the Scope of a Recall	C-
5. The timeliness of responses to potential food poisonings	C	a) Traceability Records	C-
		b) Recall Management	C
		c) Logistical Support	C
6. The quality of responses	C	a) Identify Product	C-
		b) Inform the Consumer	C
		c) Comprehensive Traceability Records	B-
		d) Recall Training and Testing	C
7. Mitigating actions taken to ameliorate the potential for future food poisonings	D	a) Nature of R&D Investments	D+
		b) Tangible Results	D
		c) Planning for Future Government Investments	D

Figure 1: 2012 Food Industry and Government Report Card

The report identifies four findings of general significance.

Finding	Report Observation
1. No set of common standards or criteria to guide the protection the food supply exists.	Instead, there are numerous government and industry schemas, all with different risk countermeasures, that are used by different food companies along the food supply chain at different locations across the globe.
2. Government and industry are not using scientifically derived measures to judge their food protection performance.	Methods are currently available to scientifically quantify the value of food protection risk reduction performance measures but they are not being used by the government or the food industry.
3. Industry and government do not use a systems approach for gauging the performance of the food protection system.	Without a systems approach you cannot establish an effective framework for the collection and analysis of the specific information you must have to gauge the performance of the food protection system.
4. The types of information and data required to quantitatively evaluate industry and government food protection performance is not being collected or analyzed.	Government and industry have not systematically developed food protection performance benchmarks and the data keeping, collection and analysis requirements necessary to evaluate their actual performance on creating a safer food supply.

Figure 2: Findings of General Significance

The report identifies ten additional findings by category of interest.

Category of Interest	Additional Findings
Deterring the incidence of food borne poisoning	1. The government and industry continue to rely on non-science and non-risk based methods to protect the food supply.
	2. The timeliness, quality and focus of government inspections are deficient.
	3. Government efforts to educate consumers in the safe handling of food are effective.
Detecting contaminated foods	4. Government and industry have the scientific and technical means to make more informed decisions to identify contaminated food product but they do not fully utilize them.
Communicating possible threats of contaminated food	5. In the food industry today, interdiction of consumption begins almost exclusively with the first report of illness or death. By the time affected consumers "get the message" they may be sick, dying or dead. The current system remains reactive rather than preventive.
Delay to give responders the time they need to effectively respond	6. Current efforts by the government and industry to reduce the time between suspecting that something might be wrong with a food product and taking the actions necessary to prevent consumer illness and death requires improvement.
The timeliness of responses to potential food poisonings	7. The timeliness of downstream and upstream notification requires improvement.
The quality of responses	8. Recall training and testing requires improvement.
Mitigating actions taken by industry and the government to ameliorate the consequences of food poisonings	9. There is a significant lag time between investments in food related university research and the emergence of practical food safety solutions that can be applied by the food industry.
	10. Current planning for future government investments to make the food supply safer lack the focus necessary to produce tangible near term results.

Figure 3: Additional Findings by Categories of Interest

The report identifies four recommendations of general significance.

Government and Industry Need	Recommendation
1. Common food protection standards.	Utilize available technology and quantify the value of food protection standards and criteria to create a common set of high prevention and response value food protection standards.
2. Scientifically derived risk based food protection measures .	Better utilize the scientific method and use risk management methods as you create a common set of high prevention and response value food protection standards.
3. A systems approach to guide the collection and analysis of the right data and information food protection needed to gauge system performance.	Adopt a systems approach that considers prevention and response and across the food threat and risk continuum.
4. The collection and analysis of data and information to quantitatively evaluate performance.	Establish data keeping, collection and analysis requirements in order to gauge performance.

Figure 4: Recommendations of General Significance

The report identifies seven additional recommendations by category of interest.

Category of Interest	Additional Recommendations
Deterring the incidence of food borne poisoning	1. Take the development and use of science and risk based food safety and food defense countermeasures seriously by using quantitatively derived measures of actual performance.
	2. Use these quantitative measures of performance to better focus the objectivity and validity of assessments and audits in order to reduce the required frequency of government oversight inspections.
Detecting contaminated foods	3. Make more informed decisions by placing greater emphasis on better and more frequent testing of ingredients and food products at all stages of the food supply chain to identify contaminated food product before it reaches the consumer.
Communicating possible threats of contaminated food	
Delay to give responders the time they need to effectively respond	4. Reduce the time between suspecting that something might be wrong with a food product and taking the actions necessary to prevent consumer illness and death.
The timeliness of responses to potential food poisonings	5. Continue to increase investments in traceability, recall management and the testing of recall management systems. This recommendation applies especially to small and medium businesses.
The quality of responses	
Mitigating actions taken by industry and the government to ameliorate the future potential of food poisonings	6. Better leverage the land grant university system to conduct highly focused programs of basic scientific research involving the biological contamination of food as dictated by actual industry needs.
	7. Place greater emphasis on technology innovation and the applied research necessary to address specific industry needs based on the use of quantitative performance benchmarks.

Figure 5: Additional Recommendations by Category of Interest

Introduction

The Complexity Systems Management Method (CSM Method®) is a patented systems model for understanding how things, regarded as ***systems***, influence one another within a whole. Using the CSM Method, systems are understood by examining the linkages and interconnections among the different elements that compose the entirety of the food protection system.[i] Food protection systems include both food safety and food defense risk countermeasures.

Any food protection system shares the two common goals of ***preventing*** and, when necessary, ***responding*** to untoward events. There are seven distinct elements of a food protection system known, in CSM Method parlance, as the food threat and risk continuum.

Thinking about food protection using the seven elements of the food threat and risk continuum allows you to quantify the performance of a food protection system and the relative value of food safety and food defense risk countermeasures.

The first element of the food threat continuum is ***deterrence.*** Deterrence means the actions that we take to discourage people from intentionally or accidentally contaminating food.

CSM Method®: Threat Continuum for Food	
1. ***Deterrence*** means the actions we take to discourage people from intentionally or accidentally contaminating food	
2. ***Detection*** means learning about an intentional or accidental poisoning early enough so that you can communicate an alarm to those people who are in the position to respond to the incident	
3. ***Communication*** means sounding an alert to responders to come to your assistance	
4. ***Delay*** means the actions taken to reduce the risk of an intentional or accidental poisoning while awaiting a response	Food Defense: The physical barriers in place to slow the adversary down long enough for a sufficient number of responders to arrive on the scene in order to interdict the incident
	Food Safety: Promptly taking the precautionary measures necessary to stop the further distribution of contaminated food, inform the consumer not to eat contaminated food product and any other actions to reduce the potential risk to food products and consumers
5. ***Response Time*** means the actual elapsed time from the sounding of an alert and the actions of responders	Food Defense: The actual elapsed time from a communicated alert to the time responders arrive on scene to interdict an adversary.
	Food Safety: The actual elapsed time from a communicated alert to the time responders take action to ameliorate the consequences of an event
6. ***Response Quality*** means how effectively responders do their jobs	
7. ***Mitigation*** means the measures that are taken to ameliorate the potential for future intentional attacks or accidental poisonings	

Figure 6: The Food Protection Threat Continuum

The second element of the food threat continuum is ***detection***. Detection means learning about an intentional or accidental poisoning early enough so that you can communicate an alarm to those people who are going to respond to the incident. The third element of the food threat continuum is ***communication***. Communication means sounding an alert for responders to come to your assistance.

The fourth element of the food threat continuum is ***delay***. In the case of an intentional attack against the food supply, delay constitutes the physical barriers that are in place to slow down the adversary down long enough for a sufficient number of responders to arrive on scene in order to interdict the adversary. For example, a locked door will provide greater delay time than an unlocked door.

In the case of accidental poisoning, delay constitutes promptly taking the precautionary measures necessary to stop the further distribution of contaminated food, inform the consumer not to eat contaminated food product and any other actions that reduce the potential risk to consumers. For example, the decision to stop potentially contaminated shipments of food products and prompt public announcements of potentially contaminated food product are two of many actions that could be taken to reduce the risk that consumers will ingest poisoned food while awaiting a full scale response.

The fifth element of the food threat continuum is ***response time***. Response time means the actual elapsed time from the sounding of an alert to the time responders take action to prevent an incident from escalating. In the case of an intentional attack against the food supply, response time constitutes the actual elapsed time from a communicated alert to the time responders arrive on scene to interdict the adversary. In the case of accidental poisoning, response time constitutes the actual elapsed time from the sounding of an alert to the time responders take actions to ameliorate the consequences of the event.

The sixth element of the food threat continuum is ***response quality***. Response quality means how effectively responders do their jobs of preventing an incident from escalating. The seventh element of the food threat continuum is ***mitigation***. Mitigation means the measures that are taken to ameliorate the possibility of future intentional attacks or accidental poisonings.

In this paper we use the CSM Method to establish a ***systems*** approach for grading the food protection performance of government and industry. Performance is gauged across the 7 major categories of interest and the 23 specific areas of related concern as depicted in Figure 1 on page 1 of this paper. Levels of government and industry performance are graded on a scale from A to F where A means a score of 90-100%; B means 89-80%; C means 79-70%; D means 69-60%, and; F means 59% and below.

Using the CSM Method systems model for food protection and the above grading scheme we derived both prevention and response values across the applicable categories of interest and related areas of related concern (see Figure1). For example, as depicted in Figure 7, below, if we can a) discourage someone from intentionally or accidentally poisoning food, i.e., deterrence; b) discover the incident soon enough to stop it from escalating, i.e., detection; c) quickly alert responders about the problem, i.e., communicate; d) take actions to reduce the potential for the ingestion of contaminated foods until a full scale response can be mustered, i.e., delay; e) respond quickly enough to stop the incident from escalating, i.e., response time, and; f) respond effectively, i.e., response quality, then we are in the position to interdict events before they escalate, i.e., prevention. In CSM Method parlance, this is known as the ***probability of interdiction***.

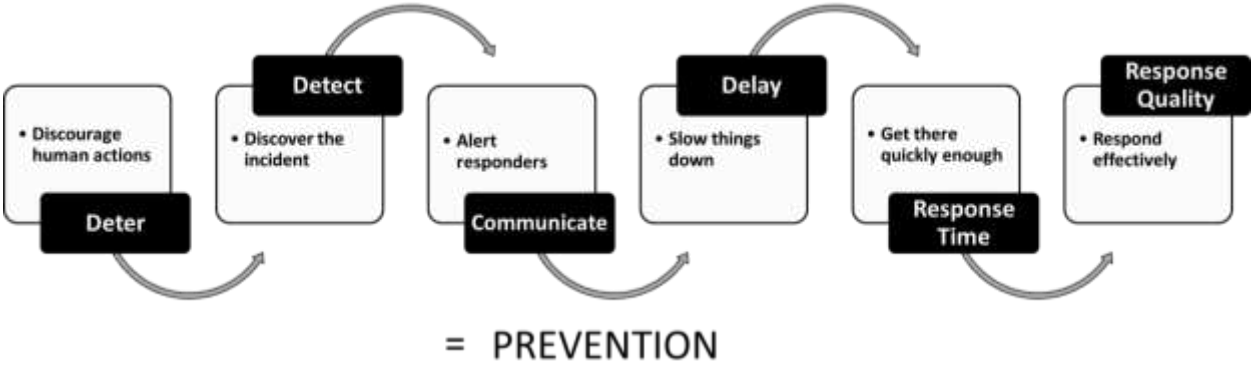


Figure 7: Preventing Food Protection Incidents and the Probability of Interdiction

Using the CSM Method systems model for food protection and our grading scheme, we also derived response values, i.e., grades, across the applicable categories of interest and related areas of concern (see Figure1). For example, as depicted in Figure 8, below, if we a) respond quickly enough to stop the incident from escalating, i.e., response time; b) respond effectively, i.e., response quality, and; c) ameliorate the consequences of an incident, i.e., mitigation, then we are in the position to respond to events in a way that reduces consequences and prevents future incidents.

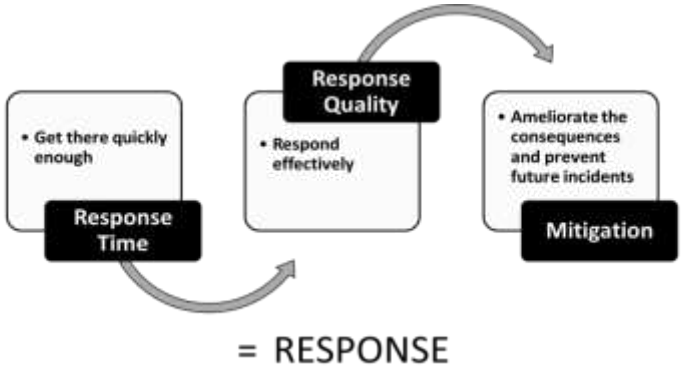


Figure 8: Responding to Food Protection Incidents

Grading Food Protection System Performance

The author concludes that almost all of the information available to grade the performance of government and industry is anecdotal because it does not represent confirmed or current data collected against specific performance benchmarks. The lack of quantitative data and information for the specific benchmarks of performance represents a significant limitation in deriving objective levels of industry and government performance in creating a safer food supply. The absence of quantitative performance data means that the "grades" assigned to industry and government may be biased by the nature of government, industry, media reporting and the age of the data or information itself. Frequently, we found the issuance of highly critical government reports in past years with no indication of successful

closure on their findings. Thus, the underlying purpose of this paper is to propose a framework for government and industry to consider that will encourage the continuous reporting of performance against quantitative scientifically derived benchmarks. Without a solid baseline of performance and the up-to-date quantitative scientific data to support it, the performance of government and industry efforts to create a safer food supply will remain the subjective art it has traditionally been rather than the science and risk based endeavor it must become.

To obtain direct inputs from food protection practitioners, this paper is accompanied by a web-based survey that allows practitioners to "grade" industry and government performance across the seven performance benchmarks used in this paper based on their own experience. The survey can be accessed at: https://www.surveymonkey.com/s/JBC96WC. Readers are invited to share their opinions with respect to the performance of industry and the government by completing the short survey. We will issue a subsequent publication showing how the results of the survey compare with the results presented in this paper.

The assessment results presented in this paper are generalized and include the Food and Drug Administration, the U.S. Department of Agriculture and the estimated 175,000 small, medium and large food companies (not including small farms) operating in the United States. We recognize that many food companies may excel in addressing the criteria used to benchmark their food protection performance in this report while others may not.

For purposes of this analysis, ***deterrence*** means the actions being taken by the Food and Drug Administration and the U.S. Department of Agriculture to regulate the food industry by: 1) the use of science and risk-based methods; 2) the timeliness and quality of government inspection, and; 3) efforts to educate consumers in the safe handling of food.

Shift to Science and Risk Based Standards	Timeliness and Quality of Government Inspection	Efforts to Educate Consumers	Average Grade for Deterrence
C-	D	B+	C

Figure 9: Performance of the Industry and Government in Deterring the Contamination of Food

The results of the assessment found that government and industry are slow to adopt science and risk based methods to protect the food supply.[ii] Instead, the government continues to pursue a "one size fits all" solution for small, medium and large food companies. The problem is being exacerbated by the food industry itself. Some companies, instead of raising the science and technology bar on their own to improve the safety of the products they sell, defer to the government in the mistaken belief that their companies can save money by meeting a lower regulatory compliance standard when, in fact, the opportunities to increase cost efficiencies by moving to science and risk based standards are much greater than the current approach.[iii]

The timeliness and quality of the government inspection process requires improvement. Government inspections of the food industry continue to rely primarily on the subjective application of largely non-

science and non-risk-based regulatory standards developed using the same qualitative processes that have existed in the United States since the turn of the 20th century. This problem is further exacerbated by the use of a third party audit system that relies on subjective evaluations of performance in the absence of science and risk based performance standards.[iv]

The assessment also found that government efforts to educate consumers in the safe handling of food are somewhat effective.[v]

Detection means actions by government and industry to: 1) identify contaminated food product; 2) take timely actions to reduce the risks associated with the consumption of the product by consumers, and; 3) interdict the consumption of the contaminated product by consumers.

Identify Contaminated Food Product	Reduce the Risk of Consumption	Interdict Consumption	Average Grade for Detection
C-	C+	C-	C

Figure 10: Performance of the Industry and Government in Detecting the Contamination of Food

The results of the assessment found that government and industry have the scientific and technical means to make much more informed decisions to identify contaminated food product but they do not use them. For example, large bulk testing at the beginning of the food manufacturing process with less or no effective testing of the manufactured product downstream.[vi] The assessment found that determining the risk associated with a specific food type and manufacturing process relies on scientifically valid testing protocols and their faithful implementation. If you do not sufficiently test for the possibility of contamination it is not possible to determine risk. In the food industry today, interdiction of consumption begins most frequently with the first report of illness or death. The current system remains reactive rather than preventive.

Communication means actions to quickly notify: 1) the consumer; 2) downstream customers; 3) upstream industry suppliers, and; 4) government authorities of contaminated or potentially contaminated food products before they are ingested by the consumer.

Timely Notification of Consumers	Timely Downstream Notification	Timely Upstream Notification	Timely Notification of Government	Average Grade for Communication
D	C	C	B	C-

Figure 11: Performance of the Industry and Government in Communicating the Contamination of Food

The result of the assessment found that interdiction of consumption begins most frequently with the first report of illness or death. Thus, the timeliness of downstream and upstream notification requires improvement. While industry may make prompt notifications to the government in the event of contaminated or potentially contaminated food products that result in consumer illnesses or deaths, they are largely made after people become ill and or die. Current efforts focus on containment of illness and death after the fact rather than prevention.[vii]

Delay means the actions taken by the government and the food industry, while awaiting a full scale response, to promptly reduce the risk of consumer poisoning by: 1) informing consumers of the possibility of contaminated product; 2) making "recall" "no recall" decisions, and; 3) determining the scope of a recall.

Inform the Consumer	Make a "Recall" No Recall" Decision	Determine the Scope of a Recall	Average Grade for Delay
C	C	C-	C

Figure 12: Performance of the Industry and Government in Delaying the Ingestion of Contaminated Food

The assessment found that the actions taken by industry and government to promptly reduce the risk of consumer poisoning, while awaiting a full scale response, i.e., delay, requires improvement. We reached this conclusion because the interdiction of consumption of contaminated product by consumers begins most frequently with the first report of illness or death. Thus, current efforts by the government and industry to take actions to reduce the risk that consumers will ingest poisoned food by promptly: 1) informing the consumer of potential threats; 2) making "recall" "no recall" decisions, and; 3) determining the scope of a recall require improvement. Because consumers are not informed until after the decision is made to recall a product, the threat of possible consumption remains very high until they are notified. Even after notification, the threat of possible consumption may remain high depending on the scale of distribution. The assessment found that the timeliness of making "recall" and "no recall" determinations are adversely influenced by multiple, often conflicting, and sometimes subjective risk factors including likelihood of possible deaths and severity of illnesses, the scope of product distribution, the cost-benefit analysis between recall in favor of litigation, impact on brand name and many other factors.[viii] The assessment also found that determining the scope of recalls is adversely impacted by complex interrelated supply chains that broaden the scope of product recalls.[ix]

Response time means the elapsed time from the determination to recall a product to the elimination of the threat of ingestion by a consumer including: 1) availability of traceability records; 2) recall management actions, and; 3) providing logistical support.

Traceability Records	Recall Management	Logistical Support	Average Grade for Response Time
C-	C	C	C

Figure 13: Performance of the Industry and Government in Making Timely Responses to the Ingestion of Contaminated Food by Consumers

The timeliness of responses to potential food poisonings is complicated by complex interrelated supply chains that broaden the scope of product recalls to include multiple companies and their suppliers.[x] The assessment found that while recent scientific and technological advances in the traceability of food products have been made they are not timely. The timeliness of recall management is marred by numerous high profile cases where government and industry delayed the implementation of large scale

recalls that later resulted in consumer illnesses and deaths.[xi] The timely availability of the logistical support necessary to quickly remove tainted product from the food shelf is a function of urgency. Actions by the government and industry to forestall "recall" "no-recall" determinations impact the urgency with which tainted or potentially tainted food products are removed from the food shelf.

Response Quality means the quality of actions taken to: 1) identify a specific product as a possible cause of food borne illness; 2) inform the consumer of the danger; 3) the comprehensiveness of traceability records; 3) the quality of training and testing of recall response teams.

Identify Product	Inform the Consumer	Comprehensive Traceability Records	Recall Training and Testing	Average Grade for Response Quality
C-	C	B-	C	C

Figure 14: Performance of the Industry and Government in Making Quality Responses to the Ingestion of Contaminated Food by Consumers

The result of the assessment found that interdiction of consumption begins most frequently with the first report of illness or death. While industry may make prompt notifications to the government in the event of contaminated or potentially contaminated food products that result in consumer illnesses or deaths they are largely made after the fact. The quality of recall efforts is marred by numerous high profile cases where government and industry delayed the implementation of large scale recalls that later resulted in consumer illnesses and deaths.[xii] The industry has made some progress since the passage of the Bioterrorism Act of 2002 to implement "one-up and one-back" traceability for food products, however, further improvement is required.[xiii] The assessment found that recall training and testing requires improvement.[xiv]

Mitigation means actions taken by industry and the government to ameliorate the potential for future intentional and accidental food poisonings. The benchmarks for this category of performance are: 1) the nature of government and industry investments in science-based technology solutions; 2) the tangible results of these investments in making the food supply safer, and; 3) government plans for science and technology investments to make the food supply safer.

Nature of R&D Investments	Tangible Results	Planning for Future Government Investments	Average Grade for Mitigation
D+	D	D	D

Figure 15: Performance of the Industry and Government in Mitigating the Consequences and Preventing Future Food Poisonings

The assessment found that because the government and industry use no systems approach to gauge their own performance against specific food protection system benchmarks, the investments being made to create a safer food supply lack necessary focus. The conundrum is that the significant investments being made cannot be focused on the solutions to specific industry problems that hold the

greatest potential for solving the problem. It is difficult for the government to make sound investments to solve problems unless they really understand what the problem is. The results of the assessment found that there is a significant lag time between investments in food related university research and the emergence of practical food safety solutions that can be applied by the food industry.[xv] The assessment also found that continuing large investments in the Land Grant University System to make the food supply safer are not producing enough tangible near term results because universities are not effective in commercializing products and they have a proclivity to conduct basic rather than applied research.

As depicted in Figure 16, below, using the CSM Method systems model for the protection of the food supply, industry and government efforts to ***deter*** intentional attacks and accidental poisonings received the average grade of a C indicating the need for improvement. Government and industry efforts for the early ***detection*** of intentional attacks and accidental poisonings received the average grade of a C indicating the need for improvement. Because current risk ***communication*** efforts focus on containment of illness and death after the fact, rather than prevention before the fact, industry and government were assigned a grade of C- indicating the need for improvement. The actions taken by industry and government to promptly reduce the risk of consumer poisoning while awaiting a full scale response, i.e., ***delay***, were given the average grade of C indicating the need for improvement. The ***timeliness*** of industry and government responses to potential food poisonings received a grade of C indicating the need for improvement. The ***quality*** of industry and government responses to potential food poisonings received a grade of C indicating the need for improvement. Because the government and industry use no systems approach to gauge their own performance against specific food protection system benchmarks, and the significant lag time between basic university research and the commercial development of technology to solve specified problems, a grade of D was assigned for efforts to prevent future intentional and accidental poisonings, i.e., ***mitigation. <u>The assessment found that for 2012, industry and government efforts to create a safer food supply received an average overall grade of a C on a scale of A to F.</u>***

Deterrence	Detection	Communication	Delay	Response Time	Response Quality	Mitigation	Average Grade
C	C	C-	C	C	C	D	C

Figure 16: Industry and Government Efforts to Create a Safer Food Supply

In Figure 7, on page 7, we illustrate the linkages and interconnections among the different elements of the food protection system that comprise prevention as the probability of interdiction. As depicted in Figure 17, below, using the CSM systems model, prevention is a function of the relationship among deterrence, detection, communication, delay, response time, and response quality. ***<u>The assessment found that for 2012, industry and government efforts to prevent American consumers from becoming ill or dying as the result of eating contaminated food received a grade of C- on a scale of A to F.</u>***

Deterrence	Detection	Communication	Delay	Response Time	Response Quality	Average Grade for Prevention
C	C	C-	C	C	C	C-

Figure 17: Industry and Government Performance in Preventing American Consumers from Becoming Ill or Dying as the Result of Eating Contaminated Food

In Figure 7, on page 7, we illustrate the linkages and interconnections among the different elements of the food protection system that compose response. As depicted in Figure 18, below, using the CSM systems model, response is a function of the relationship among response time, response quality and mitigation. ***The assessment found that for 2012, government and the food industry received a grade of C- for the effectiveness of responses to food poisonings.***

Response Time	Response Quality	Mitigation	Response Grade
C	B-	D	C-

Figure 18: Industry and Government Performance in Effectively Responding to Food Poisonings

Summary of Report Findings

Against the CSM Method systems model used in this paper to benchmark the performance of government and industry we have identified the four general findings depicted in Figure 19, below. Industry and Government have not come together around any set of common standards or criteria to guide the protection of the food supply. Instead there are numerous government and industry schemas that are used by different food companies at different sites along the food supply chain at locations across the globe. All too frequently, the food protection standards and performance criteria in use today do not reflect the scientific method or the principles of good risk management. To an outside observer it would appear that the world is engaged in a highly subjective standards war of large and unhelpful proportions.[xvi]

Finding	Report Observation
1. No set of common standards or criteria to guide the protection the food supply exists.	Instead, there are numerous government and industry schemas, all with different risk countermeasures, that are used by different food companies at different sites along the food supply chain at locations across the globe.
2. The government and industry are not using scientifically derived measures to judge their food protection performance.	Methods are currently available to scientifically quantify the value of food protection risk reduction measures but they are not being used by the government or the food industry.
3. Industry and government do not use a systems approach for gauging the performance of the food protection system.	Without a systems approach you cannot establish an effective framework for the collection and analysis of scientifically derived food protection risk reduction measures.
4. The types of information and data required to quantitatively evaluate industry and government food protection performance is not being collected or analyzed.	Government and industry have not systematically developed food protection performance benchmarks and the data keeping, collection and analysis requirements necessary to evaluate their actual performance on creating a safer food supply.

Figure 19: Summary of General Findings

Although technological breakthroughs now allow for the scientific quantification of food protection risk reduction measures[xvii] they are not being used by government or the food industry. The quantification of food protection risk reduction measures allows food companies to discriminate between "what works" and "what doesn't work" to guide the selection of the "best" and most cost effective food protection investments.[xviii]

In the absence of a systems model for the food protection system it is not possible to accurately judge government and industry performance in creating a safer food supply. While many food safety and food defense approaches such as HACCP and C.A.R.V.E.R. + Shock, respectively, are in wide use today it is not possible to scientifically prove or disprove their degree of effectiveness in creating a safer food supply in the absence of a systems model. This problem is exacerbated because the types of food protection performance data and information necessary to benchmark actual performance are not being collected or analyzed by industry or by the government using a systems approach.

Category of Interest	Additional Findings
Deterring the incidence of food borne poisoning	1. The government and industry continue to rely on non-science and non-risk based methods to protect the food supply.
	2. The timeliness, quality and focus of government inspections are deficient.
	3. Government efforts to educate consumers in the safe handling of food are effective.
Detecting contaminated foods	4. Government and industry have the scientific and technical means to make more informed decisions to identify contaminated food product but they do not fully utilize them.
Communicating possible threats of contaminated food	5. In the food industry today, interdiction of consumption begins almost exclusively with the first report of illness or death. By the time affected consumers "get the message" they may be sick, dying or dead. The current system remains reactive rather than preventive.
Delay to give responders the time they need to effectively respond	6. Current efforts by the government and industry to reduce the time between suspecting that something might be wrong with a food product and taking the actions necessary to prevent consumer illness and death requires improvement.
The timeliness of responses to potential food poisonings	7. The timeliness of downstream and upstream notification requires improvement.
The quality of responses	8. Recall training and testing requires improvement.
Mitigating actions taken by industry and the government to ameliorate the consequences of food poisonings	9. There is a significant lag time between investments in food related university research and the emergence of practical food safety solutions that can be applied by the food industry.
	10. Current planning for future government investments to make the food supply safer lack the focus necessary to produce tangible near term results.

Figure 20: Summary of Additional Findings by Category of Interest

Against the CSM Method systems model used in this paper to benchmark the performance of government and industry, we have identified the ten additional findings depicted in Figure 20, above. To deter the incidence of food borne poisonings we found three areas of concern. Government inspections of the food industry continue to rely primarily on the subjective application of regulations using the same qualitative processes that have existed in the United States since the turn of the 20th century. The timeliness and quality of government inspections require improvement. Government efforts to educate consumers in the safe handling of food are somewhat effective.

To detect contaminated food products before they are ingested by consumers, we found numerous high profile cases where the government and industry are aware of the scientific and technical means to make much more informed decisions to identify contaminated food products but they are not being

fully utilized. The assessment found that determining the risk associated with a specific food type and manufacturing process relies on scientifically valid testing protocols and their faithful implementation. If you do not sufficiently test for the possibility of contamination it is not possible to determine risk. In the food industry today, interdiction of consumption begins most frequently with the first report of illness or death. The current system remains reactive rather than preventive.

To communicate possible threats to consumers before they can ingest potentially contaminated food we found that interdiction of consumption begins most frequently with the first report of illness or death. Thus, the timeliness of downstream and upstream notification requires improvement. While industry may make prompt notifications to the government in the event of contaminated or potentially contaminated food products that result in consumer illnesses or deaths they are largely made after people become ill and or die. Current efforts focus on containment of illnesses after the fact rather than proactive prevention.

The assessment found that the actions taken by industry and government to promptly reduce the risk of consumer poisoning, while awaiting a full scale response, i.e., delay, requires improvement.[xix] The assessment found that the timeliness of making "recall" and "no recall" determinations are adversely influenced by multiple, often conflicting, and sometimes subjective risk factors. The assessment also found that determining the scope of recalls is adversely impacted by complex interrelated supply chains that broaden the scope of product recalls.

The assessment found that the timeliness of downstream and upstream notifications requires improvement. The assessment also found that while recent scientific and technological advances in the traceability of food products have been made they are not used in a timely fashion. The timely availability of the logistical support necessary to quickly remove tainted product from the food shelf is a function of urgency. Actions by the government and industry to forestall "recall" "no-recall" determinations impact the urgency with which tainted or potentially tainted food products are removed from the food shelf.

With respect to the quality of food protection responses, we found that consumers are often not informed of the potential danger of poisoned food until government and industry complete a deliberative process that frequently includes confirmation of the offending agent, an impact assessment and ultimate government pressure to force a recall. The industry has made significant progress since the passage of the Bioterrorism Act of 2002 to implement "one-up and one-back" traceability for food products, however, the traceability of food ingredients and finished products requires improvement. The assessment found that recall training and testing requires improvement.

Finally, we found that industry and government efforts to ameliorate the potential of future intentional attacks and accidental food poisonings are lacking. The bulk of research and development investments focus on basic university research not the delivery of commercial products that can produce near term tangible results in creating a safer food supply.[xx]

Recommendations

Against the CSM Method systems model used in this paper to benchmark the performance of government and industry, we have identified the four general recommendations depicted in Figure 21, below, for government and industry to consider as they move forward to create a safer food supply.

Government and Industry Need	Recommendation
1. Common food protection standards.	Utilize available technology and quantify the value of food protection standards and criteria to create a common set of high prevention and response value food protection standards.
2. Scientifically derived risk based food protection measures .	Better utilize the scientific method and use risk management methods as you create a common set of high prevention and response value food protection standards.
3. A systems approach to guide the collection and analysis of the right data and information food protection needed to gauge system performance.	Adopt a systems approach that considers prevention and response and across the food threat and risk continuum.
4. The collection and analysis of data and information to quantitatively evaluate performance.	Establish data keeping, collection and analysis requirements in order to gauge performance.

Figure 21: Summary of General Recommendations

Our first general recommendation is to adopt available technology to produce a common set of food protection standards that are scientifically vetted to determine "what works" and "what doesn't work." The technology to do this already exists and has been commercially applied to identify those food protection standards that have the greatest value in preventing food poisonings and enhancing responses to food emergencies. The technology can be quickly and easily adopted the food industry to enhance food protection performance while simultaneously reducing the costs of implementing both food safety and food defense programs.[xxi]

The second general recommendation is for government and industry to adopt a systems approach to protect the food supply that uses the food threat and risk continuum to determine performance benchmarks.

Third, we recommend that these performance benchmarks be integrally tied to those food protection standards that have the greatest value in preventing intentional and accidental food poisonings and enhancing responses to food emergencies to enhance performance while simultaneously reducing costs.

Fourth, we recommend that government and the food industry establish data keeping, collection and analysis requirements around each of the performance benchmarks identified using a systems approach.

Category of Interest	Additional Recommendations
Deterring the incidence of food borne poisoning	1. Take the development and use of science and risk based food safety and food defense countermeasures seriously by using quantitatively derived measures of actual performance.
	2. Use these quantitative measures of performance to better focus the objectivity and validity of assessments and audits in order to reduce the required frequency of government oversight inspections.
Detecting contaminated foods	3. Make more informed decisions by placing greater emphasis on better and more frequent testing of ingredients and food products at all stages of the food supply chain to identify contaminated food product before it reaches the consumer.
Communicating possible threats of contaminated food	
Delay to give responders the time they need to effectively respond	4. Reduce the time between suspecting that something might be wrong with a food product and taking the actions necessary to prevent consumer illness and death.
The timeliness of responses to potential food poisonings	5. Continue to increase investments in traceability, recall management and the testing of recall management systems. This recommendation applies especially to small and medium businesses.
The quality of responses	
Mitigating actions taken by industry and the government to ameliorate the future potential of food poisonings	6. Better leverage the land grant university system to conduct highly focused programs of basic scientific research involving the biological contamination of food as dictated by actual industry needs.
	7. Place greater emphasis on technology innovation and the applied research necessary to address specific industry needs based on the use of quantitative performance benchmarks.

Figure 22: Summary of Additional Recommendations by Category of Interest

Against the CSM Method systems model used in this paper to benchmark the performance of government and industry to create a safer food supply, we have identified seven additional recommendations.

To deter the incidence of food borne poisoning we recommend that industry and government take the development and use of science and risk based countermeasures seriously. Although the technology now exists to quantitatively derive measures of actual performance, government and industry are too slow in adopting it. We also recommend that government and industry adopt quantitative measures of performance to better focus the objectivity of assessments and audits in order to reduce the required frequency of government oversight inspections.

To more effectively detect contaminated foods and communicate the risk before they are ingested by consumers, we recommend that the food industry make more informed decisions about the food they ship to consumers by placing greater emphasis on testing food products at all stages of production along the food supply chain to identify contaminated food products before they reach the consumer.

To provide the delay responders need to effectively respond to the threat of potential poisoning of consumers we recommend that industry and government reduce the time between suspecting that something might be wrong with a food product and taking the actions necessary to warn consumers of the risk.

To enhance both the timeliness and quality of responses to threats of contaminated food we recommend that industry and government increase investments in traceability, recall management and the testing of recall management systems. This recommendation applies especially to small and medium businesses.

To improve mitigation by reducing the risk of future food poisonings we recommend that industry and government better leverage the significant investments that are now being made in the Land Grant University System. The role of the Land Grant University System should be limited to the conduct of the basic research necessary for the advancement of science. The role of applied research and the commercialization of tangible products needed by the food industry are much better suited to industry. As it stands now, the critical innovation that should be coming from small business to create a safer food supply is being lost because of government funded university grants that place universities in the position to compete directly with small businesses.

For many years, the defense industrial base has relied on the innovation of small business to conduct the applied research and the commercialization of the products necessary to solve the most difficult scientific and technical challenges. These programs have been highly successful. We recommend that the government agencies responsible for the protection of the food supply expand their programs of cooperation with small business around applied research and new product development in order to produce the tangible products in the short term to improve food industry performance. These programs of applied small business research and innovation should focus on the specific technological needs of the food industry that arise from actual industry performance against quantitatively derived benchmarks using a food protection systems approach.

End Notes

[i] Hnatio, J. H. (January 2012) Complexity Systems Management Method, Patent No.: US 8,103,601 B2. Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

[ii] Overbosch, Peter (February/March 2013) Food Safety Management: Hazard- or Risk-Based? Food Safety Magazine as retrieved from the World Wide Web on February 19, 2013 at: http://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2013/food-safety-management-hazard-or-risk-based/

[iii] Hnatio J. H. (December 2012) Managing Food Defense Risk: Technical Paper No. 5, FoodQuestTQ LLC, Frederick, MD. Read more at: http://www.nfpcportal.com

[iv] FDA OFFICE OF INSPECTOR GENERAL (December 2011) VULNERABILITIES IN FDA'S OVER SIGHT OF STATE FOOD FAC ILITY INSPECTIONS, U.S. Department of Health and Human Services, Washington DC, as retrieved from the World Wide Web on February 22, 2013, at: https://oig.hhs.gov/oei/reports/oei-02-09-00430.pdf **AND**
Bottemiller, H. (November 1, 2012) Investigation: USDA Quietly Eliminated 60 Percent of Foreign Meat Inspections-Agency also lacks foreign audit transparency, Food Safety News, as retrieved from the World Wide Web on February 22, 2013 at: http://www.foodsafetynews.com/2012/11/usda-quietly-eliminated-60-percent-of-foreign-meat-inspections/#.USe7X6WsiSo

[v] U.S. Government Interagency, Food Safety.gov, presented as only one of many excellent federal, state and university examples, as retrieved from the World Wide Web on February 22, 2013, at:

http://www.foodsafety.gov/keep/events/holidays/index.html

[vi] Moss, M. (October 2009), The Burger That Shattered Her Life, New York Times, as retrieved from the World Wide Web on February 22, 2013, at: http://www.nytimes.com/2009/10/04/health/04meat.html?pagewanted=all&_r=0

[vii] General Accounting Office (July 26, 2012), FDA's Food Advisory and Recall Process Needs Strengthening GAO-12-589, as retrieved from the World Wide Web on February 22, 2013, at: http://www.gao.gov/products/GAO-12-589

[viii] Ibid.

[ix] Hsieh, D. (October 4, 2012), Food Recalls: An Ounce Of Prevention Is Worth A Pound Of Cure, Food Manufacturing®, as retrieved from the World Wide Web on February 22, 2013, at: http://www.foodmanufacturing.com/articles/2012/10/food-recalls-ounce-prevention-worth-pound-cure

[x] Lawless, J. and Hinnant, L. (February 13, 2013) Horsemeat scandal exposes complex food chain, Associated Press, as retrieved from the World Wide Web on February 22, 2013, at: http://news.yahoo.com/horsemeat-scandal-exposes-complex-food-chain-184211089--finance.html

[xi] Associated Press (September 27, 2011), Cantaloupe outbreak is deadliest in a decade, as retrieved from the World Wide Web at: http://yourlife.usatoday.com/fitness-food/safety/story/2011-09-27/Cantaloupe-outbreak-could-be-deadliest-in-a-decade/50572084/1

[xii] Gannett Company (October 2012), History of Outbreaks, USA Today, as retrieved from the World Wide Web on February 22, 2013, at: http://mediagallery.usatoday.com/A-history-of-outbreaks/G2777,A10281

[xiii] Fleming, G. and Gombas, D. (April/May 2009), Continuous Improvement Trends in Produce Traceability, Food Safety Magazine, as retrieved from the World Wide Web on February 22, 2013, at: http://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2009/continuous-improvement-trends-in-produce-traceability/

[xiv] Pallaske, G. (August/September 2011), Toward a Better American Product Recall System, Food Safety Magazine, as retrieved from the World Wide Web on February 22, 2013, at: http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2011/toward-a-better-american-product-recall-system/

[xv] U.S. Congress, Office of Technology Assessment (August 1992), Chapter 16, Institutional Change Within the Land-Grant System, A New Technological Era for American Agriculture, OTAF474, Washington, DC: U.S. Government Printing Office, as retrieved from the World Wide Web on February 22, 2013, at: http://www.princeton.edu/~ota/disk1/1992/9201/920117.PDF

[xvi] Palma M.A., Luis A. Ribera, L.A., Mechel, P., and Knutson, R. (May 2010) Food Safety Standards for the U. S. Fresh Produce Industry, Policy Issues, Agricultural & Applied Economics Association, as retrieved from the World Wide Web on February 23, 2013 at: http://www.choicesmagazine.org/magazine/pdf/PI8.pdf

[xvii] FoodQuestTQ LLC (July 2012), Food Defense Architect™, description available on the World Wide Web at: http://www.nfpcportal.com

[xviii] Hnatio J. H. (December 2012) Managing Food Defense Risk: Technical Paper No. 5, FoodQuestTQ LLC, Frederick, MD. Read more at: http://www.nfpcportal.com

[xix] General Accounting Office (July 26, 2012), FDA's Food Advisory and Recall Process Needs Strengthening GAO-12-589, as retrieved from the World Wide Web on February 22, 2013, at: http://www.gao.gov/products/GAO-12-589

[xx] U.S. Department of Agriculture (2012), FY 2012 Budget Summary and Annual Performance Plan, as retrieved from the World Wide Web on February 23, 2013, at: http://www.obpa.usda.gov/budsum/FY12budsum.pdf

[xxi] FoodQuestTQ LLC (July 2012), Food Defense Architect™, description available on the World Wide Web at: http://www.nfpcportal.com

Mr. Hnatio:

With respect to your email of March 22, 2013 to Ms. Zahirieh and on which I was copied, I take strong exception to your characterization of Ms. Seeley's recent communication to you as "threatening," and your suggestion that our agency does not intend to investigate your allegations of "wrongdoing."

Ms. Seeley's email merely returned your proposed Non-Disclosure Agreement ("NDA") with a few minor changes, and introduced me as the intellectual property attorney who will be helping with the analysis of your allegations. Her email properly suggested that you obtain competent legal counsel, in view of your earlier communication to us that you are unrepresented, with respect to an area of the law that is highly technical.

In your letter of February 12, 2013 to Ms. Dickinson you claimed that FDA duplicated your Food Defense TQ tool and took elements of your FREE and FEAST computer software tools and incorporated them into FDA tools.

In order to evaluate this claim I will need to compare the FDA tools to each of your company's tools, and you indicated in a previous communication that you were willing to provide a copy of your tools to us for this purpose under a Non-Disclosure Agreement ("NDA") that you proposed.

Please find an executed copy of the NDA, which has been modified consistent with our standard practices. In return, please forward a copy of the tools that are the subject of your complaint along with a description of those parts of the FDA tools that you believe incorporate subject matter from your tools.

With respect to your claim of infringement of U.S. Patent No. 8,103,601, the regulations at 48 C.F.R. 227.7004 describe the information necessary to evaluate your claim. In particular, we need, as applicable:

1. A sufficient designation of the alleged infringing item or process to permit identification, giving the military or commercial designation, if known, to the claimant;
2. A designation of at least one claim of each patent alleged to be infringed; or
3. A detailed identification of the accused article or process, particularly where the article or process relates to a component or subcomponent of the item procured, an element by element comparison of the representative claims with the accused article or process. If available, this identification should include documentation and drawings to illustrate the accused article or process in suitable detail to enable verification of the infringement comparison.
4. Names and addresses of all past and present licenses under the patent(s), and copies of all license agreements and releases involving the patent(s).
5. A brief description of all litigation in which the patent(s) has been or is now involved, and the present status thereof.
6. A list of all persons to whom notices of infringement have been sent, including all departments and agencies of the Government, and a statement of the ultimate disposition of each.

7. A list of all Government contracts under which the inventor, patent owner, or anyone in privity with him performed work relating to the patented subject matter.

Pages 155 through 156 redacted for the following reasons:
- -
Entire page withheld under (b)(5).

NONDISCLOSURE AGREEMENT

This Confidential Disclosure Agreement ("**Agreement**") is effective as of the date of the last party to sign this Agreement ("**Effective Date**")

Between:

FoodQuestTQ LLC, doing business at 7420 Hayward Road, Suite 102, Frederick, Maryland 21702 ("**FQTQ**"); and

The Department of Health and Human Services, doing business at 200 Independence Ave SW, Washington, DC 20201 ("**HHS**").

FQTQ and HHS are referred to herein individually as a Party and collectively as the Parties.

The Parties agree as follows:

1) Definitions

"Affiliates" means the legal entities that (directly or indirectly) control, are controlled by, or are under common control with the named party.

"Confidential Information" means all information, other than Exempt Information, that concerns the following tools in their entirety, except to the extent that they are or contain Exempt Information: FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST (collectively referred to as "FQTQ commercial products"). In each case, the information disclosed by the Disclosing Party or its Affiliates to the Receiving Party or its Affiliates pursuant to this Agreement, will either be marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure.

"Disclosing Party" means the Party to this Agreement which discloses Confidential Information to the other Party under this Agreement.

"Exempt Information" means information that: (i) the Receiving Party or any of its Affiliates legally possessed before the Disclosing Party or its Affiliates disclosed it under this Agreement; or (ii) is or becomes publicly known (other than as a result of breach of this Agreement by the Receiving Party or its Representatives); (iii) the Receiving Party or any of its Affiliates obtains from a third party free of any confidentiality obligation to the Disclosing Party or its Affiliates with respect to such information; or (iv) is independently developed by or on behalf of the Receiving Party or its Affiliates without the use of the Confidential Information.

"Purpose" means the evaluation of FQTQ's allegations against FDA.

"Receiving Party" means the Party to this Agreement which receives Confidential Information from the other Party under this Agreement.

2) Treatment of Confidential Information

(a) The Receiving Party shall maintain the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care as it maintains the confidentiality of its own confidential information, and in any event, not less than a reasonable standard of care. This means in

situations where HHS is the Receiving Party that HHS will protect the Disclosing Party's Confidential Information in accordance with 21 U.S.C. § 331(j), 18 U.S.C. 1905, 21 CFR Part 20 and other pertinent laws and regulations governing the confidentiality of non-public information.

(b) The Receiving Party may use, copy and make extracts of the Disclosing Party's Confidential Information only in connection with the Purpose.

(c) The Receiving Party shall not disclose any of the Disclosing Party's Confidential Information to any third party other than the Receiving Party's Affiliates and the directors, officers, employees, contractors, consultants and agents of the Receiving Party and its Affiliates who have a need to know the Confidential Information for the Purpose and who are bound by obligations of confidentiality substantially similar to those in this Agreement (collectively, "**Representatives**").

(d) Anything to the contrary contained herein notwithstanding, the Receiving Party shall be permitted to disclose any of the Disclosing Party's Confidential Information that is required or requested to be disclosed by a governmental authority or applicable law, such as the Freedom of Information Act (5 U.S.C. § 552), provided that the Receiving Party shall: (i) notify the Disclosing Party of any such disclosure requirement as soon as practicable; (ii) cooperate with the Disclosing Party (at the Disclosing Party's cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which the Receiving Party is legally required to disclose. FQTQ hereby certifies that the Confidential Information to be provided under this agreement is being voluntarily provided to HHS for the Purpose, and is of a type held in strict confidence and not customarily disclosed to the public by FQTQ.

3) Other Matters

(a) Neither this Agreement nor the performance by either Party hereunder shall transfer to the Receiving Party any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including any intellectual property rights subsisting therein).

(b) Under this Agreement, the Disclosing Party provides the Receiving Party nonexclusive access to its Confidential Information and at no time does this affect the Disclosing Party's ability to otherwise distribute or dispose of the Confidential Information.

(c) Neither Party is obligated to negotiate or enter into any other agreement, and any discussions may be terminated at the sole discretion of either Party at any time and for any reason.

(d) This Agreement sets forth the Parties' entire understanding about its subject matter and supersedes any other agreement or understanding between the Parties about its subject matter. Neither Party can assign, amend, or terminate any part of this Agreement except in writing signed by both Parties.

(e) If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deleted or revised to the extent necessary to be enforceable, and, if possible, replaced by a term or provisions which, so far as practicable, achieves the legitimate aims of the Parties.

(f) This Agreement may be executed in two counterparts (including by facsimile or electronic copies), both of which shall be deemed an original, and both of which together shall constitute one and the same instrument.

(g) This Agreement shall be governed by and construed in accordance with the laws of Maryland and both Parties submit to the non-exclusive jurisdiction of the Maryland federalcourts.

IN WITNESS WHEREOF, duly-authorized representatives of the Parties have signed as of the Effective Date.

Signed on behalf of FQTQ

By: _____

Print Name: _____

Title: _____
(Duly authorized)

Date: _____

Signed on behalf of HHS

By: _____

Print Name: _____

Title: _____
(Duly authorized)

Date: _____

NONDISCLOSURE AGREEMENT

This Confidential Disclosure Agreement ("**Agreement**") is effective as of the date of the last party to sign this Agreement ("**Effective Date**")

Between:

FoodQuestTQ LLC, doing business at 7420 Hayward Road, Suite 102, Frederick, Maryland 21702 ("**FQTQ**"); and

The Department of Health and Human Services, doing business at 200 Independence Ave SW, Washington, DC 20201 ("**HHS**").

FQTQ and HHS are referred to herein individually as a Party and collectively as the Parties.

The Parties agree as follows:

1) Definitions

"Affiliates" means the legal entities that (directly or indirectly) control, are controlled by, or are under common control with the named party.

"Confidential Information" means all information, other than Exempt Information, that concerns the following tools in their entirety, except to the extent that they are or contain Exempt Information: FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST (collectively referred to as "FQTQ commercial products"). In each case, the information disclosed by the Disclosing Party or its Affiliates to the Receiving Party or its Affiliates pursuant to this Agreement, will either be marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure.

"Disclosing Party" means the Party to this Agreement which discloses Confidential Information to the other Party under this Agreement.

"Exempt Information" means information that: (i) the Receiving Party or any of its Affiliates legally possessed before the Disclosing Party or its Affiliates disclosed it under this Agreement; or (ii) is or becomes publicly known (other than as a result of breach of this Agreement by the Receiving Party or its Representatives); (iii) the Receiving Party or any of its Affiliates obtains from a third party free of any confidentiality obligation to the Disclosing Party or its Affiliates with respect to such information; or (iv) is independently developed by or on behalf of the Receiving Party or its Affiliates without the use of the Confidential Information.

"Purpose" means the evaluation of FQTQ's allegations against FDA.

"Receiving Party" means the Party to this Agreement which receives Confidential Information from the other Party under this Agreement.

2) Treatment of Confidential Information

(a) The Receiving Party shall maintain the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care as it maintains the confidentiality of its own confidential information, and in any event, not less than a reasonable standard of care. This means in

situations where HHS is the Receiving Party that HHS will protect the Disclosing Party's Confidential Information in accordance with 21 U.S.C. § 331(j), 18 U.S.C. 1905, 21 CFR Part 20 and other pertinent laws and regulations governing the confidentiality of non-public information.

(b) The Receiving Party may use, copy and make extracts of the Disclosing Party's Confidential Information only in connection with the Purpose.

(c) The Receiving Party shall not disclose any of the Disclosing Party's Confidential Information to any third party other than the Receiving Party's Affiliates and the directors, officers, employees, contractors, consultants and agents of the Receiving Party and its Affiliates who have a need to know the Confidential Information for the Purpose and who are bound by obligations of confidentiality substantially similar to those in this Agreement (collectively, "**Representatives**").

(d) Anything to the contrary contained herein notwithstanding, the Receiving Party shall be permitted to disclose any of the Disclosing Party's Confidential Information that is required or requested to be disclosed by a governmental authority or applicable law, such as the Freedom of Information Act (5 U.S.C. § 552), provided that the Receiving Party shall: (i) notify the Disclosing Party of any such disclosure requirement as soon as practicable; (ii) cooperate with the Disclosing Party (at the Disclosing Party's cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which the Receiving Party is legally required to disclose. FQTQ hereby certifies that the Confidential Information to be provided under this agreement is being voluntarily provided to HHS for the Purpose, and is of a type held in strict confidence and not customarily disclosed to the public by FQTQ.

3) **Other Matters**

(a) Neither this Agreement nor the performance by either Party hereunder shall transfer to the Receiving Party any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including any intellectual property rights subsisting therein).

(b) Under this Agreement, the Disclosing Party provides the Receiving Party nonexclusive access to its Confidential Information and at no time does this affect the Disclosing Party's ability to otherwise distribute or dispose of the Confidential Information.

(c) Neither Party is obligated to negotiate or enter into any other agreement, and any discussions may be terminated at the sole discretion of either Party at any time and for any reason.

(d) This Agreement sets forth the Parties' entire understanding about its subject matter and supersedes any other agreement or understanding between the Parties about its subject matter. Neither Party can assign, amend, or terminate any part of this Agreement except in writing signed by both Parties.

(e) If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deleted or revised to the extent necessary to be enforceable, and, if possible, replaced by a term or provisions which, so far as practicable, achieves the legitimate aims of the Parties.

(f) This Agreement may be executed in two counterparts (including by facsimile or electronic copies), both of which shall be deemed an original, and both of which together shall constitute one and the same instrument.

(g) This Agreement shall be governed by and construed in accordance with the laws of Maryland and both Parties submit to the non-exclusive jurisdiction of the Maryland federal courts.

IN WITNESS WHEREOF, duly-authorized representatives of the Parties have signed as of the Effective Date.

Signed on behalf of FQTQ

By: _____

Print Name: _____

Title: _____
(Duly authorized)

Date: _____

Signed on behalf of HHS

By: Dale D. Berkley

Print Name: DALE D. BERKLEY

Title: SENIOR ATTORNEY
(Duly authorized)

Date: 3/27/2013

Pages 163 through 164 redacted for the following reasons:
- -
Entire page withheld under (b)(5).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
Room 2B-50, NIH Bldg. 31
31 Center Dr., MSC 2111
Bethesda, Maryland 20892-2111
(301) 496-6043
Fax (301) 402-1034

March 27, 2013
VIA EMAIL

Dr. John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702

Re: FDA's Food Defense Team

Dear Dr. Hnatio:

With respect to your email of March 22, 2013 to Ms. Zahirieh on which I was copied, I take exception to your characterization of Ms. Seeley's recent email to you as "threatening," and your suggestion that our agency does not intend to investigate your allegations of "wrongdoing." Neither of your statements is true or the least bit accurate.

Ms. Seeley's email merely introduced me as the intellectual property attorney who will be helping with the analysis of your allegations. Her email properly suggested that you obtain competent legal counsel, in view of your earlier communication to us that you are unrepresented, with respect to an area of the law that is highly technical.

In your letter of February 12, 2013 to Ms. Dickinson, you claimed that FDA duplicated your Food DefenseTQ tool and took elements of your FREE and FEAST computer software tools and incorporated them into FDA tools.

In order to evaluate this claim I will need to compare the FDA tools with each of your company's tools for any similarities. However, we do not have a copy of your company's tools, and you indicated in a previous communication that you were willing to provide them to us for this purpose under a Non-Disclosure Agreement ("NDA").

Ms. Seeley's March 13, 2013 email contained an executed copy of the NDA, which was modified consistent with our standard practices. You proposed in your March 14, 2013 response that certain changes be made to the NDA. I accepted some of your changes as follows: (1) I revised the "Purpose" of the NDA, (2) I revised the definition of "Confidential Information" to account for its intended relationship to the "Exempted Information," and (3) I revised the definition of "Exempted Information."

Please find an executed copy of the NDA, which has been modified to accommodate some of your suggestions. In return, please forward a copy of the tools that are the subject of your complaint directly to me, along with a description of those parts of the FDA tools that you believe incorporate subject matter from your tools.

With respect to your claim of infringement of U.S. Patent No. 8,103,601, the regulations at 48 C.F.R. § 227.7004 describe the information necessary to evaluate a claim of this kind. In particular we need, as applicable, the following:

1. A detailed identification of the accused article or process, and an element by element comparison of the representative claims with the accused article or process. If available, this identification should include documentation and drawings to illustrate the accused article or process in suitable detail to enable verification of the infringement comparison;
2. Names and addresses of all past and present licenses under the patent, and copies of all license agreements and releases involving the patent;
3. A brief description of all litigation in which the patent has been or is now involved, and the present status thereof;
4. A list of all persons to whom notices of infringement have been sent, including all departments and agencies of the Government, and a statement of the ultimate disposition of each; and
5. A list of all Government contracts under which the inventor, patent owner, or anyone in privity with him performed work relating to the patented subject matter.

If you have any questions or wish to discuss this further, please contact me at (301) 496-6043, of at Berkleyd@od.nih.gov.

Sincerely,

Dale D. Berkley, Ph.D., J.D.
HHS IP Counsel

Attachment: Executed NDA

Dr. Dale D. Berkley
Office of the General Counsel
Public Health Division
Room 2B-50, NIM Bldg. 31
31 Center Drive, MSC 2111
Bethesda, Maryland 20892-2111

March 28, 2013

Dear Dr. Berkley:

We have received your letter of March 27, 2013.

In your letter, you refer to my March 22nd e-mail to Ms. Zahirieh of the Office of the National Ombudsman for Small Business. In your letter you take exception to our concerns that the FDA did not and never intended to conduct a good faith review of our concerns. But, in fact, it was for this reason that we were forced to turn to the National Ombudsman for Small Business for help.

I am very surprised to hear that you do not understand why Ms. Seeley's e-mail is so threatening. Please let me explain.

I too was a civil servant. On my first day of government service I took an oath to uphold the Constitution and the laws of the United States. There were many times during my 30 year career with the government that this oath was sorely tested. In the face of serious wrongdoing in my own agency and at serious risk to my own well-being, I held fast to my oath. When my agency was guilty of wrongdoing my loyalty was always guided by my oath to uphold the Constitution and the laws of the United States first- certainly not the defense of my colleagues in the agency who engaged in the misconduct in the first place.

Please keep in mind that it was Ms. Seeley's own decision to turn this matter into an adversary legal defense of her colleagues on the FDA Food Defense Team instead of an impartial and objective fact finding mission to determine the truth. We certainly do not want to hurt Ms. Seeley. But her e-mail is, in fact, very clear. To the FDA, this matter is not about finding the truth. Rather, it is about mounting a legal defense for the FDA's own unconscionable actions in this matter. Based on your letter and your defense of Ms. Seeley's misguided actions, this now appears to be your motivation as well.

We also want thank you very much for your concern about the need for us to hire legal assistance to defend us against your investigation of this matter. But, if you intend to conduct a fair and impartial good faith review of this matter, then why do we have to pay money that we desperately need to feed our families to pay for an expensive legal defense? At this time, all of us in FoodQuestTQ have been forced into unemployment by the actions taken against us by the FDA. We simply cannot afford the expense of engaging in a legal battle with the government.

The non-disclosure agreement (NDA) you sent to us, still does not contain several important recommendations that we have already provided to the FDA legal counsel. Among the most important changes that must be made to the draft NDA involve he "Purpose" of the agreement.

As we have said from the very beginning, this matter involves three inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered if there is to be any true good faith review of this matter, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of ideas, trade secrets and proprietary information from Thought Quest LLC, FoodQuestTQ LLC and Projectioneering LLC, and;

3. Projectioneering LLC and FQTQ proof that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

The reason for these changes is because the FDA legal counsel has repeatedly attempted to pigeon hole the FQTQ complaint against the FDA as solely and exclusively a matter of patent infringement. This is not the case. Our complaint to the National Ombudsman for Small Business goes well beyond the single isolated issue of patent infringement to include violations of the FAIR Act, the theft of our ideas, trade secrets and intellectual property, the duplication of our products and unlawful government competition against FoodQuestTQ. Thus, the NDA must clearly reflect that your good faith review will encompass all aspects of the formal complaint we have filed with the National Ombudsman for Small Business.

The NDA must also reflect a fair and reasonable quid pro quo in the sharing of information between FQTQ and Department of Health and Human Services and the FDA. If FQTQ provides you with information regarding their tools then the FDA should share information with FQTQ regarding each of the FDA tools under suspicion for further evidence of theft of our ideas, trade secrets and intellectual property and infringement on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

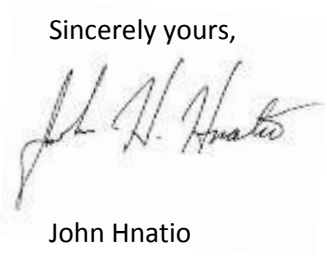
Several weeks ago, we suggested such a quid-pro-quo but the FDA counsel declined. We requested that the FDA provide us with an in-depth demonstration of the tools they duplicated and the opportunity for us to ask further questions. Thereafter, FoodQuestTQ would provide the FDA with a complete demonstration of our tools that would demonstrate the specific ideas, trade secrets and intellectual property that was stolen from us. Both presentations would be done via webinar and recorded for independent review by the National Ombudsman for Small Business, the office of Inspector General, the Department of Justice and others who may become involved in this matter. We now extend this same offer to you. Such demonstrations will quickly and conclusively demonstrate the truth of this matter as part of the official record.

The provisions at 48 C.F.R. §227.7004 relate to the resolution of patent infringement claims on the part of the offended party. The information you request is not germane to the conduct of a good faith fact finding mission by the either the FDA or the Department of Health and Human Services under the administrative law provisions at 48 C.F.R. §227.7002 and 48 C.F.R. §227.7004. As you are well aware, we are not yet at the resolution phase of this process.

At this juncture, you have a copy of our USPTO granted patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 and a detailed list of the specific ideas, trade secrets and intellectual property that were stolen from us by the FDA that I have provided to the National Ombudsman for Small Business. I understand that this information has already been provided to you by the National Ombudsman. On prior occasions, we have also offered FDA counsel a detailed technical crosswalk of how our patent was reduced to practice for our food applications. But the offer was declined.

Again, thank you very much for your letter. I can be reached at 240-439-4476 x-11 if you have any questions.

Sincerely yours,



John Hnatio
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

cc: Ms. Elahe Zahirieh, NOSB
Ms. Ariel Seeley, FDA Counsel

FDA-iRISK History and Key Contacts:

Key contacts:

1. FDA contact
   Sherri Dennis
   Email: Sherri.Dennis@fda.hhs.gov Office Phone: 240-402-1914
   Organization: FDA Center for Food Safety and Applied Nutrition

2. IFT prototype framework
   Rosetta Newsome
   Email: rnewsome@ift.org Office Phone: (312) 782-8424
   Organization: Institute of Food Technologists

3. Operationalized IFT prototype into Web-based format
   Greg Paoli
   Email: gpaoli@risksciencesint.com Office Phone: 613-260-1424
   Organization: Risk Sciences International

4. RTI inventory and evaluation
   Stephen Beaulieu
   Email: steveb@rti.org Office Phone: 919-541-7425
   Organization: RTI International

May 4, 2009

RTI Number 0211460.002

Tools and Methods for Ranking and Prioritizing Food and Feed Safety Risks

Submitted to:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Submitted by:

RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Table of Contents

List of Tables

List of Figures

Executive Summary

The results of this task order support the U.S. Food and Drug Administration's (FDA's) 2007 Food Protection Plan, which specifies the need to use risk-based approaches that integrate sound science with state-of-the-art information technology to appropriately manage food safety risks using a farm-to-fork approach. As such, the purpose of this study was twofold:

- To develop an inventory of available tools and methods for relative risk ranking and prioritization
- To evaluate the applicability of the identified tools and methods for use by the FDA to address food and feed safety risks.

In the first phase of the work, relevant sources of information about risk ranking and prioritization were identified. Information was garnered from government agencies, published literature, and the Internet. Specific information for food safety risk ranking was abundant; however, for risk prioritization, it was necessary to use more general information.

This report is divided into two major sections: **Section II** focuses on risk ranking and **Section III** covers risk prioritization. These are preceded by a section describing the purpose and approach to the work (**Section I**). Each major section presents reviews of specific models (risk ranking) or approaches (risk prioritization), including a description of the purpose and scope of each approach, its common uses, design and implementation considerations, and its strengths and limitations. Each risk ranking and risk prioritization method was also evaluated against a set of performance criteria (e.g., transparency, credibility, documentation, ease of use, flexibility, adaptability) for comparison purposes. Based on full consideration of the attributes of the candidate methods, a recommendation for future use is made.

We reviewed three qualitative and five semi-quantitative food safety risk ranking models in detail. Several other risk ranking approaches applied to other disciplines are also described briefly. Only models with food safety application were evaluated with respect to the specified performance criteria. These models were also evaluated for consistency with FDA-specified functional features (i.e., presence of two modules [a predictive, multistage, farm-to-fork process risk module and a hazard characterization module]; ability to rank and compare chemicals and microbiological agents in a single model; and transparency and adaptability). The relatively poor degree of resolution provided by qualitative methods suggested the need for a semiquantitative approach. The five semi-quantitative models (Risk Ranger, Food Sector Risk Ranking Model, Foodborne Illness Risk Ranking Model, Food Safety Universe Database Model, and Food Hazard Risk Registry [also called iRISK]) were compared. Although none of these models scored highly on all performance criteria, the Food Safety Universe Database Model and the iRISK model came close. After careful deliberation, we recommend that the FDA use iRISK for future risk ranking efforts because the model structure is most consistent with the FDA's specified functional features; it is more flexible than other reviewed models; and it is more sophisticated with respect to characterization of uncertainty, software, and documentation of inputs and outputs.

Multiple criteria decision analysis (MCDA), also referred to as risk prioritization, combines the tools of risk assessment and decision analysis to support complex decision making. We reviewed six general MCDA approaches:

- Elementary methods
- Decision trees and influence diagrams
- Multi-objective optimization
- Multi-attribute value/utility theory (MAUT)
- Outranking
- Analytic hierarchy process (AHP).

We also reviewed the two MCDA approaches (Multi-Factorial Risk Prioritization Framework for Food-borne Pathogens and an outranking approach) that have previously been applied to food safety; however these should be considered preliminary. Based on the implicit assumption that the MCDA approach to be chosen by the FDA should enable structured, well-justified, transparent decision-making from a wide variety of risk management options, and applicable to many different hazards and foods, we recommend MAUT or certain AHP methods. The major advantage of these approaches is the ability to quantify benefits through a single score representing the relative, proportional benefit of each alternative. We also recommend that aspects of fundamental resource allocation theory be incorporated into the FDA's decision-making process and that facilitated decision conferencing be implemented to aid in structuring the decision-making process and model construction.

I. Statement of Purpose and Methodological Approach

The results of this task order support the U.S. Food and Drug Administration's (FDA's) 2007 Food Protection Plan, which specifies the need to use risk-based approaches that integrate sound science with state-of-the-art information technology to appropriately manage food safety risks using a farm-to-fork approach. Taken together, these Food Protection Plan actions are best served using two common risk and decision analysis tools: risk ranking and risk prioritization. Therefore, the purpose of Task Order 2 was twofold:

- To develop an inventory of available tools and methods for relative risk ranking and prioritization
- To evaluate the applicability of the identified tools and methods for use by the FDA (including the Center for Food Safety and Applied Nutrition [CFSAN], the Center for Veterinary Medicine [CVM], and the Office of Regulatory Affairs [ORA]) to address food and feed safety risks.

Four specific objectives were identified:

- Conduct a comprehensive literature review and summary inventory of available methods and tools for risk ranking.
- Conduct a comprehensive literature review and summary inventory of available methods and tools for risk prioritization.
- Evaluate the available methods and tools for risk ranking for their ability to rank commodity/hazard pairs based on public health matrices and other relevant measures.
- Evaluate the available methods and tools for risk prioritization for their ability to be used in the following applications:
  - Prioritizing the use of investigation and sampling resources toward the areas of greatest public health concern for domestic, foreign, and/or imported products
  - Prioritizing future baseline studies
  - Prioritizing data collection efforts to resolve uncertainties
  - Focusing research, outreach, and prevention strategies on areas of greatest public health concern
  - Directing compliance and enforcement
  - Informing guidance and rulemaking
  - Prioritizing potential international activities.

In the first phase of the work, we identified sources of information to identify candidate risk ranking and prioritization models that might be relevant to FDA needs. We used three information sources: government agencies, published literature, and the Internet. We conducted a comprehensive search of all relevant documents, including the grey literature. Our access to information sources included the libraries of North Carolina State University, the University of North Carolina at Chapel Hill, and Duke University. In addition, we used extensive in-house capabilities for conducting computerized literature searches. Databases searched included Chemical Information Systems (CIS), DIALOG, LEXIS/NEXIS, PubMed, TOXNET, Environmental Fate Database (Syracuse Research Corporation), and STN International. These database systems provide access to hundreds of bibliographic files. In addition to traditional online databases, we also searched for additional information on food risk ranking and

prioritization topics via Internet search engines and through personal contacts. Of the methods available, we found publicly accessible contract reports (available via the Internet) to be the most fruitful source of information for risk ranking. For risk prioritization, books and published journal articles provided the most information. A detailed description of our findings is provided in the body of this report.

II. Risk Ranking

II.1 Introduction

Risk ranking, sometimes called hazard ranking or comparative risk assessment, is applied to identify the most significant risks for a given situation. The method has a history of use in engineering, insurance, transportation, and environmental sciences and has been applied in both the private and public sectors. One important public sector interest is food safety, for which risk ranking can be used to guide policy development. Although somewhat later on the scene than other disciplines, the importance of risk ranking in food safety is now well established (Havelaar and Melse, 2003).

Most rankings are nowhere near as complete as a full quantitative risk assessment (except perhaps the FDA relative risk assessment of foodborne *Listeria monocytogenes*, U.S. FDA, 2003). Nonetheless, the process roughly follows the risk assessment paradigm and requires the sequential steps of hazard identification, risk evaluation, and development of a comparative ranking scale and list. Depending on the purpose of the ranking, the needs of the analyst, available resources, and availability of data, risk ranking can range from very simple to highly complex.

Because risk ranking will be used as a risk management tool, a critical first step is to identify the specific purpose or designated use of the ranking. Food safety risks, like risks in other sectors of society, are inherently complex and differ from one another in ways that make it difficult to compare one agent to another in any sort of simplified manner. Consequently, assumptions must be made, and all approaches to risk ranking include some degree of subjectivity and uncertainty. Certainly no one model can account for every important input or assumption, and risk ranking models differ substantially in basic approach.

Once the purpose of risk ranking is defined, the next step is to identify and define key inputs and risk attributes. In the case of food safety, the "risk" is usually related to the likelihood and severity of disease caused by a specific agent-food combination. The "agent" or "hazard" can be microbiological (pathogen) or chemical (toxic), while the "vehicle" or "food" may be categorized broadly (e.g., beef, poultry, fresh produce) or narrowly (e.g., ground beef, steak, roast). Risk ranking tools for use in food safety have been applied to a single hazard in multiple commodities, to a single commodity with multiple hazards, or to compare multiple commodity-hazard combinations.

A major consideration when initially categorizing agents and foods must be the degree of resolution. For agents, for example, does one categorize broadly (e.g., bacteria, viruses, parasitic protozoa) or more specifically (e.g., *Salmonella* and *Escherichia coli* [*E. coli*] O157:H7; norovirus and hepatitis A virus; *Cryptosporidium parvum* and *Cyclospora cayetanensis*). The same situation exists for foods (i.e., broad categories such as meat or produce vs. specific commodities such as ground beef or whole broilers). In most instances, a higher degree of resolution within agent and food categories is of greater value, but such resolution may not be possible given the limitations of supporting data sets used to estimate inputs.

Identification of the key risk attributes can also be complicated. Some risk attributes are specific to the agent (e.g., infectious dose), while others may be specific to the agent-food combination

(e.g., potential for the pathogen to grow in the product). In many instances, the attributes impacting overall public health are associated primarily with the agent or the food, and these may not necessarily influence one another, but on some occasions, they do. In addition, most public health risks are multi-attribute, meaning there is more than one way in which the hazard or vehicle can affect the outcome, making the ranking process that much more complex. Clearly, designing a good risk ranking method requires simplification, assumption, and subjectivity with respect to the choice of input variables, the choice of the data on which to characterize these inputs, and the weighting approach taken to express the relative importance of the different inputs. Uniformity and transparency are critical to providing a justifiable means by which to compare risks.

The simplest approach to risk ranking involves the use of personal judgment to create a "risk versus severity" table or matrix to assign rankings. A more complicated approach involves consideration of the body of scientific evidence about the risk(s) posed by the various agent-food combinations to inform values for input variables. These input variables serve as the basis for the creation of a mathematical model, frequently functionalized into a computer program. The mathematical algorithm assigns a rank based on the unique values or weights given to each input variable (criteria) for that specific agent-food combination. Often, risk ranking models involve the combination of personal judgment and scientific evidence to inform the outputs.

Another useful way to differentiate risk ranking approaches is based on the type of data used in model construction, in which case models are categorized as either surveillance-based (or "top-down") or prediction-based (or "bottom-up"). For microbial hazards, the top-down surveillance-based approaches infer the level of risk due to foods, hazards, or their combinations, based on information gathered by various observation systems such as active or passive disease reporting systems or outbreak databases, and a variety of other observations, including prevalence of pathogens in various commodities. Ideally, such databases are the best source of information for overall ranking because they reflect disease at the consumer (patient) level. However, these databases are invariably incomplete, meaning that quantitative linkages to particular foods are often difficult to justify from these data sources alone or might be estimated only for foods that account for a relatively high proportion of the risk.

The top-down approach has not been applied to chemical agents, largely because there is no systematic capacity to observe the health effects of food-associated chemical exposures in the human population. Therefore, when attempting to compare chemicals to microbes, a bottom-up approach is usually applied. This involves predictive modeling of the fate of microbes and chemicals in the food supply and their virulence or toxicity. The design of bottom-up risk ranking models requires the synthesis of both data and expert judgment to generate a prediction of the relative level of risk to human health. The approach may also be appealing because it can be used to investigate the potential for changes in the level of risk associated with possible interventions throughout the farm-to-fork chain. However, like all risk ranking models, predictive models are still simplifications of reality based on assumptions, and substantial uncertainty is associated with the results.

In **Section II.2**, we provide more detailed descriptions of qualitative risk ranking approaches that have been applied to food safety. The degree of detail in the narratives is determined by the information available in the public sector. In **Section II.3**, we provide detailed descriptions of

semi-quantitative risk ranking approaches that are well documented and have been previously applied to food safety (microbiological or chemical). For these models, a ranking attributes table is also included. This section also covers models with food safety applications but for which only minimal information is available. In **Section II.4**, we describe a number of risk ranking approaches that have been applied to disciplines outside food safety. In **Section II.5**, we provide synthesis comments and recommendations to the FDA.

II.2 Qualitative Food Safety Risk Ranking Approaches

II.2.1 The CFSAN Relative Risk Ranking

The Center for Food Safety and Applied Nutrition (CFSAN) relative risk ranking was conducted within the FDA with various scientists providing their expert consultation in assigning ranks. In this approach, relative risk rank is determined as the qualitative combination of two axes: (1) likelihood of an adverse event occurring from consumption or use of a product containing the hazard, and (2) the relative severity of that hazard. The term "likelihood" describes the relative probability that the hazard occurs in the food and causes illness, and "severity" describes the relative seriousness of symptoms consumers would experience.

Severity was determined for each hazard, irrespective of food source. The data used to determine severity ranks originated from a combination of expert opinion, the scientific literature, and estimates previously generated using the Food Handling Practices Model. Severity scores (expressed descriptively as Moderate, Serious, or Severe) reflect what would occur in a typical case with consideration of mitigating circumstances such as at-risk population. In instances of significant uncertainty or conflicting data, a higher severity category was chosen as a more conservative estimate. **Table II-1** describes the three severity categories and examples of agents included in each category.

Table II-1. Severity Ranking Descriptions

Severity Ranking	Description	Examples
Moderate	Not usually life threatening, no sequelae, normally short duration, symptoms are self-limiting, can include severe discomfort	Norovirus Histamine toxin *Clostridium perfringens*
Serious	Incapacitating but not life threatening, sequelae infrequent, moderate duration	Hepatitis A virus Ciguatera toxin *Salmonella* spp. *E. coli* O157:H7
Severe	Life-threatening or substantial chronic sequelae or long duration	*Listeria monocytogenes* *Enterobacter sakazakii* Undeclared or unapproved food or color additives Algal biotoxins

The second qualitative factor considered in the relative risk ranking was the likelihood that the hazard occurs in the identified product and will cause illness or death. This was estimated by taking into account the following:

- The epidemiological link between the hazard and illness due to consumption of the particular product (i.e., outbreaks)
- Data on the prevalence and level of the hazard in the product
- Frequency of consumption or use of product and amount consumed
- The effect of production, processing, and handling in terms of how they influence the hazard in the product at the point of consumption or use
- Impact of existing regulatory or non-regulatory management systems.

The data used to determine the likelihood ranks originated from a combination of expert opinion, the scientific literature, and consumption data available through the U.S. Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII) database. A likelihood rank was assigned for each product/hazard combination. **Table II-2** describes the three likelihood categories.

Table II-2. Likelihood Ranking Descriptions

Likelihood Ranking	Factors to Consider
Unlikely	§ Little or no evidence that the hazard has caused illness (i.e., no outbreaks) § Limited consumption or use of the commodity by the general population or consumption primarily restricted to a select sub-population § Limited or no data demonstrating presence of the hazard (i.e., no recalls)
Likely	§ Limited evidence that the hazard has caused illness (i.e., a few outbreaks) § Eaten or consumed periodically § Data demonstrating the presence of the hazard in product (i.e., recalls)
Very likely	§ Evidence that the hazard is associated with reported incidences of illness § Widely or frequently eaten or used by the general population § Data demonstrating the presence of the hazard in the product

The relative risk ranking was determined using the matrix shown in **Table II-3**. (The document describing this method was provided to RTI by the FDA; to our knowledge, it is not available in the public domain.) For example, if the severity rank was "serious" and the likelihood was "very likely," the relative rank for that product/hazard combination was "higher." For the same "serious" hazard in another product with a likelihood rank of "unlikely," the relative risk rank would be assigned "lower." Note that relative risk is described in three categories, such that there is overlap between certain combinations of severity and likelihood rank. This ranking scheme was applied to a wide variety of products and associated hazards under FDA jurisdiction.

Table II-3. Relative Risk Rank Matrix

		Likelihood		
		Unlikely	**Likely**	**Very likely**
Severity	**Moderate**	Lower	Lower	Medium
	Serious	Lower	Medium	Higher
	Severe	Medium	Higher	Higher

II.2.2 The FAO-WHO Risk Ranking for Fresh Produce

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) convened an expert consultation in October 2007 to consider how to adequately address the range of microbiological hazards associated with many different types of fresh produce (FAO-WHO, 2008). The intent was to use all the available information (which included review of the literature and unpublished data submitted by various countries) to establish the priority commodities of concern. The scope of the work was limited to produce that is marketed fresh or physically altered from its original form but that is commonly consumed raw. The experts considered the entire production-to-consumption continuum in their deliberations. Six major criteria were identified upon which to rank:

- Frequency and severity of disease
- Size and scope of production
- Diversity and complexity of the production chain and industry
- Potential for amplification of foodborne pathogens through the food chain
- Potential for control
- Extent of international trade and economic impact.

The rankings were qualitative, not quantitative. The commodities were placed into three general categories based only on the input of the experts:

- **Level 1 Priorities (leafy green vegetables):** The experts concluded that globally, leafy green vegetables presented the greatest microbiological food safety concern because (1) multiple outbreaks with large numbers of illnesses associated with these products have occurred in at least three regions of the world; (2) production and export volumes are high; and (3) the diversity of production and processing practices mean that post-harvest activities can contribute to amplification of pathogens.
- **Level 2 Priorities (berries, green onions, melons, tomatoes, seed sprouts):** The experts identified these commodities as being of intermediate concern. The first four products (berries, green onions, melons, and tomatoes) were considered to be similarly problematic, but they could not be prioritized one from another on a global scale, although the experts did conclude that such prioritization might be possible on a regional basis. Sprouted seeds were considered separately due their unique production issues and the availability of existing Codex Alimentarius guidelines for their production.
- **Level 3 Priorities (carrots, cucumbers, almonds, baby corn, sesame seeds, onions and garlic, mango, paw paw, celery, and maimai):** The experts considered these to be

of lowest priority because, although implicated in outbreaks of foodborne disease, the overall public health impact was considered minimal. However, limited data were available for many of these commodities and some of the problems have only recently been recognized, so these may be considered emerging problems.

Additional justification for the rankings is provided in Table 3 of FAO-WHO (2008).

The FAO-WHO ranking is the first ranking effort that was applied to fresh produce on a global scale. Critical factors that impacted the ranking resolution were identified as (1) limited and variable amount of information for most commodities; (2) limited understanding of hazards, routes of contamination, and controls; and (3) substantial differences in production systems both within and between countries. The experts concluded that prioritization of limited resources (e.g., research, risk assessment, controls) will be necessary to ensure that the issues of greatest concern are adequately and appropriately addressed.

II.2.3 The Carnegie-Mellon Risk Ranking Approach

This approach is based on initial work described by Florig et al. (2001) of Carnegie-Mellon University, which has since been applied to evaluate the differences between experts and the public when it comes to ranking the relative importance of food safety risks (Webster et al., 2008). The general approach is a five-step process:

1. Define and categorize the risks to be ranked
2. Determine risk attributes for each category identified in Step 1
3. Develop risk summary sheets for each risk that include the list of attributes from Step 2, characterizations for each attribute (as determined by experts; e.g., low, medium, or high factors), and a brief description of the risk and references for technical information, if needed (see **Table II-4** for the types of information captured in the risk summary sheets for different hazard attributes)
4. Select risk rankers and rank the risks
5. Assess the rankings and conduct statistical analysis.

Table II-4. Information Captured in Carnegie-Mellon Food Safety Risk Ranking Hazard Sheets

Risk Attributes	Risk Attribute Descriptions
Cases per year	Quantitative: estimated as unknown, worldwide, or U.S., depending on agent
Fatalities per year	Quantitative: estimated as unknown, worldwide, or U.S. based on number of cases or percentage of cases resulting in fatality
Likelihood of fatality	Qualitative: certain, low-medium, or rare or unknown; can also be estimated as percentage of cases likely to result in death
Likelihood of contracting disease	Qualitative: rare, low-medium, unknown
Chronic health effects	Descriptive
High risk groups	Descriptive
Types of food agent is found in	Descriptive
Geographic area agent is found	Descriptive but includes “ubiquitous”
Prevention measures in place	Descriptive

Risk Attributes	Risk Attribute Descriptions
Time between exposure and health effects	Descriptive for both acute and chronic effects
Scientific knowledge	Qualitative: estimated as medium or high
Ability to prevent exposure	Qualitative: estimated as medium or high

This approach was applied by Webster et al. (2008) to six food safety hazards: (1) bovine spongiform encephalopathy (mad cow disease); (2) *E. coli* O157:H7; (3) *Salmonella*; (4) botulism (*Clostridium botulinum*); (5) paralytic shellfish poisoning; and (6) acrylamide. Participants in the ranking exercise included both food safety experts and members of the lay public. Each participant was asked to read through the six risk summary sheets and rank the six hazards from highest risk (ranking of one) to lowest risk (ranking of six). Individual rankings from the lay public (n=29) and food safety experts (n=21) were summarized in frequency tables, and the Mann-Whitney statistical test was used to determine the significance of differences in ranking choices. Results for the food safety experts are summarized in **Table II-5**.

Table II-5. Public and Expert Rankings of Six Food Safety Issues

	Food Safety Issue											
	BSE[a]		E. coli		Salmonella		Botulism		PSP[b]		Acrylamide	
Rank	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)
1	3.4%	0.0%	41.4%	38.1%	20.7%	52.4%	0.0%	4.8%	0.0%	4.8%	34.5%	0.0%
2	13.8%	0.0%	41.4%	61.9%	34.5%	19.0%	6.9%	14.3%	3.4%	4.8%	0.0%	4.8%
3	27.6%	14.3%	6.9%	0.0%	13.8%	19.0%	41.4%	57.1%	3.4%	4.8%	13.8%	0.0%
4	20.7%	19.0%	10.3%	0.0%	6.9%	4.8%	17.2%	19.0%	31.0%	47.6%	17.2%	9.5%
5	13.8%	28.6%	0.0%	0.0%	20.7%	4.8%	24.1%	4.8%	20.7%	23.8%	20.7%	42.9%
6	20.7%	38.1%	0.0%	0.0%	3.4%	0.0%	10.3%	0.0%	41.4%	14.3%	13.8%	42.9%

[a] BSE = bovine spongiform encephalopathy (mad cow disease).
[b] PSP = paralytic shellfish poisoning.

The goal of this work was not merely to rank a variety of food safety concerns, but rather to characterize the differences between ranking scores provided by experts vs. the public and to try to understand the reasons for such differences. In this regard, the investigators were able to conclude that the Carnegie-Mellon Risk Ranking approach could be applied using subjects (rankers) with different backgrounds, both laypersons and technical, and that the results of both individual and group work had a strong correlation. However, this remains a highly subjective approach.

Perhaps the most useful feature of the Carnegie-Mellon method is the production of risk summary sheets that provide a snapshot of relevant information about the agent. A similar approach could be applied to foods or food-hazard combinations. Given the summary sheets, risk rankers can then individually decide if more weight should be given to one or more attributes relative to others.

II.3 Semiquantitative Food Safety Risk Ranking Models

This section describes five semi-quantitative food safety risk ranking models: Risk Ranger, the Food Sector Risk Ranking and Prioritization Model, the Foodborne Illness Risk Ranking Model (FIRRM), the Food Safety Universe Database (FSUDB), and the Food/Hazard Risk Registry (FHRR), also called iRISK. Each section includes Purpose and Objectives, Model Overview (including application and availability and intended users), Scope, Detailed Model Description, Platform, Uncertainty, Model Attributes, and Model Limitations. In addition, the developer, contacts, and references are provided for each model.

II.3.1 Risk Ranger

Developer/Sponsor
Australian Food Safety Centre of Excellence, based on the peer-reviewed work of Ross and Sumner (2002).

Contact
Dr. Mark Tamplin, Director, FSC
College Road, Private Bag 54, Room 320
Life Sciences Building
Tasmanian Institute of Agricultural Research
School of Agricultural Sciences
Hobart TAS 7001, Australia
Mark.Tamplin@utas.edu.au
Phone: +61 3 6226 6378
Mobile: +61 420 520 583,
Fax: +61 3 6226 7450
Website: www.foodsafetycentre.com.au

Documentation
Ross and Sumner (2002)
Sumner and Ross (2002)
Sumner et al. (2004)
Sumner et al. (2005)

Intended Users
Policy makers, risk managers, risk analysts, and others with specific expertise in foods safety. The limited number of inputs and relatively simple design makes this a very user-friendly platform. Designed specifically for food safety applications.

Availability
Available as a free download at http://www.foodsafetycentre.com.au/docs/RiskRanger.xls

Platform
Microsoft Excel

Purpose/Objectives

The purpose of this work was to develop a simple and accessible food safety risk calculation tool intended to be used as an aid to determine the relative risks from different product-pathogen-processing combinations. As such, this is probably the first real effort in semi-quantitative risk ranking, with model development done as early as 2000–2002.

Model Overview

Risk Ranger is a spreadsheet-based risk ranking tool that requires users to select from qualitative statements or to provide quantitative data concerning factors that affect the food safety risk of a specific population for selected product-hazard combinations. The general approach is bottom up, because it evaluates risk from harvest to consumption. A total of 11 inputs are grouped into three general categories. The spreadsheet converts the qualitative inputs to numerical scores, and using three different multiplicative algorithms, provides a risk ranking score (scaled logarithmically from 0 to 100) that approximates probabilities of disease or death. Risk estimates include predicted annual illnesses or probability of illness per day in the target population. Risk Ranger has been widely used internationally, largely because it is simple to use and publicly available as a free download. It has been applied to ranking hazards in the seafood and red meat industries and has also caught the attention of the FAO-WHO. Most of these applications have been vetted in the peer-reviewed literature.

Scope

The 11 inputs are grouped into three major categories: (1) susceptibility and severity; (2) probability of exposure to the food; and (3) probability of the food containing an infectious dose. The model is designed for ranking microbial agents in candidate foods, although it is also possible to rank microbial toxins. For a hazard-food combination, the user selects from a choice of qualitative responses to each question. Most of the responses were designed by experts based on the literature but are nevertheless somewhat arbitrary. About half of the questions allow user-specified responses under an "other" response, while the other half must be weighted using the given scales and their values. Inputs must be based on the judgment of the user, which may be based on experience, the literature, or any other means by which experts obtain information.

Detailed Model Description

The 11 inputs (which Risk Ranger calls questions, even though they are not all cast as questions) are detailed below, along with candidate responses. To make response as objective as possible and to maintain transparency, descriptions are provided and many of the weighting factors are specified.

Category 1: Susceptibility and Severity

The severity of the hazard is a function of the intrinsic features of the pathogen/toxin and the susceptibility of the consumer. These are addressed in Questions 1 and 2.

- **Question 1, Hazard severity:** The possible responses to this question, based on the severity of the symptoms caused by the hazard, are as follows; the weighting factors are arbitrary:

Response	Description	Score	Examples
Severe	Causes death in most cases	1.0	Tetrodotoxin, botulinum toxin
Moderate	Requires medical intervention in most cases	0.01	*Listeria monocytogenes*, *Vibrio vulnificus*, *Vibrio cholerae*, enterohemorrhagic *E. coli*
Mild	Sometimes requires medical attention	0.001	*Vibrio parahaemolyticus*, hepatitis A virus, noroviruses, histamine, ciguatera, algal biotoxins, *Salmonella*
Minor	Patient rarely seeks medical attention	0.0001	*Staphylococcus aureus*, *Clostridium perfringens*

- **Question 2, How susceptible is the population of interest?** Four populations that vary in their level of susceptibility are identified:

Response	Description	Score	Examples
General	All members of the population	1	
Slight	Slightly increased susceptibility	5	Young children, the aged

Response	Description	Score	Examples
Very	Very susceptible	30	Newborns; children under one year; and people with conditions such as diabetes, cancer, and liver damage
Extreme	Extremely susceptible	200	People with AIDS, transplant recipients

The various weightings (5, 30, and 200) are loosely based on the relative susceptibility of each population subgroup to *Listeria monocytogenes* and population estimates based on Australian health statistics. When the subpopulation is chosen, the program automatically makes changes in Questions 5 and 10, as detailed below.

Category 2: Probability of Exposure to Food

Absolute risk is based on the population size, the proportion of the population consuming the food, and how frequently people eat the food. These factors are addressed in Questions 3–5.

- **Question 3, Frequency of consumption:** This is scored on a simple algebraic weighting scale in absolute terms based on annual consumption, so the units are days and the selections and scores are as follows:

Response	Score
Daily	365
Weekly	52
Monthly	12
A few times per year	3
Other	user specified

- **Question 4, Proportion of population consuming the product:** The proportion consuming the product may be set as follows; this scale is considered arbitrary:

Response	Score
All (100%)	1
Most (75%)	0.75
Some (25%)	0.25
Very few (5%)	0.05

- **Question 5, Size of consuming population:** This is expressed as an absolute number. Risk Ranger has population estimates for Australia pre-programmed, but if a different country or region is desired, the user can simply input another population by selecting "Other" and specifying the size of that population. If a subset of the general population was chosen in Question 2, Risk Ranger automatically estimates the number in that category based on proportions specific for Australia, which is approximately the same as in most developed countries.

Category 3: Probability of Food Containing an Infectious Dose

The probability of exposure to an infectious dose depends on (1) the amount of food consumed; (2) the probability of contamination in the raw product and, if contamination is present, the initial level of contamination; (3) the probability of contamination at subsequent stages of the farm-to-fork continuum; and (4) changes in the level or concentration of the hazard that may occur during the transition from farm to fork (e.g., concentration, dilution, growth, or inactivation). These factors are addressed in Questions 6–11.

- **Question 6, What is the probability of contamination of raw product per serving?** Choices are as follows: (1) rare (0.1%); (2) infrequent (1%); (3) sometimes (10%); (4) common (50%); (5) all (100%); or (6) other. If "other" is chosen, the user can specify an estimate of probability of contamination.

Response	Score
Rare (0.1%)	0.001
Infrequent (1%)	0.01
Sometimes (10%)	0.1
Common (50%)	0.5
All (100%)	1
Other	user specified

- **Question 7, Effect of processing:** The following responses are possible; the weighting scale is arbitrary:

Response	Score
The process reliably eliminates hazards	0
The process usually (99% of cases) eliminates hazards	0.01
The process slightly (50% of cases) reduces hazards	0.5
The process has no effect on hazard	1
The process increases (10-fold) hazards	10
The process greatly increases (1000-fold) hazards	1,000
Other	user specified

- **Question 8, Is there a potential for recontamination after processing?** Four possible answers are possible; these are arbitrary values:

Response	Score
No	0
Yes, minor (1% frequency)	0.01
Yes, major (50% frequency)	0.5
Other	user specified

§ **Question 9, How effective is the post-processing control system?** Five answers are possible; again, the scaling is arbitrary:

Response	Description	Score
Well controlled	Reliable, effective systems in place	1
Controlled	Mostly reliable systems in place	3
Not controlled	No systems, untrained staff	10
Gross abuse occurs	[no description given]	1,000
Not relevant	Level of risk agent does not change	1

§ **Question 10, What level of increase in the post-processing contamination level would cause infection or intoxication in the average consumer?** Five answers are possible; these are also based on an arbitrary scale:

Response	Description	Score
None		1
Slight	10-fold increase	0.1
Moderate	100-fold increase	0.01
Significant	10,000-fold increase	0.0001
Other	NA	user input

To answer this question appropriately, the user must have some idea of the amount of the hazard that would be required to cause illness, and Risk Ranger provides a supporting table with benchmark infectious doses for relevant microorganisms. If a specific subgroup was identified in Question 2, Risk Ranger automatically adjusts the infectious dose down to take into account the increased vulnerability of subgroups.

§ **Question 11, What is the effect of meal preparation before serving?** The following answers form the basis for this weighting scale, which was determined arbitrarily:

Response	Score
Meal preparation reliably eliminates hazards	0
Meal preparation usually eliminates (99%) hazards	0.01
The process slightly reduces (50%) hazards	0.5
The process has no effect on hazards	1
Other	user specified

Risk Ranking

A simple mathematical model converts the answers to Questions 1–11 into a numerical value or "weighting." Risk Ranger then combines the scores to provide a risk ranking value that is scaled logarithmically between 0 and 100. A score of 0 represents a probability of foodborne illness of less than or equal to one case per 10 billion people (greater than current global population) per 100 years. At the upper limit (risk ranking = 100), every member of the population eats a meal

that contains a lethal dose of the hazard every day. A risk ranking change of 6 points corresponds to a 10-fold difference in the absolute risk. Therefore, an increase in risk ranking from 36 to 48 would be interpreted as a 100-fold increase in risk. Further details of the logic and equations are provided in Ross and Sumner (2002).

Outputs

In addition to the risk ranking score, Risk Ranger provides two other estimates of risk. The first of these is the predicted total number of illnesses in the population specified in Question 5. The higher the risk ranking, the greater the proportion of the population that is predicted to become ill. The other output is an estimate of the probability of illness per day in the target population, reflected by the answer to Question 2. Obviously, the risk ranking remains the same, irrespective of whether the general population or a highly susceptible subpopulation is considered; however, the probability of illness increases in the target population, allowing for representation of where illnesses may be focused.

Platform

The model was developed using Microsoft Excel with standard mathematical and logical functions. The listbox macro tool was used to automate much of the conversion from qualitative inputs to quantities for calculations, such that each selection made from the range of options is converted into a numerical value by the software.

Uncertainty

Neither uncertainty nor variability is addressed by Risk Ranger; questions are answered by scores given as point estimates.

Model Attributes

- Risk Ranger can theoretically be applied to compare risks of microbial hazards and microbial toxins
- It uses the same methodology to rank all agents and all commodities
- Simplicity in design and implementation has facilitated wide use
- The user is provided some choice (by using the “other” designation for some of the inputs)
- It produces multiple outputs, which include both risk ranking and risk estimates
- The method is well documented, has been subjected to performance evaluation and peer review, and has been applied in several risk management scenarios.

Model Limitations

- Risk Ranger may be considered a substantial oversimplification, hindering its use for discrimination of small but critical differences
- Weighting factors for most inputs are arbitrarily derived
- It does not address variability or uncertainty in any measurable way.

II.3.2 The Food Sector Risk Ranking and Prioritization Model

Purpose/Objectives

The Food Sector Risk Ranking and Prioritization Model (FSRRPM) is a combined risk ranking-risk prioritization model, the risk ranking component of which is based on the Australia-New Zealand Food Safety Authority priority classification system (NZFSA, 2006) and the Canadian Risk Characterization Model for Food Retail-Food Service Establishments (FAO-WHO, 2006).This project formed part of the Domestic Food Review of New Zealand, whose long-term (5+ years) goal was to put in place a food regulatory program across all sectors of the New Zealand domestic food industry. Because implementation of such a wide-reaching regulatory program could not be done in a short timeline, this model was intended to be used to prioritize which nonregulated food sectors should be targeted for immediate regulatory activity and which could be put off for efforts in future years. In short, the businesses estimated to provide the highest risk are slated to meet the Food Control Plan requirements first.

Developer/Sponsor
Australia-New Zealand Food Safety Authority

Contact
New Zealand Food Safety Authority
68-86 Jervois Quay, PO Box 2835
Wellington, NEW ZEALAND
Phone: +64 4 894 2500
Fax: +64 4 894 2501

Documentation
NZFSA (2006)

Intended Users
The model in its current format is only relevant to food safety authorities interested in ranking for purposes of regulatory oversight.

Availability
Unknown

Platform
Not described in current documentation.

Model Overview

The FSRRPM is intended to be applied only to those sectors of the industry not already under regulatory oversight. Food businesses are classified into 30 food sectors; the model ranks each sector according to the food safety risks posed by that sector. This is a farm-to-fork model and hence could be considered bottom-up in approach. The model consists of two different parts, each of which is subdivided into sections that consider different parameters that may affect risk. These two parts are described as follows: (1) Part One (Sections 1–4) applies the best available scientific information to provide an initial estimation of food safety risk associated with a food sector; and (2) using Part One as the basis, Part Two (Sections 5–7) considers the impact of the sector organization and business practices on food safety. The model output can serve as the basis for making management decisions about regulation or other control measures to be implemented.

Further information about specific applications of this model were unavailable.

Scope

The New Zealand Food Safety Authority obtained a list of sector groupings currently used in regulatory or nonregulatory settings, which served as the basis for the 30 food sector categories. The model is designed for ranking pathogens, not chemicals or toxins, in these commodities. Generally accepted information about pathogens, their disease outcomes and susceptible populations, and their entry and behavior in the food system were used to inform estimates of the

inputs. In cases where robust data were not available, opinion from recognized experts was elicited and used to parameterize parts of the model. The New Zealand Total Diet Survey Food List was used to inform consumption estimates. The weighting categories and subsequent scores are somewhat arbitrary in nature. Additional information on data sources are provided in the Detailed Model Description section below.

Detailed Model Description

Part One: Characterization of Risk title??

Part One of the model is divided into four sections, each of which is detailed below. In general, numerical values for each input in Part One were selected by considering a range that was sufficient to separate the sectors on the basis of risk. The relative risk weightings are comparable between sections and reflect the approximately equivalent impact of each section on overall food safety risk. Higher weights reflect greater risk.

Section 1: Food Type and Intended Use by Customer

This section is designed to capture the inherent risks associated with different types of foods. Factors considered include the following:

- The potential for any of three types of hazards (microbiological, chemical, physical) to occur in any of the foods produced by a food sector
- Whether the food supports the growth of microorganisms
- Whether or not the food is sold ready-to-eat
- The available foodborne illness, food complaint, and monitoring data from New Zealand, or international trend analysis highlighting specific or inherent risks associated with food types, which may include risks associated with food safety or suitability.

Briefly, foods are categorized in two domains, i.e., (1) based on three risk levels and (2) whether or not they are ready-to-eat (RTE). In the first domain:

- **High-risk** foods are defined as those associated with Group 1 biological hazards (detailed in an appendix to the original documentation, NZFSA [2006]) or associated with • 10% of complaints lodged in FoodNet since 1997
- **Medium-risk** foods are those associated with Group 2 pathogenic microorganisms or their toxins or associated with 1–9.99% of complaints lodged in FoodNet since 1997
- **Low-risk** foods are those associated with Group 3 pathogenic microorganisms or toxins and which were not previously captured in the high or medium risk categories above.

In the second domain, foods are categorized by whether or not they are ready to eat: a ready-to-eat food is one that is ordinarily consumed in the same state as that in which it is sold. For any one food product, the risk levels are combined with the ready-to-eat classification to create four overall food categories which are weighted as follows:

Category	Weight
High-risk foods that are ready-to-eat	20
Medium-risk foods that are ready-to-eat	15
High-risk or medium-risk foods that are not ready-to-eat	10
Low-risk foods that may or may not be ready-to-eat	5

A number of assumptions were necessary when functionalizing this section:

- For sectors that make multiple foods, the highest risk food is used to determine the weight
- Ready-to-eat foods are more likely to cause foodborne illness if they contain an uncontrolled hazard and are therefore given a greater weight
- No food is considered completely without risk; therefore, even low-risk foods are assigned a nonzero weight.

Section 2: Food Preparation and Processing

This section is designed to capture the additional risks introduced through food processing and handling based on consideration of the following factors:

- The number of processing steps that could increase the risk of contamination
- The amount of contact that occurs between the foods, the general environment in which the food is produced, or direct contact with humans
- Whether the food undergoes physical or chemical changes that affect its safety to the consuming public
- Whether the final processing step effectively controls any risks associated with prior steps in the farm-to-fork chain.

Based on these factors, the following risk weights are assigned:

Category	Weight
Extensive level of preparation/processing	20
Moderate level of preparation/processing	15
Low level of preparation/processing	10
No preparation/processing steps	0
Hazard reduction/elimination step at last point of process	–10

Inherent assumptions include the following:

- As the degree of processing increases, so does the likelihood of a food contamination event occurring; therefore, the highest weight is assigned to food sectors with the greatest number of processing or preparation steps
- Any business undertaking a hazard mitigation function as the final step in processing is given a lower weight, because this final step reduces risk

- If food has no preparation or processing steps (e.g., distribution or sale of shelf-stable prepackaged items) no additional risk is introduced, therefore a weight of zero can be assigned.

Section 3: Food Targeted for Vulnerable Populations

This section is designed to identify the additional risk food poses to vulnerable populations. It considers only foods made specifically for vulnerable populations, which are defined as children under the age of 5, adults over the age of 65, the sick and immunocompromised, and pregnant women. Specific assumptions made include the following:

- Disease can occur in the vulnerable populations after exposure to lower doses than would cause disease in normal people
- People within vulnerable populations may be susceptible to organisms that do not normally affect the general population.

Based on these assumptions, the following risk weights are assigned:

Category	Weight
Foods targeted specifically for vulnerable populations	20
All other foods	0

Section 4: Community Reach

This section is designed to account for the impact a food sector would have on the community if it produced unsafe food. Two major factors are considered: (1) the proportion of the population regularly consuming the food type (based on the 2003–2004 NZ Total Diet Survey Food List, provided in the source document appendix, NZFSA [2006]); and (2) the volume of food produced by the food sector. It is assumed that foods consumed by the majority of consumers or foods with wide distribution networks would impact more individuals and therefore should be assigned a higher risk weighting. On the other hand, foods with limited distribution or availability and consumption by a minority of consumers would present some risk, albeit lower. Risk weights are assigned as follows:

Category	Weight
Commodity/Wide Community Reach	20
Mid-range/Moderate Community Reach	10
Specialty food/Restricted Community Reach	5

Part Two: Potential for Control title

Part Two is divided into four sections, each of which is detailed below. The values assigned to each section in Part Two are lower than those applied in Part One, to reflect the more subjective nature of the inputs and associated data. As a result, the overall risk assigned to a sector will be more strongly influenced by factors in Part One of the risk ranking model than those in Part Two.

Section 5: Food Safety Systems/Structure in Place

The purpose of this section is to provide some indication of the level of business structure in which that food sector is operating. Factors considered include the following:

- Whether the food sector has a cooperative or industry association active in areas of food safety, and if so, the proportion of membership from within the sector
- Whether the food sector operates a voluntary Food Safety Code of Practice or similar tools, and if so, the proportion of businesses within the sector that have adopted the code or tools
- Whether the voluntary systems in place have been validated and verified for effectiveness in controlling food safety risks.

It is assumed that food sectors with recognized food safety risks that have voluntarily applied a structure or systems to self-regulate and control these risks will pose lower risk to food safety. Therefore, sectors are assigned a lower risk weighting when voluntary systems and structures to promote food safety are in place and adopted by a high proportion of businesses within the sector. Weights are assigned as follows:

Category	Weight
Poor systems/structure	10
Some systems/structure	5
Good systems/structure	0

Section 6: Appropriate Skill/Competency Levels Within the Sector

This section is designed to indicate the level of skill/competency of people operating within the food sector. It considers (1) the approximate average level of skill/competency of people working in the food sector; (2) whether New Zealand unit standards are available for training in appropriate skills for the food sector; and (3) the approximate proportions of attendance at such training courses.

It is assumed that food sectors that actively participate in food safety training or recruit highly trained individuals have a greater awareness of food safety requirements and therefore a lower food safety risk. In some food sectors, the level of food safety skill/competency required to effectively produce safe food is high. These sectors would receive an appropriate (good) weight; however, if a high skill level is required but not available, a weight corresponding to the poor category would be applied. In the case of food sectors for which the skill/competency required to produce or maintain safe food is low, an appropriate (good) weighting would be applied if skills/competencies are present. However, if absent, a low weight would be applied. The risk weights are assigned as follows:

Category	Weight
Poor skill/competency	10
Low skill/competency	5
Appropriate (good) skill/competency	0

Section 7: Regulatory Starting Point

This section is designed to indicate the level of regulation that is currently actively applied to the food sector. It considers the relevance of the regulation(s) for the sector and also takes into

consideration operational or administrative decisions in relation to application of that regulation. The following assumptions were made in describing this input:

- Where there are active, co-operative relationships between the regulator and the food sector, there is a greater awareness and understanding of food safety requirements, and it is assumed that the food sector has a lower food safety risk
- The regulatory starting point is considered poor if current regulations are not sufficient to provide food safety assurance
- The regulatory starting point is considered irrelevant for businesses with a level of exemption from the regulations or if the active enforcement of these regulations would have negligible impact on food safety assurance
- The regulatory starting point is considered good if the sector is currently actively regulated and the regulations provide a reasonable level of food safety; there is an inherent recognition here that food safety may be improved by the application of different or more appropriate regulatory requirements.

On the basis of these assumptions, there are two categories for weighting:

Category	Weight
Poor regulatory starting point	10
Irrelevant or good regulatory starting point	0

Calculating Risk Rank

An overall numerical score is determined additively, such that higher scores indicate higher risk. Once each food sector has an overall numerical value based on risk, it is possible to determine an initial priority of the food sector with regards to implementation of Food Control Plans.

Outputs

The current documentation does not specify outputs. However, the intention is to produce an initial relative risk ranking based on Parts 1 and 2 described above; hence, the individual results from Parts 1 and 2 can be viewed separately or combined. Apparently, a risk prioritization model can be run as an overlay to the risk ranking model, but little documentation is provided about the prioritization tool.

Uncertainty

It appears that scores are given as point estimates and then summed; therefore, neither uncertainty nor variability are addressed by this model.

Model Attributes

- The FSRRPM can theoretically be applied to compare risks of microbial hazards and microbial toxins
- It uses same methodology to rank all agents and all commodities
- Simplicity in design and implementation could facilitate wide use
- Strong emphasis on food safety control makes this model a good candidate for comparing control options across agents, commodities, or agent-commodity pairs

- The potential for linking the risk ranking directly with a companion risk prioritization model is appealing

Model Limitations

- Risk weighting is highly arbitrary and may not be justifiable in all cases
- The model does not address variability or uncertainty at all
- Application is limited by the question posed during design, i.e., it is limited to use as a risk ranking model specifically applied to food industry sectors not already under regulatory oversight for the purpose of making management decisions about future regulation or control
- All inputs are categorically specified; custom input is not possible
- The model produces only a single output (value), which has relevance to the risk ranking alone, thereby limiting the usefulness of the approach.

II.3.3 The Foodborne Illness Risk Ranking Model (FIRRM)

Purpose/Objectives

The Foodborne Illness Risk Ranking Model (FIRRM) was developed by Resources for Future under the advisement of the Food Safety Research Consortium, a multi-disciplinary collaboration of researchers from eight institutions with a common mission to improve public health by making food safety decision-making and priority-setting more science- and risk-based. The overall purpose of the FIRRM project was to develop a science-based tool for prioritization of food safety hazards which considers the distribution of risk across products and throughout the farm-to-fork chain. The outcome was an analytical software tool to facilitate the identification, comparison, and ranking of foodborne pathogens in multiple food types using several measures of public health impact.

Developer/Sponsor
Resources for Future under the advisement of the Food Safety Research Consortium, funded by the Robert Wood Johnson Fellowship Program and the USDA Cooperative State Research, Education, and Extension Service Integrated Food Safety Initiative

Contact
Sandra A. Hoffman
Resources for the Future
1616 P Street NW
Washington, DC 20036 hoffmann@rff.org

Documentation
Batz et al. (2004)
FSCR (2004)
Batz (2007)
Hoffmann et al. (2007)

Intended Users and Applications
Food Safety policymakers, risk managers, and risk analysts. Designed specifically for food safety applications.

Availability
Reputedly available as a free download at http://www.rff.org/fsrc/; however, attempting to access this website returns a page not available error. Appears to be currently available at http://www.thefsrc.org/firrm.htm.

Platform
Analytica

Model Overview

FIRMM takes a surveillance-based, top-down approach, using epidemiological surveillance data on pathogen illnesses and tracing those illnesses back to food origin (i.e., food source attribution). FIRRM consists of four modules. Module 1 (Disease Incidence Estimates) estimates the annual number of cases, hospitalizations, and

fatalities caused by each foodborne pathogen. Module 2 (Valuation of Health Outcomes) converts the results of Module 1 to two different metrics: economic costs and quality adjusted life year (QALY) losses. Module 3 (Attribution) determines the pathogen-specific illnesses and association with specific categories of food vehicles using one of three approaches (outbreak data, risk assessment, or expert judgment). Module 4 ranks pathogen-food combinations according to five different measures of social burden (estimated number of cases, hospitalizations, and deaths, as well as estimated economic impact and loss of QALYs). A general flow diagram for the model is provided in **Figure II-1**.

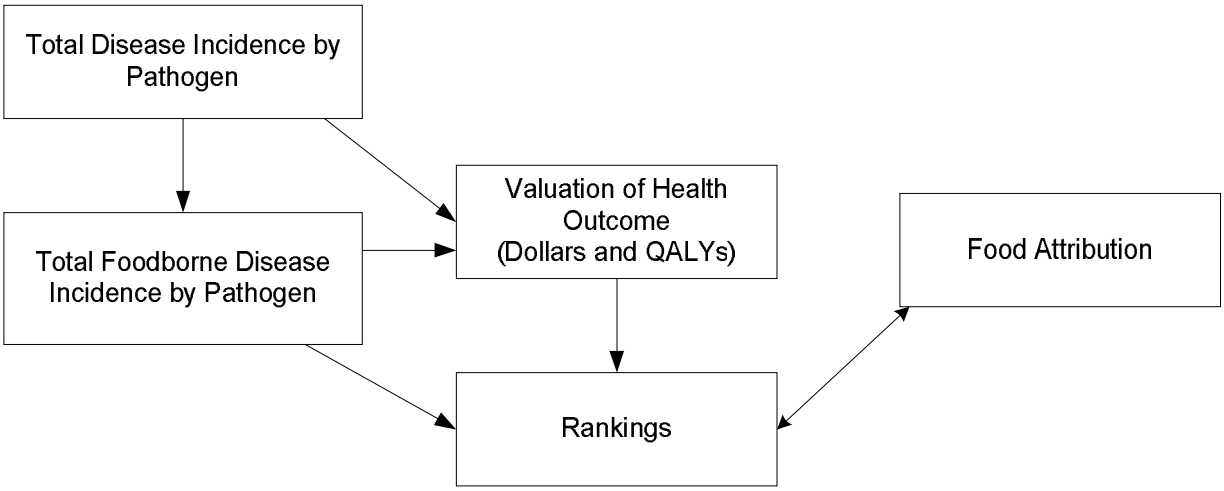


Figure II-1. Flow diagram of FIRRM model structure.

Many presentations of the model have been done and it is widely referenced on the Internet, including demonstration of outputs. However, to our knowledge, FIRRM has not yet been used by regulatory agencies for risk ranking.

Scope

The model covers the 28 bacterial, viral, and parasitic foodborne pathogens included in Mead et al. (1999). A complete list is shown in the box at right. Chemical agents are not ranked in FIRRM.

FIRRM Pathogens

Bacterial
Bacillus cereus
Botulism
Brucella
Campylobacter
Clostridium perfringens
E. coli O157:H7
E. coli non-O157 STEC
E. coli enterotoxigenic
E. coli other diarrheogenic
Listeria monocytogenes
Salmonella typhi
Salmonella nontyphoidal
Shigella
Staphylococcus toxin
Streptococcus
Vibrio cholerae toxigenic

Bacterial (cont'd)
Vibrio vulnificus
Vibrio other (*parahaemolyticus*)
Yersinia enterocolitica

Parasitic
Cryptosporidium parvum
Cyclospora cayetanensis
Giardia lamblia
Toxoplasma gondii
Trichinella spiralis

Viral
Norwalk-like viruses
Rotavirus
Astrovirus
Hepatitis A

The model covers the food categories described in the outbreak database managed by the Center for Science in the Public Interest (CSPI). Foods are identified by major food category and subcategory and are listed in **Table II-6**. Level of food categorization depends on attribution method chosen for application in Module 3. A major deviation from the CSPI

categorization is that FIRRM separates multisource outbreaks into their own major category and subcategories.

Table II-6. FIRRM Food Categories and Subcategories

Major Food Category	Food Subcategory	Major Food Category	Food Subcategory
Seafood	Finfish	Multi-ingredient	Salads
	Molluscan shellfish		Rice/beans/stuffing/hot pasta dishes
	Other seafood		Sandwiches
	Seafood dishes		Sauces/dressings/oils
	Seafood combo		Other foods
Eggs	Eggs		Multi-ingredient combo
	Egg dishes	Game	Game
	Egg combo	Poultry	Chicken
Produce	Fruits		Turkey
	Vegetables		Other poultry
	Produce dishes		Chicken dishes
	Produce combo		Turkey dishes
Beverages	Juices	Pork	Ham
	Other beverages		Other pork
	Beverage combo		Pork dishes
Dairy	Milk	Luncheon/ Other Meats	Luncheon meats
	Cheese		Other meats
	Ice cream		Other meat dishes
	Other dairy	Multisource	USDA
	Dairy combo		FDA
Breads and Bakery	Breads		USDA and FDA/Unknown
	Bakery	Unattributable	Unattributable
	Breads and bakery combo		

Detailed Description of Model

Module 1: Disease Incidence Estimates

The sources of data for this module are disease incidence and severity (hospitalization and death) estimates produced by Mead et al. (1999); in some instances, these data are supplemented with state-specific estimates from FoodNet and data from the USDA Economic Research Service (ERS) online foodborne illness cost calculator (USDA, 2003). This module is designed to produce estimates of the total annual number of cases of foodborne illness caused by each agent. In addition, the annual number of hospitalizations and deaths caused by that pathogen, attributable exclusively to the foodborne transmission route, are also estimated. **Figure II-2** provides an overview of the module.

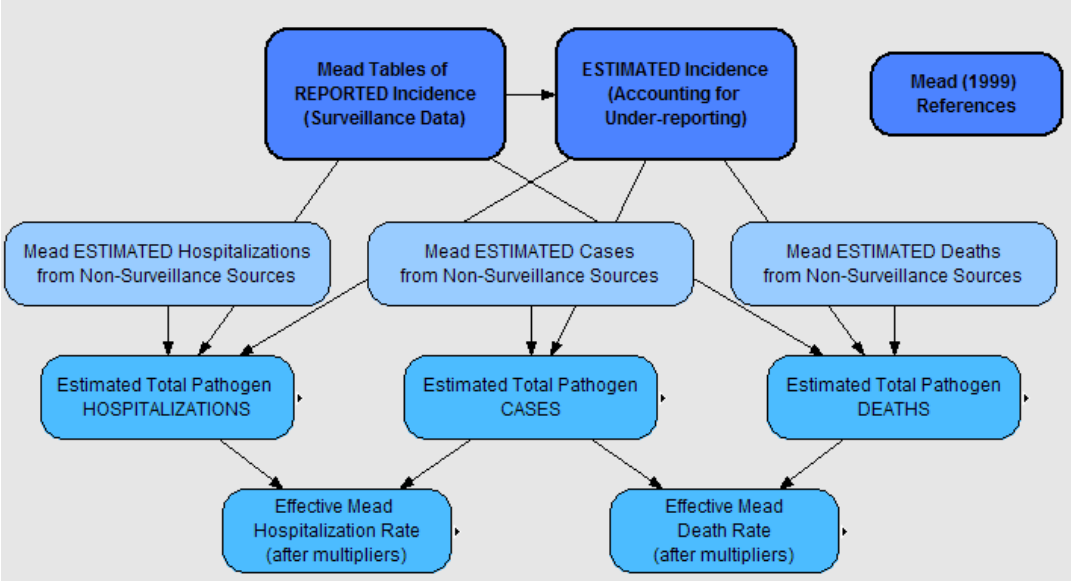


Figure II-2. Overview of FIRRM Module 1 disease incidence estimates using data from Mead et al. (1999).

Module 2: Valuation of Health Outcomes

Initially, all cases of disease for each pathogen are classified into various health outcomes. More specifically, for each pathogen, all cases are first divided into those who are hospitalized, those who visit a physician, and those who do not seek medical care. These three health states are further divided into subcategories (e.g., pregnant women, newborns) where appropriate. Cases of each health outcome subsequently recover or decline into a worse health outcome, such as chronic sequelae or premature death. This is referred to as the system-severity outcome tree approach. Economic valuation is calculated for each health outcome using two metrics (economic costs or QALY). Economic costs are calculated based on a combination of cost of illness (for morbidity) and willingness to pay (for mortality) using the general method applied by USDA (Buzby et al., 1996; USDA, 2003). Economic costs and QALY losses are summed to obtain totals for each pathogen. The overall scheme is detailed in **Figure II-3**, using non-typhoidal *Salmonella* as an example.

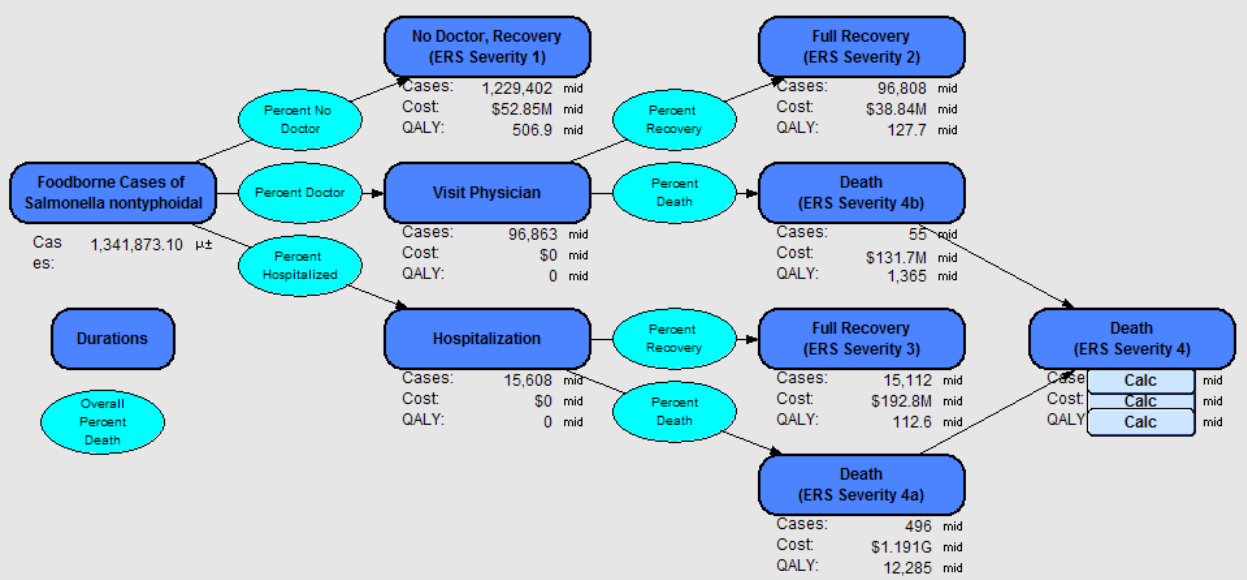


Figure II-3. Example of symptom-severity outcome tree using nontyphoidal *Salmonella*.

Module 3: Food Attribution

This module calculates pathogen-specific disease burden attributable to the different food categories using three different data sets and approaches. The user has the option of selecting which of these approaches to take. Each is briefly described below:

- **Food attribution using CSPI data:** CSPI maintains an outbreak database compiled from U.S. Centers for Disease Control and Prevention (CDC) line listings supplemented with information about documented outbreaks not included in the CDC database. For the 28 pathogens in the model, a total of 2,000 outbreaks representing over 83,000 cases of reported foodborne illness are included, dating from 1990 to present. This module is composed of two parallel computations: according to food subcategories and according to food major categories. Criteria are set (minimum of five outbreaks per pathogen) for inclusion in the attribution database to avoid misattribution, which might occur when the number of outbreaks is too low to give reasonable estimates of food attribution. Food attribution percentages are first calculated by pathogen and food subcategory, where the food attribution for each subcategory equals the number of cases associated with a selected pathogen for that specific subcategory divided by the total number of cases associated with that pathogen for all subcategories. The exercise is repeated for each major food category using the summation of the data for each subcategory in that major category. In this case, the food attribution for each major category equals the number of cases associated with a selected pathogen for that major category divided by the total number of cases associated with that pathogen for all major categories. Therefore, attributions are expressed as percentages.

- **Food attribution using risk assessment approach (also called consumption and contamination method):** This method uses publicly available information on the consumption of specific food products (ERS food consumption data system and CFSII data), probability of contamination (from the literature), dose-response relationship (from previous models), and information about consumer handling practices from U.S. FDA (2002) to estimate attributable disease for a particular pathogen as a function of food

category. Food attribution percentages are calculated from estimations of annual infections per person, by pathogen and major food category. The general approach is diagrammed in **Figure II-4**. The first three inputs are (1) annual per capita consumption by major food category; (2) total annual consumption (in kg), and (3) contamination rates (colony forming units [CFU]/kg) by pathogen and major food category. These are used to calculate contamination level experienced annually (CFU/yr). The contamination level experienced annually is multiplied by the percent of time consumers engage in "risky" behavior to provide an estimate of contamination level to which the consumer is exposed (CFU/yr). For each pathogen, the infectious dose (CFU/illness) is also specified. The ratio between the amount of the contaminant consumed and the infectious dose is estimated per pathogen and per major food category, providing a proxy for infections (illnesses/yr) by pathogen and food. To calculate food-pathogen percentages for use in food attribution, FIRRM simply sums the infections for each pathogen across all foods and divides by that total.

§ **Food attribution using expert judgment:** This method is based on expert elicitation of food attribution percentages for a subset of foodborne pathogens for all major food categories (as reported by Hoffmann et al., 2007).

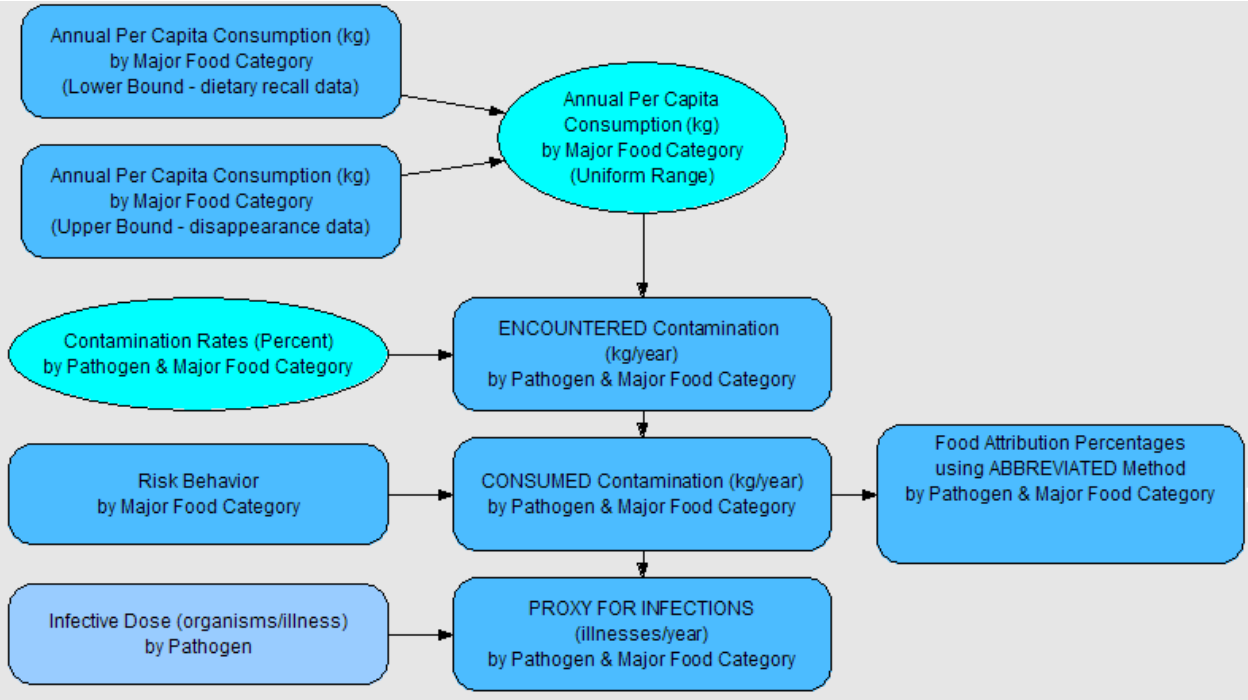


Figure II-4. Food attribution using a risk assessment method.

Module 4: Calculation of Rankings

Foodborne pathogen incidence (output of Module 1) and valuation of pathogen health outcomes (output of Module 2) are combined to provide pathogen-level measures of disease burden. Food attribution (output of Module 3) transforms pathogen-level estimates to estimates for pathogen-food combinations.

Outputs

The user selects which of the five measure of disease burden on which to rank. These include three disease incidence measures and two valuation measures:

- **Number of illness cases:** Rank disease burden according to estimated number of cases
- **Number of hospitalized cases:** Rank disease burden according to estimated number of hospitalizations
- **Number of deaths:** Rank disease burden according to estimated number of deaths caused by acute effects of disease, limited to deaths recorded in incidence data (i.e., does not include premature deaths due to chronic sequelae or latent complications)
- **Monetary valuation:** Rank disease burden according to estimated economic impact of health outcomes of disease based on cost of illness and willingness to pay
- **QALY valuation:** Rank disease burden according to estimated loss of quality of life due to health outcomes of disease, as measured by the QALY.

In addition to ranking pathogen-food combinations, the model also ranks pathogens (without attributing to food) and foods (by summation across all pathogens). Results are displaying in units appropriate to each measure or as a percentage of the total measure. Outputs can be viewed graphically.

Platform

FIRMM is designed in Analytica, a visual modeling and Monte Carlo simulation program in which mathematical models are developed using functional influence diagrams. The model is designed to be "point-and-click" for the user and includes built-in documentation and references. Uncertainty analysis is embedded in the program, and a "dashboard" interface allows the user to change some of the assumptions. It appears that significant training (~1 day) of user time would be required to become competent in model use.

Uncertainty

The model incorporates probabilistic uncertainty within a Monte Carlo simulation framework and produces intervals and statistics for outputs. To date, the primary driver of uncertainty bounds is associated with per-case valuation estimates.

Model Attributes

- The topdown approach has value because the rankings are based on final public health measure (i.e., product-specific attribution)
- FIRRM has a high degree of resolution in food categories if the CSPI method for food attribution is chosen
- It uses the same methodology to rank all pathogens and all commodities
- Valuation of health outcomes provides a well recognized metric for comparison/ranking of various public health outcomes
- It provides several measures of public health outcome(s) to facilitate comparison of different pathogens
- The user is provided some choice (e.g., method of attribution calculation, outcome metric, selecting specific data years to include in analysis, inclusion/exclusion of mixed products)

- It addresses uncertainty (to some degree) by using upper/lower bounds and probability distributions to describe some inputs (e.g., annual consumption, contamination rates, expert elicitation values) and uses Monte Carlo simulation
- Although it currently produces measures at the national level (United States), it could be refined to produce regional or country-specific rankings.
- It is relatively simple to update as new surveillance or attribution data become available.

Model Limitations

- FIRRM is based almost exclusively on epidemiological data, which can provide an incomplete picture of the true impact of the various pathogens and foods on disease burden and attribution
- Gaps in data, most importantly in regard to food attribution and the statistical uncertainty of disease incidence estimates, limit the utility of the model
- FIRMM does not consider the breadth of the farm-to-fork chain, because ranking is based solely on food source attribution; as a result, the model cannot be used to evaluate candidate mitigation strategies at various phases in the farm-to-fork continuum.
- Some (perhaps important) pathogen-product combinations are not subjected to attribution analysis because of relatively stringent criteria to prevent misattribution
- The model applies to microbiological agents only; chemical agents are not considered.

II.3.4 The Food Safety Universe Database (FSUDB)

Purpose/Objectives

The purpose of the Food Safety Universe Database (FSUDB) is to systematically assess and rank food safety risks for the ultimate purpose of optimizing the use of finite resources to best manage food safety issues.

Developer/Sponsor
Ontario Ministry of Agriculture and Food

Contact
Dr. Bruce McNab
Bruce.McNab@omaf.gov.on.ca

Documentation
OMAF (2003)

Intended Users
Food safety policymakers, risk managers, and risk analysts. Access is limited to a few authorized individuals within the sponsoring agency, likely due to inclusion of the impact of food-system sabotage or terrorism.

Availability
The database and associated algorithms are not available in the public domain.

Platform
Microsoft Access

Model Overview

This semi-quantitative food safety risk assessment tool ranks food safety hazards on two axes: likelihood (probability) and consequence (impact). The general model structure is a "universe" or cloud of likelihood and consequence data for every possible combination of food, hazard, and location along the farm-to-fork chain. Therefore, there are three dimensions to the model: (1) food; (2) hazard; and (3) location in the chain (e.g., production, processing, consumption). The two axes are further described as model components. Component A, Probability, includes the subcategories of (1) consumption; (2) proportion of the food contaminated with that hazard at a specified location; and (3) if contamination occurs, proportion of the food that would lead to exposure. Each subcategory is

scored at a value that can range from 0.01 and 10. Component B, Impact, also has three subcategories: (1) proportion who become ill; (2) severity of disease; and (3) difficulty to control. Each of these is scored between 1 and 10. For any one food-hazard-location combination, the scores for each of the subcategories from the Probability Component and the Impact Component are multiplied, resulting in a score ranging from 1 to 10^6. Note that all subcategory scores are ordinal and should not be construed as proportions in the strict mathematical sense.

Scope

The scope of the three dimensions is as follows:

- **Foods:** The food dimension is coded at several levels. The most basic level is the broad food category (e.g., meat, dairy, or plant origin foods). Within each category, subclassifications exist (e.g., chicken, pork, beef). For further detail, specific products within these subclassifications can be chosen (e.g., fresh whole beef, fresh ground beef, ready-to-eat beef).
- **Hazards:** Hazards are likewise coded with several levels of detail. The first level consists of broad categories of biological, chemical, or physical hazards. The broad categories are subdivided into subclassifications (e.g., bacteria, viruses, parasites). The third and most specific level of classification addresses specific hazards within each subclassification (e.g., *Listeria monocytogenes,* pathogenic *Salmonella*)
- **Location along the food chain:** The specific locations in the food chain include production, processing, distribution, and final food preparation.

Detailed Description of the Model

There are two components (Probability and Impact), both of which consist of three criteria each.

Component A, Probability

The Probability Component consists of three subcategories designated Pa, Pb, and Pc. Each subcategory in the Probability Component is given a score which may be as low as 0.01 to a high of 10. The subcategories and their scoring are described below:

- **Pa–Consumption:** The scale of consumption score reflects the amount of the selected food consumed per person per day. The scores are based on information reported in several Canadian and American studies. The score depends on the food in question and the segment of society being considered. For biological hazards, it is based on the number of servings consumed, whereas for chemical hazards, it is based on the number of grams of the food consumed per day. The more a food is consumed, the higher it is scored. Scoring definitions/details are as follows; note scaling is not linear. The original documentation provides examples of foods that fall into each category.

Score	Chemical Agents: Weighted Average Consumption (g/person/day)	Biological Agents: (servings/person/day)
1	<0.49	0-0.005
2	0.5-1.9	0.005-0.020

Score	Chemical Agents: Weighted Average Consumption (g/person/day)	Biological Agents: (servings/person/day)
3	2-4.9	0.020-0.05
4	5-9.9	0.05-0.1
5	10-19.9	0.1-0.2
6	20-39.9	0.2-0.3
7	40-59.9	0.3-0.4
8	60-79.9	0.4-0.5
9	80-100	0.5-0.6
10	>100	>0.6

§ **Pb–Contamination:** The proportion of food contaminated can be scored in one of two ways. The proportion accidentally contaminated (Pbi) is influenced by the food, the hazard, and the location in the food chain being considered. This score can be modified to reflect situations which span from extremely unlikely to extremely likely that contamination with a particular hazard will occur at a particular point along the food chain. The more likely the food in question is of being newly contaminated (or additionally contaminated) by the hazard at the particular point (including increased contamination due to hazard growth or concentration), the higher the score. The details of the scoring criteria are as shown below; for chemical contamination, the score is based on the frequency of chemical use; for biological agents, frequency of contamination. Scoring is not linear. The documentation provides examples of food-hazard-location combinations that fall into each score category.

Score	Chemical Contaminants: Used (tons/year) Treated batches (%) Environmental contamination (ppm)	Biological Agents: Proportion Accidentally Contaminated
0.01	Never intentionally used at this point Negligible probability of accidental contamination	Negligible
0.1	<0.5 t/yr No reason or incentive to use: negligible–0.01% <0.01 ppb	Negligible–0.01
1	0.5–1 t/yr Used on 0.01–0.1% of batches 0.01–0.5 ppb	0.01–0.1
2	1–5 t/yr Used on 0.1–1% of batches 0.5–5 ppb	0.1–1
3	5–10 t/yr Used on 1–5% of batches 5–50 ppb	1–5%

Score	Chemical Contaminants: Used (tons/year) Treated batches (%) Environmental contamination (ppm)	Biological Agents: Proportion Accidentally Contaminated
4	10–25 t/yr Used at least once on 5–15% of batches 50–250 ppb	5–15%
5	25–50 t/yr Used at least once on 15–30% of batches 250–500 ppb	15–30%
6	50–75 t/yr Used at least once on 30–50% of batches 500–750 ppb	30–50%
8	75–100 t/yr Used at least once on 50–90% of batches 750–1,000 ppb	50–90%
10	>100 t/yr Routinely used more than twice on the same batch on >90% of batches >1 ppm	>90%

For intentional contamination circumstances, the proportion contaminated by sabotage score (Pbii) is derived using the risk assessor's expert opinion of the sabotage appeal of contaminating that food with that hazard at that point along the food-chain. This is based on ease of logistics of acquisition and introduction of that hazard to the food at that point in the chain and the terror that such a deliberate introduction would cause. Detailed scoring information for Pbii is withheld from public access.

§ **Pc–Exposure:** This subcategory characterizes the likelihood that consumers will be exposed to the hazard given that contamination occurs. For biological hazards, this is based on the likelihood of an organism surviving to consumption, given the location of its introduction relative to inactivation steps (e.g., thermal or chemical treatments). For chemical hazards, the ranking is based on processing steps that would reduce concentration, chemical half-life, pre-harvest intervals, and drug withdrawal periods. The greater the likelihood of exposure, the higher the score. Subscores are not directly proportional to their nonlinear definitions. Probability of exposure to chemical hazards is scored as follows:

Score	Processing factors reduce residue by:	Half-life of chemical (days)	Bioaccumulation BCF Log Kow	Pre-harvest interval or withdrawal period (days)
0.01	>99%	<1	<100 <3	<0.25
0.1	>99%	1–3	100–150 <3	<0.25
1	>99%	3–5	150–200 3–3.25	0.25–0.5

Score	Processing factors reduce residue by:	Half-life of chemical (days)	Bioaccumulation BCF Log Kow	Pre-harvest interval or withdrawal period (days)
2	95–99%	5–8	200–300 3.25–3.5	0.5–1
3	90–95%	8–12	300–500 3.5–4	1–2
4	80–90%	12–20	500–750 4–4.5	2–5
5	60–80%	20–40	750–1,000 4.5–5	5–10
6	40–60%	40–60	1,000–2,000 5–5.5	10–20
8	5–40%	60–100	2,000–5,000 5.5–6.5	20–40
10	<5%	>100	>5,000 >6.5	>40

Probability of consumer exposure to biological hazards is scored as follows; for microbiological agents, the documentation provides examples of applicable foods:

Score	Subsequent Contamination Reduction	Contamination occurs PRIOR to:
0.01	>5 log	Thermal processing Pasteurization Commercial cooking
0.1	3–5 log	Commercial non-thermal processing (e.g., smoking, curing, fermentation, long aging period)
1	2–3 log	Commercial non-thermal processing (e.g., smoking curing, fermentation, aging period)
2	95–99%	Consumer cooking: pathogens not distributed internally and product has small surface area
3	90–95%	Commercial non-thermal processing: medium aging period Long-term exposure in the environment
4	80–90%	Consumer cooking: pathogens distributed internally and consumer may prefer product undercooked; or product has large surface area
5	60–80%	Washing: easy-to-wash produce Commercial nonthermal processing: minimal aging period
6	40–60%	Washing: moderately difficult-to-wash produce Commercial nonthermal processing: minimal aging period
8	5–40%	Washing: hard-to-wash produce Commercial nonthermal processing: minimal or no aging period
10	<5%	All foods contaminated at point of consumption (ready-to-eat) or post-cooking or pasteurization

Component B, Impact

The Impact Component consists of three subcategories designated Ia, Ib, and Ic. Each subcategory in the Impact Component is given a score from 1 to 10. The subcategories and their scoring are as follows:

- **Ia–Proportion of Exposed Consumers That Become Ill:** The proportion of exposed consumers that become ill as a result of exposure to a specific hazard is influenced by the toxicity or virulence of the hazard and the amount to which the consumer is exposed relative to the critical amount required to cause illness. For chemicals, the rankings are based on exposure concentrations relative to maximum residue limits (MRLs). For biological agents, ranking is based on available data on the dose required to cause infection and consideration of the fraction of that infective dose to which consumers are likely to be exposed given the particular hazard-food-point-of-contamination scenario. The greater the exposure, the greater the impact score. Scoring criteria are as follows; for microbiological agents, the documentation provides examples:

Score	Frequency of Violations Observed in Surveys or Expected Concentrations Relative to MRL	Fraction of Infectious Dose at Point of Consumption
1	<10 MRL	$<1/10^8$
2	<1% and 10–100 MRL	$1/10^8$–$1/10^6$
3	1–10% and 10–100 MRL	$1/10^6$–$1/10^5$
4	<1% and 100–1,000 MRL	$1/10^5$–$1/10^4$
5	>10% and 10–100 MRL	$1/10^4$–$1/10^3$
6	1–10% and 100–1,000 MRL	0.001–0.01
7	<1% and >1,000 MRL	0.01–0.1
8	>10% and 100–1,000 MRL	0.1–1
9	1–10% and >1,000 MRL	1–2
10	>10% and >1,000 MRL	>2

- **Ib–Severity of Illness:** This impact factor is evaluated based on the severity of illness among consumers who become ill. For chemicals, this is based on both acute and chronic toxicity data; in this case, a score for a particular agent may be calculated using the combined impact of these factors, so-called sub-sub-scoring. For biological agents, the ranking is based on data describing the average cost per case for specific illnesses, including treatment, hospitalization, lost time, and statistical value of life as expressed in the disability adjusted life years (DALY) metric. Scoring criteria are as follows; for microbiological agents, the documentation provides examples:

Score	Oral LD_{50} (mg/kg)	Oral Reference Dose/ Acceptable/Tolerable Daily Intake (mg/kg/day)	Cancer potency, Factor q1, TD_{50} (mg/kg/day), IARC Classification	Health-Related Cost per Case ($$ Canadian)
1	>5,000	≥10	• 0.0001 • 1000 4 = probable not carcinogen	Impact unknown or unproven
2	500–5,000	5–10	0.0001–0.001 100–1,000 3 = not classifiable as carcinogen	<1,200
3	100–500	1–5	001–0.01 10–100	1,200–2,500
4	50–100	0.5–1	0.01–0.1 1–10	2,500–5,000
5	25–50	0.1–0.5	0.1–1 0.1–1	5,000–20,000
6	10–25	0.05–0.1	1–10 0.01–0.1	20,000–50,000
7	5–10	0.01–0.05	10–100 0.001–0.01	50,000–200,000
8	2–5	0.005–0.01	100–1,000 0.001–0.01 2B = possible human carcinogen	200,000–1 million
9	0.5–2	0.001–0.005	1,000–10,000 0.001–0.01 2A = probable human carcinogen	>1 million
10	<0.5	≤0.001	• 10,000 • 0.001 1 = known human carcinogen	>50% mortality regardless of cost/case

§ **Ic–Difficulty to Limit Impact:** This score reflects how difficult it is to reduce or limit the impact of the hazard in the food. Ranking is based on factors such as time to realize the problem, size of the distribution network, the ease with which recall may be initiated, the ease with which the hazard can be identified and eliminated, and indirect economic effects. For biological agents, the potential for secondary spread is also considered. Because multiple factors are considered in scoring, the combined impact of these factors is calculated using so-called sub-sub-scoring. Final scores are ordinal from 1 to 10; the more difficult it is to limit impact, the higher the score. The scoring descriptions are as follows.

Score	Time to realization of problem (days)	Extent of Required Recall, Difficulty to Eliminate Source of Contamination	Secondary Spread (biohazards), Indirect Economic Impacts
1	0.5	Small defined source, no recall Easy to identify and eliminate source	No secondary infection No indirect economic impacts
2	1	Local distribution, small recall Easy to identify and eliminate source	No secondary infection No indirect economic impacts

Score	Time to realization of problem (days)	Extent of Required Recall, Difficulty to Eliminate Source of Contamination	Secondary Spread (biohazards), Indirect Economic Impacts
3	1–2	Regional distribution, moderate recall Easy to identify and eliminate source	No secondary infection No indirect economic impacts
4	3	Provincial distribution, moderate to large recall Can identify source with investigation and eliminate at some cost	No secondary infection No indirect economic impacts
5	4	2–3 Province distribution Can identify source with investigation and eliminate at some cost	No secondary infection No indirect economic impacts
6	5	National distribution, national recall Can identify source with investigation and eliminate at some cost	Some secondary spread of infection Some indirect economic impacts
7	5–10	North American but good tracing and specific product recall Can identify source with investigation and eliminate at some cost	Some secondary spread of infection Some indirect economic impacts
8	10–15	Trans continental but good tracing and specific product recall Very difficulty to identify source and very difficult to eliminate	Some secondary spread of infection Some indirect economic impacts
9	15–30	North American but poor tracing and Imprecise recall Very difficulty to identify source and very difficult to eliminate	Significant secondary infection Significant indirect economic impacts
10	>30	Trans continental but poor tracing and imprecise recall Very difficult to identify source and very difficult to eliminate	Significant secondary infection Significant indirect economic impacts

Risk Ranking

The overall risk score for any one food-agent-location trio is calculated multiplicatively as the product of the six subscores (three probability and three impact); the range is 1 to 1,000,000:

$$Risk\ score = Pa \times Pb \times Pc \times Ia \times Ib \times Ic$$

Outputs

Outputs are produced in two forms, designated per-serving risk and societal risk. These two outputs are influenced by the scale of consumption and the proportion of food servings contaminated. This is done very simply by including or excluding the scale of consumption (Pa) in the calculation of the overall risk score. Including Pa in the calculation gives a risk rank range of 1 to 1,000,000 and reflects societal risk. Excluding Pa from the calculation provides a risk ranking range of 1 to 100,000 and expresses risk from a per-serving perspective.

The FSUDB can also be manipulated to produce scores as applied to specific segments of society (e.g., susceptible subpopulations, age-related differences in consumption patterns) by maintaining separate data records for very specific food-hazard-location combinations. Information is also captured to allow comparison of risk scores by food source, type of establishment, and regulatory authority responsible for the food. Furthermore, notes on references, explanations of scoring, and who assigned or changed scores and when and why are also captured in the FSUDB. Similarly, notes on potential tools to control risks for that hazard-food-location combination may also be recorded.

Platform

The FSUDB database program was developed in Microsoft Access. A primary data-entry screen allows the user to enter the data, which in most cases is facilitated by pick-lists. The left-hand side of the screen prompts the user to enter different types of data. The middle part of the screen provides pop-up pick-lists from which the user picks appropriate available codes. The description of each code is provided in the pick-list and appears on the right side of the screen once a code has been selected. Pick-lists and descriptions are stored in tables in the background of this relational database. The database administrator controls any changes to the code tables. The overall risk score is calculated automatically by an algorithm programmed into the system. This algorithm may be changed or weighted differently by the database administrator, if appropriate. Training requirements appear to be moderate, about 4–6 hours.

Uncertainty

Risk assessors' uncertainties about probability and impact subscores are captured in uncertainty scores of 1 to 10. An uncertainty score of 1 represents no or negligible uncertainty. A score of 10 represents extreme uncertainty about probability or impact scores. These uncertainty scores are used in algorithms programmed into the database to place a type of confidence interval on the calculated risk-scores. However, because the database is not publicly available, it is not clear how these uncertainty scores are reflected in the associated outputs.

Model Attributes

- FUSDB can be applied to compare risks of microbial hazards and chemical hazards
- It uses the same methodology to rank all agents and all commodities
- User-friendly interface could facilitate wide use
- Production of two risk measures (risk per serving and societal risk) provides flexibility
- The model is applicable to both accidental and intentional contamination scenarios
- The documentation is straightforward and in most instances, specific examples are provided to help the user in choice of scaling values for the different inputs
- The evidence base for the model is relatively transparent; however, scoring criteria might be considered arbitrary by some and justification/definitions for specific scores are simply designated as "developed by the authors and used for internal consistency."

Model Limitations

- There is limited consideration of uncertainty
- As currently designed, each of six individual criteria (subcategorizations) have equal importance (or weight), although this could probably be remediated by minor coding changes
- The tool is not publicly available
- Although the approach allows for ranking within specific sectors of the food chain (e.g., production, processing), it currently does not have a simple means by which to allow aggregation of results so that one could follow the combined impacts of each phase of the farm-to-fork continuum for risk ranking purposes.

II.3.5 The Food/Hazard Risk Registry (FHRR) or iRISK

Purpose/Objectives

The purpose of this project was to support the development and implementation of a risk ranking framework to evaluate potential high-threat microbiological agents, toxins, and chemicals in food. The framework was to include a model for quantitatively or semi-quantitatively comparing and determining the potential threats of these agents and the ability to evaluate interventions or control points (e.g., manufacturing/processing, warehouses, transport, retail) at various places in the farm-to-fork chain. In the development of this model, FDA specifically requested the use of criteria that, at a minimum, addressed compatibility of a hazard with food as a vehicle, toxicity (or dose necessary to result in disease), accessibility, and likelihood of effect (illness).

Developer/Sponsor
FHRR developed by the Institute of Food Technologists and FDA CFSAN and operationalized as iRisk by Risk Sciences International (formerly Decisionalysis). Funded by FDA CFSAN.

Contacts

Rosetta Newsome
Institute of Food Technologists
525 W. Van Buren, Ste. 1000
Chicago, IL 60607
rlnewsome@ift.org
Phone: 312.782.8424
Fax: 312.782.8348

Greg Paoli
Risk Sciences International
1831 Yale Ave
Ottawa, ON Canada K1H 6S3
gpaoli@analyzerisk.com
Phone: (613) 260-1424

Documentation
Newsome et al. (In press)
Paoli (2008a,b)

Intended Users and Applications
Policy makers, risk managers, risk analysts, and others with specific expertise in foods safety. Designed specifically for food safety applications.

Availability
The iRISK model is meant to be accessible on-line with FDA-CFSAN permission, although at the time of this writing, permission for on-line access had not yet been granted.

Platform
Visual Basic (web-based user interface)
Analytica

Model Overview

The iRISK model is designed to analyze data concerning hazards (both chemical and biological) in food and return an estimate of the resulting health burden on a population level. This is a bottom-up, or predictive modeling approach to risk ranking that requires the application of data and expert judgment to assemble sufficient information to predict

the fate of the hazards in the food supply through the farm-to-fork chain. These results are combined with food intake data and information on hazard virulence or toxicity to produce a prediction of the relative level of risk to human health of the particular hazard-food pair. The model produces a semi-quantitative characterization of the disease burden, which can be used for comparison (ranking) purposes and can facilitate the evaluation of the impacts of hazard control measures.

The model is organized into two major modules, Exposure (farm-to-table) and Hazard Characterization (health impacts), and one sub-module. The Exposure module is subdivided into three major sections representing the farm-to-fork continuum: (1) primary production; (2) processing; and (3) distribution, storage, retail, foodservice, and home. The Hazard Characterization module addresses (1) agent pathogenicity or toxicity and (2) potential public health burden. The submodule addresses consumption/food intake. The overall model structure is provided in **Figure II-5**.

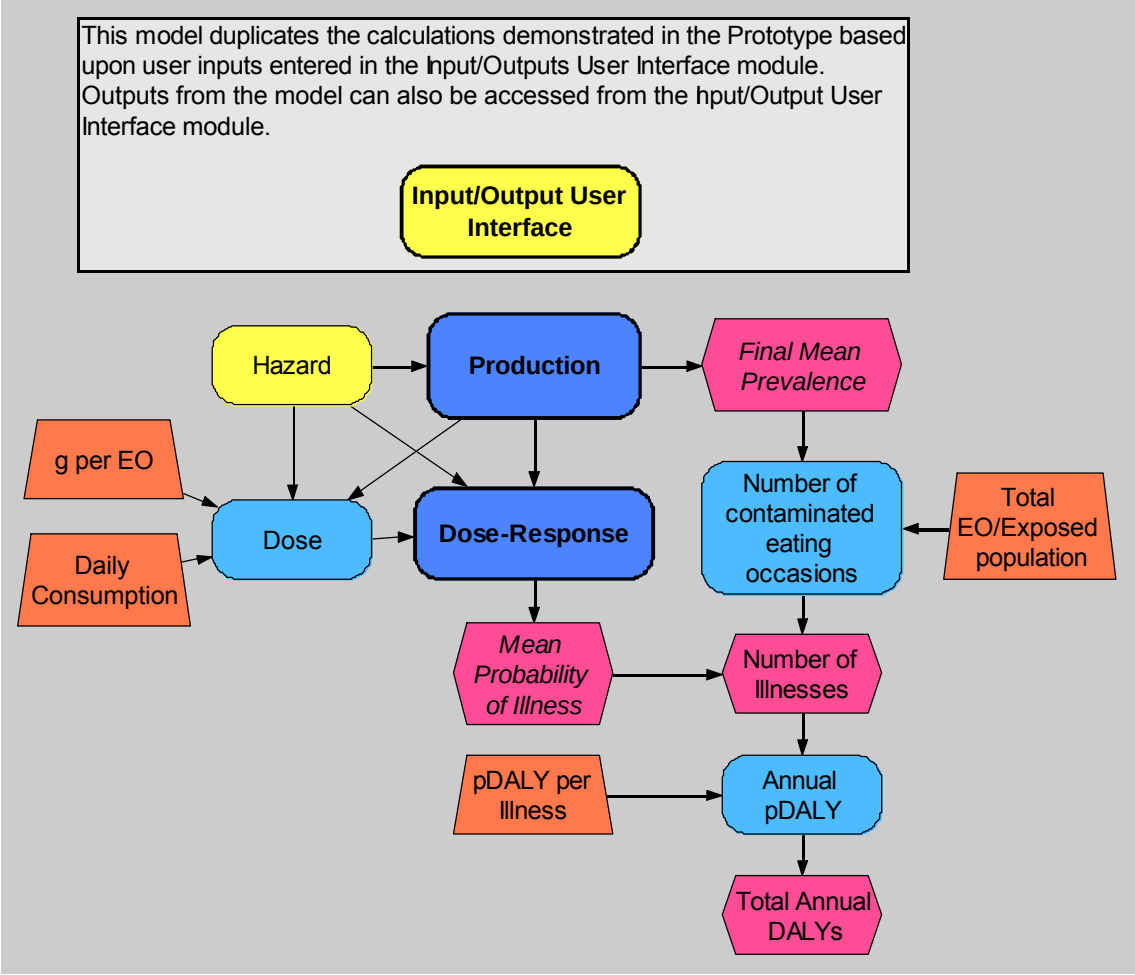


Figure II-5. Overview of iRISK model (in Analytica).

The metric used for reporting risk is a modification of the DALY, designated the "pseudo-DALY or pDALY; this metric allows for a semi-quantitative characterization of the disease burden of disparate health impacts. The usual approach to measuring the DALY is to assign a severity

weight and duration weight to discrete, relatively well-characterized health outcomes. The pDALY approach allows for the characterization of a standard health outcome (such as a mild illness) without further definition of the exact impact. This was developed primarily to facilitate risk ranking of chemical substances which may present a risk of diverse, poorly characterized outcomes (e.g., noncancer toxicity) that may not be easily assigned individual weights and durations. In short, the pDALY method allows the impact of the hazard, whether cancer, infectious, or toxic, to be put on a relative scale.

To date, 24 food-hazard pairs have been used to test the prototype. No other applications are known at this time.

Scope

The data required to execute iRISK includes information about the food (which foods, along with the associated consumption data and processing/preparation methods) and the hazard (hazard-specific dose-response curve and anticipated health effects in humans). The user can specify any combination of these elements, providing capability to evaluate a broad range of risk scenarios. For example, risk can be compared for the same food contaminated with different hazards; the same hazard present in multiple foods; multiple agent-food combinations; or a single hazard-food combination processed or prepared in different ways.

Detailed Description of the Model

Input Variables and Data Sources

The Institute of Food Technologists convened a panel of experts having expertise in the farm-to-fork food system, food safety, risk assessment and management, microbiology, chemistry, toxicology, predictive microbiology, and computer modeling to develop the risk-ranking framework prototype. The panel's expertise and efforts were supplemented with additional developmental assistance by other experts, as needed. Hence, the evidentiary base for the model development was the expert elicitation framework supplemented by expert panel judgment and publicly available peer-reviewed scientific information.

The experts identified potential input variables or risk criteria which would be critical to a risk ranking tool:

- Initial prevalence
- Initial concentration before processing
- Change in concentration at primary production
- Likelihood of introduction at primary production
- Introduced concentration at primary production
- Change in prevalence during primary production
- Change in concentration at processing
- Likelihood of introduction at processing
- Introduced concentration at processing
- Change in prevalence (processing)
- Change in concentration at distribution, storage, retail, foodservice, and in the home

- Likelihood of introduction at distribution, storage, retail, foodservice, and in the home
- Introduced concentration at distribution, storage, retail, foodservice, and in the home
- Change in prevalence at distribution, storage, retail, foodservice, and in the home
- Total eating occasions/exposed population
- Grams per eating occasion
- pDALY per illness
- Daily consumption
- Dose-response model
- Dose.

The panel then designed a series of key questions that could be answered by the user to provide a predicted value or description for each of the risk criteria. The format for answering these questions depends on the particular question, but can be qualitative (e.g., high, medium, low, likely/not likely), quantitative (metric/scale), objective (available data), subjective (expertise), or rationale-based. Metrics (values assigned to individual risk input criteria) for the risk criteria in the Exposure and Hazard Characterization modules were systematically developed by the panelists. The panelists also developed decision logic (supporting rationale and guidance), including pertinent examples, to define the answer options and guide users in answering the questions and entering data. The decision logic and supporting rationale define the answer options for each question, provide intellectual justification for the relevance to the metrics for each question, and provide the necessary user interface.

Module 1: Exposure

Users first determine the hazard-food category for which they wish to enter information. They are then prompted by specific questions for pertinent details on hazard prevalence and hazard concentration, and the predicted changes in hazard prevalence and concentration at each of the three food system stages (i.e., primary production; processing; and distribution, storage, retail, foodservice, and home) for that product.

- **Hazard Prevalence (Introduction and Changes):** The model addresses the likelihood of hazard introduction at each of the three stages, the change in prevalence that might occur during each stage, and the predicted prevalence after each stage. This results in a final prevalence estimate. Initial prevalence is expressed on the basis of percentage of total units in which the hazard is present (contaminated units/total units, 0–100%). Within each of the three food system stages, hazard presence is considered on a bulk lot or truck load type basis rather than by individual consumer or retail units. Change in prevalence (occurring independently of initial concentration, change in concentration, or introduced concentration within each of the three food system stages) is represented using multipliers, where 1 corresponds to unchanged prevalence, values <1 represent reduction in prevalence, and values >1 represent relative increases in prevalence.

- **Hazard Concentration (Introduction and Changes):** Hazard concentration is expressed as initial concentration (in $\log_{10}$ CFU/g for microbes and g/g for chemicals) at the earliest point of contamination, and subsequent concentration as a result of any increases, decreases, or additions occurring during the three stages of the farm-to-fork continuum. Monte Carlo simulation computes final estimated concentration of the agent

from triangular distributions (minimum, most likely, or maximum concentration values). The simulation engine examines each possible pathway of contamination explicitly, and the resulting concentrations are weighted (because not all concentrations are equally likely) by their respective probability of occurrence calculated in concentration weights. As a result, 16 pathways track probabilities for concentration throughout each of the three food system stages.

Submodule for Consumption/Food Intake

This submodule estimates the proportion of the population that is exposed to the hazard and how much of a given food is eaten. Using the USDA's CSFII 1994–1998 database, an aggregate approach was taken in terms of grouping the food products. CSFII data are compiled for four population groups (entire United States, women 16–49 years of age, children 1–6 years of age, and the elderly [65+ years of age]). The user may specify what percentage of a given population is at risk (e.g., percentage of pregnant women). The consumption of foods contaminated with various chemicals is based on the mg/kg body weight/day measure. Population size is based on Census estimates for each population group in the database to compute population risk for chemicals. Microbial risk is calculated using mean serving size and total number of servings (eating occasions). For chemical hazards, risk (probability of illness) is calculated on the basis of the 90th percentile for consumption.

Module 2: Hazard Characterization

This module addresses (1) agent pathogenicity or toxicity and (2) potential public health burden. The user first specifies the agent and the hazard outcome type(s) to be considered (see list under Input Variables and Data Sources, above). When selecting a specific health impact, space is provided in boxes to provide rationale and supporting references.

- **Dose-Response Relationships:** Multiple dose response models are available for each potential hazard outcome type (i.e., threshold linear, non-threshold linear, step-threshold, beta-Poisson, or exponential). Templates for each of the dose-response models in association with each of the health outcomes are part of the software and cannot be changed by the user. Therefore, the dose-response section of the module specifies appropriate parameters for each model as applied to each outcome. All dose-response pages allow consideration of probability of illness given response, addressing the question of what proportion of infections would result in illness. Dose-response curves are incorporated into the risk calculations.

- **Potential Public Health Burden:** Users create pDALY templates by assigning a fraction of cases to appropriate health impacts. Hence, the results of exposure are captured semi-quantitatively on two dimensions—impact severity (mild, moderate, severe, and death) and duration (short, medium, long). Basically, the user assigns a fraction of cases to appropriate health impacts so that there are up to 12 ways of describing a health impact:

  - Mild illness, with short, medium, or long term impacts (3 combinations)
  - Moderate illness with short, medium, or long term impacts (3 combinations)
  - Severe illness with short, medium, or long term impacts (3 combinations)
  - Mortality in child, adult, or the elderly (depending on population)

- Specific syndromes including hemorrhagic colitis, hemolytic uremic syndrome, enteric fever, reactive arthritis/Reiter's' syndrome
- New health impact(s).

pDALY templates available to date are as follows:

- Acute (chemicals)
- Blood target organ (chemical)
- Cancer (chemical)
- *E. coli* O157:H7
- Gastroenteritis only (rare fatality)
- Hepatitis A virus
- Neural tube defect
- Neurodevelopmental (chemical)
- Reproductive (chemical)
- *Salmonella*
- Severe pathogen
- New pDALY template.

Calculation of Rankings

Monte Carlo simulation computes a range of doses based on the concentration of the hazard in the food and average serving size. The computed doses are then applied to hazard dose-response models to compute mean probability of illness for distinct population groups. Prevalence values are used to determine the number of contaminated servings. Combining the consumption estimates with probability of illness and the burden of disease (pDALY) values generates a final risk characterization metric in the form of annual pDALYs. Risks that are inferred based on lifetime exposures (for chemical hazards) are prorated to an annual risk estimate (by dividing by an arbitrary lifetime value of 70 years) to allow for compatible timeframes for comparison between disparate agents.

Outputs and Reports

The major outputs are as follows:

- Final mean concentration in positive lots
- Final mean prevalence
- Mean probability of illness
- Number of illnesses
- Annual pDALY

The prototype is coded such that there is an option to include or exclude any foods, hazards, or specific hazard-food combinations, as chosen by the user. The prototype also provides a basic mechanism that reports back selected contents of the database (the evidence) according to foods, hazards, processes, and their combinations.

A risk-ranking summary report can be generated that lists (in ascending or descending order) the results, aggregated by hazard or food and ordered by total risk, expressed as pDALY. The

summary report also provides a list of currently excluded foods, hazards, and combinations and summarizes the following:

- The dose-response model and parameters
- Grams consumed and number of eating occasions
- Mean hazard prevalence (%)
- Number of contaminated servings from once contaminated lots
- Mean concentration in food
- Mean dose
- Mean probability of illness
- Number of illnesses
- pDALY per illness
- Annual pDALY.

Platform

The FHRR model is available in two platforms: an Analytica (Lumina Decision Systems, Los Gatos, Calif.) which constitutes the prototype; and a web-based user interface implemented in Visual Basic (Microsoft, Redmond, Wash.). The latter is now referred to as iRISK. The Analytica model (Figure II-5) was built initially to facilitate the development of calculations and computational features, for visualization of logic flow and interrelationships between input and output variables, and to serve as the basis for further development, discussion, and review of the algorithms. The Analytica model allows calculations based on only a single hazard-food pair and does not allow relative risk rankings of different hazard-food pairs.

The web-based platform was developed to provide a user-friendly input/output interface that facilitates concurrent use and data sharing without significant time delay by multiple individuals (**Figure II-6**). This tool begins as something of a "blank slate" such that the user must identify the hazard, food, population group, and at least one health effect, as well as some other user-specified inputs (e.g., parameters for the Exposure module). However, other aspects are fixed and cannot be changed by the user (e.g., hazard-specific dose response parameters, food consumption and intake). The web-based platform has advantages in that it allows users to explore the complex ranking hierarchy, view the current evidence, edit evidence, and update assumptions. Calculations are performed using Visual Basic; a relational database (Microsoft Access) stores the relationships between variables (foods, hazards, processes, and evidence) individually, and in their many combinations. It appears that significant training (~1 day) of users would be required.

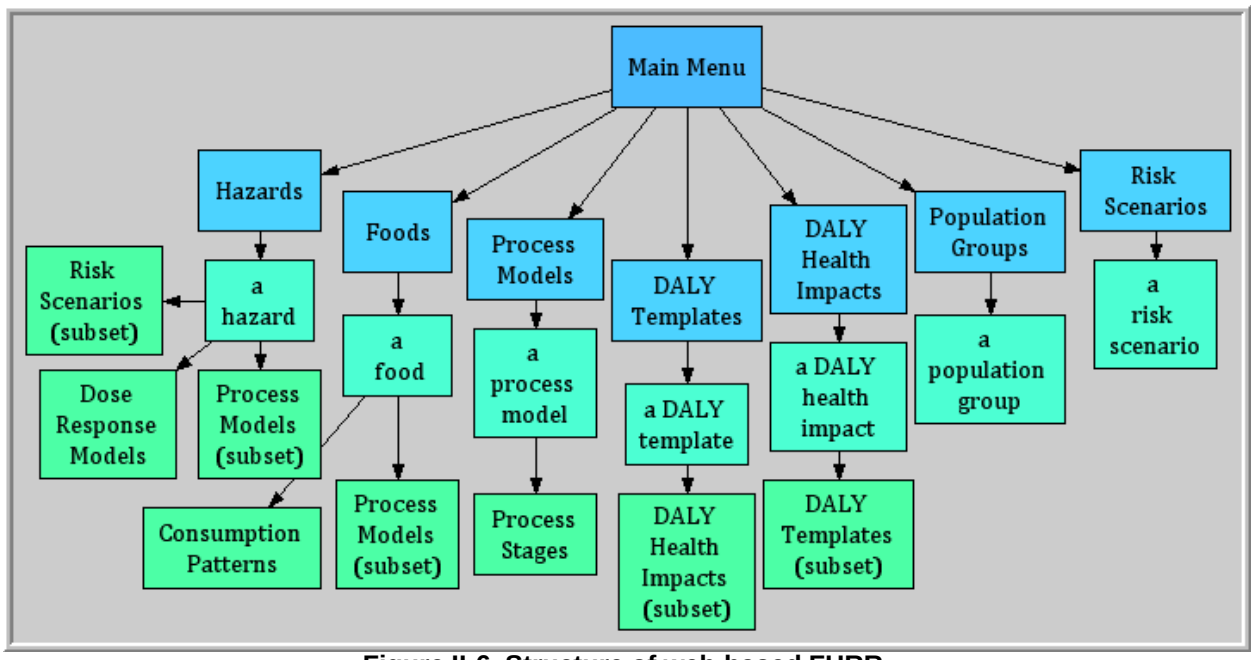


Figure II-6. Structure of web-based FHRR.

Uncertainty

The web-based version (iRISK) uses Monte Carlo simulation to compute a range of doses based on the concentration of the hazard in the food and the average serving size. Triangular distributions were chosen for characterization of agent concentration; other distributions (e.g., Beta Pert) could readily be used in future iterations of the model.

Model Attributes

- FHRR/iRisk has specific application to food safety, including both microbiological and chemical (including microbial toxins) risks
- The model is based on the classic microbial risk assessment paradigm
- The bottom-up farm-to-fork approach is amenable to the evaluation of candidate mitigation strategies
- The model uses the same methodology to rank all agents and all commodities
- It provides a novel measure of public health outcome (pDALY) to facilitate comparison of disparate agents; the pDALY is proposed as a harmonization of burden of disease measures given that the spectrum and relative frequency of health outcomes varies widely among hazards
- The user is provided some choice (dose-response model, combinations of disease endpoints)
- The model addresses (to some degree) uncertainty by using triangular distributions for many inputs and using Monte Carlo simulation to compute a range of doses
- The model is flexible, theoretically allowing its use for considering the impact of regional, seasonal, or geographic inputs on risk
- The evidence base for the model is relativity transparent and the documentation is good

- The production of risk summary reports for hazard-food pairs provides a synopsis of the inputs used for the ranking of each hazard-commodity pair
- The prototype can accommodate any number of possible modifications, including improved scientific documentation, incorporation of additional data, accounting for data quality or strength of judgment, or the addition of a feature that accommodates the input of confidence intervals for input and output estimates.

Model Limitations

- FHRR/iRisk may be considered by some as an oversimplification of the farm-to-fork chain
- Gaps in many of the data inputs may limit reliability of the risk estimates
- The uncertainty bounds of the model are inherently large given the simplified, three-category representation of the food system and reliance on expert opinion to develop the inputs; the current model does not overcome any fundamental uncertainty and right now, there is no quantitative way to measure uncertainty and variability in the inputs and outputs
- Requires substantial scientific expertise and training on the part of the user.
- The web-based version (iRISK) is not populated with defined data sets (such as consumption or dose-response relationships), meaning that the user must personally enter all data into the database; this is a time-consuming process.

II.4 Risk Ranking Examples in Other Disciplines

Other disciplines have taken a variety of approaches to risk ranking. This section discusses the application of risk ranking to evidence-based medicine (Section II.4.1) and the impact of pharmaceuticals on the aquatic environment (Section II. 4.2). We also describe a recent application of the Delphi technique to food safety (Section II. 4.3), a risk ranking approach to compare the environmental impact of veterinary pharmaceutical substances (Section II. 4.4), and correspondence analysis (Section II. 4.5). Additional approaches are summarized in Section II. 4.6.

II.4.1 Evidence-Based Medicine Approach

Björkstén et al. (2008) used an evidence-based medicine approach to rank (and prioritize) a list of allergenic foods that are of sufficient public health importance to be included in allergen lists. The attributes include clinical issues (diagnosis, potency of allergen, severity of reactions), population elements (prevalence, exposure), and modulating factors (food processing). In the process, the investigators developed a set of criteria on which to evaluate the scientific literature based on quality, relevance, and statistical power. Each piece of evidence was given a relative weight ranging from 1 (strong, associated with several well designed studies) to 5 (weak, an expert opinion based on limited data or theoretical considerations). Thereafter, a systematic process was applied to (1) determine whether the allergen in question caused immunoglobulin E (IgE)–mediated food allergy; (2) evaluate all the other criteria (e.g., potency, severity of reaction, prevalence of the allergen in the population, and exposure to the allergen in the population characteristics) and weight the strength of evidence; and (3) determine if the allergen is of public health concern. Björkstén et al. use the example of ranking the quality of evidence for egg as a

food allergen of public health importance. Several clinical studies have proven the IgE-mediated mechanism or allergenicity (rank of 1). Scores for prevalence of the food allergy across the population based on severity (rank of 1), potency (rank of 2), and exposure (rank of 1) were assessed and plotted on a graph, where the x-axis represents the potency (as a ratio of the severity of the adverse reaction to the potency of the dose required to elicit reaction) and the y-axis represents the likelihood of an adverse reaction. Based on such graphs, foods can then be categorized as "minor allergenic foods" (those with low severity and likelihood), "emerging allergenic foods" (those with moderate severity and likelihood), or "major allergenic foods requiring risk management measures" (those with high severity and likelihood). Based on the outcome of the ranking scheme, and because eggs are a well characterized and fairly common allergenic food, they were recommended for mandatory labeling.

Björkstén et al.'s evidence-based medicine approach has several appealing features. First, it is based on the classic risk assessment paradigm to identify a hazard (allergenic foods), assess the hazard (prevalence, severity of reactions, allergenic potency), assess the exposure (e.g., use of food, form of allergen in food, evidence of impact of processing), and perform risk characterization. Second, it provides a concrete set of criteria by which to evaluate the strength and quality of scientific evidence associated with the inputs. However, the division of allergens into the three possible groups is based on the ranks in each category for each specific allergen, and there is no mathematical model to combine these scores. Therefore, the assigning of allergens into one of the three potential outcomes is arbitrary. This approach was developed to support decision making as to which allergenic foods are of sufficient public health importance through a systematic and consistent evaluation of the evidence to help facilitate dialog among stakeholders and risk managers from different geographical jurisdictions. The framework developed in this approach may be applicable and useful in other aspects of food safety.

II.4.2 Risk Ranking of Pharmaceuticals Based on Aquatic Environmental Impacts

Cooper et al. (2008) ranked (and prioritized) pharmaceuticals on the basis of their aquatic environmental impacts using a two-step process: (1) compilation of a preliminary risk assessment database for common pharmaceuticals; and (2) risk ranking based on five different combinations of the physical-chemical and toxicological data. The database was built from the scientific literature, various online sources, and regulatory and drug manufacturer information. The drugs were ranked for potential environmental exposure and risk-based combinations of the following attributes:

- Annual prescriptions dispensed
- Surface water concentrations
- Effluent concentrations
- Environmental and biological half-lives
- Mammal, fish, and crustacean toxicity
- Octanol-water partition coefficient (K_{ow})
- Solubility
- Toxicity values in the Ecological Structure Activity Relationship (ECOSAR) online database (U.S. EPA, 2009).

Five different combinations of the physical-chemical and toxicological data sets were used to do five rankings of the pharmaceuticals (e.g., ECOSAR data only, All data categories, All data minus the ECOSAR data, Most data [pharmaceuticals with the most data to minimize uncertainty], and Aquatic Environment data [drug categories that best describe environmental transport, fate, and aquatic toxicity]). The values of each individual attribute were compiled and converted to the same units (e.g., all aquatic toxicity values were converted to mg/L), and then active pharmaceutical ingredients were ranked in each attribute category. All values for each attribute for each active pharmaceutical ingredient were then summed to create an overall ranking value. An uncertainty value was calculated for each active pharmaceutical ingredient to estimate the amount of missing data for each drug. The main finding of the study was that central nervous system, cardiovascular, and anti-infective drugs were heavily represented in the top 100 ranked drugs, and that anti-infective agents appeared to pose the greatest overall risk based on environmental transport, fate, and aquatic toxicity.

This is a very simple risk ranking model in which the investigators included only pertinent variables for which ample data were available. Although the model is data driven, the exclusion of agents for which data are lacking may bias the rankings (because an absence of data does not necessarily mean an agent poses little risk). The approach does not translate literally to microbiological food safety issues because of differences in the environmental behaviors of microbes and chemicals. However, the concept of creating a database of pertinent microbial information and then using a simple summation ranking scheme to prioritize according to highest risk could be applicable to food safety.

II.4.3 Delphi Technique

Hillers et al. (2003) applied a four-round Delphi technique to rank consumer food handling behaviors associated with the transmission and potential prevention of illnesses caused by 13 foodborne pathogens. Briefly, the Delphi method is a systematic, interactive forecasting method that relies on a panel of independent experts. The experts answer questionnaires in two or more rounds, and after each round, a facilitator provides a summary of the experts' responses. In the next round, the experts rank the issues at hand with knowledge of how the entire panel ranked everything in the first round. The intent is that the large range of responses will decrease with each round and that the group will eventually converge towards a consensus answer. The process stops after a predefined criterion (e.g., number of rounds, consensus, or stability of results), and the mean or median scores of the final rounds determine the results.

Hillers et al. (2003) used a panel of nationally recognized food microbiology experts. In the first round, the experts were asked to edit (by adding to or deleting from) a list of food handling behaviors compiled from a literature search. In the second round, they ranked these behaviors for each of the 13 pathogens according to the importance of that behavior in preventing illness, with the most important behavior scored at 1, and the least important given the highest score. The third round focused on the classification of food handling behaviors into five major categories: personal hygiene, adequate cooking, avoidance of cross-contamination, maintenance of foods at safe temperatures, and avoidance of food from unsafe sources. This round was also used to identify the behaviors most likely to be associated with reducing the risk of foodborne illness among high-risk populations. In the fourth and final round, the experts ranked the combinations of food handling behavior and pathogen again, and a mean rank score was calculated by averaging the rankings, using the same importance scales described above. By way of example,

the study found that the use of a thermometer during cooking was of primary importance in preventing illness caused by *Campylobacter jejuni*, *Salmonella* spp., *E. coli* O157:H7, *Toxoplasma gondii*, and *Yersinia enterocolitica*.

The Delphi technique does not require empirical data per se, which has its strengths and weaknesses; it may be appropriate in situation where limited data are available, but it suffers from the inherent disadvantages of expert elicitation. However, by careful design of the expert panel, the investigator can get a full range of opinions (estimates) on inputs; total agreement is not necessarily expected, and without it, one can obtain some estimate of uncertainty. The method is a highly structured and a transparent means by which to compile expert knowledge for use in risk ranking.

II.4.4 Risk Ranking of Veterinary Pharmaceutical Substances for Environmental Impact

Kools et al. (2008) developed a risk-based ranking tool to rank (and prioritize) European veterinary pharmaceutical substances that have potential environmental impacts and should therefore be considered as candidates for more complex risk assessments. The approach consisted of four steps: (1) compilation of active pharmaceutical substances (usage estimation); (2) exposure characterization (dung, soil, surface water, and aquatic organisms); (3) effects characterization (based on therapeutic doses); and (4) risk characterization (ratio of exposure to effects, or risk index). The agents were ranked according to four exposure scenarios: intensively reared animals, pasture animals, companion animals, and aquaculture. A total of 233 active veterinary medical products that had sufficient information for the four exposure scenarios were compiled from European Union databases.

The predicted environmental concentrations (PECs) of the veterinary medical products were calculated for the four different exposure scenarios using straightforward models and formulas. For example, the PEC in surface water (µg active substance (a.s.)/L) was calculated as follows:

$$PEC_{sw} = \frac{PEC_{soil}}{(K_{oc} \times f_{oc} \times 10)}$$

where

PEC_{soil}	=	predicted environmental concentration in soil (µg a.s./kg soil)
K_{oc}	=	organic carbon normalized soil sorption coefficient (L/kg soil)
f_{oc}	=	fraction of organic carbon in the soil (kg oc/kg soil)
10	=	default dilution factor when runoff enters surface water after a rain event.

Next, lowest therapeutic doses (TD_{low}) were used as a surrogate for ecotoxicological effects, where biological concentration factors (BCFs) were normalized for therapeutic dose–based ecotoxicity predictions (TD_{low}/BCF). Finally, risk indices were calculated (e.g., RI_{soil} = PEC_{soil}/TD_{low}) for each pharmaceutical in soil, dung, surface water or aquatic organisms. A frequency of use index was also determined to reflect the likelihood of widespread use (in tonnage). The risk index and frequency of use indices were used to rank the veterinary medical products. In general, the top-ranked substances were antibiotics and parasiticides. Distinct

differences appeared between intensively reared animals, where anticoccidia are used as feed additives in large doses over a long time (ranked higher), versus pastured animals, where anticoccidia are seldom or rarely used (ranked lower).

This risk ranking approach was particularly simple, using concepts that can be easily applied to a large number of veterinary pharmaceuticals without requiring extensive expert knowledge. It was also applicable to situations in which ecotoxicological data were absent. However, the approach is not directly applicable to microbiological food safety because the equations used to estimate chemical concentrations and dosage will not translate to microbes. However, the conceptual model could be used by modifying the equations to reflect microbial prevalence, growth and inactivation schemes, and other factors relevant to microbes. Nonetheless, the concepts behind the equations used for chemicals may be too simple to capture the complex processes of microbes in animals and the environment.

II.4.5 Correspondence Analysis

Salguerio et al. (2008) used correspondence analysis as a qualitative prediction tool to assess the risk of large-scale spills in mine tailing dams. The method relies on a historical database containing two sets of qualitative data: 1) variables that are observable before an "event" or dam failure (e.g., type and size of dam, location), and 2) variables that concern the consequences of the "event" (e.g., dam failure type, sludge characteristics, downstream range of damage). The approach consists of four steps:

1. Extract a set of observable "predictor" variables (in this case, size, type of dam, dam fill material, location, failure type, fatalities, downstream range of damage) for a new case for which the investigator intends to estimate risk of failure and place them in a complete disjunctive (or indicator) matrix

2. Select a set of qualitative variables from the database that are linked to the failure episode and resulting damage and place in a similar matrix

3. Establish a specific graphical relationship between the two matrices by projecting the qualitative matrix onto factorial axes resulting from the eigenvalue decomposition of the predictor matrix through the corresponding analysis algorithm (factorial axes are a transfer function between the two matrices)

4. Use the relationship given by Step 3 to forecast the modalities in which the quantitative variables fall, giving a new matrix that will outline the levels of risk.

This method uses three mathematical equations: (1) correspondence analysis of one matrix onto another under the complete disjunctive format; (2) the relative contribution of one axis to modality, which is parallel to a correlation coefficient in regression analysis; and (3) the new, or generated, matrix that is then projected onto the previously obtained axes with a third equation. Using this method, the investigators were able to prioritize Mediterranean mines for review to prevent future breakages.

The approach is mathematically rigorous but based on empirical data. Salguerio et al. found their results to be robust and were able to validate them at actual test sites and by expert knowledge.

The method might be applicable to food safety if a historical database of certain observable qualitative variables existed or could be compiled (e.g., farm location, farm size, type of produce, frequency and type of irrigation) and if there were existing data on the same input variables for which outbreaks have occurred in the past. The correspondence analysis method could then be used to generate an empirical scale of risk from which guidelines for prioritizing further data collection might be derived. In this way, past history could potentially be used to predict future behavior of, for instance, an emerging pathogen or chemical agent that had features similar to better characterized agents.

II.4.6 Other Approaches

An overview of recent applications of risk ranking in a variety of other fields is provided in **Table II-7**, including the five discussed above. This is not a full inventory, as that is beyond the scope of this document.

Table II-7. Candidate Risk Ranking Methods/Models and Their Applications

Method/Model	Applications	Variables	References
Ranking from evidence-based medicine: allergenic foods	Used to decide which allergenic foods are of sufficient public health importance to be included in allergen lists	Clinical (diagnosis, potency of allergen, severity of reactions), population (prevalence, exposure), modulating factors (food processing)	Björkstén et al. (2008)
Risk ranking: pharmaceuticals	Preliminary risk assessment database of pharmaceuticals used to prioritize those that threaten the environment and aquatic life	Five different combinations of physical-chemical and toxicological data	Cooper et al. (2008) http://www.chbr.noaa.gov/peiar/
Delphi technique for risk ranking: food-handling and consumption	Expert elicitation technique used to identify and rank food-handling and consumption behaviors associated with 13 major foodborne pathogens	Safe temperatures, thermometer use, avoidance of cross-contamination, hand washing	Hillers et al. (2003)
Risk-based ranking: veterinary pharmaceuticals	Used to assess the potential for environmental risks of active substances of veterinary medicinal products	Four exposure scenarios (soil, surface water, aquatic organisms), i information on drug usage and dose	Kools et al. (2008)
Correspondence analysis (qualitative prediction tool)	Used to determine risk of breakage in mine tailings dams	Historical qualitative data (size, type of dam, location, failure type, fatalities, downstream range of damage)	Salgueiro et al. (2008)
Multicriteria decision analysis: toilet selection	Used to evaluate the use of NoMix urine separating toilets for managing environmental risk and postponing expensive upgrades to a large wastewater treatment plant	Ranking of alternative technology pathways on the basis of technical, financial, and social concerns	Borsuk et al. (2008)

Method/Model	Applications	Variables	References
Risk ranking: chemical release	New index used for environmental risk management considering both toxicity and release amount of chemicals	Toxicity data; reference concentrations; toxicity-weighted release amount for human health protection in water, atmosphere, and aquatic life	Nakamura et al. (2008)
Risk ranking: transgenic plants	Used to prioritize nontarget invertebrates for risk analysis regarding transgenic plants	Risk presented by plant to invertebrate species; environmental impact; economic, social, and cultural values for each species	Todd et al. (2008)

II.5 Comments and Recommendations

II.5.1 Criteria for Risk Ranking Model Selection

The first consideration in recommending a candidate risk ranking model is that its analytical framework is appropriate or "fit for purpose." The model recommended from the information gathered in this task order will be used as the basis for Task Order #3 (*Public Health Risk Assessment for FDA-Regulated Commodity/Hazard Combinations Using Risk Ranking Methodology and Tools*). The specific goal of Task Order #3 is to critique and implement a systematic public health risk assessment for FDA-regulated products that considers the relative ranking of commodity-hazard pairs. The FDA has identified the following functional features upon which to base the choice of a recommended risk ranking approach:

1. Consists of two modules: a predictive, multistage (farm-to-fork) process risk module and a hazard characterization module
2. Can rank and compare chemicals and microbiological agents in a single model
3. Readily adaptability to multiple agents or commodities without the need to change modeling approach or code
4. Can group agents or commodities consistent with the Domestic Priorities List
5. Clearly documents assumptions
6. Considers/characterizes uncertainty in the modeling approach.

In Task Order #2, we operationalized these general functional features into a set of criteria (i.e., specific model attributes) with which we could compare and contrast all of the candidate risk ranking models that have been specifically applied to food safety. The models were scored on the following criteria:

- **Scientific credibility (Sci Cred):** The model is scientifically sound and supported by high-quality data
- **Characterization of uncertainty (CoU):** The model provides uncertainty analysis in both model design and in model output
- **Transparency (Trans):** Both the structure and the data incorporated in the model are readily discernible and explained to the analyst
- **Documentation (Doc):** The model software allows the user to input comments or documentation to support rankings for any input or factor

- **Balance (Bal):** The model has the appropriate balance of resolution and dimensionality such that it is both detailed enough while maintaining a relatively simple structure
- **Ease of use (EoU):** The model can be used with a minimal amount of training on the part of the user
- **Flexibility (Flex):** The analyst can choose from among several ranking parameters and data sets and can alter many of the assumptions underlying the model and data
- **Adaptability (Adapt):** The model can be updated readily as new data become available
- **Accessibility (Access):** The model is readily available and can be designed to be web accessible or downloaded to PCs without the need for extensive additional software
- **Usefulness (Use):** The model provides information which facilitates ranking or prioritization in a systematic manner
- **Applicability (Appl):** The model is applicable to the desired use, which includes comparison of hazard-commodity pairs over a wide range of food products, considering the complete farm-to-fork continuum, and including both microbial and chemical hazards

The criteria were scored as follows:

– Poor
0 Unknown or neutral
+ Good
++ Excellent
NA Not applicable.

Table II-8 presents the specific scores for each of the candidate food safety models; the abbreviations of the criteria used in the header row are shown above in the list of criteria.

Table II-8. Evaluation of Risk Ranking Strategies for Applicability for Intended Use

Method	Sci Cred	CoU	Trans	Doc	Bal	EoU	Flex	Adapt	Access	Use	Appl
Semiquantitative Food Safety Risk Ranking Approaches											
FIRRM	++	+	++	++	++	–	++	+	++	++	–
FSUDB	++	0	++	+	++	0	+	+	–	++	+
FHRR/iRISK	++	+	++	++	++	–	++	+	++	++	++
Risk Ranger	+	–	+	0	++	++	–	+	++	+	0
FSRRPM	+	–	+	–	0	+	–	+	+	+	–
Qualitative Food Safety Risk Ranking Approaches											
FAO-WHO	0	–	+	–	–	+	–	–	NA	+	–
CFSAN	0	–	+	–	–	+	–	–	NA	+	0
Carnegie-Mellon	+	–	+	–	0	++	–	–	NA	+	+

II.5.2 Justification for Recommendation

None of the models scored good (+) or excellent (++) for all of the attributes listed above. Three models came close: FIRRM, FSUDB, and FHRR/iRISK. Therefore, the justification for our final recommendation will focus on a comparison of these three top-ranked models.

The first means by which to judge these models was by whether they meet all six functional features. FIRRM does not meet functional features 1 and 2: it does not contain either a predictive, multistage process risk model, nor does it have a hazard characterization module (thus, it gets a score of poor [–] for applicability). Rather, as a topdown epidemiological model, FIRRM infers the level of risk due to foods, hazards, or their combinations based on information gathered by epidemiological observation systems, such as active or passive disease reporting systems and outbreak databases. Although this approach may be considered advantageous because it reflects risk at the consumer (patient) level, it does not allow the user to take into consideration the product's life cycle from production to consumption. In addition, because of the principle reliance on epidemiological surveillance data (which is not broadly available for chemical agents), the topdown epidemiological approach is not well suited for comparing risks associated with microbes and chemical agents in a single model. This is apparent in the absence of a chemical ranking component in FIRRM.

The two remaining models, FSUDB and iRISK, ranked identically on scientific credibility, transparency, balance, adaptability, and usefulness. For example, both are able to rank chemical and microbial hazards against one another and should be applicable to evaluation of both accidental and intentional contamination scenarios. Both models have high resolution within hazard and food categories; in other words, both are designed to allow for categorization of the hazards and foods into logical subcategories that are relevant from control and regulatory standpoints. The description of inputs and scoring for each of the models is relatively transparent and based on sound scientific justification. Likewise, both models are theoretically adaptable upon the availability of new data and accessible via the web. Both are coded in Microsoft Access and allow for the creation of databases. In addition, both make ample use of pull-down screens and point-and-click icons, which facilitate use. Both models are appropriately balanced, although iRISK is somewhat more complicated than FSUDB.

There are, however, a number of differences between the models that can be used in making a recommendation. Perhaps most important is the issue of applicability. iRISK is obviously a predictive process risk model that considers the three phases in the farm-to-fork continuum (production, processing, and distribution/end user) and includes a hazard characterization module, corresponding to functional feature 1. As such, this approach is in keeping with the classic microbial risk assessment paradigm (which includes separate exposure assessment and hazard characterization). FSUDB has roughly the same structure if one considers the Probability module as addressing exposure and the Impact module as a form of hazard characterization. However, FSUDB modules do not provide the degree of resolution that iRISK does. For example, FSUDB does not have a dose-response function.

Another major difference is in the dimensionality of the two models. The iRISK model works in two dimensions, such that the user specifies the agent and the food and then proceeds with modeling across the continuum. FSUDB works in three dimensions: agent, food, and location in the food chain. Therefore, the FSUDB output is specific for location in the food chain.

According to the FSUDB documentation, the user can compare the impacts of the various phases in the farm-to-fork continuum because the model is coded to allow the user to average and sum scores across hazards, foods, and locations along the food chain. The user is, however, cautioned to scrutinize this function so that a "biased view is avoided" (OMAF, 2003).

FSUDB and iRISK also differ with respect to flexibility, documentation, and accessibility. From a flexibility standpoint, iRISK is coded so that the user has the option to include or exclude any foods, hazards, or specific hazard-food combinations. This allows the user to consider a full range of comparisons, including a single agent transmitted by multiple foods, a single food contaminated with different agents, or user-designed specified combinations of agent-food pairs. It would also facilitate comparisons between agent-hazard pairs to compare seasonal, temporal, or geographic impacts on hazard prevalence or total number of contaminated servings. iRISK also allows the user to compile consumption data for four population groups, and users may specify what percentage of a given population is at risk for a particular simulation. On the other hand, FSUDB captures information that allows comparison of risk scores by food source, type of establishment, and regulatory authority responsible for the food. FSUDB can be manipulated to produce scores as applied to specific segments of society (e.g., susceptible subpopulations, age-related differences in consumption patterns); however, in its current state, this can only be done by maintaining separate data records for very specific food-hazard-location combinations.

With respect to documentation, the software associated with FSUDB allows the user to capture notes on references; explanations of scoring; and who assigned or changed scores, when, and why. FSUDB also allows the user to record potential tools to control risks for that hazard-food-location combination, as well as the type of establishment and regulatory authority responsible for the food. Although the prototype (FHRR) of iRISK does not necessarily provide for such detailed documentation, the web-based iRISK model has been upgraded to allow the user to input substantial documentation and justification for parameter estimates entered into the model.

The iRISK model is web-accessible as long as the user has received appropriate clearance. The user creates his/her own personal database, but users can share their databases with others by providing the appropriate specifications within their workspace. The FSUDB database and associated algorithms are not available in the public domain and availability to the agency would need to be negotiated with the developer/sponsor.

While both models consider uncertainty, FSUDB is somewhat less sophisticated. For example, FSUDB collects user uncertainties about probability and impact subscores using an uncertainty score of 1 (negligible uncertainty) to 10 (extreme uncertainty); these uncertainty scores are used in algorithms programmed into the database to place a type of confidence interval on the calculated point estimates of risk. On the other hand, iRISK allows the user to specify distribution type for several inputs in the process section of the exposure module. Further, in risk ranking, iRISK is coded to use Monte Carlo simulation to compute a range of doses based on the concentration of the hazard in the food and the average serving size. The embedded use of Monte Carlo simulation provides for a more rigorous consideration of uncertainty by iRISK that is not captured by FSUDB. Nonetheless, in an ideal world, both parameter and user uncertainty would be captured by the recommended model. In point of fact, the creators of iRISK do acknowledge the need to further develop uncertainty characterization in future versions of the model.

The models also differ in a few ways not captured by the scoring criteria. One of these is described as differences in outputs and reporting capabilities.. Specifically, FSUDB produces only two outputs (per-serving risk and societal risk), while the iRISK model has a much more sophisticated reporting system. Specifically, iRISK provides a basic mechanism that reports back selected contents of the database (the evidence) according to foods, hazards, processes, and their combinations. The iRISK also produces much more detailed outputs in the form of risk summary reports for hazard-food pairs; these reports provide information on the pertinent dose-response model(s) and parameters and the impact on hazard concentration and prevalence of primary production, processing, and the combined steps of distribution, storage, retail, food service, and home. In short, the iRISK output is more in keeping with what might be produced by a traditional quantitative risk assessment model.

Another difference that makes the iRISK model particularly appealing is the inclusion of a public health metric (in the form of the pDALY). Although we recognize the need to further evaluate the appropriateness of the pDALY approach, the production of a public health metric (instead of a simple rank or risk estimate, as is produced by FSUDB) adds value to the risk ranking exercise. Specifically, the pDALY approach allows for harmonization of the burden of disease across a broad spectrum and frequency of health outcomes, which vary widely among hazards. It also provides an output more in keeping with the traditional risk assessment paradigm.

II.5.3 Recommendation

Food safety risks, like risks in other sectors of society, are inherently complex and differ from one another in ways that make it difficult to compare one agent to another in any sort of simplified manner. Consequently, assumptions must be made and all approaches to risk ranking include some degree of subjectivity and uncertainty. This was common to all the models reviewed in this report, as was a general lack of available scientific data, or at the very least, gaps in the science. Nonetheless, based on our analysis, we recommend that the FDA give preference to the iRISK model for future risk ranking efforts for the following reasons:

- The iRISK model is currently available to the FDA in both formats (Analytica and web-based); access to some of the other models (particularly FSUDB) may be more difficult due to restrictions imposed by their sponsoring agencies.

- Of all the models evaluated, iRISK excels on applicability because it is the only model that consists of two distinct modules representing both a predictive, multistage (farm-to-fork) process risk module and a hazard characterization module.

- iRISK also excels in adaptability. Its creators state that the prototype can accommodate any number of possible modifications, including improved scientific documentation, incorporation of additional data, accounting for data quality or strength of judgment, or the addition of a feature that accommodates the input of confidence intervals for input and output estimates.

- The iRISK scores are equal to or better than the scores of all other models with respect to scientific credibility, characterization of uncertainty, transparency, flexibility, balance, accessibility, and usefulness. Particularly strong features of iRISK are its scientific

grounding, use of a public health metric for estimation of risk, excellent software features, and the provision of a full range of details in the reporting phases.

§ Although iRISK (and the FIRMM and FSUDB models, for that matter) require more extensive user training than do some of the simpler risk ranking models, the added value provided by iRISK justifies the more rigorous training requirements.

II.6 References

Batz, M. 2007. *An approach to ranking microbial foodborne hazards*. Presented at the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) Workshop, Tools for Prioritizing Food Safety Concerns, Greenbelt, MD. June 4–6. Available at www.jifsan.umd.edu/presentations/tools_2007/PDF/6.Batz_JIFSAN_Food_Safety.pdf (accessed December 9, 2008).

Batz, M., S.A. Hoffmann, A.J. Krupnik, J.G. Morris, D.M. Sherman, M.R. Taylor, and J.S. Tick. 2004. *Identifying the most significant foodborne hazards to public health: a new risk ranking model.* The Food Safety Research Consortium Discussion Paper Series (1). Available at http://www.thefsrc.org/Discussion%20Papers/FRSC-DP-01.pdf (accessed December 9, 2008).

Björkstén, B., R. Crevel, C. Hischenhuber, M. Lovik, F. Samuels, S. Strobel, S.L. Taylor, J.M. Wal, and R. Ward. 2008. Criteria for identifying allergenic foods of public health importance. *Regul. Toxicol. Pharmacol.* 51(1):42–52.

Borsuk, M.E., M. Maurer, J. Lienert, and T.A. Larsen. 2008. Charting a path for innovative toilet technology using multicriteria decision analysis. *Environ. Sci. Tech.* 42(6):1855–1862.

Buzby, J.C., T. Roberts, C.T.J. Lin, and J.M. Macdonald. 1996. *Bacterial Foodborne Disease: Medical Costs and Productivity Losses.* AER-741. U.S. Department of Agriculture, Economic Research Service, Washington, DC.

Cooper, E.R., T.C. Siewicki, and K. Phillips. 2008. Preliminary risk assessment database and risk ranking of pharmaceuticals in the environment. *Sci. Total Environ.* 398(1–3):26–33.

FAO-WHO (Food and Agriculture Organization of the United Nations and World Health Organization). 2008. *Microbiological hazards in fresh fruits and vegetables*. Microbiological Risk Assessment Series, Meeting Report (prepublication version). Available at www.who.int/entity/foodsafety/publications/micro/MRA_FruitVeges.pdf (accessed January 13, 2009).

Florig, H.K., M.G. Morgan, K.M. Morgan, K.E. Jenni, B. Fischhoff, P.S. Fischbeck, and M.L. DeKay. 2001. A deliberative method for ranking risks (1): Overview and test bed development. *Risk Anal.* 21:913–921.

FSCR (Food Safety Research Consortium). 2004. *Methodology primer for the Foodborne Disease Risk Ranking Model*. Available at www.card.iastate.edu/food_safety/papers/FIRRM_Primer_for_Conf.pdf (accessed December 9, 2008).

Havelaar, A., and Melse, J.M. 2003. *Quantifying Public Health Risk in the WHO Guidelines for Drinking-Water Quality: A Burden of Disease Approach.* Rijkinstituut voor Volskgezondheid en Milieu (RIVM), Bilthoven, Netherlands. RIVM Report 734301022

Hillers, V.N., L. Medeiros, P. Kendall, G. Chen, and S. DiMascola. 2003. Consumer food-handling behaviors associated with prevention of 13 foodborne illnesses. *J. Food Prot.* 66(10):1893–1899.

Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2007. Using expert elicitation to link foodborne illness in the U.S. to Food. *J. Food Prot.* 70:1220–1229.

Kools, S.A., A. Boxall, J.F. Moltmann, G. Bryning, J. Koschorreck, and T. Knacker. 2008. A ranking of European veterinary medicines based on environmental risks. *Integr. Environ. Assess. Manag.* 4(4):399–408.

Mead, P.S., L. Slutsker, V. Dietz, L.F. McCraig, H,S, Bresee, C. Shapiro, P.M. Griffin, and R.B. Tauxe. 1999. Food-related illness and death in the United States. *Emerg. Infect. Dis.* 5:607–625.

Nakamura, J., N. Azuma, T. Kameya, T. Kobayashi, and K. Urano. 2008. Analysis of the toxicity-weighted release amount ranking of PRTR chemicals in Japan. *J. Environ. Sci. Health. Part A, Tox. Hazard Subst. Environ. Eng.* 43(5):452–459.

Newsome, R., N. Tran, G.M. Paoli, L.A. Jaykus, B. Tompkin, M. Miliotis, T. Ruthman, E. Hartnett, F.F. Busta, B. Petersen, F. Shank, J. McEntire, J. Hotchkiss, M. Wagner, and D.W. Schaffner. In press. Development of a Risk Ranking Framework to Evaluate Potential High Threat Microorganisms, Toxins, and Chemicals in Food. Submitted to *J. Food Sci.*, December 8, 2008.

NZFSA (New Zealand Food Safety Authority). 2006. *Food Sector Risk Ranking and Prioritization Model: The Methods. Domestic Food Review.* Available at www.nzfsa.govt.nz/policy-law/projects/domestic-food-review/risk-ranking/riskranking-methods.pdf (accessed November 5, 2008).

OMAF (Ontario Ministry of Agriculture and Food). 2003. *Food Safety Universe Database: A Semi-Quantitative Risk Assessment Tool.* Draft. V7, November 3. Available at https://ospace.scholarsportal.info/bitstream/1873/6231/1/10318750.pdf (accessed November 17, 2008).

Paoli, G. 2008a. *Introductory workshop on the web-based tool to evaluate food risk.* Decisionalysis Risk Consultants, Inc., Ottawa, Ontario, Canada. Presented in Washington DC, October 24.

Paoli, G. 2008b. *Risk Registry User Manual*. Decisionalysis Risk Consultants, Inc., Ottawa, Ontario, Canada. September. Available at http://foodrisk.org/exclusives/iRISK/index.cfm (accessed December 9, 2008).

Ross, T. and J. Sumner. 2002. A simple, spreadsheet-based, food safety risk assessment tool. Int. *J. Food Microbiol.* 77:39–43.

Salgueiro, A.R., H.G. Pereira, M.-T. Rico, G. Benito, and A. Diez-Herreo. 2008. Application of Correspondence Analysis in the Assessment of Mine Tailings Dam Breakage Risk in the Mediterranean Region. *Risk Analysis* 28(1):13–23.

Sumner, J and T. Ross. 2002. A semi-quantitative seafood safety risk assessment. *Int. J. Food Microbiol.* 77:55–59.

Sumner, J., T. Ross, and L. Ababouch. 2004. *Application of risk assessment in the fish industry*. FAO Fisheries Technical Paper 442, FAO-WHO, Rome, Italy. Available at http://www.fao.org/docrep/007/y4722e/y4722e00.htm.

Sumner, J., T. Ross, I. Jenson, and A. Pointon. 2005. A risk microbiological profile of the Australian red meat industry: Risk ratings of hazard-product pairings. *Int. J. Food Microbiol.* 105:221–232.

Todd, J.H., P. Ramankutty, E.I. Barraclough, and L.A. Malone (2008). A screening method for prioritizing non-target invertebrates for improved biosafety testing of transgenic crops. *Environ Biosafety Res.* 7(1):35–56.

USDA (U.S. Department of Agriculture). 2003. *Foodborne Illness Cost Calculator. USDA Economic Research Service.* Available at http://www.ers.usda.gov/data/foodborneillness (accessed December 9, 2008).

U.S. EPA (Environmental Protection Agency). 2009. *Ecological Structure Activity Relationships (ECOSAR)*. Version 1.00a. Available at http://www.epa.gov/oppt/newchems/tools/21ecosar.htm.

U.S. FDA (Food and Drug Administration). 2002. *Food Safety Survey: Summary of Major Trends in Food Handling Practices and Consumption of Potentially Risky Foods.* Center for Food Safety and Applied Nutrition, Consumer Studies Branch. Available at http://www.cfsan.fda.gov/~dms/fssurvey.html.

U.S. FDA (Food and Drug Administration). 2003. *Quantitative Assessment of Relative Risk to Public Health from Foodborne* Listeria Monocytogenes *Among Selected Categories of Ready-to-Eat Foods.* U.S. FDA Center for Food Safety and Nutrition with the U.S. Department of Agriculture's Food Safety and Inspection Service and the Centers for Disease Control and Prevention. September. Available at http://www.foodsafety.gov/ ~dms/Lmr2-toc.html.

Webster, K.D., C.G. Jardine, L. McMullen and S.B. Cash. 2008. *Risk Ranking: Investigating Expert and Public Differences in Evaluating Food Safety Risks.* Department of Agricultural, Food and Nutritional Science and Department of Rural Economy, University of Alberta, Alberta, CA. Available at http://ageconsearch.umn.edu/bitstream/6378/2/pr080002.pdf (accessed January 13, 2009).

III. Risk Prioritization

III.1 Introduction

Risk prioritization uses tools of both risk assessment and decision analysis to determine the importance of one risk relative to another, usually in the context of mitigation. Risk prioritization is multifactorial in that it considers a whole cadre of factors (in addition to public health) that might influence prioritization. For example, the Food and Agriculture Organization of the United Nations (FAO)–World Health Organization (WHO) guidelines on microbial risk assessment in food safety (FAO-WHO, 2006) identify factors such as economic burden and facilitation of fair trade as key prioritization considerations. Others factors might include food attribution, risk perception, social sensitivity, and practicality of control (Henson et al., 2008). It should be apparent that there is a role for other disciplines such as economics and social psychology in the design and implementation of risk prioritization models. Unlike risk ranking, which is more of a risk assessment exercise, risk prioritization is inherently used as a risk management tool. This document evaluates tools and their potential application to risk prioritization with a focus on the comparative evaluation of mitigation alternatives and the allocation of resources to support those alternatives.

Many decisions are influenced by multiple potentially competing objectives. For example, in its mission to protect the public food supply, FDA may consider the following:

- Minimizing negative public health impact
- Minimizing negative economic consequences of actions
- Minimizing cost (budgetary limitations)
- Considering the concerns of various stakeholder (e.g., the public, farmers, food processing industry)
- Increasing the understanding and characterization of uncertain food safety issues.

Potential alternative actions, such as facility inspections, public outreach, and research, achieve these various objectives to differing degrees, and a single alternative typically will not outperform other alternatives with respect to all objectives. Therefore, decision making can become quite complex, with many competing objectives and alternatives.

The field of multiple criteria decision analysis (MCDA) provides tools to support complex decision making. MCDA approaches are used to systematically structure and model decision problems in multiple dimensions. In so doing, MCDA aids decision making by integrating value judgments, as well as objective, quantitative measurements, within a transparent and systematic framework so that decision makers can achieve a preferred course of action. A primary goal is to achieve a well considered and justified decision and to provide a transparent explanation of the decision's basis (an audit trail). Within this context, it is important to emphasize that MCDA cannot provide an objective "right" answer (Belton and Stewart, 2002), but rather provides enhanced understanding, the explicit weighting of different objectives (e.g., stakeholder concerns), a decision-making structure, and transparency that enable well justified and systematic decisions to be made. One of the particular strengths of MCDA methods is the transparent incorporation of qualitative value judgments into the decision and the ability to consider the influence of alternative value preferences.

The following sections provide a general overview of MCDA (Section III.2), a more detailed review of specific MCDA approaches (Section III.3), example risk prioritization as applied specifically to food safety (Section III.4), and finally, a recommended approach for FDA to develop tools to better enable prioritization of food safety mitigation measures (Section III.5).

III.2 MCDA Overview

This section presents a basic overview of MCDA techniques, including characteristics shared by different approaches. The general MCDA procedural framework, which involves problem structuring and preference modeling, is presented. The next section discusses some common analytic components of MCDA methods, including the development of a performance matrix. Finally, the application of MCDA methods to resource allocation problems and the importance of benefit/cost ratios in maximizing potential benefits for available resources are discussed.

III.2.1 MCDA Procedural Framework

The general procedural framework for decision analysis has several common elements, even though the specific approaches may differ in details. The problem is generally divided into components, which are then analyzed independently. For example, criteria are defined to describe different dimensions of the problem. Once analyzed independently, the components are then aggregated in some way to give insights about the problem as a whole. The MCDA process consists of three basic phases: problem structuring, preference modeling, and sensitivity analysis.

Problem structuring includes defining the decision problem and identifying objectives, stakeholders, alternatives, criteria, and attributes. Alternatives are the potential actions to be compared in the analysis. Criteria are the categories/perspectives from which to compare the alternatives. Attributes measure the performance of a given alternative with respect to each criterion.

In defining the decision-making problem, there is a difference between situations with predefined alternatives and situations with undefined or infinite alternatives. “Discrete” MCDA methods are used in situations with clearly defined alternatives, whereas “continuous” MCDA methods are used in situations with poorly defined or infinite alternatives. An example of discrete alternatives would be the evaluation of specific research grant applications. An example with continuous alternatives would be deciding the percentage of available funds to allot to different investments, where the percentage can vary continuously. Multi-objective optimization methods such as goal programming (discussed further below) have been developed to address continuous MCDA decision problems directly.

Criteria and attributes define the measures that will be used to compare the alternatives. A useful approach for structuring objectives, criteria, and attributes is a value tree (also known as an objectives hierarchy). The high-level objectives within the hierarchy are fundamental objectives that define general goals for the decision makers (e.g., protecting public health, minimizing negative socio-economic impacts). The hierarchy also includes “means” objectives that influence the parent fundamental criteria. The objectives become more concrete at lower levels of the objectives hierarchy and can be thought of as criteria for comparing alternatives. The lower-level objectives/criteria within the hierarchy should be characterized by attributes associated with the

performance of specific alternatives. **Figure III-1** shows an example of a value tree for evaluating stream rehabilitation projects (Hostmann, 2005).

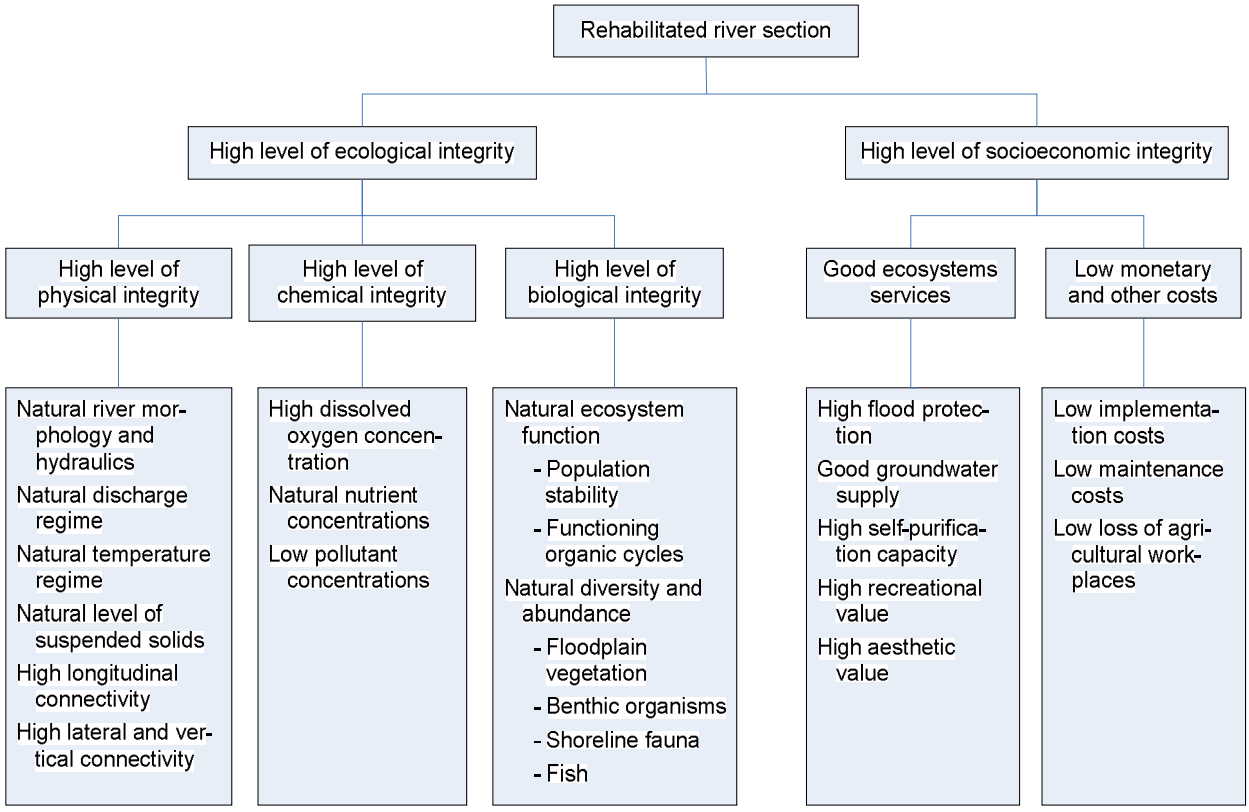


Figure III-1. Example objectives hierarchy (value tree) for evaluating stream rehabilitation projects. Source: Hostmann (2005)

Preference modeling is the next phase in MCDA. As described by Belton and Stewart (2002), preference modeling contains two primary components: evaluating preferences relative to each criterion and developing an aggregation model that combines preferences across criteria and allows comparison of alternatives.

The first component of preference modeling relies on the lowest level/most specific criteria (e.g., as developed in a value tree). These criteria should be defined such that a relatively unambiguous ordering of the alternatives can be developed with respect to each criterion; this ordering should adequately express the preferences of the decision-maker (Belton and Stewart, 2002). The ordering may be based on observable, quantitative measures or value judgments elicited from the decision-makers and stakeholders. If such an ordering is not possible, the decision problem may need to be redefined (e.g., splitting of criteria). The detailed approach for eliciting preferences and ordering the alternatives relative to each criterion varies widely for different MCDA methods.

In the second component of preference modeling, decision-makers specify how important criteria are relative to each other. The relative importance of different criteria may be expressed, for

example, by a weight parameter, with more important criteria having greater weight values. The specific approach for aggregating preferences varies for different MCDA methods.

Sensitivity analysis to analyze the robustness of the results is the final phase of MCDA. Sensitivity analysis identifies the most influential criteria and attributes (objective and value based). Sensitivity analysis also can evaluate the influence of different preference judgments, which may lead to different ranking of the alternatives. In other words, if one criterion were considered more important, then another alternative may exhibit superior performance. The sensitivity analysis phase is critical to fully evaluate the underlying assumptions, uncertainties, and the results of the decision analysis.

The MCDA process is inherently iterative and exploratory. For example, the problem may be restructured (additional alternatives, modified criteria) as understanding is enhanced through later stages of the MCDA process.

III.2.2 MCDA Fundamental Elements and Characteristics

This section describes some of the analytic elements and comparative characteristics of many MCDA approaches. The discussion provides insight into the kinds of information and decisions required by an MCDA analysis and some basic differences between approaches.

The problem structuring phase of the analysis generates a set of n alternatives, a_i ($i = 1, \ldots, n$) and m criteria, Z_j ($j = 1, \ldots, m$). Note that criteria may also be called attributes in some contexts. The criteria should be measurable in the sense that the alternatives can be ordered relative to each criterion (Seppälä et al., 2002). The measurement scale may be based on an inherently quantitative measure (e.g., an estimated health outcome), or it may be based on some ordinal scale representing qualitative judgments of the decision-maker (e.g., strongly preferred, preferred, not preferred). The score for alternative i relative to criterion j can then be expressed as $z_j(a_i)$, with all scores represented in the following performance matrix:

		Criteria			
		Z_1	Z_2	L	Z_m
	a_1	$z_1(a_1)$	$z_2(a_1)$	L	$z_m(a_1)$
Alternatives	a_2	$z_1(a_2)$	$z_2(a_2)$	L	$z_m(a_2)$
	M	M	M	L	M
	a_n	$z_1(a_n)$	$z_2(a_n)$	L	$z_m(a_n)$

Once the various alternatives are scored relative to each criterion, the values for all criteria are aggregated in some way to allow comparison of alternatives. Many of the MCDA approaches require the criteria values to be transformed into some normalized scale so that inter-criteria values can be compared. For example, the common dimension might be monetary value or a dimensionless scale between zero and one, with one representing the highest scoring alternative.

Results of the aggregation model vary with the MCDA approach. The results may be a complete ranking of alternatives ($a_i > a_j > \ldots > a_n$), the best alternative ($a_i > a_j, a_k, \ldots, a_n$), a set of

acceptable alternatives (a_i, a_j, $a_k > a_l$, a_m, a_n), or an incomplete ranking of alternatives (Seppälä et al., 2002).

A general classification of preference modeling divides MCDA approaches into two groups: performance aggregation methods and preference aggregation methods (Guitouni and Martel, 1998).

In **performance aggregation**, the various criteria scores for a given alternative are aggregated into a single performance function, which is then compared between alternatives. For example, in multi-attribute utility theory (MAUT) methods, an additive value function may be developed that is simply the sum of attribute values multiplied by criteria weights.

Preference aggregation typically involves pair-wise comparison of alternatives relative to each criterion. Preference information is aggregated to determine which alternatives can be regarded as better than others. For example, the outranking MCDA approach uses the following relations presented by Roy (1973):

- Alternative "a" is indifferent to alternative "b"
- Alternative "a" is strictly preferred to "b"
- Alternative "a" is weakly preferred to "b."

Thus, rather than computing an aggregate function to compare alternatives, preference information is aggregated to determine the preferred alternatives. The specific approaches for preference aggregation vary.

Another important concept differentiating MCDA methods is the degree to which they are compensatory. This characteristic refers to whether poor performance in one criterion can be compensated by good performance in other criteria. If poor performance in one criterion will automatically lead to poor overall performance, the method is noncompensatory. Most methods are partially compensatory. However, there are relative differences whereby, for example, MAUT is relatively more compensatory than the outranking approach.

III.2.3 MCDA Application to Resource Allocation

When MCDA methods are used for resource allocation problems, many organizations simply score and then sort the available projects (alternatives) from highest to lowest performance. Projects are then funded in that order as allowed by the available budget. Although this approach may appear rational, it ignores fundamental relationships between costs and benefits and does not ensure that the greatest value is obtained from the available resources (Phillips and Bana e Costa, 2005).

In contrast, resource allocation approaches that consider the benefit/cost ratio can maximize the potential benefit for given available resources, as illustrated by the example benefit/cost triangle in **Figure III-2**. A benefit/cost triangle can be constructed for each available project by comparing a measure of costs with a measure of benefits. In contrast to traditional cost/benefit analysis, MCDA approaches can include multiple factors in the evaluation of costs and benefits. Accordingly, an MCDA estimate of benefits can incorporate both quantitative information (e.g., financial values, risk) and qualitative information (e.g., value judgments). The benefit/cost ratio indicates the relative value for money provided by the project.

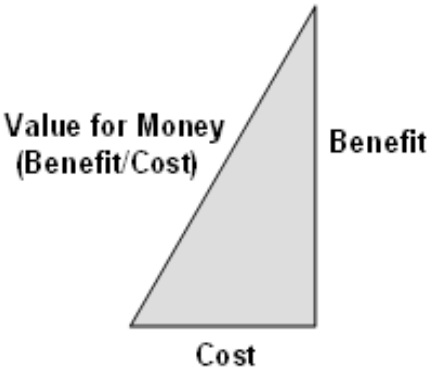


Figure III-2. A benefit/cost triangle expresses the relative value for money provided by a project. Source: adapted from Phillips and Bana e Costa (2005)

Projects can be sorted by their benefit/cost ratios and then plotted on a graph of cost (x axis) versus benefit (y axis). Such a graph represents the "efficient frontier" where project portfolios provide the maximum benefit for a given available budget (cost). **Figure III-3** shows an example of the efficient frontier (Phillips and Bana e Costa, 2005). The graph shows the cumulative cost versus benefit for projects prioritized according to two different schemes: maximum benefit only (green curve) and maximum cost versus benefit (red curve). The graph shows cumulative costs and benefits, whereby the incremental cost and benefit for a given project are added to the cumulative total cost and benefit for the portfolio. The current cumulative total value is plotted for a given project, so that the placement of projects on the graph depends on their rank ordering and the associated prioritization scheme. Accordingly, the left-most projects on the graph have the highest priority, while the lowest priority projects appear on the far right. It can easily be seen in the graph that prioritizing projects by benefit alone does not generate portfolios on the efficient frontier, because projects may be funded even though they provide less relative benefit per unit of cost. By funding projects providing the maximum benefit per cost, an organization can achieve the maximum aggregate benefit for available resources.

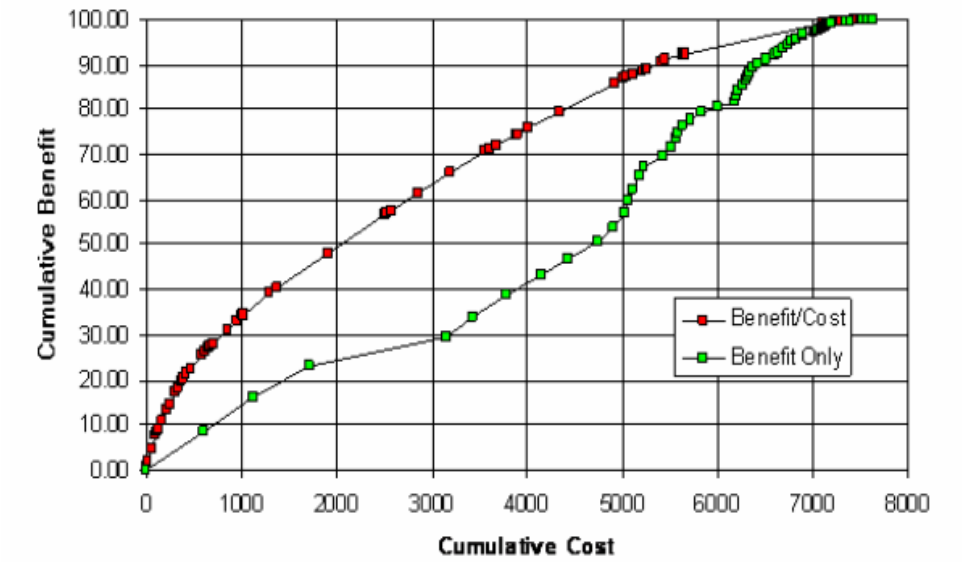


Figure III-3. Example of prioritizing projects by benefit/cost ratio (red line, the efficient frontier) vs. benefit only (green line).
Source: Phillips and Bana e Costa (2005)

Once the efficient frontier is calculated, an existing project portfolio can be plotted as shown in **Figure III-4**. Point P represents the existing portfolio. The light green shaded area in the figure shows all of the possible portfolios for the available projects. Point B represents a portfolio available for approximately the same cost that provides greater overall benefit. Point C represents a portfolio providing approximately the same benefit at lower cost.

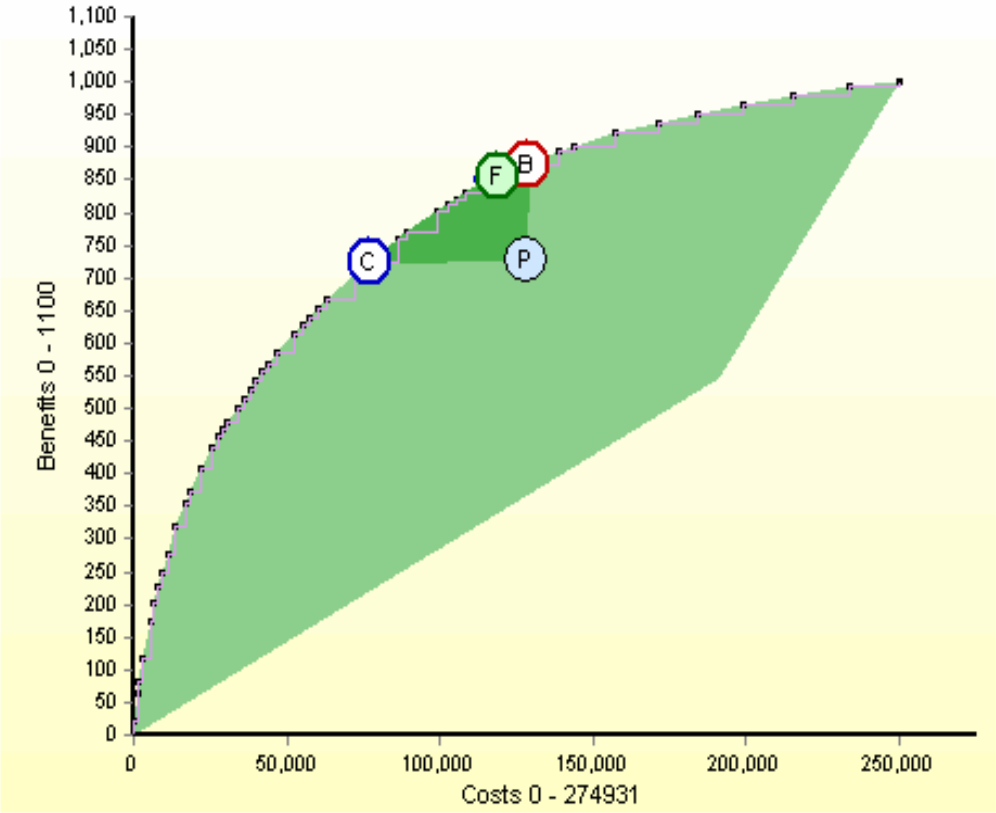


Figure III-4. Example comparing an existing portfolio (P) to the efficient frontier. Source: Phillips and Bana e Costa (2005)

To support resource allocation based on benefit versus cost considerations, a proportional measure of relative benefit must be calculated for each project. The result of some MCDA approaches (outranking and most analytic hierarchy process [AHP] implementations) is a rank ordering of alternatives, and the MCDA score associated with these methods is not meaningful outside of this ranking. The associated quantitative result is not a proportional estimate of benefits and thus not useful for resource allocation based on benefit/cost ratios. In contrast, MAUT-based methods (including some AHP implementations) provide a quantitative result that estimates benefit, and the associated MCDA score does reflect the relative, proportional benefit associated with alternatives. In addition, methods rooted in multi-objective optimization have been developed to allocate resources and develop project portfolios on the efficient frontier.

III.3 MCDA Method Descriptions

This section provides more detailed descriptions of specific MCDA approaches, including elementary methods, decision trees and influence diagram analysis, MAUT, AHP, and outranking. **Table III-1** provides a summary comparison of the reviewed MCDA approaches with respect to the following measures:

- **Transparency (Trans):** The method is readily discernible to the decision-maker (straightforward) and provides a clear audit trail to justify decision-making
- **Ease of Use (EoU):** The method is relatively simple to implement
- **Uncertainty (Unc):** The method supports uncertainty analysis

- **Adaptability (Adapt):** The method easily allows updates as new projects or data become available
- **Applicability (Appl):** The method is applicable to the desired use (resource allocation)
- **Software Support (Software):** Software packages that implement the method are readily available.

Each of these measures was scored as follows:

–	Poor
0	Unknown or neutral
+	Good
++	Excellent.

Table III-1. Summary Comparison of MCDA Approaches for Resource Allocation

Approach	Trans	EoU	Unc	Adapt	Appl	Software
Decision trees and influence diagrams	++	+	++	0	0	++
Multi-objective optimization	–	–	+	+	+	+
Multi attribute value theory (MAUT)	++	+	+	+	++	++
Analytic hierarchy process (AHP)	+	++	+	0	0	++
Outranking	–	++	+	0	–	++

III.3.1 Elementary Methods

Several MCDA methods are described as elementary, in that their required calculation procedures are relatively simple and straightforward. It is important to keep in mind that most comprehensive MCDA applications are based on a more involved approach, but results from these elementary methods are relatively less labor and resource intensive and can provide valuable insights to the decision-maker.

In the **maximin** method, each alternative is scored based on the performance of its weakest attribute. The analogous **maximax** method scores each alternative based on the performance of its strongest attribute. Comparison of the alternatives requires that all attributes be scored on comparable scales.

The **conjunctive method** is designed to screen alternatives based on whether they exceed minimum performance thresholds for all criteria. One useful application of the conjunctive approach is to decrease a large number of alternatives to allow more detailed evaluation of a subset. The conjunctive method does not require attributes to be scored on a common scale, thereby limiting the effort needed for the analysis. In the analogous **disjunctive method**, alternatives pass the screening test if they exceed the minimum performance threshold for at least one attribute (as opposed to all attributes in the conjunctive method).

In the **lexicographic method**, the criteria are ordered in terms of importance. The alternative with the best performance is the alternative with the strongest performance for the most important criterion. If multiple alternatives are tied with respect to the most important criterion,

these alternatives are compared for the next criterion, and so on, until the highest performing alternative is selected.

In the **TOPSIS method** (technique for order preference by similarity to ideal solution), the selected alternative should be as close to the ideal as possible and as far from the negative ideal as possible. The ideal is defined as a hypothetical alternative with the highest individual criteria scores. The negative ideal is the combination of minimum scores.

III.3.2 Decision Trees and Influence Diagram Analysis

General Description

A **decision tree** is a graphical representation of a sequential decision-making problem. It consists of decision nodes (squares), chance nodes (circles), and end nodes (triangles). The order of the nodes (from left to right) represents the progression of the decision, whereby information is revealed and decisions are made sequentially. Branches emanating from decision nodes represent the available alternatives, and branches emanating from chance nodes represent possibilities and their associated probabilities.

An **influence diagram** is generally more compact than a decision tree, in that it represents the structure of a decision rather than each possible outcome explicitly. Decision trees can usually be converted into influence diagrams and vice versa. Influence diagrams may contain several types of nodes: a decision node (rectangle), an uncertainty node (oval), a deterministic node (double oval), and a value node (octagon or diamond). The arcs connecting the nodes can be categorized as follows: functional arcs ending in value nodes, conditional arcs ending in uncertainty nodes, and informational arcs ending in decision nodes. Generally, alternatives are represented by decision nodes with incoming informational arcs. Information is represented by uncertainty nodes, deterministic nodes, and conditional arcs. Preferences are represented by value nodes and incoming functional arcs.

Example Applications

Lasry et al. (2008) used influence diagrams within the context of MCDA to estimate the effectiveness of various funding priorities for HIV/AIDS prevention.

The Analytica software package includes an example application for portfolio analysis that evaluates the cost versus benefit of potential projects as calculated using a MCDA-based scoring approach.

Advantages

Decision trees and influence diagrams provide powerful tools to evaluate uncertainty. Formalized methods are available for “solving” these diagrams and generating probability distributions for the potential outcomes (Clemen and Reilly, 2001).

Available influence diagram software (e.g., Analytica) can be used to develop sophisticated and powerful models, including standalone user interfaces that do not require the user to own the software.

As described below, graphical analysis methods can be cumbersome for large, complex decision problems. However, these methods can be useful for analyzing components of larger decisions. For example, a decision tree or influence diagram could be used to estimate the performance of alternatives for specific criteria.

Limitations

Because these graphical analysis methods can become quite large and cumbersome, they have not been used as extensively as other MCDA methods for complex decisions with many criteria and alternatives. However, some software platforms (e.g., Analytica) provide significant flexibility and power (e.g., nested influence diagrams, embedded algorithms) to analyze more complex problems. Many of the multicriteria methods (e.g., MAUT) can be implemented within such a software environment.

Software Tools

Several decision tree analysis software packages are available, including TreeAge (http://www.treeage.com/) and Precision Tree (http://www.palisade.com/). Available software for developing influence diagrams includes Analytica (http://www.lumina.com/index.html) and Netica (http://www.norsys.com/netica.html).

III.3.3 Multi-Objective Optimization

General Description

Multi-objective optimization refers to a class of approaches derived from linear (and nonlinear) programming that were developed primarily in the operations research field. Multi-objective optimization has been applied in many disciplines, particularly in engineering and finance. Multi-objective optimization involves the design of alternatives from continuously varying options rather than selection from discrete, preselected options. In multi-objective optimization, several objective functions are optimized simultaneously, as opposed to traditional linear programming, in which a single function is optimized. The approach explicitly accounts for trade-offs between competing objectives, such as maximizing effectiveness while minimizing cost.

Many multi-objective optimization methods require the decision-maker to specify performance goals (or “aspiration levels”) for each criterion, defined in terms of the corresponding attribute values (Belton and Stewart, 2002). Three types of performance goals can be described: the minimum level of performance considered satisfactory, the maximum level of performance considered satisfactory, or a target level of performance. Some of the multi-objective optimization approaches (e.g., goal programming) will search for a solution within a minimum distance from the specified goals.

Multi-objective optimization approaches typically do not achieve a single, optimal solution. Rather, the analysis produces a range of options that achieve different goals to differing degrees. Some multi-objective optimization tools are interactive and allow the user to specify adjustments to the aspiration levels and, for example, generate solutions that fall between different specified goals.

Multi-objective optimization is a broad field with many different specific methodologies and several supporting software tools (see below). Example methodologies include data envelopment analysis (Mohan et al., 2008), goal programming (Chaerul et al., 2008), the normal boundary intersection method (Das and Dennis, 1998), the normal constraint method (Messac et al., 2003), and the Pareto surface generation for convex multiobjective instances method (Craft et al., 2006).

Example Applications

Chaerul et al. (2008) used goal programming to evaluate alternative healthcare waste management strategies considering multiple objectives, budget constraints, and different priorities.

Advantages

The multi-objective optimization approach is typically customized to specific problems. When the performance of alternatives can be expressed in equation form, multi-objective optimization can be a powerful approach to achieve optimal solutions with a formal mathematical basis.

Limitations

The multi-objective optimization approach generally involves more complex mathematical algorithms than do discrete MCDA methods, and multi-objective optimization requires explicit quantification of the decision problem. Accordingly, functions must be specified to capture the performance of alternatives relative to the criteria. In many situations, particularly those involving qualitative judgments, such formal mathematical relationships are difficult to achieve. In some cases, the objective function can be developed based on a discrete MCDA formulation.

Fewer user-friendly supporting software tools are available to support multi-objective optimization than for some of the other MCDA methods, and custom tool development is often required. Although some software packages are available to support multi-objective optimization methods, they still require the development of equations describing the problem.

Software Tools

Multi-objective optimization-based decision support tools are often customized and developed in standard programming languages, such as C++, or mathematical programming software, such as MATLAB. Specialized software implementing specific multi-objective optimization techniques is also available, including NIMBUS (http://nimbus.mit.jyu.fi/) and DecisionPro (http://www.decisionpro.biz/).

III.3.4 Multi-Attribute Utility Theory (MAUT)

General Description

The MAUT approach provides a transparent and defensible means of quantifying and comparing the value of alternatives in terms of both quantitative and qualitative judgment criteria. In MAUT, the term “utility” refers to a measure of the desirability or relative satisfaction derived from something. MAUT calculates the utility of the various alternatives based on multiple criteria.

The term MAUT is used in this discussion to refer collectively to MAUT and multi-attribute value theory (MAVT). MAVT refers to decision analysis without formal uncertainty analysis, while MAUT refers to methodologies that formally account for uncertainty. In the literature, MAVT is typically treated as a subset of MAUT, and the more general term (MAUT) is more commonly used.

Within the MAUT framework, the decision-makers establish utility functions that capture the relative performance of alternatives. A single-attribute utility function describes the performance for a particular attribute, whereby the utility is maximum for the most preferred alternative and minimum for the least preferred alternative. Generally, the utility is scaled between 0 and 1, as shown in the hypothetical utility function in **Figure III-5**.

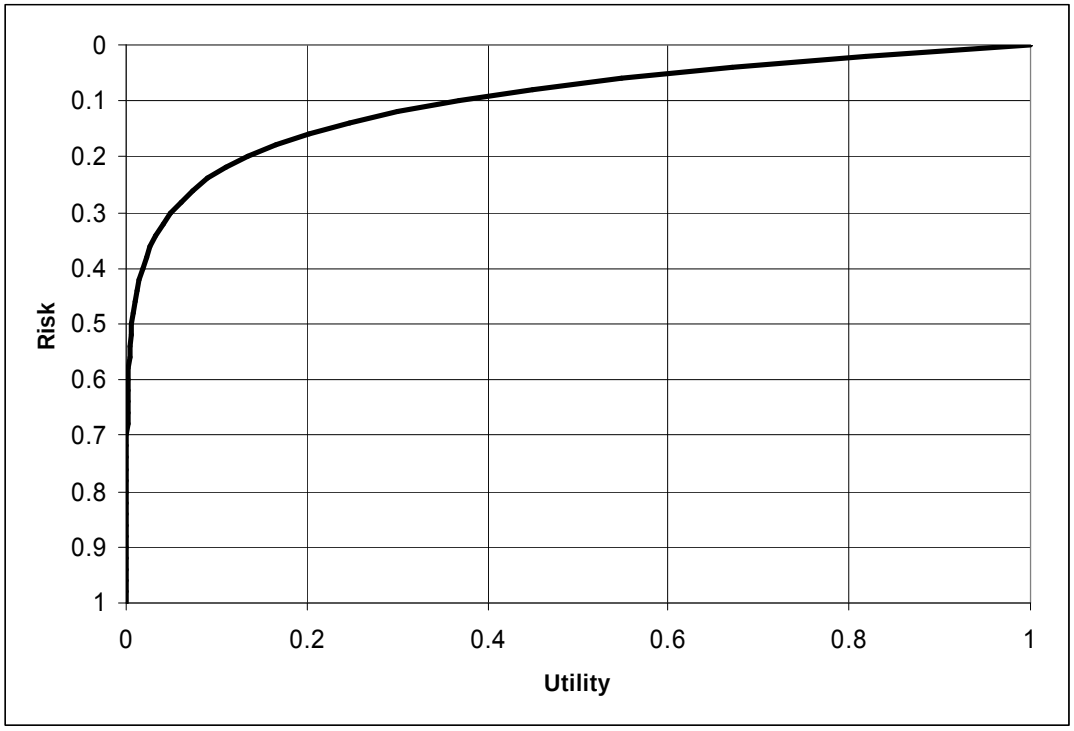


Figure III-5. Example utility function describing increasing utility with decreasing risk.

In this figure, the maximum utility occurs at the minimum risk, and the utility decreases exponentially as risk increases. Approaches are available to simplify the development of these utility functions (e.g., MACBETH) in terms of quantitative and judgment-based information (Bana e Costa and Vansnick, 1999). MACBETH involves pair-wise comparison of alternatives similar to other MCDA approaches (AHP and outranking); however, it produces a function that proportionally measures utility across criteria.

Once single-attribute utility functions are developed, the information for multiple criteria is aggregated using a multi-attribute utility function (MAUF). This produces a single number expressing the utility of each alternative. Development of the MAUF includes the assignment of relative weights to the criteria that express their relative importance. This process requires explicit value judgments from the decision-makers. Although the process can be challenging and controversial, it provides transparency and consistency to the decision-making process.

Approaches are available to simplify the development of weights for the MAUF (e.g., the simple multi-attribute rating technique [SMART] and swing weighting).

The MAUF is often an additive function of the weights multiplied by the attribute values; however, other forms (e.g., multiplicative) are possible. The simple additive form requires preferential independence between criteria, so that each criterion has no dependence on the performance relative to other criteria. If preferential independence is not established, the problem often can be restructured (e.g., by splitting criteria) to achieve it. Alternatively, aggregation functions can be developed to capture criteria interdependence; however, this can significantly increase the complexity of the analysis.

The performance of each alternative relative to each criterion is measured through values of the attribute(s) characterizing each criterion. Thus, each alternative is evaluated for each attribute. In some cases, this may involve an independent model (e.g., a risk ranking or risk assessment result). In other cases, it may be a qualitative judgment that is measured on an ordinal scale (e.g., strongly agree, agree, neutral, disagree, strongly disagree) and then converted to a quantitative measure.

Once all attribute values for each alternative are established, the alternatives can be given a comparative score. The alternatives can be compared based on their overall score, as well as relative to their performance for specific criteria. If the problem was structured using a value tree, the results may be aggregated at any level of criteria aggregation.

Example Applications

MAUT and MAVT are among the more widely applied methods of MCDA, accounting for the many practical applications in a broad range of fields such as energy, manufacturing, medical, military, and public policy (Belton and Stewart, 2002). Some examples in the field of environmental management include nuclear emergency management (Hämäläinen et al., 2000), climate change policy evaluation (Keeney and McDaniels, 2001), energy policy analysis (Jones et al., 1990), and regional forest resource planning (Ananda and Herath, 2003). Specific example applications relative to resource allocation are described below.

Bana e Costa (2001) used MAUT to evaluate the allocation of public resources for proposed road projects. The project considered multiple criteria, including effectiveness, as well as environmental, social, and economic measures, to develop a plan within the fixed available budget.

Bana e Costa et al. (2006) also used a MAUT approach to allocate public investments for social services to children, the elderly, and the disabled. Objectives of the decision analysis were increased transparency, "rationality," and making the best use of limited resources. The effort included decision conferencing to elicit preferences from multiple stakeholders and build consensus.

Phillips and Bana e Costa (2005) describe how a pharmaceutical company used MAUT to evaluate research and development projects in terms of multiple criteria, including cost, medical need, and strategic objectives. The company evaluated the projects in terms of their value for the

money (the cost to benefit ratio). Over a period of a few funding cycles, they then managed their resource allocation into a portfolio of projects that provided increasing benefits relative to costs.

Advantages

The MAUT approach is relatively straightforward, transparent, and intuitive. Decision-makers generally can easily understand the underlying algorithms, particularly when the alternatives are scored based on a weighted average across criteria (the typical approach). The logic behind the algorithms is explicit, and can readily be reviewed and modified. For example, criteria weights can be modified explicitly to evaluate the implications of specific alternative value judgments and assumptions.

MAUT provides a detailed record and basis for decision-making. The audit trail is a particularly attractive feature of the method for many decision-makers, especially in government applications, where public policy decisions can be controversial. Clearly, MAUT provides transparency and consistency to the decision-making process.

A distinct advantage of MAUT for resource allocation problems is that the method provides a single number expressing the overall benefit of an alternative. This number is a proportional, scaled measure of benefits; in other words, doubling of the benefit score implies an estimated doubling of the benefit. Using the benefits measure, projects can be evaluated in terms of their relative value for money, thus maximizing the potential benefit for a given amount of resources. This advantage is in contrast to other MCDA approaches (the standard AHP approach and outranking), which provide a rank ordering of alternatives rather than a proportional measure of benefits.

Limitations

The MAUT approach can require more time and effort to implement compared with some of the other MCDA methods. MAUT requires the development of utility functions describing the performance of alternatives for each criterion, whereas some other approaches have less demanding preference elicitation methods (e.g., pair-wise comparison in AHP and outranking). However, approaches have been developed to simplify the processes of developing single-attribute utility functions (e.g., MACBETH) and intercriteria weighting (e.g., SMART).

Software Tools

The algorithms associated with the most common MAUT implementations are relatively straightforward and can be developed using spreadsheets. However, specialized applications developed specifically for MAUT provide distinct advantages through user-friendly interfaces, graphical presentation tools, sensitivity and uncertainty analysis capabilities, and other features. Many software packages are available that support standard MAUT approaches, such as Criterium Decision Plus (http://www.infoharvest.com) and Web HIPRE (http://www.hipre.hut.fi/). Several other applications provide MAUT capabilities specifically designed for resource allocation problems, including Equity (http://www.catalyze.co.uk), HiPriority (http://www.krysalis.co.uk/), and Logical Decisions Portfolio (http://logicaldecisions.com/).

III.3.5 Analytic Hierarchy Process (AHP)

General Description

The AHP method is closely related to MAUT; however, it has a unique preference scale and elicitation procedure. In addition, the underlying algorithm uses eigenvalues and eigenvectors rather than a simple weighted average as in the typical MAUT implementation. Elicitation of preferences is done through pair-wise comparison of alternatives relative to each criterion using a nine-point preference scale. Once scores are established for each pair, the algorithm provides a rank ordering of the alternatives.

Example Applications

Britten et al. (2006) used AHP to identify appropriate amounts from each food group that together will meet nutritional goals for various age/gender groups based on Dietary Reference Intakes and Dietary Guidelines.

Febriamansyah (2006) used AHP to evaluate water allocation scenarios within a river basin in Sumatra considering multiple stakeholder interests, physical limitations, and socio-institutional factors.

Advantages

The AHP approach is relatively simpler to implement than many MAUT methods because it does not require the performance of alternatives to be evaluated explicitly (only through pair-wise comparison). AHP has been a very popular approach, likely due to strong software support and relatively straightforward implementation procedures.

Limitations

The AHP approach has been criticized because the ranking of alternatives may be affected by the addition of new alternatives or new criteria (the rank reversal problem). In addition, because the performance of alternatives is not predicted explicitly, the alternatives' scores in AHP provide only limited information about the relative benefits of one alternative compared to another (e.g., a score of 10 versus 5 does not necessarily indicate a doubling of estimated benefit). This characteristic limits the potential of fully evaluating the benefits versus costs for resource allocation problems. Cost can be included in AHP as an additional criterion for evaluation; however, the results do not provide scores for alternatives that proportionally represent their benefits.

Alternative AHP implementations are available that address this problem through elicitation procedures similar to MAUT; these help ensure that quantitative measures for alternatives proportionally represent their benefits. The level of effort required is similar to MAUT approaches, so the advantages of this AHP approach versus MAUT are not clear.

Because the AHP approach is based on pair-wise comparison of alternatives relative to all criteria, the number of required comparisons can become large if many alternatives and criteria are considered. Also, the addition of a new alternative requires comparative evaluation relative to all other alternatives (as opposed to scoring the new alternative independently as in MAUT).

Software Tools

The software packages Expert Choice (http://www.expertchoice.com) and Decision Lens (http://www.decisionlens.com) are widely used, standard implementations of AHP.

III.3.6 Outranking

General Description

Outranking methods involve the aggregation of preferences between alternatives. The decision-maker assigns preference (strict preference, weak preference, or indifference) between alternatives and relative to each criterion. The "outranking relation" applies when alternative "a" is at least as good as alternative "b," considering all criteria. Using the terminology associated with outranking, alternative "a" is then "dominant" relative to "b." Through pair-wise comparison of alternatives for all criteria, the method determines whether one alternative is better than another. In one example outranking method (ELECTRE II), the dominance relation is expressed through a concordance index and a discordance index. The concordance index represents the superiority of alternative "a" relative to alternative "b." The discordance index represents the inferiority of alternative "a" relative to "b." The decision-maker must assign concordance and discordance thresholds (e.g., representing minimum allowable performance) through which to calculate concordance and discordance indices. Different outranking approaches calculate these indices in different ways and with different levels of complexity. In addition to ELECTRE, example outranking methods include PROMETHEE (Brans and Vincke, 1985), ORESTE (Roubens, 1980), and MELCHIOR (Leclerc, 1984). All of these methods share the general idea that poor performance on one criterion (below a specified threshold) cannot be compensated for by good performance on other criteria. Thus, the methods are noncompensatory.

Example Applications

Roussat et al. (2009) used ELECTRE to assess the sustainability of alternative demolition waste management strategies considering criteria such as economics, environmental consequences, and social issues.

The PROMETHEE outranking approach was also used to evaluate food safety intervention alternatives (Fazil et al., 2008; see details in Section III.4.2). Measurement criteria included effectiveness, cost, weight of evidence, and practicality.

Advantages

Outranking approaches are generally easier to implement than MAUT. Preference elicitation involves pair-wise comparison of alternatives, which can reflect the natural decision-making process. Furthermore, preferences do not have to be quantified; for example, performance can be based on ordinal scales. In addition, outranking approaches are noncompensatory, whereby minimum threshold performance levels for specific criteria must be exceeded for sufficient overall performance.

Limitations

The algorithms underlying outranking methods are less intuitive and transparent than the standard MAUT approach. In addition, it can be challenging to develop performance thresholds specifying, for example, the minimum allowable performance.

For resource allocation problems, a particular disadvantage of outranking methods is that the result is not a single score that proportionally represents the benefit of a given alternative. Instead, outranking provides a rank ordering of alternatives. Some of the methods generate quantitative results (e.g., concordance and discordance indices in ELECTRE). However, the values do not provide a proportional measure of benefit. Without such a measure of benefit, project prioritization cannot be based on the maximum potential benefit per cost.

Because outranking is based on pair-wise comparison of alternatives relative to all criteria, the number of required comparisons can become large if many alternatives and criteria are considered. Also, the addition a new alternative requires comparative evaluation relative to all other alternatives (as opposed to scoring the new alternative independently, as in MAUT).

Software Tools

Many outranking implementations are based on custom applications developed using other software platforms (e.g., spreadsheets). Decision Lab (http://www.visualdecision.com/) is commercial software supporting the PROMETHEE outranking approach.

III.4 Food Safety Examples

III.4.1 Multi-Factorial Risk Prioritization Framework

The Multi-Factorial Risk Prioritization Framework for Food-borne Pathogens (MFRPF), developed by the Food Safety Research Consortium and Canadian Public Health agencies provides an approach for prioritizing food-pathogen pairs in terms of several criteria in addition to public health (Hensen et al., 2007). In this framework, four factors are considered as important to risk managers:

- **Public health:** This criterion considers the impact and burden of disease as quantified by disability adjusted life year and cost of illness measures.

- **Market-level impacts:** This criterion considers the potential economic losses from disease and outbreaks.

- **Consumer risk perception and acceptance:** This criterion considers differential consumer acceptance of foodborne risks. A Delphi-based rating system based on five criteria is proposed to measure consumer risk perception and acceptance:

  - The degree to which risk is perceived as uncontrollable by consumers
  - The degree to which risk is perceived as unknown to the individual
  - The degree to which risk is perceived as unknown to scientists
  - The degree to which exposure to the hazard is perceived as involuntary
  - The degree to which consumers perceive the outcome(s) as severe.

- **Social sensitivity:** This criterion is intended to capture increased societal sensitivity to risk for particular groups, from the perspective of both consumers and industries/firms. Sensitive consumer groups may include, for example, the elderly or children. The industry/firm side may include, for example, groups with historical or cultural significance, particularly in marginal or rural areas. Note that the social sensitivity criterion does not measure health impacts to these groups (as measured by the public health criterion), but rather the increased societal sensitivity associated with potential impacts. A Delphi-based rating system is also proposed for measuring social sensitivity.

Operationalizing the MFRPF framework includes the generation of information cards and cobweb diagrams. Information cards summarize the basic data for each criterion for a given pathogen-food pair. There are several information cards for each pathogen-food pair, including one card per criterion and a summary card. The cobweb diagrams graphically summarize the results for a given pathogen-food pair presenting the quantitative results for each criterion on a separate axis, as illustrated in the example in **Figure III-6**.

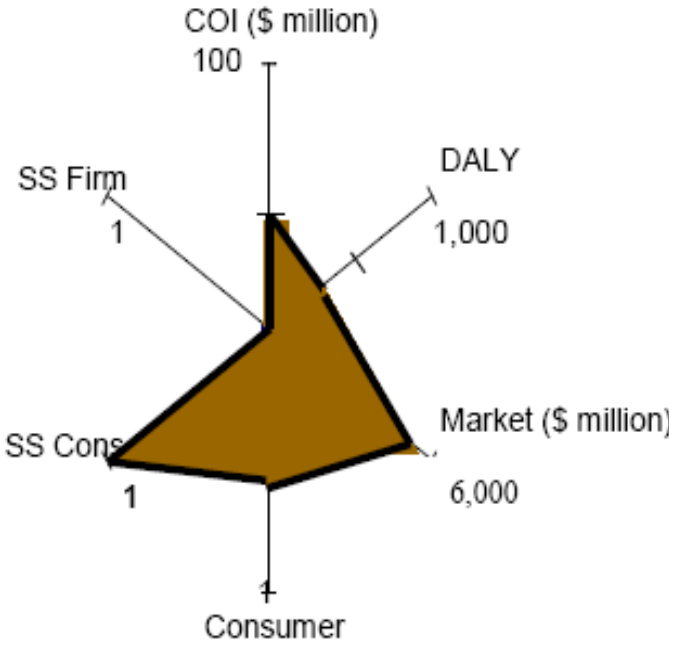


Figure III-6. Example cobweb diagram from the MFRPF approach for *E.coli* O157/beef
Source: Hensen et al. (2007)

An MCDA approach is then proposed to aggregate the performance across criteria for each pathogen-food pair. The authors discuss the potential use of MAUT and outranking to compare and prioritize the food-pathogen pairs. The MCDA approach chosen is intended to allow comparative evaluation of different stakeholder priorities through alternative weighting of different criteria. The result should be an ordered ranking of food-pathogen pairs based on their aggregated performance as measured through MCDA. To our knowledge, the MCDA implementation had not yet been completed for the model described by Hensen et al. (2007).

The authors discuss potential ways to incorporate uncertainty and feasibility of interventions into the analysis. The MCDA approach would generate an "A" list of ordered food-pathogen pairs. A "B" list would be a prioritized list of those food-pathogen pairs with reasonably feasible interventions. The authors mention the importance of considering the ease of implementation and the benefits associated with a given intervention; however, a specific approach is not presented. A "C" list would include the food-pathogen pairs without known feasible interventions and ordered to reflect the need for further information characterizing the food-pathogen pair. No specific approaches for prioritization based on information needs are presented.

The MFRPF approach provides some significant advances in the prioritization of food-pathogen pairs for food safety applications. Specifically, the approach considers several different criteria besides public health, provides innovative approaches for presenting data (information cards and cobweb diagrams), and is perhaps the first specific application of MCDA techniques to food safety risk prioritization. However, explicit approaches for comparing intervention alternatives are not provided, even though the authors do recognize the importance of benefits and feasibility. The method also does not explicitly consider the costs of interventions. For these reasons, the framework is not directly applicable to FDA resource allocation problems; nevertheless, some aspects of the approach may be useful (e.g., criteria, information cards, cobweb diagrams).

III.4.2 Outranking MCDA Approach for Food Safety Risk Prioritization

Fazil et al. (2008) recently presented an example of evaluating food safety interventions using an outranking MCDA approach that considered the following criteria:

- **Weight of evidence:** This criterion is intended to capture the scientific evidence supporting a given intervention. The authors used a strength-of-evidence index based on available research studies. This index compares and weighs research studies of different types with positive and negative evidence of the intervention's effectiveness. Weights assigned to different types of studies include the following: randomized clinical trials (weight=5), randomized field trials (weight=5), nonrandomized field trials (weight=4), cohort (weight=2), and cross-sectional (weight=1).

- **Effectiveness:** This criterion measures how well an intervention works. The authors consider two dimensions to effectiveness: effectiveness at the point of application (e.g., the farm or transport truck) and effectiveness at other points of interest (e.g., when the consumer receives the product, impact on public health outcome). The first dimension can often be quantified by direct evidence in the literature, while the latter will generally require modeling.

- **Cost:** This is considered as an additional criterion in this MCDA analysis. The authors discuss three cost components: capital costs (initial and depreciated costs over time), material costs, and labor costs. They note that obtaining cost information may require reference to the grey literature and expert opinion.

- **Practicality:** This criterion considers the relative ease of implementation of a given intervention. This is a more subjective measure that would require input from stakeholders and experts.

The authors propose four additional potential criteria, including trade implications, consumer perception, unintended positive consequences, and unintended negative consequences. The example analysis does not consider these additional criteria because they are more difficult to measure and are less generally applicable.

Fazil et al. (2008) adopted the PROMETHEE outranking approach. This includes criteria weighting and the assignment of preference functions based on indifference and preference thresholds (similar to concordance and discordance thresholds discussed in Section III.3.5). The approach involves pair-wise comparison of alternatives relative to each criterion. The results include a "positive flow," measuring the degree to which an option dominates (outperforms) others; a "negative flow," measuring the degree to which an option is dominated; and a "net flow," measuring the overall preference for each alternative.

The Fazil et al. (2008) approach provides an excellent framework for evaluating potential food safety intervention alternatives. The criteria appear well thought out and effective. Additional criteria, such as trade implications, may be important in many cases, a fact the authors acknowledge. The primary drawbacks of the method are related to inherent limitations of the outranking approach and the treatment of cost. Outranking results (e.g., net flow) are meaningful only in a relative sense and for purposes of ordering the alternatives. Unlike MAUT and some implementations of AHP, outranking does not provide a proportional measure of benefits, whereby, for example, a doubling of the MCDA score implies an estimated doubling of the benefits. Without a proportional measure of benefits, the approach cannot consider the relative cost versus benefit, which is a critical consideration for resource allocation problems. Fazil et al. (2008) consider cost only as an additional criterion. Their approach does not allow calculation of the cost/benefit ratio through which overall benefit can be maximized for available resources. Nevertheless, Fazil et al. (2008) provide criteria and approaches for evaluating criteria that appear very applicable and useful for FDA resource allocation problems.

III.5 Recommendation

In this section, we synthesize our findings and make a recommendation for approaches to be used by FDA for allocating resources to be used for potential food safety intervention alternatives. Clearly, the desired approach would be rooted in MCDA methods, thus enabling structured, well-justified, and transparent decision-making. In addition, the approach should be based on fundamental resource allocation techniques in an effort to maximize benefits for available resources.

Specifically, we recommend the use of MCDA approaches, such as MAUT or certain AHP methods, that can quantify benefits through a single score representing the relative, proportional benefit of each alternative. These approaches do require performance evaluation of alternatives relative to each criterion, which can be more time consuming than the preference elicitation used for some of the other MCDA methods (e.g., standard AHP, outranking). However, the power of the information provided by proportional benefits lies in the ability to fully evaluate cost versus benefits and maximize the potential benefit for available resources.

Although the evaluation of costs versus benefits may be reminiscent of standard cost/benefit analysis, there are fundamental differences. The proposed approach is based on the evaluation of multiple criteria, including both qualitative judgment and directly measurable criteria.

Cost/benefit analysis is restricted to quantifiable measures that can be converted into monetary values. One of the more significant criticisms of cost/benefit analysis is the attribution of monetary value to seemingly nonquantifiable factors and the associated operational and stakeholder perception challenges. In contrast, an MCDA-based measure of benefits allows performance evaluation in terms of metrics that are more naturally associated with the criteria. Furthermore, each criterion may be associated with its own measurement scale (not just monetary value, as in cost/benefit analysis). The benefits include the potential inclusion of additional relevant, value judgment–based criteria and a transparent scoring system without many of the pitfalls of standard cost/benefit analysis.

A critical component of MCDA is the structuring of the decision problem, including the development of objectives, alternatives, criteria, and attributes. In an organizational setting, one of the most effective and productive approaches of MCDA problem structuring is decision conferencing. A decision conference is a facilitated workshop where the decision-makers and stakeholders meet to brainstorm and collaboratively develop a decision analysis model. An impartial facilitator with MCDA expertise provides the structure for the meeting, guides discussion, and captures the group's thinking (typically using interactive, computer-based tools). Bana e Costa et al. (2006) and Phillips (2006) provide useful references for decision conferencing. The emphasis during the workshop is on the process, increased understanding, collaboration, insights, and creative thinking. Decision conferencing helps organizations develop a shared understanding, common purpose, and commitment to the adopted approach across the organization. This benefit can be in contrast to decision support tools developed independently, which may not have collective organizational support and may not adequately reflect all perspectives. Following a decision conference, the facilitator's organization will typically finalize the MCDA model for later presentation to the decision-makers and potential further refinement using an iterative process. Given its distinct advantages, we recommend that FDA consider decision conferencing to structure their resource allocation issues and to develop a decision-making model.

As described in Section III.3.4 under Software Tools, several software packages are available to support MCDA-based resource allocation approaches, including Equity, HiPriority, and Logical Decisions Portfolio. We recommend that FDA evaluate these software options in more detail, as well as the option of developing a custom implementation.

In summary, we recommend that FDA consider the following options to further evaluate and develop an approach to assist in resource allocation for food safety problems:

- Use an MCDA approach that results in a single measure that proportionally represents benefit. Both MAUT and some implementations of AHP provide this capability.

- Incorporate fundamental resource allocation theory into the decision-making process. Specifically, evaluate alternatives in terms of their benefit/cost ratio, thus allowing maximum potential cumulative benefit for available resources (having a project portfolio on the efficient frontier).

- Consider a facilitated decision conference to structure the decision-making problem and develop a decision-making model. Such a facilitated workshop allows decision-makers to

brainstorm and discuss the problem and collaboratively develop objectives, alternatives, criteria, and measurement attributes through which to develop a decision-making model.

- Evaluate available software supporting MCDA-based resource allocation and consider the potential benefits of developing a custom tool.

III.6 References

Ananda, J., and G. Herath. 2003, Incorporating Stakeholder Preferences into Forest Planning: A Value Function Approach. *Ecological Economics* 45(1):75–90.

Bana e Costa, C.A., and J.-C. Vansnick. 1999. The MACBETH Approach: Basic Ideas, Software, and an Application. In *Advances in Decision Analysis* (*Mathematical Modelling: Theory and Applications 4*), edited by N. Meskens and M. Roubens. Kluwer Academic Publishers. pp. 131–157.

Bana e Costa, C.A. 2001. The Use of Multi-Criteria Decision Analysis to Support the Search for Less Conflicting Policy Options in a Multi-Actor Context: Case Study. *Journal of Multi-Criteria Decision Analysis* 10(2):111–125. Available at http://dx.doi.org/10.1002/mcda.292

Bana e Costa, C.A., T.G. Fernandes, and V.D.P. Correia. 2006. Prioritisation of Public Investments in Social Infrastructures Using Multicriteria Value Analysis and Decision Conferencing: A Case Study. *International Transactions in Operational Research* 13(4):279–297.

Belton, V., and T.J. Stewart. 2002. *Multiple Criteria Decision Analysis: An Integrated Approach.* Kluwer Academic Publishers: Boston.

Brans, J.P., and P. Vincke. 1985. A Preference Ranking Organization Method (the PROMETHEE Method for Multiple Criteria Decision-Making). *Management Science* 31(6):647–656.

Britten, P., K. Marcoe, S. Yamini, and C. Davis. 2006. Development of food intake patterns for the MyPyramid Food Guidance System. *Journal of Nutrition Education and Behavior* 38(6 Suppl.):S78–92.

Chaerul, M., M. Tanaka, and A.V. Shekdar. 2008. Resolving Complexities in Healthcare Waste Management: A Goal Programming Approach. *Waste Management and Research* 26(3):217–232.

Clemen, R.T., and T. Reilly. 2001. *Making hard decisions with DecisionTools.* Duxbury Press: Pacific Grove, CA.

Craft, D., T. Halabi, H. Shih, and T. Bortfeld. 2006. Approximating Convex Pareto Surfaces in Multiobjective Radiotherapy Planning. *Medical Physics* 33:3309–3407.

Das, I., and J.E. Dennis. 1998. Normal-Boundary Intersection: A New Method for Generating the Pareto Surface in Nonlinear Multicriteria Optimization Problems. *SIAM Journal on Optimization* 8(3):531–657.

FAO-WHO (Food and Agriculture Organization of the United Nations–World Health Organization). 2006. *Food Safety Risk Analysis: A Guide for National Food Safety Authorities.* Food and Nutrition Paper 87. Available at ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf.

Fazil, A., A. Rajic, J. Sanchez, and S. McEwen. 2008. General Interest Choices, Choices: The Application of Multi-Criteria Decision Analysis to a Food Safety Decision-Making Problem. *Journal of Food Protection* 71(11):2323–2333

Febriamansyah, R. 2006. *The Use of AHP (the Analytic Hierarchy Process) Method for Irrigation Water Allocation in a Small River basin (Case Study in Tampo River Basin in West Sumatra, Indonesia)*. Presented at the 11th Conference of the International Association for the Study of Common Property (Survival of the Commons: Mounting Challenges and New Realities), Bali, Indonesia. June 19–23.

Florig, H.K., M.G. Morgan, K.M. Morgan, K.E. Jenni, B. Fischhoff, P.S. Fishbeck, and M.L. DeKay. 2001. A Deliberative Method for Ranking Risks (1): Overview and Test Bed Development. *Risk Analysis* 21:913–921.

Guitouni, A. and J.-M. Martel. 1998. Tentative Guideline to Help Choosing an Appropriate MCDA Method. *European Journal of Operational Research* 109:501–521.

Hämäläinen, R.P., M. Lindstedt, and K. Sinkko. 2000. Multiattribute Risk Analysis in Nuclear Emergency Management. *Risk Analysis* 20(4):455–467.

Henson, S.J., J.A. Caswell, J.A.L. Cranfield, A. Fazil, V.J. Davidson, S.M. Manders, and C. Schmidt. 2007. A Multi-Factorial Risk Prioritization Framework for Food-Borne Pathogens. University of Massachusetts Amherst, Department of Resource Economics, Working Paper No. 2007-2008. Available at http://www.umass.edu/resec/workingpapers.

Hostmann, M. 2005. Decision Support for River Rehabilitation. Dissertation. Swiss Federal Institute of Technology Zurich. Available at http://www.wsl.ch/land/products/rhone-thur/entscheidung/docs/hostmann_2005.pdf.

Jones, M., C. Hope, and R. Hughes. 1990. A Multi-Attribute Value Model for the Study of UK Energy Policy. *Journal of the Operational Research Society* 41:919–929.

Keeney, R. L., and T.L. McDaniels. 2001. A Framework to Guide Thinking and Analysis Regarding Climate Change Policies. *Risk Analysis* 21(6):989–1000.

Lasry, A., M.W. Carter, and G.S. Zaric. 2008. S4HARA: System for HIV/AIDS Resource Allocation. *Cost Effectiveness and Resource Allocation* 6:7. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2386442.

Leclerc, J.P. 1984. Propositions d'extension de la notion de dominance en presence de relations d'orde sur les pseudocriteres: MELCHIOR. [Proposals to Extend the Notion of Dominance in the Presence of Orders Based on Pseudocriteria: MELCHOIR.] *Mathematical Social Science* 8:45–61.

Messac, A., A. Ismail-Yahaya, and C.A. Mattson. 2003. The Normalized Normal Constraint Method for Generating the Pareto Frontier. *Structural and Multidisciplinary Optimization* 25(2):86–98.

Mohan, S.V., B.P. Reddy, and P.N. Sarma. 2008. Ex Situ Slurry Phase Bioremediation of Chrysene Contaminated Soil with the Function of Metabolic Function: Process Evaluation by Data Enveloping Analysis (DEA) and Taguchi Design of Experimental Methodology (DOE). *Bioresource Technology* 100(1):164–172.

Phillips, L.D. 2006. *Decision Conferencing*. London School of Economics and Political Science Working Paper LSEOR 06.85.

Phillips, L.D., and C.A. Bana e Costa. 2005. *Transparent Prioritisation, Budgeting, and Resource Allocation with Multi-Criteria Decision Analysis and Decision Conferencing*. London School of Economics and Political Science Working Paper LSEOR 05.75.

Roubens, M. 1980. Analyse et aggregation des preferences: Modelisation, adjustement et resume de donnees relationelles. [Analysis and Aggregation of Preferences: Modeling, Adjustment and Summary of Relational Data.] *Revue Belge de Statistique d'Informatique et de Recherche Operationelle* 20(2):36–37.

Roussat N., C. Dujet, and J. Méhu. 2009. Choosing a Sustainable Demolition Waste Management Strategy Using Multicriteria Decision Analysis. *Waste Management* 29(1):12–20.

Roy, B. 1973. How Outranking Relation Helps Multiple Criteria Decision Making. In *Multiple Criteria Decision Making*, edited by J.L. Cochrane and M. Zeleny. Columbia, SC: University of South Carolina Press.

Seppälä, J., L. Basson, and G.A. Norris. 2002. Decision Analysis Frameworks for Life Cycle Impact Assessment. *Journal of Industrial Ecology* 5(4):45–68.

Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 16, 2013

Dear Ms. Dickinson:

First, we want to thank-you very much for the hard work of Ariel Seeley of your staff. She has worked very diligently on this matter and we appreciate her efforts very much. You must be proud to have her as a member of your staff. We recognize the extremely difficult situation she is in trying, on the one hand, to defend the actions of the Food and Drug Administration while, at the same time, attempting to conduct an honest and good faith review of the situation. We can appreciate the terrible conflict this must create for her. Please extend our thanks to her.

When we first asked to meet with you I was sincerely hoping that we could simply sit down together, talk honestly to one another as people of mutual integrity and quickly move forward to fairly resolve our concerns. But instead the train of justice has fallen off the tracks. It has now been over three months since we first asked to meet with you and we still are not even able to agree that any wrong has actually happened here. As I shared with Ariel earlier, I am a simple man who is not an attorney and I cannot afford to hire one to advocate on my behalf in an adversary legal setting. But it does seem to me, as a layman, that while there is way too much FDA legal jockeying going on, there is way too little effort to resolve the real issues a play here. In the meantime, however, the lives of real people are being destroyed.

Our company, just when we were in the position to make the food supply safer for all Americans, has been forced out of business by the FDA; on our side of the equation we are now in the unemployment lines, we can no longer pay our bills, the credit ratings that we have worked to a lifetime to preserve have been destroyed and all of our families have suffered terribly as the result of the actions taken against us by the FDA. The extended order effects of improper actions have had devastating consequences in this case.

For example, did you know that one of my company's employees is an 80% disabled military veteran who has an extended family that relies on him as the principal breadwinner? Can you possibly imagine what that must be like for him and his family? In another case, a member of the FoodQuestTQ family of employees has worked, scrimped and sacrificed literally everything he owns including his house, his retirement and his entire life savings to make our business a success. He too is the principal breadwinner for an extended family whose elderly in-laws live with his family. There are many other stories of anguish too. It is much too easy to forget that the actions we take can hurt real people.

This is why I am again pleading for your help and understanding to resolve this matter as quickly as possible. What is happening here is not some far away abstraction of reality. It is the real thing. People's lives and futures depend on our integrity, honesty and willingness to come together in a responsible way to resolve this matter quickly and fairly. That is why I am asking for the opportunity to meet with you personally to get the train of justice back on the tracks here. In the meeting, we would like to simply share with you the honest story of exactly what has happened here. I am sure that once you hear the true and complete story you will be appalled and take whatever actions are necessary to immediately turn this bizarre situation around.

It is true that we are at the mercy of the FDA and our own government because we simply cannot afford a long and expensive legal battle to achieve justice for ourselves. In my case, I am a 62 year old white male with few prospects for any possibility of future employment who would likely die before receiving any relief for my family as the result of this terrible situation. I do not like to think about leaving my wife impoverished as the result of the risks I have taken to create a small business. Thus, we have no choice but to rely on you and our own government to act with integrity to fairly protect our interests.

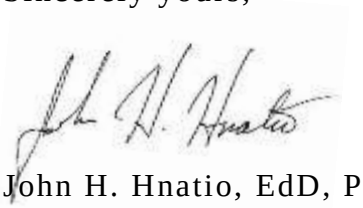
But time is definitely running out for us. This is why we have reached out to the Small Business Administration Office of Small Business Advocacy and the National Ombudsman for Small Business to help the FDA and FoodQuestTQ LLC come together. Our hope is that the SBA Ombudsman will carefully watch what is going on as an objective third party to help the FDA and FoodQuestTQ balance the need for FDA legal propriety against the real world needs of FoodQuestTQ to fairly resolve the situation as soon as possible. We believe that this approach will help both the FDA and FoodQuestTQ work through the issues fairly and objectively. The wonderful added advantage of this approach

is the requirement that we must complete our work within 30 days and file a full report to the Small Business Administration. Of course, this is critically important if FoodQuestTQ is to have any hope of surviving the actions that have been taken against us by the FDA.

Thank-you very much for your help in working with us. It is truly appreciated. We know how busy you are. If the personal meeting I suggest is agreeable to you please let me know and I will work our schedules to meet at any time that is convenient for you and your staff.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,



John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

cc: Ms. Ellie Zahirieh, Office of the SBA Ombudsman

Pages 267 through 268 redacted for the following reasons:
- -
Entire page withheld under (b)(5).

Federal Agency Comment Form

Small Business Administration – Office of the National Ombudsman

OMB Control #3245-0313

Exp. date 5/31/2013

Purpose: Small business owners may use this form to submit comments on Federal enforcement/compliance actions that they consider excessive or unfair. The National Ombudsman will use the form to contact the Federal agency for a review of the action.

Case #: 1303150001

Instructions

1. Complete, sign and date this form. (Signature not required if completed at www.sba.gov/ombudsman).
2. Provide a brief written statement on the reverse side regarding the specific enforcement or compliance action taken against your organization by the federal agency.
3. Submit copies of substantiating documentation, such as correspondence, citation, or notice (Note: Can be submitted separately from this form by fax or mail. Make sure to reference your name or company's name with this information).
4. If your comments concern the IRS, you must also submit a completed IRS Tax Information Authorization Form 8821, available at http://www.irs.gov/forms (Can be sent by fax or mail).
5. Fax, e-mail or send this form and requested information to: (1) Fax: (202) 481-5719; (2) E-mail: Ombudsman@sba.gov; (3) Address: SBA, Office of the National Ombudsman, 409 Third Street, SW, Washington, DC 20024. Telephone : (202) 205-2417.

Please Print

Organization/Company Name: FoodQuestTQ LLC

Address: 7420 Hayward Drive, Suite 102

City: FREDERICK **State:** MD **Zip:** 21702

Phone: 240-439-4476 **Fax :** **E-mail:** jhnatio@thoughtquest.com

Contact Name: Mr. ☑ Ms. ☐ John Hnatio **Title:** Chief Science Officer

Please indicate your organization type:

✓ Small Business ——Not-for-Profit, Representing _____ Members

—— Small Government (population of less than 50,000)

List the federal agency with which you are having a problem:

Federal Agency Name: Food and Drug Administration

Agency Contact person: Dr. Margaret Hamburg

Agency Office/Division: Office of Chief Counsel

√ Did the federal agency listed above inform you of your right to contact the SBA Office of the National Ombudsman?

☐ Yes ☑ No If not, how did you learn about this office?

On my own via web search

Confidentiality / Disclosure

The Small Business Regulatory Enforcement Fairness Act (SBREFA), allows you to keep your identity and other information private, and limit its access only to the SBA's (See 15 U.S.C. 657 (b) (2) (B)). However, by requesting confidentiality the federal agency may not have sufficient information to investigate your specific problem, possibly delaying or preventing any potential resolution of your situation.

I request that my information be kept confidential. ☐ Yes ☑ No (If yes, results may be limited.)

Signature: John Hnatio **Date:** 03/15/2013

Your signature authorizes the SBA Ombudsman to proceed on your behalf.

Pursue all legal options you believe are in your company's best interest.
This process is not a substitute for legal action.

SBA FORM 1993 (3-10) Previous Editions Obsolete

Please Note: The estimated burden for completing this form is 45 minutes. You will not be required to respond to this information collection if a valid OMB approval number is not displayed. If you have any questions or comments concerning this estimate or other aspects of this information collection, please contact the U. S. Small Business Administration, Chief, Administrative Information Branch, Washington, D.C. 20416 and/or Office of Management and Budget, Clearance Officer, Paperwork Reduction Project (3245-0313), Washington, D.C. 20503. PLEASE DO NOT SEND FORMS TO OMB.

Type or (print) your comments below:

We have been in contact with Ms. Ellie Zahirieh of the Office of National Ombudsman and provided her with a detailed report describing our concerns. In summary, the FDA has duplicated several of our commercial products under contract with Battelle Memorial Institute and, by so doing, undercut our sales and forced us out of business. FDA officials stole our trade secret and intellectual property information to duplicate our tools, infringed on our patent and entered into unfair competition with us in violation of the FAIR Act (OMB Circular A-76) and other statutes. We are a small company with no resources to pay for a protracted legal battle with the lawyers at the FDA and they are aware of our status as a small business that cannot afford to pay for a team of lawyers to fight for our rights. All principals of our small company have been laid off without pay since November of 2012 and are currently on unemployment. Our business has been ruined and our families have been left to suffer. We are in desperate need of relief from the actions taken against us by the FDA. We have been working with the FDA since January 2013 but the matter is being treated by legal maneuvering on the part of FDA to avoid seeking the truth and trying to fairly resolve the matter. That is why we are now forced to file a complaint with the Office of National Ombudsman.

SBA Ombudsman Case No. 1303150001

COMPETITION BY THE FOOD AND DRUG ADMINISTRATION WITH SMALL BUSINESS

The parties: FoodQuestTQ LLC, a small business with offices situated at 4720 Hayward Drive, Frederick, Maryland, 21702, and the Food and Drug Administration (FDA) with offices situated 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993.

FOODQUESTTQ LLC CONTACT INFORMATION

Dr. John Hnatio
Chief Science Officer
(o) 240.439.4476 x-11
(c) 301.606.9403
E-mail: jhnatio@thoughtquest.com

BACKGROUND

Projectioneering LLC is a small Frederick, Maryland-based company working with two other Frederick Maryland-based companies, ThoughtQuest LLC and FoodQuest LLC. Projectioneering LLC owns the intellectual property used by both ThoughtQuest LLC and FoodQuest LLC. ThoughtQuest LLC was created in 2008 for the purpose of supporting the start-up of companies across different industry verticals using the intellectual property owned by Projectioneering LLC. From 2008 to 2012, ThoughtQuest LLC reduced the Projectioneering LLC owned patent to practice for the food and agricultural fields of use. In early 2012, FoodQuestTQ LLC was established to commercially sell a suite of computer software tools across the food industry vertical that are based on the Projectioneering LLC patent.

SUMMARY

FoodQuestTQ LLC has filed a complaint with the Office of Small Business Advocacy and the Small Business Ombudsman. The complaint is based on three inextricably intertwined prohibited actions that the company alleges have been taken against them by the Food and Drug Administration, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, in violation of Title 18 U.S.C. and other statutes, and;

3. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in violation of Title 18 U.S.C. and other statutes.

Until December 2012, the FoodQuestTQ LLC employed five people. In January 2013, faced with the continuing prospect of direct government competition that interfered with their commercial sales, FoodQuestTQ was unable to obtain an essential operating loan it required to stay in business. In December 2012, the company was forced to lay off all of its employees because of lagging sales resulting from the public release of similar products by the FDA.

This document describes the events leading up to and surrounding the actions allegedly taken by the Food and Drug Administration (FDA) to duplicate products that were already developed and for commercial sale by FoodQuestTQ LLC.

CASE DESCRIPTION

Over the period of the past three years representatives of ThoughtQuest LLC and FoodQuestTQ LLC have met extensively with FDA employees and shared with them information regarding the reduction of their patented technology for commercial use/sale to the food industry.

The information provided to FDA personnel was clearly marked as containing industry proprietary information. In addition, ThoughtQuest LLC and FoodQuestTQ LLC principals state that FDA employees they spoke with were verbally advised that the information being shared with them was proprietary and contained ThoughtQuest LLC and FoodQuestTQ LLC business proprietary and trade secret information.

In September 2012, FoodQuestTQ LLC principals became concerned that the FDA was, unbeknownst to them, taking their business proprietary and trade secret information to duplicate their products, under a contract with Battelle Memorial Institute.

In late October 2012, under pressure to avoid direct competition with the FDA that would put them out of business, FoodQuestTQ LLC, with the permission of their Board of Directors, offered the FDA a $1/yr. license to use their technology. FDA officials did not respond to the FoodQuestTQ LLC offer.

FDA and their contractor, Battelle Memorial Institute, continue to deploy products free of charge to the food industry that duplicate the products that were already developed and being commercially sold by FoodQuestTQ LLC.

The FDA actions have severely impacted FoodQuestTQ LLC sales. In early December 2012 when they were no longer able to meet payroll FoodQuestTQ LLC was forced to lay off all of their company's employees.

SBA Ombudsman Case No. 1303150001

In January 2013, based on continuing competition by the FDA resulting in poor sales of their products, FoodQuestTQ LLC was denied a critical operating loan they needed to stay in business.

TIMELINE OF EVENTS LEADING TO THE LAYOFF OF FOODQUESTTQ PRINCIPALS AND EMPLOYEES

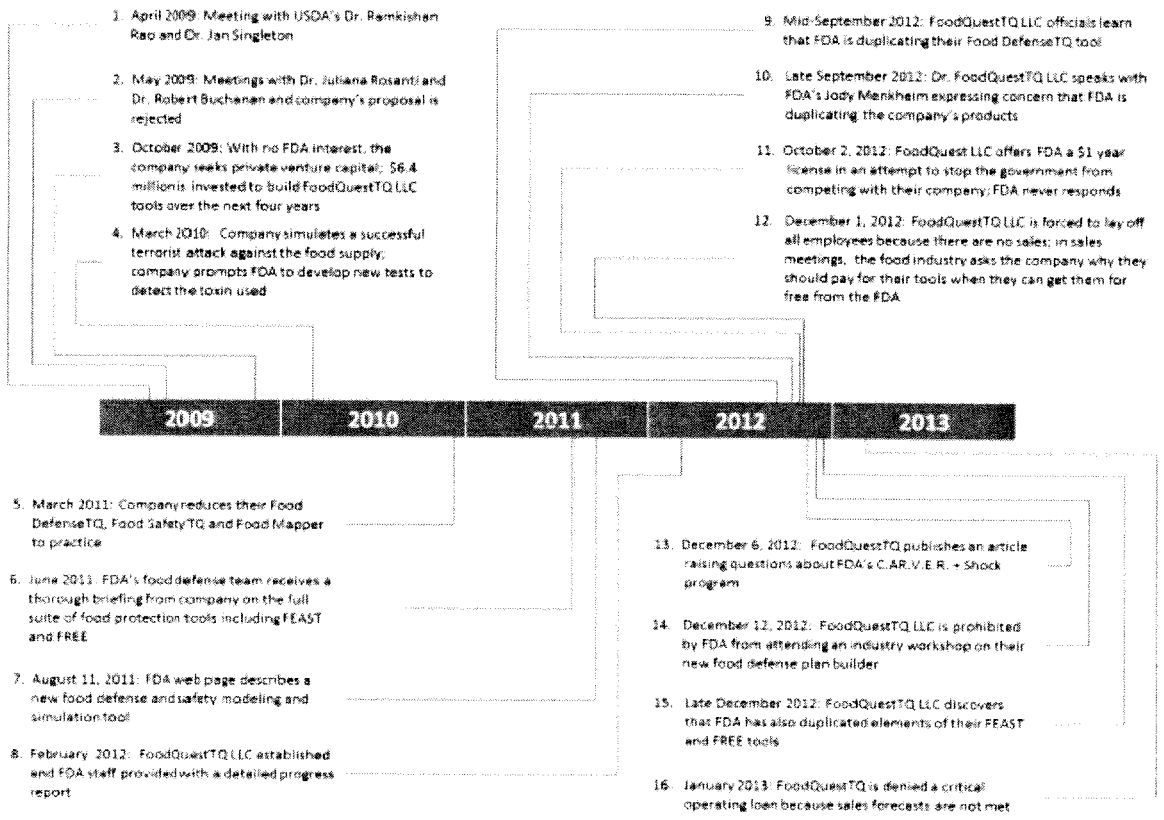


Figure 1: Timeline of FoodQuestTQ LLC and FDA Activities

1. In April 2009, representatives of ThoughtQuest LLC first contacted the U.S. Department of Agriculture (USDA). They met with Drs. Ramkishan Rao and Jan Singleton who were senior leaders at the U.S. Department of Agriculture's, National Institute of Food and Agriculture (NIFA). The purpose of the meeting was to forge a public-private partnership to make the food supply safer. ThoughtQuest LLC representatives shared their scientific breakthroughs, proprietary technology, and business plans for creating a safer food supply. Drs. Rao and Singleton were highly supportive of ThoughtQuest LLC's efforts. After the meeting, the company had follow-on meetings with Dr. Jeannette Thurston and other members of the USDA staff at NIFA to share their progress.

2. In May 2009, ThoughtQuest LLC representatives had their first contact with FDA when they met with Dr. Juliana Rosanti at the Joint Institute for Safety and Nutrition (JIFSAN). Their objective was to explore the possibility of a joint project with JIFSAN using their patent to make the food supply safer; this lead to a second meeting with Dr. Robert Buchanan, the head of the University of Maryland's Center for Food Safety and Nutrition (CIFSAN). Dr. Buchanan was a retired FDA senior food safety official and still serves as a senior scientific advisor to the FDA. At that time, Dr. Leanne Jackson, current head of the FDA's Food Defense Team was on the staff of CIFSAN.[i] As a result of these meetings, ThoughtQuest LLC representatives were asked to submit a detailed proposal to Dr. Buchanan describing their patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply. The proposal was clearly marked as containing proprietary information. The proposal was subsequently rejected by Dr. Buchanan.

   Note: Over the next three and a half years, the company continued to maintain very close contacts with both the USDA and FDA as they developed their products. The company briefed USDA and FDA officials on every step of their scientific and technological progress. They hoped that, at some point, USDA and FDA would join them in the public-private partnership they originally envisioned to improve the safety of the food supply based on the company's new science and technology innovations.

3. In October 2009, when the FDA showed no apparent interest in their patent and supporting technology, ThoughtQuest LLC sought venture capital. In addition to the $3.5 million invested by the two principals of ThoughtQuest LLC, the company received an additional $2.9 million in venture capital over the next four years to build and commercially deploy their suite of computer software tools to help the food industry prevent and improve responses to accidental and intentional food poisonings.

4. In 2010, ThoughtQuest LLC was asked by a large global food manufacturer to use their patent and technology to simulate a worst case terrorist attack using a biological agent against one of their major food product lines. The goal was to "bring down the company." Based on this tasking, ThoughtQuest LLC was able to scientifically simulate the successful take down of the company as a result of terrorists introducing a particular toxic agent into their product. The simulation was highly successful because no effective laboratory test existed at that time for detecting the presence of the agent that was used to poison the particular product. With the permission of the company involved, ThoughtQuest LLC representatives closely coordinated the results of the simulation and the methodology they used with Dr. Reginald Bennet and other officials at the FDA in

order to prompt the development of specific laboratory and field tests that would detect the deadly agent.

5. By early 2011, ThoughtQuest TQ LLC personnel reduced three of their products to practice and began commercial sales of their Food DefenseTQ, Food SafetyTQ and Food Mapper tools.

6. In June 2011, Mr. Menkhiem, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim to give him periodic updates on their progress.

7. On August 11, 2012, Mr. David Park, then Principal Scientist of FoodQuestTQ LLC came across an official FDA website that described a new FDA tool for modeling and simulating food defense and food safety scenarios.

   Note: As further discussed below, in late December 2012, Dr. Hnatio conducted a detailed review of the FDA website to discover that the FDA had duplicated the elements of two of FoodQuestTQ tools-the Food Event and Analysis Simulation Tool (FEAST) and the Food Response and Emergency Evaluation (FREE) tool. The FDA slightly modified the name of their new tool from the original FoodQuestTQ commercial name of FREE to the new FDA name "FREE-B."

8. In early February 2012, Projectioneering LLC and ThoughtQuest LLC stood up a new company called FoodQuestTQ LLC that would assume responsibility for the further development and sales of their computer software tools across the food industry.

   Also, Mr. Menkheim and his staff were provided with a detailed progress briefing and proprietary documents that included both business confidential and trade secret information describing the industry uses of the FoodQuestTQ LLC tools, the system architecture and the algorithms supporting the FoodQuestTQ tools. All this information was clearly marked as containing company proprietary information.

9. In mid-September 2012, FoodQuestTQ LLC officials learned for the first time, that the FDA had been working with Battelle Memorial Institute to build their own food defense

plan builder to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ, to call Mr. Menkheim to express his concerns that FDA was developing a product that already existed. Mr. Menkheim explained that FDA was not competing with FoodQuestTQ LLC had because the food defense plan builder tool being built by the FDA was not nearly as sophisticated as the FoodQuestTQ tools.

10. In late September 2012, Dr. Hnatio had another telephone another conversation with Mr. Menkheim and asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012. Mr. Menkheim told Dr. Hnatio that the principal purpose of the upcoming meeting was to discuss a terrorist targeting tool known as C.A.R.V.E.R. + Shock. He advised that FDA's food defense planner was being developed in order to make it easier for industry to use C.A.R.V.E.R. + Shock.[ii]

11. The next interaction between FoodQuestTQ LLC and the FDA took place on October 2, 2012, when a "go-to-meeting" webinar was held. During the webinar, FoodQuestTQ LLC FDA staff updated Dr. Menkheim and his staff on the company's continued progress to upgrade their suite of computer software tools. Particular attention was given to the use of the company's Food DefenseTQ tool as the way to build food defense plan. A more advanced tool known as Food Defense Architect that would make it even easier for food companies to develop their own food defense plans was also demonstrated.

    During the webinar, FoodQuestTQ again raised their concerns that FDA was building a food defense planner tool to compete with FoodQuestTQ LLC's existing Food DefenseTQ and Food Architect products. To avoid any potential conflict with FDA that could adversely impact their business, FoodQuestTQ LLC offered the FDA a license to use their technology across the food vertical for $1/yr. Prior to the webinar, FoodQuestTQ officials met with a member of their Board of Directors, Mr. Joe Welty, to discuss the FDA's actions and received permission to offer the $1/yr. license in order to avoid direct competition by the FDA. During the webinar, Mr. Menkheim advised that he could not make such a decision but would take the matter to his FDA bosses. FDA never responded to FoodQuestTQ LLC on the matter.

12. On December 1, 2012, when sales failed to materialize for FoodQuestTQ LLC's Food DefenseTQ and Food Defense Architect line of food defense tools, the company was forced to lay off all of their employees including the two founders of the company. Without pay, FoodQuestTQ LLC principals continued to prepare for the December 12,

2012, industry workshop on C.A.R.V.E.R. + Shock and the FDA's new food defense builder tool. The company developed an internet survey to ask the food industry how effective the FDA's C.A.R.V.E.R. + Shock approach was to them in protecting the food supply.

13. On December 6, 2012, Dr. Hnatio of FoodQuestTQ LLC published an article on the potential dangers of using C.A.R.V.E.R. + Shock as a counter-terrorist assessment tool. The article shared the preliminary results of the FoodQuestTQ survey. The results were mixed with a majority of respondents raising questions about the utility of C.A.R.V.E.R. + Shock. The C.A.R.V.E.R. + Shock article written by Dr. Hnatio was a matter of very significant interest throughout the FDA. For example, the web based software used to conduct the survey indicates that Dr. Leanne Jackson, (the former CIFSAN official referenced in entry 2. Above) who is now in charge of FDA's Food Defense Oversight Team, opened the article for review and/or further distribution over 40 times. It is noted that C.A.R.V.E.R. + Shock is a major $13 million funding line item for Dr. Jackson's office.

14. The December 12th 2012, FDA sponsored industry workshop was hosted by the Grocery Manufacturer's Association (GMA) at their Headquarters building in Washington, D.C. Mr. Warren Stone, Senior Director of Science Policy coordinated the meeting. At FoodQuestTQ's request, Mr. Stone allowed for a 20 minute slot on the workshop agenda for FoodQuestTQ to demonstrate their food defense plan builder tool that was already commercially available to the food industry.

    From e-mails sent to us by Mr. Stone as he coordinated the FDA workshop, we first learned that FDA was working under a multi-million dollar contract to help the FDA develop their food defense plan builder. We found the name of Mr. Colin Barthel, who is the Battelle Memorial technical manager for FDA's food defense mission. FoodQuestTQ LLC tried repeatedly to reach Mr. Barthel to discuss our concerns that Battelle Memorial Institute may be using the company's intellectual property to duplicate their products for use by the FDA. After repeated attempts to reach Mr. Barthel by e-mail and telephone to discuss the situation, FoodQuestTQ LLC finally received an abrupt e-mail from him stating he would not speak with them and that the FDA sponsored workshop on December 12th 2012 was strictly limited to food processors. Mr. Barthel referred FoodQuestTQ LLC back to the FDA's Food Defense Oversight Team to discuss any concerns.

    On the evening December 11, 2012, FoodQuestTQ LLC principals were notified by Mr. Stone that FDA had specifically disinvited any ThoughtQuest LLC (now FoodQuestTQ

LLC) personnel from participating in the FDA industry workshop to be held at GMA Headquarters the following day. Mr. Stone was told by the FDA that they did not want to give any preference or any endorsement to one commercial product over any other. FoodQuestTQ LLC was prohibited by the FDA from attending the workshop.

FoodQuestTQ LLC did, however, independently brief a few of the remaining food industry participants late in the day after the FDA sponsored workshop for industry was over and FDA officials had left the building. When FoodQuestTQ LLC officials signed into the conference room where they were going to demonstrate their products, they saw the attendee list of companies that participated in the earlier FDA sponsored industry workshop. The list included numerous companies that were not food processors but, in fact, competitors of FoodQuestTQ LLC, such as Tyco Integrated Systems.

15. In late December 2012, FoodQuestTQ LLC's concerns about the FDA action to prohibit their attendance at the FDA industry workshop caused them to go back and conduct a review of their work with FDA. It was at this time Dr. Hnatio took a closer look at Mr. Park's earlier reference (August 2011) to an FDA web site on modeling, simulation and responses to food defense and food safety emergencies. When Dr. Hnatio fully explored the FDA web page he discovered that the FDA had duplicated elements of their FEAST and FREE tools. Unbeknownst to FoodQuestTQ LLC, the FDA had slightly modified the name of the FDA tool from the FoodQuestTQ LLC's commercial name of FREE to the new government FDA name of "FREE-B."

    Note: During the preceding months, prior to learning about the actions of the FDA to compete with them, company officials were befuddled as to why their sales projections were not being met. They could not figure out why their products were not selling. It was not until after the FDA industry workshop that they began to receive direct feedback from food processing companies. In these sales meetings, industry asked FoodQuestTQ LLC why they should buy their products when the FDA was providing the same thing for free.

16. In January 2013, FoodQuestTQ LLC was denied a vital investor loan to continue operations. During the period from September 2012 through January 2013, FoodQuestTQ LLC was in critical negotiations to obtain an operating loan from their investors. In early October 2012, as the evidence mounted that FDA and Battelle Memorial Institute were duplicating their products and as sales were failing to materialize, FoodQuestTQ LLC principals were left with no option but to inform their Board of Directors of the situation. The news that FDA was spending millions of dollars under a contract with Battelle Memorial Institute to duplicate FoodQuestTQ's products

and poor sales raised the risk of future investment by their investors to an unacceptably high level. In early January 2013, their request for an operating loan was denied.

CURRENT STATUS

In January 2013, representatives of FoodQuestTQ LLC contacted members of Congress to request their assistance in obtaining a meeting with Ms. Elizabeth Dickinson, Chief Counsel at the Food and Drug Administration. Company officials felt that if Ms. Dickinson was made personally aware of the circumstances she would quickly act to correct the situation. At this time, the matter has become tied up in legal maneuvering by the FDA. Company officials still have not been allowed to personally meet with Ms. Dickinson. This is a matter of great concern to FoodQuestTQ LLC since the owners of the business and all employees had to be laid off without pay several months ago and the company cannot afford to pay the attorney's fees required to fight a long protracted legal battle with the FDA.

In February and March 2013, the inventor of the Projectioneering LLC owned patent undertook a comprehensive review of the FDA web site to identify any possible activities where the FDA had infringed on the Projectioneering LLC patent (The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.) The inventor identified five FDA products that accomplished the same or similar functions as the Projectioneering LLC patent and FoodQuestTQ software tools that were already or were in the final process of being made ready for commercial sale before they were duplicated by the FDA. A subsequent technical crosswalk of the five duplicate FDA products against each of the 20 claims and 101 objects of the Projectioneering LLC patent demonstrates flagrant infringement by the FDA.

PRINCIPAL ISSUES

1. FOOD AND DRUG ADMINISTRATION USE OF CONFIDENTIAL FOODQUESTTQ LLC BUSINESS AND PRODUCT INFORMATION

   Over a period of approximately three years FoodQuestTQ LLC met extensively with FDA employees and provided them with detailed briefings which included the proprietary and trade secret information relating to the reduction of their patent for commercial sale to the food industry. All proprietary information shared with FDA employees was clearly marked as containing industry proprietary information. In addition, FoodQuestTQ principals verbally advised the FDA employees they shared any proprietary information with that the information they were sharing required protection pursuant to the Code of Federal Regulations (48 CFR 27.402) and other government statutes.

Note: Title 18 USC 1905 applies to disclosure by a government employee of any information provided to the government by a company or other nongovernment organization, if the provider of the information identified it as proprietary or as being provided to the government in confidence. The penalty is mandatory removal from office (termination of employment), and the offender may be fined not more than $1,000 and imprisoned not more than one year.

Specific legal statutes and portions of the Federal Acquisition Regulations that pertain to the protection of commercially owned proprietary information include:

- Title 18 USC 1831–39 - Protection of Trade Secrets [Chapter 90].
- Title 18 USC 1905 – Disclosure of Confidential Information.
- Title 41 USC 423 – Procurement Integrity.
- Title 5 CFR 734 – Employee Responsibilities and Conduct.
- FAR 3.104-1 – Procurement Integrity, General (48 CFR).
- FAR 27.4 – Rights in Data and Copyrights (48 CFR).
- FAR 52.215-12 – Restriction on Disclosure and Use of Data (48 CFR).
- FAR 52.227-14 – Rights in Data (48 CFR).[iii]

2. FOOD AND DRUG ADMINISTRATION COMPETETITION WITH FOODQUESTQ LLC

The government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry. FQTQ offered the FDA Food Defense Team a $1/yr. license to use FoodQuestTQ LLC technology in order to avoid unfair competition by the government. FDA never responded to the offer. Based on proprietary business information provided to them, FDA was fully aware that the products they were developing with Battelle Memorial Institute were already developed and being commercially sold by FoodQuestTQ LLC.

Efforts to make the food supply safer are a shared responsibility between the government and the private sector and non-regulatory activities have never been considered an inherently government function. A simple Google search of food safety and food defense, identifies literally hundreds of "hits" with private sector companies doing everything from consulting, risk assessments, third party audits in support of FDA's governmental regulatory compliance responsibilities. The FDA itself promotes the use third party private sector companies to assure the quality of food safety and food defense at food operations all across the food supply.

The FDA actions in this case also raise questions regarding the Agency's compliance with OMB Circular A-76. This document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector.

3. THE IMPACT OF THE FOOD AND DRUG ADMINISTRATION POLICY AND ACTIONS ON SMALL BUSINESSES GENERALLY

FoodQuestTQ LLC is only one of millions of small businesses in America that provide the innovation required to solve national challenges. The nation depends on small businesses and the entrepreneurs who risk everything to create them. The jobs the nation must create to keep people employed are generated by small businesses like FoodQuestTQ LLC. Much of the innovation that the nation and our government must have to solve national problems comes from small businesses like FoodQuestTQ LLC. By competing with small businesses like FoodQuestTQ LLC and forcing them out of business, the FDA risks losing the genius and innovation the nation desperately needs to solve the country's food protection and food safety problems.

---

[i] See: http://www.linkedin.com/pub/leeanne-jackson/19/920/718

[ii] Note: C.A.R.V.E.R. + Shock was developed by the military special forces to plan attacks against the critical infrastructures of the enemy. In the aftermath of 9-11, FDA attempted to convert the tool for civilian use by the food industry with mixed results. Currently, the pursuit of C.A.R.V.E.R. + Shock is a continuing $13 million dollar FDA budget line item.

[iii] http://www.wrc.noaa.gov/wrso/security_guide/propriet.htm

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

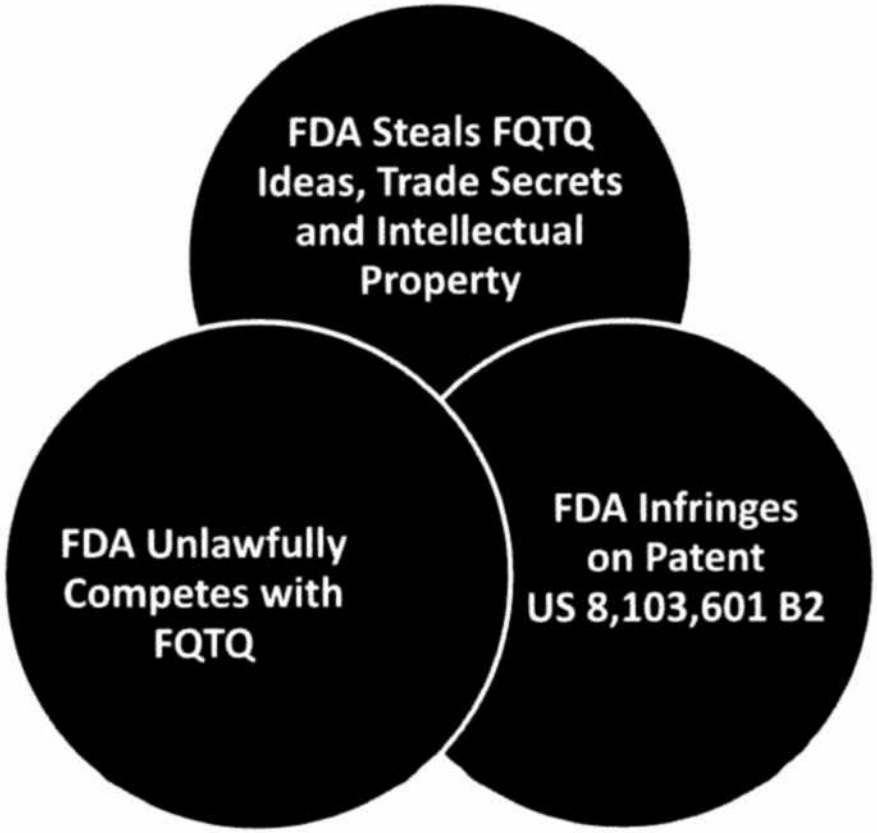
FoodQuestTQ LLC

March 19, 2013

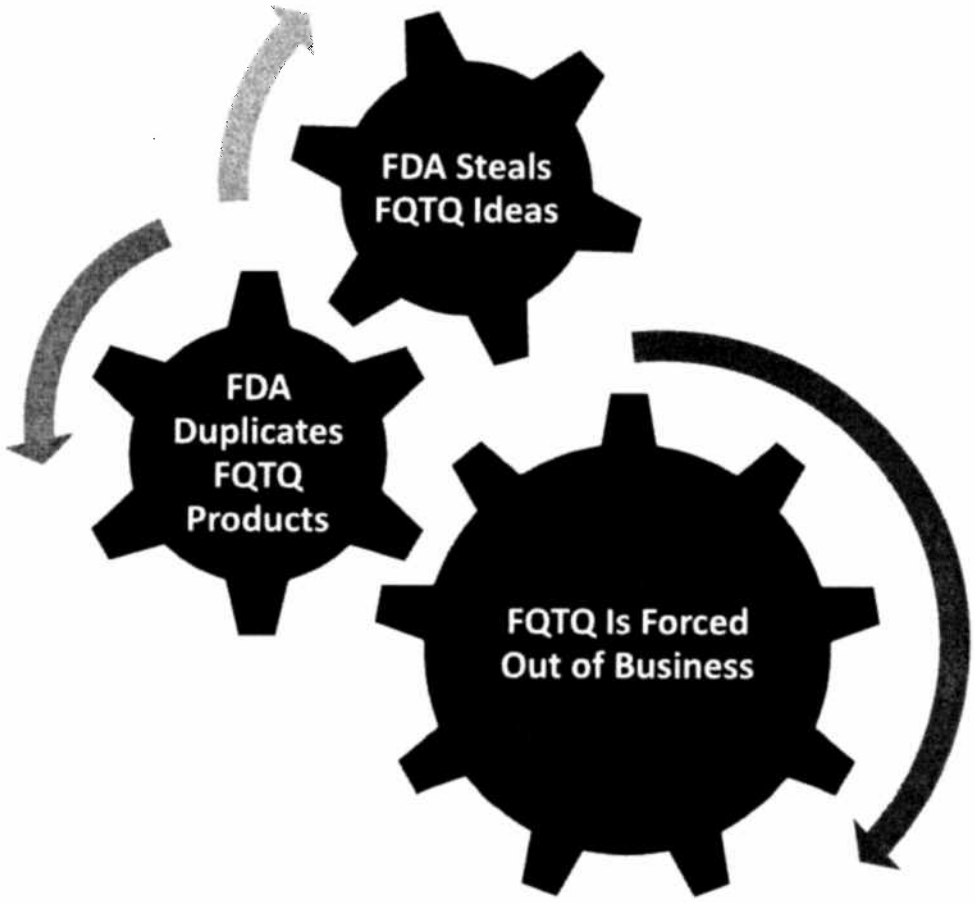
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed.

- The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectiviity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

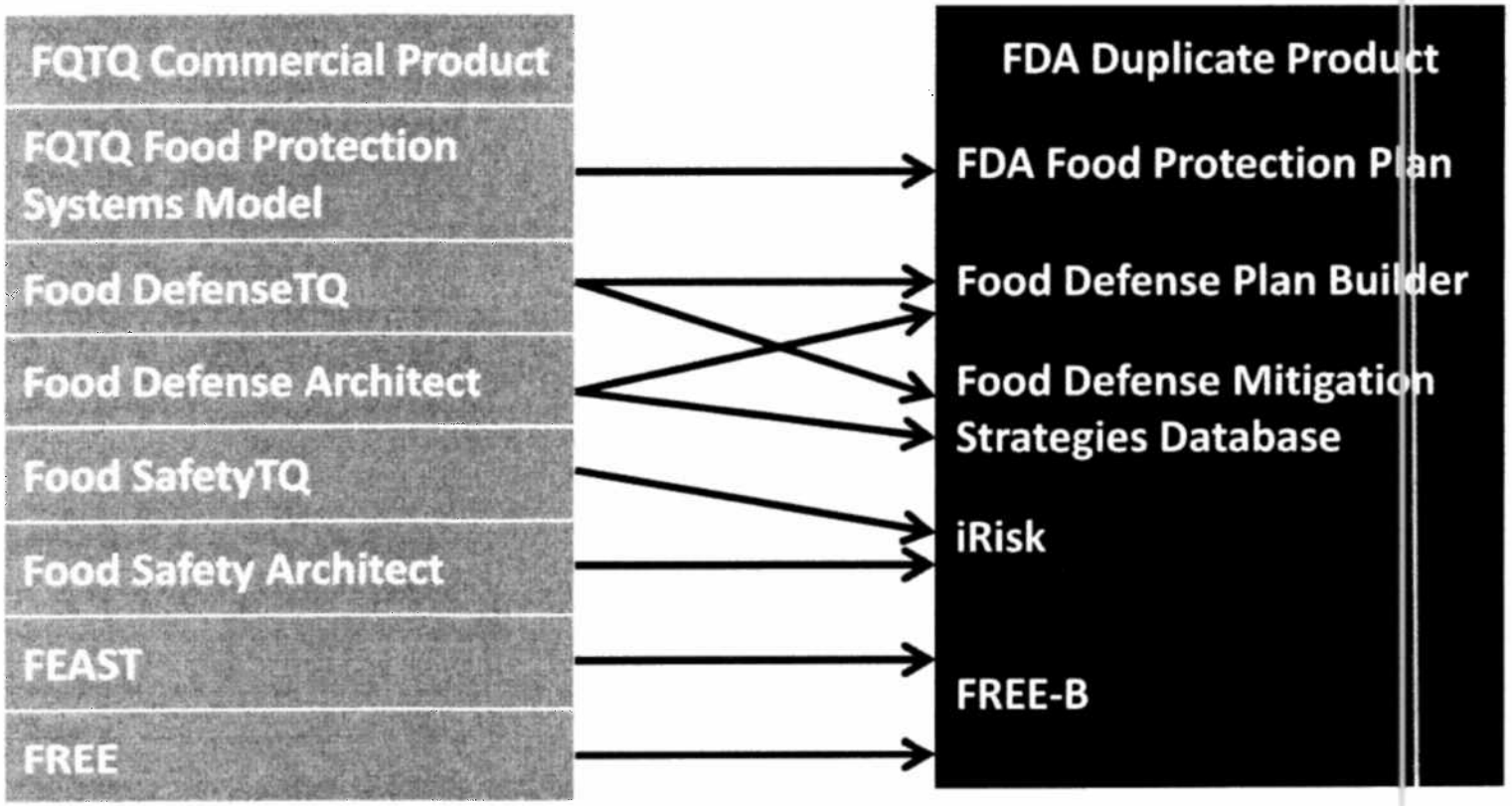
- The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.
- The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.

25. FQTQ Enhanced Risk Communications

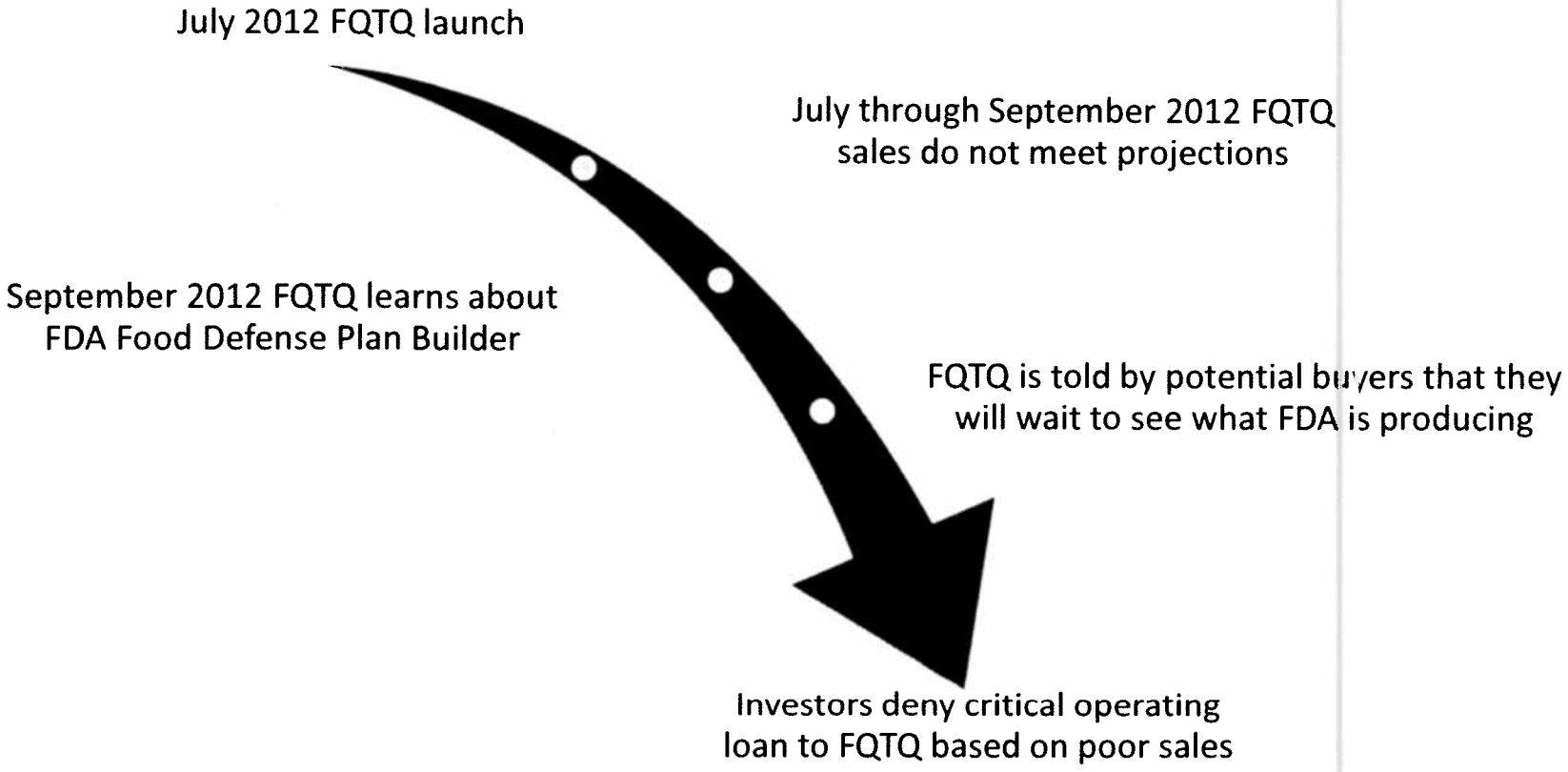
The FQTQ systems model for food protection improves risk communications.

- The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.

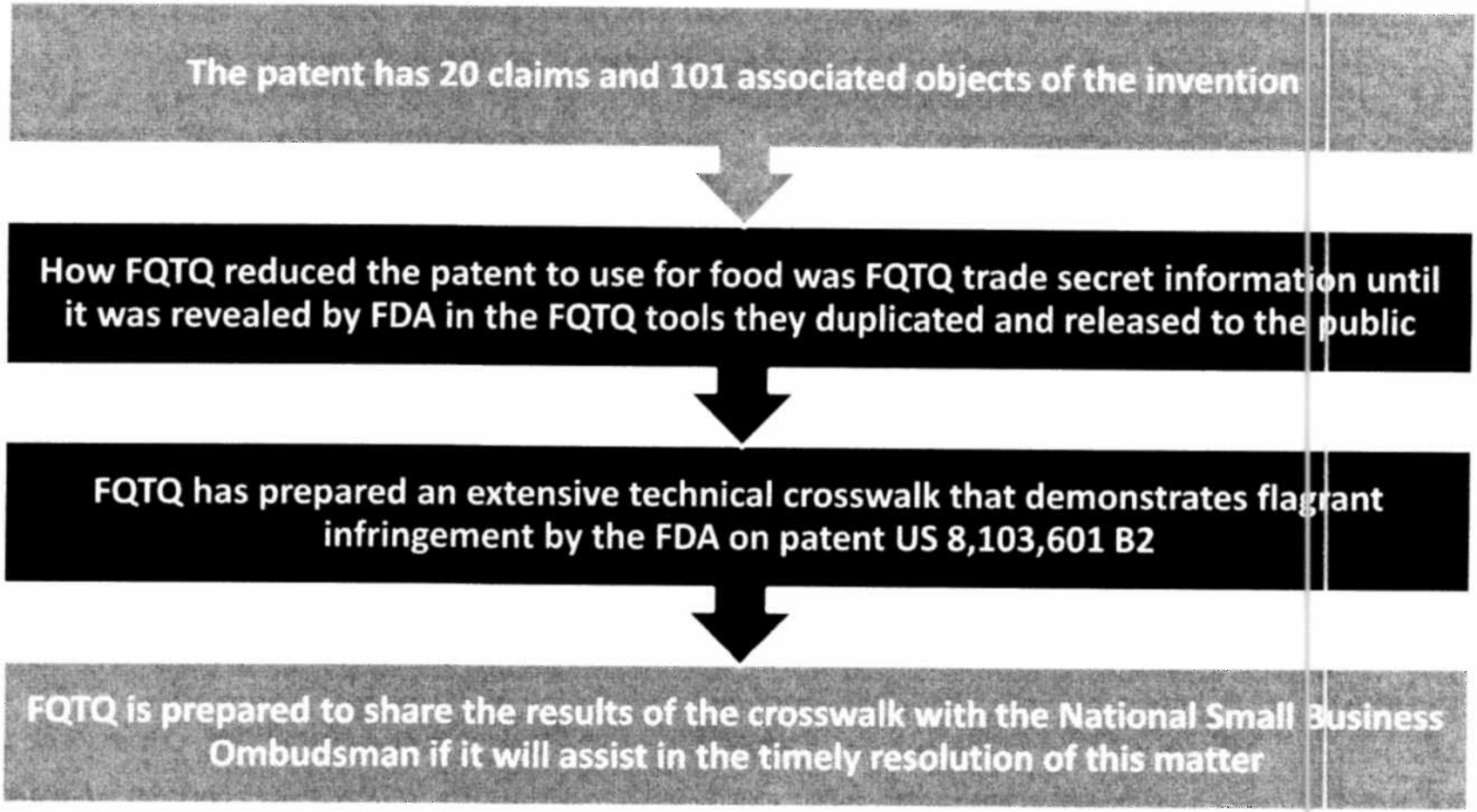
FDA Duplicates FQTQ Products



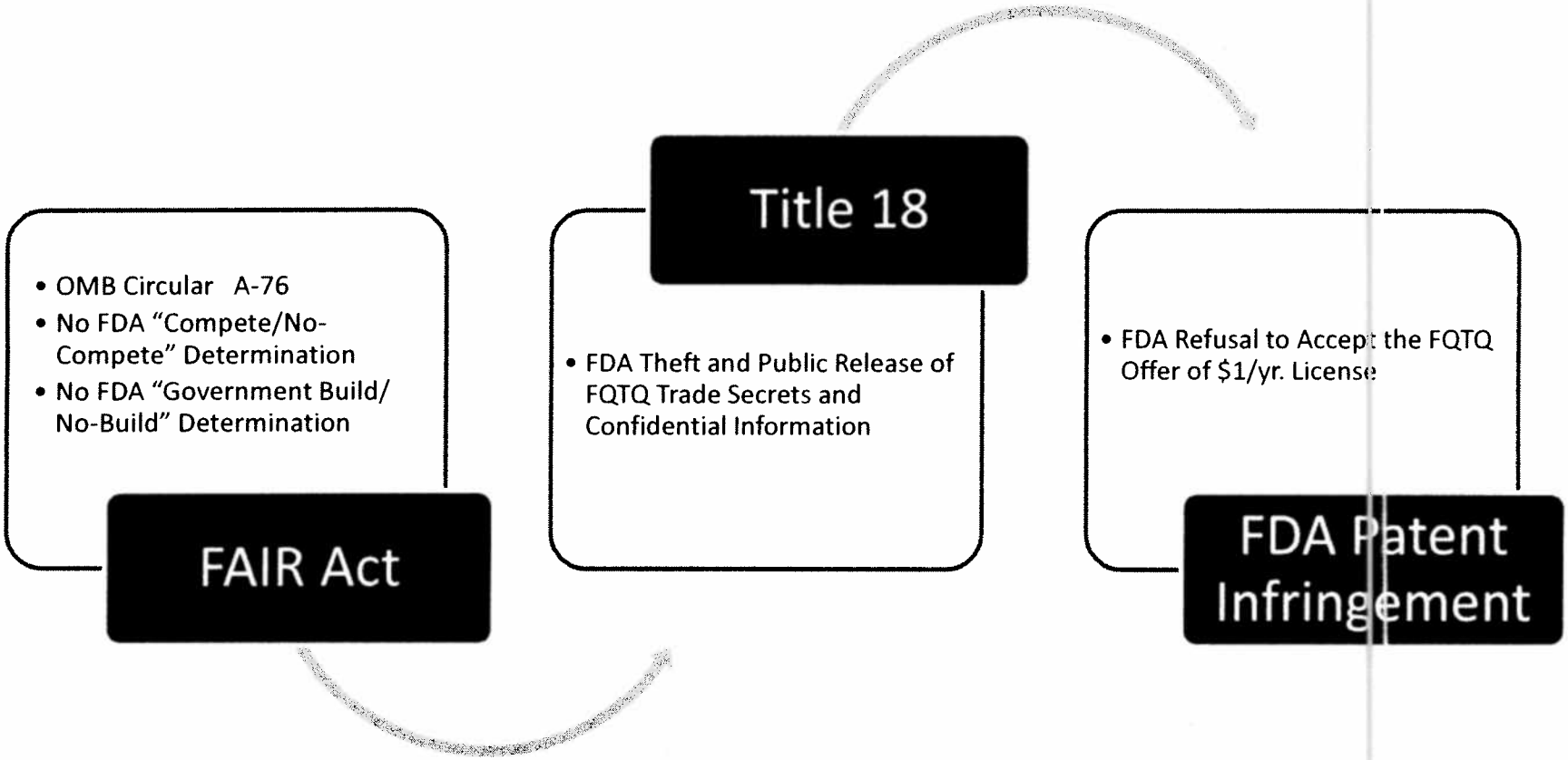
FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2



FDA Unlawfully Competes with FQTQ



Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

March 16, 2013

Dear Ms. Dickinson:

First, we want to thank-you very much for the hard work of Ariel Seeley of your staff. She has worked very diligently on this matter and we appreciate her efforts very much. You must be proud to have her as a member of your staff. We recognize the extremely difficult situation she is in trying, on the one hand, to defend the actions of the Food and Drug Administration while, at the same time, attempting to conduct an honest and good faith review of the situation. We can appreciate the terrible conflict this must create for her. Please extend our thanks to her.

When we first asked to meet with you I was sincerely hoping that we could simply sit down together, talk honestly to one another as people of mutual integrity and quickly move forward to fairly resolve our concerns. But instead the train of justice has fallen off the tracks. It has now been over three months since we first asked to meet with you and we still are not even able to agree that any wrong has actually happened here. As I shared with Ariel earlier, I am a simple man who is not an attorney and I cannot afford to hire one to advocate on my behalf in an adversary legal setting. But it does seem to me, as a layman, that while there is way too much FDA legal jockeying going on, there is way too little effort to resolve the real issues a play here. In the meantime, however, the lives of real people are being destroyed.

Our company, just when we were in the position to make the food supply safer for all Americans, has been forced out of business by the FDA; on our side of the equation we are now in the unemployment lines, we can no longer pay our bills, the credit ratings that we have worked to a lifetime to preserve have been destroyed and all of our families have suffered terribly as the result of the actions taken against us by the FDA. The extended order effects of improper actions have had devastating consequences in this case.

For example, did you know that one of my company's employees is an 80% disabled military veteran who has an extended family that relies on him as the principal breadwinner? Can you possibly imagine what that must be like for him and his family? In another case, a member of the FoodQuestTQ family of employees has worked, scrimped and sacrificed literally everything he owns including his house, his retirement and his entire life savings to make our business a success. He too is the principal breadwinner for an extended family whose elderly in-laws live with his family. There are many other stories of anguish too. It is much too easy to forget that the actions we take can hurt real people.

This is why I am again pleading for your help and understanding to resolve this matter as quickly as possible. What is happening here is not some far away abstraction of reality. It is the real thing. People's lives and futures depend on our integrity, honesty and willingness to come together in a responsible way to resolve this matter quickly and fairly. That is why I am asking for the opportunity to meet with you personally to get the train of justice back on the tracks here. In the meeting, we would like to simply share with you the honest story of exactly what has happened here. I am sure that once you hear the true and complete story you will be appalled and take whatever actions are necessary to immediately turn this bizarre situation around.

It is true that we are at the mercy of the FDA and our own government because we simply cannot afford a long and expensive legal battle to achieve justice for ourselves. In my case, I am a 62 year old white male with few prospects for any possibility of future employment who would likely die before receiving any relief for my family as the result of this terrible situation. I do not like to think about leaving my wife impoverished as the result of the risks I have taken to create a small business. Thus, we have no choice but to rely on you and our own government to act with integrity to fairly protect our interests.

But time is definitely running out for us. This is why we have reached out to the Small Business Administration Office of Small Business Advocacy and the National Ombudsman for Small Business to help the FDA and FoodQuestTQ LLC come together. Our hope is that the SBA Ombudsman will carefully watch what is going on as an objective third party to help the FDA and FoodQuestTQ balance the need for FDA legal propriety against the real world needs of FoodQuestTQ to fairly resolve the situation as soon as possible. We believe that this approach will help both the FDA and FoodQuestTQ work through the issues fairly and objectively. The wonderful added advantage of this approach

is the requirement that we must complete our work within 30 days and file a full report to the Small Business Administration. Of course, this is critically important if FoodQuestTQ is to have any hope of surviving the actions that have been taken against us by the FDA.

Thank-you very much for your help in working with us. It is truly appreciated. We know how busy you are. If the personal meeting I suggest is agreeable to you please let me know and I will work our schedules to meet at any time that is convenient for you and your staff.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,

John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

cc: Ms. Ellie Zahirieh, Office of the SBA Ombudsman

President Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

January 12, 2013

Dear Mr. President,

We desperately need your help. I am an owner and the Chief Science Officer of a small Maryland-based company that specializes in making the food we all eat safer.

In 2002, I began a program of extensive research on new ways to reduce the risks associated with protecting the nation's critical infrastructures from adverse events as part of my doctoral dissertation studies at the George Washington University. The results of my research have received public acclaim. For example, in 2008, I was highly honored to receive the Navigator Award along with Senator Lieberman, Representative Dana Rohrabacher and the CIA Director for Science and Technology for the quality of my research. The results of the research are now patented.

In 2009, I joined a group of highly dedicated people who wanted to make a difference in the world and we began the process of reducing the patent to practice across the global food supply by creating a revolutionary system that actually quantifies the risk of adverse events happening and provides ways to prevent and mitigate the consequences of untoward events including accidents, intentional attacks and natural disasters. From 2009 through December 2012, we extensively coordinated our work directly with staff at the Food and Drug Administration (FDA).

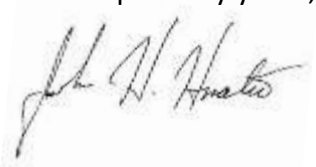
In December 2012, however, we were absolutely dumbfounded to learn that the FDA staff, completely unbeknownst to us, was taking our patented approach and the proprietary confidential information we were sharing with them to duplicate our products under a multi-million dollar contract with Battelle Memorial Institute. Of course, we cannot understand how our own government can take our patent, our ideas and hard work in this way. We cannot understand why the FDA is investing millions of taxpayer dollars to do what we have already done.

Since December, we have been unable to sell our products. The food companies we work with are now asking us why they should buy our products if they can get the very same thing for free from the government. We have been forced to lay off all of our employees. I am particularly concerned about one member of our team who is a 70% disabled military veteran who gave up everything to join our company.

Mr. President we are writing to you as a last resort. We have no money left to pay for a long and expensive legal battle involving the FDA. The FDA knows this. Our life savings are completely gone. We cannot even afford to pay our own salaries. Our situation cannot wait.

We want to thank-you very much for reading this letter and we hope that you will be able to help us turn this bizarre situation around.

Most respectfully yours,



John Hnatio, Ed.D., Ph.D.
Chief Science Officer
FoodQuestTQ LCC (Suite 104)
4720 Hayward Road
Frederick, MD 21702
(O) 240-439-4476 x-11
(C) 301-606-9403
E-mail: jhnatio@thoughtquest.com

President Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Via E-mail and Post

April 1, 2013

Dear Mr. President,

On January 12, 2013, we wrote you a letter requesting your help in resolving a dispute with the Food and Drug Administration but we never received any response. A copy of our previous letter to you dated January 12th is attached. We recognize how busy you are but we still desperately need your help and that is why we are writing to you again.

We are a small business located in Frederick, Maryland. We are writing to you to ask for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA). At FoodQuestTQ we produce advanced risk management software to help industry produce safer food.

Last year, we discovered that the FDA took our intellectual property and duplicated our products and, in so doing, tried to drive us out of business. In December 2012, we requested a personal meeting with Ms. Elizabeth Dickinson, the Chief Counsel at the FDA. Our objective was to simply sit down with Ms. Dickinson to explain the actions that were taken against us by the FDA and to work with her to fairly resolve the matter. But Ms. Dickinson refused to meet with us.

Instead, the FDA engaged in a harmful and non-productive dialogue with us as we attempted to work with them to try and resolve this matter. Earlier this month, we had no choice but to reach out to the National Ombudsman for Small Business because of the impasse. In response to our complaint to the National Ombudsman for Small Business, the matter was elevated to the DHHS Office of the General Counsel.

I am very disappointed to report to you that our interactions with the DHHS counsel assigned to this matter continue to be very non-productive. It appears that the counsel's efforts to defend the wrongdoing of his friends and colleagues in the FDA may have now out shadowed the importance of engaging in an honest dialogue about what has happened and working together with us to try and resolve any problems.

That is why we recently requested the opportunity to meet with personally with Secretary Sebelius so that we might be able to describe the actions taken against by the FDA us and work with her to try and resolve this problem. The time now being spent on non-productive efforts by the government to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. Mr. President, would it not be better for everyone

involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?

I want to personally assure you, as I have already assured Secretary Sebelius, we at FoodQuestTQ LLC are simply looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, government and industry can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

Mr. President, we hope that you will encourage Secretary Sebelius to meet with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people.

You can learn more about our situation by visiting YOU TUBE at https://www.youtube.com/watch?v=xKHdJhGLQok where we have also posted a link for people to sign a petition requesting that you and Congress help protect the millions of small businesses across America from being forced out of business by the federal government. Our petition asks that you and Congress enact new laws to prevent the federal government from unfairly competing with small businesses in America to force them out of business.

We want to thank-you very much for reading this letter and we hope that your intervention in this matter can help us to turn this bizarre situation around.

Most respectfully yours,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LCC (Suite 102)
4720 Hayward Road
Frederick, MD 21702
(O) 240-439-4476 x-11
(C) 301-606-9403
E-mail: jhnatio@thoughtquest.com

Attach: (1) 1-12-2013 Letter to President Obama

cc: Secretary Sebelius, DHHS
Dr. Dale Berkley, DHHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA
Ms. Ellie Zahirieh, NOSB

ThoughtQuest LLC
We make your complex world simpler

FDA BRIEFING BOOK: FOOD DEFENSETQ™

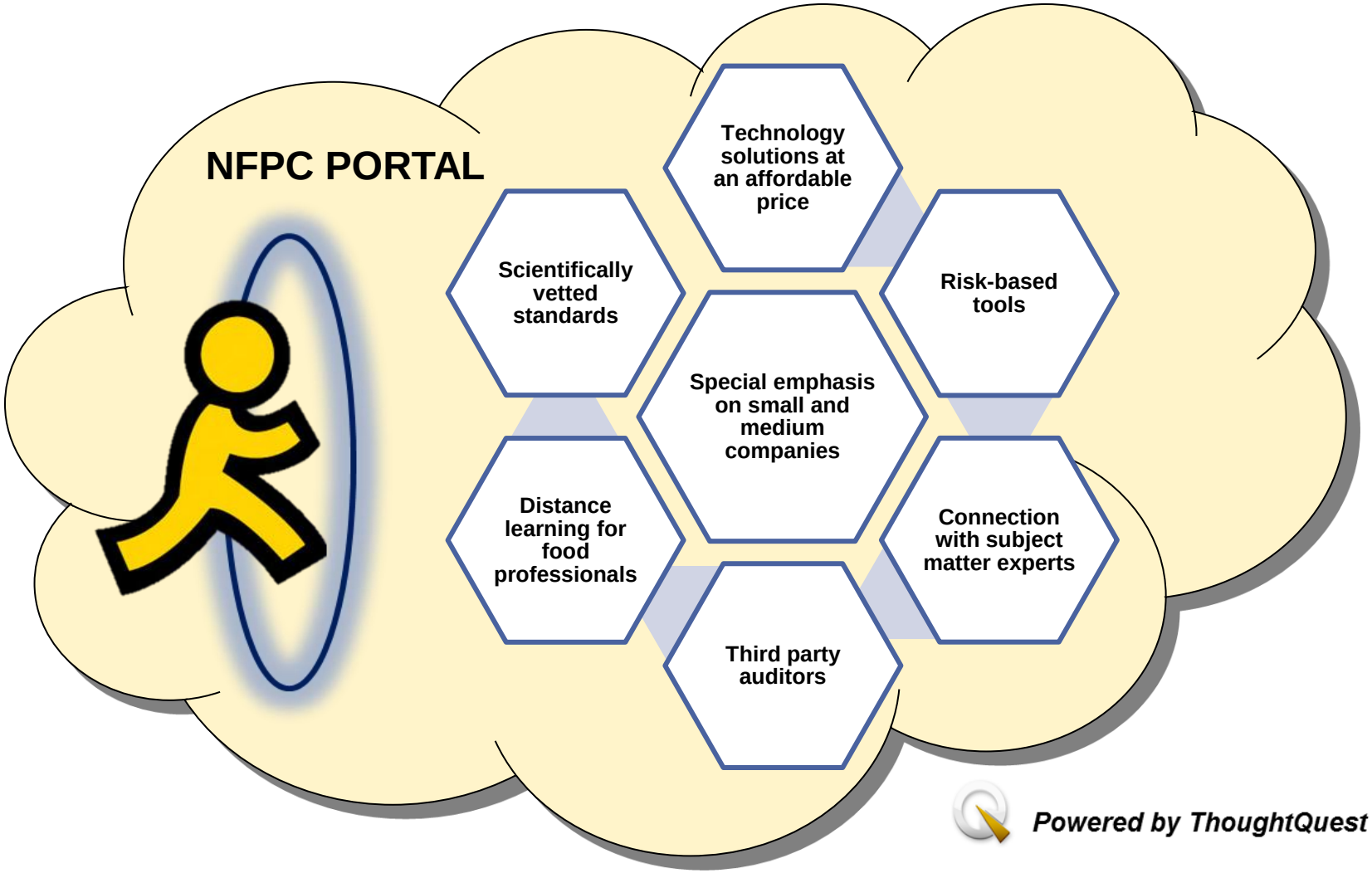
JOHN HNATIO

FEBRUARY 2012

SUMMARY

ThoughtQuest has developed a suite of patented science and risk-based tools known as Food ProtectionTQ™ (with TQ standing for threat quotient)	Address assessment, prevention and response
	Look at all-hazards events
	Science and risk-based
One of the tools is called Food DefenseTQ™ that looks at:	Food defense incidents
	Fires and arson
	Equipment failure
	Industrial accidents
	Natural disasters
Designed to support Carver + SHOCK	Uses quantitative risk values
	Computer intensive analytics
	All data is scientifically and independently vetted
We are now establishing the National Food Protection Collaboratory™ (NFPC) web-based portal to make the new technology available to small and medium sized food business	A community of interest for small and medium businesses around affordable easy to use technology solutions
	Science and risk-based vetted tools
	Low cost consulting to establish food defense plans
	Programs of food defense education

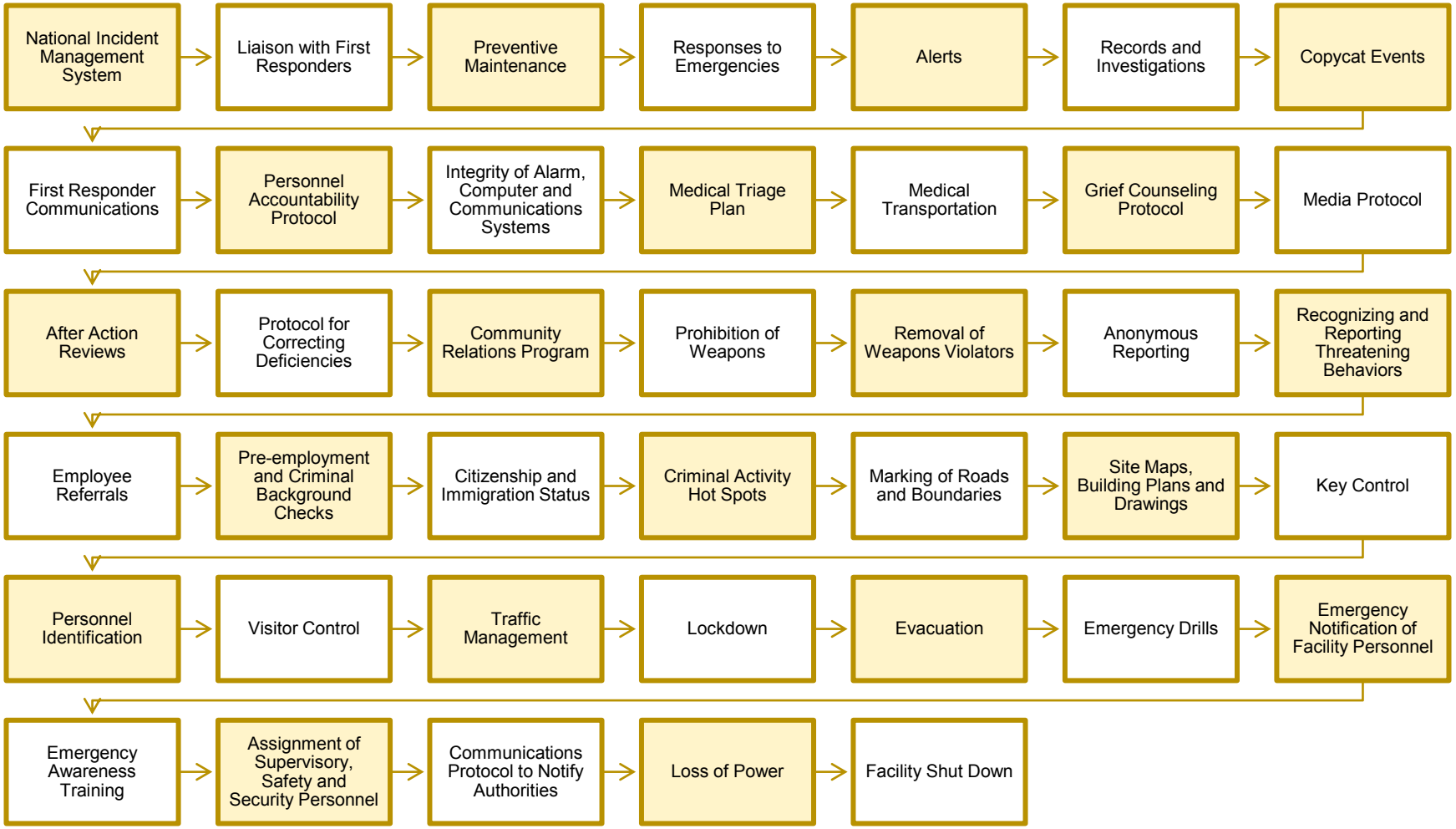
THE NATIONAL FOOD PROTECTION COLLABORATORY™ (NFPC) PORTAL



ONE OF SIX TOOLS THAT COMPRISE FOOD PROTECTIONTQ™

FPTQ Tool	Capability	
POISON™	Repository of all hazards events affecting the food supply chain. By studying these past events:	Tells you what worked and what didn't work;
		Helps you figure out the best things to do when confronted with a similar situation, and;
		Helps identify the early warning signals to prevent bad things before they happen.
Food Mapper™	Powerful search engine of regulations and best practices that tells you:	Who's responsible for what;
		What you must comply with, and;
		The best industry practices.
Food SafetyTQ™ and ***Food DefenseTQ™***	***Real time assessment of all aspects of plant operations including food safety and defense to:***	***Tell if you are in compliance;***
		Tell if you are using best industry practices, and;
		What needs to be fixed and how.
FEAST™	Prevents all hazards events by:	Telling you the type of events most likely to happen at your facility, and;
		Telling you how to prevent the events from happening.
FREE Tool™	Guides more effective responses to food emergencies by:	Using an automated system that assures the most timely and effective responses

FOOD DEFENSETQ™ (FDTQ) HAS 40 CROSS CUTTING SURVEY QUESTIONS



FOOD DEFENSETQ™ HAS 75 CATEGORY SPECIFIC SURVEY QUESTIONS

Adulteration of Food and Water	• Twelve Question Sets
Communicable Disease	• Eight Question Sets
Workplace Violence	• Six Question Sets
Improvised Destructive Devices	• Eight Question Sets
Fires and Arson	• Eleven Question Sets
Transportation Security	• Eight Question Sets
Nuclear, Biological, and Chemical Emergencies	• Eight Question Sets
Other Crimes	• Seven Question Sets
Natural Disasters	• Seven Question Sets

THE FOUR COMPONENTS OF AN FDTQ QUESTION SET

1. Minimum Compliance Standards

For those questions addressed by government regulations, the minimum compliance level is defined as meeting the government requirement as contained in the Code of Federal Regulations (CFR's), USDA Directives, agency statute and state requirements.

2. Best Practices

Best practices go beyond minimum compliance and come from best science and risk-based standards.

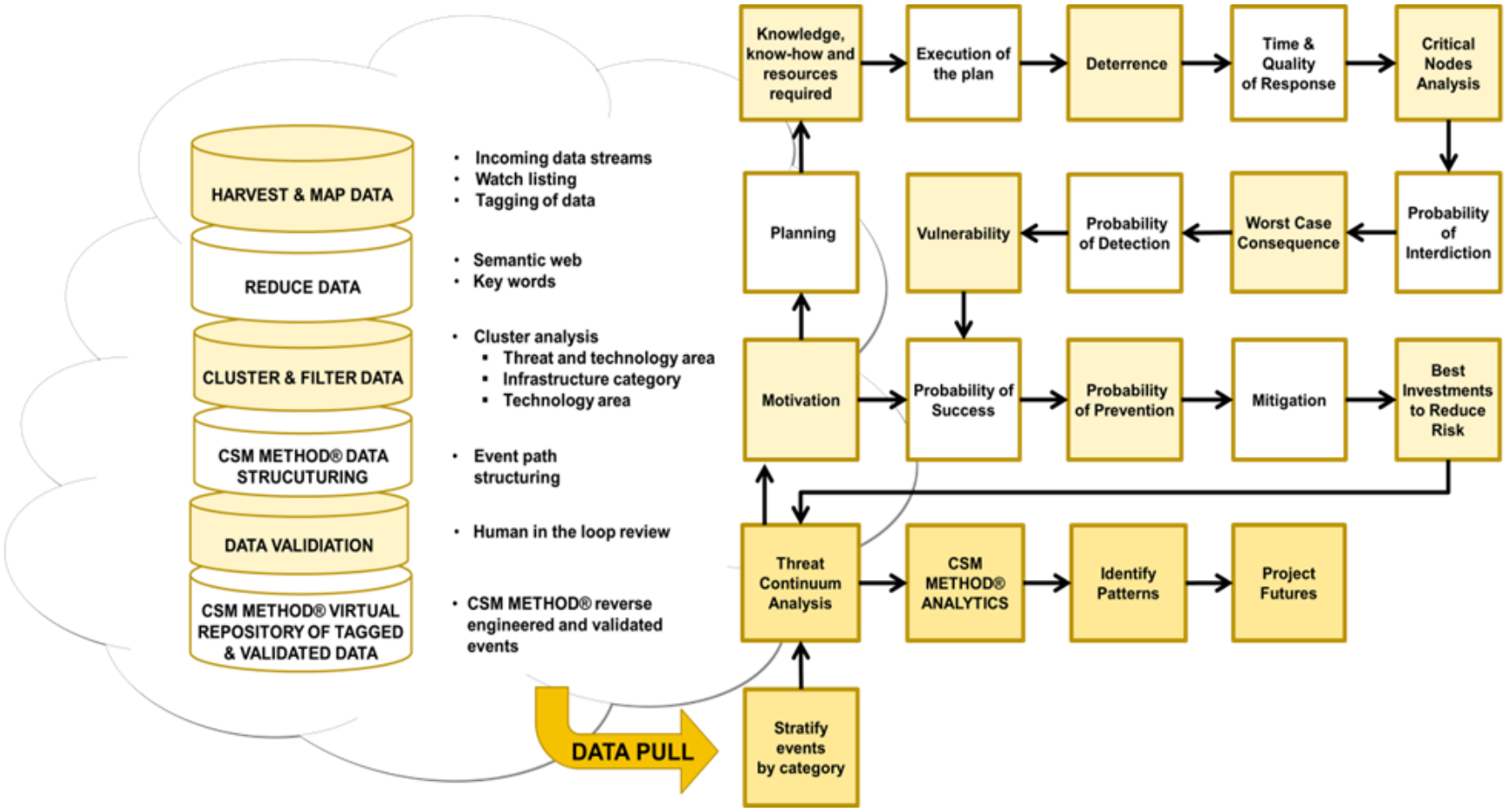
3. Control Questions

Control questions are designed to quantify varying levels of implementation of minimum compliance standards and science and risk-based standards.

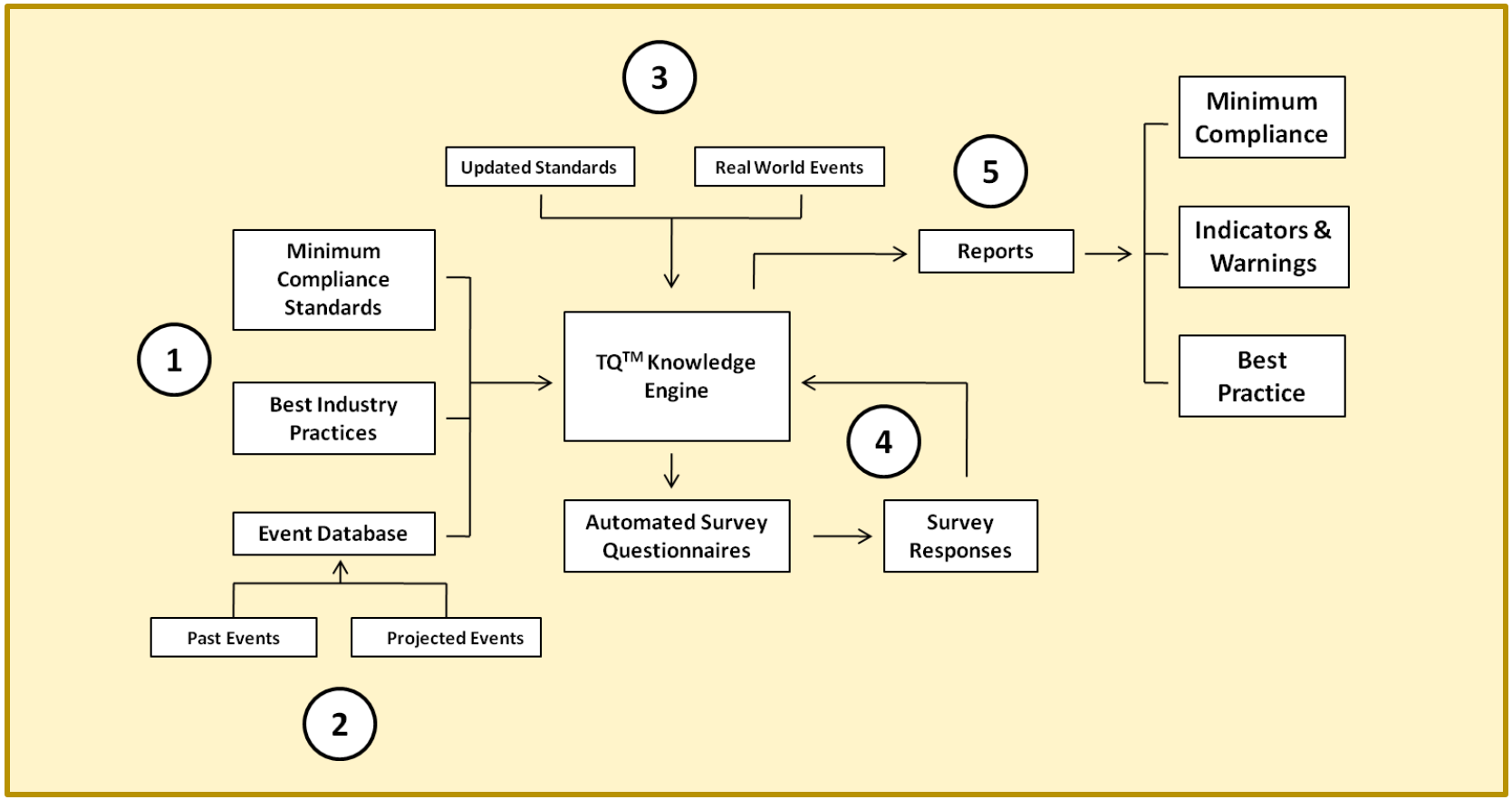
4. References

References are "hot linked" to the specific requirements of the CFR's; best industry practices and specific information further describing the minimum compliance regulations and/or science and risk-based standard.

THE FOOD DEFENSETQ™ ARCHITECTURE



THE FDTQ SOFTWARE STRUCTURE



1. Food Mapper™ compliance standards and best industry practices
2. POISON™ to provide past and projected events
3. Real time threat and risk warnings/continuous 24/7 update of Food Mapper™ and POISON™
4. & 5. Food DefenseTQ™ and Food SafetyTQ™ assessment

FDTQ APPLIES A UNIQUE SET OF ALGORITHMS TO TRANSFORM DATA

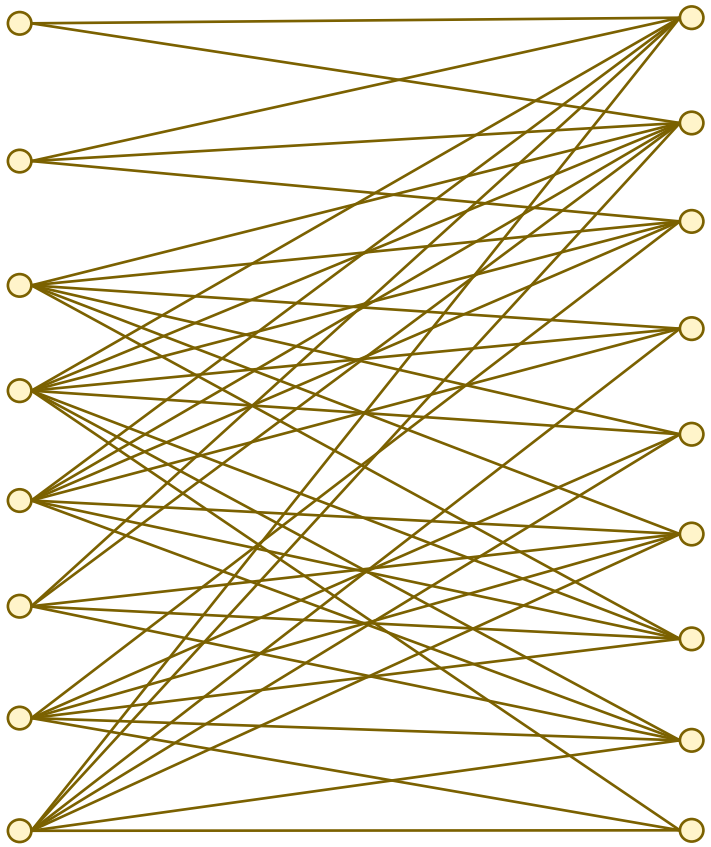
Function	Algorithm	Description
Probability of Occurrence	PO f (v) (c)	The probability of an adverse food event occurring (PO) is a function of the vulnerability (v) of the target multiplied by the worst case consequences (c) if the target were successfully attacked or interrupted
Mitigation	(v) (c) f m	The vulnerability of the target (v) multiplied by the consequences if it were successfully attacked or interrupted (c), become a function of the mitigating actions taken to prevent or limit the consequences of the attack or interruption as depicted by m
Natural Phenomenon	(v) f PO (c)	For natural events the vulnerability of the target (v) is a function of the probability of the natural event occurring based on frequency, trends analysis and modeling projections (PO) multiplied by the worst case consequences (c) should the target be subjected to a natural event
Estimate of Event Sequence Interruption (EESI^{TM})	I f (dn_t))(c_t) (dy_t) (r_t) (r_q)	The interruption of an event sequence is a function of time of detection (dn_t), delay time (dy_t), time to communicate a response action (C_t), time to respond (r_t) and quality of response (r_q)

FDTQ USES MULTIPLE COMPUTER INTENSE DATA ANALYTICS

EPA™ (Event Path Analysis)	Events are gathered, scientifically reverse engineered to produce event paths and grouped, based on category.
(v) (Vulnerability)	Each event is weighted based on the degree of vulnerability of the target.
(c) (Consequence)	Each event is weighted based on the potential worst case consequences of the event.
PO (Probability of Occurrence)	Each event is scored to produce a probability of occurrence (PO) value.
Mitigation	The factors that could mitigate the consequences of each event are systematically identified and weighted.
CNA™ (Critical Nodes Analysis)	A set of baseline critical nodes representing intersecting activities, i.e., vertices, for each event path are identified.
TCA™ (Threat Continuum Analysis)	Baseline values for deterrence, detection, prevention, response and mitigation are calculated for each critical node.
FEAST™ (Food Event Analysis and Simulation Tool)	Critical nodes are weighted against “actual” and “expected” performance.
	Actual and expected performance are graphically portrayed.
	Best investments are graphically portrayed.
EESI™ (Estimate of Event Sequence Interruption)	An estimate of the facility’s ability to prevent the event is calculated.
DPA™ (Decision Path Analysis)	Each event is analyzed to identify critical decisions and decision paths to improve responses.

FPTQ IS DESIGNED TO HELP COMPANIES BETTER MEET FOOD PROTECTION REQUIREMENTS

Requirements
Science & risk-based standards
Mandatory recalls
Production of records
Mandatory food defense
Enhanced food safety
Prevention
Enhanced traceability
Increased inspection



FPTQ Capability
Standards are vetted by scientists
Risk is quantitatively derived
Automated recall management
Epidemiological modeling
Automated record keeping
Perpetual food safety assessment
Perpetual food defense assessment
Modeling to prevent events
Computer guided responses

Pages 314 through 358 redacted for the following reasons:
- -
Entire page withheld under (b)(5).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
Room 2B-50, NIH Bldg. 31
31 Center Dr., MSC 2111
Bethesda, Maryland 20892-2111
(301) 496-6043
Fax (301) 402-1034

April 26, 2013

VIA FEDEX AND EMAIL

Dr. John Hnatio
FoodQuestTQ, LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
jhnatio@thoughtquest.com

Dear Dr. Hnatio:

We were asked to respond to your letter of April 1, 2013, to Secretary Sebelius.[1] As we describe below, the Food and Drug Administration (FDA) and other operational divisions within the Department of Health and Human Services (HHS), including their respective counsels' offices, have investigated your claims. These include serious allegations of patent and copyright infringement, misappropriation of allegedly confidential material, and various statutory violations.

Despite our best efforts to undertake a thorough investigation of your claims, you have refused to provide us with copies of the works that you allege the Agency has infringed. Consequently, we have done all that we can to evaluate the many allegations that you have made—set forth in multiple communications to disparate parties throughout the agency and indeed the government—with the evidence we have available. For the reasons set forth below and because we have found no supporting evidence for your allegations, we consider this matter closed.

Summary of Contacts and Communications

On January 9, 2013, FDA's Office of the Chief Counsel, which is also the Food and Drug Division of the HHS Office of General Counsel, received a letter dated December 19, 2012 from Senator Barbara Mikulski on your behalf, forwarding your letter of December 14, 2012.[2] In your December 14, 2012

[1] Exhibit 1: April 1, 2013 letter from John Hnatio to Secretary Sebelius.
[2] Exhibit 2: December 14, 2012 letter from John Hnatio to Sen. Mikulski, forwarded to FDA by Sen. Mikulski by letter dated December 19, 2012.

letter, you claimed that FDA took your patented technology (specifically, "Food Defense Architect") and used it to build an FDA software system. You also complained that you were unfairly excluded from the Agency's process for developing its food safety tools. In particular, you claimed that you were scheduled to participate in a FDA industry workshop and were disinvited because FDA did not want to endorse a specific company's product, and you complained that another company who produces similar products (Tyco Integrated Systems) was allowed to attend.

By letter dated January 28, 2013, Elizabeth Dickinson, FDA's Chief Counsel and HHS Associate General Counsel for the Food and Drug Division, responded to you stating that she was looking into your concerns and she asked for more information, including identification of the patents to which you referred in your December 14, 2012 letter, identification of the FDA software system you allege uses your ideas, and identification of the individuals with whom you were communicating at FDA about those patents.[3] On February 22, 2013, Ms. Dickinson sent you a second letter again requesting the information previously requested on January 28, 2013.[4]

On February 25, 2013, you emailed and faxed Ms. Dickinson's office a letter dated February 12, 2013, explaining that you had faxed this letter to the office previously on February 12, 2013.[5] In this letter you referenced the FDA Food Defense Plan Builder (FDPB), which you claim duplicates your "FoodDefenseTQ"/"Food Defense Architect" tool, and FDA FREE-B, which you claim duplicates your "FREE" and "FEAST" tools. You also referenced U.S. Patent No. 8,103,601 and claimed that FDA had infringed its claims.

On February 28, 2013, Ariel Seeley, an attorney in FDA's Office of Chief Counsel, responded to you by email, noting the allegations referenced above.[6] Ms. Seeley stated that "[i]n order for us to evaluate these claims, we would need to compare your products to ours. Accordingly, please provide us with copies of your Food DefenseTQ tool and the FREE and FEAST software tools, in whatever form you think would be convenient for this purpose."

On March 2, 2013, you emailed Ms. Seeley.[7] In this email you requested that FDA sign a non-disclosure agreement before you would share your software tools with FDA, and you included a draft agreement. You also added a new claim that FDA's iRISK tool "duplicates" your "Food Mapper" tool.

On March 8, 2013, you emailed Ms. Seeley.[8] In this email you sought a status update and also added new claims that the FDA Food Protection Plan "duplicates" your "CSM Method" and that the FDA Food Defense Mitigation Strategies Database "duplicates" your "POISON," "FoodDefenseTQ," "Food Safety Architect," "Food Defense Architect," and "Food Mapper" tools.

On March 11, 2013, you emailed Ms. Seeley asking her to contact you. Ms. Seeley emailed you back the same day indicating that she would get back to you later in the week.[9]

On March 13, 2013 you emailed Ms. Seeley, repeating your claims, adding another FDA tool you suggest

---

[3] Exhibit 3: January 28, 2013 letter from Elizabeth Dickinson to John Hnatio.
[4] Exhibit 4: February 22, 2013 letter from Elizabeth Dickinson to John Hnatio.
[5] Exhibit 5: February 25, 2013 email from John Hnatio to Mark Raza, attaching February 12, 2012 fax from John Hnatio to Elizabeth Dickinson.
[6] Exhibit 6: February 28, 2013 email from Ariel Seeley to John Hnatio.
[7] Exhibit 7: March 2, 2013 email from John Hnatio to Ariel Seeley.
[8] Exhibit 8: March 8, 2013 email from John Hnatio to Ariel Seeley.
[9] Exhibit 9: March 11, 2013 12:06 PM email from John Hnatio to Ariel Seeley; March 11, 2013 12:22 PM email from Ariel Seeley to John Hnatio.

may copy some of your technology (FDA EMS), and seeking a status update.[10] In this email you also referenced the FAIR Act and OMB Circular A-76.

Later in the day on March 13, 2013, Ms. Seeley emailed you, and attached a revised non-disclosure agreement signed by Ms. Dickinson on behalf of FDA and repeated, for clarity, that FDA was only requesting nonexclusive access to the tools that you claim were infringed in order to evaluate your concerns.[11]

Later the same day, you responded to Ms. Seeley, questioning why FDA was only requesting nonexclusive access to your software tools that were at issue.[12]

On March 14, 2013, Ms. Seeley emailed you, explaining that the information you had already provided about your patent was sufficient for the time being, and that her request was limited to the tools at issue because she needed to evaluate your claims (which appeared to be largely based on a claim of copyright infringement) by comparing your products to FDA's products.[13]

Later on March 14, 2013, you emailed Ms. Seeley with requested changes to the non-disclosure agreement.[14] You also repeated your earlier questions and noted that you could not afford legal counsel.

On March 22, 2013, Ms. Seeley emailed you and introduced me, an intellectual property attorney in the HHS Office of General Counsel. She indicated that I had been provided with background information and materials.[15] In response to your repeated questions and your statement that you could not afford legal counsel, Ms. Seeley recommended that you consult with an attorney and noted that there are organizations that provide free or low-cost legal services to people who cannot otherwise afford legal representation.

On March 27, 2013, I emailed you, stating that I needed to compare FDA's tools to your tools to evaluate your claims of "duplication," that I needed a copy of your tools to do this, and I included a revised copy of the non-disclosure agreement accepting some, but not all, of your changes.[16] I also listed information that we would need to evaluate your patent infringement claim.

On March 28, 2013, you responded and, ignoring the fact that you have made serious accusations of patent and copyright infringement against this Agency, complained that we had "turned this matter into an adversary legal defense."[17] Furthermore, after insisting that you could not provide us with copies of the works that we allegedly infringed without a non-disclosure agreement, you rejected the latest version of the revised non-disclosure agreement apparently because you were unhappy with a statement of its "purpose." In this letter, you expressed your expectation that FDA must provide you with certain information about FDA's tools in exchange for receiving access to your tools to evaluate your claims of "duplication."

At this point we reached an impasse. Attorneys in the Office of General Counsel had repeatedly explained that we needed access to your tools to evaluate whether FDA's tools in fact have any similarity to them, but you refused to provide access to those tools without receiving a contractual commitment to

---

[10] Exhibit 10: March 13, 2013 11:36 AM email from John Hnatio to Ariel Seeley.
[11] Exhibit 11: March 13, 2013 4:05 PM email from Ariel Seeley to John Hnatio.
[12] Exhibit 12: March 13, 2013 4:17 PM email from John Hnatio to Ariel Seeley.
[13] Exhibit 12: March 14, 2013 9:31 AM email from Ariel Seeley to John Hnatio.
[14] Exhibit 12: March 14, 2013 10:53 AM email from John Hnatio to Ariel Seeley.
[15] Exhibit 13: March 22, 2013 email from Ariel Seeley to John Hnatio.
[16] Exhibit 14: March 27, 2013 email from Dale Berkley to John Hnatio.
[17] Exhibit 15: March 28, 2013 email from John Hnatio to Dale Berkley.

an unspecified disclosure of FDA information. This was an unreasonable request and not something that FDA was prepared to do. FDA was willing to sign a standard non-disclosure agreement for the limited purpose of receiving and reviewing your software tools in response to your allegations. However, every reasonable version of the agreement was rejected by you based on some minor pretense. Thus, we have conducted an investigation of your complaints using the limited information you did provide, and in this letter we summarize the results of that investigation.

At various times during and after the communications described above, you contacted others about your claims, including the Small Business Administration (SBA)[18], the Secretary of the Department of Health and Human Services[19], the President of the United States[20], and the FDA Ombudsman[21]. Because your March 19, 2013 email to the SBA contained the most detailed statement of your allegations, this response focuses primarily on your allegations as described in that email.[22]

FDA's Food Defense Documents and Tools

In May 2007, the Secretary of HHS and the Commissioner of FDA charged FDA to develop a comprehensive food protection plan to keep the nation's food supply safe from both unintentional and deliberate hazards and counter them before they do harm. In response, FDA developed and released the FDA Food Protection Plan in November 2007. The plan addresses both food safety and food defense for domestic and imported products. The plan operates through integrated strategies that: focus on risks over a products life cycle from production to consumption; target resources to achieve maximum risk reduction; address both unintentional and deliberate contamination; and use science and modern technology systems. The Food Protection Plan is available for free on FDA's website.[23]

In February 2011, FDA began development of the Food Defense Plan Builder through a contract with Battelle Memorial Institute. FDA planned for this tool to combine its other food defense tools (then under development, at various stages of completion) into one user-friendly program that food companies could use to develop food defense plans specific to their operations, drawing on other FDA preexisting sources of information and guidance. The Food Defense Plan Builder has not yet been released on the FDA website.

In March 2011, FDA released the FDA Mitigations Database to the public. This tool is a database that provides a range of preventive measures that companies may choose to better protect their facility, personnel, and operations. Safety measures in the database are specific to individual categories that impact every step of the food production and distribution process. The database is available for free on FDA's website.[24] The development of FDA's Mitigation Strategies Database began in 2006.

---

[18] Exhibit 16: March 16, 2013 email from John Hnatio to Elizabeth Dickinson, CCing Elahe Zahirieh, Office of the SBA Ombudsman; March 19, 2013 10:38 AM email from John Hnatio to Elahe Zahirieh; March 19, 2013 4:05 PM email from John Hnatio to Elahe Zahirieh; March 22, 2013 email from John Hnatio to Elahe Zahirieh; April 15, 2013 letter from John Hnatio to Yolanda Swift.

[19] Exhibit 1: April 1, 2013 letter from John Hnatio to Kathleen Sebelius, Secretary of the Department of Health and Human Services; Exhibit 17: April 19, 2013 letter from John Hnatio to Kathleen Sebelius (with cover letter dated April 20 to Nancy Gunderson).

[20] Exhibit 18: April 1, 2013 letter from John Hnatio to Barack Obama, President of the United States.

[21] Exhibit 19: April 18, 2013 email from John Hnatio to Laurie Lenkel, FDA Ombudsman.

[22] Specifically, this response focuses on the email attachment in Exhibits 16 with the file name "Summary report for Ms. Dickinson" and document title "SBA Ombudsman Case No. 1303150001." This document will be cited in this letter as "Exhibit 16: SBA Ombudsman Case No. 1303150001."

[23] Exhibit 20: print out of http://www.fda.gov/Food/GuidanceRegulation/FoodProtectionPlan2007/default.htm

[24] Exhibit 21: print out of http://www.accessdata.fda.gov/scripts/fooddefensemitigationstrategies/

In July 2011, FDA publicly released its FREE-B tool.[25] The tool is available for free on FDA's website.[26] The tool is a compilation of scenarios based on intentional and unintentional food contamination events, and was designed with the intention of assisting government regulatory and public health agencies in assessing existing food emergency response plans, protocols and procedures that may be in place, or may be in the process of revising or developing. FDA developed FREE-B in cooperation with the Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS). Development of FREE-B began in 2007.

We note that, as discussed below, FDA's Food Defense Team's first contact with you occurred when you emailed Don Kautter and Jody Menikheim to introduce yourself on December 23, 2011, and the team's first and only in-person meeting with you occurred on February 2, 2012.

On October 4, 2012, FDA publicly released its "iRisk" tool.[27] The tool is available for free online.[28] FDA-iRisk is a web based system that can be used to compare and rank (1) estimated risks from multiple microbial or chemical food safety hazards and (2) estimated effectiveness of various changes to specific steps of a food's farm-to-table pathway. FDA began developing FDA-iRisk in 2006.

Facts and Allegations

You claim that your first contact with FDA was in a meeting with Drs. Juliana Ruzante, Robert Buchanan, and Leanne Jackson at the Joint Institute of Safety and Nutrition (JIFSAN). You claim that during this meeting you submitted a "detailed proposal describing the patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply."[29] JIFSAN is partially supported through a collaborative agreement between FDA's Centers for Food Safety and Nutrition and Veterinary Medicine and the University of Maryland at College Park; however, FDA and JIFSAN are separate entities. No one from FDA attended or has records of this meeting. Dr. Leanne Jackson is an FDA employee, but she was not present at this meeting, nor did she have any other interaction with you or your companies in 2009. Drs. Ruzante and Buchanan of JIFSAN do recall attending this meeting; however, they recall that your company did not share detailed information during the meeting. Instead, according to Dr. Buchanan, your company requested a meeting with JIFSAN, shared a general prospectus for a project you wanted to pursue, and explored the possibility of working collaboratively with JIFSAN. JIFSAN indicates that it declined your offer and did not establish any formal or financial relationship with your company after this meeting. JIFSAN has no written materials from this meeting and, to the best of our knowledge, shared no information from this meeting with FDA.

You claim that in 2010 you "closely coordinated the results of [a] simulation [you conducted for a private company] and the methodology [you] used with Dr. Reginald Bennet [sic] and other officials at the FDA in order to prompt the development of specific laboratory and field tests that would detect the deadly agent."[30] Dr. Bennett is an FDA employee. Dr. Bennett has no knowledge of you or of ThoughtQuest LLC, and no memory or documentation of this alleged interaction.

You claim that "in June 2011, Mr. Menikheim, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for

---

[25] Exhibit 22: Press Release July 20, 2011, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm263213.htm.
[26] Exhibit 23: print out of http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295902.htm.
[27] Exhibit 24: Fact sheet: FDA-iRisk, food safety modeling tool, http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM316705.pdf.
[28] Exhibit 25: print out of https://irisk.foodrisk.org/.
[29] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 3.
[30] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 4-5.

commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim [sic] to give him periodic updates on their progress."[31] FDA has no record of such a briefing and Mr. Menikheim has no memory of such a briefing, or of contact following up on such a briefing. In fact, the first record of your contact with FDA's Food Defense Team that we are aware of occurred six months later, as documented in an email you sent to FDA on December 23, 2011.

On December 23, 2011, you emailed Don Kautter and Jody Menikheim to introduce yourself, your company, and your tools, and to request a meeting to share the tools with and obtain guidance from FDA.[32] In that email you stated, "Don & Jody: We received you [sic] names from Jenny Scott who suggested that we contact you." Jenny Scott is an FDA employee. Ms. Scott recalls stopping by your company's booth at a conference and being shown a demonstration of your company's work. Because your company's work was relevant to an area covered by others at FDA, Ms. Scott referred your company to FDA's Food Defense Team, specifically to Mr. Kautter and Mr. Menikheim. You attached three documents to your December 23, 2011 email. In the email and its attachments, you describe your product "FoodProtectionTQ" as consisting of six tools (POISON, Food Mapper, FoodDefenseTQ, FoodSafetyTQ, FEAST, and FREE), each of which you described only in general terms. FDA's Food Defense Team has no record of interaction with you or your companies prior to this email.

On January 11, 2012 you emailed Mr. Kautter and Mr. Menikheim, following up on your December 23, 2011 request for a meeting.[33] On January 17, 2012 you emailed Mr. Menikheim, referring to a phone call you received from him and stating "thank-you for your guidance on how best to proceed... look forward to the possibility of talking with you."[34] On January 23, 2012 you emailed Mr. Menikheim again seeking a meeting date.[35] On January 24, 2012, Mr. Menikheim emailed you, agreeing to the requested meeting but stating that FDA would not be able to provide you with any guidance.[36] After emails agreeing on February 2, 2012 as the meeting date,[37] you emailed Mr. Menikheim on February 1, 2012 attaching a slide show for the upcoming meeting.[38] The slide show describes the same six tools as the documents you provided the FDA Food Defense Team in your December 23, 2011 email. The slide show contains different information from the December 2011 documents, but the descriptions of your tools in the slide show were general and high-level in nature and did not include specific questions or items, and merely included references to broad subject matter categories, like "emergency drills" and "loss of power."

According to your email of February 1, 2012, you planned to quickly review the power point slides and demonstrate your tools.[39] On February 2, 2012, Mr. Menikheim and other members of the FDA Food Defense Team, specifically Julia Guenther and Mike Dixon, met with you, Dave Park, and Bart Michelson from your company, and Bill Wright from MRI Global (a company you described as doing certain work related to your tools). Mr. Menikheim's recollection of the meeting is that you gave an overview of your tools using the slides you sent on February 1, 2012, and then the group moved to the

---

[31] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 5.
[32] Exhibit 26: December 23, 2011 email from John Hnatio to Donald Kautter and Jody Menikheim, with attachments "Briefing Book: Executive Summary," "Briefing Book: The Need," "Briefing Book: The Solution" all dated December 2011.
[33] Exhibit 26: January 11, 2012 email from John Hnatio to Don Kautter and Jody Menikheim.
[34] Exhibit 27: January 17, 2012 email from John Hnatio to Jody Menikheim.
[35] Exhibit 27: January 23, 2012 email from John Hnatio to Jody Menikheim.
[36] Exhibit 27: January 24, 2012 9:22 AM email from Jody Menikheim to John Hnatio.
[37] Exhibit 27: January 24, 2012 2:05 PM email from John Hnatio to Jody Menikheim; January 26, 2012 email from Jody Menikheim to John Hnatio.
[38] Exhibit 27: February 1, 2012 email from John Hnatio to Jody Menikheim, with attachment "FDA Briefing Book: Food DefenseTQ" dated February 2012.
[39] Exhibit 27: February 1, 2012 email from John Hnatio to Jody Menikheim, with attachment "FDA Briefing Book: Food DefenseTQ" dated February 2012.

Center for Food Safety and Nutrition (CFSAN) café so that you could briefly demonstrate the tools using a public Wi-Fi network on your laptop. The entire meeting took approximately one hour. The only materials you provided for FDA to keep were the slides you sent on February 1, 2012.

FDA did not share these documents outside of the agency, did not share these documents with its contractors working on the Food Defense Plan Builder, and did not use these documents to duplicate or copy your tools. Any material that you may have displayed in the CFSAN café beyond the February 1, 2012 slides was eyes-only, and we have no evidence that whatever may have been briefly displayed was incorporated into an FDA product.

Based on a review of the February 1, 2012 slides, the "Food DefenseTQ" software described in those slides apparently implements the methods described in U.S. Patent No. 8,103,601.[40] The slides describe an algorithm that purports to account for the degree of vulnerability of a "target," the potential worst case consequences of an adverse food safety event, and factors that could mitigate the consequences of an adverse event. The objective is apparently to determine a probability of occurrence of any particular adverse event.

There is no evidence that any analysis of the kind described in the slides or in U.S. Patent No. 8,103,601 was used to develop the FDA products like FDA's FDPB. While FDA's FDPB is obviously the subject of careful consideration of the potential vulnerabilities that an organization might face from any number of threats, its core is essentially a well-organized checklist of questions and issues that an organization should address to minimize threats. The methods claimed in the patent, on the other hand, offer one very distinct and purportedly sophisticated technique for determining the probability that certain adverse scenarios or events would occur, and there is no suggestion from anything in the record that determining such probability in this way was a part of the FDA process for developing its FDPB tool.

Between July 25, 2012, and September 25, 2012, you exchanged emails and phone calls with Mr. Menikheim.[41] In these communications you requested another meeting with FDA to demonstrate your tools and seek guidance from FDA, and Mr. Menikheim agreed to a webinar on October 2, 2012. You claim that in mid-September 2012, your company learned that "FDA had been working with Battelle Memorial Institute to build their own food defense tool to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted [you] to call Mr. Menkheim [sic] to express [your] concerns that FDA was developing a product that already existed."[42] You also claim that in late September 2012, you had another phone call with Mr. Menikheim in which you "asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012.[43]

Mr. Menikheim does not recall either of these alleged calls, and FDA has no records relating or referring to such calls. To the contrary, in your emails in September 2012, you did not express concern about FDA's Food Defense Plan Builder and proceeded to work on scheduling another meeting with FDA to

---

[40] Exhibit 27: February 1, 2012 email from John Hnatio to Jody Menikheim, with attachment "FDA Briefing Book: Food DefenseTQ" dated February 2012.

[41] Exhibit 28: July 25, 2012 5:16 PM email from John Hnatio to Jody Menikheim; July 25, 2012 5:42 PM email from Jody Menikheim to John Hnatio; August 10, 2012 email from John Hnatio to Jody Menikheim; August 20, 2012 email from John Hnatio to Jody Menikheim; August 21, 2012 email from Jody Menikheim to John Hnatio; August 22, 2012 7:57 AM email from John Hnatio to Jody Menikheim; August 22, 2012 11:30 AM email from Jody Menikheim to John Hnatio; September 6, 2012 email from John Hnatio to Jody Menikheim; September 25, 2012 1:54 PM email from John Hnatio to Jody Menikheim; September 25, 2012 4:50 PM email from Jody Menikheim to John Hnatio; September 25, 2012 5:05 PM email from John Hnatio to Jody Menikheim; September 25, 2012 5:12 PM email from Jody Menikheim to John Hnatio.

[42] Exhibit 16: SBA Ombudsman Case No. 1303150001, pp. 5-6.

[43] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 6.

demonstrate your company's products. On October 1, 2012, you emailed Mr. Menikheim and Ms. Jackson and attached a short, outline-format description of the software tools you intended to demonstrate at the next day's webinar ("Food Defense Architect," "Food DefenseTQ," "Food Mapper," "Poison," " FEAST," and "FREE Tool").[44]

You held a webinar for Mr. Menikheim and other members of the FDA Food Defense Team, specifically Julia Guenther, Michael Dixon, Wendy Buckler, and Jon Woody, on October 2, 2012 to demonstrate your software tools.[45] The only material you provided for FDA to keep was the short outline sent to FDA on October 1, 2012. You claim that in addition to presenting your tools, you raised concerns that FDA was building a food defense planner tool that would compete with FTQTQ's Food DefenseTQ and Food Architect products during the webinar; and thus, you offered FDA a license to use your companies' technology for $1 /year.[46] According to those at FDA who attended the meeting, the webinar included an update on the status of your tools, and you asked Mr. Menikheim if FDA was developing a food defense plan tool. Mr. Menikheim informed you that FDA was in the process of developing a tool (the FDPB) that would combine all of FDA's existing food defense tools into one tool. You did offer FDA a $ 1 /year license of your technology to FDA, but Mr. Menikheim said that he was not in a position to accept such an offer.

On November 15, 2012, Warren Stone of the Grocery Manufacturers Association (GMA) emailed members of its Food Defense Committee and other interested industry professionals to invite them to a focus group meeting to test FDA's Food Defense Plan Builder.[47] This email stated the purpose of the meeting: "To ensure that the tool is user-friendly and in line with industry needs, FDA is seeking feedback from industry members in this upcoming focus group." Bruce Becker, an employee of your company FoodQuestTQ, was on the CC list for this email.

Between November 16, 2012 and November 27, 2012, you repeatedly emailed Colin Barthel, an employee of Batelle Memorial Institute listed as a contact in Warren Stone's November 15, 2012 email.[48] In these emails you asked to speak with Mr. Barthel "to give [Mr. Barthel] a short pre-demo of what we will be presenting to the industry at the meeting on a webinar," referencing your "Food Defense Architect."[49] On November 27, 2012, Mr. Barthel responded by email and informed you that he could not speak about this project without written permission from FDA, and that the GMA meeting "is a focus group feedback session."[50] As far as we are aware, this is the only contact you and your companies had with the contractors assisting in the development of FDA's Food Defense Plan Builder tool.

After your correspondence with Mr. Barthel, Mr. Menikheim became aware that you intended to give a presentation of your own tools to the focus group. Mr. Menikheim was concerned that it would be an inappropriate use of the focus group if you were allowed to use that time to give a presentation of your own tools. Mr. Menikheim spoke with Mr. Stone of GMA and asked that you be uninvited from participating in the focus group.

On December 11, 2012, you emailed Mr. Menikheim "to touch base before the session tomorrow,"

---

[44] Exhibit 29: October 1, 2012 email from John Hnatio to Jody Menikheim and LeeAnne Jackson, with attachment titled "Food Defense ArchitectTM Specifications."
[45] Exhibit 30: October 2, 2012 1:14 PM email from John Hnatio to Jody Menikheim; October 2, 2012 1:16 PM email from Jody Menikheim to John Hnatio.
[46] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 6.
[47] Exhibit 31: November 15, 2012 email from Warren Stone to GMA-FoodDefenseInfo@lists.gmaonline.org.
[48] Exhibit 32: November 16, 2012 email from John Hnatio to Colin Barthel; November 20, 2012 10:35 AM email from John Hnatio to Colin Barthel; November 20, 2012 3:49 PM email from John Hnatio to Colin Barthel; November 27, 2012 email from John Hnatio to Colin Barthel.
[49] Exhibit 32: November 16, 2012 email from John Hnatio to Colin Barthel.
[50] Exhibit 32: November 27, 2012 email from Colin Barthel to John Hnatio.

attaching a document titled "Managing Food Defense Risk" dated December 2012.[51] Later in the day after your email on December 11, 2012, Mr. Menikheim emailed Mr. Stone and asked when you would be presenting to the group, and stated "I just want to make sure that ThoughtQuest will not be attending our focus group."[52] Mr. Stone responded that you would be presenting at 4:30 pm, which was the time the FDA focus group was scheduled to end.[53] Mr. Menikheim reiterated that he did not want you participating in or attending the FDA focus group, but that "I do not have any issue with Bruce or anyone from ThoughtQuest presenting to your group before or after our focus group."[54] Mr. Stone responded, "Sorry about the mix up too. I'll take care of it."[55] FDA does not have any record of how Mr. Stone or GMA communicated this message to you. According to your letter to the SBA, you presented your tools to the focus group after FDA left the building. [56]

Your Claims

First, for a copyright infringement claim to lie, the infringer must have had access to the work that is infringed, and the infringing work must be found to be substantially similar to the infringed work. You have provided no evidence that FDA or its contractors had access to any of the works allegedly infringed. Because you have refused to provide us with copies of the allegedly infringed work, there is no way for us to determine whether the agency's works are substantially similar to yours.

Second, with respect to your claims of infringement of U.S. Patent No. 8,103,601, in order to infringe a patent the infringer must practice each and every step of the patent claim. Claim 10 of the patent is representative.[57]

In order to infringe Claim 10, one must practice four highly complex and specific steps, which we paraphrase for simplicity here:

(a) Defining fundamental elements which control a complex adaptive system.
(b) Assigning a plurality of sets of initial values.
(c) Determining which of a set of features are directly related to the fundamental elements for each of the initial conditions
(d) Measuring an effect of each one of the sets of initial conditions of each respective one of said developed plurality of scenarios on said ones of said plurality of features most directly related to said fundamental elements to generate sets of data functionally related to the likelihood of a particular occurrence in said complex adaptive system.

There is no evidence that FDA personnel or their contractors practiced even one of these steps, let alone all of them, as would be required for a claim of patent infringement.

---

[51] Exhibit 33: December 11, 2012 4:41 PM email from John Hnatio to Jody Menikheim.
[52] Exhibit 34: December 11, 2012 6:31 PM email from Jody Menikheim to Warren Stone.
[53] Exhibit 34: December 11, 2012 7:06 PM email from Warren Stone to Jody Menikheim.
[54] Exhibit 34: December 11, 2012 9:33 PM email from Jody Menikheim to Warren Stone.
[55] Exhibit 34: December 11, 2012 9:53 PM email from Warren Stone to Jody Menikheim.
[56] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 8.
[57] Claim 10. A method of increasing the likelihood of behavior of a complex adaptive system, comprising the steps: defining fundamental elements which control the functioning of the complex adaptive system; assigning a plurality of sets of initial values at a respective plurality of times to a plurality of features of the complex adaptive system; determining which ones of said plurality of features of the complex adaptive system are most directly related to said fundamental elements for each of said plurality of sets of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system; measuring an effect of each one of said plurality of sets of initial conditions of each respective one of said developed plurality of scenarios on said ones of said plurality of features most directly related to said fundamental elements to generate sets of data functionally related to the likelihood of a particular occurrence in said complex adaptive system.

Third, you allege that "the government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry."[58] This is not what the FAIR Act does. Rather, the FAIR Act requires the head of each executive agency to 'submit to the Director of the Office of Management and Budget a list of activities performed by Federal Government sources for the executive agency that, in the judgment of the executive agency, are not inherently governmental functions.' Pub. L. No. 105-270, sec. 2. Based on our understanding of the complaint FoodQuestTC LLC has filed with the Office of Small Business Advocacy, FoodQuest's allegations do not appear to implicate the FAIR Act because, *inter alia*, there is no indication that your complaint takes issue with any inventory submitted by the FDA under the FAIR Act.

Similarly, you allege that "FDA actions in this case raise questions regarding the Agency's compliance with OMB Circular A-76 [because] this document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector."[59] This too is incorrect. Even if your complaint were correct in alleging that the FDA has violated OMB Circular A-76, Section 5(g) of the Circular states that "Noncompliance with this Circular shall not be interpreted to create a substantive or procedural basis to challenge agency action or inaction, except as stated in Attachments A and B." OMB Circular A-76, Sec. 5(g)(May 29, 2003). Attachment A permits a challenge by an interested party within 30 days of publication in the Federal Register of the list of activities required under the FAIR Act noted above, while Attachment B permits a protest by a directly interested party when the Agency conducts a standard competition under Circular A-76. Because the FDA has not conducted such a competition for the services you have described, the Circular does not create any right or benefit enforceable at law by FoodQuestTC LLC against the United States or the FDA.

In spite of your unwillingness to cooperate, and your insistence on sending additional letters to different recipients rather than working with the counsel assigned to evaluate your claims, we have done our best to investigate your allegations, as much as we can understand them. We have uncovered no evidence that FDA or its contractors took or used any trade secrets that you might own. We have uncovered no evidence that FDA or its contractors infringed your patent or copyrighted works. We have uncovered no evidence that FDA or its contractors violated any statute in its dealings with you or your company. In light of the information that we have reviewed and in light of your failure to cooperate with our requests for necessary information to further evaluate your claims, we consider this matter closed.

Sincerely,

Dale D. Berkley, Ph.D., J.D.
HHS IP Counsel

Attachment: Exhibits

[58] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 10.
[59] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 10.

EXHIBIT 1

Seeley, Ariel

From: Berkley, Dale (NIH/OD) [E] [BerkleyD@OD.NIH.GOV]
Sent: Monday, April 01, 2013 10:04 AM
To: Seeley, Ariel; Lovas, Julie
Subject: FW: Request for a meeting from FoodQuestTQ
Attachments: Letter to DHHS Secretary.pdf

This just in.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, April 01, 2013 9:58 AM
To: Sebelius, Kathleen (HHS/OS)
Cc: Dickinson, Elizabeth (FDA/OC); Berkley, Dale (NIH/OD) [E]; Zahirieh, Elahe
Subject: Request for a meeting from FoodQuestTQ

Secretary Sibelius:

Attached is a letter to you requesting a meeting. The letter is self-explanatory. Thank-you.

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington DC 20201
Via e-mail

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

April 1, 2013

Dear Secretary Sebelius:

We are a small business located in Frederick, Maryland. We are writing to you to ask for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA). At FoodQuestTQ we produce advanced risk management software to help industry produce safer food.

Last year, we discovered that the FDA took our intellectual property and duplicated our products and, in so doing, tried to drive us out of business. In December 2012, we requested a personal meeting with Ms. Elizabeth Dickinson, the Chief Counsel at the FDA. Our objective was to simply sit down with Ms. Dickinson to explain the actions that were taken against us by the FDA and to work with her to fairly resolve the matter. But Ms. Dickinson refused to meet with us.

Instead, the FDA engaged in a harmful and non-productive dialogue with us as we attempted to work with them to try and resolve this matter. Earlier this month, we had no choice but to reach out to the National Ombudsman for Small Business because of the impasse. In response to our complaint to the National Ombudsman for Small Business, the matter was elevated to the DHHS Office of the General Counsel.

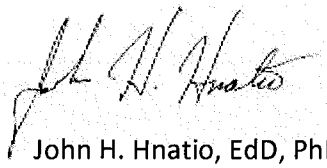
I am very disappointed to report to you that our interactions with the DHHS counsel assigned to this matter continue to be very non-productive. It appears that the counsel's efforts to defend the wrongdoing of his friends and colleagues in the FDA may have now out shadowed the importance of engaging in an honest dialogue about what has happened and working together with us to try and resolve any problems.

That is why we are requesting the opportunity to meet with you personally to describe the actions taken against us and to try and resolve this problem. The time now being spent on non-productive efforts to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. Would it not be better for everyone involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?

I want to personally assure you that we are looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, we can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

We hope that you will look favorably on the possibility of meeting with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people. We look forward to the possibility of meeting with you.

Sincerely,



John H. Hnatio, EdD, PhD
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB
Dr. Dale Berkley, DHHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA

EXHIBIT 2

FAX TRANSMISSION

OFFICE OF SENATOR BARBARA MIKULSKI
Brown's Wharf
1629 Thames St., Suite 400
Baltimore, Maryland 21231
410-962-4510
Fax: 410-962-4760

To: FDA Congressional

Fax #: 301-847-8602

From: Bart Kennedy

Subject: Constituent John Hnatio

Date: December 19, 2012

Pages: 4 , including this cover sheet

BARBARA A. MIKULSKI
MARYLAND

COMMITTEES:

APPROPRIATIONS

HEALTH, EDUCATION, LABOR, AND PENSIONS

United States Senate

WASHINGTON, DC 20510-2003

IN REPLY PLEASE REFER TO OFFICE INDICATED:

☑ 901 SOUTH BOND STREET, SUITE 310
BALTIMORE, MD 21231
(410) 962-4510
VOICE/TDD: (410) 962-4512

☐ 60 WEST STREET, SUITE 202
ANNAPOLIS, MD 21401-2448
(410) 263-1605
BALTIMORE: (410) 269-1650

☐ 6404 IVY LANE, SUITE 406
GREENBELT, MD 20770-1407
(301) 345-5517

☐ 32 WEST WASHINGTON STREET
ROOM 203
HAGERSTOWN, MD 21740-4804
(301) 797-2826

☐ THE PLAZA GALLERY BUILDING
212 MAIN STREET, SUITE 200
SALISBURY, MD 21801-2403
(410) 546-7711

December 19, 2012

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Dr. Hamburg:

I am forwarding a letter from one of my constituents, Mr. John Hnatio of FoodQuestTQ, LLC, who reports that his firm has been working with your agency in the development of new technology that would protect the security and safety of the Nation's food supply.

Mr. Hnatio states that his firm was scheduled to participate in a FDA workshop with industry leaders on December 12 but was disinvited shortly before the workshop was to begin. Mr. Hnatio believes he has been treated unfairly and is requesting a meeting with Ms. Elizabeth Dickinson, Chief Counsel for the FDA.

I am requesting that you have the appropriate staff review this matter to ensure that Mr. Hnatio was treated fairly and that dues process was followed. I am also requesting that Ms. Dickinson give his request for a meeting appropriate consideration. Please send your response directly to Bart Kennedy in my Baltimore office, at the above address.

Thank you very much for your consideration. I look forward to hearing from you.

Sincerely,

Barbara A. Mikulski
United States Senator

BAM:wbk
Enclosure(s)

2012-10062

Senator Barbara Mikulski
Washington, DC
503 Hart Senate Office Building
Washington, D.C. 20510

December 14, 2012

Dear Senator Mikulski:

I am a small business owner and a constituent living in Frederick, Maryland. I need your assistance.

In 2010, we started a small business in Frederick. We received the help of Maryland TEDCO in starting up our company. The business is built on a patented technology I developed. The technology deals with risk management and the safety and security of the food supply. We have invested over $6M in developing the technology and a software system to use it. Until recently we employed five people.

Over the past two years, we have been closely coordinating every step of our development work with the Food and Drug Administration (FDA). On several occasions we have given the FDA demonstrations of the new product we have built called Food Defense Architect™. Food Defense Architect is a software system that is designed to help food companies build their own plans for protecting the food they produce and handle from intentional poisoning and other security risks including terrorist attacks. Because our technology is patented, we offered to let FDA license our patent for FDA use for $1.00 a year.

Recently, however, we learned that the people we were working with at the FDA secretly took our ideas and are now working with Battelle Memorial Institute under a multi-million dollar government contract to re-build their own FDA software system using our ideas. I have recently had to lay off our entire staff because industry is now looking to the Food and Drug Administration and the government instead of our company to provide the solution even though we have an existing and patented system. This is particularly disturbing to me because of the tremendous personal sacrifices my employees have made to make our business a success. For example, one member of our team is a 70% disabled military veteran who gave up everything in order to join our company.

On Wednesday (December 12, 2012) of this week we were scheduled to participate in a Food and Drug Administration workshop with industry to solicit industry feedback on the new food security tool being developed by FDA with Battelle. Just before the meeting we were specifically disinvited from participating by FDA. FDA told the host of the meeting we would not be allowed to attend because they (FDA) did not want to endorse any particular company's product. But the attendee list included other companies such as Tyco Integrated Systems that we know produces security systems software just like we do.

We do not understand why the FDA is investing millions of taxpayer dollars to do what we have already done. We do not understand why the FDA would specifically disinvite us from important industry

meetings where other competing private sector companies are allowed to attend. We do not understand how the government can take our ideas and patent in this way. Why is this happening?

Senator Mikulski we respectfully request your help to arrange for a meeting with Ms. Elizabeth Dickinson who is a lawyer and the Chief Counsel at FDA. I am sure that when we get the chance to explain the situation personally to her that she will work with us to try and resolve the issue so that my employees can come back to work as soon as possible.

Sincerely yours,

John Hnatio
FoodQuestTQ LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403
(H) 301-829-5514

EXHIBIT 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993.0002

January 28, 2013

Mr. John Hnatio
FoodQuestTQ, LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702

Dear Mr. Hnatio:

On December 19, 2012, Senator Mikulski forwarded us your letter of December 14, 2012, for our consideration. We are looking into your concerns.

As a preliminary matter, please identify the patents to which you were referring in your letter and the FDA software system which you allege uses your ideas. In addition, please identify with whom you were communicating at FDA about those patents. This will be helpful to us as we look into the concerns set forth in your letter. Once we have the information we need to evaluate your concerns, it may be appropriate to meet to discuss further.

Sincerely,

Elizabeth Dickinson
Chief Counsel

EXHIBIT 4

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 22, 2013

Mr. John Hnatio
FoodQuestTQ, LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702

Dear Mr. Hnatio:

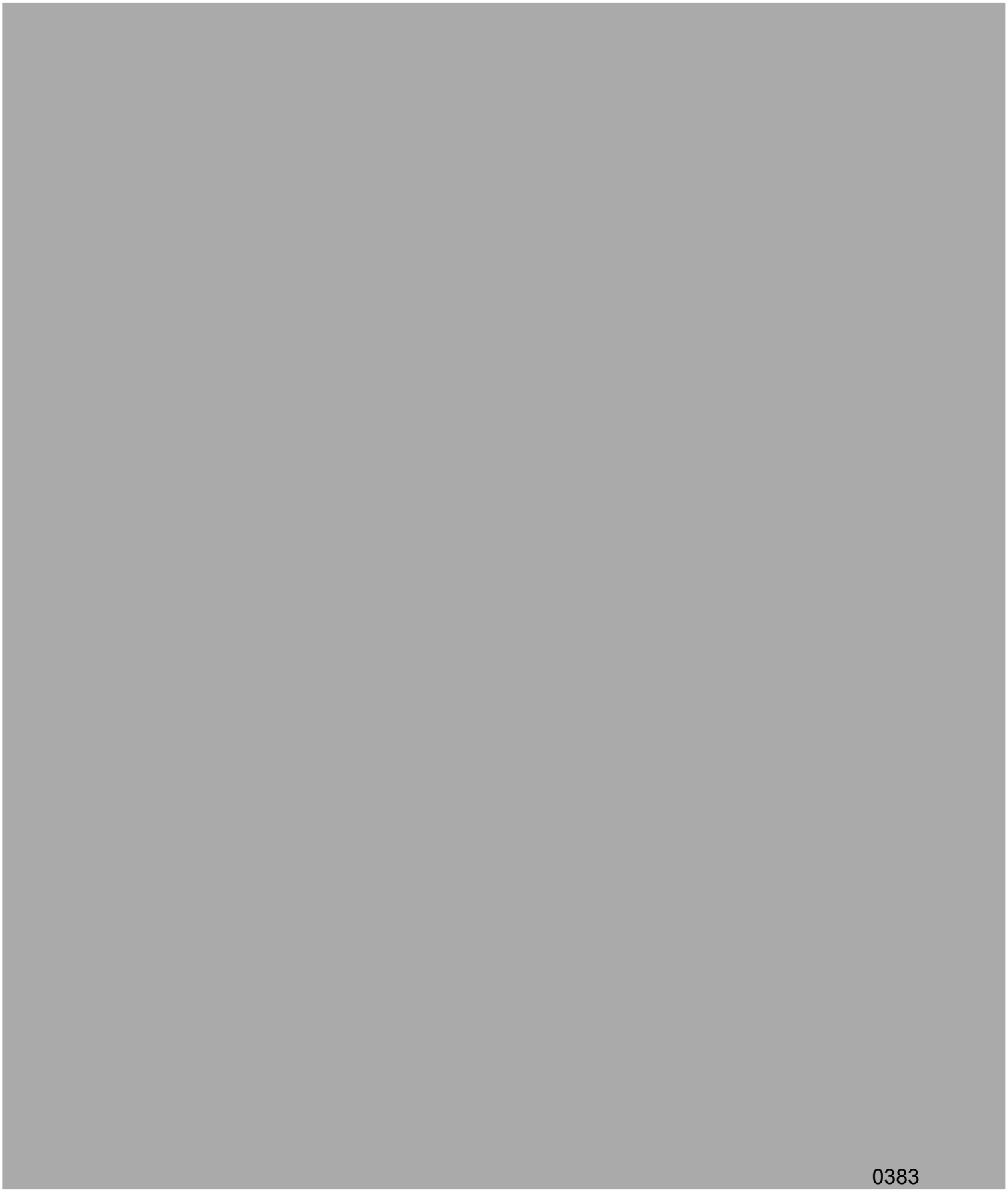
On January 28, 2013, we sent you a letter asking for additional information about the concerns raised in your letter of December 14, 2012. In that letter we requested that you, as a preliminary matter, identify the patents to which you were referring in your letter and the FDA software system which you allege uses your ideas. In addition, we requested that you identify with whom you were communicating at FDA about those patents. Please provide us this information by March 4, 2013. We look forward to hearing from you.

Best regards,

Elizabeth Dickinson
Chief Counsel

EXHIBIT 5

Seeley, Ariel



From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, February 25, 2013 11:33 AM
To: Raza, Mark
Cc: Dickinson, Elizabeth
Subject: FW: FoodQuestTQ Materials

Mark: Thanks for helping me out. You are a good man. Just wanted to make sure that Liz received this in a timely way. Thank-you sir. My full contact info. appears below if you guys need anything more from me. Best John

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403
E-mail: jhnatio@thoughtquest.com

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, February 25, 2013 11:14 AM
To: 'Elizabeth.Dickinson@fda.hhs.gov'
Subject: FoodQuestTQ Materials

Dear Ms. Dickinson:

We received your letter of February 22, 2013, asking for a response to your letter of January 28, 2013.

On February 12, 2013, we faxed our response directly to your office at your official fax number of 301-847-8637.

I have made direct contact with your office to make certain that you receive another fax that I am sending to you today with copies of the information provided previously on the 12th.

If you do not receive my fax this morning please have your secretary call me and we will make other arrangements to get the information to you. If you have any questions please feel free to contact me at 240-439-4476 x-11.

Thank-you very much for your willingness to look into this matter. It is appreciated. Best, John

DATE: 2-25-2013

FAX To: Ms. Elizabeth Dickinson, Esq.

Chief Counsel
Rm. 4536
Food and Drug Administration
Silver Spring, MD 20993-0002
(T) 301-796-8540
(F) 301-847-8637
E-mail: Elizabeth.Dickinson@fda.hhs.gov

SUBJECT: YOUR LETTER OF FEBRUARY 22, 2013, TO MR. JOHN HNATIO AT FOODQUEST TQ, LLC

NOTE:

Dear Ms. Dickinson:

We received your letter of February 22, 2013, asking for a response to your letter of January 28, 2013. On February 12, 2013, we faxed our response directly to your office. I have made direct contact with your office to make certain that you receive the attached copy of our original response. Thank you very much for your willingness to look into this matter. If you have any questions, please feel free to contact me at 240-439-4476 x-11. You can also reach me at e-mail: jhnatio@thoughtquest.com Best regards, John.

FROM:

John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702
240-439-4476 X-11
E-mail: jhnatio@thoughtquest.com

COPY

DATE: 2-12-2013

FAX TO:

Ms. Elizabeth Dickinson, Esq.
Chief Counsel
Rm. 4536
Food and Drug Administration
Silver Spring MD 20993-0002
(T) 301-796-8540
(F) 301-847-8637
E-mail: Elizabeth.Dickinson@fda.hhs.gov

SUBJECT: RESPONSE TO YOUR LETTER OF JANUARY 28, 2013 TO MR. JOHN HNATIO, FOODQUESTTQ, LLC

FROM:

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702
240-439-4476 x-11
E-mail: jhnatio@thoughtquest.com

COPY

ORIGINAL SENT ON: 2-12-21013 COPY PROVIDED ON 2-25-2013

Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

February 12, 2013

Dear Ms. Dickinson:

Thank-you very much for your letter of January 28, 2013. In your letter you refer to the letter that we wrote to Senator Barbara Mikulski on December 19, 2012. We truly appreciate your help and we are looking forward to working with you as we move forward together to fairly resolve this matter.

In the Fall of 2012, our company became concerned that the Food and Drug Administration (FDA) Food Defense Team may be improperly using FoodQuestTQ LLC generated trade secrets and other business proprietary information to duplicate several of our products.

We have since learned that members of the FDA's Food Defense Team have taken our FoodQuestTQ LLC product descriptions and our proprietary commercial and trade secret information and duplicated three of our products. Other new products that duplicate our pre-existing commercial offerings may also be in development by the FDA that we are not yet aware of at this time.

1. The new ***FDA Food Defense Plan Builder*** tool takes our pre-existing **Food DefenseTQ** tool, which is used to build food defense plans (just recently upgraded to become **Food Defense Architect**) and duplicates it.

2. The new ***FDA FREE-B*** tool takes elements of our pre-existing **FREE** and **FEAST** computer software tools, which are used to simulate and manage food emergencies, and duplicates them.

In your letter you refer to our December 19, 2012, letter to Senator Mikulski and you ask us to "identify the patents to which you are referring in your letter and the FDA software system which you allege uses your ideas." The patent upon which the entire FoodQuestTQ integrated Food Protection computer software tool suite is based is:

- USPTO Patent No.: US 8,103,601 B2, DOI: January 24, 2012.

The patent describes methods and techniques that are an expression of the Complexity Systems Management Method or CSM Method®. The CSM Method® is a registered trademark business process and data transformation patent for dealing with complex and evolving risks and risk countermeasures across all critical infrastructures including food and agriculture. It consists of 92 objects of invention that are integrally tied to each of the 20 claims granted by USPTO under the patent.

It is important to note, however, that our company's concerns go well beyond the possibility that the FDA may have infringed on our patent to include the more immediate concern that the Food Defense

ORIGINAL SENT ON: 2-12-21013 COPY PROVIDED ON 2-25-2013

Team has improperly taken FoodQuestTQ LLC product information and company proprietary commercial and trade secret information to duplicate our products.

Attached please find a brief description of some specific topics that you may wish to discuss directly with the FDA Food Defense Team. We wanted to provide this information to you now in order to make our upcoming meeting as productive as possible.

Again, thank you very much for looking into our concerns. We are still very interested in building a cooperative relationship with the FDA so that we can work together to make the food we all eat safer. We very much look forward to meeting with you personally to lay out a plan on how we can work together to fairly resolve this issue in a mutually beneficial way.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,

John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

COPY OF ORIGINAL DATED 2/12/201 FOR YOUR EYES ONLY

Informal Note for: Elizabeth Dickinson

From: John Hnatio J.H.

Date: 2/12/2013

For many years prior to my retirement from government service, I had the great privilege of serving in senior positions in both the Executive and Legislative Branches of our government where I dealt directly with technology transfer issues and the vital relationship between the government and industry in achieving national objectives. For example, I was the leader of the technology transfer program for the nuclear weapons program that included all ten of the national laboratories where I oversaw billions of dollars of cooperative work between the government and the private sector. I also served as a loaned Executive from the White House to the Senate to spearhead efforts to strengthen the defense industrial base and promote greater cooperation between government and industry. Suffice it to say that I have "lived and breathed this stuff" for well over 30 years.

Based on my significant expertise in this area, there may be several specific aspects of this situation that you may wish to explore directly with the FDA Food Defense Team before we have the opportunity to meet.

First and foremost, is the requirement that federal employees protect and keep as confidential proprietary commercial information provided to them by the private sector. In all of our interactions with the FDA Food Defense Team we clearly advised them whenever we were sharing proprietary commercial information. In addition, all of the proprietary commercial information we provided to the FDA Food Defense Team was clearly marked as containing proprietary information. The FDA Food Defense Team used this proprietary information and other publicly available descriptions of our product to duplicate three of our products.

Second, are the numerous laws and statutes that dictate when the government can and cannot internally "build" products. Here the rules are very clear. Among these important rules is a documented "build-no build" determination by a government agency based on the notion that the activity involved is an "inherently government function." While the authority to regulate the food industry certainly is an inherently government function, food defense and food safety undertakings to assist the food industry implement and comply with those regulations are not. Rather, they represent a shared responsibility between the government and the private sector. The FDA Food Defense Team did not make a good faith "build-no build" determination before they decided to duplicate our products.

Another important government determination requires that no government agency or its subcontractors, including Battelle Memorial Institute in this case, be permitted to compete with the private sector. Here the rules are also very clear. Before and as part of any funding decision by a federal agency to contract with a Federally Funded Research and Development Center (FFRDC) the agency must make a "compete-no compete" determination. This requires that each federal agency systematically consider and reach a considered determination that the activity they are funding will not compete with the same, similar or better product offering that is already available in industry. In many federal

COPY OF ORIGINAL DATED 2/12/201 FOR YOUR EYES ONLY

agencies this responsibility is shared by the Head Contracting Official and is basis to the procurement process. The FDA Food Defense Team did not make a good faith "compete-no compete" determination before they decided to duplicate our products.

There are several other issues that raise serious concerns about the integrity of the FDA Food Defense Team's actions that are disturbing that their supervisors should be made aware of.

On October 6, 2012, we briefed the FDA Food Defense Team. During that briefing we attempted to discourage them from pursuing a course of action that would only result in a waste of taxpayer dollars to duplicate pre-existing commercial products. At that meeting, we offered the FDA Food Defense Team a one dollar a year license to use our tools for all FDA personnel across the Food and Agricultural industry vertical. The FDA Food Defense Team never responded to our offer. But they did tell us that our company's products were far better than the ones that the FDA was developing under their contract with Battelle Memorial Institute.

In December 2012, we were invited by the Grocery Manufacturer's Association (GMA) to attend an FDA Food Defense Team sponsored workshop. Before the meeting we were told by the FDA Food Defense Team that the principal purpose of the workshop was to discuss the use of a food defense targeting tool originally developed by the military Special Forces that has been converted by the FDA Food Defense Team for use by food facilities. After speaking personally with a member of the FDA Food Defense Team about the "true purpose" of the meeting, FoodQuestTQ created a web based survey to reach out to industry to obtain their input on the usefulness of the FDA targeting tool.

CONFIDENTIAL

Just days before the scheduled Food Defense Team sponsored workshop at GMA, we published an article giving the preliminary results of the industry survey. The results of the survey raised serious questions about the utility of the FDA targeting tool by industry. This article received very significant notoriety within the FDA Food Defense Team as evidenced by the fact that the FoodQuestTQ article was "opened" for reading and further distribution by the leader of the FDA Food Defense Team more than 40 times.

A few days before the FDA Food Defense Team sponsored workshop was scheduled to take place on December 12, 2012, we were provided with a copy of the FDA Food Defense Team agenda for the workshop by GMA. We realized at this time that the Food Defense Team intentionally misled us about the true purpose of the workshop. The agenda made it clear that the real purpose of the workshop was for the FDA Food Defense Team to demonstrate and receive inputs from the food industry on the FDA's new Food Defense Plan Builder tool. A representative of Battelle Memorial Institute wrote the company an e-mail stating that the FDA Food Defense Team industry workshop to demonstrate their new Food Defense Plan Builder tool could only be attended by food processing companies.

Late in the evening of December 11, 2012, we were informed by GMA that the FDA had prohibited our company from attending the following day's workshop to demonstrate our FoodQuestTQ food defense plan builder tool (known as Food Defense Architect). The GMA advised us that the FDA Food Defense Team prohibited us from attending the workshop because they (the FDA Food Defense Team) did not want to give our company any unfair competitive advantage. After the workshop, we were able to

COPY OF ORIGINAL DATED 2/12/201 FOR YOUR EYES ONLY

verify that we were again misled by the FDA Food Defense Team when we found that attendees at the workshop included many other non-food processing companies including competing software companies.

COPY

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Senator Barbara Mikulski
Washington, DC
503 Hart Senate Office Building
Washington, D.C. 20510

February 12, 2013

Dear Senator Mikulski:

We would like to thank-you very much for your help in arranging a meeting with Ms. Dickinson at the Food and Drug Administration. We would like to extend our particular thanks to Mr. Barton Kennedy of your staff for his diligent efforts working through the federal bureaucracy on our behalf. We express our personal thanks to Bart.

We recently received a letter from Ms. Dickinson asking for background information on our concerns. We have responded to her request and hope to meet with her very soon to resolve the matter. We feel confident that when Ms. Dickinson gets the opportunity to review the materials she will take the appropriate actions necessary to resolve our concerns.

With your permission, we will keep you apprised of our progress in working with the Food and Drug Administration to resolve our concerns. Again, thanks to you and your staff.

Sincerely,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC

cc: Elizabeth Dickinson, FDA-OGC

COPY

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Representative John Delaney
1632 Longworth House Office Building
Washington, DC 20515

February 12, 2013

Dear Representative Delaney:

We wanted to thank-you for your assistance in obtaining the opportunity to meet with Ms. Elizabeth Dickinson at the Food and Drug Administration. We realize that without your help such a meeting would never have been possible.

There is one particular person on your staff who worked diligently on our behalf. Kevin Mack deserves our special thanks. You must be proud to have him as a member of your staff.

We recently received a letter from Ms. Dickinson asking for background information on our concerns. We have responded to her request and hope to meet with her very soon to resolve the matter. We feel confident that when Ms. Dickinson gets the opportunity to review the materials she will take the appropriate actions necessary to resolve our concerns.

With your permission, we will keep you apprised of our progress in working with the Food and Drug Administration to resolve our concerns. Again, thank-you for all of your help.

Sincerely,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC

cc: Elizabeth Dickinson, FDA-OGC

EXHIBIT 6

Seeley, Ariel

From: Seeley, Ariel
Sent: Thursday, February 28, 2013 10:34 AM
To: 'jhnatio@thoughtquest.com'
Cc: Raza, Mark; Dickinson, Elizabeth
Subject: RE: FoodQuestTQ Materials

Dear Mr. Hnatio:

Thank you for your letter to FDA's Chief Counsel, Elizabeth Dickinson, dated February 12, 2013 and received by fax on February 25, 2013. I was asked to respond to this letter on her behalf.

You suggested on the first page of your letter that the FDA Food Defense Plan Builder duplicates your Food DefenseTQ tool. You also suggested that the FDA FREE-B tool takes elements of your FREE and FEAST computer software tools and duplicates them.

In order for us to evaluate these claims, we would need to compare your products to ours. Accordingly, please provide us with copies of your Food DefenseTQ tool and the FREE and FEAST software tools, in whatever form you think would be convenient for this purpose.

Please let me know if you have any questions.

Sincerely,
Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, February 25, 2013 11:33 AM
To: Raza, Mark
Cc: Dickinson, Elizabeth
Subject: FW: FoodQuestTQ Materials

Mark: Thanks for helping me out. You are a good man. Just wanted to make sure that Liz received this in a timely way. Thank-you sir. My full contact info. appears below if you guys need anything more from me. Best John

John Hnatio, EdD, PhD
Chief Science Officer

FoodQuestTQ LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403
E-mail: jhnatio@thoughtquest.com

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, February 25, 2013 11:14 AM
To: 'Elizabeth.Dickinson@fda.hhs.gov'
Subject: FoodQuestTQ Materials

Dear Ms. Dickinson:

We received your letter of February 22, 2013, asking for a response to your letter of January 28, 2013.

On February 12, 2013, we faxed our response directly to your office at your official fax number of 301-847-8637.

I have made direct contact with your office to make certain that you receive another fax that I am sending to you today with copies of the information provided previously on the 12th.

If you do not receive my fax this morning please have your secretary call me and we will make other arrangements to get the information to you. If you have any questions please feel free to contact me at 240-439-4476 x-11.

Thank-you very much for your willingness to look into this matter. It is appreciated. Best, John

EXHIBIT 7

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail
Follow Up Flag: Follow up
Flag Status: Blue
Attachments: Note for Ariel at FDA 2-2-2013.pdf; FQTQ-FDA NDA.pdf

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Date: March 2, 2013

Note for: Ariel Seeley, FDA Counsel

From: John Hnatio, FoodQuestTQ LLC

Subject: More information on FoodQuestTQ tools and yesterday's E-mail

Hi Ariel,

Please call me John. It's good to meet you. We really want to thank you and Ms. Dickinson for your response and your good faith efforts to review the situation. Please say thank-you to her for me too.

I wanted to let you know that we have shared the nuts and bolts of literally everything we've developed with the Food Defense Team, JIFSAN, and CIFSAN over the past three or so years. This includes proprietary briefings and proposals including detailed information on our tools for building food defense plans, searching food standards and regulations, developing food emergency simulations, responses to food emergencies and much more. This is the same information that was used to duplicate our products.

But, if this information is not available to you from the FDA Food Defense Team, or if you want to have an independent read from us on the nuts and bolts of our technology, then we'd be happy to set up a demonstration for the folks in your office so that we can walk you through our Food Defense Architect, Food DefenseTQ, FEAST and FREE tools. The similarities between the tools duplicated by the Food Defense Team using our confidential information and ideas are quite obvious.

Also, the opportunity to get more specific information from you on the nuts and bolts of the operation of FDA's Food Defense Plan Builder and FREE-B would allow us to prepare a detailed "technical crosswalk" between the FDA Food Defense Team's and Battelle's Food Defense Plan Builder, FREE-B and our FoodQuestTQ tools. The "technical crosswalk" can put the entire issue of infringement and the use of our trade secret and proprietary information by the Food Defense team "to bed" very quickly.

As you do your good faith review, we hope that you will focus on all of the issues raised in the letter we sent Ms. Dickinson. The issue of patent infringement, while certainly of great importance, is only one of several critical issues that were raised in our letter. All of the issues we identified in our letter require careful consideration because they involve violations of specific statutes and violations of clearly established government-wide policies that specifically limit FDA's authority to build the same or similar products already available in the private sector.

Thus, we are really looking forward to working with you and Ms. Dickinson to fully explore the issues created by the Food Defense Team when they intentionally took our confidential information and used it to duplicate our tools in order to improperly compete with us. These highly significant issues go well beyond any specific patent infringements that have occurred in this case.

Please find a copy of a FoodQuestTQ LLC and FDA non-disclosure agreement (NDA). We would like to go ahead and execute an NDA with you at this time since we are uncertain of FDA's position with respect to adhering to the provisions of Title 18, as they relate to the protection of industry proprietary information. Our concern is based on the actions taken by the Food Defense Team to take our trade secrets and other proprietary ideas and information in order to duplicate our products.

As soon as we get an NDA in place, then I will call you to arrange a demonstration of our tools for you and other members of the FDA counsel's office and simultaneously make arrangements for you to share with us the information we will use to prepare the detailed "technical crosswalk" of the FDA/Battelle Food Defense Plan Builder and FREE-B tools against our Food Defense Architect, Food DefenseTQ and FREE tools.

We really look forward to working with you Ariel. If you have any questions please don't hesitate to call me. My best number is 240-439-4476. I'm at extension 11. Hope to meet you in person very soon. All the best.

PS!

Ariel we've got another serious problem. When it rains it pours. We just came across FDA's new iRisk tool this morning. You can take a look at the new FDA offering at: http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/ . The new iRisk tool duplicates our Food Mapper tool and is based on proprietary information that we provided to the Food Defense Team and JIFSAN. We'll need to include the FDA iRisk tool as part of the above technical crosswalk against our Food Mapper tool.

CONFIDENTIALITY AGREEMENT

This agreement is entered into between FoodQuestTQ LLC, hereinafter referred to as "FQTQ", doing business at 7420 Hayward Road, Suite 102, Frederick, Maryland 21702 and the Food and Drug Administration, hereinafter referred to as the "FDA", doing business at 10903 New Hampshire Avenue Silver Spring, MD 20993.

WHEREAS, and in connection with anticipated communications between the two named parties to this Agreement concerning allegations by FQTQ that the FDA has taken FQTQ proprietary and trade secret information to duplicate FQTQ commercial products in violation of laws, government policies and required federal procedures. It is expected that FQTQ will disclose to the FDA Confidential Information including but not limited to a patent called the Complexity Systems Management Method (CSM®), Patent No.: US 8,103,601 B2 and proprietary and trade secret information on how Patent No.: US 8,103,601 B2 was reduced to practice in a suite of FQTQ commercial computer automated food defense, food safety and food risk management tools. It is also anticipated that the parties to this Agreement will share Confidential FQTQ Information as they work together to develop a detailed technical crosswalk between the FQTQ suite of tools and FDA-Battelle Memorial Laboratory developed tools listed below.

FQTQ Commercial Tools	FDA-Batelle Developed Tools	Purpose of Tool
Food Defense Architect Food DefenseTQ	Food Defense Plan Builder	Build Food Defense Plans
Food Mapper	iRisk	Computer search and risk management tool
FREE Tool FEAST	FREE-B	Emergency response mapping and simulation tool

NOW THEREFORE, in assurance of a full and good faith review by the Chief Counsel of the FDA as to the FQTQ allegations that FDA has infringed on Patent No.: US 8,103,601 B2 and taken FQTQ proprietary and trade secret information to duplicate FQTQ commercial products in violation of laws, government policies and required federal procedures, the parties agree as follows:

1. The FDA shall protect and keep confidential and shall not use for other purposes than those established in this Agreement, publish or otherwise disclose to third parties any and all Confidential Information of FQTQ. The obligation of confidentiality and restriction on use under this Agreement shall survive any termination of this Agreement.

2. By way of illustration, but not limitation, Confidential Information includes improvements, inventions, concepts, structures, formulas, techniques, processes, apparatus, know-how, and related data, clinical plans, business records, business or sales forecasts, past or current proposals, financial information, patent applications or legal opinions and documents which are disclosed to the FDA under this Agreement. Confidential Information may be supplied in written or oral form and may be identified as "confidential" but the lack of such explicit label or designation shall not preclude information from being treated as confidential under this Agreement.

3. To assist in protecting Confidential Information, the FDA agrees (a) not to disclose any Confidential Information of FQTQ to anyone except government employees of the FDA who are specifically bound by the terms of this Agreement and directly involved in conducting a good faith review of the FQTQ allegations and; (b) not to copy any FQTQ Confidential Information except for the purpose of doing a good faith review of FQTQ allegations; (c) to take all reasonable steps necessary to prevent the unauthorized disclosure, copying or use of any FQTQ Confidential Information, and (d) to use at least the same degree of care it uses to protect its own Confidential Information.

4. The FDA agrees that upon a written request by FQTQ that all Confidential Information, all tangible expressions of the Confidential Information, together with all copies thereof shall be promptly destroyed or returned to FQTQ.

5. This Agreement shall be binding upon the parties hereto and their respective heirs, successors or assigns, from the date of signing and none of the benefits of this Agreement shall be assigned by the FDA without the written consent of FQTQ.

6. This Agreement shall be governed by the laws of Maryland. If any one or more of the provisions of this Agreement shall be held invalid or unenforceable, such provision shall be modified to the minimum extent necessary to make it valid and enforceable, and the validity of enforceability of all other provisions hereof shall not be affected thereby.

IN WITNESS WHEREOF, the parties have executed this Agreement.

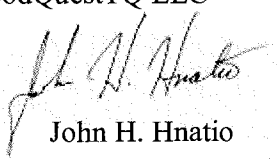
For FoodQuestTQ LLC	For the Food and Drug Administration
By: 	By: _____
John H. Hnatio	Elizabeth Dickinson
Title: Chief Science Officer, TQ	Title: Chief Counsel
Date: March 2, 2013	Date: _____

EXHIBIT 8

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Friday, March 08, 2013 2:49 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: John Checking In

FQTQ Tools	FDA Duplicate Tools
CSM Method®	FDA Food Protection Plan
POISON; Food DefenseTQ; Food SafetyTQ; Food Safety Architect, and; Food Defense Architect; Food Mapper	FDA Food Defense Mitigation Strategies Database
Food DefenseTQ; Food Defense Architect; Food SafetyTQ; Food Safety Architect	FDA Food Defense Plan Builder
Food Response Emergency Evaluation (FREE) Tool; Food Event Analysis and Simulation Tool (FEAST)	FDA (FREE-B)
FREE ; FEAST	*iRisk*

our intellectual property. The accompanying table identifies five FDA activities where we have found areas very significant infringement on our patent. We aren't through looking for other tools yet but wanted to give you an update on what we are finding. We will update you as we move along in the process.

What I'm doing on my side is to lay out a technical crosswalk (based on any publicly available information on the web) showing where the FDA Food Defense Team, Battelle, JIFSAN/CIFSAN (and likely other FDA contractors) have infringed on our 20 claims and our 101 associated objects of the original patent filed with USPTO. It paints a bit of an overwhelming picture. But we will still want to include the more detailed description of the nuts and bolts of the FDA duplicated tools that you provide. We are looking forward to sitting down with you soon.

What's the status of things on your side? Any questions? If so, please call. Have a good weekend.

Best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

EXHIBIT 9

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Monday, March 11, 2013 12:27 PM
To: Seeley, Ariel
Subject: RE: John Hnatio Checking In

Ariel: I'm very sorry to hear that. My condolences to you and the other folks in the office. It is hard to lose a good friend. I look forward to talking with you when you can. Best, j

---

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Monday, March 11, 2013 12:22 PM
To: jhnatio@thoughtquest.com
Subject: Re: John Hnatio Checking In

Thank you for your call. My office lost a valued colleague on Thursday. I intend to respond to sometime later this week.

Ariel

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, March 11, 2013 12:06 PM
To: Seeley, Ariel
Subject: John Hnatio Checking In

Hi Ariel: Called this morning and left you a VM. My number is 240-439-4476 x-11. Please call me when you get the chance. Best, j

EXHIBIT 10

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Wednesday, March 13, 2013 11:36 AM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Status Report

Hi Ariel:

I'm sorry to hear about the loss of your colleague. I hope you are feeling better. We just wanted to let you know that a detailed review of laws and statutes including the FAIR Act and OMB Circular A-76 as it pertains to government competition with the private sector, Title 18 as it pertains to the government requirements to protect industry confidential information and patent infringement along with a detailed claim-by-claim/object by object technical crosswalk of our 20 patent claims and the 101 objects of our invention that are integrally tied to the claims. A technical crosswalk against the following FDA food defense and food safety tools is now complete:

1. FDA Food Defense Plan;
2. FDA Food Defense Mitigation Strategies Database;
3. FDA Food Defense Plan Builder;
4. FDA FREE-B;
5. FDA iRisk, and;
6. FDA EMS.

In cases one through five, above, the crosswalk demonstrates flagrant infringement by FDA. The analysis of EMS (based on the information currently available) demonstrates no infringement. Please note that the search for FDA tools was limited to a web-based search of public source information available at the FDA web site. Thus, there may be other tools already released by the FDA or in development by the FDA that infringe against the patent.

We are looking forward to working with you to resolve this matter as soon as humanly possible. This matter has been pending since January and we have quite literally been put out of business and are now on unemployment as the result of the Food Defense Team's actions to undercut our sales. There are many lives and the well-being of many families at stake here. We need timely relief from the actions that the FDA has taken against us in order to survive. I hope you understand the urgency of the situation. Thank-you and Ms. Dickinson for your help.

Best, j

EXHIBIT 11

Seeley, Ariel

From: Seeley, Ariel
Sent: Wednesday, March 13, 2013 4:05 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail
Attachments: NDA Hnatio.pdf

Mr Hnatio:

Thank you for your email of March 2, 2013. I appreciate your willingness to work with me as I look into this matter. As you are most likely aware, dealing with the Food and Drug Administration (FDA), a federal agency, differs from dealing with private entities. Federal agencies must act according to a number of laws and regulations that govern their use of and ability to protect information submitted or provided to them. I attach to this email a non-disclosure agreement (NDA) that meets FDA's legal requirements. FDA has signed the attached NDA to make this process more efficient.

Furthermore, I would like to clarify that, at this time, FDA is only requesting nonexclusive access to FoodQuestTQ LLC's (FQTQ) software tools that you claim FDA's software tools, the Food Defense Plan Builder, FREE-B, and FDA-iRisk, duplicate. Specifically, these tools are FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST. Such access will allow FDA to evaluate the concerns raised by your previous communications. We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information. We ask that you do not send us such information at this time.

Please review the attached NDA and, if it is acceptable to you, send a signed copy to FDA with the FQTQ tools mentioned above by March 20, 2013, so that we can proceed with our evaluation. I look forward to hearing from you.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

NONDISCLOSURE AGREEMENT

This Confidential Disclosure Agreement ("**Agreement**") is effective as of the date of the last party to sign this Agreement ("**Effective Date**")

Between:

FoodQuestTQ LLC, doing business at 7420 Hayward Road, Suite 102, Frederick, Maryland 21702 ("**FQTQ**"); and
The Food and Drug Administration, doing business at 10903 New Hampshire Avenue Silver Spring, MD 20993 ("**FDA**").

FQTQ and FDA are referred to herein individually as a Party and collectively as the Parties.

The Parties agree as follows:

1) Definitions

"Affiliates" means the legal entities that (directly or indirectly) control, are controlled by, or are under common control with the named party.

"Confidential Information" means the following tools in their entirety: FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST (collectively referred to as "FQTQ commercial products"). In each case, the information disclosed by the Disclosing Party or its Affiliates to the Receiving Party or its Affiliates pursuant to this Agreement, will either be marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure.

"Disclosing Party" means the Party to this Agreement which discloses Confidential Information to the other Party under this Agreement.

"Exempt Information" means information that: (i) the Receiving Party or any of its Affiliates possessed before the Disclosing Party or its Affiliates disclosed it under this Agreement; or (ii) is or becomes publicly known (other than as a result of breach of this Agreement by the Receiving Party or its Representatives); (iii) the Receiving Party or any of its Affiliates obtains from a third party free of any confidentiality obligation to the Disclosing Party or its Affiliates with respect to such information; or (iv) is independently developed by or on behalf of the Receiving Party or its Affiliates without the use of the Confidential Information.

"Purpose" means the evaluation of FQTQ's allegations that FDA has taken FQTQ proprietary and trade secret information to duplicate FQTQ commercial products.

"Receiving Party" means the Party to this Agreement which receives Confidential Information from the other Party under this Agreement.

2) Treatment of Confidential Information

(a) The Receiving Party shall maintain the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care as it maintains the confidentiality of its own confidential information, and in any event, not less than a reasonable standard of care. This means in situations where FDA is the Receiving Party that FDA will protect the Disclosing Party's Confidential

Information in accordance with 21 U.S.C. § 331(j), 18 U.S.C. 1905, 21 CFR Part 20 and other pertinent laws and regulations governing the confidentiality of non-public information.

(b) The Receiving Party may use, copy and make extracts of the Disclosing Party's Confidential Information only in connection with the Purpose.

(c) The Receiving Party shall not disclose any of the Disclosing Party's Confidential Information to any third party other than the Receiving Party's Affiliates and the directors, officers, employees, contractors, consultants and agents of the Receiving Party and its Affiliates who have a need to know the Confidential Information for the Purpose and who are bound by obligations of confidentiality substantially similar to those in this Agreement (collectively, "**Representatives**").

(d) Anything to the contrary contained herein notwithstanding, the Receiving Party shall be permitted to disclose any of the Disclosing Party's Confidential Information that is required or requested to be disclosed by a governmental authority or applicable law, such as the Freedom of Information Act (5 U.S.C. § 552), provided that the Receiving Party shall: (i) notify the Disclosing Party of any such disclosure requirement as soon as practicable; (ii) cooperate with the Disclosing Party (at the Disclosing Party's cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which the Receiving Party is legally required to disclose. FQTQ hereby certifies that the Confidential Information to be provided under this agreement is being voluntarily provided to FDA for the Purpose, and is of a type held in strict confidence and not customarily disclosed to the public by FQTQ.

3) Other Matters

(a) Neither this Agreement nor the performance by either Party hereunder shall transfer to the Receiving Party any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including any intellectual property rights subsisting therein).

(b) Under this Agreement, the Disclosing Party provides the Receiving Party nonexclusive access to its Confidential Information and at no time does this affect the Disclosing Party's ability to otherwise distribute or dispose of the Confidential Information.

(c) Neither Party is obligated to negotiate or enter into any other agreement, and any discussions may be terminated at the sole discretion of either Party at any time and for any reason.

(d) This Agreement sets forth the Parties' entire understanding about its subject matter and supersedes any other agreement or understanding between the Parties about its subject matter. Neither Party can assign, amend, or terminate any part of this Agreement except in writing signed by both Parties.

(e) If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deleted or revised to the extent necessary to be enforceable, and, if possible, replaced by a term or provisions which, so far as practicable, achieves the legitimate aims of the Parties.

(f) This Agreement may be executed in two counterparts (including by facsimile or electronic copies), both of which shall be deemed an original, and both of which together shall constitute one and the same instrument.

(g) This Agreement shall be governed by and construed in accordance with the laws of Maryland and both Parties submit to the non-exclusive jurisdiction of the Maryland federal courts.

IN WITNESS WHEREOF, duly-authorized representatives of the Parties have signed as of the Effective Date.

Signed on behalf of FQTQ

By: _____

Print Name: _____

Title: _____
(Duly authorized)

Date: _____

Signed on behalf of FDA

By: Elizabeth Dickinson

Print Name: Elizabeth Dickinson

Title: Chief Counsel
(Duly authorized)

Date: March 13, 2013

EXHIBIT 12

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Thursday, March 14, 2013 10:53 AM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail
Attachments: Comments on the NDA for Ariel 3-14-2013.pdf

Hi Ariel:

I have taken a few minutes this morning and reviewed the proposed NDA you sent over to me. Attached is a short note with our recommendations. We have clearly described the changes and they should be quick and easy to make. I know how busy you are and we are happy to make the changes for you if you can send along a soft copy in *Word*. I'll use *track changes* to make sure that you can see and approve everything.

I read your e-mail below and I still do not understand how you can make even a preliminary determination regarding infringement or violation of trade secret without seeing how the original invention was reduced to practice in the context of our tools. I am not attorney like you are and, under the circumstances, cannot afford to pay for one. I feel like an innocent man thrown in jail who must serve as his own lawyer because of the unfortunate circumstances here. I am a simple man and it is difficult for me to understand the complexities of the law like you do. Since I am at such a disadvantage here, I really need your help. All that I ask is that you be patient with me and explain things so that I can clearly understand them.

I do not understand how your e-mail answers my question. My question is: How will it be possible for you (the FDA) to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the FQTQ tools (reduction to practice for food) that were duplicated by the FDA? As I have explained to you before, our reduction to practice of the invention for food involves trade secrets that were stolen by the FDA Food Defense Team and others at the FDA. In the absence of having this information how can you possibly do a thorough and good faith review of the matter?

I am sincerely asking for your patience and understanding. I really need your help here as a wise, fair attorney of high integrity who obviously has a tremendous command of the law to just honestly answer my question in a clear and simple way that I can understand. I need your reassurance that we are all operating in good faith here. Thank-you for your hard work on this and all of us really appreciate your help. Best, j

---

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Thursday, March 14, 2013 9:31 AM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

We appreciate your willingness to share information about your patent, how it was reduced to practice in a suite of tools, and other business process information with us. However, the information you provided about your patent so far has been sufficient. We will contact you for additional information, if necessary, at a later date. Thus, at this time, we need to evaluate your claims by comparing your products to ours. To do so, we will need nonexclusive

access to Food QuestTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE tool, and FEAST. Again, we appreciate your willingness to work with and provide us with requested information in a timely manner.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, March 13, 2013 4:17 PM
To: Seeley, Ariel
Subject: RE: Response to your e-mail

Hi Ariel:

Thank-you and I will look over the NDA.

Please be advised that the patent in question is a combination business process and data transformation patent.

In your e-mail you state "We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information."

Question

How then, will it be possible for you to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the tools that were duplicated by the FDA.

Please advise. Thank-you. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Wednesday, March 13, 2013 4:05 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr Hnatio:

Thank you for your email of March 2, 2013. I appreciate your willingness to work with me as I look into this matter. As you are most likely aware, dealing with the Food and Drug Administration (FDA), a federal agency, differs from dealing with private entities. Federal agencies must act according to a number of laws and regulations that govern their use of and ability to protect information submitted or provided to them. I attach to this email a non-disclosure agreement (NDA) that meets FDA's legal requirements. FDA has signed the attached NDA to make this process more efficient.

Furthermore, I would like to clarify that, at this time, FDA is only requesting nonexclusive access to FoodQuestTQ LLC's (FQTQ) software tools that you claim FDA's software tools, the Food Defense Plan Builder, FREE-B, and FDA-iRisk, duplicate. Specifically, these tools are FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST. Such access will allow FDA to evaluate the concerns raised by your previous communications. We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information. We ask that you do not send us such information at this time.

Please review the attached NDA and, if it is acceptable to you, send a signed copy to FDA with the FQTQ tools mentioned above by March 20, 2013, so that we can proceed with our evaluation. I look forward to hearing from you.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and

JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Date: March 14, 2013

Note for: Ariel Seeley, FDA Counsel

From: John Hnatio, FoodQuestTQ LLC

Subject: Suggested Changes to FDA Non-disclosure Agreement (NDA)

Hi Ariel:

We have completed a review of the FDA proposed NDA and it is acceptable to FQTQ with the following four modifications.

1. The "Purpose" of the agreement requires expansion to cover all three of the inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered as part of any good faith FDA review of this matter, namely:

    a. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;
    b. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, and;
    c. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

2. The "Purpose" of the agreement must indicate a fair and reasonable *quid pro quo* in the sharing of information between the two parties. If FQTQ provides the FDA with information regarding their tools for FDA evaluation then why does not the FDA share information with FQTQ regarding the FDA tools under suspicion for further evidence of theft of trade secrets and intellectual property and potential infringement in Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2?

    In addition, the agreement must reflect that the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2, is a business process and a data transformation patent. This is necessary since the guiding FDA national process document for food safety and food defense, *The FDA Food Protection Plan*, seriously infringes on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in addition to the other FQTQ tools duplicated by the FDA.

    Thus, we further suggest that the "Purpose" of the agreement be modified to explicitly state that the "parties" are engaged in a good faith review of the three allegations (as identified in 1. a.-c., above) and in so doing, must share information regarding the following FoodQuestTQ LLC food safety and food defense commercially developed tools, namely, Food SafetyTQ, Food

Safety Architect, Food DefenseTQ, Food Defense Architect, Food Mapper, the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation tool (FREE), and; the following federal government FDA guiding process document and tools, namely, *The FDA Food Protection Plan*, the FDA Food Defense Mitigation Strategies Database; the FDA Food Defense Plan Builder; the FDA Food Response Emergency Exercise-Bundled (FREE-B), and; the FDA iRisk tool.

3. The definition of "Confidential Information" requires expansion to identify the FDA national policy document and FDA tools and any FQTQ patent information and tools that must be evaluated in order to conduct a good faith review of the three allegations (as identified in 1. a.-c., above). This list currently includes Food SafetyTQ, Food Safety Architect, Food DefenseTQ, Food Defense Architect, Food Mapper, the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation tool (FREE), and; the following federal government FDA guiding process document and tools, namely, *The FDA Food Protection Plan*, the FDA Food Defense Mitigation Strategies Database; the FDA Food Defense Plan Builder; the FDA Food Response Emergency Exercise-Bundled (FREE-B), and; the FDA iRisk tool.

4. The term "Exemptions" has been defined in the standard FDA non-disclosure agreement but the term does not appear anywhere in the body of the document. This is a bit odd. In any event, the existing language, if it is to be included, requires modification by inserting the word "legally" in the verbiage as follows: "...(i) the Receiving Party or any of its Affiliates **legally** [emphasis added] possessed before the Disclosing Party or its Affiliates disclosed it under this agreement;..."

   This change is necessary because we are dealing with FQTQ "Confidential Information" i.e., trade secrets and intellectual property, that have already been taken by the FDA and are now being publicly disclosed by the FDA without FQTQ permission.

We recognize how busy you are and appreciate all of your hard efforts on our behalf. If it would be at all easier for you or save you time, we would be happy to make the above changes in the NDA and return the document to you for Ms. Dickinson's signature. All that we would require is that you e-mail to me a "soft copy" of the document in *Word* format. We will be sure to use "track changes" so that you can clearly see any modifications we make to your original document. Just let me know.

In any event, as soon as we receive the modified document we will immediately sign it and return it to you. Please call me at 240-439-4476 x-11 if you have any questions that I can help you with. Thank-you.

EXHIBIT
13

Seeley, Ariel

From: Seeley, Ariel
Sent: Friday, March 22, 2013 12:21 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Tracking:

Recipient	Delivery
'John Hnatio'	
Dickinson, Elizabeth	Delivered: 3/22/2013 12:21 PM
Raza, Mark	Delivered: 3/22/2013 12:21 PM

Mr. Hnatio:

Thank you for your email of March 14, 2013 suggesting changes to the nondisclosure agreement (NDA). You will be contacted shortly by a colleague of mine within the Department of Health and Human Services' (HHS) Office of General Counsel, Dale Berkley, who is our intellectual property attorney. I have provided Mr. Berkley with all necessary background information and materials.

Going forward, please understand that Mr. Berkley and I are lawyers representing HHS/FDA and cannot provide you with legal advice. If you want legal advice on this matter, I recommend that you consult with an attorney. I understand that you have indicated this would not be financially feasible for you. There are various organizations that exist to provide free or low-cost legal services to people who cannot otherwise afford legal representation.

Best,
Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, March 14, 2013 10:53 AM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Hi Ariel:

I have taken a few minutes this morning and reviewed the proposed NDA you sent over to me. Attached is a short note with our recommendations. We have clearly described the changes and they should be quick and easy to make. I know how busy you are and we are happy to make the changes for you if you can send along a soft copy in *Word*. I'll use *track changes* to make sure that you can see and approve everything.

I read your e-mail below and I still do not understand how you can make even a preliminary determination regarding infringement or violation of trade secret without seeing how the original invention was reduced to practice in the context of our tools. I am not attorney like you are and, under the circumstances, cannot afford to pay for one. I feel like an innocent man thrown in jail who must serve as his own lawyer because of the unfortunate circumstances here. I am a simple man and it is difficult for me to understand the complexities of the law like you do. Since I am at such a disadvantage here, I really need your help. All that I ask is that you be patient with me and explain things so that I can clearly understand them.

I do not understand how your e-mail answers my question. My question is: How will it be possible for you (the FDA) to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the FQTQ tools (reduction to practice for food) that were duplicated by the FDA? As I have explained to you before, our reduction to practice of the invention for food involves trade secrets that were stolen by the FDA Food Defense Team and others at the FDA. In the absence of having this information how can you possibly do a thorough and good faith review of the matter?

I am sincerely asking for your patience and understanding. I really need your help here as a wise, fair attorney of high integrity who obviously has a tremendous command of the law to just honestly answer my question in a clear and simple way that I can understand. I need your reassurance that we are all operating in good faith here. Thank-you for your hard work on this and all of us really appreciate your help. Best, j

---

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Thursday, March 14, 2013 9:31 AM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

We appreciate your willingness to share information about your patent, how it was reduced to practice in a suite of tools, and other business process information with us. However, the information you provided about your patent so far has been sufficient. We will contact you for additional information, if necessary, at a later date. Thus, at this time, we need to evaluate your claims by comparing your products to ours. To do so, we will need nonexclusive access to Food QuestTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE tool, and FEAST. Again, we appreciate your willingness to work with and provide us with requested information in a timely manner.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, March 13, 2013 4:17 PM
To: Seeley, Ariel
Subject: RE: Response to your e-mail

Hi Ariel:

Thank-you and I will look over the NDA.

Please be advised that the patent in question is a combination business process and data transformation patent.

In your e-mail you state "We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information."

Question

How then, will it be possible for you to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the tools that were duplicated by the FDA.

Please advise. Thank-you. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Wednesday, March 13, 2013 4:05 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr Hnatio:

Thank you for your email of March 2, 2013. I appreciate your willingness to work with me as I look into this matter. As you are most likely aware, dealing with the Food and Drug Administration (FDA), a federal agency, differs from dealing with private entities. Federal agencies must act according to a number of laws and regulations that govern their use of and ability to protect information submitted or provided to them. I attach to this email a non-disclosure agreement (NDA) that meets FDA's legal requirements. FDA has signed the attached NDA to make this process more efficient.

Furthermore, I would like to clarify that, at this time, FDA is only requesting nonexclusive access to FoodQuestTQ LLC's (FQTQ) software tools that you claim FDA's software tools, the Food Defense Plan Builder, FREE-B, and FDA-iRisk, duplicate. Specifically, these tools are FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST. Such access will allow FDA to evaluate the concerns raised by your previous communications. We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information. We ask that you do not send us such information at this time.

Please review the attached NDA and, if it is acceptable to you, send a signed copy to FDA with the FQTQ tools mentioned above by March 20, 2013, so that we can proceed with our evaluation. I look forward to hearing from you.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

EXHIBIT
14

Seeley, Ariel

From: Berkley, Dale (NIH/OD) [E] [BerkleyD@OD.NIH.GOV]
Sent: Wednesday, March 27, 2013 11:53 AM
To: Seeley, Ariel; Lovas, Julie
Subject: FW: Letter to Dr. Hnatio and NDA
Attachments: Letter to Dr Hnatio3-27-2013.pdf; NDA ----3--27-2013.docx.pdf

I sent this today.

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesdo, MD 20892
301-496-6043
301-402-2528(Fax)

From: Berkley, Dale (NIH/OD) [E]
Sent: Wednesday, March 27, 2013 11:52 AM
To: 'jhnatio@thoughtquest.com'
Subject: Letter to Dr. Hnatio and NDA

Dr. Hnatio:

Please see the attached letter and NDA.

Regards, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the Generol Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Friday, March 22, 2013 2:10 PM
To: Zahirieh, Elahe
Cc: Dickinson, Elizabeth (FDA/OC); Raza, Mark (FDA/OC); Berkley, Dale (NIH/OD) [E]
Subject: FW: Response to your e-mail

Hello Ellie:

I wanted to forward this e-mail to you and let you know that my concerns that DHHS/FDA are using any of the information we provide them not to conduct a good faith review as we asked Ms. Dickinson to do for us last January but instead have turned the matter into an adversary legal matter. **The e-mail is definitely threatening.** I do not believe that HHS/FDA are seriously considering ferreting out any possibility of their own wrongdoing here at all.

I also want to tell you that I believe Ms. Dickinson and her staff are working with HHS to pigeon hole what they

have done under the single label of patent infringement. While patent infringement is most certainly an issue here it is only one of three inextricably intertwined issues that must be considered in this case, namely: 1) FDA theft of FoodQuestTQ ideas, intellectual property and trade secrets; 2) unfair government competition with FoodQuestTQ, and; 3) patent infringement. I believe that FDA/HHS are intentionally trying to avoid dealing with issues 1 and 2, above, in order to avoid the separate unlawful actions that go well beyond the single issue of patent infringement in this case.

I would appreciate it if you could please forward a copy of this e-mail and my concerns to the FDA Ombudsman so that he is aware of the HHS/FDA legal jockeying in this case.

Thank-you very much for your help. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Friday, March 22, 2013 12:21 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

Thank you for your email of March 14, 2013 suggesting changes to the nondisclosure agreement (NDA). You will be contacted shortly by a colleague of mine within the Department of Health and Human Services' (HHS) Office of General Counsel, Dale Berkley, who is our intellectual property attorney. I have provided Mr. Berkley with all necessary background information and materials.

Going forward, please understand that Mr. Berkley and I are lawyers representing HHS/FDA and cannot provide you with legal advice. If you want legal advice on this matter, I recommend that you consult with an attorney. I understand that you have indicated this would not be financially feasible for you. There are various organizations that exist to provide free or low-cost legal services to people who cannot otherwise afford legal representation.

Best,
Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, March 14, 2013 10:53 AM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Hi Ariel:

I have taken a few minutes this morning and reviewed the proposed NDA you sent over to me. Attached is a short note with our recommendations. We have clearly described the changes and they should be quick and easy to make. I know how busy you are and we are happy to make the changes for you if you can send along a soft copy in *Word*. I'll use *track changes* to make sure that you can see and approve everything.

I read your e-mail below and I still do not understand how you can make even a preliminary determination regarding infringement or violation of trade secret without seeing how the original invention was reduced to practice in the context of our tools. I am not attorney like you are and, under the circumstances, cannot afford to pay for one. I feel like an innocent man thrown in jail who must serve as his own lawyer because of the unfortunate circumstances here. I am a simple man and it is difficult for me to understand the complexities of the law like you do. Since I am at such a disadvantage here, I really need your help. All that I ask is that you be patient with me and explain things so that I can clearly understand them.

I do not understand how your e-mail answers my question. My question is: How will it be possible for you (the FDA) to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the FQTQ tools (reduction to practice for food) that were duplicated by the FDA? As I have explained to you before, our reduction to practice of the invention for food involves trade secrets that were stolen by the FDA Food Defense Team and others at the FDA. In the absence of having this information how can you possibly do a thorough and good faith review of the matter?

I am sincerely asking for your patience and understanding. I really need your help here as a wise, fair attorney of high integrity who obviously has a tremendous command of the law to just honestly answer my question in a clear and simple way that I can understand. I need your reassurance that we are all operating in good faith here. Thank-you for your hard work on this and all of us really appreciate your help. Best, j

---

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Thursday, March 14, 2013 9:31 AM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

We appreciate your willingness to share information about your patent, how it was reduced to practice in a suite of tools, and other business process information with us. However, the information you provided about your patent so far has been sufficient. We will contact you for additional information, if necessary, at a later date. Thus, at this time, we need to evaluate your claims by comparing your products to ours. To do so, we will need nonexclusive access to Food QuestTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE tool, and FEAST. Again, we appreciate your willingness to work with and provide us with requested information in a timely manner.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS

301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, March 13, 2013 4:17 PM
To: Seeley, Ariel
Subject: RE: Response to your e-mail

Hi Ariel:

Thank-you and I will look over the NDA.

Please be advised that the patent in question is a combination business process and data transformation patent.

In your e-mail you state "We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information."

Question

How then, will it be possible for you to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the tools that were duplicated by the FDA.

Please advise. Thank-you. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Wednesday, March 13, 2013 4:05 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr Hnatio:

Thank you for your email of March 2, 2013. I appreciate your willingness to work with me as I look into this matter. As you are most likely aware, dealing with the Food and Drug Administration (FDA), a federal agency, differs from dealing with private entities. Federal agencies must act according to a number of laws and regulations that govern their use of and ability to protect information submitted or provided to them. I attach to this email a non-disclosure agreement (NDA) that meets FDA's legal requirements. FDA has signed the attached NDA to make this process more efficient.

Furthermore, I would like to clarify that, at this time, FDA is only requesting nonexclusive access to FoodQuestTQ LLC's (FQTQ) software tools that you claim FDA's software tools, the Food Defense Plan Builder, FREE-B, and FDA-iRisk, duplicate. Specifically, these tools are FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST. Such access will allow FDA to evaluate the concerns raised by your previous communications. We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information. We ask that you do

not send us such information at this time.

Please review the attached NDA and, if it is acceptable to you, send a signed copy to FDA with the FQTQ tools mentioned above by March 20, 2013, so that we can proceed with our evaluation. I look forward to hearing from you.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer

FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
Room 2B-50, NIH Bldg. 31
31 Center Dr., MSC 2111
Bethesda, Maryland 20892-2111
(301) 496-6043
Fax (301) 402-1034

March 27, 2013
VIA EMAIL

Dr. John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702

Re: FDA's Food Defense Team

Dear Dr. Hnatio:

With respect to your email of March 22, 2013 to Ms. Zahirieh on which I was copied, I take exception to your characterization of Ms. Seeley's recent email to you as "threatening," and your suggestion that our agency does not intend to investigate your allegations of "wrongdoing." Neither of your statements is true or the least bit accurate.

Ms. Seeley's email merely introduced me as the intellectual property attorney who will be helping with the analysis of your allegations. Her email properly suggested that you obtain competent legal counsel, in view of your earlier communication to us that you are unrepresented, with respect to an area of the law that is highly technical.

In your letter of February 12, 2013 to Ms. Dickinson, you claimed that FDA duplicated your Food DefenseTQ tool and took elements of your FREE and FEAST computer software tools and incorporated them into FDA tools.

In order to evaluate this claim I will need to compare the FDA tools with each of your company's tools for any similarities. However, we do not have a copy of your company's tools, and you indicated in a previous communication that you were willing to provide them to us for this purpose under a Non-Disclosure Agreement ("NDA").

Ms. Seeley's March 13, 2013 email contained an executed copy of the NDA, which was modified consistent with our standard practices. You proposed in your March 14, 2013 response that certain changes be made to the NDA. I accepted some of your changes as follows: (1) I revised the "Purpose" of the NDA, (2) I revised the definition of "Confidential Information" to account for its intended relationship to the "Exempted Information," and (3) I revised the definition of "Exempted Information."

Please find an executed copy of the NDA, which has been modified to accommodate some of your suggestions. In return, please forward a copy of the tools that are the subject of your complaint directly to me, along with a description of those parts of the FDA tools that you believe incorporate subject matter from your tools.

With respect to your claim of infringement of U.S. Patent No. 8,103,601, the regulations at 48 C.F.R. § 227.7004 describe the information necessary to evaluate a claim of this kind. In particular we need, as applicable, the following:

1. A detailed identification of the accused article or process, and an element by element comparison of the representative claims with the accused article or process. If available, this identification should include documentation and drawings to illustrate the accused article or process in suitable detail to enable verification of the infringement comparison;
2. Names and addresses of all past and present licenses under the patent, and copies of all license agreements and releases involving the patent;
3. A brief description of all litigation in which the patent has been or is now involved, and the present status thereof;
4. A list of all persons to whom notices of infringement have been sent, including all departments and agencies of the Government, and a statement of the ultimate disposition of each; and
5. A list of all Government contracts under which the inventor, patent owner, or anyone in privity with him performed work relating to the patented subject matter.

If you have any questions or wish to discuss this further, please contact me at (301) 496-6043, of at Berkleyd@od.nih.gov.

Sincerely,

Dale D. Berkley, Ph.D., J.D.
HHS IP Counsel

Attachment: Executed NDA

NONDISCLOSURE AGREEMENT

This Confidential Disclosure Agreement ("**Agreement**") is effective as of the date of the last party to sign this Agreement ("**Effective Date**")

Between:

FoodQuestTQ LLC, doing business at 7420 Hayward Road, Suite 102, Frederick, Maryland 21702 ("**FQTQ**"); and

The Department of Health and Human Services, doing business at 200 Independence Ave SW, Washington, DC 20201 ("**HHS**").

FQTQ and HHS are referred to herein individually as a Party and collectively as the Parties.

The Parties agree as follows:

1) Definitions

"Affiliates" means the legal entities that (directly or indirectly) control, are controlled by, or are under common control with the named party.

"Confidential Information" means all information, other than Exempt Information, that concerns the following tools in their entirety, except to the extent that they are or contain Exempt Information: FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST (collectively referred to as "FQTQ commercial products"). In each case, the information disclosed by the Disclosing Party or its Affiliates to the Receiving Party or its Affiliates pursuant to this Agreement, will either be marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure.

"Disclosing Party" means the Party to this Agreement which discloses Confidential Information to the other Party under this Agreement.

"Exempt Information" means information that: (i) the Receiving Party or any of its Affiliates legally possessed before the Disclosing Party or its Affiliates disclosed it under this Agreement; or (ii) is or becomes publicly known (other than as a result of breach of this Agreement by the Receiving Party or its Representatives); (iii) the Receiving Party or any of its Affiliates obtains from a third party free of any confidentiality obligation to the Disclosing Party or its Affiliates with respect to such information; or (iv) is independently developed by or on behalf of the Receiving Party or its Affiliates without the use of the Confidential Information.

"Purpose" means the evaluation of FQTQ's allegations against FDA.

"Receiving Party" means the Party to this Agreement which receives Confidential Information from the other Party under this Agreement.

2) Treatment of Confidential Information

(a) The Receiving Party shall maintain the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care as it maintains the confidentiality of its own confidential information, and in any event, not less than a reasonable standard of care. This means in

situations where HHS is the Receiving Party that HHS will protect the Disclosing Party's Confidential Information in accordance with 21 U.S.C. § 331(j), 18 U.S.C. 1905, 21 CFR Part 20 and other pertinent laws and regulations governing the confidentiality of non-public information.

(b) The Receiving Party may use, copy and make extracts of the Disclosing Party's Confidential Information only in connection with the Purpose.

(c) The Receiving Party shall not disclose any of the Disclosing Party's Confidential Information to any third party other than the Receiving Party's Affiliates and the directors, officers, employees, contractors, consultants and agents of the Receiving Party and its Affiliates who have a need to know the Confidential Information for the Purpose and who are bound by obligations of confidentiality substantially similar to those in this Agreement (collectively, "**Representatives**").

(d) Anything to the contrary contained herein notwithstanding, the Receiving Party shall be permitted to disclose any of the Disclosing Party's Confidential Information that is required or requested to be disclosed by a governmental authority or applicable law, such as the Freedom of Information Act (5 U.S.C. § 552), provided that the Receiving Party shall: (i) notify the Disclosing Party of any such disclosure requirement as soon as practicable; (ii) cooperate with the Disclosing Party (at the Disclosing Party's cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which the Receiving Party is legally required to disclose. FQTQ hereby certifies that the Confidential Information to be provided under this agreement is being voluntarily provided to HHS for the Purpose, and is of a type held in strict confidence and not customarily disclosed to the public by FQTQ.

3) **Other Matters**

(a) Neither this Agreement nor the performance by either Party hereunder shall transfer to the Receiving Party any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including any intellectual property rights subsisting therein).

(b) Under this Agreement, the Disclosing Party provides the Receiving Party nonexclusive access to its Confidential Information and at no time does this affect the Disclosing Party's ability to otherwise distribute or dispose of the Confidential Information.

(c) Neither Party is obligated to negotiate or enter into any other agreement, and any discussions may be terminated at the sole discretion of either Party at any time and for any reason.

(d) This Agreement sets forth the Parties' entire understanding about its subject matter and supersedes any other agreement or understanding between the Parties about its subject matter. Neither Party can assign, amend, or terminate any part of this Agreement except in writing signed by both Parties.

(e) If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deleted or revised to the extent necessary to be enforceable, and, if possible, replaced by a term or provisions which, so far as practicable, achieves the legitimate aims of the Parties.

(f) This Agreement may be executed in two counterparts (including by facsimile or electronic copies), both of which shall be deemed an original, and both of which together shall constitute one and the same instrument.

(g) This Agreement shall be governed by and construed in accordance with the laws of Maryland and both Parties submit to the non-exclusive jurisdiction of the Maryland federal courts.

IN WITNESS WHEREOF, duly-authorized representatives of the Parties have signed as of the Effective Date.

Signed on behalf of FQTQ

By: _____

Print Name: _____

Title: _____
(Duly authorized)

Date: _____

Signed on behalf of HHS

By: Dale D. Berkley

Print Name: DALE D. BERKLEY

Title: SENIOR ATTORNEY
(Duly authorized)

Date: 3/27/2013

EXHIBIT
15

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Thursday, March 28, 2013 11:43 AM
To: Dale.Berkley@nih.hhs.gov
Cc: Zahirieh, Elahe; Seeley, Ariel
Subject: FW: Response to Your Letter of 3-27-2013 w/ attach
Attachments: DHHS-Dr. Berkley 3-28-2013.pdf

The attachment to the previous e-mail is attached herewith.

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, March 28, 2013 11:41 AM
To: Dale.Berkley@nih.hhs.gov
Cc: Ariel.Seeley@fda.hhs.gov; Zahirieh, Elahe (Elahe.Zahirieh@sba.gov)
Subject: Response to Your Letter of 3-27-2013

Dr. Berkley: Thank-you very much for your letter. Attached is our response. If you have any questions please feel free to call me. John

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Dr. Dale D. Berkley
Office of the General Counsel
Public Health Division
Room 2B-50, NIM Bldg. 31
31 Center Drive, MSC 2111
Bethesda, Maryland 20892-2111

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

March 28, 2013

Dear Dr. Berkley:

We have received your letter of March 27, 2013.

In your letter, you refer to my March 22nd e-mail to Ms. Zahirieh of the Office of the National Ombudsman for Small Business. In your letter you take exception to our concerns that the FDA did not and never intended to conduct a good faith review of our concerns. But, in fact, it was for this reason that we were forced to turn to the National Ombudsman for Small Business for help.

I am very surprised to hear that you do not understand why Ms. Seeley's e-mail is so threatening. Please let me explain.

I too was a civil servant. On my first day of government service I took an oath to uphold the Constitution and the laws of the United States. There were many times during my 30 year career with the government that this oath was sorely tested. In the face of serious wrongdoing in my own agency and at serious risk to my own well-being, I held fast to my oath. When my agency was guilty of wrongdoing my loyalty was always guided by my oath to uphold the Constitution and the laws of the United States first- certainly not the defense of my colleagues in the agency who engaged in the misconduct in the first place.

Please keep in mind that it was Ms. Seeley's own decision to turn this matter into an adversary legal defense of her colleagues on the FDA Food Defense Team instead of an impartial and objective fact finding mission to determine the truth. We certainly do not want to hurt Ms. Seeley. But her e-mail is, in fact, very clear. To the FDA, this matter is not about finding the truth. Rather, it is about mounting a legal defense for the FDA's own unconscionable actions in this matter. Based on your letter and your defense of Ms. Seeley's misguided actions, this now appears to be your motivation as well.

We also want thank you very much for your concern about the need for us to hire legal assistance to defend us against your investigation of this matter. But, if you intend to conduct a fair and impartial good faith review of this matter, then why do we have to pay money that we desperately need to feed our families to pay for an expensive legal defense? At this time, all of us in FoodQuestTQ have been forced into unemployment by the actions taken against us by the FDA. We simply cannot afford the expense of engaging in a legal battle with the government.

The non-disclosure agreement (NDA) you sent to us, still does not contain several important recommendations that we have already provided to the FDA legal counsel. Among the most important changes that must be made to the draft NDA involve he "Purpose" of the agreement.

As we have said from the very beginning, this matter involves three inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered if there is to be any true good faith review of this matter, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of ideas, trade secrets and proprietary information from Thought Quest LLC, FoodQuestTQ LLC and Projectioneering LLC, and;

3. Projectioneering LLC and FQTQ proof that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

The reason for these changes is because the FDA legal counsel has repeatedly attempted to pigeon hole the FQTQ complaint against the FDA as solely and exclusively a matter of patent infringement. This is not the case. Our complaint to the National Ombudsman for Small Business goes well beyond the single isolated issue of patent infringement to include violations of the FAIR Act, the theft of our ideas, trade secrets and intellectual property, the duplication of our products and unlawful government competition against FoodQuestTQ. Thus, the NDA must clearly reflect that your good faith review will encompass all aspects of the formal complaint we have filed with the National Ombudsman for Small Business.

The NDA must also reflect a fair and reasonable quid pro quo in the sharing of information between FQTQ and Department of Health and Human Services and the FDA. If FQTQ provides you with information regarding their tools then the FDA should share information with FQTQ regarding each of the FDA tools under suspicion for further evidence of theft of our ideas, trade secrets and intellectual property and infringement on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

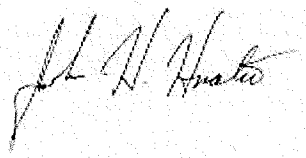
Several weeks ago, we suggested such a quid-pro-quo but the FDA counsel declined. We requested that the FDA provide us with an in-depth demonstration of the tools they duplicated and the opportunity for us to ask further questions. Thereafter, FoodQuestTQ would provide the FDA with a complete demonstration of our tools that would demonstrate the specific ideas, trade secrets and intellectual property that was stolen from us. Both presentations would be done via webinar and recorded for independent review by the National Ombudsman for Small Business, the office of Inspector General, the Department of Justice and others who may become involved in this matter. We now extend this same offer to you. Such demonstrations will quickly and conclusively demonstrate the truth of this matter as part of the official record.

The provisions at 48 C.F.R. §227.7004 relate to the resolution of patent infringement claims on the part of the offended party. The information you request is not germane to the conduct of a good faith fact finding mission by the either the FDA or the Department of Health and Human Services under the administrative law provisions at 48 C.F.R. §227.7002 and 48 C.F.R. §227.7004. As you are well aware, we are not yet at the resolution phase of this process.

At this juncture, you have a copy of our USPTO granted patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 and a detailed list of the specific ideas, trade secrets and intellectual property that were stolen from us by the FDA that I have provided to the National Ombudsman for Small Business. I understand that this information has already been provided to you by the National Ombudsman. On prior occasions, we have also offered FDA counsel a detailed technical crosswalk of how our patent was reduced to practice for our food applications. But the offer was declined.

Again, thank you very much for your letter. I can be reached at 240-439-4476 x-11 if you have any questions.

Sincerely yours,



John Hnatio
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

cc: Ms. Elahe Zahirieh, NOSB
Ms. Ariel Seeley, FDA Counsel

EXHIBIT
16

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Saturday, March 16, 2013 3:14 PM
To: Dickinson, Elizabeth
Cc: Seeley, Ariel; Raza, Mark
Subject: FQTQ Request for help from the National Ombudsman for Small Business, Office of Small Business Advocacy, SBA
Attachments: Elizabeth D 3-16-2013.pdf

Hello Ms. Dickinson:

Attached is a letter explaining our situation and why we have requested the help of the National Ombudsman for Small Business to join with both FDA and FoodQuestTQ LLC to oversee the good faith review now being conducted by your office into the concerns we have raised. I believe their support can really help all of us to get to the bottom of things quickly and in a way that does not upset FDA's desire for legal propriety in the way we work together to resolve the issues. Please let me know if the meeting we suggest in the attached is agreeable to you. Thank-you and have a good weekend. Best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-208
(C) 301.606.9403

Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

March 16, 2013

Dear Ms. Dickinson:

First, we want to thank-you very much for the hard work of Ariel Seeley of your staff. She has worked very diligently on this matter and we appreciate her efforts very much. You must be proud to have her as a member of your staff. We recognize the extremely difficult situation she is in trying, on the one hand, to defend the actions of the Food and Drug Administration while, at the same time, attempting to conduct an honest and good faith review of the situation. We can appreciate the terrible conflict this must create for her. Please extend our thanks to her.

When we first asked to meet with you I was sincerely hoping that we could simply sit down together, talk honestly to one another as people of mutual integrity and quickly move forward to fairly resolve our concerns. But instead the train of justice has fallen off the tracks. It has now been over three months since we first asked to meet with you and we still are not even able to agree that any wrong has actually happened here. As I shared with Ariel earlier, I am a simple man who is not an attorney and I cannot afford to hire one to advocate on my behalf in an adversary legal setting. But it does seem to me, as a layman, that while there is way too much FDA legal jockeying going on, there is way too little effort to resolve the real issues a play here. In the meantime, however, the lives of real people are being destroyed.

Our company, just when we were in the position to make the food supply safer for all Americans, has been forced out of business by the FDA; on our side of the equation we are now in the unemployment lines, we can no longer pay our bills, the credit ratings that we have worked to a lifetime to preserve have been destroyed and all of our families have suffered terribly as the result of the actions taken against us by the FDA. The extended order effects of improper actions have had devastating consequences in this case.

For example, did you know that one of my company's employees is an 80% disabled military veteran who has an extended family that relies on him as the principal breadwinner? Can you possibly imagine what that must be like for him and his family? In another case, a member of the FoodQuestTQ family of employees has worked, scrimped and sacrificed literally everything he owns including his house, his retirement and his entire life savings to make our business a success. He too is the principal breadwinner for an extended family whose elderly in-laws live with his family. There are many other stories of anguish too. It is much too easy to forget that the actions we take can hurt real people.

This is why I am again pleading for your help and understanding to resolve this matter as quickly as possible. What is happening here is not some far away abstraction of reality. It is the real thing. People's lives and futures depend on our integrity, honesty and willingness to come together in a responsible way to resolve this matter quickly and fairly. That is why I am asking for the opportunity to meet with you personally to get the train of justice back on the tracks here. In the meeting, we would like to simply share with you the honest story of exactly what has happened here. I am sure that once you hear the true and complete story you will be appalled and take whatever actions are necessary to immediately turn this bizarre situation around.

It is true that we are at the mercy of the FDA and our own government because we simply cannot afford a long and expensive legal battle to achieve justice for ourselves. In my case, I am a 62 year old white male with few prospects for any possibility of future employment who would likely die before receiving any relief for my family as the result of this terrible situation. I do not like to think about leaving my wife impoverished as the result of the risks I have taken to create a small business. Thus, we have no choice but to rely on you and our own government to act with integrity to fairly protect our interests.

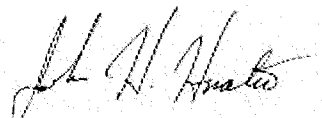
But time is definitely running out for us. This is why we have reached out to the Small Business Administration Office of Small Business Advocacy and the National Ombudsman for Small Business to help the FDA and FoodQuestTQ LLC come together. Our hope is that the SBA Ombudsman will carefully watch what is going on as an objective third party to help the FDA and FoodQuestTQ balance the need for FDA legal propriety against the real world needs of FoodQuestTQ to fairly resolve the situation as soon as possible. We believe that this approach will help both the FDA and FoodQuestTQ work through the issues fairly and objectively. The wonderful added advantage of this approach

is the requirement that we must complete our work within 30 days and file a full report to the Small Business Administration. Of course, this is critically important if FoodQuestTQ is to have any hope of surviving the actions that have been taken against us by the FDA.

Thank-you very much for your help in working with us. It is truly appreciated. We know how busy you are. If the personal meeting I suggest is agreeable to you please let me know and I will work our schedules to meet at any time that is convenient for you and your staff.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,



John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

cc: Ms. Ellie Zahirieh, Office of the SBA Ombudsman

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Tuesday, March 19, 2013 10:38 AM
To: ombudsman@sba.gov
Cc: Dickinson, Elizabeth; Seeley, Ariel; Raza, Mark
Subject: ATTN: Ellie Zahirieh: Office of the National Ombudsman for Small Business, Office of Small Business Advocacy, SBA; Case No. 1303150001
Attachments: Briefing for the SBA National Ombudsman.pdf

Good morning Ellie. A short update.

Please find attached a very short briefing for the SBA Ombudsman concerning our complaint. The briefing lays out the situation with the FDA and identifies the specific FQTQ ideas that were stolen by the FDA food defense team and others in the FDA in order for them to duplicate our products.

The list of the things stolen by the FDA all involve infringement on our patent and we have prepared a very extensive technical crosswalk of our patent against the FDA duplicated products that demonstrates flagrant FDA infringement. We would very much like to share the technical crosswalk with the National Ombudsman in order to help resolve this matter.

Many weeks ago, we offered the FDA Chief Counsel and her staff a demonstration of our tools so they could see for themselves the ideas that were stolen by the FDA to duplicate our products. The FDA declined our offer.

At this time, we would like to arrange a webinar for the SBA Office of Small Business Advocacy to demonstrate our tools to you. The webinar will include a "side-by-side" click through of the FQTQ tools against those duplicated by the FDA and will last no more than one hour. I will reach out to you shortly to arrange a mutually convenient date and time for the webinar.

Thank-you for your help and assistance in this matter. Best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

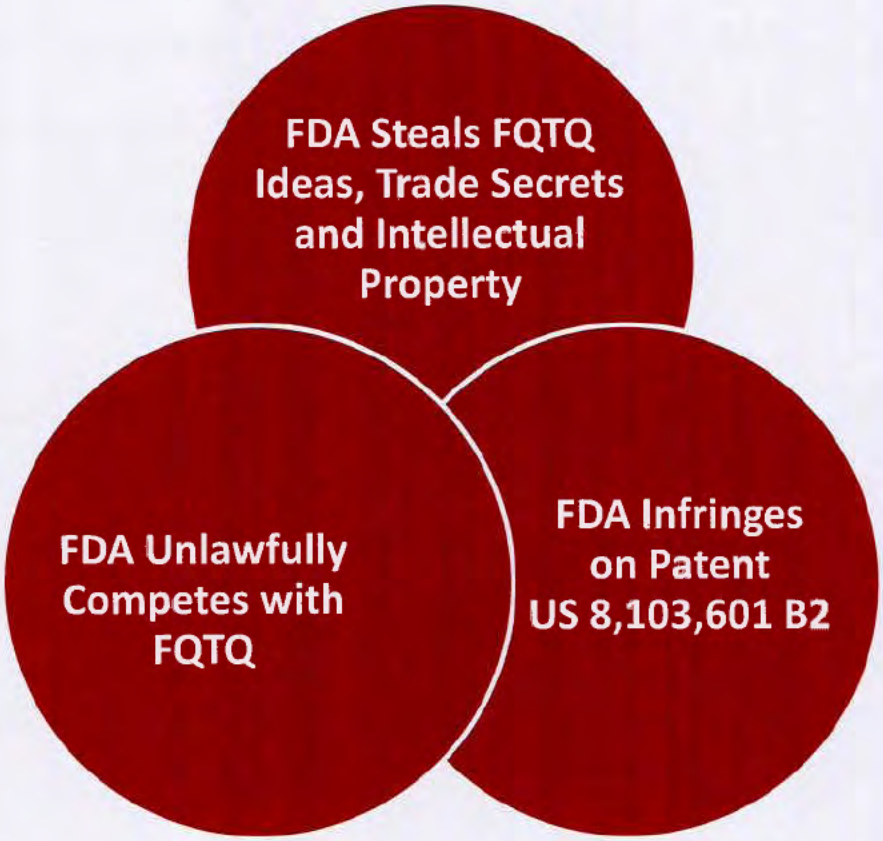
FoodQuestTQ LLC

March 19, 2013

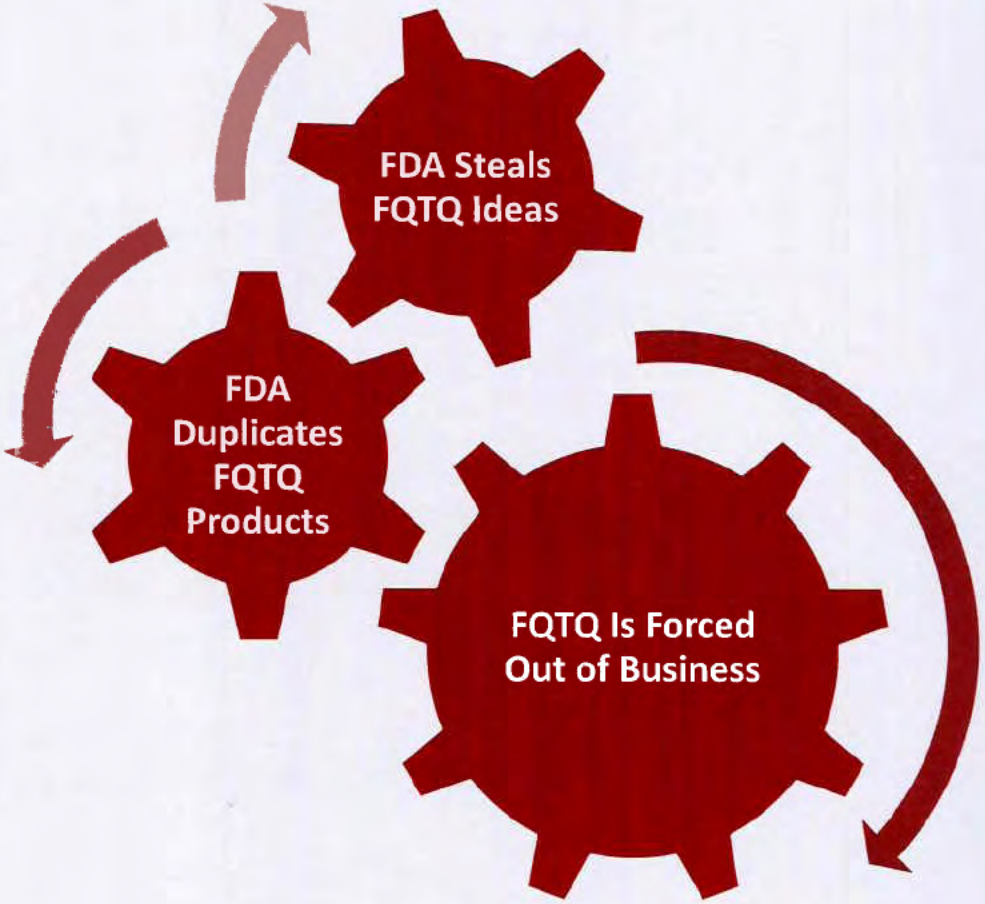
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- **The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.**

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- **The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.**

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- **The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.**

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- **The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."**

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- **The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."**

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- **The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.**

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- **The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.**

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- **The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.**

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed

- **The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.**

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- **The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.**

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.**

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- **The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.**

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- **The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.**

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.**

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- **The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.**

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- **The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.**

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- **The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.**

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- **The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.**

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- **The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.**

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- **The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.**

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- **The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.**

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- **The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool**

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- **The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectiviity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.**

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

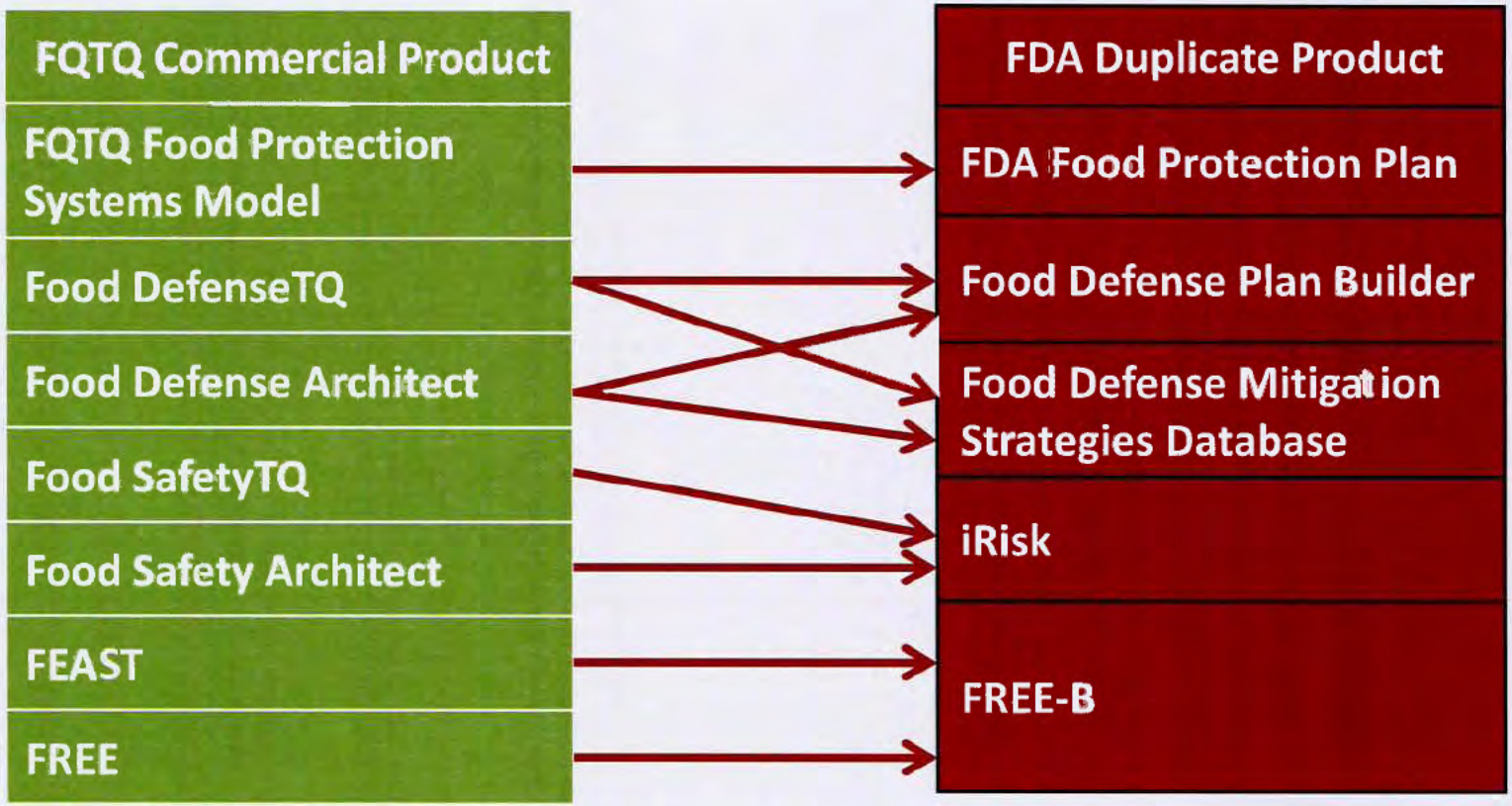
- **The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.**
- **The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.**

25. FQTQ Enhanced Risk Communications

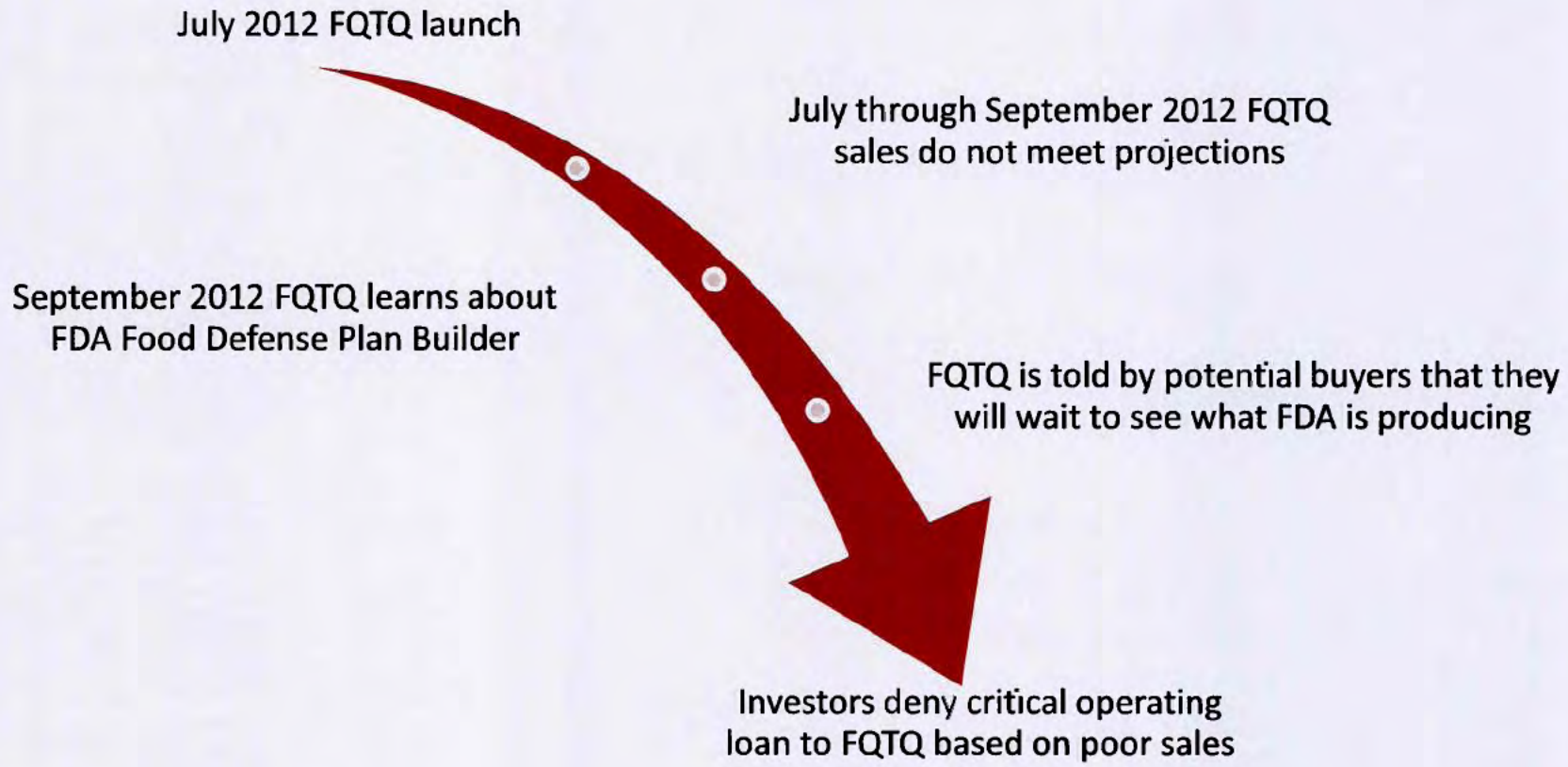
The FQTQ systems model for food protection improves risk communications.

- **The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.**

FDA Duplicates FQTQ Products



FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2

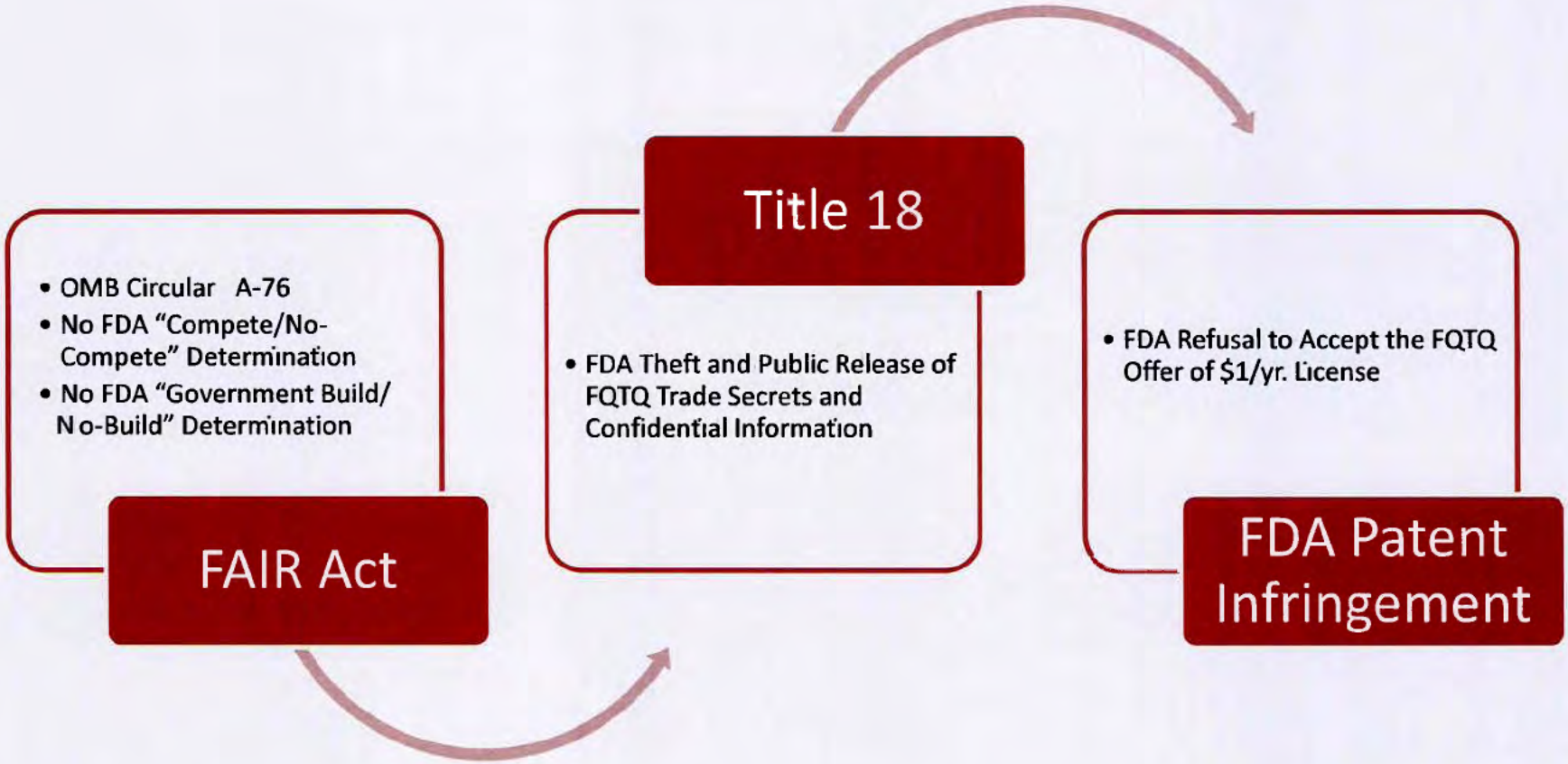
The patent has 20 claims and 101 associated objects of the invention

How FQTQ reduced the patent to use for food was FQTQ trade secret information until it was revealed by FDA in the FQTQ tools they duplicated and released to the public

FQTQ has prepared an extensive technical crosswalk that demonstrates flagrant infringement by the FDA on patent US 8,103,601 B2

FQTQ is prepared to share the results of the crosswalk with the National Small Business Ombudsman if it will assist in the timely resolution of this matter

FDA Unlawfully Competes with FQTQ



Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Tuesday, March 19, 2013 4:05 PM
To: 'Zahirieh, Elahe'
Cc: Dickinson, Elizabeth; Seeley, Ariel; Raza, Mark
Subject: RE: ATTN: Ellie Zahirieh: Office of the National Ombudsman for Small Business, Office of Small Business Advocacy, SBA; Case No. 1303150001
Attachments: Summary report for Ms. Dickinson.pdf; Briefing for the SBA National Ombudsman.pdf

Ellie:

Thank-you very much for your help and your e-mail. I have sent a copy of this e-mail and both attachments to Ms. Dickinson and her staff at the FDA Office of Chief Counsel.

But I need to share the following very brief points with you for the record.

1. Without the power to investigate the actions of the FDA, the outcome of our situation does not appear at all favorable.

2. The FDA has already begun the process of legal jockeying and delay in order to defend their own unlawful actions in this case. I now believe that they have never had any intention whatsoever to conduct a good faith review of this matter. Without the ability to investigate the FDA, I am very concerned that Ms. Dickinson will simply continue to pursue the tactic of delay and legal jockeying until FoodQuestTQ simply "fades away."

3. We requested to meet with Ms. Dickinson in January 2013. She still has not met with us.

4. We have already offered the FDA a demonstration of our tools but they have declined.

5. When we were forced to turn to the SBA Ombudsman for help, we noticed the SBA's admonition that treating any information as "Confidential" can result in delays in processing our case. We simply cannot afford any further delays. Under the circumstances, the timely processing of our case is the absolute forced priority for us. If we don't receive timely relief our business is kaput.

6. Thus, at this juncture we are left with no other option but to forgo the proper protection of our intellectual property by the FDA in favor of a timely resolution to this matter before we are forced to close our doors and simply "fade away."

7. But we must go on record stating that we believe the real intention of the FDA in this matter is to simply disregard our concerns and their own unlawful actions in favor of their own legal defense. We believe that they will use the attached information not to conduct a good faith review, but rather, to marshal their own legal defense.

8. I am attaching a copy of the case summary I sent to you for Ms. Dickinson to read. I have removed all markings. We have very extensive documentation that supports everything we say in the summary.

Ellie, if I can, I would like to keep you and the National Ombudsman for Small Business closely apprised of any developments in this case as they occur. I will "cc" on all further correspondence with the FDA. While the

outcome may already be pre-destined because you do not have the essential investigatory authority you must have to make a difference in our case, I want to assure that the record of how the FDA handles this matter is totally transparent and part of the open public record.

All the best and thank-you for your help. John

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

From: Zahirieh, Elahe [mailto:Elahe.Zahirieh@sba.gov]
Sent: Tuesday, March 19, 2013 2:26 PM
To: jhnatio@thoughtquest.com
Subject: RE: ATTN: Ellie Zahineh: Office of the National Ombudsman for Small Business, Office of Small Business Advocacy, SBA; Case No. 1303150001

Good afternoon Dr. Hnatio,

Thank you for bringing your concerns to the attention of the Office of the National Ombudsman (ONO). I received your Federal Agency Comment Form and supporting documentation regarding your issues with the FDA. After reviewing your case, we will refer your submission to the FDA with a request from the National Ombudsman for a high-level review and a response to this office in a timely manner. However, please be advised that the ONO's role is to liaise with federal agencies regarding cases of federal regulatory enforcement and compliance assistance against small businesses. ONO is not authorized to conduct any investigation on the comments it receives from small businesses.

Since you have marked your supporting documentation 'confidential for the SBA Ombudsman', please let me know whether or not I have your permission
to send it to the FDA for their review. If yes, please remove the water mark (confidential draft) from the entire document and send it to me.

Also, may I provide the FDA with a copy of your 'briefing for the SBA National Ombudsman' (demonstration of your tools) for their review?

Dr. Hnatio, please contact me at 202-205-6499, or via e-mail if you have any questions in this matter.

We look forward to assisting you with this issue.

Thank you and best regards,

Ellie Zahirieh
Case Management Specialist
Office of the National Ombudsman
U.S. Small Business Administration
Phone: 202-205-6499

Fax: 202-481-6062

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, March 19, 2013 10:38 AM
To: SBA National Ombudsman
Cc: Elizabeth.Dickinson@fda.hhs.gov; Ariel.Seeley@fda.hhs.gov; mark.raza@fda.hhs.gov
Subject: ATTN: Ellie Zahirieh: Office of the National Ombudsman for Small Business, Office of Small Business Advocacy, SBA; Case No. 1303150001

Good morning Ellie. A short update.

Please find attached a very short briefing for the SBA Ombudsman concerning our complaint. The briefing lays out the situation with the FDA and identifies the specific FQTQ ideas that were stolen by the FDA food defense team and others in the FDA in order for them to duplicate our products.

The list of the things stolen by the FDA all involve infringement on our patent and we have prepared a very extensive technical crosswalk of our patent against the FDA duplicated products that demonstrates flagrant FDA infringement. We would very much like to share the technical crosswalk with the National Ombudsman in order to help resolve this matter.

Many weeks ago, we offered the FDA Chief Counsel and her staff a demonstration of our tools so they could see for themselves the ideas that were stolen by the FDA to duplicate our products. The FDA declined our offer.

At this time, we would like to arrange a webinar for the SBA Office of Small Business Advocacy to demonstrate our tools to you. The webinar will include a "side-by-side" click through of the FQTQ tools against those duplicated by the FDA and will last no more than one hour. I will reach out to you shortly to arrange a mutually convenient date and time for the webinar.

Thank-you for your help and assistance in this matter. Best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

SBA Ombudsman Case No. 1303150001

COMPETITION BY THE FOOD AND DRUG ADMINISTRATION WITH SMALL BUSINESS

The parties: FoodQuestTQ LLC, a small business with offices situated at 4720 Hayward Drive, Frederick, Maryland, 21702, and the Food and Drug Administration (FDA) with offices situated 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993.

FOODQUESTTQ LLC CONTACT INFORMATION

Dr. John Hnatio
Chief Science Officer
(o) 240.439.4476 x-11
(c) 301.606.9403
E-mail: jhnatio@thoughtquest.com

BACKGROUND

Projectioneering LLC is a small Frederick, Maryland-based company working with two other Frederick Maryland-based companies, ThoughtQuest LLC and FoodQuest LLC. Projectioneering LLC owns the intellectual property used by both ThoughtQuest LLC and FoodQuest LLC. ThoughtQuest LLC was created in 2008 for the purpose of supporting the start-up of companies across different industry verticals using the intellectual property owned by Projectioneering LLC. From 2008 to 2012, ThoughtQuest LLC reduced the Projectioneering LLC owned patent to practice for the food and agricultural fields of use. In early 2012, FoodQuestTQ LLC was established to commercially sell a suite of computer software tools across the food industry vertical that are based on the Projectioneering LLC patent.

SUMMARY

FoodQuestTQ LLC has filed a complaint with the Office of Small Business Advocacy and the Small Business Ombudsman. The complaint is based on three inextricably intertwined prohibited actions that the company alleges have been taken against them by the Food and Drug Administration, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, in violation of Title 18 U.S.C. and other statutes, and;

3. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in violation of Title 18 U.S.C. and other statutes.

Until December 2012, the FoodQuestTQ LLC employed five people. In January 2013, faced with the continuing prospect of direct government competition that interfered with their commercial sales, FoodQuestTQ was unable to obtain an essential operating loan it required to stay in business. In December 2012, the company was forced to lay off all of its employees because of lagging sales resulting from the public release of similar products by the FDA.

This document describes the events leading up to and surrounding the actions allegedly taken by the Food and Drug Administration (FDA) to duplicate products that were already developed and for commercial sale by FoodQuestTQ LLC.

CASE DESCRIPTION

Over the period of the past three years representatives of ThoughtQuest LLC and FoodQuestTQ LLC have met extensively with FDA employees and shared with them information regarding the reduction of their patented technology for commercial use/sale to the food industry.

The information provided to FDA personnel was clearly marked as containing industry proprietary information. In addition, ThoughtQuest LLC and FoodQuestTQ LLC principals state that FDA employees they spoke with were verbally advised that the information being shared with them was proprietary and contained ThoughtQuest LLC and FoodQuestTQ LLC business proprietary and trade secret information.

In September 2012, FoodQuestTQ LLC principals became concerned that the FDA was, unbeknownst to them, taking their business proprietary and trade secret information to duplicate their products, under a contract with Battelle Memorial Institute.

In late October 2012, under pressure to avoid direct competition with the FDA that would put them out of business, FoodQuestTQ LLC, with the permission of their Board of Directors, offered the FDA a $1/yr. license to use their technology. FDA officials did not respond to the FoodQuestTQ LLC offer.

FDA and their contractor, Battelle Memorial Institute, continue to deploy products free of charge to the food industry that duplicate the products that were already developed and being commercially sold by FoodQuestTQ LLC.

The FDA actions have severely impacted FoodQuestTQ LLC sales. In early December 2012 when they were no longer able to meet payroll FoodQuestTQ LLC was forced to lay off all of their company's employees.

In January 2013, based on continuing competition by the FDA resulting in poor sales of their products, FoodQuestTQ LLC was denied a critical operating loan they needed to stay in business.

TIMELINE OF EVENTS LEADING TO THE LAYOFF OF FOODQUESTTQ PRINCIPALS AND EMPLOYEES

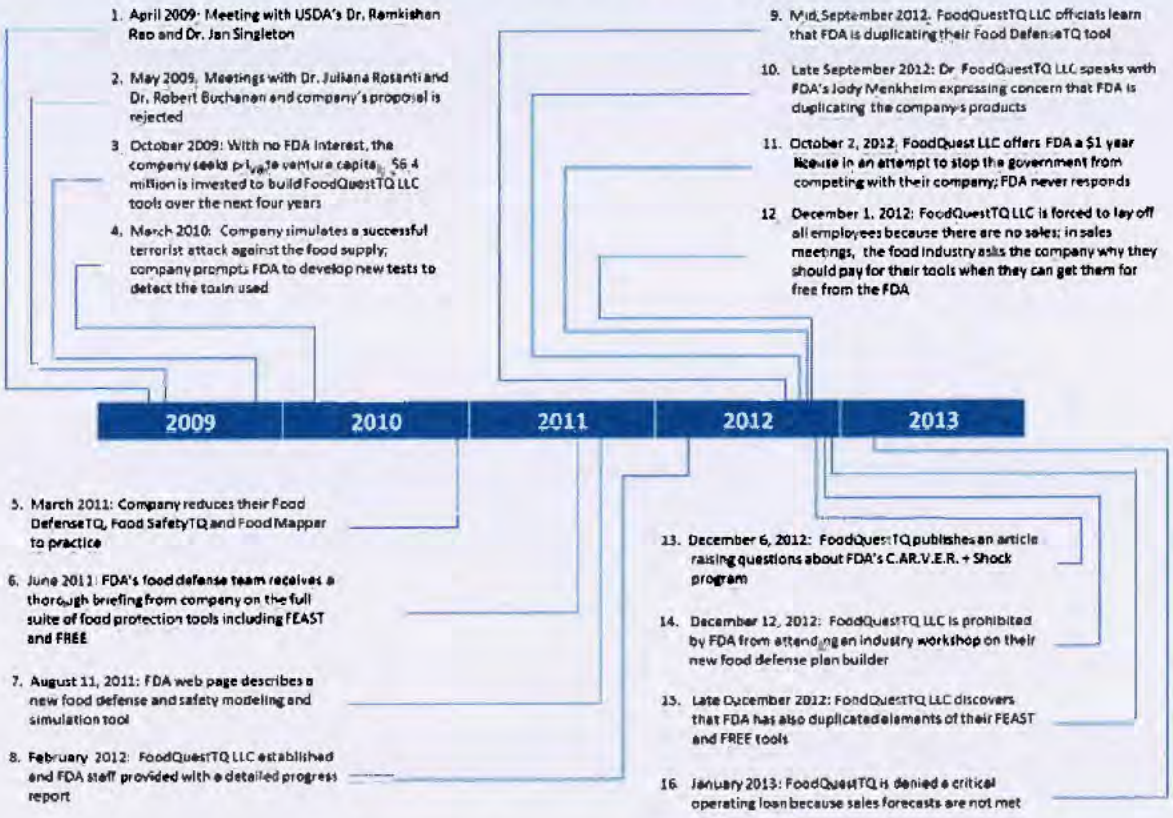


Figure 1: Timeline of FoodQuestTQ LLC and FDA Activities

1. In April 2009, representatives of ThoughtQuest LLC first contacted the U.S. Department of Agriculture (USDA). They met with Drs. Ramkishan Rao and Jan Singleton who were senior leaders at the U.S. Department of Agriculture's, National Institute of Food and Agriculture (NIFA). The purpose of the meeting was to forge a public-private partnership to make the food supply safer. ThoughtQuest LLC representatives shared their scientific breakthroughs, proprietary technology, and business plans for creating a safer food supply. Drs. Rao and Singleton were highly supportive of ThoughtQuest LLC's efforts. After the meeting, the company had follow-on meetings with Dr. Jeannette Thurston and other members of the USDA staff at NIFA to share their progress.

2. In May 2009, ThoughtQuest LLC representatives had their first contact with FDA when they met with Dr. Juliana Rosanti at the Joint Institute for Safety and Nutrition (JIFSAN). Their objective was to explore the possibility of a joint project with JIFSAN using their patent to make the food supply safer; this lead to a second meeting with Dr. Robert Buchanan, the head of the University of Maryland's Center for Food Safety and Nutrition (CIFSAN). Dr. Buchanan was a retired FDA senior food safety official and still serves as a senior scientific advisor to the FDA. At that time, Dr. Leanne Jackson, current head of the FDA's Food Defense Team was on the staff of CIFSAN.[i] As a result of these meetings, ThoughtQuest LLC representatives were asked to submit a detailed proposal to Dr. Buchanan describing their patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply. The proposal was clearly marked as containing proprietary information. The proposal was subsequently rejected by Dr. Buchanan.

   Note: Over the next three and a half years, the company continued to maintain very close contacts with both the USDA and FDA as they developed their products. The company briefed USDA and FDA officials on every step of their scientific and technological progress. They hoped that, at some point, USDA and FDA would join them in the public-private partnership they originally envisioned to improve the safety of the food supply based on the company's new science and technology innovations.

3. In October 2009, when the FDA showed no apparent interest in their patent and supporting technology, ThoughtQuest LLC sought venture capital. In addition to the $3.5 million invested by the two principals of ThoughtQuest LLC, the company received an additional $2.9 million in venture capital over the next four years to build and commercially deploy their suite of computer software tools to help the food industry prevent and improve responses to accidental and intentional food poisonings.

4. In 2010, ThoughtQuest LLC was asked by a large global food manufacturer to use their patent and technology to simulate a worst case terrorist attack using a biological agent against one of their major food product lines. The goal was to "bring down the company." Based on this tasking, ThoughtQuest LLC was able to scientifically simulate the successful take down of the company as a result of terrorists introducing a particular toxic agent into their product. The simulation was highly successful because no effective laboratory test existed at that time for detecting the presence of the agent that was used to poison the particular product. With the permission of the company involved, ThoughtQuest LLC representatives closely coordinated the results of the simulation and the methodology they used with Dr. Reginald Bennet and other officials at the FDA in

order to prompt the development of specific laboratory and field tests that would detect the deadly agent.

5. By early 2011, ThoughtQuest TQ LLC personnel reduced three of their products to practice and began commercial sales of their Food DefenseTQ, Food SafetyTQ and Food Mapper tools.

6. In June 2011, Mr. Menkhiem, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim to give him periodic updates on their progress.

7. On August 11, 2012, Mr. David Park, then Principal Scientist of FoodQuestTQ LLC came across an official FDA website that described a new FDA tool for modeling and simulating food defense and food safety scenarios.

   Note: As further discussed below, in late December 2012, Dr. Hnatio conducted a detailed review of the FDA website to discover that the FDA had duplicated the elements of two of FoodQuestTQ tools-the Food Event and Analysis Simulation Tool (FEAST) and the Food Response and Emergency Evaluation (FREE) tool. The FDA slightly modified the name of their new tool from the original FoodQuestTQ commercial name of FREE to the new FDA name "FREE-B."

8. In early February 2012, Projectioneering LLC and ThoughtQuest LLC stood up a new company called FoodQuestTQ LLC that would assume responsibility for the further development and sales of their computer software tools across the food industry.

   Also, Mr. Menkheim and his staff were provided with a detailed progress briefing and proprietary documents that included both business confidential and trade secret information describing the industry uses of the FoodQuestTQ LLC tools, the system architecture and the algorithms supporting the FoodQuestTQ tools. All this information was clearly marked as containing company proprietary information.

9. In mid-September 2012, FoodQuestTQ LLC officials learned for the first time, that the FDA had been working with Battelle Memorial Institute to build their own food defense

plan builder to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ, to call Mr. Menkheim to express his concerns that FDA was developing a product that already existed. Mr. Menkheim explained that FDA was not competing with FoodQuestTQ LLC had because the food defense plan builder tool being built by the FDA was not nearly as sophisticated as the FoodQuestTQ tools.

10. In late September 2012, Dr. Hnatio had another telephone another conversation with Mr. Menkheim and asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012. Mr. Menkheim told Dr. Hnatio that the principal purpose of the upcoming meeting was to discuss a terrorist targeting tool known as C.A.R.V.E.R. + Shock. He advised that FDA's food defense planner was being developed in order to make it easier for industry to use C.A.R.V.E.R. + Shock.[ii]

11. The next interaction between FoodQuestTQ LLC and the FDA took place on October 2, 2012, when a "go-to-meeting" webinar was held. During the webinar, FoodQuestTQ LLC FDA staff updated Dr. Menkheim and his staff on the company's continued progress to upgrade their suite of computer software tools. Particular attention was given to the use of the company's Food DefenseTQ tool as the way to build food defense plan. A more advanced tool known as Food Defense Architect that would make it even easier for food companies to develop their own food defense plans was also demonstrated.

    During the webinar, FoodQuestTQ again raised their concerns that FDA was building a food defense planner tool to compete with FoodQuestTQ LLC's existing Food DefenseTQ and Food Architect products. To avoid any potential conflict with FDA that could adversely impact their business, FoodQuestTQ LLC offered the FDA a license to use their technology across the food vertical for $1/yr. Prior to the webinar, FoodQuestTQ officials met with a member of their Board of Directors, Mr. Joe Welty, to discuss the FDA's actions and received permission to offer the $1/yr. license in order to avoid direct competition by the FDA. During the webinar, Mr. Menkheim advised that he could not make such a decision but would take the matter to his FDA bosses. FDA never responded to FoodQuestTQ LLC on the matter.

12. On December 1, 2012, when sales failed to materialize for FoodQuestTQ LLC's Food DefenseTQ and Food Defense Architect line of food defense tools, the company was forced to lay off all of their employees including the two founders of the company. Without pay, FoodQuestTQ LLC principals continued to prepare for the December 12,

2012, industry workshop on C.A.R.V.E.R. + Shock and the FDA's new food defense builder tool. The company developed an internet survey to ask the food industry how effective the FDA's C.A.R.V.E.R. + Shock approach was to them in protecting the food supply.

13. On December 6, 2012, Dr. Hnatio of FoodQuestTQ LLC published an article on the potential dangers of using C.A.R.V.E.R. + Shock as a counter-terrorist assessment tool. The article shared the preliminary results of the FoodQuestTQ survey. The results were mixed with a majority of respondents raising questions about the utility of C.A.R.V.E.R. + Shock. The C.A.R.V.E.R. + Shock article written by Dr. Hnatio was a matter of very significant interest throughout the FDA. For example, the web based software used to conduct the survey indicates that Dr. Leanne Jackson, (the former CIFSAN official referenced in entry 2. Above) who is now in charge of FDA's Food Defense Oversight Team, opened the article for review and/or further distribution over 40 times. It is noted that C.A.R.V.E.R. + Shock is a major $13 million funding line item for Dr. Jackson's office.

14. The December 12th 2012, FDA sponsored industry workshop was hosted by the Grocery Manufacturer's Association (GMA) at their Headquarters building in Washington, D.C. Mr. Warren Stone, Senior Director of Science Policy coordinated the meeting. At FoodQuestTQ's request, Mr. Stone allowed for a 20 minute slot on the workshop agenda for FoodQuestTQ to demonstrate their food defense plan builder tool that was already commercially available to the food industry.

    From e-mails sent to us by Mr. Stone as he coordinated the FDA workshop, we first learned that FDA was working under a multi-million dollar contract to help the FDA develop their food defense plan builder. We found the name of Mr. Colin Barthel, who is the Battelle Memorial technical manager for FDA's food defense mission. FoodQuestTQ LLC tried repeatedly to reach Mr. Barthel to discuss our concerns that Battelle Memorial Institute may be using the company's intellectual property to duplicate their products for use by the FDA. After repeated attempts to reach Mr. Barthel by e-mail and telephone to discuss the situation, FoodQuestTQ LLC finally received an abrupt e-mail from him stating he would not speak with them and that the FDA sponsored workshop on December 12th 2012 was strictly limited to food processors. Mr. Barthel referred FoodQuestTQ LLC back to the FDA's Food Defense Oversight Team to discuss any concerns.

    On the evening December 11, 2012, FoodQuestTQ LLC principals were notified by Mr. Stone that FDA had specifically disinvited any ThoughtQuest LLC (now FoodQuestTQ

LLC) personnel from participating in the FDA industry workshop to be held at GMA Headquarters the following day. Mr. Stone was told by the FDA that they did not want to give any preference or any endorsement to one commercial product over any other. FoodQuestTQ LLC was prohibited by the FDA from attending the workshop.

FoodQuestTQ LLC did, however, independently brief a few of the remaining food industry participants late in the day after the FDA sponsored workshop for industry was over and FDA officials had left the building. When FoodQuestTQ LLC officials signed into the conference room where they were going to demonstrate their products, they saw the attendee list of companies that participated in the earlier FDA sponsored industry workshop. The list included numerous companies that were not food processors but, in fact, competitors of FoodQuestTQ LLC, such as Tyco Integrated Systems.

15. In late December 2012, FoodQuestTQ LLC's concerns about the FDA action to prohibit their attendance at the FDA industry workshop caused them to go back and conduct a review of their work with FDA. It was at this time Dr. Hnatio took a closer look at Mr. Park's earlier reference (August 2011) to an FDA web site on modeling, simulation and responses to food defense and food safety emergencies. When Dr. Hnatio fully explored the FDA web page he discovered that the FDA had duplicated elements of their FEAST and FREE tools. Unbeknownst to FoodQuestTQ LLC, the FDA had slightly modified the name of the FDA tool from the FoodQuestTQ LLC's commercial name of FREE to the new government FDA name of "FREE-B."

    Note: During the preceding months, prior to learning about the actions of the FDA to compete with them, company officials were befuddled as to why their sales projections were not being met. They could not figure out why their products were not selling. It was not until after the FDA industry workshop that they began to receive direct feedback from food processing companies. In these sales meetings, industry asked FoodQuestTQ LLC why they should buy their products when the FDA was providing the same thing for free.

16. In January 2013, FoodQuestTQ LLC was denied a vital investor loan to continue operations. During the period from September 2012 through January 2013, FoodQuestTQ LLC was in critical negotiations to obtain an operating loan from their investors. In early October 2012, as the evidence mounted that FDA and Battelle Memorial Institute were duplicating their products and as sales were failing to materialize, FoodQuestTQ LLC principals were left with no option but to inform their Board of Directors of the situation. The news that FDA was spending millions of dollars under a contract with Battelle Memorial Institute to duplicate FoodQuestTQ's products

and poor sales raised the risk of future investment by their investors to an unacceptably high level. In early January 2013, their request for an operating loan was denied.

CURRENT STATUS

In January 2013, representatives of FoodQuestTQ LLC contacted members of Congress to request their assistance in obtaining a meeting with Ms. Elizabeth Dickinson, Chief Counsel at the Food and Drug Administration. Company officials felt that if Ms. Dickinson was made personally aware of the circumstances she would quickly act to correct the situation. At this time, the matter has become tied up in legal maneuvering by the FDA. Company officials still have not been allowed to personally meet with Ms. Dickinson. This is a matter of great concern to FoodQuestTQ LLC since the owners of the business and all employees had to be laid off without pay several months ago and the company cannot afford to pay the attorney's fees required to fight a long protracted legal battle with the FDA.

In February and March 2013, the inventor of the Projectioneering LLC owned patent undertook a comprehensive review of the FDA web site to identify any possible activities where the FDA had infringed on the Projectioneering LLC patent (The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.) The inventor identified five FDA products that accomplished the same or similar functions as the Projectioneering LLC patent and FoodQuestTQ software tools that were already or were in the final process of being made ready for commercial sale before they were duplicated by the FDA. A subsequent technical crosswalk of the five duplicate FDA products against each of the 20 claims and 101 objects of the Projectioneering LLC patent demonstrates flagrant infringement by the FDA.

PRINCIPAL ISSUES

1. FOOD AND DRUG ADMINISTRATION USE OF CONFIDENTIAL FOODQUESTTQ LLC BUSINESS AND PRODUCT INFORMATION

   Over a period of approximately three years FoodQuestTQ LLC met extensively with FDA employees and provided them with detailed briefings which included the proprietary and trade secret information relating to the reduction of their patent for commercial sale to the food industry. All proprietary information shared with FDA employees was clearly marked as containing industry proprietary information. In addition, FoodQuestTQ principals verbally advised the FDA employees they shared any proprietary information with that the information they were sharing required protection pursuant to the Code of Federal Regulations (48 CFR 27.402) and other government statutes.

Note: Title 18 USC 1905 applies to disclosure by a government employee of any information provided to the government by a company or other nongovernment organization, if the provider of the information identified it as proprietary or as being provided to the government in confidence. The penalty is mandatory removal from office (termination of employment), and the offender may be fined not more than $1,000 and imprisoned not more than one year.

Specific legal statutes and portions of the Federal Acquisition Regulations that pertain to the protection of commercially owned proprietary information include:

- Title 18 USC 1831–39 - Protection of Trade Secrets [Chapter 90].
- Title 18 USC 1905 – Disclosure of Confidential Information.
- Title 41 USC 423 – Procurement Integrity.
- Title 5 CFR 734 – Employee Responsibilities and Conduct.
- FAR 3.104-1 – Procurement Integrity, General (48 CFR).
- FAR 27.4 – Rights in Data and Copyrights (48 CFR).
- FAR 52.215-12 – Restriction on Disclosure and Use of Data (48 CFR).
- FAR 52.227-14 – Rights in Data (48 CFR).[iii]

2. FOOD AND DRUG ADMINISTRATION COMPETETITION WITH FOODQUESTQ LLC

The government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry. FQTQ offered the FDA Food Defense Team a $1/yr. license to use FoodQuestTQ LLC technology in order to avoid unfair competition by the government. FDA never responded to the offer. Based on proprietary business information provided to them, FDA was fully aware that the products they were developing with Battelle Memorial Institute were already developed and being commercially sold by FoodQuestTQ LLC.

Efforts to make the food supply safer are a shared responsibility between the government and the private sector and non-regulatory activities have never been considered an inherently government function. A simple Google search of food safety and food defense, identifies literally hundreds of "hits" with private sector companies doing everything from consulting, risk assessments, third party audits in support of FDA's governmental regulatory compliance responsibilities. The FDA itself promotes the use third party private sector companies to assure the quality of food safety and food defense at food operations all across the food supply.

The FDA actions in this case also raise questions regarding the Agency's compliance with OMB Circular A-76. This document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector.

3. THE IMPACT OF THE FOOD AND DRUG ADMINISTRATION POLICY AND ACTIONS ON SMALL BUSINESSES GENERALLY

FoodQuestTQ LLC is only one of millions of small businesses in America that provide the innovation required to solve national challenges. The nation depends on small businesses and the entrepreneurs who risk everything to create them. The jobs the nation must create to keep people employed are generated by small businesses like FoodQuestTQ LLC. Much of the innovation that the nation and our government must have to solve national problems comes from small businesses like FoodQuestTQ LLC. By competing with small businesses like FoodQuestTQ LLC and forcing them out of business, the FDA risks losing the genius and innovation the nation desperately needs to solve the country's food protection and food safety problems.

---

[i] See: http://www.linkedin.com/pub/leeanne-jackson/19/920/718

[ii] Note: C.A.R.V.E.R. + Shock was developed by the military special forces to plan attacks against the critical infrastructures of the enemy. In the aftermath of 9-11, FDA attempted to convert the tool for civilian use by the food industry with mixed results. Currently, the pursuit of C.A.R.V.E.R. + Shock is a continuing $13 million dollar FDA budget line item.

[iii] http://www.wrc.noaa.gov/wrso/security_guide/propriet.htm

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

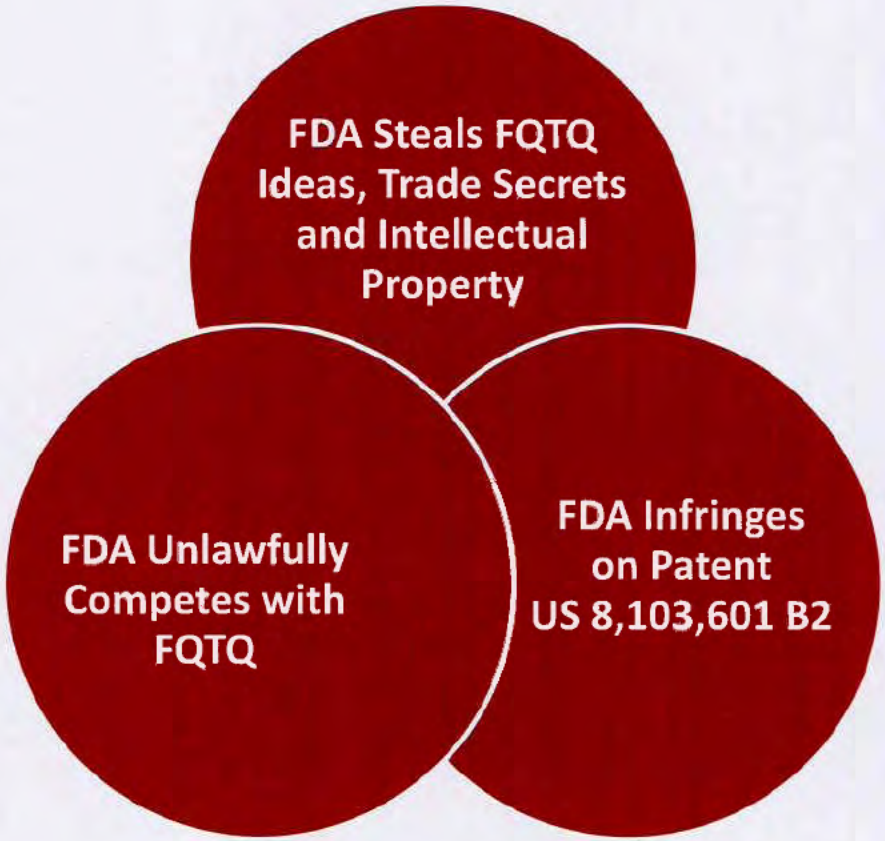
FoodQuestTQ LLC

March 19, 2013

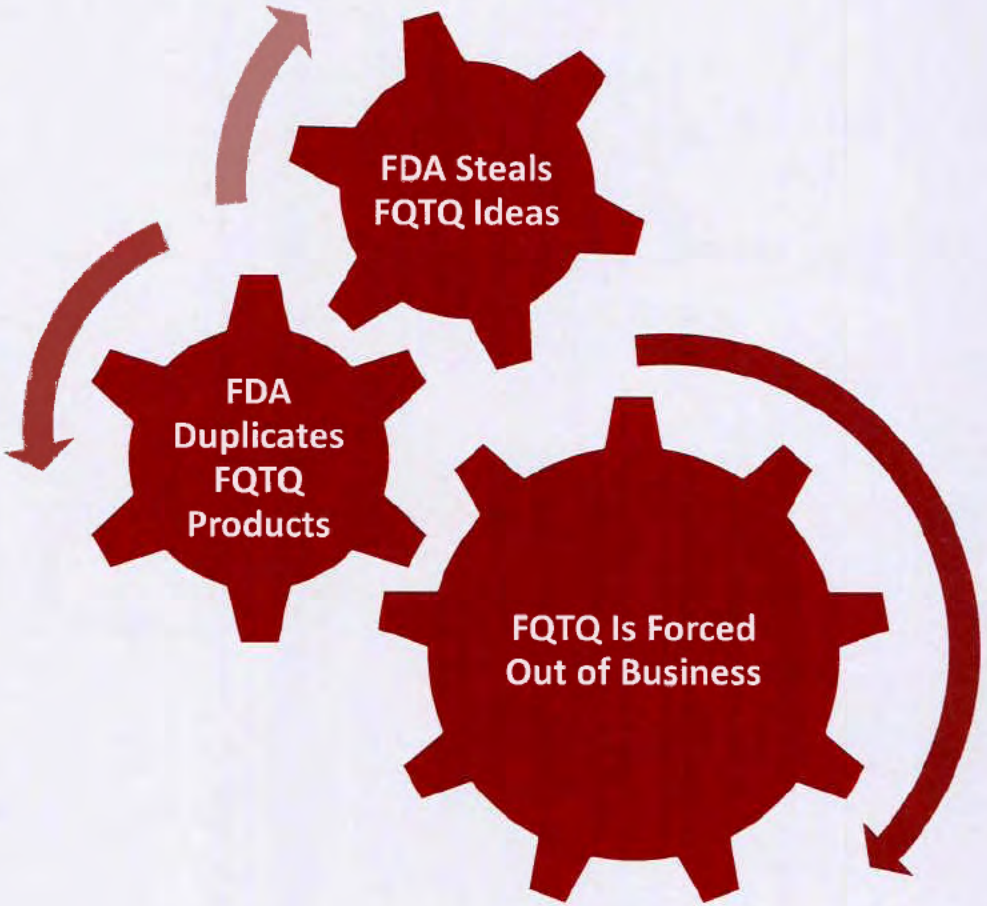
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- **The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.**

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- **The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.**

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- **The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.**

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- **The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."**

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- **The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."**

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- **The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.**

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- **The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.**

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- **The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.**

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed

- **The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.**

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- **The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.**

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.**

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- **The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.**

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- **The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.**

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.**

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- **The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.**

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- **The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.**

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- **The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.**

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- **The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.**

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- **The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.**

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- **The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.**

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectiviity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

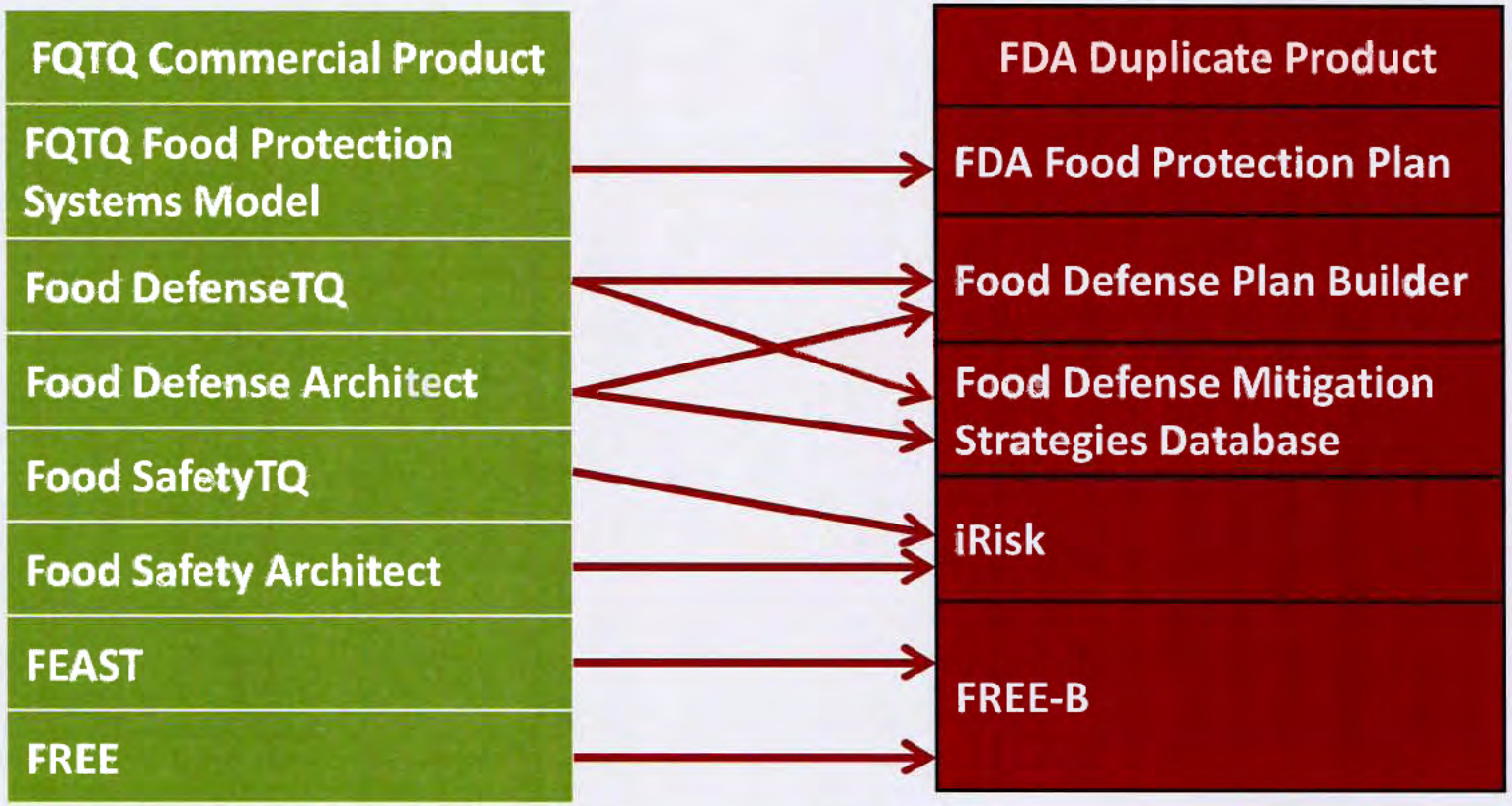
- The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.
- The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.

25. FQTQ Enhanced Risk Communications

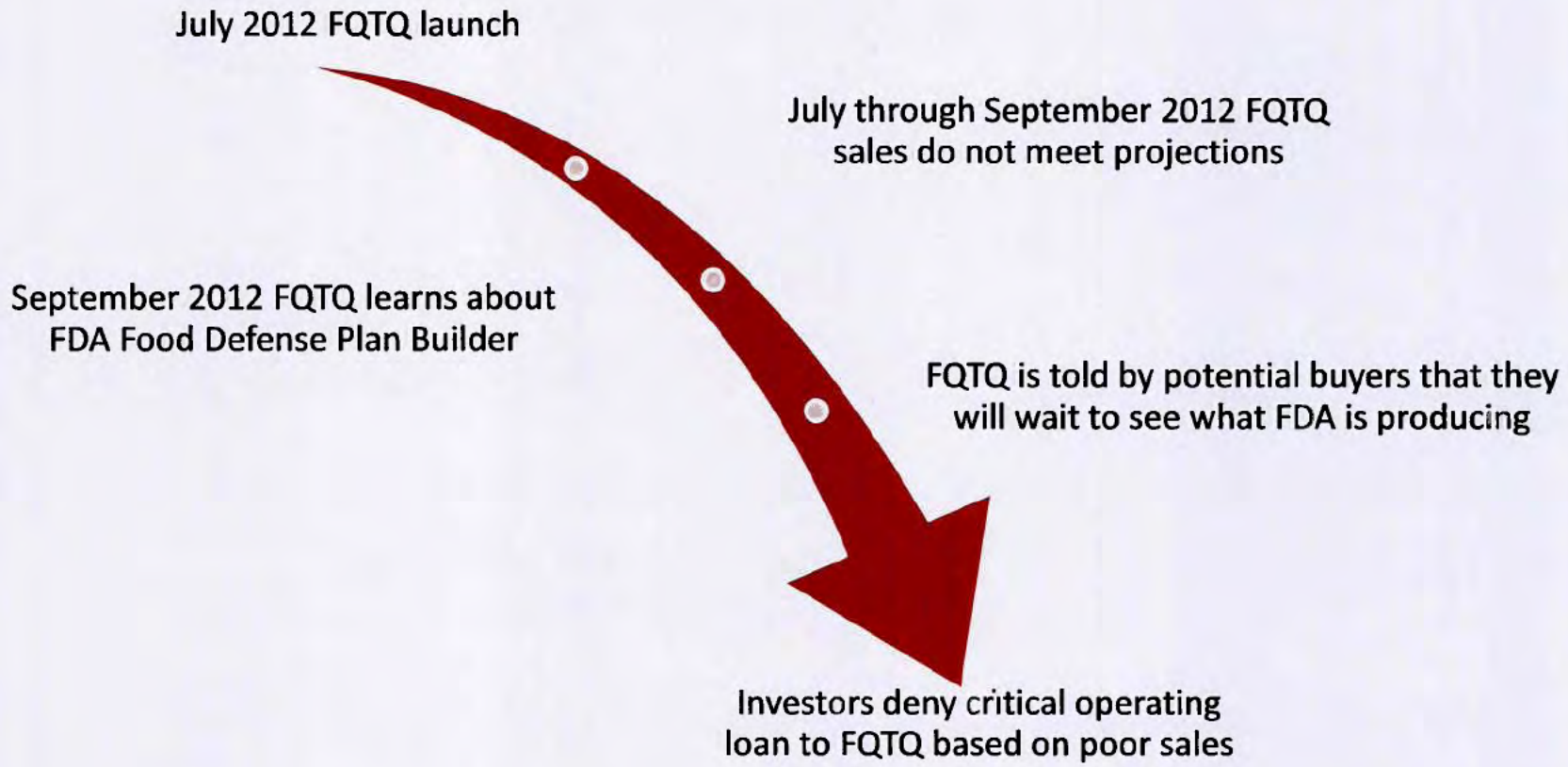
The FQTQ systems model for food protection improves risk communications.

- The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.

FDA Duplicates FQTQ Products



FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2

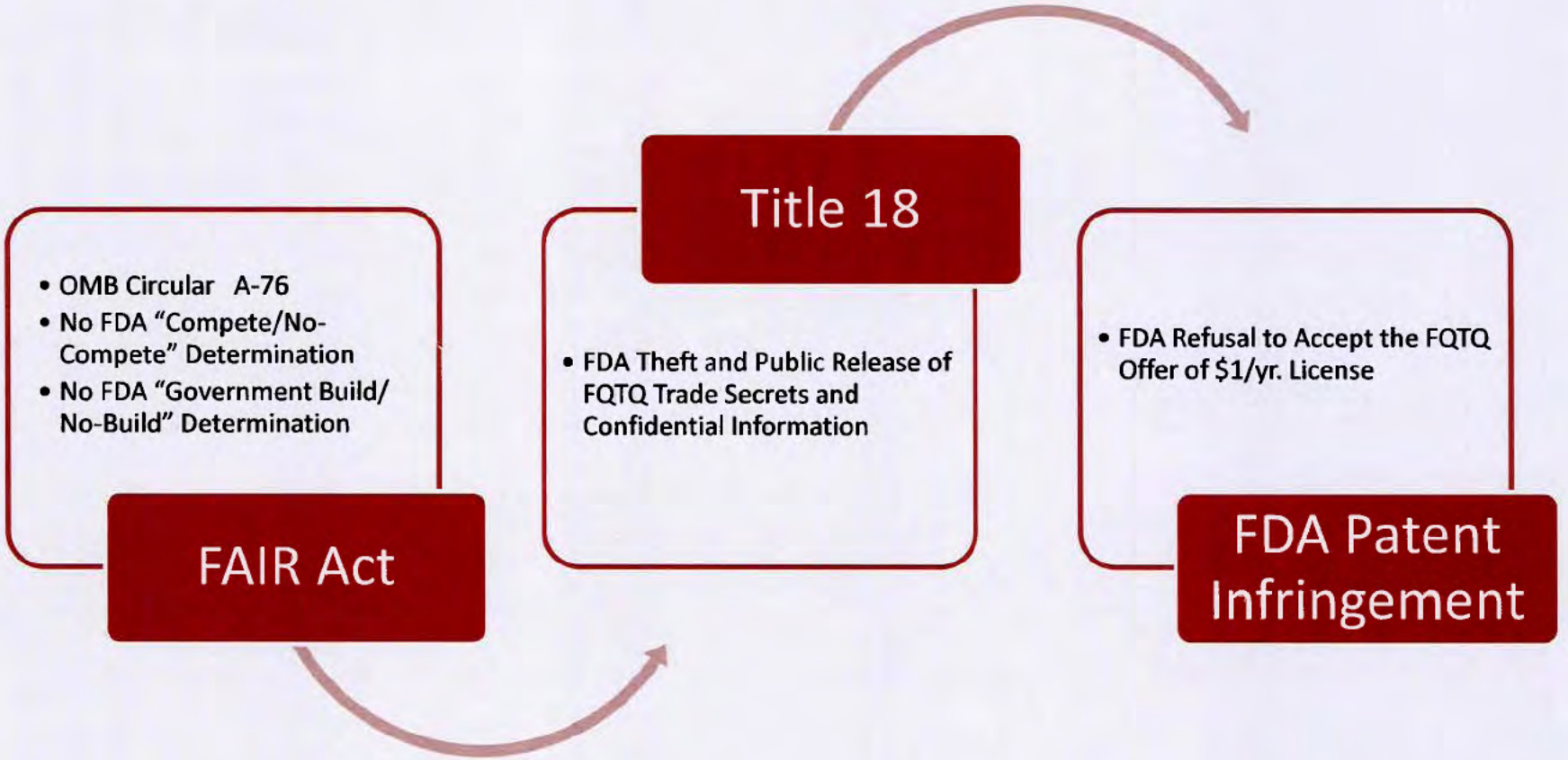
The patent has 20 claims and 101 associated objects of the invention

How FQTQ reduced the patent to use for food was FQTQ trade secret information until it was revealed by FDA in the FQTQ tools they duplicated and released to the public

FQTQ has prepared an extensive technical crosswalk that demonstrates flagrant infringement by the FDA on patent US 8,103,601 B2

FQTQ is prepared to share the results of the crosswalk with the National Small Business Ombudsman if it will assist in the timely resolution of this matter

FDA Unlawfully Competes with FQTQ



Seeley, Ariel

From: Raza, Mark
Sent: Friday, March 22, 2013 3:41 PM
To: Beckerman, Peter; Seeley, Ariel
Subject: Fw: Response to your e-mail

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Friday, March 22, 2013 02:09 PM
To: Zahirieh, Elahe <Elahe.Zahirieh@sba.gov>
Cc: Dickinson, Elizabeth; Raza, Mark; Dale.Berkley@nih.hhs.gov <Dale.Berkley@nih.hhs.gov>
Subject: FW: Response to your e-mail

Hello Ellie:

I wanted to forward this e-mail to you and let you know that my concerns that DHHS/FDA are using any of the information we provide them not to conduct a good faith review as we asked Ms. Dickinson to do for us last January but instead have turned the matter into an adversary legal matter. **The e-mail is definitely threatening.** I do not believe that HHS/FDA are seriously considering ferreting out any possibility of their own wrongdoing here at all.

I also want to tell you that I believe Ms. Dickinson and her staff are working with HHS to pigeon hole what they have done under the single label of patent infringement. While patent infringement is most certainly an issue here it is only one of three inextricably intertwined issues that must be considered in this case, namely: 1) FDA theft of FoodQuestTQ ideas, intellectual property and trade secrets; 2) unfair government competition with FoodQuestTQ, and; 3) patent infringement. I believe that FDA/HHS are intentionally trying to avoid dealing with issues 1 and 2, above, in order to avoid the separate unlawful actions that go well beyond the single issue of patent infringement in this case.

I would appreciate it if you could please forward a copy of this e-mail and my concerns to the FDA Ombudsman so that he is aware of the HHS/FDA legal jockeying in this case.

Thank-you very much for your help. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Friday, March 22, 2013 12:21 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

Thank you for your email of March 14, 2013 suggesting changes to the nondisclosure agreement (NDA). You will be contacted shortly by a colleague of mine within the Department of Health and Human Services' (HHS) Office of General Counsel, Dale Berkley, who is our intellectual property attorney. I have provided Mr. Berkley with all necessary background information and materials.

Going forward, please understand that Mr. Berkley and I are lawyers representing HHS/FDA and cannot provide you with legal advice. If you want legal advice on this matter, I recommend that you consult with an attorney. I

understand that you have indicated this would not be financially feasible for you. There are various organizations that exist to provide free or low-cost legal services to people who cannot otherwise afford legal representation.

Best,
Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301.796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, March 14, 2013 10:53 AM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Hi Ariel:

I have taken a few minutes this morning and reviewed the proposed NDA you sent over to me. Attached is a short note with our recommendations. We have clearly described the changes and they should be quick and easy to make. I know how busy you are and we are happy to make the changes for you if you can send along a soft copy in *Word*. I'll use *track changes* to make sure that you can see and approve everything.

I read your e-mail below and I still do not understand how you can make even a preliminary determination regarding infringement or violation of trade secret without seeing how the original invention was reduced to practice in the context of our tools. I am not attorney like you are and, under the circumstances, cannot afford to pay for one. I feel like an innocent man thrown in jail who must serve as his own lawyer because of the unfortunate circumstances here. I am a simple man and it is difficult for me to understand the complexities of the law like you do. Since I am at such a disadvantage here, I really need your help. All that I ask is that you be patient with me and explain things so that I can clearly understand them.

I do not understand how your e-mail answers my question. My question is: How will it be possible for you (the FDA) to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the FQTQ tools (reduction to practice for food) that were duplicated by the FDA? As I have explained to you before, our reduction to practice of the invention for food involves trade secrets that were stolen by the FDA Food Defense Team and others at the FDA. In the absence of having this information how can you possibly do a thorough and good faith review of the matter?

I am sincerely asking for your patience and understanding. I really need your help here as a wise, fair attorney of high integrity who obviously has a tremendous command of the law to just honestly answer my question in a clear and simple way that I can understand. I need your reassurance that we are all operating in good faith here. Thank-you for your hard work on this and all of us really appreciate your help. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Thursday, March 14, 2013 9:31 AM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

We appreciate your willingness to share information about your patent, how it was reduced to practice in a suite of tools, and other business process information with us. However, the information you provided about your patent so far has been sufficient. We will contact you for additional information, if necessary, at a later date. Thus, at this time, we need to evaluate your claims by comparing your products to ours. To do so, we will need nonexclusive access to Food QuestTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE tool, and FEAST. Again, we appreciate your willingness to work with and provide us with requested information in a timely manner.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, March 13, 2013 4:17 PM
To: Seeley, Ariel
Subject: RE: Response to your e-mail

Hi Ariel:

Thank-you and I will look over the NDA.

Please be advised that the patent in question is a combination business process and data transformation patent.

In your e-mail you state "We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information."

Question

How then, will it be possible for you to make any type of good faith determination regarding matters of

infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the tools that were duplicated by the FDA.

Please advise. Thank-you. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Wednesday, March 13, 2013 4:05 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr Hnatio:

Thank you for your email of March 2, 2013. I appreciate your willingness to work with me as I look into this matter. As you are most likely aware, dealing with the Food and Drug Administration (FDA), a federal agency, differs from dealing with private entities. Federal agencies must act according to a number of laws and regulations that govern their use of and ability to protect information submitted or provided to them. I attach to this email a non-disclosure agreement (NDA) that meets FDA's legal requirements. FDA has signed the attached NDA to make this process more efficient.

Furthermore, I would like to clarify that, at this time, FDA is only requesting nonexclusive access to FoodQuestTQ LLC's (FQTQ) software tools that you claim FDA's software tools, the Food Defense Plan Builder, FREE-B, and FDA-iRisk, duplicate. Specifically, these tools are FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST. Such access will allow FDA to evaluate the concerns raised by your previous communications. We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information. We ask that you do not send us such information at this time.

Please review the attached NDA and, if it is acceptable to you, send a signed copy to FDA with the FQTQ tools mentioned above by March 20, 2013, so that we can proceed with our evaluation. I look forward to hearing from you.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM

To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Monday, April 15, 2013 1:44 PM
To: Elahe.Zahirieh@sba.gov
Cc: Seeley, Ariel; Dale.Berkley@nih.hhs.gov; Sebelius, Kathleen (OS); OC Ombudsman; Dickinson, Elizabeth
Subject: FQTQ Response to the FDA Ombudsman's Ltr. of 3-26-2013
Attachments: Ms. Yolanda Swift 4-15-2013.pdf; Letter to DHHS Secretary for NOSB.pdf

RESPONSE TO FDA DEPUTY OMBUDSMAN'S LETTER OF MARCH 26, 2013

Ms. Zahirieh: Thank-you for your letter forwarding the FDA Ombudsman's response to the complaint we filed with your office. Please find attached our official response. My thanks to you, Mr. Mendez and Ms. Swift for all that you do in defense of small business. All the best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
7420 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Ms. Yolanda V. Swift
Acting Ombudsman and Assistant Administrator
for Regulatory Enforcement Fairness
Office of the National Ombudsman
U.S. Small Business Administration
409 3rd Street, SW (MC 2120)
Washington, DC 20416-0005

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

April 15, 2013

Dear Ms. Swift;

Thank-you very much for your letter of April 10, 2013 regarding our complaint to the National Ombudsman that the FDA is stealing our intellectual property, intentionally duplicating our products and forcing us out of business.

The FDA letter to you dated March 26, 2013, from Mr. Andrew Moss is misleading. Mr. Moss indicates that representatives of the Office of General Counsel, Department of Health and Human Services (HHS) and the Office of the FDA Chief Counsel have been in recent contact with me and that they are actively reviewing our concerns. ***Please be advised that this is not the truth.***

The reason we were forced to file our complaint with the National Ombudsman in the first place is because the Office of the FDA Chief Counsel refused to work with us to fairly resolve this matter. Instead, the FDA Chief Counsel mounted a legal defense of those personnel in the FDA who stole our intellectual property, duplicated our products and forced us out of business in the first place. The Office of General Counsel, HHS, has now joined league with the FDA Chief Counsel. Attached is a copy of a recent letter that we sent to Secretary Sebelius at HHS expressing our concerns.

We recently came across a flier for a major food industry conference called the *Food Safety Summit* that will be held at the Baltimore Convention Center. On the morning of April 30, 2013, the FDA is scheduled to conduct several workshops with the food industry in which they will unveil one of the FoodQuestTQ products they duplicated, i.e., FDA's *Food Defense Plan Builder,* based on intellectual property that the FDA has stolen from our small company. We request the assistance of the National Ombudsman for Small Business to prevent the FDA from continuing to steal our intellectual property in this way and further damaging any possibility of saving our small business.

Thank-you again for all that you do in defense of small business. We at FoodQuestTQ very much appreciate your help in turning this bizarre situation around.

Sincerely,

John H. Hnatio
Chief Science Officer

cc: The Honorable Kathleen Sebelius, Secretary, HHS

FoodQuestTQ LLC, 7420 Hayward Drive, Frederick, Maryland 21702 Telephone 240-439-4476 ext. 11

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington DC 20201
Via e-mail

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

April 1, 2013

Dear Secretary Sebelius:

We are a small business located in Frederick, Maryland. We are writing to you to ask for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA). At FoodQuestTQ we produce advanced risk management software to help industry produce safer food.

Last year, we discovered that the FDA took our intellectual property and duplicated our products and, in so doing, tried to drive us out of business. In December 2012, we requested a personal meeting with Ms. Elizabeth Dickinson, the Chief Counsel at the FDA. Our objective was to simply sit down with Ms. Dickinson to explain the actions that were taken against us by the FDA and to work with her to fairly resolve the matter. But Ms. Dickinson refused to meet with us.

Instead, the FDA engaged in a harmful and non-productive dialogue with us as we attempted to work with them to try and resolve this matter. Earlier this month, we had no choice but to reach out to the National Ombudsman for Small Business because of the impasse. In response to our complaint to the National Ombudsman for Small Business, the matter was elevated to the DHHS Office of the General Counsel.

I am very disappointed to report to you that our interactions with the DHHS counsel assigned to this matter continue to be very non-productive. It appears that the counsel's efforts to defend the wrongdoing of his friends and colleagues in the FDA may have now out shadowed the importance of engaging in an honest dialogue about what has happened and working together with us to try and resolve any problems.

That is why we are requesting the opportunity to meet with you personally to describe the actions taken against us and to try and resolve this problem. The time now being spent on non-productive efforts to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. Would it not be better for everyone involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?

I want to personally assure you that we are looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, we can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

We hope that you will look favorably on the possibility of meeting with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people. We look forward to the possibility of meeting with you.

Sincerely,

John H. Hnatio, EdD, PhD
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB
Dr. Dale Berkley, DHHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA

EXHIBIT 17

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Saturday, April 20, 2013 6:48 PM
To: Gunderson, Nancy J (OS)
Cc: Dickinson, Elizabeth; Dale.Berkley@nih.hhs.gov; ContactOGE@oge.gov; Sebelius, Kathleen (OS); Waters, Linda K (PSC); sbmail@hhs.gov; CFSAN-Industry; Carter, Courtney (OS); Zahirieh, Elahe; Seeley, Ariel
Subject: Request to Hand Carry a Letter to Secretary Sebelius
Attachments: Letter to Nancy Gunderson, FDA.pdf; 4-19-2013 letter to Sec. Sebelius.pdf

Ms. Gunderson, please see the attached letter asking for your help. In our letter we ask that you hand deliver our prior letter to Secretary Sebelius directly into her hands. We are extremely concerned that certain members of the FDA/HHS staff may be obstructing justice in the resolution of this matter because of their own involvement in these matters by intercepting our correspondence to Secretary Sebelius before it reaches her. Thank-you.

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11

Nancy J, Gunderson
Deputy Assistant Secretary for Grants and
Acquisition Policy and Accountability
Department of Health and Human Services
200 Independence Avenue SW
Room 537H, Humphrey Building
Washington, D.C. 20201

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Via e-mail

April 20, 2013

Dear Ms. Gunderson:

FoodQuestTQ is a small business that produces risk management software to the help the food industry produce safe food for the American people to eat.

The reason we are writing to you is because government employees of the Food and Drug Administration (FDA) are stealing our intellectual property, duplicating our commercial products and marketing them for free to industry in order to force us out of business.

Please find attached a recent letter I sent to Secretary Sebelius which provides additional information detailing the issues in this case.

As the attached letter to Secretary Sebelius details, FDA and Department of Health and Human Services (HHS) employees are engaging in conduct that is specifically precluded under the Federal Acquisition Regulations, Public Law 95-521 (EIGA), E.O. 12674, 5CFR Part 2635, especially Subparts A., E. and G. and numerous other aspects of existing administrative law and statute all of which relates to the ethical sourcing of government products, prohibitions against federal employees endorsing commercial products and the ethical conduct of federal employees.

The reason we are writing to you is to request that you personally make Secretary Sebelius aware of the situation and assist the Secretary to take the actions necessary to implement each of the requests as outlined in the attached letter to Secretary Sebelius.

Unfortunately, the office of General Counsel, (HHS), the Chief Counsel, FDA, and other offices are complicit in obstructing the fair resolution of this matter and we are concerned that they may be intercepting and withholding our attempts to bring the serious violations of law and unethical conduct of the FDA and HHS employees involved in this matter to the personal attention of Secretary Sebelius.

As we have already attempted to share with Secretary Sebelius, we want to personally assure you that we are looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, we can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

We want to thank-you very much for helping us get the message personally to Secretary Sebelius. If I can answer any questions or if you need any further information please feel free to contact me at 240-439-4476 ext. 11. I look forward to talking with you.

Sincerely,

John H. Hnatio, EdD, PhD
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB
Secretary Sebelius, HHS

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington DC 20201

FQTQ
Powered by FoodQuestTQ
TQ stands for three quotients

Via e-mail

April 19, 2013

REF: April 1, 2013, Letter from Dr. Hnatio to Secretary Sebelius

Dear Secretary Sebelius:

We are a small business located in Frederick, Maryland. On April 1, 2013, we wrote to you asking for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA).

In my letter to you I explained that the Food and Drug Administration has stolen our small business' intellectual property and duplicated our entire commercial offering of computer software tools. As a result the government is forcing us out of business. In our letter we requested the opportunity to meet with you personally to describe the actions being taken against us and to try and resolve this problem. But we never received any response from you. ***We are very concerned that members of your own staff may be intentionally withholding our letters from you.***

I have been informed by the National Ombudsman for Small Business that this entire matter was elevated from the Office of Chief Counsel in the FDA to the Office of General Counsel of the Department of Health and Human Services (HHS) for a high level review. Please be advised that our interactions with both FDA and HHS legal counsels have been at an impasse for several months. Instead of conducting a good faith review that could lead to resolving this matter before it escalated to this point they have "circled the wagons" in order to defend the FDA's own errors in this matter.

Over this entire period, the FDA has continued to market and give away at no cost to the public and the food industry the tools they duplicated by stealing our intellectual property and trade secrets. ***No timely actions are being taken by either the Department of Health and Human Services or the FDA to work with us to prevent the further public distribution of our intellectual property including our trade secrets.*** Every day that our trade secrets are further disseminated to the public by the FDA just serves to put another nail in the coffin of our small business.

For all of the above reasons, we are officially requesting that HHS immediately direct the FDA to stop the further marketing of FQTQ FDA-duplicated software tools and immediately remove all of the FDA-duplicated FoodQuestTQ LLC computer software tools from the official FDA government website pending the resolution of this matter. This formal request includes the immediate removal from the FDA website of the following specific information and software tools that are based on the intellectual property and trade secrets that the FDA has stolen from us, namely the FDA:

1. *Food Protection Plan*;
2. *Food Defense Plan Builder*;
3. *Food Defense Mitigation Strategies Database*;
4. *iRisk*, and;
5. *FREE-B.*

For the record, we would like to note that it is highly possible that the FDA has duplicated other products based on our intellectual property and trade secrets that we are not yet aware of.

This past week we discovered that the FDA has publicly endorsed the products of one of our industry competitors, *Tyco Integrated Systems*. (See: http://www.foodmanufacturing.com/videos/2013/04/food-defense-strategy-part-1-assess). It is both highly unethical and unlawful for any federal agency to engage in such conduct. Engaging in such activities is specifically prohibited by the Office of Government Ethics and under 5 C.F.R. Part 2635: Standards of ethical conduct for employees of the executive branch and under numerous other statutes.

We also find this most disturbing based on the fact that FoodQuestTQ was singled out by the FDA and excluded from participating in a December 12, 2012, industry workshop held by the FDA to obtain industry inputs on one of the software tools the FDA duplicated based on the intellectual property they stole from us. FDA officials lied when they told the Grocery Manufacturer's Association that we were prohibited from attending the workshop because the FDA did not want to endorse any commercial products. Clearly, this was nothing but a ruse by the FDA to prevent us from finding out that they were stealing our intellectual property. We found out after the workshop that *Tyco Integrated Systems* was invited by the FDA and actually attended the same FDA workshop we were prohibited from attending.

For the above reasons, we are formally requesting that HHS immediately stop endorsing the commercial products of our competitors in reprisal against us for expressing that the FDA has, in fact, stolen our intellectual property, duplicated our products and is forcing us out of business.

We have also discovered that the FDA is holding a major workshop with the food industry on April 30, 2013, to unveil for the food industry FDA's *Food Defense Plan Builder* that duplicates our Food DefenseTQ and Food Defense Architect Tools based on the intellectual property stolen from us by the FDA. By holding such a public forum, the FDA is not only continuing to engage in the theft of our intellectual property but also further distributing to the public at large our commercial trade secrets.

For the above reasons, we are formally requesting that HHS instruct FDA to cancel their food industry workshops on Food Defense Plan Builder to be held on Tuesday, April 30, 2013, at the Food Safety Summit that is being held at the Baltimore Convention Center in Baltimore, Maryland.

This last week a major business partnership critical to the future of our small company was unexpectedly terminated. The agreement was terminated by our industry partner because they feared FDA reprisal in obtaining future contracts from the FDA or being blacklisted by FDA themselves as the result of their association with FoodQuestTQ LLC. Earlier, in December 2012, a member of the FDA Food Defense Team widely distributed, off her government computer, a news article written by FoodQuestTQ about the FDA endorsed "C.A.R.V.E.R. + Shock" risk assessment tool. In the article FoodQuestTQ raised doubts about the utility of the "C.A.R.V.E.R. + Shock" method as it is currently being used by the FDA to assess risks to the U.S. food supply. The FDA budget contains a $13 million appropriation to support the use of the "C.A.R.V.E.R. + Shock" method.

For the above reasons, we formally request that HHS direct the FDA to stop "blacklisting" FoodQuestTQ in the food industry. We also request that the FDA place an apology at their main web site publicly apologizing for this type of conduct. If the FDA is allowed to continue "blacklisting" us in this way there will be no further hope for the survival of our small business.

In our previous letter to you of April 1, 2013, we requested a meeting with you to try and resolve this problem. We expressed our feeling that the time now being spent on non-productive efforts to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. We asked you the question, "Would it not be better for everyone involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?"

Again, we want to personally assure you that we are looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, we can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

We hope that you will look favorably on the possibility of meeting with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people. We look forward to the possibility of meeting with you.

Sincerely,

John H. Hnatio, EdD, PhD
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB
Dr. Dale Berkley, HHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA
Ms. Laurie Lenkel, Small Business Ombudsman, FDA

EXHIBIT 18

Seeley, Ariel

From: Berkley, Dale (NIH/OD) [E] [BerkleyD@OD.NIH.GOV]
Sent: Monday, April 01, 2013 1:55 PM
To: Seeley, Ariel; Lovas, Julie
Subject: FW: Recent FoodQuestTQ correspondence with the White House
Attachments: Second Letter to President Obama.pdf; President Obama.pdf

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, April 01, 2013 1:54 PM
To: Sebelius, Kathleen (HHS/OS); Berkley, Dale (NIH/OD) [E]; Dickinson, Elizabeth (FDA/OC)
Cc: Zahirieh, Elahe
Subject: Recent FoodQuestTQ correspondence with the White House

Secretary Sebelius et. al. please find your copies of the correspondence sent today to the White House. Thank-you. John

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4270 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

President Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Via E-mail and Post

April 1, 2013

Dear Mr. President,

On January 12, 2013, we wrote you a letter requesting your help in resolving a dispute with the Food and Drug Administration but we never received any response. A copy of our previous letter to you dated January 12th is attached. We recognize how busy you are but we still desperately need your help and that is why we are writing to you again.

We are a small business located in Frederick, Maryland. We are writing to you to ask for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA). At FoodQuestTQ we produce advanced risk management software to help industry produce safer food.

Last year, we discovered that the FDA took our intellectual property and duplicated our products and, in so doing, tried to drive us out of business. In December 2012, we requested a personal meeting with Ms. Elizabeth Dickinson, the Chief Counsel at the FDA. Our objective was to simply sit down with Ms. Dickinson to explain the actions that were taken against us by the FDA and to work with her to fairly resolve the matter. But Ms. Dickinson refused to meet with us.

Instead, the FDA engaged in a harmful and non-productive dialogue with us as we attempted to work with them to try and resolve this matter. Earlier this month, we had no choice but to reach out to the National Ombudsman for Small Business because of the impasse. In response to our complaint to the National Ombudsman for Small Business, the matter was elevated to the DHHS Office of the General Counsel.

I am very disappointed to report to you that our interactions with the DHHS counsel assigned to this matter continue to be very non-productive. It appears that the counsel's efforts to defend the wrongdoing of his friends and colleagues in the FDA may have now out shadowed the importance of engaging in an honest dialogue about what has happened and working together with us to try and resolve any problems.

That is why we recently requested the opportunity to meet with personally with Secretary Sebelius so that we might be able to describe the actions taken against by the FDA us and work with her to try and resolve this problem. The time now being spent on non-productive efforts by the government to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. Mr. President, would it not be better for everyone

involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?

I want to personally assure you, as I have already assured Secretary Sebelius, we at FoodQuestTQ LLC are simply looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, government and industry can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

Mr. President, we hope that you will encourage Secretary Sebelius to meet with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people.

You can learn more about our situation by visiting YOU TUBE at https://www.youtube.com/watch?v=xKHdJhGLQok where we have also posted a link for people to sign a petition requesting that you and Congress help protect the millions of small businesses across America from being forced out of business by the federal government. Our petition asks that you and Congress enact new laws to prevent the federal government from unfairly competing with small businesses in America to force them out of business.

We want to thank-you very much for reading this letter and we hope that your intervention in this matter can help us to turn this bizarre situation around.

Most respectfully yours,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LCC (Suite 102)
4720 Hayward Road
Frederick, MD 21702
(O) 240-439-4476 x-11
(C) 301-606-9403
E-mail: jhnatio@thoughtquest.com

Attach: (1) 1-12-2013 Letter to President Obama

cc: Secretary Sebelius, DHHS
Dr. Dale Berkley, DHHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA
Ms. Ellie Zahirieh, NOSB

President Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

January 12, 2013

Dear Mr. President,

We desperately need your help. I am an owner and the Chief Science Officer of a small Maryland-based company that specializes in making the food we all eat safer.

In 2002, I began a program of extensive research on new ways to reduce the risks associated with protecting the nation's critical infrastructures from adverse events as part of my doctoral dissertation studies at the George Washington University. The results of my research have received public acclaim. For example, in 2008, I was highly honored to receive the Navigator Award along with Senator Lieberman, Representative Dana Rohrabacher and the CIA Director for Science and Technology for the quality of my research. The results of the research are now patented.

In 2009, I joined a group of highly dedicated people who wanted to make a difference in the world and we began the process of reducing the patent to practice across the global food supply by creating a revolutionary system that actually quantifies the risk of adverse events happening and provides ways to prevent and mitigate the consequences of untoward events including accidents, intentional attacks and natural disasters. From 2009 through December 2012, we extensively coordinated our work directly with staff at the Food and Drug Administration (FDA).

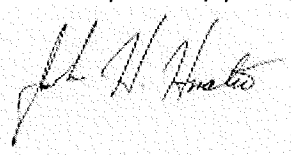
In December 2012, however, we were absolutely dumbfounded to learn that the FDA staff, completely unbeknownst to us, was taking our patented approach and the proprietary confidential information we were sharing with them to duplicate our products under a multi-million dollar contract with Battelle Memorial Institute. Of course, we cannot understand how our own government can take our patent, our ideas and hard work in this way. We cannot understand why the FDA is investing millions of taxpayer dollars to do what we have already done.

Since December, we have been unable to sell our products. The food companies we work with are now asking us why they should buy our products if they can get the very same thing for free from the government. We have been forced to lay off all of our employees. I am particularly concerned about one member of our team who is a 70% disabled military veteran who gave up everything to join our company.

Mr. President we are writing to you as a last resort. We have no money left to pay for a long and expensive legal battle involving the FDA. The FDA knows this. Our life savings are completely gone. We cannot even afford to pay our own salaries. Our situation cannot wait.

We want to thank-you very much for reading this letter and we hope that you will be able to help us turn this bizarre situation around.

Most respectfully yours,



John Hnatio, Ed.D., Ph.D.
Chief Science Officer
FoodQuestTQ LCC (Suite 104)
4720 Hayward Road
Frederick, MD 21702
(O) 240-439-4476 x-11
(C) 301-606-9403
E-mail: jhnatio@thoughtquest.com

EXHIBIT
19

Seeley, Ariel

From: Dickinson, Elizabeth
Sent: Thursday, April 18, 2013 2:56 PM
To: Seeley, Ariel; Beckerman, Peter; Wion, Ann; Lovas, Julie
Subject: FW: Note for Laurie Lenkel
Attachments: Summary report for Ms. Dickinson.pdf; Note for Ariel at FDA 2-2-2013.pdf; Comments on the NDA for Ariel 3-14-2013.pdf; Elizabeth D 3-16-2013.pdf; Briefing for the SBA National Ombudsman.pdf; Letter to Dr Hnatio3-27-2013.pdf; DHHS-Dr. Berkley 3-28-2013.pdf; Letter to DHHS Secretary for NOSB.pdf; Ms. Yolanda Swift 4-15-2013.pdf

FYI

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, April 18, 2013 2:16 PM
To: OC Ombudsman; Dickinson, Elizabeth; Dale.Berkley@nih.hhs.gov; Sebelius, Kathleen (OS)
Cc: Zahirieh, Elahe
Subject: Note for Laurie Lenkel

Hello Laurie. You can get a quick overview of our situation by visiting the following link: https://www.youtube.com/watch?v=xKHdJhGLQok Attached are the documents we have already shared with the National Ombudsman as part of our complaint.

Please tell Andrew that he was misled by the FDA and HHS counsel. The reason we had to go to the National Ombudsman in the first place is because Ms. Dickinson and her staff turned the situation into an adversary legal proceeding instead of trying to resolve the problem. After we filed our complaint with the National Ombudsman the matter then got kicked up to Dale Blakely in HHS who supported his FDA friend and colleagues in the Counsel's office and chose to continue the path of mounting an FDA legal defense instead of conducting a good faith review of the matter to try and resolve the problem fairly. After that, we were forced to write directly to Secretary Sibelius. The Secretary never answered our request for help to try and resolve the situation. All of these documents are attached for you and Andrew to look at.

Please let Andrew know at this point no one at FDA (other than you) is talking with us. Also, we recently found out that the FDA is: 1) continuing to market our tools under the FDA banner on their website; 2) has publicly endorsed a competitor's product (Tyco Integrated Systems, see: http://www.foodmanufacturing.com/videos/2013/04/food-defense-strategy-part-1-assess); 3) is holding a major workshop with the food industry on April 30th to unveil FDA's Food Defense Plan Builder that duplicates our Food DefenseTQ and Food Defense Architect Tools based on intellectual property that was stolen from us, and; 4) blacklisting FoodQuestTQ LLC with the food industry. We have heard this directly from the people we work with leading to the termination of critical business partnerships with us out of fear of reprisal in obtaining future contracts from the FDA or being blacklisted by FDA themselves as the result of their association with us.

Best, John

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11

SBA Ombudsman Case No. 1303150001

COMPETITION BY THE FOOD AND DRUG ADMINISTRATION WITH SMALL BUSINESS

The parties: FoodQuestTQ LLC, a small business with offices situated at 4720 Hayward Drive, Frederick, Maryland, 21702, and the Food and Drug Administration (FDA) with offices situated 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993.

FOODQUESTTQ LLC CONTACT INFORMATION

Dr. John Hnatio
Chief Science Officer
(o) 240.439.4476 x-11
(c) 301.606.9403
E-mail: jhnatio@thoughtquest.com

BACKGROUND

Projectioneering LLC is a small Frederick, Maryland-based company working with two other Frederick Maryland-based companies, ThoughtQuest LLC and FoodQuest LLC. Projectioneering LLC owns the intellectual property used by both ThoughtQuest LLC and FoodQuest LLC. ThoughtQuest LLC was created in 2008 for the purpose of supporting the start-up of companies across different industry verticals using the intellectual property owned by Projectioneering LLC. From 2008 to 2012, ThoughtQuest LLC reduced the Projectioneering LLC owned patent to practice for the food and agricultural fields of use. In early 2012, FoodQuestTQ LLC was established to commercially sell a suite of computer software tools across the food industry vertical that are based on the Projectioneering LLC patent.

SUMMARY

FoodQuestTQ LLC has filed a complaint with the Office of Small Business Advocacy and the Small Business Ombudsman. The complaint is based on three inextricably intertwined prohibited actions that the company alleges have been taken against them by the Food and Drug Administration, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, in violation of Title 18 U.S.C. and other statutes, and;

SBA Ombudsman Case No. 1303150001

COMPETITION BY THE FOOD AND DRUG ADMINISTRATION WITH SMALL BUSINESS

The parties: FoodQuestTQ LLC, a small business with offices situated at 4720 Hayward Drive, Frederick, Maryland, 21702, and the Food and Drug Administration (FDA) with offices situated 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993.

FOODQUESTTQ LLC CONTACT INFORMATION

Dr. John Hnatio
Chief Science Officer
(o) 240.439.4476 x-11
(c) 301.606.9403
E-mail: jhnatio@thoughtquest.com

BACKGROUND

Projectioneering LLC is a small Frederick, Maryland-based company working with two other Frederick Maryland-based companies, ThoughtQuest LLC and FoodQuest LLC. Projectioneering LLC owns the intellectual property used by both ThoughtQuest LLC and FoodQuest LLC. ThoughtQuest LLC was created in 2008 for the purpose of supporting the start-up of companies across different industry verticals using the intellectual property owned by Projectioneering LLC. From 2008 to 2012, ThoughtQuest LLC reduced the Projectioneering LLC owned patent to practice for the food and agricultural fields of use. In early 2012, FoodQuestTQ LLC was established to commercially sell a suite of computer software tools across the food industry vertical that are based on the Projectioneering LLC patent.

SUMMARY

FoodQuestTQ LLC has filed a complaint with the Office of Small Business Advocacy and the Small Business Ombudsman. The complaint is based on three inextricably intertwined prohibited actions that the company alleges have been taken against them by the Food and Drug Administration, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, in violation of Title 18 U.S.C. and other statutes, and;

3. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in violation of Title 18 U.S.C. and other statutes.

Until December 2012, the FoodQuestTQ LLC employed five people. In January 2013, faced with the continuing prospect of direct government competition that interfered with their commercial sales, FoodQuestTQ was unable to obtain an essential operating loan it required to stay in business. In December 2012, the company was forced to lay off all of its employees because of lagging sales resulting from the public release of similar products by the FDA.

This document describes the events leading up to and surrounding the actions allegedly taken by the Food and Drug Administration (FDA) to duplicate products that were already developed and for commercial sale by FoodQuestTQ LLC.

CASE DESCRIPTION

Over the period of the past three years representatives of ThoughtQuest LLC and FoodQuestTQ LLC have met extensively with FDA employees and shared with them information regarding the reduction of their patented technology for commercial use/sale to the food industry.

The information provided to FDA personnel was clearly marked as containing industry proprietary information. In addition, ThoughtQuest LLC and FoodQuestTQ LLC principals state that FDA employees they spoke with were verbally advised that the information being shared with them was proprietary and contained ThoughtQuest LLC and FoodQuestTQ LLC business proprietary and trade secret information.

In September 2012, FoodQuestTQ LLC principals became concerned that the FDA was, unbeknownst to them, taking their business proprietary and trade secret information to duplicate their products, under a contract with Battelle Memorial Institute.

In late October 2012, under pressure to avoid direct competition with the FDA that would put them out of business, FoodQuestTQ LLC, with the permission of their Board of Directors, offered the FDA a $1/yr. license to use their technology. FDA officials did not respond to the FoodQuestTQ LLC offer.

FDA and their contractor, Battelle Memorial Institute, continue to deploy products free of charge to the food industry that duplicate the products that were already developed and being commercially sold by FoodQuestTQ LLC.

The FDA actions have severely impacted FoodQuestTQ LLC sales. In early December 2012 when they were no longer able to meet payroll FoodQuestTQ LLC was forced to lay off all of their company's employees.

In January 2013, based on continuing competition by the FDA resulting in poor sales of their products, FoodQuestTQ LLC was denied a critical operating loan they needed to stay in business.

TIMELINE OF EVENTS LEADING TO THE LAYOFF OF FOODQUESTTQ PRINCIPALS AND EMPLOYEES

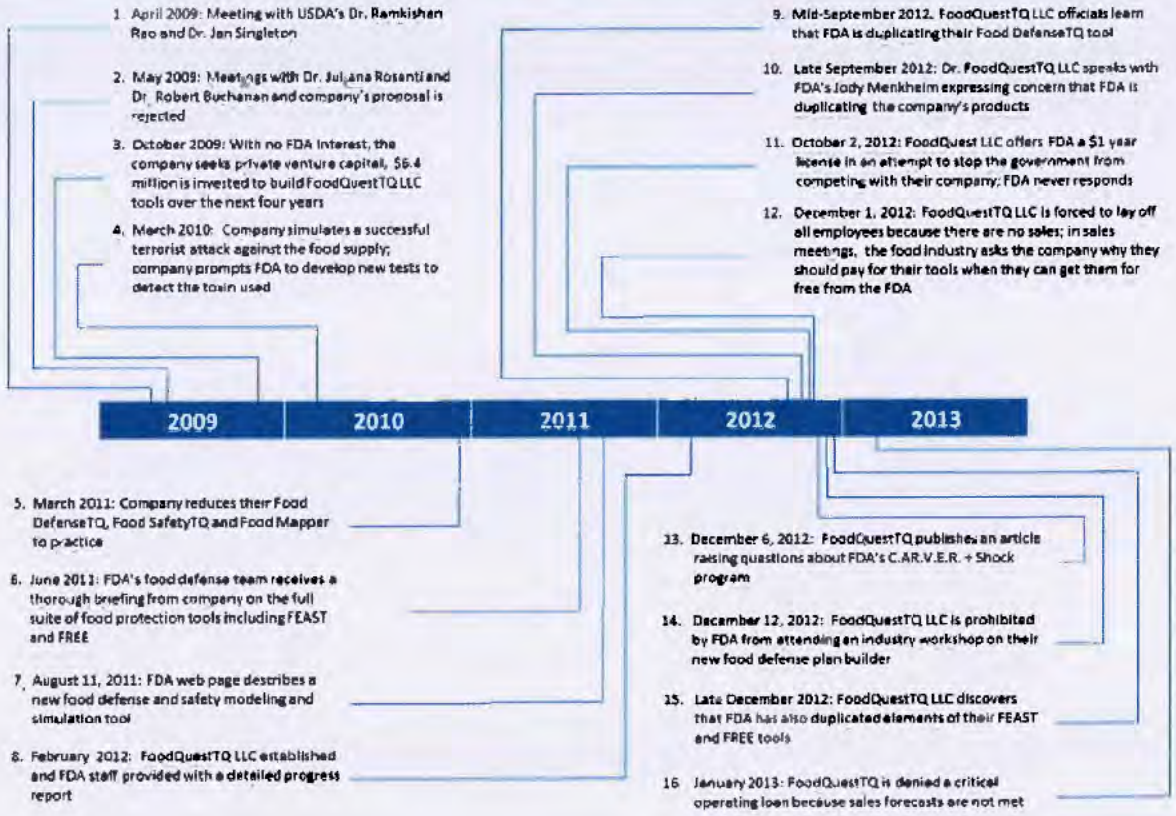


Figure 1: Timeline of FoodQuestTQ LLC and FDA Activities

1. In April 2009, representatives of ThoughtQuest LLC first contacted the U.S. Department of Agriculture (USDA). They met with Drs. Ramkishan Rao and Jan Singleton who were senior leaders at the U.S. Department of Agriculture's, National Institute of Food and Agriculture (NIFA). The purpose of the meeting was to forge a public-private partnership to make the food supply safer. ThoughtQuest LLC representatives shared their scientific breakthroughs, proprietary technology, and business plans for creating a safer food supply. Drs. Rao and Singleton were highly supportive of ThoughtQuest LLC's efforts. After the meeting, the company had follow-on meetings with Dr. Jeannette Thurston and other members of the USDA staff at NIFA to share their progress.

2. In May 2009, ThoughtQuest LLC representatives had their first contact with FDA when they met with Dr. Juliana Rosanti at the Joint Institute for Safety and Nutrition (JIFSAN). Their objective was to explore the possibility of a joint project with JIFSAN using their patent to make the food supply safer; this lead to a second meeting with Dr. Robert Buchanan, the head of the University of Maryland's Center for Food Safety and Nutrition (CIFSAN). Dr. Buchanan was a retired FDA senior food safety official and still serves as a senior scientific advisor to the FDA. At that time, Dr. Leanne Jackson, current head of the FDA's Food Defense Team was on the staff of CIFSAN.[i] As a result of these meetings, ThoughtQuest LLC representatives were asked to submit a detailed proposal to Dr. Buchanan describing their patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply. The proposal was clearly marked as containing proprietary information. The proposal was subsequently rejected by Dr. Buchanan.

   Note: Over the next three and a half years, the company continued to maintain very close contacts with both the USDA and FDA as they developed their products. The company briefed USDA and FDA officials on every step of their scientific and technological progress. They hoped that, at some point, USDA and FDA would join them in the public-private partnership they originally envisioned to improve the safety of the food supply based on the company's new science and technology innovations.

3. In October 2009, when the FDA showed no apparent interest in their patent and supporting technology, ThoughtQuest LLC sought venture capital. In addition to the $3.5 million invested by the two principals of ThoughtQuest LLC, the company received an additional $2.9 million in venture capital over the next four years to build and commercially deploy their suite of computer software tools to help the food industry prevent and improve responses to accidental and intentional food poisonings.

4. In 2010, ThoughtQuest LLC was asked by a large global food manufacturer to use their patent and technology to simulate a worst case terrorist attack using a biological agent against one of their major food product lines. The goal was to "bring down the company." Based on this tasking, ThoughtQuest LLC was able to scientifically simulate the successful take down of the company as a result of terrorists introducing a particular toxic agent into their product. The simulation was highly successful because no effective laboratory test existed at that time for detecting the presence of the agent that was used to poison the particular product. With the permission of the company involved, ThoughtQuest LLC representatives closely coordinated the results of the simulation and the methodology they used with Dr. Reginald Bennet and other officials at the FDA in

order to prompt the development of specific laboratory and field tests that would detect the deadly agent.

5. By early 2011, ThoughtQuest TQ LLC personnel reduced three of their products to practice and began commercial sales of their Food DefenseTQ, Food SafetyTQ and Food Mapper tools.

6. In June 2011, Mr. Menkhiem, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim to give him periodic updates on their progress.

7. On August 11, 2012, Mr. David Park, then Principal Scientist of FoodQuestTQ LLC came across an official FDA website that described a new FDA tool for modeling and simulating food defense and food safety scenarios.

   Note: As further discussed below, in late December 2012, Dr. Hnatio conducted a detailed review of the FDA website to discover that the FDA had duplicated the elements of two of FoodQuestTQ tools-the Food Event and Analysis Simulation Tool (FEAST) and the Food Response and Emergency Evaluation (FREE) tool. The FDA slightly modified the name of their new tool from the original FoodQuestTQ commercial name of FREE to the new FDA name "FREE-B."

8. In early February 2012, Projectioneering LLC and ThoughtQuest LLC stood up a new company called FoodQuestTQ LLC that would assume responsibility for the further development and sales of their computer software tools across the food industry.

   Also, Mr. Menkheim and his staff were provided with a detailed progress briefing and proprietary documents that included both business confidential and trade secret information describing the industry uses of the FoodQuestTQ LLC tools, the system architecture and the algorithms supporting the FoodQuestTQ tools. All this information was clearly marked as containing company proprietary information.

9. In mid-September 2012, FoodQuestTQ LLC officials learned for the first time, that the FDA had been working with Battelle Memorial Institute to build their own food defense

plan builder to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted Dr. John Hnatio, the Chief Science Officer of FoodQuestTQ, to call Mr. Menkheim to express his concerns that FDA was developing a product that already existed. Mr. Menkheim explained that FDA was not competing with FoodQuestTQ LLC had because the food defense plan builder tool being built by the FDA was not nearly as sophisticated as the FoodQuestTQ tools.

10. In late September 2012, Dr. Hnatio had another telephone another conversation with Mr. Menkheim and asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012. Mr. Menkheim told Dr. Hnatio that the principal purpose of the upcoming meeting was to discuss a terrorist targeting tool known as C.A.R.V.E.R. + Shock. He advised that FDA's food defense planner was being developed in order to make it easier for industry to use C.A.R.V.E.R. + Shock.[ii]

11. The next interaction between FoodQuestTQ LLC and the FDA took place on October 2, 2012, when a "go-to-meeting" webinar was held. During the webinar, FoodQuestTQ LLC FDA staff updated Dr. Menkheim and his staff on the company's continued progress to upgrade their suite of computer software tools. Particular attention was given to the use of the company's Food DefenseTQ tool as the way to build food defense plan. A more advanced tool known as Food Defense Architect that would make it even easier for food companies to develop their own food defense plans was also demonstrated.

    During the webinar, FoodQuestTQ again raised their concerns that FDA was building a food defense planner tool to compete with FoodQuestTQ LLC's existing Food DefenseTQ and Food Architect products. To avoid any potential conflict with FDA that could adversely impact their business, FoodQuestTQ LLC offered the FDA a license to use their technology across the food vertical for $1/yr. Prior to the webinar, FoodQuestTQ officials met with a member of their Board of Directors, Mr. Joe Welty, to discuss the FDA's actions and received permission to offer the $1/yr. license in order to avoid direct competition by the FDA. During the webinar, Mr. Menkheim advised that he could not make such a decision but would take the matter to his FDA bosses. FDA never responded to FoodQuestTQ LLC on the matter.

12. On December 1, 2012, when sales failed to materialize for FoodQuestTQ LLC's Food DefenseTQ and Food Defense Architect line of food defense tools, the company was forced to lay off all of their employees including the two founders of the company. Without pay, FoodQuestTQ LLC principals continued to prepare for the December 12,

2012, industry workshop on C.A.R.V.E.R. + Shock and the FDA's new food defense builder tool. The company developed an internet survey to ask the food industry how effective the FDA's C.A.R.V.E.R. + Shock approach was to them in protecting the food supply.

13. On December 6, 2012, Dr. Hnatio of FoodQuestTQ LLC published an article on the potential dangers of using C.A.R.V.E.R. + Shock as a counter-terrorist assessment tool. The article shared the preliminary results of the FoodQuestTQ survey. The results were mixed with a majority of respondents raising questions about the utility of C.A.R.V.E.R. + Shock. The C.A.R.V.E.R. + Shock article written by Dr. Hnatio was a matter of very significant interest throughout the FDA. For example, the web based software used to conduct the survey indicates that Dr. Leanne Jackson, (the former CIFSAN official referenced in entry 2. Above) who is now in charge of FDA's Food Defense Oversight Team, opened the article for review and/or further distribution over 40 times. It is noted that C.A.R.V.E.R. + Shock is a major $13 million funding line item for Dr. Jackson's office.

14. The December 12th 2012, FDA sponsored industry workshop was hosted by the Grocery Manufacturer's Association (GMA) at their Headquarters building in Washington, D.C. Mr. Warren Stone, Senior Director of Science Policy coordinated the meeting. At FoodQuestTQ's request, Mr. Stone allowed for a 20 minute slot on the workshop agenda for FoodQuestTQ to demonstrate their food defense plan builder tool that was already commercially available to the food industry.

    From e-mails sent to us by Mr. Stone as he coordinated the FDA workshop, we first learned that FDA was working under a multi-million dollar contract to help the FDA develop their food defense plan builder. We found the name of Mr. Colin Barthel, who is the Battelle Memorial technical manager for FDA's food defense mission. FoodQuestTQ LLC tried repeatedly to reach Mr. Barthel to discuss our concerns that Battelle Memorial Institute may be using the company's intellectual property to duplicate their products for use by the FDA. After repeated attempts to reach Mr. Barthel by e-mail and telephone to discuss the situation, FoodQuestTQ LLC finally received an abrupt e-mail from him stating he would not speak with them and that the FDA sponsored workshop on December 12th 2012 was strictly limited to food processors. Mr. Barthel referred FoodQuestTQ LLC back to the FDA's Food Defense Oversight Team to discuss any concerns.

    On the evening December 11, 2012, FoodQuestTQ LLC principals were notified by Mr. Stone that FDA had specifically disinvited any ThoughtQuest LLC (now FoodQuestTQ

LLC) personnel from participating in the FDA industry workshop to be held at GMA Headquarters the following day. Mr. Stone was told by the FDA that they did not want to give any preference or any endorsement to one commercial product over any other. FoodQuestTQ LLC was prohibited by the FDA from attending the workshop.

FoodQuestTQ LLC did, however, independently brief a few of the remaining food industry participants late in the day after the FDA sponsored workshop for industry was over and FDA officials had left the building. When FoodQuestTQ LLC officials signed into the conference room where they were going to demonstrate their products, they saw the attendee list of companies that participated in the earlier FDA sponsored industry workshop. The list included numerous companies that were not food processors but, in fact, competitors of FoodQuestTQ LLC, such as Tyco Integrated Systems.

15. In late December 2012, FoodQuestTQ LLC's concerns about the FDA action to prohibit their attendance at the FDA industry workshop caused them to go back and conduct a review of their work with FDA. It was at this time Dr. Hnatio took a closer look at Mr. Park's earlier reference (August 2011) to an FDA web site on modeling, simulation and responses to food defense and food safety emergencies. When Dr. Hnatio fully explored the FDA web page he discovered that the FDA had duplicated elements of their FEAST and FREE tools. Unbeknownst to FoodQuestTQ LLC, the FDA had slightly modified the name of the FDA tool from the FoodQuestTQ LLC's commercial name of FREE to the new government FDA name of "FREE-B."

    Note: During the preceding months, prior to learning about the actions of the FDA to compete with them, company officials were befuddled as to why their sales projections were not being met. They could not figure out why their products were not selling. It was not until after the FDA industry workshop that they began to receive direct feedback from food processing companies. In these sales meetings, industry asked FoodQuestTQ LLC why they should buy their products when the FDA was providing the same thing for free.

16. In January 2013, FoodQuestTQ LLC was denied a vital investor loan to continue operations. During the period from September 2012 through January 2013, FoodQuestTQ LLC was in critical negotiations to obtain an operating loan from their investors. In early October 2012, as the evidence mounted that FDA and Battelle Memorial Institute were duplicating their products and as sales were failing to materialize, FoodQuestTQ LLC principals were left with no option but to inform their Board of Directors of the situation. The news that FDA was spending millions of dollars under a contract with Battelle Memorial Institute to duplicate FoodQuestTQ's products

and poor sales raised the risk of future investment by their investors to an unacceptably high level. In early January 2013, their request for an operating loan was denied.

CURRENT STATUS

In January 2013, representatives of FoodQuestTQ LLC contacted members of Congress to request their assistance in obtaining a meeting with Ms. Elizabeth Dickinson, Chief Counsel at the Food and Drug Administration. Company officials felt that if Ms. Dickinson was made personally aware of the circumstances she would quickly act to correct the situation. At this time, the matter has become tied up in legal maneuvering by the FDA. Company officials still have not been allowed to personally meet with Ms. Dickinson. This is a matter of great concern to FoodQuestTQ LLC since the owners of the business and all employees had to be laid off without pay several months ago and the company cannot afford to pay the attorney's fees required to fight a long protracted legal battle with the FDA.

In February and March 2013, the inventor of the Projectioneering LLC owned patent undertook a comprehensive review of the FDA web site to identify any possible activities where the FDA had infringed on the Projectioneering LLC patent (The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.) The inventor identified five FDA products that accomplished the same or similar functions as the Projectioneering LLC patent and FoodQuestTQ software tools that were already or were in the final process of being made ready for commercial sale before they were duplicated by the FDA. A subsequent technical crosswalk of the five duplicate FDA products against each of the 20 claims and 101 objects of the Projectioneering LLC patent demonstrates flagrant infringement by the FDA.

PRINCIPAL ISSUES

1. FOOD AND DRUG ADMINISTRATION USE OF CONFIDENTIAL FOODQUESTTQ LLC BUSINESS AND PRODUCT INFORMATION

   Over a period of approximately three years FoodQuestTQ LLC met extensively with FDA employees and provided them with detailed briefings which included the proprietary and trade secret information relating to the reduction of their patent for commercial sale to the food industry. All proprietary information shared with FDA employees was clearly marked as containing industry proprietary information. In addition, FoodQuestTQ principals verbally advised the FDA employees they shared any proprietary information with that the information they were sharing required protection pursuant to the Code of Federal Regulations (48 CFR 27.402) and other government statutes.

Note: Title 18 USC 1905 applies to disclosure by a government employee of any information provided to the government by a company or other nongovernment organization, if the provider of the information identified it as proprietary or as being provided to the government in confidence. The penalty is mandatory removal from office (termination of employment), and the offender may be fined not more than $1,000 and imprisoned not more than one year.

Specific legal statutes and portions of the Federal Acquisition Regulations that pertain to the protection of commercially owned proprietary information include:

- Title 18 USC 1831–39 - Protection of Trade Secrets [Chapter 90].
- Title 18 USC 1905 – Disclosure of Confidential Information.
- Title 41 USC 423 – Procurement Integrity.
- Title 5 CFR 734 – Employee Responsibilities and Conduct.
- FAR 3.104-1 – Procurement Integrity, General (48 CFR).
- FAR 27.4 – Rights in Data and Copyrights (48 CFR).
- FAR 52.215-12 – Restriction on Disclosure and Use of Data (48 CFR).
- FAR 52.227-14 – Rights in Data (48 CFR).[iii]

2. FOOD AND DRUG ADMINISTRATION COMPETETITION WITH FOODQUESTQ LLC

The government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry. FQTQ offered the FDA Food Defense Team a $1/yr. license to use FoodQuestTQ LLC technology in order to avoid unfair competition by the government. FDA never responded to the offer. Based on proprietary business information provided to them, FDA was fully aware that the products they were developing with Battelle Memorial Institute were already developed and being commercially sold by FoodQuestTQ LLC.

Efforts to make the food supply safer are a shared responsibility between the government and the private sector and non-regulatory activities have never been considered an inherently government function. A simple Google search of food safety and food defense, identifies literally hundreds of "hits" with private sector companies doing everything from consulting, risk assessments, third party audits in support of FDA's governmental regulatory compliance responsibilities. The FDA itself promotes the use third party private sector companies to assure the quality of food safety and food defense at food operations all across the food supply.

The FDA actions in this case also raise questions regarding the Agency's compliance with OMB Circular A-76. This document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector.

3. THE IMPACT OF THE FOOD AND DRUG ADMINISTRATION POLICY AND ACTIONS ON SMALL BUSINESSES GENERALLY

FoodQuestTQ LLC is only one of millions of small businesses in America that provide the innovation required to solve national challenges. The nation depends on small businesses and the entrepreneurs who risk everything to create them. The jobs the nation must create to keep people employed are generated by small businesses like FoodQuestTQ LLC. Much of the innovation that the nation and our government must have to solve national problems comes from small businesses like FoodQuestTQ LLC. By competing with small businesses like FoodQuestTQ LLC and forcing them out of business, the FDA risks losing the genius and innovation the nation desperately needs to solve the country's food protection and food safety problems.

---

[i] See: http://www.linkedin.com/pub/leeanne-jackson/19/920/718

[ii] Note: C.A.R.V.E.R. + Shock was developed by the military special forces to plan attacks against the critical infrastructures of the enemy. In the aftermath of 9-11, FDA attempted to convert the tool for civilian use by the food industry with mixed results. Currently, the pursuit of C.A.R.V.E.R. + Shock is a continuing $13 million dollar FDA budget line item.

[iii] http://www.wrc.noaa.gov/wrso/security_guide/propriet.htm

Date: March 2, 2013

Note for: Ariel Seeley, FDA Counsel

From: John Hnatio, FoodQuestTQ LLC

Subject: More information on FoodQuestTQ tools and yesterday's E-mail

Hi Ariel,

Please call me John. It's good to meet you. We really want to thank you and Ms. Dickinson for your response and your good faith efforts to review the situation. Please say thank-you to her for me too.

I wanted to let you know that we have shared the nuts and bolts of literally everything we've developed with the Food Defense Team, JIFSAN, and CIFSAN over the past three or so years. This includes proprietary briefings and proposals including detailed information on our tools for building food defense plans, searching food standards and regulations, developing food emergency simulations, responses to food emergencies and much more. This is the same information that was used to duplicate our products.

But, if this information is not available to you from the FDA Food Defense Team, or if you want to have an independent read from us on the nuts and bolts of our technology, then we'd be happy to set up a demonstration for the folks in your office so that we can walk you through our Food Defense Architect, Food DefenseTQ, FEAST and FREE tools. The similarities between the tools duplicated by the Food Defense Team using our confidential information and ideas are quite obvious.

Also, the opportunity to get more specific information from you on the nuts and bolts of the operation of FDA's Food Defense Plan Builder and FREE-B would allow us to prepare a detailed "technical crosswalk" between the FDA Food Defense Team's and Battelle's Food Defense Plan Builder, FREE-B and our FoodQuestTQ tools. The "technical crosswalk" can put the entire issue of infringement and the use of our trade secret and proprietary information by the Food Defense team "to bed" very quickly.

As you do your good faith review, we hope that you will focus on all of the issues raised in the letter we sent Ms. Dickinson. The issue of patent infringement, while certainly of great importance, is only one of several critical issues that were raised in our letter. All of the issues we identified in our letter require careful consideration because they involve violations of specific statutes and violations of clearly established government-wide policies that specifically limit FDA's authority to build the same or similar products already available in the private sector.

Thus, we are really looking forward to working with you and Ms. Dickinson to fully explore the issues created by the Food Defense Team when they intentionally took our confidential information and used it to duplicate our tools in order to improperly compete with us. These highly significant issues go well beyond any specific patent infringements that have occurred in this case.

Please find a copy of a FoodQuestTQ LLC and FDA non-disclosure agreement (NDA). We would like to go ahead and execute an NDA with you at this time since we are uncertain of FDA's position with respect to adhering to the provisions of Title 18, as they relate to the protection of industry proprietary information. Our concern is based on the actions taken by the Food Defense Team to take our trade secrets and other proprietary ideas and information in order to duplicate our products.

As soon as we get an NDA in place, then I will call you to arrange a demonstration of our tools for you and other members of the FDA counsel's office and simultaneously make arrangements for you to share with us the information we will use to prepare the detailed "technical crosswalk" of the FDA/Battelle Food Defense Plan Builder and FREE-B tools against our Food Defense Architect, Food DefenseTQ and FREE tools.

We really look forward to working with you Ariel. If you have any questions please don't hesitate to call me. My best number is 240-439-4476. I'm at extension 11. Hope to meet you in person very soon. All the best.

PS!

Ariel we've got another serious problem. When it rains it pours. We just came across FDA's new iRisk tool this morning. You can take a look at the new FDA offering at: http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/ . The new iRisk tool duplicates our Food Mapper tool and is based on proprietary information that we provided to the Food Defense Team and JIFSAN. We'll need to include the FDA iRisk tool as part of the above technical crosswalk against our Food Mapper tool.

Date: March 14, 2013

Note for: Ariel Seeley, FDA Counsel

From: John Hnatio, FoodQuestTQ LLC

Subject: Suggested Changes to FDA Non-disclosure Agreement (NDA)

Hi Ariel:

We have completed a review of the FDA proposed NDA and it is acceptable to FQTQ with the following four modifications.

1. The "Purpose" of the agreement requires expansion to cover all three of the inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered as part of any good faith FDA review of this matter, namely:

    a. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;
    b. The alleged FDA theft of Trade Secrets and proprietary information from ThoughtQuest LLC, FoodQuest LLC and Projectioneering LLC, and;
    c. Projectioneering LLC and FQTQ allegations that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

2. The "Purpose" of the agreement must indicate a fair and reasonable *quid pro quo* in the sharing of information between the two parties. If FQTQ provides the FDA with information regarding their tools for FDA evaluation then why does not the FDA share information with FQTQ regarding the FDA tools under suspicion for further evidence of theft of trade secrets and intellectual property and potential infringement in Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2?

    In addition, the agreement must reflect that the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2, is a business process and a data transformation patent. This is necessary since the guiding FDA national process document for food safety and food defense, *The FDA Food Protection Plan*, seriously infringes on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 in addition to the other FQTQ tools duplicated by the FDA.

    Thus, we further suggest that the "Purpose" of the agreement be modified to explicitly state that the "parties" are engaged in a good faith review of the three allegations (as identified in 1. a.-c., above) and in so doing, must share information regarding the following FoodQuestTQ LLC food safety and food defense commercially developed tools, namely, Food SafetyTQ, Food

Safety Architect, Food DefenseTQ, Food Defense Architect, Food Mapper, the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation tool (FREE), and; the following federal government FDA guiding process document and tools, namely, *The FDA Food Protection Plan*, the FDA Food Defense Mitigation Strategies Database; the FDA Food Defense Plan Builder; the FDA Food Response Emergency Exercise-Bundled (FREE-B), and; the FDA iRisk tool.

3. The definition of "Confidential Information" requires expansion to identify the FDA national policy document and FDA tools and any FQTQ patent information and tools that must be evaluated in order to conduct a good faith review of the three allegations (as identified in 1. a.-c., above). This list currently includes Food SafetyTQ, Food Safety Architect, Food DefenseTQ, Food Defense Architect, Food Mapper, the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation tool (FREE), and; the following federal government FDA guiding process document and tools, namely, *The FDA Food Protection Plan*, the FDA Food Defense Mitigation Strategies Database; the FDA Food Defense Plan Builder; the FDA Food Response Emergency Exercise-Bundled (FREE-B), and; the FDA iRisk tool.

4. The term "Exemptions" has been defined in the standard FDA non-disclosure agreement but the term does not appear anywhere in the body of the document. This is a bit odd. In any event, the existing language, if it is to be included, requires modification by inserting the word "legally" in the verbiage as follows: "...(i) the Receiving Party or any of its Affiliates **legally** [emphasis added] possessed before the Disclosing Party or its Affiliates disclosed it under this agreement;..."

   This change is necessary because we are dealing with FQTQ "Confidential Information" i.e., trade secrets and intellectual property, that have already been taken by the FDA and are now being publicly disclosed by the FDA without FQTQ permission.

We recognize how busy you are and appreciate all of your hard efforts on our behalf. If it would be at all easier for you or save you time, we would be happy to make the above changes in the NDA and return the document to you for Ms. Dickinson's signature. All that we would require is that you e-mail to me a "soft copy" of the document in *Word* format. We will be sure to use "track changes" so that you can clearly see any modifications we make to your original document. Just let me know.

In any event, as soon as we receive the modified document we will immediately sign it and return it to you. Please call me at 240-439-4476 x-11 if you have any questions that I can help you with. Thank-you.

Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

March 16, 2013

Dear Ms. Dickinson:

First, we want to thank-you very much for the hard work of Ariel Seeley of your staff. She has worked very diligently on this matter and we appreciate her efforts very much. You must be proud to have her as a member of your staff. We recognize the extremely difficult situation she is in trying, on the one hand, to defend the actions of the Food and Drug Administration while, at the same time, attempting to conduct an honest and good faith review of the situation. We can appreciate the terrible conflict this must create for her. Please extend our thanks to her.

When we first asked to meet with you I was sincerely hoping that we could simply sit down together, talk honestly to one another as people of mutual integrity and quickly move forward to fairly resolve our concerns. But instead the train of justice has fallen off the tracks. It has now been over three months since we first asked to meet with you and we still are not even able to agree that any wrong has actually happened here. As I shared with Ariel earlier, I am a simple man who is not an attorney and I cannot afford to hire one to advocate on my behalf in an adversary legal setting. But it does seem to me, as a layman, that while there is way too much FDA legal jockeying going on, there is way too little effort to resolve the real issues a play here. In the meantime, however, the lives of real people are being destroyed.

Our company, just when we were in the position to make the food supply safer for all Americans, has been forced out of business by the FDA; on our side of the equation we are now in the unemployment lines, we can no longer pay our bills, the credit ratings that we have worked to a lifetime to preserve have been destroyed and all of our families have suffered terribly as the result of the actions taken against us by the FDA. The extended order effects of improper actions have had devastating consequences in this case.

For example, did you know that one of my company's employees is an 80% disabled military veteran who has an extended family that relies on him as the principal breadwinner? Can you possibly imagine what that must be like for him and his family? In another case, a member of the FoodQuestTQ family of employees has worked, scrimped and sacrificed literally everything he owns including his house, his retirement and his entire life savings to make our business a success. He too is the principal breadwinner for an extended family whose elderly in-laws live with his family. There are many other stories of anguish too. It is much too easy to forget that the actions we take can hurt real people.

This is why I am again pleading for your help and understanding to resolve this matter as quickly as possible. What is happening here is not some far away abstraction of reality. It is the real thing. People's lives and futures depend on our integrity, honesty and willingness to come together in a responsible way to resolve this matter quickly and fairly. That is why I am asking for the opportunity to meet with you personally to get the train of justice back on the tracks here. In the meeting, we would like to simply share with you the honest story of exactly what has happened here. I am sure that once you hear the true and complete story you will be appalled and take whatever actions are necessary to immediately turn this bizarre situation around.

It is true that we are at the mercy of the FDA and our own government because we simply cannot afford a long and expensive legal battle to achieve justice for ourselves. In my case, I am a 62 year old white male with few prospects for any possibility of future employment who would likely die before receiving any relief for my family as the result of this terrible situation. I do not like to think about leaving my wife impoverished as the result of the risks I have taken to create a small business. Thus, we have no choice but to rely on you and our own government to act with integrity to fairly protect our interests.

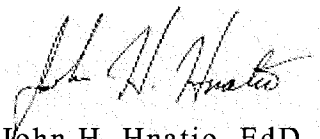
But time is definitely running out for us. This is why we have reached out to the Small Business Administration Office of Small Business Advocacy and the National Ombudsman for Small Business to help the FDA and FoodQuestTQ LLC come together. Our hope is that the SBA Ombudsman will carefully watch what is going on as an objective third party to help the FDA and FoodQuestTQ balance the need for FDA legal propriety against the real world needs of FoodQuestTQ to fairly resolve the situation as soon as possible. We believe that this approach will help both the FDA and FoodQuestTQ work through the issues fairly and objectively. The wonderful added advantage of this approach

is the requirement that we must complete our work within 30 days and file a full report to the Small Business Administration. Of course, this is critically important if FoodQuestTQ is to have any hope of surviving the actions that have been taken against us by the FDA.

Thank-you very much for your help in working with us. It is truly appreciated. We know how busy you are. If the personal meeting I suggest is agreeable to you please let me know and I will work our schedules to meet at any time that is convenient for you and your staff.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,



John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

cc: Ms. Ellie Zahirieh, Office of the SBA Ombudsman

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

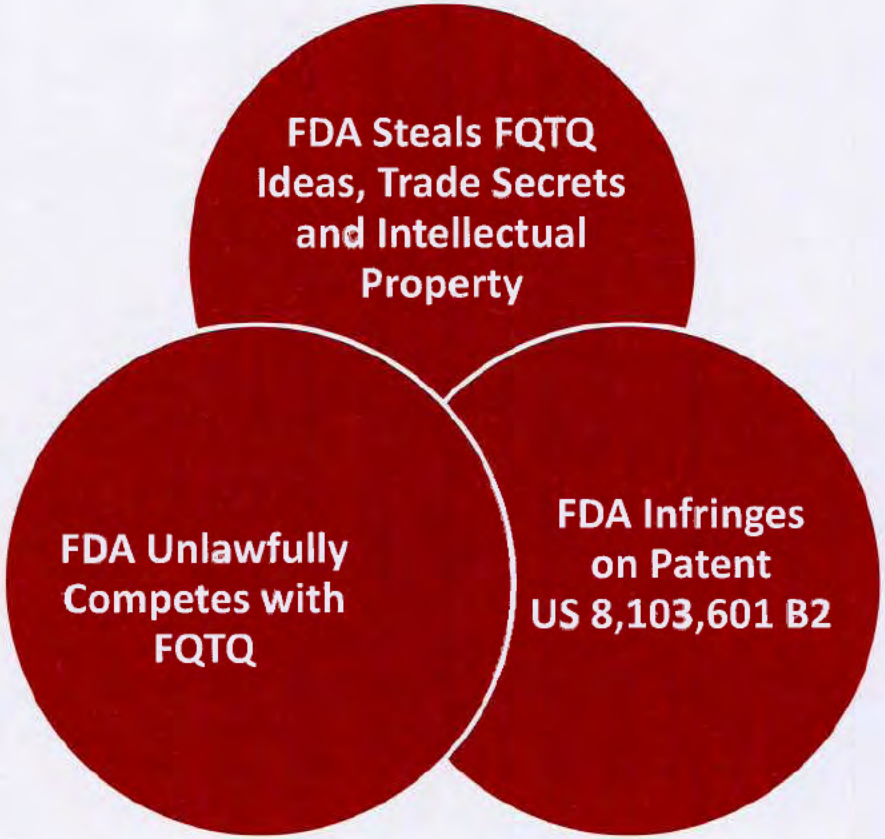
FoodQuestTQ LLC

March 19, 2013

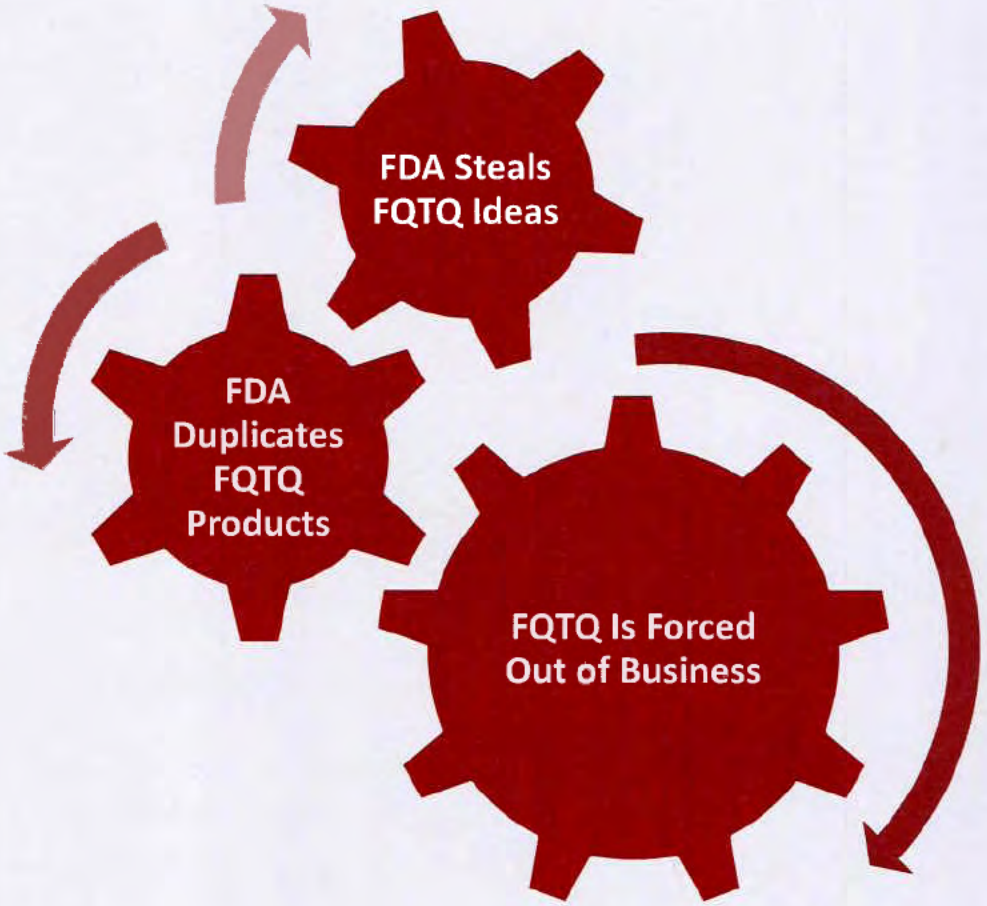
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- **The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.**

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- **The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.**

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- **The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.**

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- **The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."**

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- **The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."**

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- **The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.**

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- **The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.**

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- **The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.**

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed.

- **The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.**

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- **The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.**

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.**

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- **The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.**

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- **The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan.* More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.**

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.**

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- **The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.**

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- **The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.**

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- **The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.**

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- **The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.**

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- **The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.**

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- **The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.**

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectivity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

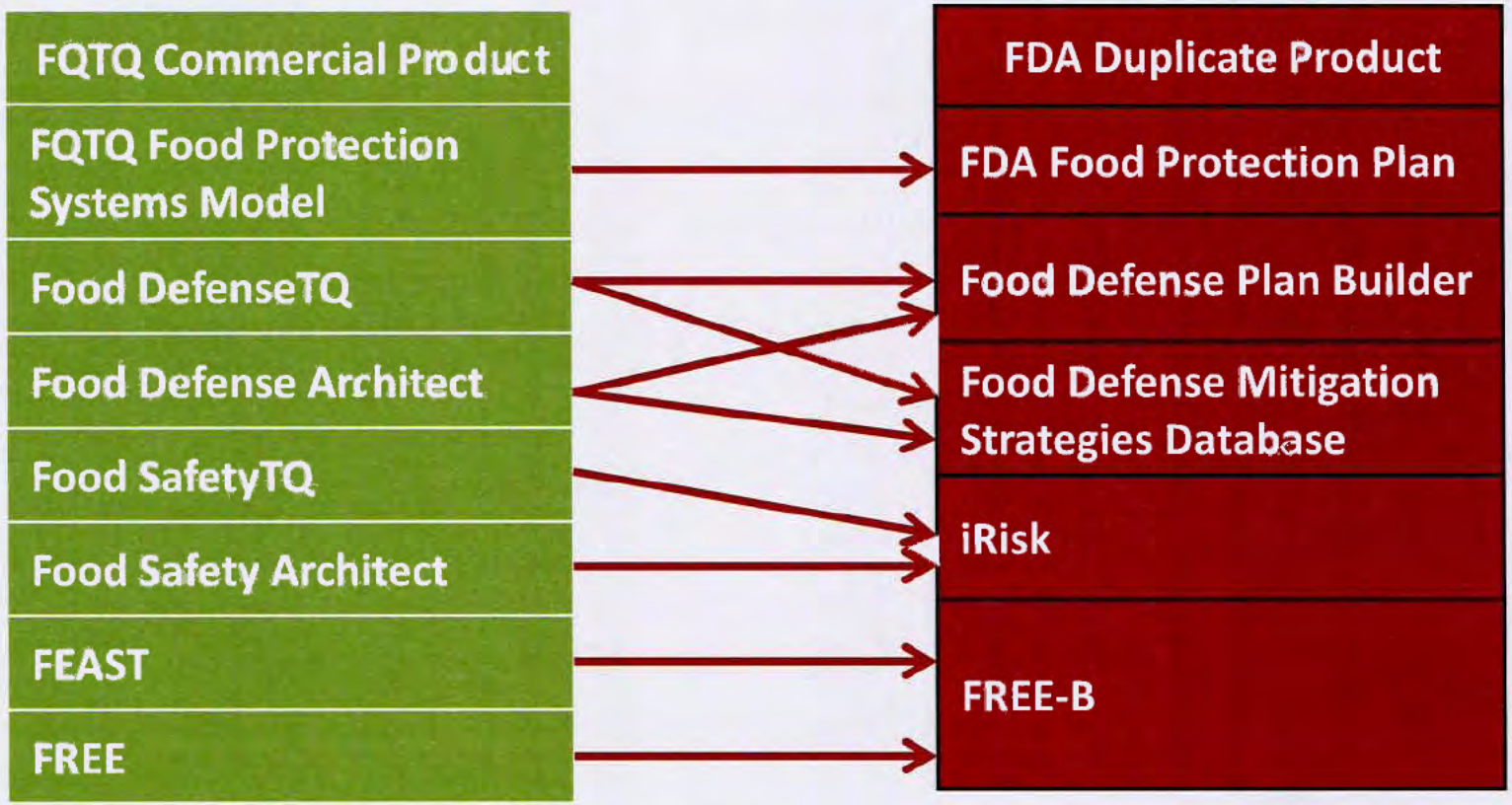
- The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.
- The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.

25. FQTQ Enhanced Risk Communications

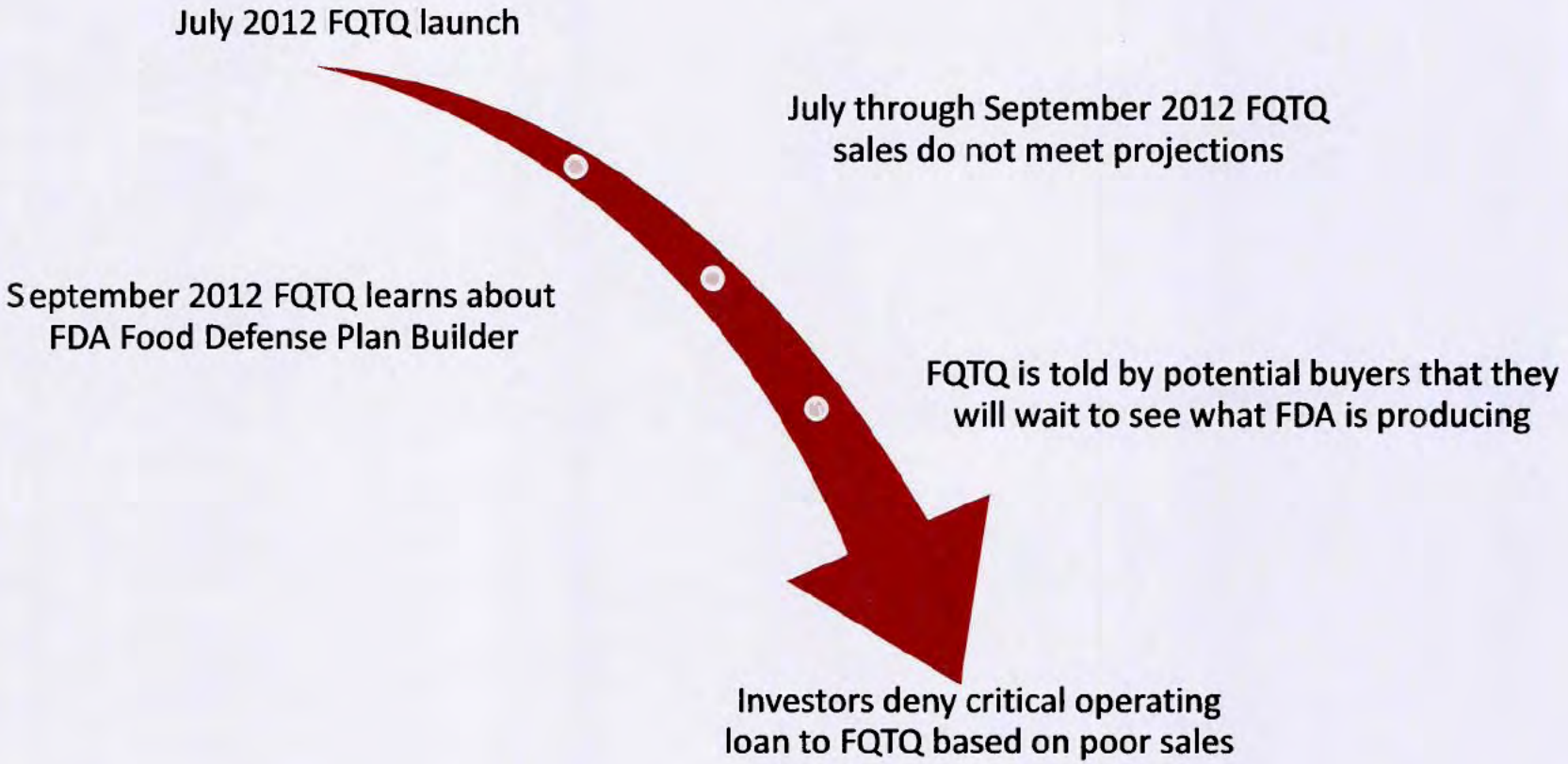
The FQTQ systems model for food protection improves risk communications.

- The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.

FDA Duplicates FQTQ Products



FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2

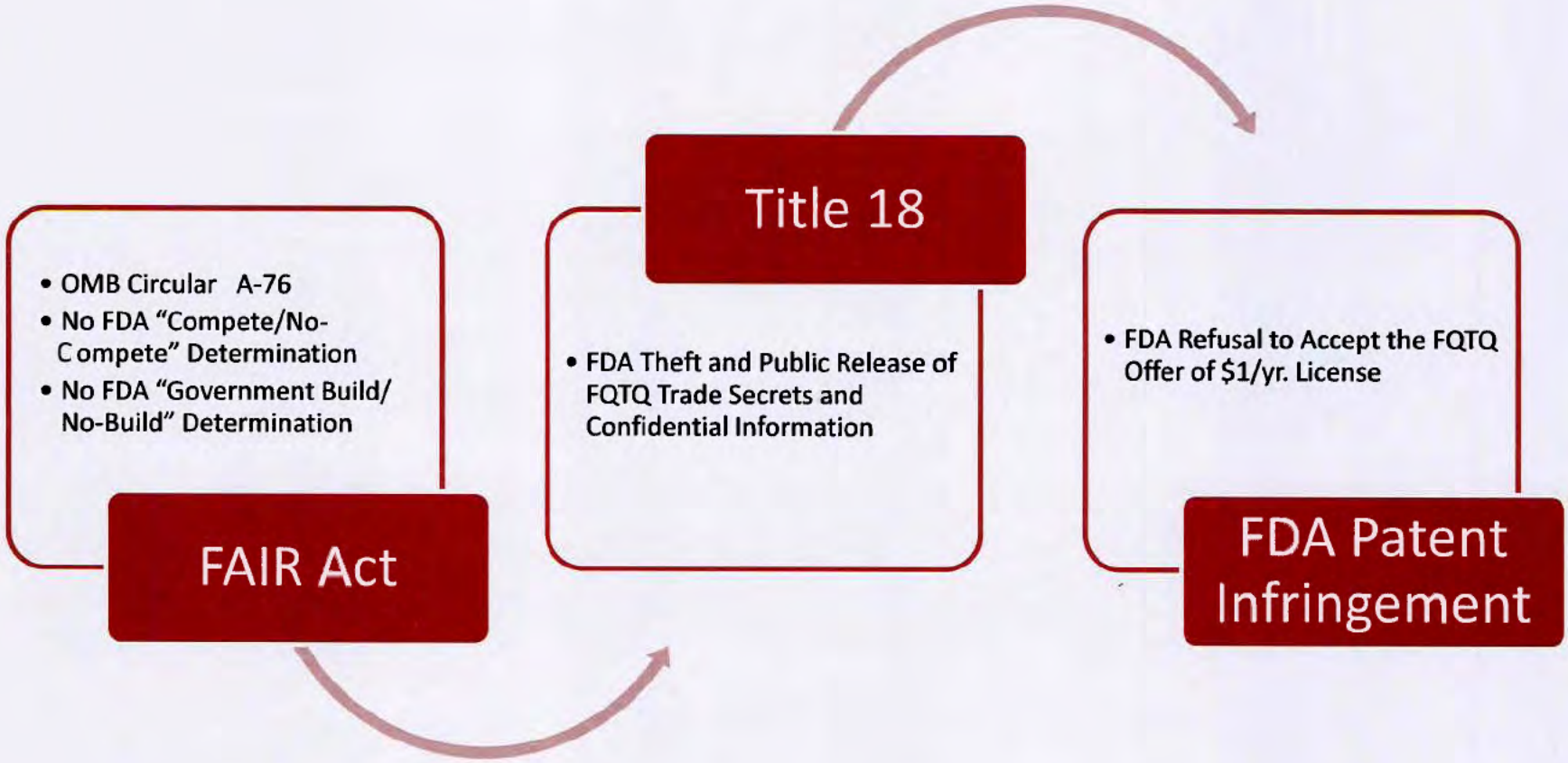
The patent has 20 claims and 101 associated objects of the invention

How FQTQ reduced the patent to use for food was FQTQ trade secret information until it was revealed by FDA in the FQTQ tools they duplicated and released to the public

FQTQ has prepared an extensive technical crosswalk that demonstrates flagrant infringement by the FDA on patent US 8,103,601 B2

FQTQ is prepared to share the results of the crosswalk with the National Small Business Ombudsman if it will assist in the timely resolution of this matter

FDA Unlawfully Competes with FQTQ



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
Room 2B-50, NIH Bldg. 31
31 Center Dr., MSC 2111
Bethesda, Maryland 20892-2111
(301) 496-6043
Fax (301) 402-1034

March 27, 2013
VIA EMAIL

Dr. John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702

Re: FDA's Food Defense Team

Dear Dr. Hnatio:

With respect to your email of March 22, 2013 to Ms. Zahirieh on which I was copied, I take exception to your characterization of Ms. Seeley's recent email to you as "threatening," and your suggestion that our agency does not intend to investigate your allegations of "wrongdoing." Neither of your statements is true or the least bit accurate.

Ms. Seeley's email merely introduced me as the intellectual property attorney who will be helping with the analysis of your allegations. Her email properly suggested that you obtain competent legal counsel, in view of your earlier communication to us that you are unrepresented, with respect to an area of the law that is highly technical.

In your letter of February 12, 2013 to Ms. Dickinson, you claimed that FDA duplicated your Food DefenseTQ tool and took elements of your FREE and FEAST computer software tools and incorporated them into FDA tools.

In order to evaluate this claim I will need to compare the FDA tools with each of your company's tools for any similarities. However, we do not have a copy of your company's tools, and you indicated in a previous communication that you were willing to provide them to us for this purpose under a Non-Disclosure Agreement ("NDA").

Ms. Seeley's March 13, 2013 email contained an executed copy of the NDA, which was modified consistent with our standard practices. You proposed in your March 14, 2013 response that certain changes be made to the NDA. I accepted some of your changes as follows: (1) I revised the "Purpose" of the NDA, (2) I revised the definition of "Confidential Information" to account for its intended relationship to the "Exempted Information," and (3) I revised the definition of "Exempted Information."

Please find an executed copy of the NDA, which has been modified to accommodate some of your suggestions. In return, please forward a copy of the tools that are the subject of your complaint directly to me, along with a description of those parts of the FDA tools that you believe incorporate subject matter from your tools.

With respect to your claim of infringement of U.S. Patent No. 8,103,601, the regulations at 48 C.F.R. § 227.7004 describe the information necessary to evaluate a claim of this kind. In particular we need, as applicable, the following:

1. A detailed identification of the accused article or process, and an element by element comparison of the representative claims with the accused article or process. If available, this identification should include documentation and drawings to illustrate the accused article or process in suitable detail to enable verification of the infringement comparison;
2. Names and addresses of all past and present licenses under the patent, and copies of all license agreements and releases involving the patent;
3. A brief description of all litigation in which the patent has been or is now involved, and the present status thereof;
4. A list of all persons to whom notices of infringement have been sent, including all departments and agencies of the Government, and a statement of the ultimate disposition of each; and
5. A list of all Government contracts under which the inventor, patent owner, or anyone in privity with him performed work relating to the patented subject matter.

If you have any questions or wish to discuss this further, please contact me at (301) 496-6043, of at Berkleyd@od.nih.gov.

Sincerely,

Dale D. Berkley, Ph.D., J.D.
HHS IP Counsel

Attachment: Executed NDA

Dr. Dale D. Berkley
Office of the General Counsel
Public Health Division
Room 2B-50, NIM Bldg. 31
31 Center Drive, MSC 2111
Bethesda, Maryland 20892-2111

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

March 28, 2013

Dear Dr. Berkley:

We have received your letter of March 27, 2013.

In your letter, you refer to my March 22nd e-mail to Ms. Zahirieh of the Office of the National Ombudsman for Small Business. In your letter you take exception to our concerns that the FDA did not and never intended to conduct a good faith review of our concerns. But, in fact, it was for this reason that we were forced to turn to the National Ombudsman for Small Business for help.

I am very surprised to hear that you do not understand why Ms. Seeley's e-mail is so threatening. Please let me explain.

I too was a civil servant. On my first day of government service I took an oath to uphold the Constitution and the laws of the United States. There were many times during my 30 year career with the government that this oath was sorely tested. In the face of serious wrongdoing in my own agency and at serious risk to my own well-being, I held fast to my oath. When my agency was guilty of wrongdoing my loyalty was always guided by my oath to uphold the Constitution and the laws of the United States first- certainly not the defense of my colleagues in the agency who engaged in the misconduct in the first place.

Please keep in mind that it was Ms. Seeley's own decision to turn this matter into an adversary legal defense of her colleagues on the FDA Food Defense Team instead of an impartial and objective fact finding mission to determine the truth. We certainly do not want to hurt Ms. Seeley. But her e-mail is, in fact, very clear. To the FDA, this matter is not about finding the truth. Rather, it is about mounting a legal defense for the FDA's own unconscionable actions in this matter. Based on your letter and your defense of Ms. Seeley's misguided actions, this now appears to be your motivation as well.

We also want thank you very much for your concern about the need for us to hire legal assistance to defend us against your investigation of this matter. But, if you intend to conduct a fair and impartial good faith review of this matter, then why do we have to pay money that we desperately need to feed our families to pay for an expensive legal defense? At this time, all of us in FoodQuestTQ have been forced into unemployment by the actions taken against us by the FDA. We simply cannot afford the expense of engaging in a legal battle with the government.

The non-disclosure agreement (NDA) you sent to us, still does not contain several important recommendations that we have already provided to the FDA legal counsel. Among the most important changes that must be made to the draft NDA involve he "Purpose" of the agreement.

As we have said from the very beginning, this matter involves three inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered if there is to be any true good faith review of this matter, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;

2. The alleged FDA theft of ideas, trade secrets and proprietary information from Thought Quest LLC, FoodQuestTQ LLC and Projectioneering LLC, and;

3. Projectioneering LLC and FQTQ proof that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

The reason for these changes is because the FDA legal counsel has repeatedly attempted to pigeon hole the FQTQ complaint against the FDA as solely and exclusively a matter of patent infringement. This is not the case. Our complaint to the National Ombudsman for Small Business goes well beyond the single isolated issue of patent infringement to include violations of the FAIR Act, the theft of our ideas, trade secrets and intellectual property, the duplication of our products and unlawful government competition against FoodQuestTQ. Thus, the NDA must clearly reflect that your good faith review will encompass all aspects of the formal complaint we have filed with the National Ombudsman for Small Business.

The NDA must also reflect a fair and reasonable quid pro quo in the sharing of information between FQTQ and Department of Health and Human Services and the FDA. If FQTQ provides you with information regarding their tools then the FDA should share information with FQTQ regarding each of the FDA tools under suspicion for further evidence of theft of our ideas, trade secrets and intellectual property and infringement on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

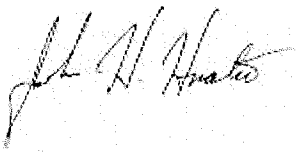
Several weeks ago, we suggested such a quid-pro-quo but the FDA counsel declined. We requested that the FDA provide us with an in-depth demonstration of the tools they duplicated and the opportunity for us to ask further questions. Thereafter, FoodQuestTQ would provide the FDA with a complete demonstration of our tools that would demonstrate the specific ideas, trade secrets and intellectual property that was stolen from us. Both presentations would be done via webinar and recorded for independent review by the National Ombudsman for Small Business, the office of Inspector General, the Department of Justice and others who may become involved in this matter. We now extend this same offer to you. Such demonstrations will quickly and conclusively demonstrate the truth of this matter as part of the official record.

The provisions at 48 C.F.R. §227.7004 relate to the resolution of patent infringement claims on the part of the offended party. The information you request is not germane to the conduct of a good faith fact finding mission by the either the FDA or the Department of Health and Human Services under the administrative law provisions at 48 C.F.R. §227.7002 and 48 C.F.R. §227.7004. As you are well aware, we are not yet at the resolution phase of this process.

At this juncture, you have a copy of our USPTO granted patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 and a detailed list of the specific ideas, trade secrets and intellectual property that were stolen from us by the FDA that I have provided to the National Ombudsman for Small Business. I understand that this information has already been provided to you by the National Ombudsman. On prior occasions, we have also offered FDA counsel a detailed technical crosswalk of how our patent was reduced to practice for our food applications. But the offer was declined.

Again, thank you very much for your letter. I can be reached at 240-439-4476 x-11 if you have any questions.

Sincerely yours,



John Hnatio
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

cc: Ms. Elahe Zahirieh, NOSB
Ms. Ariel Seeley, FDA Counsel

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington DC 20201
Via e-mail

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

April 1, 2013

Dear Secretary Sebelius:

We are a small business located in Frederick, Maryland. We are writing to you to ask for your help in resolving a dispute between my small business, FoodQuestTQ LLC, and the Food and Drug Administration (FDA). At FoodQuestTQ we produce advanced risk management software to help industry produce safer food.

Last year, we discovered that the FDA took our intellectual property and duplicated our products and, in so doing, tried to drive us out of business. In December 2012, we requested a personal meeting with Ms. Elizabeth Dickinson, the Chief Counsel at the FDA. Our objective was to simply sit down with Ms. Dickinson to explain the actions that were taken against us by the FDA and to work with her to fairly resolve the matter. But Ms. Dickinson refused to meet with us.

Instead, the FDA engaged in a harmful and non-productive dialogue with us as we attempted to work with them to try and resolve this matter. Earlier this month, we had no choice but to reach out to the National Ombudsman for Small Business because of the impasse. In response to our complaint to the National Ombudsman for Small Business, the matter was elevated to the DHHS Office of the General Counsel.

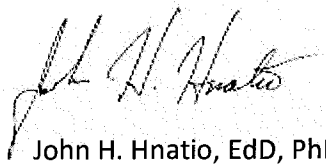
I am very disappointed to report to you that our interactions with the DHHS counsel assigned to this matter continue to be very non-productive. It appears that the counsel's efforts to defend the wrongdoing of his friends and colleagues in the FDA may have now out shadowed the importance of engaging in an honest dialogue about what has happened and working together with us to try and resolve any problems.

That is why we are requesting the opportunity to meet with you personally to describe the actions taken against us and to try and resolve this problem. The time now being spent on non-productive efforts to defend those who have made errors in the FDA is time much better spent on enhancing the safety of the food supply. Would it not be better for everyone involved, including the American people, to simply correct the errors that have happened here and take actions to prevent them from happening in the future?

I want to personally assure you that we are looking for a way to resolve the serious issues that have arisen here in a productive way that serves the best interests of the American people, the small businesses across America and the significant efforts of the FDA and DHHS to enhance the safety of the American food supply. Working together as a team, we can do much to enhance the safety of the food supply for the American people. Together, it is our responsibility to find a way to break the current circle of self-defeat.

We hope that you will look favorably on the possibility of meeting with us to resolve the issues that have arisen here so that all of us can move forward in much more productive efforts to make the food supply safer for the American people. We look forward to the possibility of meeting with you.

Sincerely,



John H. Hnatio, EdD, PhD
Chief Science Officer

cc: Ms. Elahe Zahirieh, NOSB
Dr. Dale Berkley, DHHS Counsel
Ms. Elizabeth Dickinson, Chief Counsel, FDA

Ms. Yolanda V. Swift
Acting Ombudsman and Assistant Administrator
for Regulatory Enforcement Fairness
Office of the National Ombudsman
U.S. Small Business Administration
409 3rd Street, SW (MC 2120)
Washington, DC 20416-0005

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

April 15, 2013

Dear Ms. Swift;

Thank-you very much for your letter of April 10, 2013 regarding our complaint to the National Ombudsman that the FDA is stealing our intellectual property, intentionally duplicating our products and forcing us out of business.

The FDA letter to you dated March 26, 2013, from Mr. Andrew Moss is misleading. Mr. Moss indicates that representatives of the Office of General Counsel, Department of Health and Human Services (HHS) and the Office of the FDA Chief Counsel have been in recent contact with me and that they are actively reviewing our concerns. ***Please be advised that this is not the truth.***

The reason we were forced to file our complaint with the National Ombudsman in the first place is because the Office of the FDA Chief Counsel refused to work with us to fairly resolve this matter. Instead, the FDA Chief Counsel mounted a legal defense of those personnel in the FDA who stole our intellectual property, duplicated our products and forced us out of business in the first place. The Office of General Counsel, HHS, has now joined league with the FDA Chief Counsel. Attached is a copy of a recent letter that we sent to Secretary Sebelius at HHS expressing our concerns.

We recently came across a flier for a major food industry conference called the *Food Safety Summit* that will be held at the Baltimore Convention Center. On the morning of April 30, 2013, the FDA is scheduled to conduct several workshops with the food industry in which they will unveil one of the FoodQuestTQ products they duplicated, i.e., FDA's *Food Defense Plan Builder,* based on intellectual property that the FDA has stolen from our small company. We request the assistance of the National Ombudsman for Small Business to prevent the FDA from continuing to steal our intellectual property in this way and further damaging any possibility of saving our small business.

Thank-you again for all that you do in defense of small business. We at FoodQuestTQ very much appreciate your help in turning this bizarre situation around.

Sincerely,

John H. Hnatio
Chief Science Officer

cc: The Honorable Kathleen Sebelius, Secretary, HHS

FoodQuestTQ LLC, 7420 Hayward Drive, Frederick, Maryland 21702 Telephone 240-439-4476 ext. 11

EXHIBIT 20

Food

Food Protection Plan of 2007

Introduction

American consumers enjoy one of the safest food supplies in the world; however, we know it can be made even safer. FDA regulates $417 billion worth of domestic food and $49 billion worth of imported food each year—everything we eat except for meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture.

FDA has developed a comprehensive Food Protection Plan to address the changes in food sources, production, and consumption that we face in today's world. Building upon and improving an already sound food safety protection capability, the new plan presents a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack. FDA's Food Protection Plan builds in prevention first, then intervention, and finally, response. This new strategy will help ensure that Americans continue to benefit from one of the safest food supplies in the world. The Office of Food Protection provides advice and council on the strategic and substantive agency-wide domestic and imported food related matters, including the Food Protection Plan.

VIDEO

Windows Media Player
56K[1] | 150K[2] | 300K[3]

Real Player
56K[4] | 150K[5] | 300K[6]

Guidance: Displaying[7]
Closed Captioning[8]

Audio Only (MP3)[9]

VIDEO

Windows Media Player
56K[10] | 150K[11] | 300K[12]

Real Player
56K[13] | 150K[14] | 300K[15]

Guidance: Displaying[16]
Closed Captioning[17]

Audio Only (MP3)[18]

News Updates

- 07/02/2008 FDA Food Protection Plan Shows Significant Progress [19] [ARCHIVED]
- 04/23/2008 FDA Strengthens Safeguards for Consumers of Beef [20] [ARCHIVED]

- 03/14/2008 FDA Takes Next Step in Establishing Overseas Presence [21] [ARCHIVED]
- 02/04/2008 President's FY 2009 Budget Advances Food and Medical Product Safety, and the Safety of FDA-Regulated Imports [22] [ARCHIVED]
- 01/04/2008 FDA Commissioner Names Directors to Food Safety and Veterinary Centers [23] [ARCHIVED]
- 12/21/2007 FDA Develops New Tools to Further Improve the Security of Food and Cosmetics [24] [ARCHIVED]
- 11/19/2007 FDA Awards Grants to Further Food Safety [25] [ARCHIVED]

Page Last Updated: 03/15/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.accessdata.fda.gov/videos/foodprotectionplan/FOOD_PROT_WMV_56K.asx
2. http://www.accessdata.fda.gov/videos/foodprotectionplan/FOOD_PROT_WMV_150K.asx
3. http://www.accessdata.fda.gov/videos/foodprotectionplan/FOOD_PROT_WMV_300K.asx
4. http://www.accessdata.fda.gov/videos/foodprotectionplan/FOOD_PROT_RM_56K_Web.rm
5. http://www.accessdata.fda.gov/videos/foodprotectionplan/FOOD_PROT_RM_150K_Web.rm
6. http://www.accessdata.fda.gov/videos/foodprotectionplan/FOOD_PROT_RM_300K_Web.rm
7. http://esupport.fcc.gov/index.htm?job=captions
8. http://esupport.fcc.gov/index.htm?job=captions
9. http://www.accessdata.fda.gov/videos/foodprotectionplan

/FOOD_PROT_MP3.mp3

10. http://www.accessdata.fda.gov/videos/foodprotectionplan /FP_Press_Conf_56K.asx
11. http://www.accessdata.fda.gov/videos/foodprotectionplan /FP_Press_Conf_150K.asx
12. http://www.accessdata.fda.gov/videos/foodprotectionplan /FP_Press_Conf_300K.asx
13. http://www.accessdata.fda.gov/videos/foodprotectionplan /FP_Press_Conf_56K_Web.rm
14. http://www.accessdata.fda.gov/videos/foodprotectionplan /FP_Press_Conf_150K_Web.rm
15. http://www.accessdata.fda.gov/videos/foodprotectionplan /FP_Press_Conf_300K_Web.rm
16. http://esupport.fcc.gov/index.htm?job=captions
17. http://esupport.fcc.gov/index.htm?job=captions
18. http://www.accessdata.fda.gov/videos/foodprotectionplan/FD_Press_conf.mp3
19. /NewsEvents/Newsroom/PressAnnouncements/2008/ucm116917.htm
20. /NewsEvents/Newsroom/PressAnnouncements/2008/ucm116884.htm
21. /NewsEvents/Newsroom/PressAnnouncements/2008/ucm116867.htm
22. /NewsEvents/Newsroom/PressAnnouncements/2008/ucm116850.htm
23. /NewsEvents/Newsroom/PressAnnouncements/2008/ucm116831.htm
24. /NewsEvents/Newsroom/PressAnnouncements/2007/ucm109045.htm
25. /NewsEvents/Newsroom/PressAnnouncements/2007/ucm109031.htm

EXHIBIT 21

U.S. Food & Drug Administration

U.S. Food and Drug Administration - CFSAN - Food Defense Mitigation Strategies Database

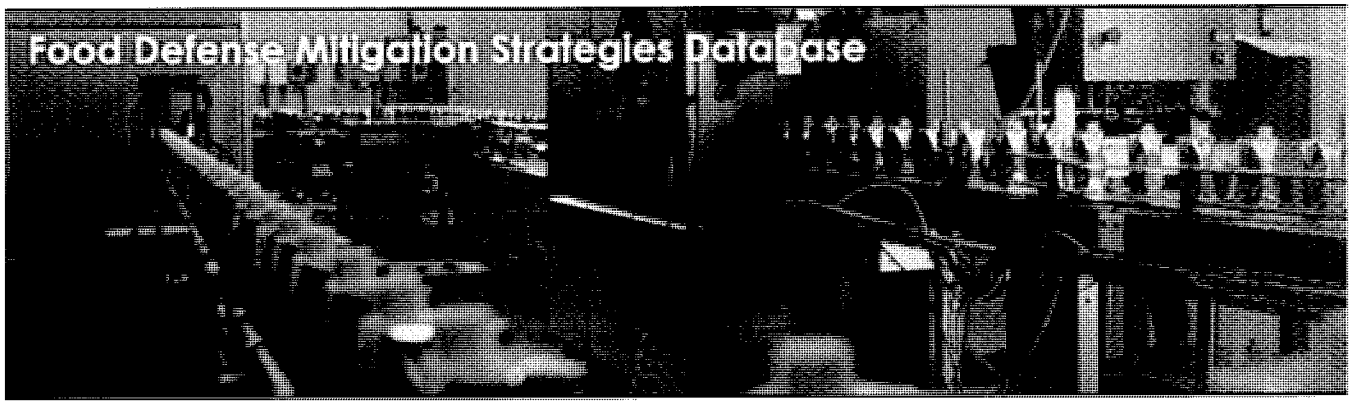
- [1]

FDA Home[2] [3]

Contains Nonbinding Recommendations

Return to Launch Page[4] | Guidance for Industry[5]

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.



HOW TO USE THIS TOOL

Welcome to the Food Defense Mitigation Strategies Database. This database is one of several tools developed by the FDA for the food industry to help protect our nation's food supply from intentional acts of contamination or tampering. Specifically, this resource is designed for companies that produce, process, store, package, distribute, or transport food or food ingredients. It provides a range of preventive measures that companies may choose to better protect their facility, personnel, and operations. These safety measures are specific to individual categories that impact every step of the food production and distribution process.

Not all measures are applicable or practical for all sizes and types of food production. It is the responsibility of the owner/operator/supervisor to choose those measures that may be helpful and appropriate for their facility.

Data can be accessed using two different methods.

1. LOOKUP TOOL: Data can be searched by a specific item, or *node*, commonly used within commercial food production and distribution. First, select a food industry category from the provided list. Once the category is selected, a list of nodes will be provided to choose from. Once the node is chosen, select "GO" to view its safety objective(s) and steps that can be taken to ensure safety.
2. SEARCH ENGINE TOOL: Data can be searched by a specific term or keyword. Similar to any search engine on the Web, type in the desired item to be found and select GO; a list of applicable items will be returned.

LOOKUP TOOL

To begin, select a category and node from the drop down menus shown below, then click on the "Go" button. Alternatively, you may search for keywords using the search engine provided. (See Below)

Category:

- SELECT A CATEGORY -

Node:

- SELECT A NODE -

GO

SEARCH ENGINE TOOL

You can access a specific Node Security Data Sheet by entering a keyword (i.e. mixing tank) into the text box. Then, select the "GO" button. The application will provide you with results that best match your keyword.

Enter Search Term:

GO

0562

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.accessdata.fda.gov/scripts/FoodDefenseMitigationStrategies
5. http://www.cfsan.fda.gov/~dms/guidance.html

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- USA.gov
- 
- 
- 
- 
- 
- 
- 
- For Government
- For Press
- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness
- International Programs
- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

 U.S.Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain

2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.accessdata.fda.gov/scripts/FoodDefenseMitigationStrategies
5. http://www.cfsan.fda.gov/~dms/guidance.html

EXHIBIT 22

News & Events

FDA PRESS RELEASE

For Immediate Release: July 20, 2011
Media Inquiries: Stephanie Yao, 301-796-0394, stephanie.yao@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA, federal partners develop tools for food-emergency readiness
FREE-B helps stakeholders respond to food-related emergencies

The U.S. Food and Drug Administration and federal partners today released the Food Related Emergency Exercise Boxed (FREE-B) set, a Web-based collection of scenarios that will help government regulators, public health organizations and the food industry test their readiness for food-related emergencies, such as a human health emergency caused by an unintentional contamination of produce with E. coli O157:H7.

FREE-B is a compilation of five scenarios designed to help test and develop food emergency response plans, protocols and procedures. It will help food and agriculture stakeholders and emergency preparedness planners collaborate better with each other, neighboring jurisdictions, the food industry and federal agencies during food emergencies.

"Being prepared for any kind of emergency is critical to a rapid and effective response," said Michael R. Taylor, FDA deputy commissioner for foods. "FREE-B helps people think about their own responsibilities in a time of crisis and how to best work with others involved."

The FDA worked with experts from the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture's Food Safety and Inspection Service and Animal and Plant Health Inspection Service to develop FREE-B.

"It is critical for decision-makers involved in a food safety incident to appreciate the varied roles each must play to reduce foodborne illness, from data collection and analysis to traceback efforts to communicating with the public about how to protect themselves," said Beth P. Bell, M.D., M.P.H., director of CDC's National Center for Emerging and Zoonotic Infectious Diseases. "FREE-B will give stakeholders such an opportunity."

FREE-B is consistent with the Food Safety Modernization Act's call for coordination among federal food-safety agencies and the development of resources to help local and state agencies involved in helping to ensure the safety of our nation's food supply.

Through participation in any of the scenarios, stakeholders will:

- Cultivate professional skills by learning how to work with dynamic, ad-hoc teams facing critical food emergency incidents that threaten the safety of the public
- Assess readiness to effectively address a food contamination incident
- Define roles and interactions with partners
- Understand the purpose and objectives of federal, state, local and industry organizations and how each provides resources to address different aspects of food contamination scenarios
- Take appropriate, timely and effective steps to remediate emergency situations that are caused by intentional or unintentional acts.

FREE-B takes a "whole-community" approach to preparedness. The term "whole-community" refers to the need for cross-discipline preparedness training for large-scale incidents through regular exercise and training, evaluation and plan revision.

For more information:

- FREE-B[1]
- Food Defense and Emergency Response [2]

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

#

Visit the FDA on Facebook[3]

RSS Feed for FDA News Releases[4] [what is RSS?[5]]

Page Last Updated: 07/20/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. ssLINK/UCM216741
2. /Food/FoodDefense/default.htm
3. http://www.facebook.com/FDA
4. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml
5. http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm

EXHIBIT 23

Food

Food Related Emergency Exercise Bundle (FREE-B)

Watch the FREE-B Informational Video

DOWNLOAD FREE-B[1]

The Food Related Emergency Exercise Bundle (FREE-B) is a compilation of scenarios based on both intentional and unintentional food contamination events. It is designed with the intention of assisting government regulatory and public health agencies in assessing existing food emergency response plans, protocols and procedures that may be in place, or that they are in the process of revising or even developing. The FREE-B is designed to allow for multiple jurisdictions and organizations (medical community, private sector, law enforcement, first responder communities) to 'play' with the host agency, or, quite simply, for an individual agency to test their own plans, protocols and procedures independently.

FDA developed FREE-B in cooperation with the Centers for Disease Control and Prevention[2] (CDC) and the U.S. Department of Agriculture's Food Safety Inspection Service[3] (FSIS) and Animal and Plant Health Inspection Service[4] (APHIS). Additionally, numerous subject matter experts participate in various rounds of reviews and refinement of the FREE-B.

The FREE-B is a set of five (5) scenarios, each of which contains a Facilitator's Guide, a Lead Planner's guide and a Situation Manual. The five scenarios and a brief intro of each are as follows:

How Sweet It Is(n't) - This scenario focuses attention on the regulatory traceback investigation that occurs after standard product testing shows that a food product contains excessive levels of a contaminant, as well as a recall of contaminated food.

Stealthy Situation - This exercise is a comprehensive scenario and highlights nuances encountered when a cluster of illness is associated with a foodservice establishment. The scenario includes the epidemiological investigation, identification of affected product through traceback procedures, implementation of a recall, and the role of regulatory agencies.

Wilted Woes - This scenario begins at the outset of early signal detection with clinical illness reports, and focuses on the epidemiological investigation process to identify the food vehicle when there is a human health emergency caused by an unintentional contamination of produce with E. coli O157:H7.

High Plains Harbinger - This scenario focuses on the investigation of animal disease caused by intentional infection of cattle with Foot and Mouth Disease (FMD) virus, highlighting the various animal agriculture agencies (Federal, state, local, territorial, and tribal) and their roles and responsibilities, as well as introducing the roles and responsibilities of law enforcement agencies during an animal health emergency.

Insider Addition - This scenario focuses attention on the intentional aspect of contamination of a raw meat product at the processor with a chemical agent. Various nontraditional organizations and expertise needed to investigate intentional contaminations and the establishment of collaborative processes and roles and responsibilities with the traditional public health and regulatory partners are highligthed.

The FDA recognizes the importance of pre-event coordination, collaboration, and communication, in addition to horizontal and vertical food emergency response plan integration, in mitigating the outcomes of a large scale food emergency. Accordingly, the FDA encourages government agencies using the FREE-B toolkit to coordinate and collaborate with neighboring jurisdictions, private sector partners, academia and Federal partners in the planning of an exercise contained within the FREE-B in order to further examine and assess the cross-jurisdiction integration of existing food emergency response plans. Within the FREE-B is a reference/resources guide that provides links to tools and resources that can assist in Food and Agriculture Sector related emergency preparedness and response guidance.

The overarching objectives of FREE-B are to:

- Cultivate professional skills by learning how to work with dynamic, ad-hoc teams facing critical food emergency incidents that threaten the safety of the public;
- Assess readiness (agency, facility, profession, department, authority, etc) to effectively address a food contamination incident;
- Define roles and interactions with partners;
- Understand the purpose and objectives of federal, state, local and industry organizations and how each provides resources to address different aspects of food contamination scenarios; and/or
- Take appropriate, timely and effective steps to remediate emergency situations that are caused by intentional or unintentional acts.

Please note, that the success of the FREE-B is hinged on several key assumptions:

1. It is assumed that jurisdictions that will be using the FREE-B have previous experience with an have a basic understanding of the Homeland Security Exercise and Evaluation Program[5] (HSEEP) methodology. While the FREE-B is not an HSEEP training tool, it does provide users a framework from which they can begin to develop trainings to assess the functionality of existin food emergency plans, protocols and / or procedures.
2. The FDA acknowledges that pre-event preparedness and resiliency efforts are best visible, whe observed from the perspective of our State, local, Tribal and territorial (SLTT) partners. In assembling the FREE-B, assumptions have been made as to the existence of food emergency response plans, and where appropriate, references are made to existing guidelines to assist ou SLTT partners in this plan development effort. Lastly, and most importantly, it is assumed that the end users of this toolkit will use it, evaluate it and provide feedback to the Food Defense Oversight Team, so that future iterations of this work can better prepare our SLTT partners. Feedback raises awareness of the Federal partners within the Food and Agriculture Sector to existing needs, gaps and barriers to successful food emergency plan development, implementation and integration.

FREE-B Informational Video

Information video on the Food Related Emergency Exercise Bundle (FREE-B) that is a compilation of scenarios based on both intentional and unintentional food contamination events. It is designed with the intention of assisting government regulatory and public health agencies in assessing existing food emergency response plans, protocols and procedures that may be in place, or that they are in the process of revising or even developing. The FREE-B is designed to allow for multiple jurisdictions and organizations (medical community, private sector, law enforcement, first responder communities) to 'play' with the host agency, or, quite simply, for an individual agency to test their own plans, protocols and procedures independently.

To hear the replay of the FREE-B conference call held on 8/17/11, callers can dial 888-566-0103. International callers will need to dial 402-998-0958

DOWNLOAD FREE-B[6]

Page Last Updated: 03/14/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. /Food/FoodDefense/ToolsEducationalMaterials/ucm295903.htm
2. http://www.cdc.gov/
3. http://www.fsis.usda.gov/

4. http://www.aphis.usda.gov/
5. https://hseep.dhs.gov/pages/1001_HSEEP7.aspx
6. /Food/FoodDefense/ToolsEducationalMaterials/ucm295903.htm

EXHIBIT 24

FDA-iRISK
food safety modeling tool

From the Food and Drug Administration

- **estimates effectiveness of interventions at all steps of food-supply chain, from farm to consumer**
- **compares and ranks risks from multiple food / hazard combinations**
- **calculates public-health outcomes of variations in processing or handling practices**
- **useful for prioritizing, decision-making, resource allocation**

FDA-iRISK is an interactive, Web-based risk assessment tool the Food and Drug Administration (FDA) has made available to the public. It compares and ranks the risks posed by multiple food/hazard combinations that involve FDA-regulated products; risks that compete for public-health resources. Beyond ranking, FDA-iRISK enables users to estimate and compare the effectiveness of proposed interventions and control measures.

FDA-iRISK includes built-in templates, mathematical functions, and other features that enable users, from a variety of backgrounds, to build food-risk scenarios that reflect their real-world (or theoretical) food-safety issues. FDA-iRISK then performs calculations to compare and rank the risks and interventions, based on any or all steps of the foods' production/supply chains. The model can be used to conduct risk assessments that evaluate and compare a broad array of scenarios. Policy-makers and other decision-makers can use FDA-iRISK results to inform their prioritization and intervention decisions.

This tool was created to meet FDA's need for a risk-based, strategic approach to comparing, collectively and numerically, the public-health impact of the various pathogens, microbial toxins, and chemicals, in various foods, that may endanger our food supply. FDA-iRISK can express the estimated impact of proposed intervention or control measures in various ways, including widely used public-health metrics, such as DALYs; i.e., years of healthy life lost to illness or death. Although simply comparing the number of illnesses caused by various foodborne hazards is useful for some purposes, it doesn't reflect the severity of illness and the health toll the hazards take from their victims. DALYs do reflect those factors, providing risk managers with a way of balancing magnitude – number of illnesses from various hazards – with the likely public-health impacts of those hazards, in facing decisions about resource allocation.

Examples: what FDA-iRISK can compare

FDA-iRISK can compare public-health impact of microbial and chemical hazards regarding:

- **one hazard in different foods** (e.g., *Salmonella* in fresh produce vs. in nuts vs. in shell eggs)
- **multiple hazards in a single food** (e.g., considering only leafy greens: pathogenic *E. coli* vs. hepatitis A vs. *Cyclospora*)
- **multiple hazards in multiple foods** (e.g., *L. monocytogenes* in soft cheese, scombrotoxin in tuna, multiple other food/hazard pairs)

FDA-iRISK allows risk comparison across many facets of food production and safety. It includes built-in mathematical architecture for seven components of a food-risk scenario: food, hazard, population, food production/processing model, consumption patterns, dose-response model, and health effects. Flexibility and choice are prominent features of this tool; for example, users may include in the scenarios they create in FDA-iRISK not only various hazards and foods, but also any stages of the food-supply system and various consumer subpopulations.

(cont'd)

Examples of how FDA-iRISK can express results:

- **Mean risk of illness** (average probability of illness from one eating occasion)
- **Health-impact metric** (disability-adjusted life years – DALYs – i.e., healthy years of life lost to illness or death, per eating occasion or per year)
- **Ranking of risk** posed to various populations by different food/hazard combinations under various food-processing/handling practices

FDA-iRISK ensures broad accessibility and facilitate data sharing and integration, by FDA and the broader user community. The Web-based interface enables users across the world to share data and outcomes. FDA envisions that this tool will lead to an improved quantitative understanding of risk in the food-supply system. For example, one long-range potential is to provide centralized knowledge management; by capturing users' input and results, FDA-iRISK will, over time, build a consistent, documented, systematic, structured, quantitative picture of (1) risk in the food supply (2) scenarios for reducing the risk.

In the meantime, FDA will use FDA-iRISK to provide information about public-health impacts as input for risk prioritization, to inform risk management. For example, the model can inform decisions about allocation of resources for competing needs; about whether more detailed, in-depth risk assessments of a given food/hazard combination should be conducted; and about research priorities. FDA-iRISK is not intended to replace more complex, in-depth risk assessments of single food/hazard pairs; rather, it achieves a balance between complexity and practicality.

In October 2012, FDA made FDA-iRISK and a detailed tutorial available for public use. To access FDA-iRISK and the tutorial, please visit the FoodRisk.org Web site of the Joint Institute of Food Safety and Applied Nutrition (JIFSAN), the FDA partner that hosts the program. A recording of an introductory webinar also is available for public viewing on the JIFSAN site.

Ask FDA-iRISK: what if?

As a simplified case study, consider the following. Decision-makers likely will find it helpful to know not only the number of illnesses associated with a hazard in a broad category of food (such as those addressed by attribution models) – for example, leafy greens, dairy products, or seafood – but also to see a breakdown by product. An example would be to look at specific dairy products, such as milk, ice cream, and cheese, rather than at dairy products as a whole. FDA-iRISK can produce estimates of the risk posed by each of those dairy products (vis-à-vis the pathogen, toxin, or chemical in question), for comparison.

As a risk manager, you might be faced with a food-safety situation that requires you to ask FDA-iRISK to do nothing more than compare the public-health impact of two different hazards in one or more foods. But built into FDA-iRISK is the capacity also to ask, and get answers to, "what if" kinds of questions. What if we reduced the holding time or temperature for milk vs. various cheeses vs. high-fat dairy products, or changed other practices, at specific steps in those foods' production processes – by how much would the estimated public-health risk from the hazard in question change, for each of those products? For what populations, specifically? How would their risk-ranking change, relative to other food/hazard pairs?

FDA-iRISK results are presented in a brief, straightforward table, which is accompanied by a full, detailed report, for the user's reference. From the brief table, users may choose whichever expression of results best suits their needs. For example, risk managers in the food industry might have more interest in results expressed as mean risk of illness (i.e., risk per serving), whereas government regulators might have more interest in the total DALY (i.e., risk per year) results. In either case, the results will answer for them such questions as "What are the 10 riskiest food/hazard pairs generated by my search, and in what order? Would the interventions I'm proposing reduce their risks, and by how much?"

December 2012

FDA

EXHIBIT
25

My Account Login

FDA-iRISK 1.0

Home | Models | Reports | Sharing | Help

Home

FDA-iRISK is a web-based system designed to analyze data concerning microbial and chemical hazards in food and return an estimate of the resulting health burden on a population level.

The data required to execute this analysis include the food and its associated consumption data and processing/preparation methods, the hazard and its dose-response curve, and the anticipated health effects of the hazard when ingested by humans. Each of these elements contributes an essential piece of information to the model on which the final estimate of risk is based.

When you register, you will be assigned your own personal workspace in which to model food/hazard risk scenarios. You may also share this workspace with others to view.

For a complete description, review the Quick Start Tutorial and User Guide on the Help page before beginning.

Please Login or Register.

Suggested Citation

Where the FDA iRISK system is used in risk assessment research and other food safety activities, reference to the system should be made as follows:

Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN), Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and Risk Sciences International (RSI). 2012. FDA-iRISK version 1.0. FDA CFSAN. College Park, Maryland. Available at http://irisk.foodrisk.org/.

EXHIBIT
26

Guenther, Julia

From: Menikheim, Jody
Sent: Friday, January 04, 2013 1:06 PM
To: Guenther, Julia
Subject: FW: New FSMA Tool
Attachments: Briefing Book Exec. Summary 12-20-2011-FDA.pdf; Briefing Book -The Need FDA-12-20-2011 (2).pdf; Briefing Book -The Solution 12-20-2011-FDA.pdf

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, January 11, 2012 12:38 PM
To: Kautter, Donald; Menikheim, Jody
Cc: Scott, Jenny
Subject: FW: New FSMA Tool

Hi Don and Jody: This is just a follow-up to my e-mail to you before the holidays. I wanted to follow-up with you to see if we might be able to coordinate a mutually convenient time to meet with you. We need FDA's guidance with respect to a new product that we will be offering to the food industry. My contact information appears below. Thank-you. Best, John

John Hnatio, EdD, PhD
Chief Science Officer
ThoughtQuest LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-208
(C) 301.606.9403
(F) 240.439.4482

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Friday, December 23, 2011 2:34 PM
To: 'Donald.Kautter@fda.hhs.gov'; 'Jody.Menikheim@fda.hhs.gov'
Cc: bmichelson@thoughtquest.com; jenny.scott@fda.hhs.gov
Subject: New FSMA Tool

Don & Jody: We received you names from Jenny Scott who suggested that we contact you. We are a science and technology firm located in Frederick, MD. We have been conducting a multi-million dollar industry-based research program for some time now and we have just recently been issued a patent for a science-based approach to risk management that has significant applications for food safety, food defense and all hazards events that affect food operations across the supply chain. The software product we have developed is known as Food ProtectionTQ™ (with TQ standing for threat quotient) and is quantitatively based and applies rigorous science. We have built the product with the goal of helping small, medium and large businesses meet the new requirements of FSMA in a faster, cheaper and more effective way. We would like to describe what we have developed to you and the FDA to receive your guidance and inputs as we move forward to make the product available to the food industry. We plan to begin deployment of the product in tandem with FDA's implementation of FSMA in 2012. Attached is some very brief explanatory information that will give you an idea of what we have developed. My contact information appears below and we would look

forward to meeting with you if that is possible to demonstrate Food ProtectionTQ and receive your feedback. Happy Holidays to you both. Best, j

John Hnatio, EdD, PhD
Chief Science Officer
ThoughtQuest LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-208
(C) 301.606.9403
(F) 240.439.4482

ThoughtQuest LLC

We make your complex world simpler

BRIEFING BOOK: EXECUTIVE SUMMARY

JOHN HNATIO

DECEMBER 2011

INTRODUCTION

TQ is a small company that specializes in the development of advanced technologies. TQ holds a patent for the CSM METHOD®.

TQ has used the CSM METHOD® technology to develop Food ProtectionTQ™ (FPTQ), with TQ standing for threat quotient.

TQ has invested $5.16M to develop FPTQ

In June 2011, after the FPTQ prototype software was completed, the technology patent and FPTQ software were vetted and determined to be sound and functional by one of the world's big four AICPA audit firms

Since June 2011, the FPTQ software has been made commercial ready for beta deployment

The FPTQ value proposition	Reduces the cost of audit and assessment by a ROM of 60-70%
	Reduces the cost of emergencies by a ROM of 10%
	Reduces the incidence and cost of recalls
	Satisfies the new requirements of FSMA

SUMMARY

The food industry is being forced to change by new laws.

The traditional checklist approach to food safety no longer meets the requirements of new laws.

Food businesses work at the margin.

Food ProtectionTQ helps food producers meet new laws while reducing costs.

The technology risk is now minimal and the technology is well-protected by patents.

The to-market business strategy is to deploy to prove value and then sell the Food ProtectionTQ application.

The return on investment for Projectioneering LLC is on the sale of the technology for the agricultural field of use.

An experienced highly qualified team is in place.

THE FOOD INDUSTRY MARKET

The Food Industry Market

Food industry represents ~13% of GDP, $1.2T U.S. economic activity, 20% of U.S. employment (direct food and agriculture and supporting businesses).

There are ~500 large multinationals; ~25,000 high end producers; ~75,000 medium and small producers; 2 million + farms.

Total potential market for Food ProtectionTQ is ROM $11.7B.

Addressable market is divided into two significant components:1) audit, assessment and certification, and; 2) losses from all hazards events.

The food industry is one of the last major industry sectors to move into IT as a way to reduce risk and lower costs.

The food industry is under pressure from the federal government to produce safer food and to secure the food supply from attack.

For the first time, they face new mandatory requirements for food safety and food defense [Food Safety Modernization Act of 2011 (the "Act")] and they can be shut down for failure to satisfy the mandated requirements.

Food manufacturers must now maintain and be able to produce comprehensive records making IT essential to meeting new regulatory requirements and reducing costs.

THE PRODUCT: FOOD PROTECTIONTQ™

We have built a decision support software tool known as Food ProtectionTQ™ (with TQ standing for threat quotient) that does the following five things:

1. Reduces the cost of assessments and audits by a ROM of 70% to produce an aggregate cost savings in providing of assessment, audit and certification services to the food industry of ROM $3.8B/yr. against a total addressable market in this segment of ROM $5.3B;

2. Reduces the risk of equipment malfunction, accidents and other threats (including accidental and intentional poisoning, industrial accidents, fires, natural disasters and recalls)

3. Identifies strategies for preventing events before they happen

4. The use of Food ProtectionTQ could reduce the losses against all hazards events by a ROM of 14% to produce an aggregate cost savings to the food industry of at least ROM $896M/yr. against a total addressable market in this segment of ROM $6.4B/yr., and;

5. This product is the only risk and science-based tool of its kind designed to satisfy the requirements of FSMA at this time.

FOOD PROTECTIONTQ™ CONSISTS OF SIX TOOLS

Tool*	Functionality**
1. POISON™	Meta database of intentional and accidental poisonings, equipment failure, industrial accidents and natural disasters involving the safety of the food supply.
2. Food Mapper™	Database of all federal government food related regulations, directives and best industry practices searchable by agency, agent, food type, etc.
3. Food DefenseTQ™	Comprehensive computer automated assessment tool for conducting both assessments and audits of food defense programs at small, medium and large growers, suppliers, processors, transporters, distributors, wholesalers and retail stores.
4. Food SafetyTQ™	Comprehensive computer automated assessment tool for conducting both assessments and audits of food safety programs at small, medium and large growers, suppliers, processors, transporters, distributors, wholesalers and retail stores.
5. FEAST™	Computer driven assessment and simulation system designed to quickly analyze ongoing events and simulate projected events at food facilities to determine if they can be prevented.
6. FREE™	Computer driven tool that is used to support responses to food safety and defense emergencies.

THE MARKET DIFFERENTIATORS

Differentiators
The solution is faster, cheaper and better than today's checklist approach to food safety. Saves up to a ROM of 70% in audit, assessment and certification. A ROM of14% reduction in cost of all hazards events.
We use large data repositories that allow for the structuring and restructuring of data on the fly.
Provides technology to simplify and help businesses manage the complexity of federal requirements incumbent upon the food industry.
All data and standards used in the software are scientifically peer reviewed.
The TQ process and product focuses on preventing adverse consequences before they occur, while other technology focuses on a response to events.
Quantitative risk calculations for all aspects of actual operational performance.
Perpetual audit process using hardened plant-floor deployable tablet technology to reduce business and operational risk across the supply chain.
Works in real time.
Visualization of data using performance dashboards, hyperbolic trees and iconography, unique to our process, product and patent; iconographic applications are embedded directly into the software.
Allows customers to prevent events before they happen (using simulations).
Uses the computer to guide responses to food emergencies to limit losses.

THE TECHNOLOGY

The technology is based on a process patent issued from USPTO that can be used across different industry segments including food, biological laboratories and commercial production facilities, electrical power girds, petrochemical facilities, mass transit systems, airports and others.

Critical infrastructure applications of the technology focus on fixed site industry facilities and the assessment of risk and the prevention of intentional attacks, accidents, equipment malfunction and natural disasters.

The technology is "cookie cutter" so that it is highly scalable, i.e., can be applied in many different applications using the same software using new data to address multi-billion dollar addressable markets across other industries.

The Food ProtectionTQ system is functional and ready for deployment.

The technology patents and the operating system have been reviewed by an AICPA big four audit firm and determined to be sound and functional.

Science supporting the technology product has been "vetted" by a national laboratory, universities, independent research bodies, industry representatives and government institutions.

ThoughtQuest LLC
We make your complex world simpler

BRIEFING BOOK: THE NEED

JOHN HNATIO

DECEMBER 2011

SUMMARY

The food industry is being subjected to greater regulation than ever before.

Reducing costs while meeting greater regulatory pressures means that the food industry must make use of IT as never before.

Federal food agencies are demanding that the food industry move to science and risk-based methods.

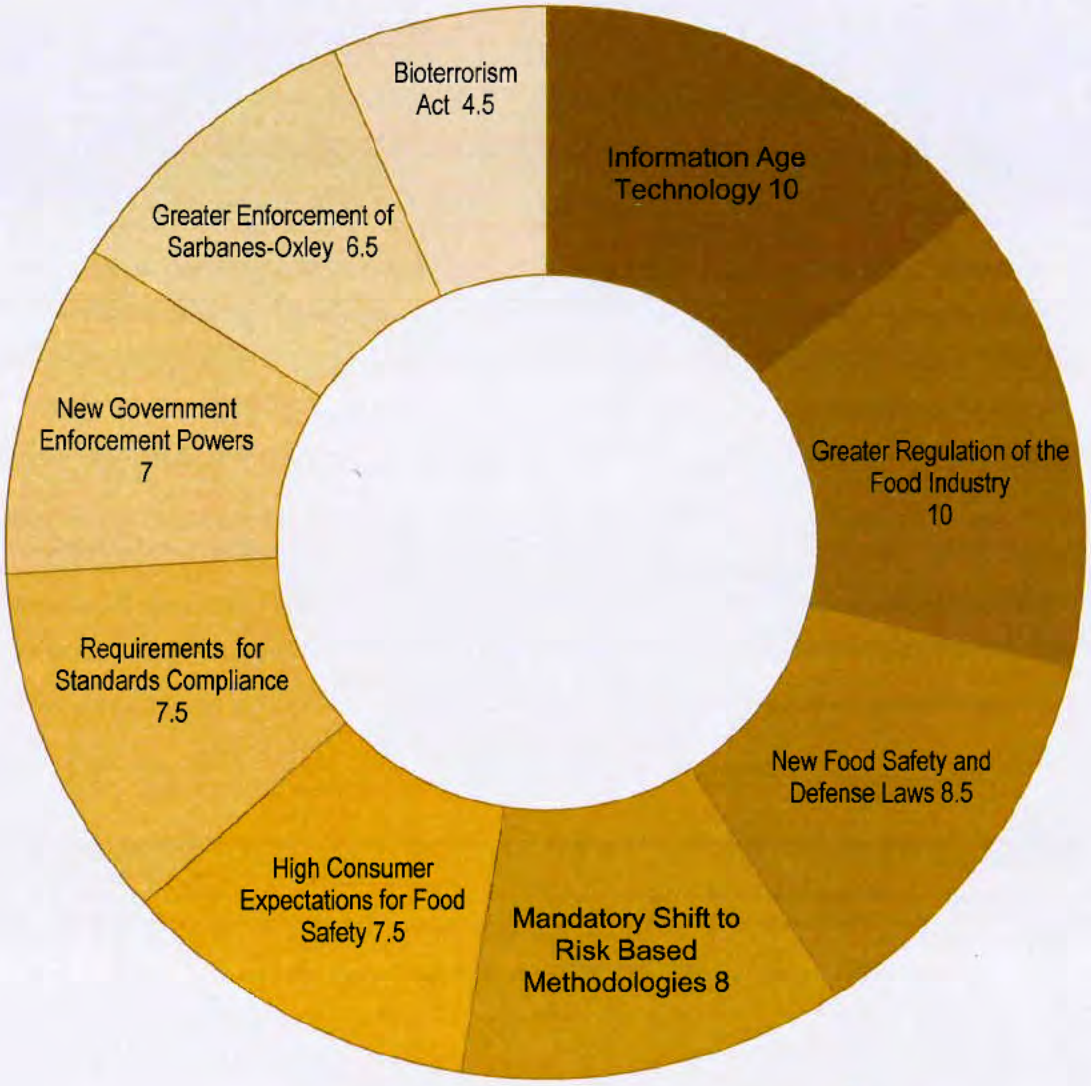
The food industry is being inundated with new and often conflicting compliance "checklists".

Greater regulatory pressures are being driven by new laws which give the federal government new authority to force plant shut-downs.

One example includes the new provisions of the Food Safety Modernization Act of 2011 that allows the government full access to food production records to demonstrate compliance.

The ~100,000 food facilities in the U.S. incur an estimated $5.1 billion each year on losses involving food poisonings, recalls, fires, industrial accidents, equipment malfunction and natural disasters.

Major Trends Facing the Food Industry

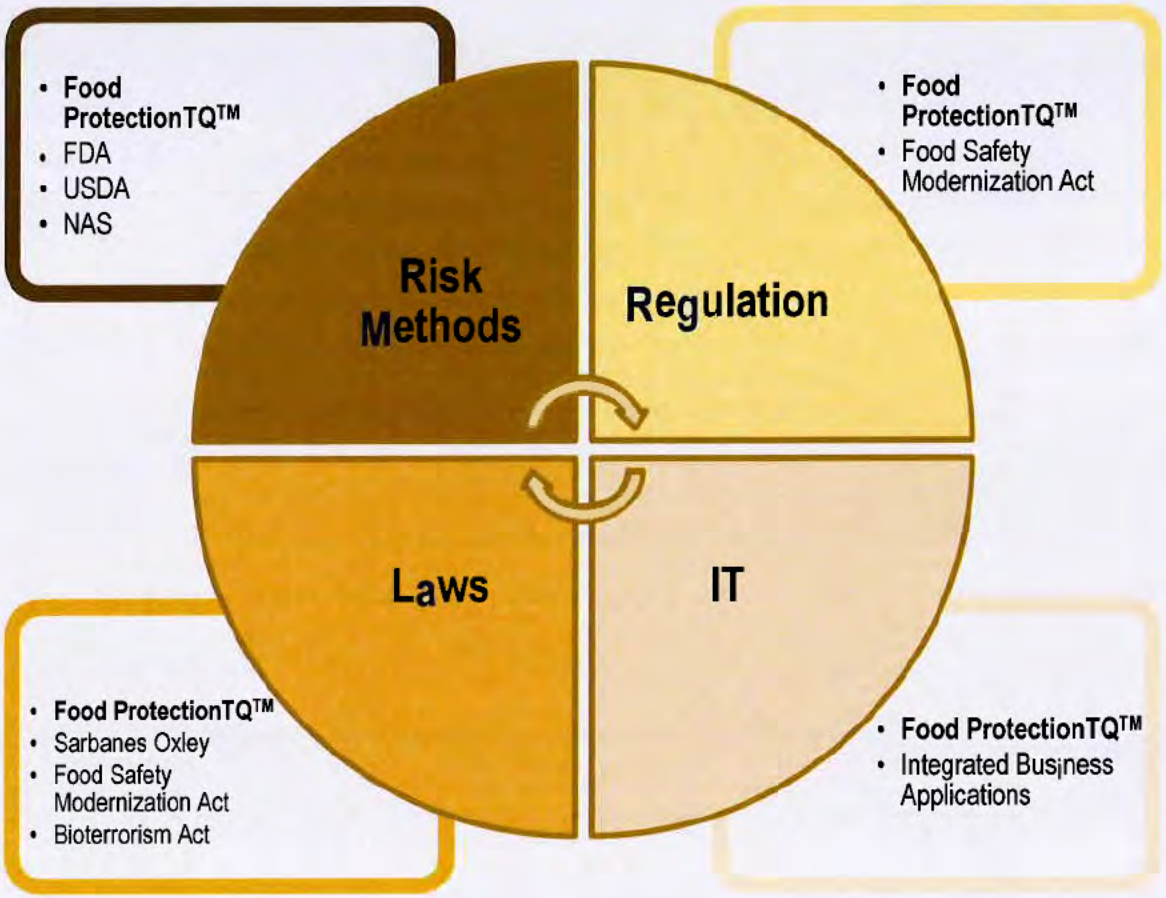


1-4 = Moderate Impact

5-7 = High Impact

8-10 = Very High Impact

FOOD INDUSTRY: DRIVERS FOR FOOD SAFETY SOLUTIONS



Food ProtectionTQ™ is the world's only fully automated risk-based assessment, audit and certification tool that when diligently implemented by the food industry will assure compliance with food safety statutes and government regulations.

REGULATION AND RISK METHODS

Food Safety Standards for the U. S. Fresh Produce Industry, by Marco A. Palma, Luis A. Ribera, Mechel Paggi, and Ronald Knutson, Agricultural & Applied Economics Association, May 2010

"A great many private and public sector resources are being invested in developing systems and often diverging standards that address food safety concerns at all levels of the supply chain. The proliferation of these standards, guidelines, and certification programs has created a situation that some have likened to an 'arms race' to prove who is providing the safest food...

The current labyrinth of food safety and protection standards includes, but is not limited to, those being promoted by international organizations, governments, producers, and food retailers—particularly supermarket and fast-food chains...

The bottom line is the need for a common set of science–based standards and regulations..."

http://www.aaea.org/publications/policy-issues/PI8.pdf

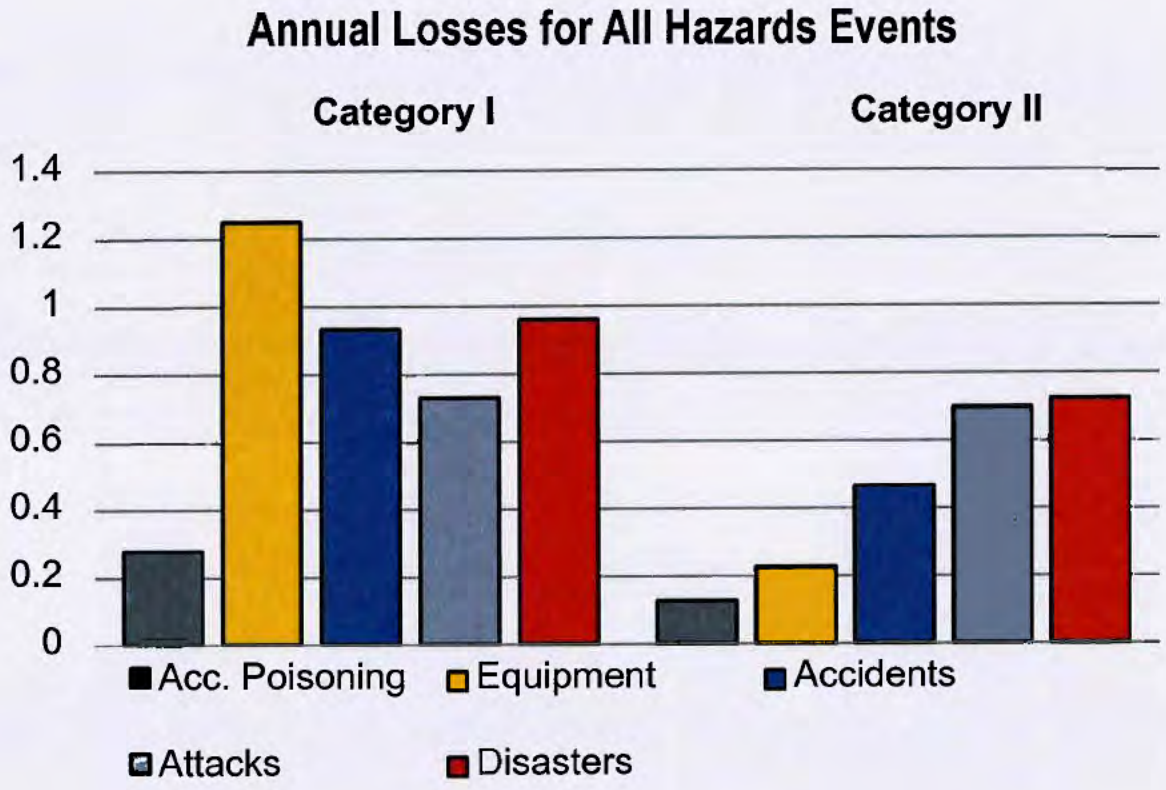
THE FOOD SAFETY MODERNIZATION ACT

Food Safety Modernization Act (FSMA)	Inspections: Food and Drug Administration inspections of food facilities would increase from about once every 10 years to at least annually for high-risk facilities and at least once every three years for facilities deemed a low risk. FDA inspectors will have access to company records. Registration: Food processors, importers and other food handlers must register annually with the FDA and pay a yearly fee of $500 for each food facility. Recalls: The FDA could mandate the recall of tainted foods, instead of relying on food makers to pull items voluntarily. Safe practices: For the first time, the FDA could set standards for safe production of food on farms, as well as require food manufacturers to meet safety standards. Imports: Those importing food to the United States must meet the same safety standards as domestic food producers. Traceability: The secretary of Health and Human Services would be required to identify technology that can be used by food growers, manufacturers and distributors to determine the origin of food and its movement in the supply chain.

ANNUAL FOOD INDUSTRY LOSSES ACROSS ALL HAZARDS EVENTS

The 100,000 food facilities in the U.S. incur an estimated **$5.1 billion each year** on losses.

- Category I: 25,000 Domestic Food Processors -- **$2.9 billion annually in losses**
- Category II: 75, 000 Suppliers, transporters, warehouse distributors and retailers -- **$2.1 billion annually in losses**



ThoughtQuest LLC
We make your complex world simpler

BRIEFING BOOK: THE SOLUTION

JOHN HNATIO

DECEMBER 2011

SUMMARY

The value proposition for Food ProtectionTQ is twofold:

Reduce the costs associated with assessment, audit and certification, and;	Reduce losses from all hazards events

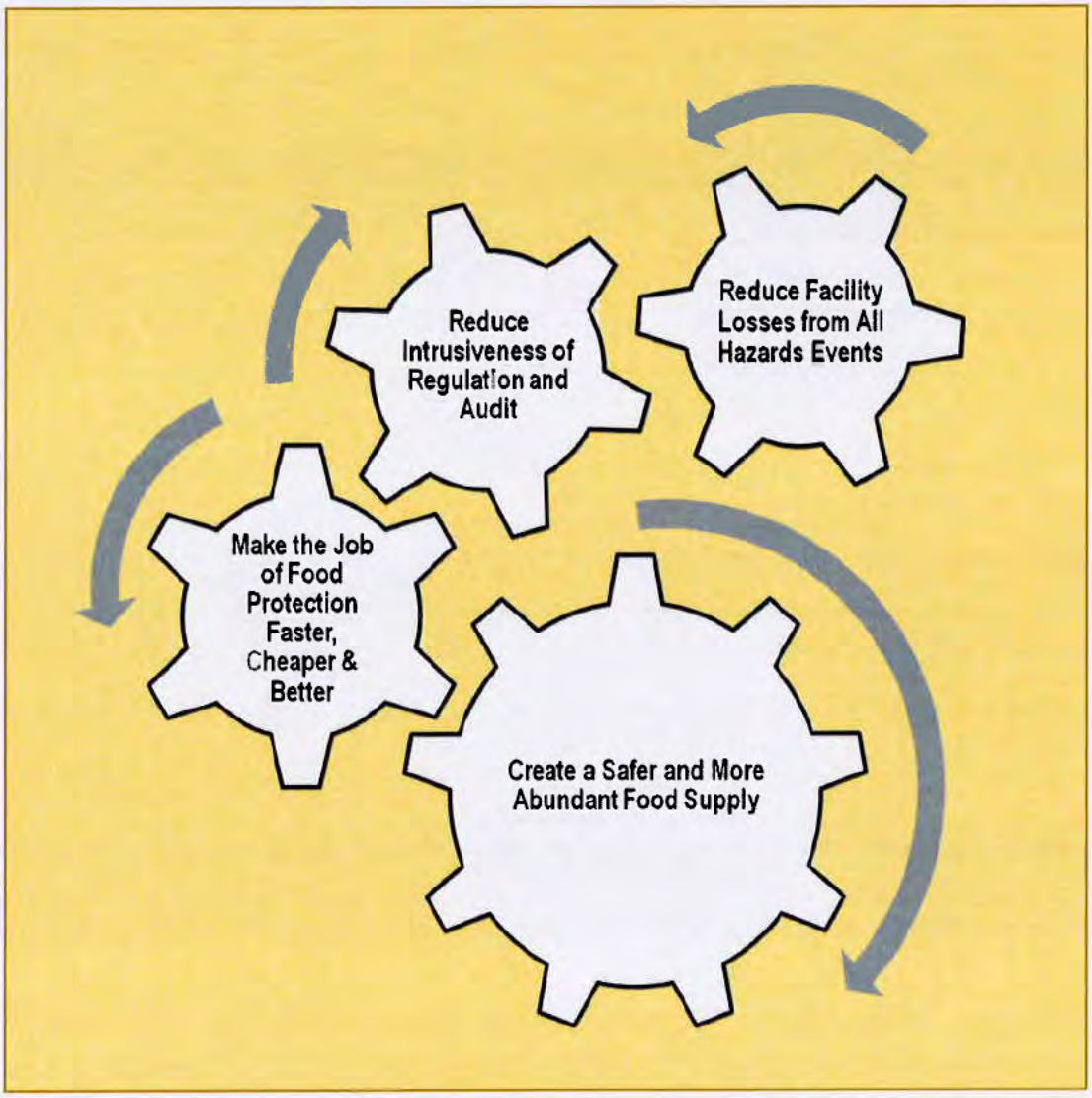
Food ProtectionTQ is an automated tool that makes the job of assessments and audits faster, cheaper and better than the current checklist approach

Food ProtectionTQ addresses food safety, food defense and prevents losses from intentional poisonings, accidental poisonings (food borne pathogens and other adulterants), industrial accidents and natural disasters.

Food ProtectionTQ is a suite of six computer software tools that work interdependently to assess performance, prevent all hazards events and guide responses to food emergencies

Food ProtectionTQ is a fully secure web-based software platform that leverages the "cloud"

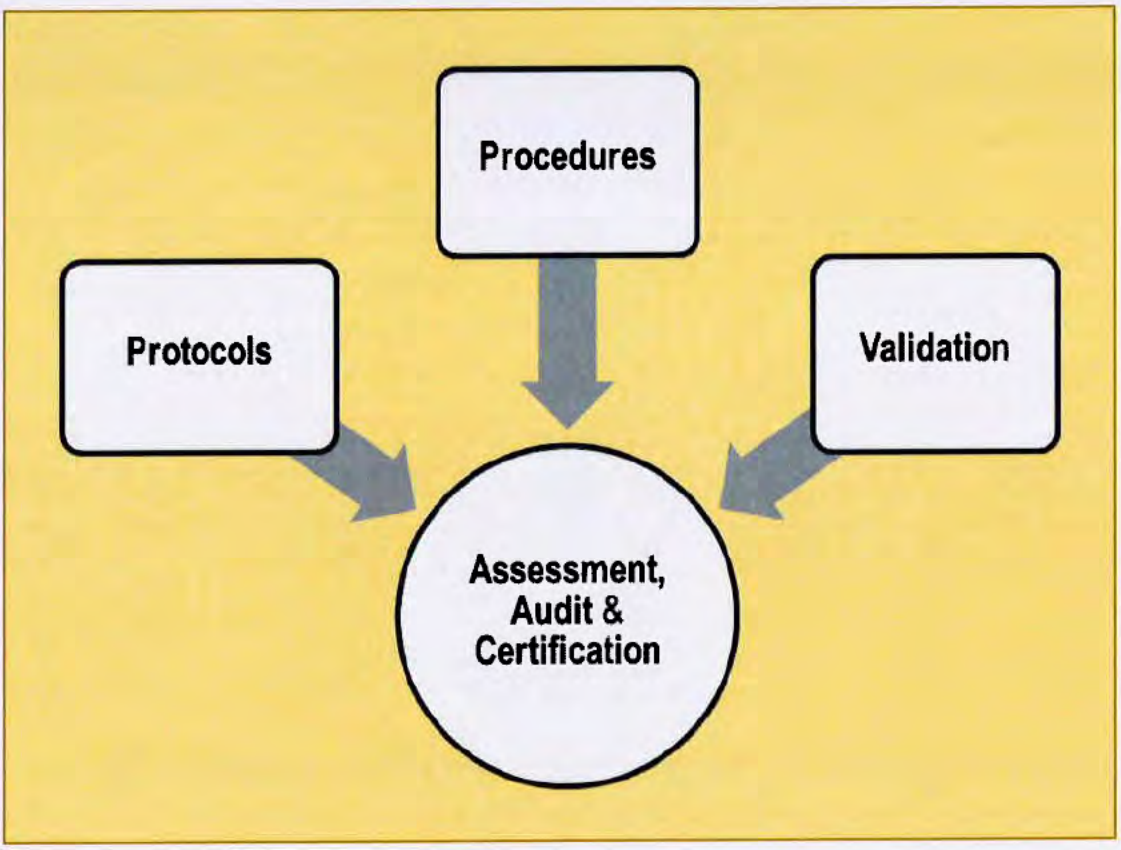
THE FOOD PROTECTIONTQ™ VALUE PROPOSITION



The Food ProtectionTQ™ value proposition:

Create a safer and more abundant food supply by making the job of protecting food and food facilities faster, cheaper and better

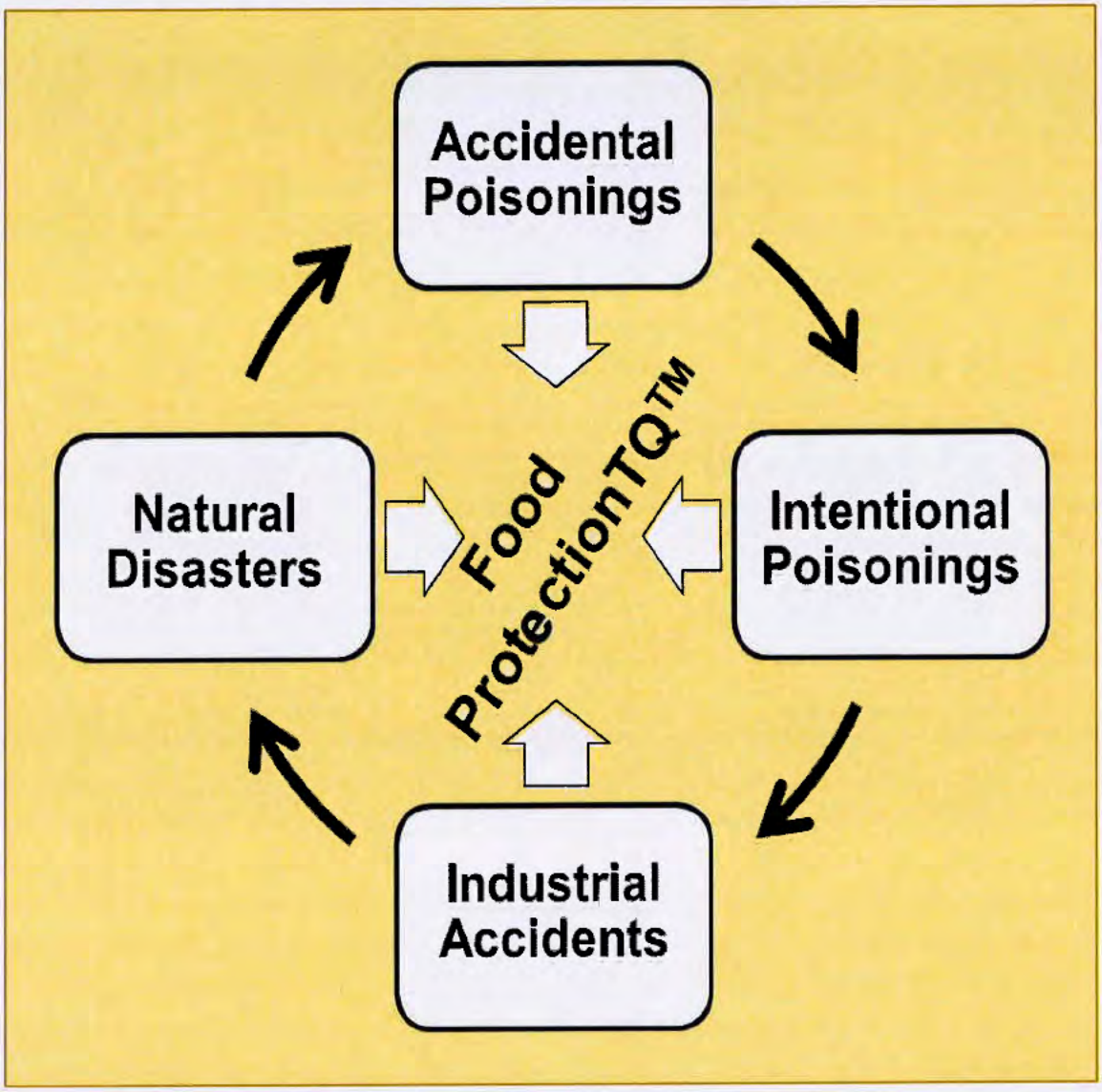
FOOD PROTECTIONTQ™ MAKES THE JOB OF ASSESSMENT, AUDIT AND CERTIFICATION FASTER, EASIER AND MORE EFFECTIVE



There are three critical aspects of assessment, audit and certification, namely:

1. **Written protocols**
2. **Procedures that implement the protocols**
3. **Validation that the procedures are implemented**

FOOD PROTECTIONTQ™ LOOKS ACROSS THE FOUR CATEGORIES OF ALL HAZARDS EVENTS



FOOD PROTECTIONTQ™ CONSISTS OF SIX TOOLS

Tool*	Functionality**
1. POISON™	Meta database of intentional and accidental poisonings, equipment failure, industrial accidents and natural disasters involving the safety of the food supply.
2. Food Mapper™	Database of all federal government food related regulations, directives and best industry practices searchable by agency, agent, food type, etc.
3. Food DefenseTQ™	Comprehensive computer automated assessment tool for conducting both assessments and audits of food defense programs at small, medium and large growers, suppliers, processors, transporters, distributors, wholesalers and retail stores.
4. Food SafetyTQ™	Comprehensive computer automated assessment tool for conducting both assessments and audits of food safety programs at small, medium and large growers, suppliers, processors, transporters, distributors, wholesalers and retail stores.
5. FEAST™	Computer driven assessment and simulation system designed to quickly analyze ongoing events and simulate projected events at food facilities to determine if they can be prevented.
6. FREE™	Computer driven tool that is used to support responses to food safety and defense emergencies.

EXHIBIT 27

Guenther, Julia

From: Menikheim, Jody
Sent: Friday, January 04, 2013 1:06 PM
To: Guenther, Julia
Subject: FW: Meeting Tomorrow
Attachments: FDA Briefing .pdf

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, February 01, 2012 2:01 PM
To: Menikheim, Jody
Cc: bmichelson@thoughtquest.com; David Park; Edward Berger; bbecker@sandybecker.com; Wright, Bill
Subject: RE: Meeting Tomorrow

Hi Jody: Attached please find some read aheads for tomorrow afternoon...what we plan to do is very quickly review the attached slides and then get immediately into the demonstration of the tools for you and whomever you'd like to include on your end...Dave Park and Dr. Michelson from ThoughtQuest and Bill Wright from MRIGlobal will be accompanying me...MRIGlobal does the scientific vetting of the data we use in our tools...look forward to meeting you face-to-face...see you at 1:00 tomorrow...best, j

---

From: Menikheim, Jody [mailto:Jody.Menikheim@fda.hhs.gov]
Sent: Thursday, January 26, 2012 8:33 AM
To: 'John Hnatio'
Subject: RE: Thank-you

John,
February 2nd at 1:00 works for me. Look forward to meeting with you and Dave. Thanks, Jody

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, January 24, 2012 2:05 PM
To: Menikheim, Jody
Subject: RE: Thank-you

Jody: Sounds real good...understand about FSMA and rulemaking...so we will hold on these questions until after rulemaking is complete...how about Thursday the 2nd at 1:00 pm? Best, j

---

From: Menikheim, Jody [mailto:Jody.Menikheim@fda.hhs.gov]
Sent: Tuesday, January 24, 2012 9:22 AM
To: 'John Hnatio'
Subject: RE: Thank-you

John,
I would welcome the opportunity for you and Dave to come to CFSAN and demonstrate the Food Protection tool you have developed. However, we will not be able to provide you any guidance. Since we are currently in the rulemaking process for the intentional contamination regulation, we are not able to discuss what we have developed so far for the intentional contamination regulation. I hope you understand that this no comment policy applies to all regulations during the rulemaking period. Again, I would be happy to see the tool you have developed but I will not be able to offer an opinion as it relates to FSMA. I am available in the afternoon on February 2nd, and after 11:00 on February 3rd if you would like to come in and demonstrate the Food Protection tool. Thanks, Jody

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, January 23, 2012 5:55 PM
To: Menikheim, Jody
Cc: David Park
Subject: FW: Thank-you

Hi Jody: We wanted to follow-up with you re: a possible date for Dave Park and I to come in and demonstrate the Food ProtectionTQ™ tools to you...what we need is guidance from you on the best way to integrate our technology with FSMA and current FDA technology initiatives like Carver + SHOCK and others...again, we are not looking for funding or any kind of endorsement...our customer base is small and medium folks in the supply chain...we are about to establish a national portal, i.e., **The National Food Protection Collaboratory™** that is designed to be the venue for new automated assessment, prevention and response tools to service the smaller fish swimming in the big food sea..we need about 45 minutes to show you our tools and receive guidance...we can tell you more about what we are doing when we meet..., best, j

John Hnatio, EdD, PhD
Chief Science Officer
ThoughtQuest LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-208
(C) 301.606.9403
(F) 240.439.4482

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, January 17, 2012 2:38 PM
To: 'Jody.Menikheim@fda.hhs.gov'
Cc: David Park (dpark@thoughtquest.com)
Subject: Thank-you

Jody: Thank you very much for calling...we want to reiterate to you and Cory that we are not trying to sell anything...we are about to put up a new national portal that will service the food industry and provide small and medium suppliers with a number of automated tools that we hope will help them better meet FSMA...we have already invested several million dollars in developing the new approach...but it is imperative that we do this in a way that supports you at the FDA and helps you help the medium and little food guys out there in the supply chain...our initial focus is squarely on medium and small sized food businesses who really need a better way to do things...thank-you for your guidance on how best to proceed...look forward to the possibility of talking with you. Best, j

ThoughtQuest LLC
We make your complex world simpler

FDA

FDA BRIEFING BOOK: FOOD DEFENSETQ™

JOHN HNATIO

FEBRUARY 2012

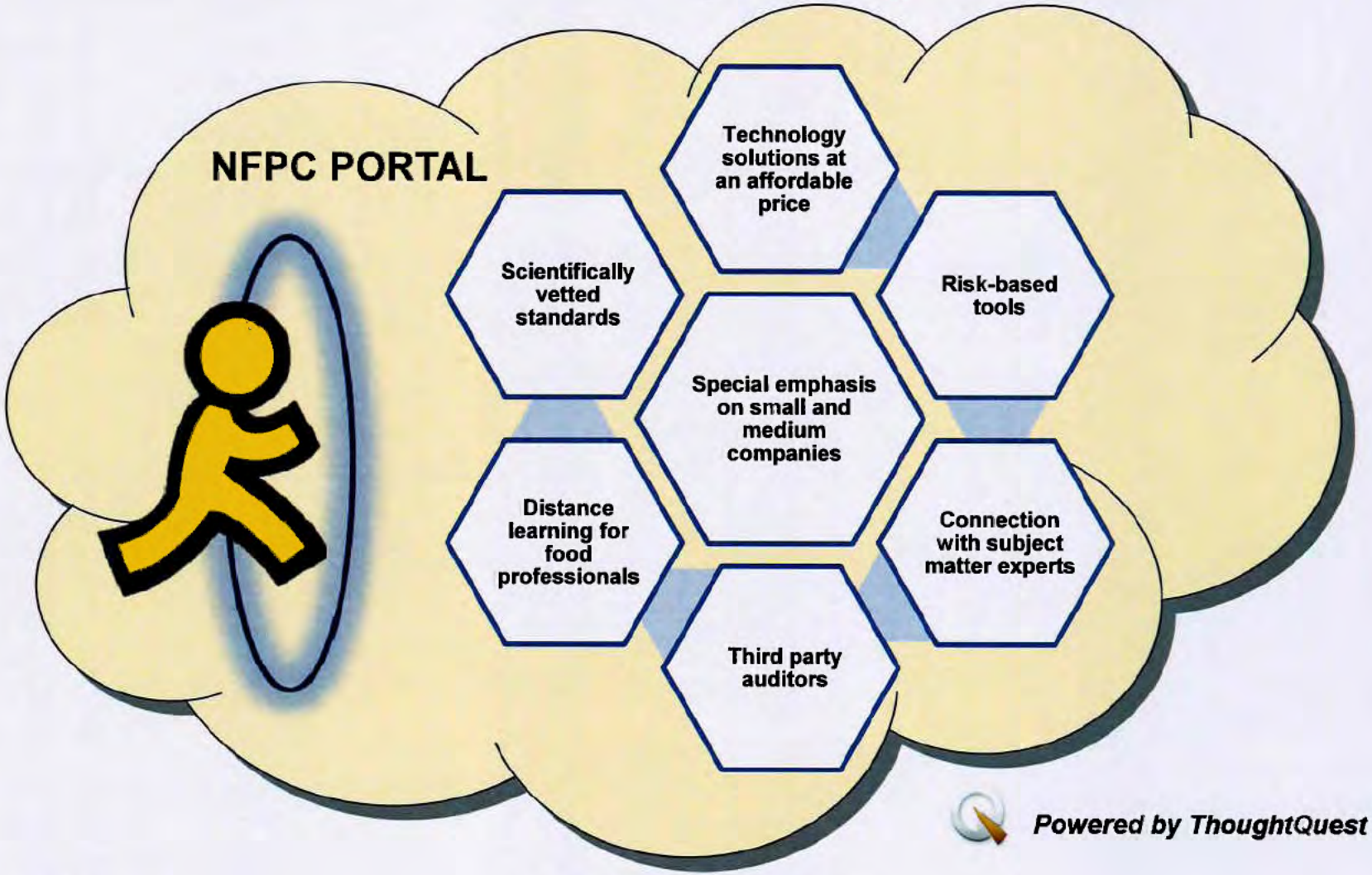
0605

SUMMARY

ThoughtQuest has developed a suite of patented science and risk-based tools known as Food ProtectionTQ™ (with TQ standing for threat quotient)	Address assessment, prevention and response
	Look at all-hazards events
	Science and risk-based
One of the tools is called Food DefenseTQ™ that looks at:	Food defense incidents
	Fires and arson
	Equipment failure
	Industrial accidents
	Natural disasters
Designed to support Carver + SHOCK	Uses quantitative risk values
	Computer intensive analytics
	All data is scientifically and independently vetted
We are now establishing the National Food Protection Collaboratory™ (NFPC) web-based portal to make the new technology available to small and medium sized food business	A community of interest for small and medium businesses around affordable easy to use technology solutions
	Science and risk-based vetted tools
	Low cost consulting to establish food defense plans
	Programs of food defense education

0606

THE NATIONAL FOOD PROTECTION COLLABORATORY™ (NFPC) PORTAL



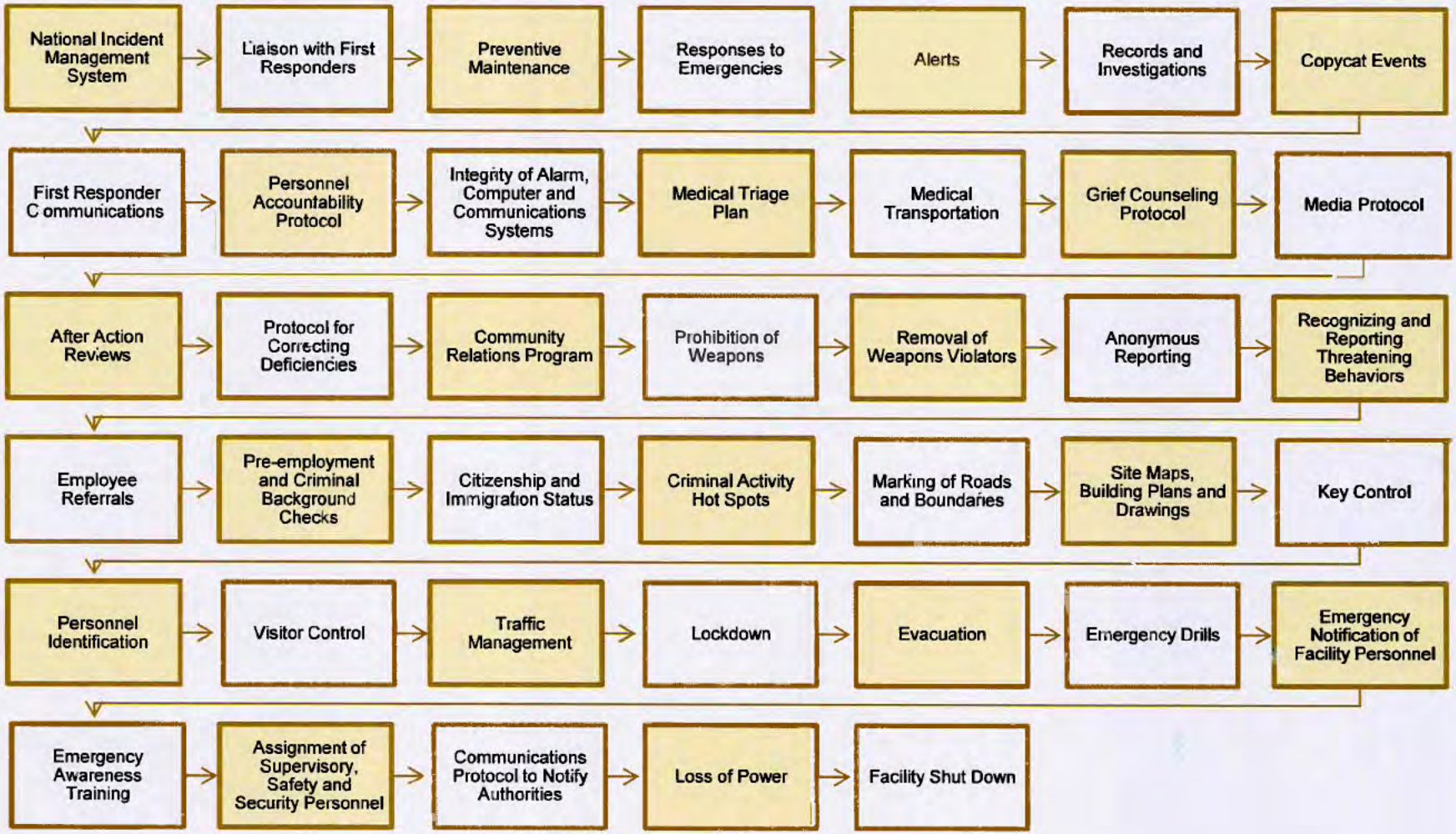
0607

ONE OF SIX TOOLS THAT COMPRISE FOOD PROTECTIONTQ™

FPTQ Tool	Capability	
POISON™	Repository of all hazards events affecting the food supply chain. By studying these past events:	Tells you what worked and what didn't work;
		Helps you figure out the best things to do when confronted with a similar situation, and;
		Helps identify the early warning signals to prevent bad things before they happen.
Food Mapper™	Powerful search engine of regulations and best practices that tells you:	Who's responsible for what;
		What you must comply with, and;
		The best industry practices.
Food SafetyTQ™ and ***Food DefenseTQ™***	***Real time assessment of all aspects of plant operations including food safety and defense to:***	***Tell if you are in compliance;***
		Tell if you are using best industry practices, and;
		What needs to be fixed and how.
FEAST™	Prevents all hazards events by:	Telling you the type of events most likely to happen at your facility, and;
		Telling you how to prevent the events from happening.
FREE Tool™	Guides more effective responses to food emergencies by:	Using an automated system that assures the most timely and effective responses

0608

FOOD DEFENSETQ™ (FDTQ) HAS 40 CROSS CUTTING SURVEY QUESTIONS



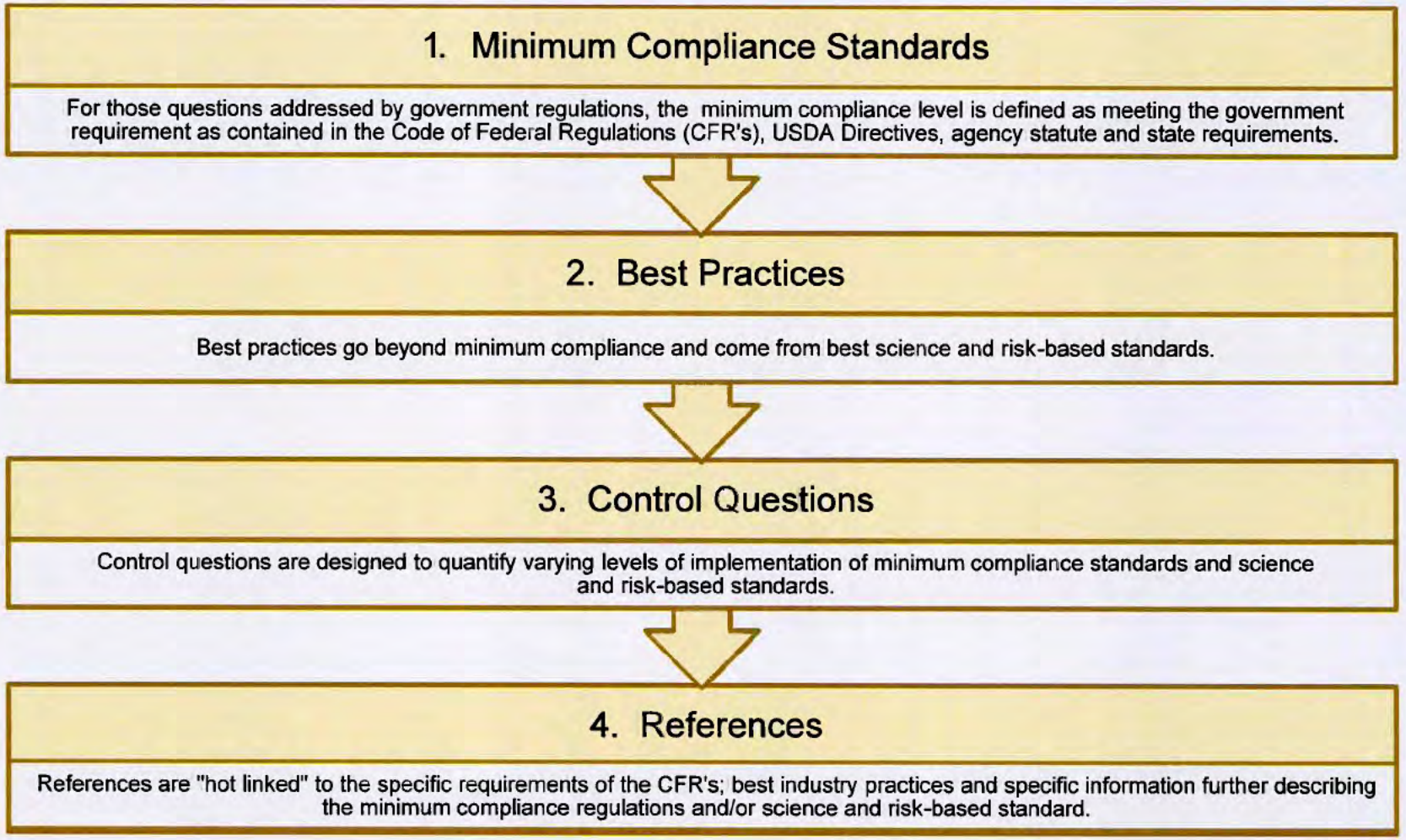
6090

FOOD DEFENSETQ™ HAS 75 CATEGORY SPECIFIC SURVEY QUESTIONS

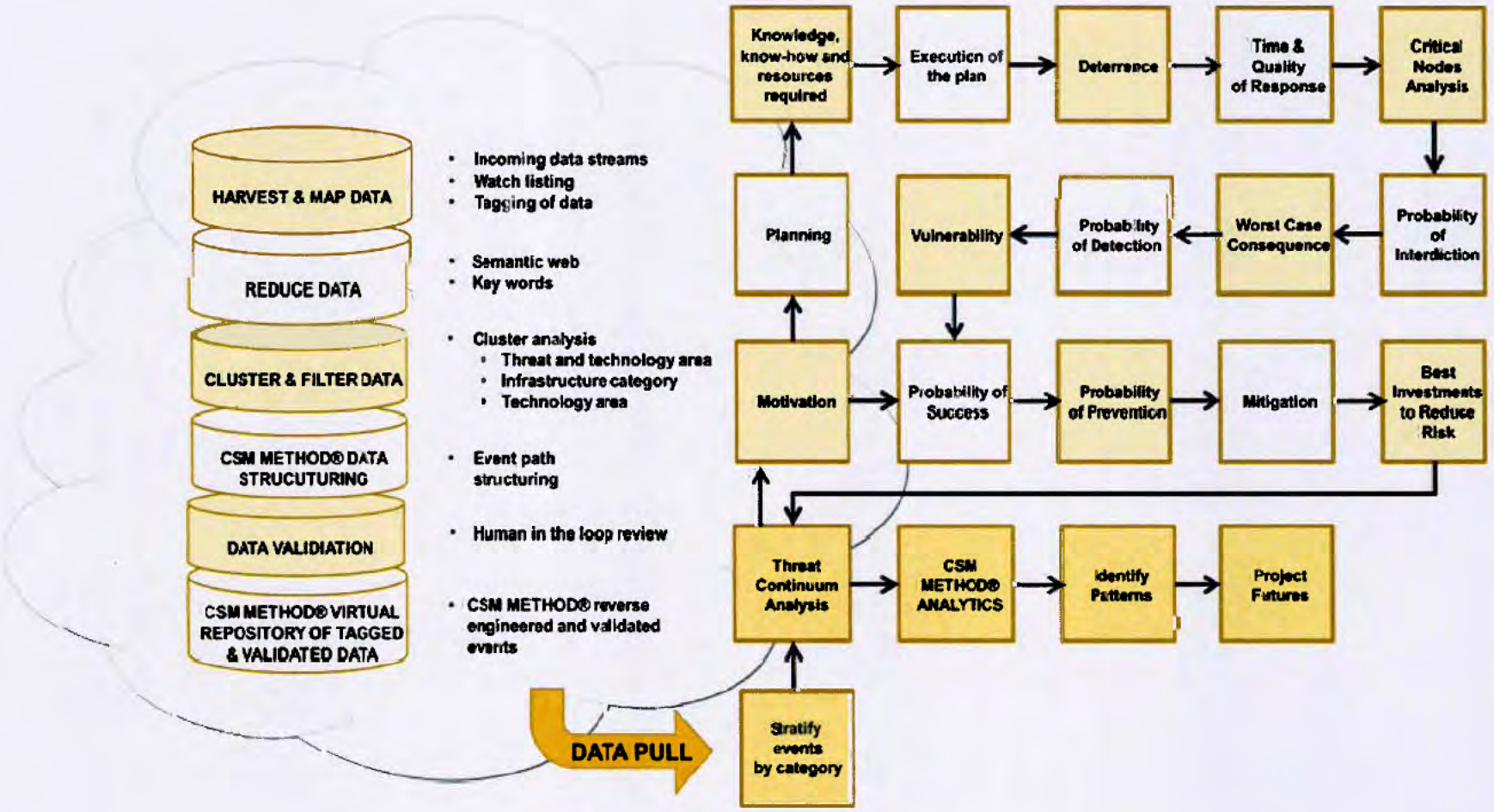
Adulteration of Food and Water	• Twelve Question Sets
Communicable Disease	• Eight Question Sets
Workplace Violence	• Six Question Sets
Improvised Destructive Devices	• Eight Question Sets
Fires and Arson	• Eleven Question Sets
Transportation Security	• Eight Question Sets
Nuclear, Biological, and Chemical Emergencies	• Eight Question Sets
Other Crimes	• Seven Question Sets
Natural Disasters	• Seven Question Sets

0610

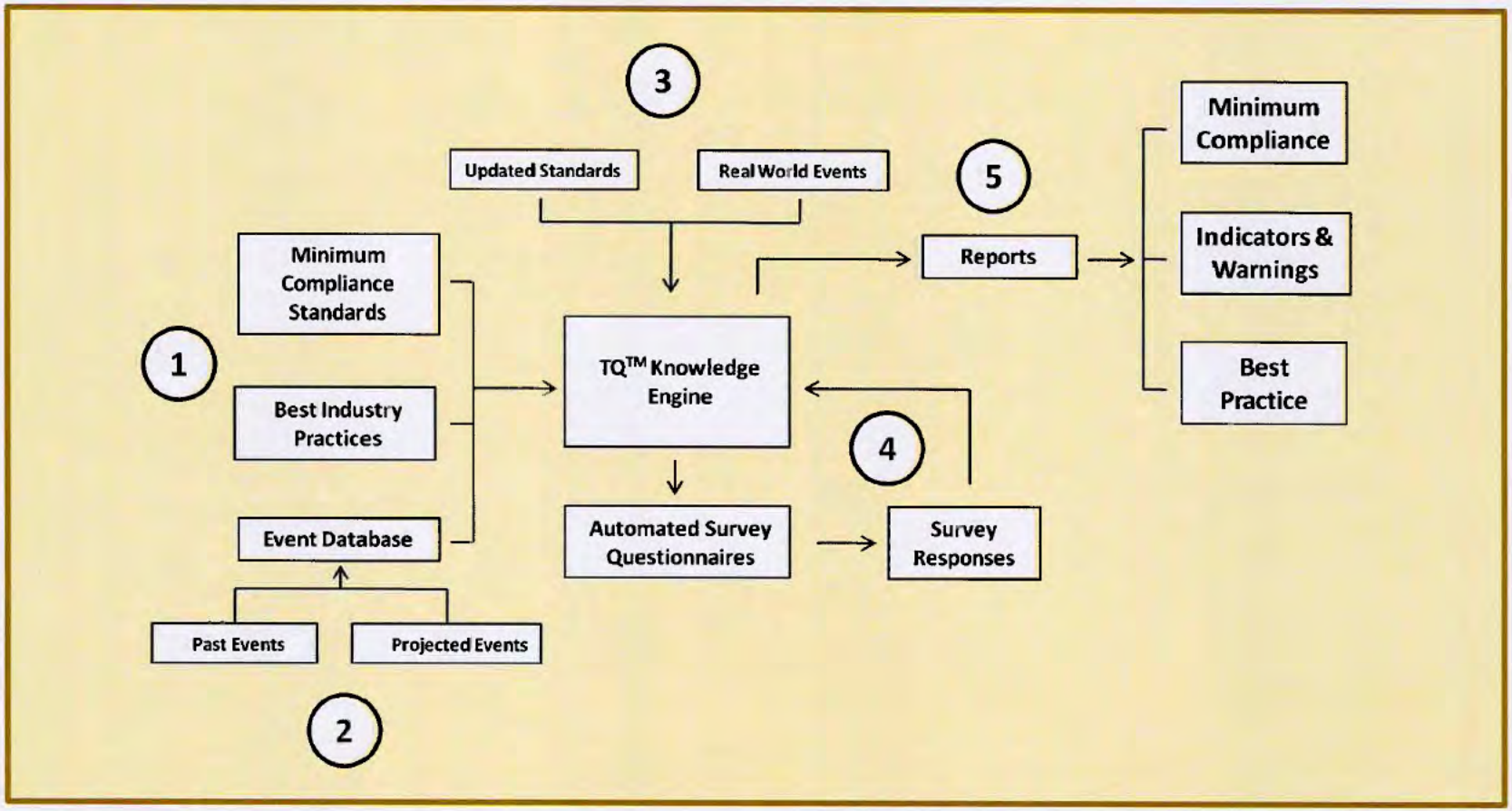
THE FOUR COMPONENTS OF AN FDTQ QUESTION SET



THE FOOD DEFENSETQ™ ARCHITECTURE



THE FDTQ SOFTWARE STRUCTURE



1. Food Mapper™ compliance standards and best industry practices
2. POISON™ to provide past and projected events
3. Real time threat and risk warnings/continuous 24/7 update of Food Mapper™ and POISON™
4. & 5. Food DefenseTQ™ and Food SafetyTQ™ assessment

0613

FDTQ APPLIES A UNIQUE SET OF ALGORITHMS TO TRANSFORM DATA

Function	Algorithm	Description
Probability of Occurrence	PO f (v) (c)	The probability of an adverse food event occurring (PO) is a function of the vulnerability (v) of the target multiplied by the worst case consequences (c) if the target were successfully attacked or interrupted
Mitigation	(v) (c) f m	The vulnerability of the target (v) multiplied by the consequences if it were successfully attacked or interrupted (c), become a function of the mitigating actions taken to prevent or limit the consequences of the attack or interruption as depicted by m
Natural Phenomenon	(v) f PO (c)	For natural events the vulnerability of the target (v) is a function of the probability of the natural event occurring based on frequency, trends analysis and modeling projections (PO) multiplied by the worst case consequences (c) should the target be subjected to a natural event
Estimate of Event Sequence Interruption (EESI™)	I f (dn_t))(c_t) (dy_t) (r_t) (r_q)	The interruption of an event sequence is a function of time of detection (dn_t), delay time (dy_t), time to communicate a response action (C_t), time to respond (r_t) and quality of response (r_q)

0614

FDTQ USES MULTIPLE COMPUTER INTENSE DATA ANALYTICS

EPA™ (Event Path Analysis)	Events are gathered, scientifically reverse engineered to produce event paths and grouped, based on category.
(v) (Vulnerability)	Each event is weighted based on the degree of vulnerability of the target.
(c) (Consequence)	Each event is weighted based on the potential worst case consequences of the event.
PO (Probability of Occurrence)	Each event is scored to produce a probability of occurrence (PO) value.
Mitigation	The factors that could mitigate the consequences of each event are systematically identified and weighted.
CNA™ (Critical Nodes Analysis)	A set of baseline critical nodes representing intersecting activities, i.e., vertices, for each event path are identified.
TCA™ (Threat Continuum Analysis)	Baseline values for deterrence, detection, prevention, response and mitigation are calculated for each critical node.
FEAST™ (Food Event Analysis and Simulation Tool)	Critical nodes are weighted against "actual" and "expected" performance.
	Actual and expected performance are graphically portrayed.
	Best investments are graphically portrayed.
EESI™ (Estimate of Event Sequence Interruption)	An estimate of the facility's ability to prevent the event is calculated.
DPA™ (Decision Path Analysis)	Each event is analyzed to identify critical decisions and decision paths to improve responses.

0615

FPTQ IS DESIGNED TO HELP COMPANIES BETTER MEET FOOD PROTECTION REQUIREMENTS

Requirements	FPTQ Capability
Science & risk-based standards	Standards are vetted by scientists
Mandatory recalls	Risk is quantitatively derived
Production of records	Automated recall management
Mandatory food defense	Epidemiological modeling
Enhanced food safety	Automated record keeping
Prevention	Perpetual food safety assessment
Enhanced traceability	Perpetual food defense assessment
Increased inspection	Modeling to prevent events
	Computer guided responses

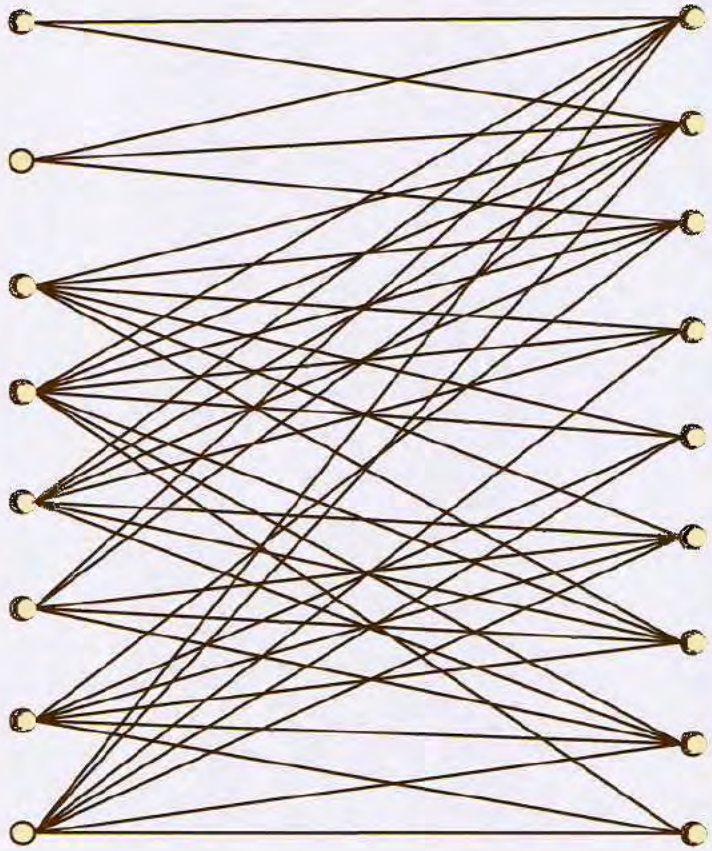


EXHIBIT 28

Seeley, Ariel

From: Menikheim, Jody
Sent: Wednesday, August 22, 2012 11:30 AM
To: 'John Hnatio'
Subject: RE: Jody this is John checking in

John,
Just tried calling your number but you were not at your desk and it wouldn't let me leave a message. I'll try later but you can call me at 240-402-1864 if you get a chance. Thanks, Jody

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, August 22, 2012 7:57 AM
To: Menikheim, Jody
Subject: RE: Jody this is John checking in

Hi Jody. Absolutely. My number is 240-439-4476 x-11. Just call whenever convenient for you. Should be at my phone today. Best, j

---

From: Menikheim, Jody [mailto:Jody.Menikheim@fda.hhs.gov]
Sent: Tuesday, August 21, 2012 6:45 PM
To: jhnatio@thoughtquest.com
Subject: Re: Jody this is John checking in

John,
Are you available to talk tomorrow morning. I have a meeting from 9-10 but I am available after that to discuss a future meeting. Thanks, jody

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Monday, August 20, 2012 08:59 AM
To: Menikheim, Jody
Cc: Bruce Becker <bbecker@foodquesttq.com>
Subject: FW: Jody this is John checking in

Jody: We know you are busy but just following up on our earlier e-mail of the 10th. How are things looking on your end? Best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-208
(C) 301.606.9403

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Friday, August 10, 2012 10:03 AM

To: 'Menikheim, Jody'
Cc: Bruce Becker (bbecker@foodquesttq.com); Dave Park (dpark@foodquesttq.com); Wright, Bill (bwright@mriglobal.org); 'sherri.mcgarry@fda.hhs.gov'; 'Leeanne.Jackson@fda.hhs.gov'; 'donald.zink@fda.hhs.gov'; david@leavittpartners.com
Subject: RE: Jody this is John checking in

Jody: We'd like to have you over (or come over to your place) to brief you. Our agenda remains unchanged from last summer when we first met. We need FDA's guidance and input as we move forward in order to push the FoodQuestTQ and FDA shared agenda of a safer food supply with industry. As we have emphasized before, we work for private food sector food companies. So the purpose of our meeting is to show you what we have done; share the high levels of interest we are getting from food industry players and to understand better how and what we can do to help the FDA achieve its objectives by better serving our private sector clients.

On July 10th we released:

1. Food Mapper™, a powerful search engine that lets you find state and federal standards and industry best practices by food type, pathogen and many other ways;
2. Food DefenseTQ™ (TQ stands for threat quotient) which is a perpetual food defense assessment/audit software tool that is tailored to company size and position along the food supply chain, i.e., they are asked only those questions about food defense that pertain to their position on the chain;
3. Food SafetyTQ™ which is a perpetual food safety assessment/audit software tool that is tailored to company size and position along the food supply chain, i.e., they are asked only those questions about food safety that pertain to their position on the chain;

We have now completed and will release our Food Defense Architect™ software which guides food companies of various sizes along the supply chain from growers, processors, transporters, warehousers, retail distribution centers, grocery stores, convenience stores and restaurants to build tailored and highly robust food defense plans for their specific types of operations. The tool will be officially released at our portal for sale to the industry on August 15th. We will demonstrate the current capability of Food Defense Architect and Food Safety Architect™ (which does the same thing for food safety) as part of the brief.

We were very well received by the industry at the IAFP meeting. This is how we ran into Dr. Jackson. Leeanne asked David Park (who you met at our last meeting) to arrange for an FDA team briefing. Since we have worked with you, I thought the best way to coordinate the brief was to work through you. Am I doing this correctly? At the IAFP, Don Zink suggested that Sherri McGarry might want to sit in on the brief to hear about the Food Event Analysis and Simulation Tool, FEAST™ the Food Response Emergency Evaluation or FREE Tool™. We are also working with David Acheson (Leavitt Partners), MRI Global (formerly the Midwest Research Institute), and our Canadian and Mexican colleagues to stand up an industry Rapid Response Deployment Team (RRDT) to support small and medium food companies manage recalls. Don thought that this would be of interest to Sherri.

We are available to brief the FDA team in late August or early September at whatever time/day is convenient for the staff. Please advise and we will adjust our schedules to accommodate. I look forward to seeing everyone and sharing ideas. Best, j

---

From: Menikheim, Jody [mailto:Jody.Menikheim@fda.hhs.gov]
Sent: Wednesday, July 25, 2012 5:42 PM
To: jhnatio@thoughtquest.com

Subject: Re: Jody this is John checking in

John,
Sorry for the delay in my response from your email last week. Things have been real busy. I look forward to speaking with you and hearing about the progress you have made. Thanks, jody

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, July 25, 2012 05:16 PM
To: Menikheim, Jody
Subject: Jody this is John checking in

Jody: Wanted to give you a heads up...we were out here at the IAFP and David Park ran into LeAnne and gave her a short run-down on the progress we've made on the tools and our new portal...LeAnne asked if we could participate in a team brief on what we are doing. We're glad to give you a run down too but just wanted to let you know about the chance encounter out here. I will call next week to follow-up. Best, j

Seeley, Ariel

From: Menikheim, Jody
Sent: Wednesday, September 12, 2012 2:05 PM
To: 'John Hnatio'
Subject: RE: Hnatio-Follow-up

John,
I am finishing up with interviews this week on a couple of positions within the office, and I will let you know by the end of the week which days may work next week for a meeting. Thanks, Jody

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, September 06, 2012 3:07 PM
To: Menikheim, Jody
Cc: 'Bruce Becker'
Subject: Hnatio-Follow-up

Hi Jody.

This is to follow-up on our earlier call to set a date for us to get together. We are really looking forward to showing you our new Food Defense Architect™ tool.

The tool is really neat...it looks across food defense criteria as they apply to small, medium and large companies at each point along the supply chain, i.e., at the individual needs of growers, processors, transporters, warehousing, food service, retail distributors and restaurants. In other words, the tool helps companies of different sizes who are doing different things on the supply chain quickly and easily build tailored food defense plans for their operations.

Also, we got the word from GMA that there's a meeting on December 12th between FDA and a number of food companies to seek industry's cooperation in building out a food defense planning tool. That's one of the reasons we're so excited to show you what we have done. Based on what I've heard about what you are trying to do, I think you will really like it.

On our call a couple of weeks ago, we talked about the second/third week in September. We can work to be flexible so as to work around people's schedules on your side since you have more kittens to herd than we do. How's it looking on your side? Best, j

Guenther, Julia

From: Menikheim, Jody
Sent: Thursday, April 04, 2013 7:53 AM
To: Guenther, Julia
Subject: FW: Hnatio-Follow-up

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Thursday, September 06, 2012 3:07 PM
To: Menikheim, Jody
Cc: 'Bruce Becker'
Subject: Hnatio-Follow-up

Hi Jody.

This is to follow-up on our earlier call to set a date for us to get together. We are really looking forward to showing you our new Food Defense Architect™ tool.

The tool is really neat...it looks across food defense criteria as they apply to small, medium and large companies at each point along the supply chain, i.e., at the individual needs of growers, processors, transporters, warehousing, food service, retail distributors and restaurants. In other words, the tool helps companies of different sizes who are doing different things on the supply chain quickly and easily build tailored food defense plans for their operations.

Also, we got the word from GMA that there's a meeting on December 12th between FDA and a number of food companies to seek industry's cooperation in building out a food defense planning tool. That's one of the reasons we're so excited to show you what we have done. Based on what I've heard about what you are trying to do, I think you will really like it.

On our call a couple of weeks ago, we talked about the second/third week in September. We can work to be flexible so as to work around people's schedules on your side since you have more kittens to herd than we do. How's it looking on your side? Best, j

Seeley, Ariel

From: Menikheim, Jody
Sent: Tuesday, September 25, 2012 5:12 PM
To: 'John Hnatio'
Subject: RE: Hnatio Check

John,
2-3 on Tuesday works for LeeAnne and I and perhaps some other members of the food defense team. Thanks, Jody

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, September 25, 2012 5:05 PM
To: Menikheim, Jody
Cc: 'Bruce Becker'
Subject: RE: Hnatio Check

Jody: Would Tuesday afternoon sometime for an hour webinar work for you and LeeAnne? Best, j

---

From: Bruce Becker [mailto:bbecker@foodquesttq.com]
Sent: Tuesday, September 25, 2012 4:59 PM
To: John Hnatio
Subject: Re: Hnatio Check

Available Monday afternoon and all day Tuesday.

Sent from my iPhone

On Sep 25, 2012, at 4:52 PM, "John Hnatio" <jhnatio@thoughtquest.com> wrote:

> Bruce: What day is better for you? Best, j
>
> ---
>
> **From:** Menikheim, Jody [mailto:Jody.Menikheim@fda.hhs.gov]
> **Sent:** Tuesday, September 25, 2012 4:50 PM
> **To:** John Hnatio
> **Subject:** RE: Hnatio Check
>
> John,
> I was talking with LeeAnne today and we have some time available on October 1st or 2nd to meet. However, a webinar would work just as well. Let me know what works best for you. Thanks, Jody
>
> ---
>
> **From:** John Hnatio [mailto:jhnatio@thoughtquest.com]
> **Sent:** Tuesday, September 25, 2012 1:54 PM
> **To:** Menikheim, Jody
> **Cc:** 'Bruce Becker'
> **Subject:** Hnatio Check
>
> Hi Jody: Just checking in. With everybody so busy I was wondering if you would be amenable to a webinar instead of a formal meeting for us to show you the Food Defense Architect tool. Can you guys join a webinar of your government computers? I think this would be a lot easier to do. We are most interested in showing you the capability so if others can attend that OK but if they are too busy that's OK too. We can always share with them later if you'd like us to do so. If you can join a webinar for an hour sometime next week I can go ahead and schedule it. You can send e-mail invites to others and they can join if interested too. What do you think? Best, j

Sent: Tuesday, September 25, 2012 1:54 PM
To: Menikheim, Jody
Cc: 'Bruce Becker'
Subject: Hnatio Check

Hi Jody: Just checking in. With everybody so busy I was wondering if you would be amenable to a webinar instead of a formal meeting for us to show you the Food Defense Architect tool. Can you guys join a webinar of your government computers? I think this would be a lot easier to do. We are most interested in showing you the capability so if others can attend that OK but if they are too busy that's OK too. We can always share with them later if you'd like us to do so. If you can join a webinar for an hour sometime next week I can go ahead and schedule it. You can send e-mail invites to others and they can join if interested too. What do you think? Best, j

EXHIBIT 29

Seeley, Ariel

From: John Hnatio [jhnatio@thoughtquest.com]
Sent: Monday, October 01, 2012 1:03 PM
To: Menikheim, Jody; Jackson, LeeAnne
Cc: 'Bruce Becker'; Dave Park
Subject: Read Ahead for Tomorrow
Attachments: Food Defense ArchitectTM Specifications.pdf

Jody/LeAnne: Hi. Attached is a read ahead for tomorrow's webinar. Please share it with others in FDA who are interested in attending. It provides in bullet form a description of the software tools that we will show you tomorrow. See you tomorrow at 2pm. Best, j

Food Defense Architect™ Specifications

1. Food Defense Architect addresses over one thousand specific food defense performance criteria as drawn from:
    a. Food safety and food defense experts
    b. Industry
    c. Former government intelligence officials
    d. Former FBI agents
    e. Public Health Command (AVC)
    f. State public health and safety officials
    g. Psychologists
    h. Law enforcement
    i. National Guard (multidisciplinary)
    j. Publicly available standards including:
        i. FDA
        ii. USDA
        iii. OSHA
        iv. DHS
            1. FEMA
        v. Other federal agencies
        vi. Codex Alimentarius
        vii. WHO Food Security and Bioterrorism
        viii. BSI
            1. PAS 96:2010
            2. PAS 220:2008
        ix. GMA SAFE
        x. IFS-V-6
        xi. SQF
        xii. F034- BRC Global Standards Auditor Checklist
        xiii. ISO/TS 22002-1
        xiv. GFSI Benchmarking Standards
            1. FSDM-19-23
            2. FSM 16-22
    k. Publicly available best food industry practices.

2. Food Defense Architect provides a threat quotient (TQ), i.e., level of importance for each criterion in creating a robust food defense program. This is done by numerically weighting the value of each individual criterion in deterring, detecting, preventing, responding and mitigating a food defense event.

3. Food Defense Architect considers each food defense criterion as it applies to small, medium or large food companies across each element of the food supply chain:

a. SML: Growers
b. SML: Processors
c. Transportation: All
d. Warehousing: All
e. Retail Distribution: All
f. Grocery Stores: All
g. SML: Food Service (including caterers)
h. Convenience Stores: All
i. SML: Restaurants

4. Food Defense Architect addresses 35 cross-cutting ***Food Defense Core Areas.*** Food Defense Core Areas comprise the basic organizational infrastructure that must be in place to support a robust food defense program.

a. Food Defense Awareness Training (FDAT)
b. Anonymous Food Defense Reporting (AFDR)
c. Food Defense Security of Alarms, Computers and Communications (FDSACC)
d. Physical Security (PS)
e. Assignment of Supervisory Food Defense, Food Safety and Security Personnel (ASFDP)
f. Diagnosis and Early Detection of System Abnormalities (DFDA)
g. Food Defense Hot Spots (FDHS)
h. Reliability of Food Defense Vendors and Suppliers (RFDVS)
i. Protocol for Company and Vendor Transportation System Security (PCVTS)
j. Protection of Critical Equipment (PCE)
k. Liaison with Food Defense First Responders (LFDR)
l. Communications with Food Defense First Responders (CFDFR)
m. Food Defense Access Controls (FDAC)
n. Food Defense After Action Reviews (FDAAR)
o. Protocol for Correcting Food Defense Deficiencies (PCFDD)
p. Protocol for Notifying Food Defense Authorities (PNFDA)
q. Food Defense Site Maps and Building Drawings (FDSM)
r. Marking of Roads and Boundaries (MRB)
s. Food Defense Records and Investigations (FDRI)
t. Food Fraud (FRAUD)
u. Food Defense Recall Management Plan (FDRMP)
v. Food Defense Media Protocol (FDMP)
w. National Incident Management System (NIMS)
x. Monitor for Serial Crimes and Copycat Events (MCE)
y. Community Relations Program (CRP)
z. Prohibition of Firearms, Explosives and Incendiaries (PFAEI)
aa. Contraband Searches (CS)
bb. Pre-employment and Criminal Background Checks (PECBC)
cc. Citizenship and Immigration Status (CIS)

dd. Food Defense Key Control (FDKC)
ee. Personnel Identification (PI)
ff. Parking Management and Vehicular Searches (PMVS)
gg. Facility Lockdown (FLD)
hh. Facility Loss of Power (FLP)
ii. Facility Shutdown (FSD)

5. Food Defense Architect addresses 6 specific ***Food Defense Categories of Interest*** that must be addressed under a food defense program:

    a. Preventing the Destruction and Sabotage of Critical Equipment and Facilities (PSCF)
    b. Protecting Facility Personnel (PFP)
    c. Preventing the Intentional Poisoning of Food and Water (PIPFW)
    d. Preparing for and Responding to Natural Hazards Events (PRNH)
    e. Responding to Site and Food Defense Emergencies (RSFDE)
    f. Implementing a Continuity of Operations Plan (COOP)

6. Food Defense Architect is a quality versus compliance driven tool (although minimum standards can be identified). Uses a scale of:

    a. Does Not Meet Expectations
    b. Meets Expectations
    c. Exceeds Expectations

7. Allows users to filter food defense criteria by company size to answer the question: What criteria apply to me?

8. Allows users to filter food defense criteria by location on the food supply chain to answer the question: What criteria apply to me?

9. Allows users to filter food defense criteria by government agency, standards and GFSI benchmark to answer the question: What do I need to do?

10. Provides step by step instructions on what the user must do to "Meet" and/or "Exceed Expectations".

Food DefenseTQ™ Specifications

1. Uses the identical criteria used in Food Defense Architect.

2. Allows users to continuously monitor the performance of their food defense programs based on the plan they developed using Food Defense Architect, i.e., conduct perpetual assessment.

3. Scored by the use of threat quotients, i.e., the statistical value of the criterion in terms of deterrence, detection, prevention, response and mitigation.

Food Mapper™

1. Allows users to search government standards and regulations in the CFR by food type, pathogen, and other criteria.
2. Allows users to search USDA Directives.
3. Allows users to search all 50 State food standards (including food defense).
4. Allows users to quickly find the CFR "shalls" and the "shoulds" for both food safety and food defense.

Poison™

1. A large database of all hazards food related events. Covers 5 types of events: intentional food poisonings, accidental food poisonings, equipment malfunction; industrial accidents including fires and natural hazards events impacting food.

2. Events are harvested from the World Wide Web, placed in one of the 6 categories above and "reverse engineered" to determine lessons learned. Each event is then given a threat quotient, i.e., statistical values for deterrence, detection, prevention, response and mitigation.

3. Lessons learned and threat quotient values from POISON are used to validate the threat quotient values used in Food Defense Architect and Food DefenseTQ.

FEAST™

1. Allows users to simulate food defense incidents based on their own facility's level of performance as provided Food DefenseTQ.

2. Allows users to prioritize best investments to reduce their risk, i.e., TQ scores.

FREE Tool™

1. Provides an automated geospatially supported incident command and control system for all events at a food facility.

EXHIBIT 30

Seeley, Ariel

From: Menikheim, Jody
Sent: Tuesday, October 02, 2012 1:16 PM
To: 'jhnatio@thoughtquest.com'
Subject: Re: New Meeting Address for This Afternoon's Webinar!

I will send the new URL to my staff. Thanks

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, October 02, 2012 01:14 PM
To: Menikheim, Jody
Cc: 'Bruce Becker' <bbecker@foodquesttq.com>; Dave Park <dpark@foodquesttq.com>; Ed Berger <eberger@foodquesttq.com>
Subject: New Meeting Address for This Afternoon's Webinar!

Jody: It appears that the Go-To-Meeting program lost our meeting for this afternoon. Please use this meeting URL instead. Could you please send this around to anyone else on the team who wants to attend. Thanks and best, j
1. Please join my meeting.
https://www4.gotomeeting.com/join/242173975

2. Use your microphone and speakers (VoIP) - a headset is recommended. Or, call in using your telephone.
Dial +1 (213) 493-0601
Access Code: 242-173-975
Audio PIN: Shown after joining the meeting
Meeting ID: 242-173-975
GoToMeeting®
Online Meetings Made Easy™
Not at your computer? Click the link to join this meeting from your iPhone®, iPad® or Android® device via the GoToMeeting app.

EXHIBIT 31

Guenther, Julia

From:	Stone, Warren <WStone@gmaonline.org>
Sent:	Thursday, November 15, 2012 2:33 PM
To:	GMA-FoodDefenseInfo@lists.gmaonline.org
Cc:	Dunaif, George; Guenther, Julia; Rubio, Audrey; Barthel, Colin A; Clay Detlefsen; Bruce Becker; Randall Gordon; Anthony, Orlondo; Shaun Kennedy
Subject:	GMA - FDA Collaboration: FDA Food Defense Plan Builder
Attachments:	FDPBFG Agenda_Dec 12 Draft.docx.docx
Importance:	High

<<FDPBFG Agenda_Dec 12 Draft.docx.docx>>

Good Afternoon Everyone,

In our continued effort to enhance the science of food protection, GMA is pleased to invite members of its Food Defense Committee and other interested industry professionals to the second focus group meeting to test FDA's new Food Defense Plan Builder (FDPB) Tool.

The FDPB Tool is a software application currently under development designed to assist owners and operators of food facilities in developing a personalized food defense plan. The intended audience and user-base for the FDPB tool is the food and agriculture industry. To ensure that the tool is user-friendly and in line with industry needs, FDA is seeking feedback from industry members in this upcoming focus group. There is no cost for you to attend this event. This focus group shall be held

WEDNESDAY, DECEMBER 12TH, 2012

1:00PM – 4:30PM

at

GROCERY MANUFACTURERS ASSOCIATION

1350 I STREET, NW

WASHINGTON, DC 20005

For those of you that attended the November 1 event in Minneapolis, Batelle and FDA have made some fairly significant changes and redesigns to the FDPB's functions. For details please contact Colin Barthel at the email below.

Please bring a laptop computer so that you can operate the trial BETA version of the software tool. If you are not planning on bringing a computer, Battelle Memorial Institute will be projecting its computer screen for attendees to preview the functionality, user interface, and capabilities of FDPB Tool. A tentative agenda is attached to this message. **Note: at this time the FDPB tool is only supported by PC formats and is not Macintosh compatible**

All redactions on this page are withheld under (b)(6).

Battelle Memorial Institute is supporting the FDA in this effort. Additional information on the focus group meeting will be delivered as it becomes available. If you have any questions, please contact Colin Barthel of Battelle at [redacted] or barthelc@battelle.org

To RSVP for this event, please contact GMA's Audrey Rubio at arubio@gmaonline.org. Space is limited, but if we find a large demand for this event, we will consider adding a morning session to accommodate the overflow.

Warren Stone

Sr. Director of Science Policy, Compliance & Inspection

Grocery Manufacturers Association

(Located in Northern California)

[redacted] cell phone

wstone@gmaonline.org

Food Defense Plan Builder Focus Group

Grocery Manufacturers Association
1350 I (Eye) Street, NW
Washington, DC 20005

December 12, 2012
1:00 PM

Please bring your personal laptop so that you can run the trial version of the Food Defense Plan Builder (FDPB) software. ***Note: the FDPB does not function on non PC-type laptops or tablets.***

Agenda

Welcome and Introductions

Food Defense Plan Builder Development Background

FDPB Overview

- Company Information
- Broad Mitigation Strategies
- Vulnerability Assessment
- Focused Mitigation Strategies
- Response Plan
- Action Plan
- Food Defense Plan
- Supporting Documents

--Break--

FDPB User Time

Feedback Session

- Overall Impressions
- Strengths
- Weaknesses
- Industry Wants/Needs

Conclusion

Note: Parking is available on 14th Street between Yogenfruz and the Hilton Garden Inn. Visitors to the Focus Group meeting will need to sign in with the building lobby desk and receive a visitor's badge.

EXHIBIT 32

Guenther, Julia

From: Barthel, Colin A <BarthelC@battelle.org>
Sent: Tuesday, November 27, 2012 4:58 PM
To: John Hnatio
Cc: 'Bruce Becker'; Dave Park
Subject: RE: Introduction

John,

While I appreciate your interest, I am not able to satisfy your request for information. I am sorry I cannot be more accommodating, but Battelle is not at liberty to discuss our relationship, statement of work, or other contractual or technical information without written authorization and approval from our FDA client. As I understand, you have their contact information should you need to get in touch with the FDA Food Defense Oversight Team. Regarding the meeting at GMA, it is a focus group feedback session for facility owner/operators. The tool is not available for further release until its public availability on the FDA website. Any additional questions on the tool, its development, and availability schedule should be directed to the FDA Food Defense Oversight Team.

Regards,

Colin A. Barthel
National Security Division
Battelle Memorial Institute
(703) 416-5838 (office)
(703) 927-8985 (cell)

1550 Crystal Drive, Ste 600
Arlington, VA 22202

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, November 27, 2012 2:39 PM
To: Barthel, Colin A
Cc: 'Bruce Becker'; Dave Park
Subject: FW: Introduction

Colin: I am reaching out to Battelle for the fourth time in ten days. I am calling officially based on Battelle's FDA government contract work involving the safety of the food supply. As a taxpayer and a member of the food industry, I would very much appreciate a return call from you to discuss the upcoming meeting at GMA. My contact information is below and I can always be reached by cell at 301-606-9403. Thank-you. Best, j

John Hnatio, EdD, PhD
Chief Science Officer
ThoughtQuest LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, November 20, 2012 3:49 PM
To: BarthelC@battelle.org
Subject: FW: Introduction

Colin: got your number from a colleague and left a VM for you to please return my call...this is with regard to GMA and Battelle's food defense work under contract to FDA...look forward to hearing from you soonest, best, j

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, November 20, 2012 10:35 AM
To: BarthelC@battelle.org
Subject: FW: Introduction

Colin: Just wanted to check in again to arrange a time for a go-to-meeting to show you what we already have and to discuss the FDA/GMA session. Please advise. Thanks, John

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Friday, November 16, 2012 3:46 PM
To: 'BarthelC@battelle.org'
Cc: 'Bruce Becker'
Subject: Introduction

Hi Colin:

Nice to meet you. I got your name off the invite list to the GMA food defense gathering on 12-12. We will also be there.

I wanted to touch base with you beforehand to see if we might be able to give you a short pre-demo of what we will be presenting to the industry at the meeting on a webinar.

We've developed a software tool call Food Defense Architect™ that is designed to help industry build a food defense plan based on 1600+ food defense criteria drawn from all sources. We cover the food defense criteria identified under Codex, WHO Food Bioterror, USDA, FDA, DOD, OSHA, DHS and FEMA along with all seven global schemas.

Would like to connect w/you before the meeting to share ideas and what we've developed with you/Batelle. My contact info. below. Best, John

John Hnatio, EdD, PhD
Chief Science Officer
ThoughtQuest LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

EXHIBIT 33

Guenther, Julia

From: Menikheim, Jody
Sent: Friday, January 04, 2013 1:07 PM
To: Guenther, Julia
Subject: FW: Courtesy copy
Attachments: Managing Food Defense Risk-TP-5 Final for Portal Sales .pdf

---

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Tuesday, December 11, 2012 4:41 PM
To: Menikheim, Jody
Subject: Courtesy copy

Hi Jody: Promised to touch base before the session tomorrow...Bruce sent Leanne a copy of the attached...just wanted to make sure you got one too...the paper outlines the results of our work using to try and get a more comprehensive forty-thousand foot handle on the threat from the top all the way down through the system using POISON and an open source intel review ...look forward to seeing you guys tomorrow...thanks and all the best, j

FoodQuestTQ

The TQ stands for threat quotient

MANAGING FOOD DEFENSE RISK

This paper provides an overview of the application of the CSM Method® to determine the specific food defense: 1) threats to the food supply; 2) vulnerabilities to the food supply, and; 3) countermeasures that can reduce the risk exposure of food companies to each of the identified threats and vulnerabilities. The CSM Method® is a patented process used for the protection of critical infrastructures including food and agriculture. The results of the analysis of a large data repository of all hazards events affecting the food supply and open source intelligence are presented. The results of the data analysis are used to determine what needs to be protected, why it needs to be protected and what it needs to be protected against. The clustering of events most commonly affecting the food supply and the characteristics of the potential perpetrators of food defense events are identified along with the seven essential elements of a comprehensive food defense threat statement. The five essential elements of an effective food defense program are presented. The paper concludes with a brief description of technology advances that can help the food industry balance the costs of operations with the right combination of food defense prevention and response risk countermeasures to maintain their economic viability while simultaneously reducing and maintaining their food defense risk exposure at manageable levels.

Food DefenseTQ Technical Paper No. 5

December 2012

MANAGING FOOD DEFENSE RISK: Technical Paper No. 5

By John Hnatio, Chief Science Officer, FoodQuestTQ LLC

Executive Summary

The food supply is one of the most exposed of all industry verticals to risk. From fires and arson, explosions, natural disasters, workplace violence, food safety, cyber-threats, food fraud, equipment malfunction, industrial accidents, tampering and many others, the list of threats and vulnerabilities is long.

When we looked across the available literature on threats and vulnerabilities to the food supply we found that it was almost exclusively anecdotal. Since 9-11, the principal focus of government efforts appears to be directed to the low probability, high consequence threat posed by terrorist cells using intelligence tradecraft. The principal threat of concern is the undetected placement of a biological agent in large batches of food at large food processing facilities resulting in mass deaths. But the reality is that the food defense threat and vulnerability spectrum is much broader and includes arson, facility sabotage, cyber-attack, bombings, workplace violence as well as many other serious threats that can affect the economic viability of a food company, curtail production and result in severe disruption.

Since no comprehensive industry or government statement of the food defense threat to the food supply exists in the open literature, we undertook a systematic process to develop one.[i] A comprehensive threat statement tells you what needs to be protected, why it needs to be protected, and what it needs to be protected against. A clear and unambiguous statement of the threat is an essential first step before you can conduct any meaningful assessment of your vulnerabilities. Using a large food event data repository called POISON™ in combination with an extensive open source intelligence review of food events we identified the three threats and the seven essential elements that must be addressed by a comprehensive food defense threat statement.

Under the threat posed by intentional poisoning we identified the intentional poisoning of food and water by introducing physical hazards, chemical toxins, biological agents or nuclear materials into food and water and the intentional distribution, sale or use of adulterated, mishandled, and/or mislabeled food and water product. Under the threat posed by the loss of production capacity we identified fixed site facility and cyber sabotage. Under the threat posed by disruption we identified inconvenience, economic losses and fear of the population to consume food.

A comprehensive threat statement must also include a description of the capabilities of potential adversaries. This is essential in order to determine the adequacy of food defense risk countermeasures against different threats and the vulnerabilities they pose. Our analysis of food defense events in the POISON food event data repository in combination with open source intelligence analysis indicates that high consequence food defense events will be motivated by disruption. ***The following spectrum of adversary characteristics and capabilities were identified: 1) an employee insider with access, opportunity and knowledge; 2) one or more outsiders that may, or may not, have insider assistance, and; 3) organized terrorist cells using intelligence tradecraft.***

Using this statement of the threat to the food supply, a vulnerability assessment of the food supply chain was conducted. All segments of the food supply chain were found to have significant food defense vulnerabilities across one of more of the following six areas of concern: 1) the intentional introduction of harmful materials into food; 2) the intentional distribution, sale or use of spoiled, adulterated or mishandled food product; 3) intentionally mislabeled food product and other forms of food fraud; 4) the sabotage of fixed site facilities; 5) cyber-sabotage, and; 6) attacks against food operations personnel including walk-in retail customers.

Based on the results of the vulnerability assessment, specific risk reduction countermeasures were identified. This was done by reviewing the open literature and extracting global, U.S. Government and industry standards, i.e., food safety and

defense schemas, related the food defense vulnerability identified. The review identified a total of 1,574 food defense related risk countermeasures.

Each of the 1,574 food defense risk countermeasures was then statistically weighted by teams of scientists, engineers and food defense experts in order to determine its risk reduction value in: 1) deterring the human actions leading to a food defense event; 2) detecting the actions of a perpetrator soon enough to prevent the food defense event; 3) preventing the event before it occurs; 4) responding to a food defense event after it has happened, and; 5) mitigating the consequences of the event. Each countermeasure was weighted in this way to determine the risk reduction value of any given food defense risk countermeasure in relation to others. ***This allows for the selection of the most effective countermeasure(s) to reduce the risk posed by a specific vulnerability.***

Finally, the 1,574 food defense countermeasures were grouped into individual areas of concern across the following five categories of food defense interest. ***The following five categories of food defense interest represent the basic components of any robust food defense plan: 1) preventing the destruction and sabotage of critical facilities and equipment; 2) protecting facility personnel; 3) preventing the intentional poisoning of food and water; 4) responding to food and facility emergencies, and; 5) building a continuity of operations plan.***

With a fundamental understanding of: 1) the threats to the food supply chain (including the characteristics of potential adversaries); 2 the vulnerabilities associated with the threats, and; 3) the value of food defense risk reduction countermeasures, an advanced computer software tool known commercially as ***Food Defense Architect™ was developed to reduce food defense risk and increase cost efficiency by identifying the right combination of low cost prevention and response risk reduction measures.***

Introduction

In this paper, we treat risk management holistically as a portfolio of different risk factors that can result in untoward events. The term "all-hazards events" is used to describe the portfolio of risk factors that can impact a food company. All-hazards events include fires, explosions; site, facility and product sabotage; cyber sabotage; the intentional poisoning of food and water, the protection of facility personnel, including retail customers, and natural hazards emergencies.

The different risk factors that can impact food businesses along the supply chain are considered in the context of all-hazards events because all of the risks faced by the food industry are interconnected and interdependent. For example, you can never have a robust food defense program unless you already have an effective food safety program upon which to build it. Likewise, any robust food safety program must contain elements of food defense. We all know that fires can certainly affect food safety. But arson is the number one cause of fires in the United States. The result is that the very same investments we make to protect our facilities and equipment from industrial fires is also used to protect us from intentional arson.

This "interconnectedness" of risk factors means that the investments a food company makes in updating things like their HACCP plans should have appreciable value in strengthening their food defense plan. Likewise, a food defense vulnerability assessment should have appreciable value in strengthening a company's HACCP plan. The evacuation drills we conduct to protect our workers from fire should also have value in protecting personnel from bomb threats and explosions and natural disasters and so on. ***The premise of this paper is that significant cost efficiencies can be achieved by leveraging this "interconnectedness" among different risk reduction factors.***

A Three Step Process: Step 1

To approach the challenge of food defense, we did three things in sequential order. First, we determined the threats to the food supply. There is a great deal of information out there but most of it is spread among a huge variety of sources and is almost exclusively anecdotal. We found that much of the threat information at the government level is focused on the notion of low probability-high consequence events based on concerns about what terrorists might do. At the food industry level, we found a more traditional approach to risk management that was focused on the types of food defense risks that food related operations have to manage every day. Things like disgruntled employees who contaminate food, steal company property and misuse computers, unreliable suppliers, hijacked trucks, tampering and a host of other problems that range from medium to high probability and medium to high consequence food defense events.

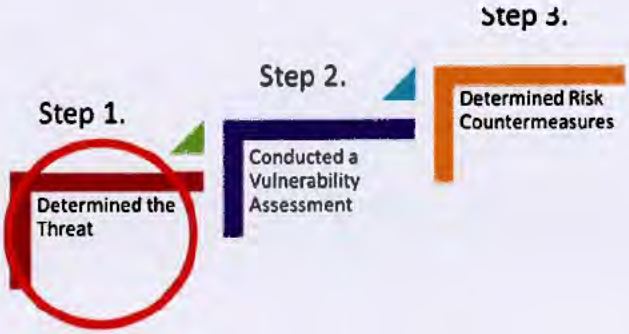


Figure1: Determining the Threat

To determine in a non-subjective way the threat to the food supply, we gathered information about the different types of events that occur at food facilities and created a large data repository known as POISON™. POISON covers intentional and accidental food poisonings, sabotage against food facilities and equipment, arson, fires, explosions, workplace violence, natural disasters and other all-hazards events that have disrupted the food supply. After pulling the events together from POISON and open source intelligence harvesting and analysis, we found five clusters where the events involving food facilities were concentrated: 1) arson and fires; 2) sabotage; 3) poisonings; 4) transport security, and; 5) personnel security.[ii]

Figure 2: Defining the Food Defense Threat

A comprehensive threat statement must also include a description of the capabilities of potential adversaries. This is essential in order to determine the adequacy of food defense countermeasures against different threats and the vulnerabilities they pose. Our analysis of food defense events in the POISON food event data repository in combination with open source intelligence analysis indicates that high consequence food defense events will be motivated by disruption. The following spectrum of adversary characteristics and capabilities were identified: 1) an employee insider with access, opportunity and knowledge 2) one or more outsiders that may, or may not, have insider assistance; 3) organized terrorist cells using intelligence tradecraft.

The next step we took was to come up with the elements of a threat statement that would apply across all of the potential threats to the food industry that we found as we analyzed the events in POISON and open source intelligence. The challenge was to unambiguously state what needs to be protected, why it needs to be protected, and what it needs to be protected against.[iii]

Based on our analysis, we identified seven critical elements that should be included in a comprehensive food defense threat statement. To address the potential of intentional food poisoning, we identified the first two critical elements. The first element addresses the intentional poisoning of food by introducing physical hazards or toxic chemicals, biological agents or nuclear materials into food. The second element involves the intentional distribution, sale or use of adulterated, mishandled, and/or mislabeled food product. To address the threat of loss of production capacity, the analysis demonstrates that the third element that must be included in any comprehensive threat statement is fixed site facility sabotage. The fourth element addresses the possibility of cyber-sabotage.

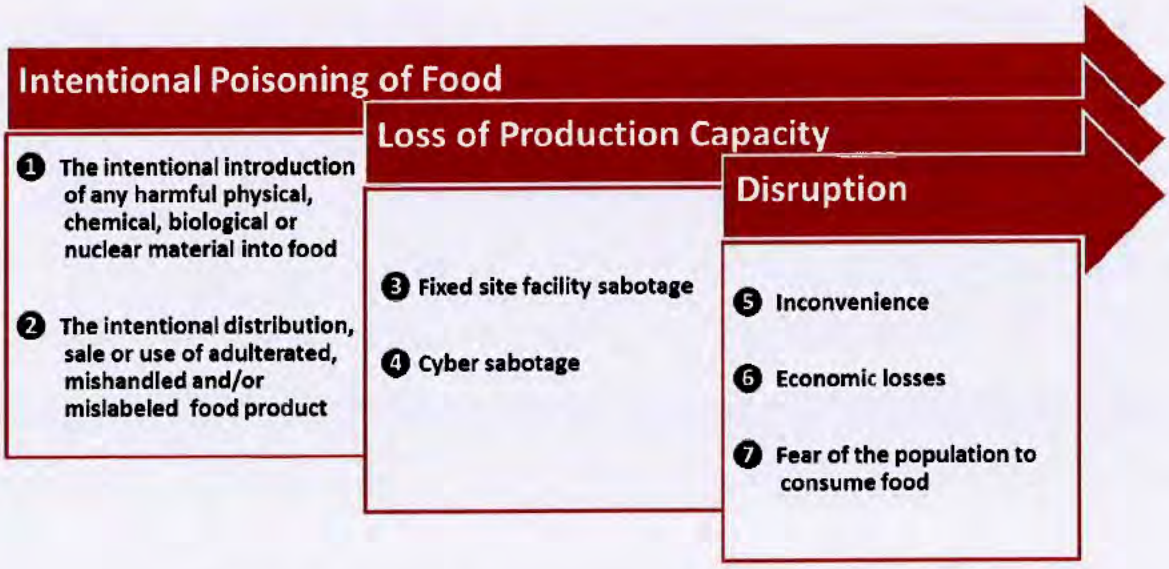


Figure 3: The Seven Elements of the Food Defense Threat

To address the types of disruption that would occur based on the intentional poisoning of food and loss of production capacity, the analysis shows that inconvenience, economic losses, and fear of the population to consume food must also be included as part of a comprehensive statement of the food defense threat.

A Three Step Process: Step 2.

Figure 4: Conducting the Vulnerability Assessment

After we determined the threat to the food supply, we were ready to move to the second step of the process. We needed to conduct a vulnerability assessment of the food supply against the design threat we developed in Step 1. We knew that without a design threat that tells you what you need to protect, why you need to protect it, and what you need to protect it against, you cannot possibly conduct a vulnerability assessment. This is because any effective vulnerability assessment must address each of the threat elements identified in Figure 3 (see page 7) and must consider the capabilities of the different types of adversaries who may attempt to take advantage of them.[iv]

After we defined what needs to be protected, why it needs to be protected, and what it needs to be protected against in a comprehensive statement of the threat to the food supply, we determined the vulnerabilities within the types of different food operations along the food supply chain. We looked across food growers (G), processors (P), transporters (T), warehouses (W), retail distributors (RD), grocery stores (GS), food service (FS), convenience stores (CS) and restaurants (R). The five clusters of events we found during our analysis of food events in POISON and from the open source intelligence review appearing in Figure 2 (see page 6) were used as threat categories. Based on the growing incidence and seriousness of computer-attacks that were found in conducting the open source intelligence analysis we identified and added the sixth cluster of cyber sabotage.

Threat		Location on Food Supply Chain								
		G	P	T	W	RD	GS	FS	CS	R
Intentional introduction of harmful materials into food	Probability	LP	MP	MP	MP	HP	HP	HP	HP	HP
	Consequence	HC	HC	MC	MC	MC	MC	MC	MC	MC
	Difficulty	L	M	L	M	L	L	L	L	L
The intentional distribution, sale or use of spoiled, adulterated or mishandled product	Probability	MP	LP	HP	MP	MP	MP	HP	HP	HP
	Consequence	HC	HC	MC	MC	MC	MC	MC	MC	MC
	Difficulty	L	L	L	L	L	L	L	L	L
Intentionally mislabeled product and other forms of food fraud	Probability	MP	MP	MP	MP	MP	MP	HP	HP	HP
	Consequence	MC	MC	MC	MC	MC	MC	MC	MC	MC
	Difficulty	L	L	L	L	L	L	L	L	L
The sabotage of fixed-site food facilities	Probability	LP	MP	LP	MP	MP	MP	MP	LP	LP
	Consequence	LC	HC	LC	MC	MC	MC	MC	MC	MC
	Difficulty	L	M	L	L	M	M	L	L	L
Cyber-sabotage	Probability	MP	MP	LP	LP	MP	LP	MP	LP	LP
	Consequence	MC	HC	MC	MC	MC	MC	MC	LC	LC
	Difficulty	L	M	L	M	M	L	M	L	L
Attacks against food operations personnel	Probability	LP	HP	HP	HP	HP	HP	HP	HP	MP
	Consequence	LC	MC	MC	MC	MC	MC	MC	HC	HC
	Difficulty	L	L	L	L	L	L	L	L	L

Figure 5: Threat Probability, Consequence and Difficulty Rankings

A traffic light approach of red to represent high, yellow to represent medium and green to represent low is used to signify the probability, consequence and difficulty associated with the different clusters of events across each segment of the food supply chain. Difficulty means the motivation, access to the materials necessary to mount a successful attack, and the know-how to plan and execute a successful attack. The probability of the event occurring is based on data in POISON and the analysis of open source intelligence including financial losses resulting to the food industry.[v] Past events of a similar nature in POISON and the analysis of open source intelligence (including economic losses) were used to estimate consequence.[vi] Knowledge of adversary motivation, access to the materials to carry out an attack and know-how to estimate the difficulty of attacking the different segments along the supply chain were drawn from open source intelligence analysis and used to assign a "difficulty" benchmark.

As part of the vulnerability assessment, events from the POISON database and from open source intelligence were analyzed and used to assign probability of occurrence and consequence rankings for the introduction of harmful materials, the distribution and sale of spoiled, adulterated and mishandled product, intentional mislabeling and other forms of food fraud, the sabotage of fixed site facilities, cyber-sabotage and the protection of food operations personnel including retail customers.

A traffic light approach was used to signify levels of concern. Red indicates the highest level of concern. All threat events with a high consequence, regardless of their probability of occurrence are marked in red. For example, even though the probability of someone intentionally introducing foot and mouth disease at several U.S. beef farms is low, the consequences could have a devastating impact on the beef industry and U.S. agricultural exports. In another example, even though the probability that a terrorist group could successfully introduce enough of the right toxin or biological agent into a large enough food batch to result in a catastrophic outcome is low, the consequences of a successful attack could have devastating consequences. In a final example, although the probability that an act of violence will occur at a retail distributor, grocery store, convenience store and a restaurant ranges from low to medium probability of occurring, the results have proven to be devastating in terms of loss of life and brand name risk exposure for many of the companies involved, so they appear in red. In similar fashion, yellow represents a very serious level of concern. All medium consequence events appear in yellow. Yellow signifies that while the impact of such an event would have very serious consequences on the company involved the outcome is still manageable. Green signifies that the event is manageable. All low consequence events appear in green. Green signifies that while such an event will adversely impact the company involved, the outcome is manageable.

In the following series of figures we show, in rank order, the specific threats of concern to food growers (G), processors (P), transporters (T), warehouses (W), retail distributors

(RD), grocery stores (GS), food service (FS), convenience stores (CS) and restaurants (R) and the associated risk countermeasures that should be emphasized.

Location	Priority	Required Risk Countermeasures
G	1. Spoiled, Adulterated and Mishandled Product (MP-HC)	Spoiled, adulterated and mishandled product risk countermeasures
	2. Harmful Materials (LP-HC)	Biological risk countermeasures for crops and livestock
	3. Food Fraud (MP-MC)	Food fraud risk countermeasures
	4. Cyber Sabotage (MP-MC)	Cyber-sabotage risk countermeasures
	5. Sabotage of Fixed Site Facilities (LP-LC)	Sabotage of fixed sites risk countermeasures
	6. Food Personnel (LP-LC)	Workplace violence and other risk countermeasures
P	1. Harmful Materials (MP-HC)	Nuclear, biological, chemical and physical risk countermeasures
	2. Spoiled, Adulterated and Mishandled Product (LP-HC)	Spoiled, adulterated and mishandled product risk countermeasures
	3. Sabotage of Fixed Sites (MP-HC)	Sabotage of fixed sites risk countermeasures
	4. Cyber-Sabotage (MP-HC)	Cyber-sabotage risk countermeasures
	5. Food Fraud (MP-MC)	Food fraud risk countermeasures
	6. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures

Figure 6: Rank Order of Threat Concerns for Growers and Processors

The occurrence of major food poisoning incidents and the introduction of spoiled, adulterated or mishandled product leading to criminal indictments and civil litigation for negligence have become major concerns for growers. In a growing number of cases, serious poisoning incidents have forced these companies into bankruptcy. For growers, the introduction of the right type of undetected toxin or biological agent into a large batch of food product could also have devastating consequences. The possibility of food fraud and cyber-sabotage (medium and large growers for traceability) would have medium consequences. The sabotage of building structures and violence against farms and farmers is considered to be a low probability and low consequence event.

Food processors have the greatest risk exposure of any single segment along the food supply chain. Although the probability is low, if the right toxin or biological agent were successfully introduced into a large batch the consequences could be devastating. In complex supply chains that allow for the fast and broad distribution of food both spoiled, adulterated and/or mishandled product and food fraud could have devastating impact on brand name. Processors are the most vulnerable to the sabotage of fixed sites with potentially devastating consequences. Cyber-sabotage could threaten food production, distribution and traceability to result in devastating consequences. Finally, the consequences of violence involving food personnel is considered as a medium consequence event due to the high cost of reparations and negative effects on employee morale and resulting decreases in production.

Location	Priority	Required Countermeasures
T	1. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	2. Harmful Materials (MP-MC)	Nuclear, biological, chemical and physical risk countermeasures
	3. Food Fraud (MP-MC)	Food fraud risk countermeasures
	4. Food Personnel (MP-MC)	Workplace violence and other risk countermeasures
	5. Cyber-Sabotage (LP-MC)	Cyber-sabotage risk countermeasures
	6. Sabotage of Fixed Site Facilities (LP-LC)	Sabotage of fixed sites risk countermeasures
W	1. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	2. Food Fraud (MP-MC)	Food fraud risk countermeasures
	3. Harmful Materials (MP-MC)	Chemical and biological risk countermeasures for crops and livestock
	4. Spoiled, Adulterated and Mishandled Product (MP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	5. Sabotage of Fixed Sites (MP-MC)	Sabotage of fixed sites risk countermeasures
	6. Cyber Sabotage (LP-MC)	Cyber-sabotage risk countermeasures

Figure 7: Rank Order of Threat Concerns for Transporters and Warehouse Facilities

For transporters the threats posed by the introduction of harmful materials, the distribution of spoiled, adulterated and mishandled product, food fraud, cyber sabotage and driver safety issues associated with the frequency of truck hijackings are all medium consequence events. As would be expected, the probability of occurrence and consequences associated with the sabotage of fixed site facilities are low for transporters.

Warehouses face medium consequences across all six threat areas.

Location	Priorities	Required Countermeasures
RD	1. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Chemical and biological risk countermeasures for crops and livestock
	3. Spoiled, Adulterated and Mishandled Product (MP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Cyber-Sabotage (MP-MC)	Cyber-sabotage risk countermeasures
	5. Food Fraud (MP-MC)	Food fraud risk countermeasures
	6. Sabotage of Fixed Site Facilities (MP-MC)	Sabotage of fixed sites risk countermeasures
GS	1. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Nuclear, biological, chemical and physical risk countermeasures
	3. Spoiled, Adulterated and Mishandled Product (MP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Cyber-Sabotage (LP-MC)	Cyber-sabotage risk countermeasures
	5. Food Fraud (MP-MC)	Food fraud risk countermeasures
	6. Sabotage of Fixed Site Facilities (MP-MC)	Sabotage of fixed sites risk countermeasures

Figure 8: Rank Order of Threat Concerns for Retail Distributors and Grocery Stores

For retail distributors the priority concern is violence affecting retail establishments of all kinds.[vii] The violence may be among employees or by outsiders. The consequences of violence, especially shootings, make retail food stores extremely vulnerable to after the

fact adverse brand name exposure. The introduction of harmful materials, spoiled and mishandled product, cyber-sabotage, food fraud and sabotage to fixed facilities are all considered to be medium consequence events.

Grocery stores are assigned the same ranking as retail distributors for the same reasons.

Location	Priorities	Required Countermeasures
FS	1. Harmful Materials (HP-MC)	Chemical and biological risk countermeasures for crops and livestock
	2. Food Personnel (HP-MC)	Workplace violence and other risk countermeasures
	3. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	5. Food Fraud (HP-MC)	Food fraud risk countermeasures
	4. Cyber Sabotage (MP-MC)	Cyber-sabotage risk countermeasures
	6. Sabotage of Fixed Site Facilities (MP-MC)	Sabotage of fixed sites risk countermeasures
CS	1. Food Personnel (HP-HC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Chemical and biological risk countermeasures for crops and livestock
	3. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Food Fraud (HP-MC)	Food fraud risk countermeasures
	5. Sabotage of Fixed Site Facilities (LP-MC)	Sabotage of fixed sites risk countermeasures
	6. Cyber-Sabotage (LP-LC)	Cyber-sabotage risk countermeasures

Figure 9: Rank Order of Threat Concerns for Food Service and Convenience Stores

Like warehouses, food service establishments face medium consequences across all six threat areas.

Convenience stores, like other food retailers, face the threat of violence against personnel. The violence is usually instigated by outsiders and robbery attempts. The consequences of violence, especially shootings, make convenience stores extremely

vulnerable to after the fact adverse brand name exposure. The introduction of harmful materials, spoiled and mishandled product, food fraud and fixed site facility sabotage (not involving workplace violence) are considered to be medium consequence events for convenience stores. The probability and consequences of cyber-sabotage are considered low.

Location	Priorities	Required Countermeasures
R	1. Food Personnel (HP-HC)	Workplace violence and other risk countermeasures
	2. Harmful Materials (HP-MC)	Nuclear, biological, chemical and physical risk countermeasures
	3. Spoiled, Adulterated and Mishandled Product (HP-MC)	Spoiled, adulterated and mishandled product risk countermeasures
	4. Food Fraud (HP-MC)	Food fraud risk countermeasures
	5. Sabotage of Fixed Site Facilities (LP-MC)	Sabotage of fixed sites risk countermeasures
	6. Cyber-Sabotage (LP-LC)	Cyber-sabotage risk countermeasures

Figure 10: Rank Order of Threat Concerns for Restaurants

Finally, restaurants like other food retailers face the threat of violence against personnel and their customers. The violence is frequently instigated by outsiders and may involve mass shootings. The consequences of violence, especially shootings, make restaurants extremely vulnerable to after the fact adverse brand name exposure. The introduction of harmful materials, spoiled, adulterated and mishandled product, cyber-sabotage and food fraud are considered to be medium consequence events for restaurants. The consequences of fixed site facility sabotage (not involving workplace violence) are considered low.

As the final step in completing the vulnerability assessment of the food supply we identified five categories of interest that must be part of a comprehensive food defense plan based on the vulnerability assessment. First, a food defense program must address the sabotage of critical equipment and facilities.

Figure 11: Five Food Defense Categories

Second, it must protect facility personnel and walk-in retail customers from intentional attacks such as shootings, bombings, arson and other threats. Third, it must prevent the intentional poisoning of food and water. Fourth, there needs to be an effective command and control system in place to respond to food facility emergencies. Fifth, food operations must be prepared to deal with the loss of production and delivery capacity by having plans in place to shorten the curtailment of their operations.

A Three Step Process: Step 3.

In the third and final phase of the CSM Method® we turned our attention to determining the most effective risk countermeasures that should be employed to address each of the threats and vulnerabilities that were identified in steps 1 and 2.

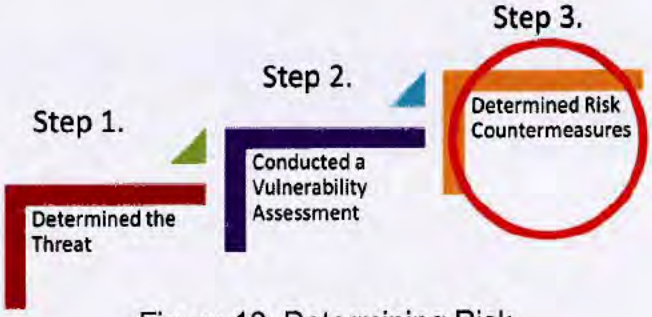


Figure 12: Determining Risk Countermeasures

We started at the global level and extracted every food defense related benchmark and audit standard associated with the five categories food defense interest of: 1) the sabotage of critical equipment and facilities including cyber-sabotage; 2) the protection of facility personnel and retail customers from intentional attacks such as shootings,

bombings, arson and other threats; 3) the intentional poisoning of food and water; 4) an effective command and control system must be in place to respond to food facility emergencies, and; 5) the presence of continuity of operations plans to deal with the loss of production capacity by having plans in place to shorten the curtailment of their operations. In similar fashion, every food defense and site security related standard across the U.S. Government and the seven principal industry food safety and food defense schemas were also extracted.

Figure 13: Sources of Food Defense Related Risk Countermeasures

A total of 1,574 food defense and site security related countermeasures were identified. The countermeasures were grouped into the five food defense categories of interest that were identified as the result of the vulnerability assessment (see Figure 11). Scientists and subject matter experts used similar events in the POISON™ food defense data repository and from open source intelligence to weight the value of each countermeasure in: 1) deterring the human actions leading to a particular type of food defense event; 2) detecting the actions of a perpetrator soon enough to prevent the event; 3) actually preventing the event; 4) improving the response to the event, and; 5) mitigating the consequences of the event. To do this, the scientists and food defense subject matter experts used a 5 point graduated Likert scale with their scores validated

by independent peer review. In this way, the value of each food defense risk countermeasure (and combinations of countermeasures) in addressing specified threats was determined. The countermeasures with the highest scores were flagged and represent the best investments a food company can make to prevent and respond food defense threats and their associated vulnerabilities.

Figure 14: Identification, Grouping and Weighting of Food Defense Risk Countermeasures

Leveraging Technology to Achieve Food Defense Cost Efficiencies and Reduce Losses

With a fundamental understanding of: 1) the threats to the food supply chain that includes the characteristics of potential adversaries; 2) the vulnerabilities associated with the threats, and; 3) the value of food defense risk reduction countermeasures, a computer software program was developed to reduce food defense risk and increase cost efficiency by identifying the right combination of low cost prevention and response risk reduction measures that should be employed to address each vulnerability.

The software tool, which is based on the patented CSM Method®[viii], is called Food Defense Artchitect™. Food Defense Architect is a secure, cloud-based software platform that allows small, medium and large food growers, processors, transporters, warehouses, retail distributors, grocery stores, and food service companies (including caterers) to develop (and strengthen) their food defense programs to reflect their business size and location on the supply chain. The software reduces personnel time on task while simultaneously encouraging multi-disciplinary problem solving through the use of a workflow management protocol where food managers can assign different categories of questions to different operating personnel. The software is also full spectrum enabled to function on workstations, lap top computers, tablet and cell phone technology. This increases personnel cost efficiencies by allowing for both "in-the-office" and "on-the-floor" data inputs.

The software tool looks across each of the five categories of food defense interest: 1) the sabotage of critical equipment and facilities including cyber-sabotage; 2) the protection of facility personnel including retail customers from intentional attacks such as shootings, bombings, arson and other threats; 3) the intentional poisoning of food and water; 4) an effective command and control system to respond to food facility emergencies, and; 5) continuity of operations plans to deal with the loss of production capacity. It uses a questions accompanied by several steps and a "yes" or "no" format. By selecting the steps that are in place, the software generates a threat quotient. A threat quotient is the average of the deterrence, detection, prevention, response and mitigation scores for the food defense risk countermeasures, i.e., steps, which are selected.[ix]

The software also reduces the costs associated with assessments and audits through perpetual assessment. Perpetual assessment means that once the desired combination of prevention and response risk countermeasures are in place their implementation is continuously monitored by real-time feedback from operating personnel using personal digital assistants (PDA's). A cost factor analysis of food safety

and food defense assessments and audits indicates that the costs associated with assessment and audits can be reduced by up to 60% through the application of perpetual assessment methods.[x]

Conclusion

The goal of risk management is to help food companies balance the cost of their operations with the right combinations of prevention and response measures that keep losses low and profits high. Thus, the cost and effectiveness of food defense risk reduction measures in preventing and responding to food defense threats and vulnerabilities must be at the heart of any successful food protection strategy.

Recent advances in science and information technology now make it possible, for the first time, to quantitatively determine the value of risk countermeasures and combinations of risk countermeasures in preventing and, when necessary, mounting the most effective responses to all-hazards risk events that can affect a food company.[xi] Using these new advances, food companies can select and put into place the most cost effective combinations of prevention and response risk countermeasures that can keep their losses low and profits high.

End Notes

[i] Complexity Systems Management Method, Patent No.: US 8,103,601 B2. Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

[ii] Note: The POISON food event data repository contains 1500 selected all hazards events impacting the food supply to include accidental and intentional poisonings of food and water, fires, arson and sabotage, industrial accidents, equipment malfunction, workplace violence and natural disasters. FoodQuestTQ LLC does not publicly share our analysis of intentionally motivated attacks to avoid assisting terrorists and criminals. Read more about POISON at: http://www.nfpcportal.com/FQTools/POISON/tabid/197/Default.aspx

[iii] Jech, Ronald. (April 2010). NATO Science for Peace and Security Programme. NATO Advanced Technology Workshop: Advances in food security and safety against terrorist threats and natural disasters. Presentation, Risk management as it relates to food. Cairo, Egypt. Read more at: http://agtechint.com/uploads/Risk_Management_as_it_Relates_to_Food.pdf

[iv] Note: The public availability of a clear statement of the threats to the food supply that includes a description of the capabilities and characteristics of potential adversaries is an essential first step before the food industry can conduct effective food defense vulnerability assessments. The use of tools such as C.A.R.V.E.R. plus SHOCK in the absence of an unambiguous design basis threat can yield serious false positives with respect to the detection, prevention and effective responses to low probability-high consequence terrorist events.

[v] ThoughtQuest LLC (May 2011). Food: Market analysis and worksheets for the costing of assessments and audits and food industry losses as the result of all hazards events. ThoughtQuest LLC: Frederick, MD

[vi] ThoughtQuest LLC (May 2011). Food: Market analysis and worksheets for the costing of assessments and audits and food industry losses as the result of all hazards events. ThoughtQuest LLC: Frederick, MD

[vii] Northwood, Joyce (December 2011). Assaults and Violent Acts in the Private Retail Trade Sector, 2003—2008. Bureau of Labor Statistics, Department of Labor: Washington D.C., as retrieved from the World Wide Web at: http://www.bls.gov/opub/cwc/sh20111202ar01p1.htm

[viii] Complexity Systems Management Method, Patent No.: US 8,103,601 B2, Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

[ix] Note: Read more about Food Defense Architect™ at: http://nfpcportal.com/FQTools/FoodDefenseArchitect/tabid/282/Default.aspx

[x] ThoughtQuest LLC (May 2011). Food: Market analysis and worksheets for the costing of assessments and audits and food industry losses as the result of all hazards events. ThoughtQuest LLC: Frederick, MD

[xi] Complexity Systems Management Method, Patent No.: US 8,103,601 B2, Date of Issue: January 24, 2012. United States Patent and Trademark Office: Washington, D.C. Read more at: http://www.patentgenius.com/patent/8103601.html

About the Author

John Hnatio is the Chief Science Officer at FoodQuestTQ. His career with the U.S. Government and industry spans a period of over 35 years where he has been involved in risk management. His service to the government includes threat analysis, vulnerability assessments and the implementation of risk countermeasures at U.S. nuclear weapons and other sensitive facilities, nuclear transportation systems and nuclear reactors worldwide. He also served as a loaned executive to the United States Senate from the Administration of President Ronald W. Reagan where he advised on risk matters involving the nuclear and biological programs of the former Soviet Union. In 2004, John retired from the U.S. government and is now an owner of several companies where he works with industry to reduce risk and enhance the resiliency of the nation's critical infrastructures including food and agriculture. He established FoodQuestTQ in 2011. John is the author of several patents and holds a doctorate degree from the George Washington University. He also holds a doctorate degree awarded honoris causa from the Urals Branch of the Russian Academy of Sciences.

EXHIBIT 34

Guenther, Julia

From: Menikheim, Jody
Sent: Wednesday, April 03, 2013 12:59 PM
To: Guenther, Julia
Subject: FW: Focus group

From: Stone, Warren [mailto:WStone@gmaonline.org]
Sent: Tuesday, December 11, 2012 9:53 PM
To: Menikheim, Jody
Subject: Re: Focus group

Sorry about the mix up too. I'll take care of it.

WS

From: Menikheim, Jody <Jody.Menikheim@fda.hhs.gov>
To: Stone, Warren
Sent: Tue Dec 11 21:33:07 2012
Subject: Re: Focus group

Warren,
(b)(5)

(b)(5) Thank you for your consideration. Look forward to our meeting tomorrow. Jody

---

From: Stone, Warren [mailto:WStone@gmaonline.org]
Sent: Tuesday, December 11, 2012 07:06 PM
To: Menikheim, Jody
Subject: Re: Focus group

Bruce is scheduled to present at 430 pm. Are saying that You don't wAnt them there at all at ll at all before 430??
Please let me know

Warren

Sent from my iPhone

On Dec 11, 2012, at 6:31 PM, "Menikheim, Jody" <Jody.Menikheim@fda.hhs.gov> wrote:

Warren,

(b)(5)

00129

00200

FedEx Express **NEW** Package US Airbill

FedEx Tracking Number 8005 1457 3711

3PH1

Form ID No. 0215

Sender's Copy

1 From *Please print and press hard.*

Date 4-26-13 Sender's FedEx Account Number SENDER'S FEDEX ACCOUNT NUMBER ONLY 2129-6361-5

Sender's Name Dale Berkley Phone (301) 496-6043

Company NIH/OGC

Address 31 CENTER DR BLDG 31 RM 2B50 Dept./Floor/Suite/Room

City BETHESDA State MD ZIP 20892-0001

2 Your Internal Billing Reference First 24 characters will appear on invoice. OPTIONAL

3 To

Recipient's Name DR. JOHN HNATIO Phone (240) 439-4476

Company FoodQuest TQ, LLC

Address 4720 Hayward Road #104 Dept./Floor/Suite/Room

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address

Use this line for the HOLD location address or for continuation of your shipping address.

City Frederick State MD ZIP 21702

HOLD Weekday FedEx location address REQUIRED. NOT available for FedEx First Overnight.

HOLD Saturday FedEx location address REQUIRED. Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.

0451092746

The FedEx US Airbill has changed. See Section 4.
For shipments over 150 lbs., order the new FedEx Express Freight US Airbill.

4 Express Package Service * To most locations. *Packages up to 150 lbs.*
For packages over 150 lbs., use the new FedEx Express Freight US Airbill.
NOTE: Service order has changed. Please select carefully.

Next Business Day	2 or 3 Business Days
☐ FedEx First Overnight — Earliest next business morning delivery to select locations. Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.	☐ NEW FedEx 2Day A.M. — Second business morning.* Saturday Delivery NOT available.
☒ FedEx Priority Overnight — Next business morning.* Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.	☐ FedEx 2Day — Second business afternoon.* Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.
☐ FedEx Standard Overnight — Next business afternoon.* Saturday Delivery NOT available.	☐ FedEx Express Saver — Third business day.* Saturday Delivery NOT available.

5 Packaging * Declared value limit $500.

☐ FedEx Envelope* ☐ FedEx Pak* ☐ FedEx Box ☐ FedEx Tube ☐ Other

6 Special Handling and Delivery Signature Options

☐ SATURDAY Delivery — NOT available for FedEx Standard Overnight, FedEx 2Day A.M., or FedEx Express Saver.

☐ No Signature Required — Package may be left without obtaining a signature for delivery.

☐ Direct Signature — Someone at recipient's address may sign for delivery. *Fee applies.*

☐ Indirect Signature — If no one is available at recipient's address, someone at a neighboring address may sign for delivery. For residential deliveries only. *Fee applies.*

Does this shipment contain dangerous goods? One box must be checked.

☒ No ☐ Yes — As per attached Shipper's Declaration. ☐ Yes — Shipper's Declaration not required. ☐ Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous goods (including dry ice) cannot be shipped in FedEx packaging or placed in a FedEx Express Drop Box. ☐ Cargo Aircraft Only

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below.

☒ Sender — Acct. No. in Section 1 will be billed. ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

FedEx Acct. No. / Credit Card No. Exp. Date

Total Packages	Total Weight	Total Declared Value†
	lbs.	$ .00

†Our liability is limited to $100 unless you declare a higher value. See back for details. By using this Airbill you agree to the service conditions on the back of this Airbill and in the current FedEx Service Guide, including terms that limit our liability.

611

Rev. Date 11/10 • Part #163134 • ©1994–2010 FedEx • PRINTED IN U.S.A. SRS

fedex.com 1.800.GoFedEx 1.800.463.3339

PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE. NO POUCH NEEDED.

7960

Page 669 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Entire page withheld under (b)(5).

From:	John Hnatio
To:	ombudsman@sba.gov
Cc:	Dickinson, Elizabeth (FDA/OC); Seeley, Ariel (FDA/OC); Raza, Mark (FDA/OC)
Subject:	ATTN: Ellie Zahirieh: Office of the National Ombudsman for Small Business, Office of Small Business Advocacy, SBA; Case No. 1303150001
Date:	Tuesday, March 19, 2013 10:37:43 AM
Attachments:	Briefing for the SBA National Ombudsman.pdf

Good morning Ellie. A short update.

Please find attached a very short briefing for the SBA Ombudsman concerning our complaint. The briefing lays out the situation with the FDA and identifies the specific FQTQ ideas that were stolen by the FDA food defense team and others in the FDA in order for them to duplicate our products.

The list of the things stolen by the FDA all involve infringement on our patent and we have prepared a very extensive technical crosswalk of our patent against the FDA duplicated products that demonstrates flagrant FDA infringement. We would very much like to share the technical crosswalk with the National Ombudsman in order to help resolve this matter.

Many weeks ago, we offered the FDA Chief Counsel and her staff a demonstration of our tools so they could see for themselves the ideas that were stolen by the FDA to duplicate our products. The FDA declined our offer.

At this time, we would like to arrange a webinar for the SBA Office of Small Business Advocacy to demonstrate our tools to you. The webinar will include a "side-by-side" click through of the FQTQ tools against those duplicated by the FDA and will last no more than one hour. I will reach out to you shortly to arrange a mutually convenient date and time for the webinar.

Thank-you for your help and assistance in this matter. Best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

From:	Seeley, Ariel (FDA/OC)
To:	Berkley, Dale (NIH/OD) [E]; Lovas, Julie (FDA/OC)
Subject:	FW: iRISK timeline, contacts, and supporting documents
Date:	Monday, March 04, 2013 3:04:33 PM
Attachments:	FDA-iRISK history and key contacts.docx Final_Report_TO_2.pdf Newsome et al. JFS 2009.pdf Chen et al. JFP 2013.pdf

FYI

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: Guenther, Julia
Sent: Monday, March 04, 2013 3:02 PM
To: Seeley, Ariel
Cc: Dennis, Sherri; Elkin, Ted; Gombas, Kathy; Menikheim, Jody
Subject: iRISK timeline, contacts, and supporting documents

Ariel,

Attached are the following documents related to iRisk:

1. iRISK history/timeline and key contacts (Word document)
2. Final Report TO 2 (PDF) – back in May 2009, FDA issued a task order for RTI, a contractor to:
   - Develop an inventory of available tools and methods for relative risk and prioritization, and
   - Evaluate the applicability of the identified tools and methods for use by the FDA to address food and feed safety risks.

   Note: ThoughtQuest's Food Mapper tool did not come up in this analysis.
3. Journal of Food Science article from 2009 – explains the risk-ranking prototype developed by IFT through a cooperative agreement with FDA
4. Journal of Food Protection article from 2013 – case studies that demonstrate the application of iRISK

From FoodQuest's website – "Food Mapper is a searchable data repository of U.S. federal and state regulations and standards." iRISK is quantitative tool for comparative risk assessment. On the surface, we do not see any similarities between iRISK and Food Mapper.

I have copied Sherri Dennis, Director of the Division of Risk Assessment, whose team developed iRISK. If you have any questions specific to iRISK feel free to contact Sherri directly.

In a separate email, I will send you the timelines and contractor contacts for the Food Defense Plan Builder.

Thanks,
Julia

From: Seeley, Ariel
Sent: Monday, March 04, 2013 10:39 AM
To: Guenther, Julia
Subject: FW: Response to your e-mail

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to

meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

Pages 674 through 702 redacted for the following reasons:
- -
Entire pages withheld under exemption (B)(5) - attorney client privilege.
Entire pages withheld under exemption (B)(5)- Attorney client privilege.

Briefing for the National Ombudsman for Small Business
Case No. 1303150001

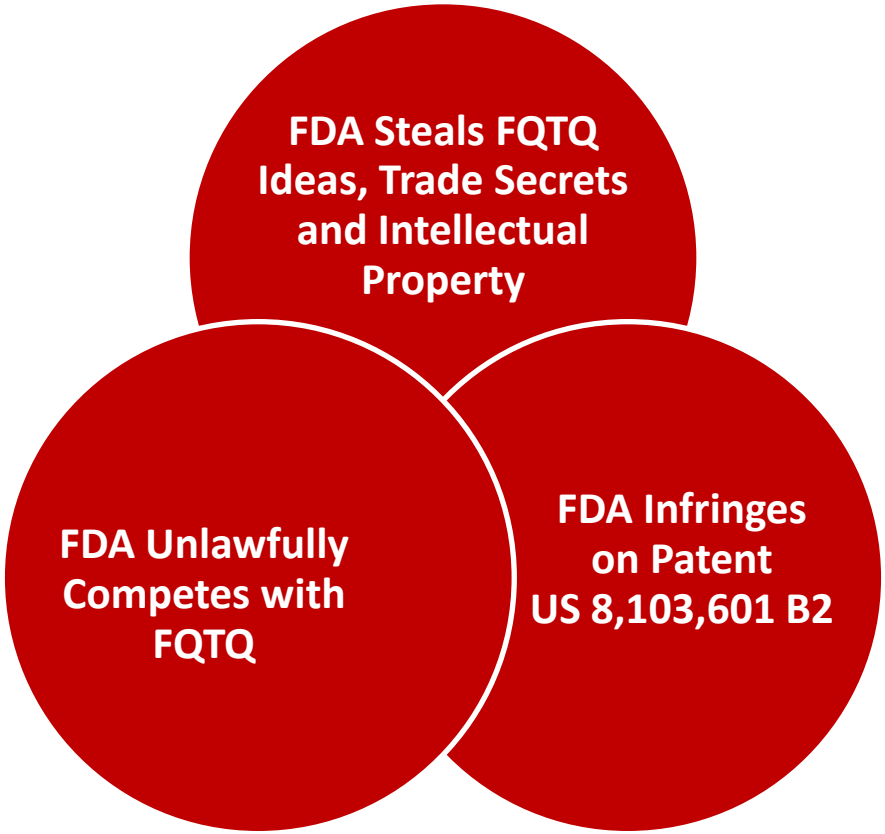
FoodQuestTQ LLC

March 19, 2013

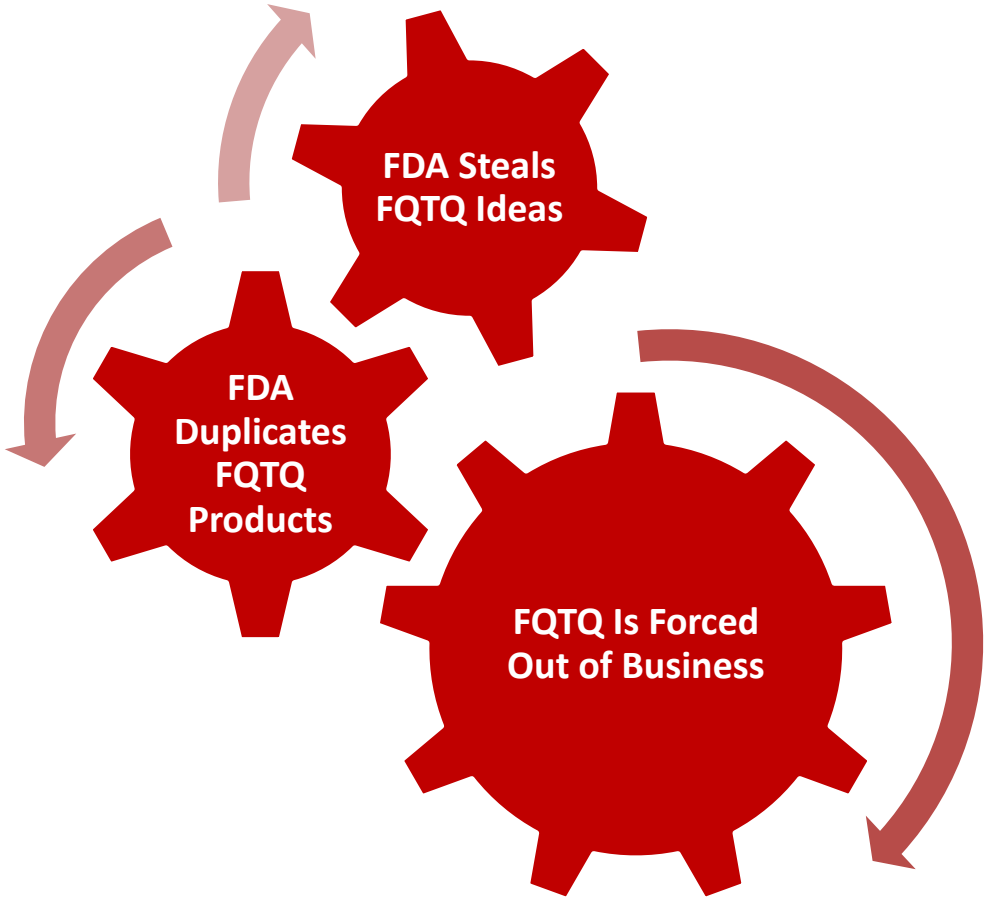
Briefing Contents

- Three Inextricably Intertwined Issues
- The Situation
- FDA Steals FQTQ Ideas
- FDA Duplicates FQTQ Products
- FQTQ Is Forced Out of Business
- FDA Infringes on Patent US 8,103,601 B2
- FDA Unlawfully Competes with FQTQ

Three Inextricably Intertwined Issues



The Situation



The FDA Has Stolen the Following FQTQ Ideas

1. FQTQ Food Protection Systems Model

The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.

- **The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response.**

2. FQTQ Indicators and Warnings

The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of "signals" in order to prevent food defense and food safety incidents.

- **The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term "signals", to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.**

3. FQTQ Probability of Occurrence

The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.

- **The FDA has stolen the FQTQ "probability of occurrence" methodology that is used to prioritize food system vulnerability and risk.**

4. FQTQ Risk, Risk Mitigation and Interventions

The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.

- **The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms "intervention" and "risk mitigation strategies."**

5. FQTQ Vulnerabilities and Risk Reduction Measures

The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.

- **The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term "teachable moments", for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term "table top exercise" to describe the same FQTQ process method called "immersions."**

The FDA Has Stolen the Following FQTQ Ideas

6. FQTQ Verification

The FQTQ systems model uses risk factors and associated risk mitigation measures called "steps."

- **The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, "Risk Mitigation Strategies" to describe the FQTQ methodology.**

7. FQTQ High Risk Areas

The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.

- **The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.**

8. FQTQ Past Incidents

Under the FQTQ systems model, past food events are gathered and analyzed.

- **The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically "reverse engineering" food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.**

9. FQTQ High Risk Agents

Under the FQTQ systems model data concerning high risk agents is gathered and analyzed.

- **The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.**

10. FQTQ Information Collection for Intelligence

The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.

- **The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents**.

The FDA Has Stolen the Following FQTQ Ideas

11. FQTQ Food Life Cycle

The FQTQ food protection systems model includes the entire food life cycle.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.**

12. FQTQ Risk and Risk Reduction

The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.

- **The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.**

13. FQTQ Food Protection Model

The same FQTQ systems model used for food safety is also used for food defense.

- **The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.**

14. FQTQ Holistic View of Food Supply

The FQTQ food protection systems model takes an holistic view of the food supply chain.

- **The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.**

15. FQTQ Assessment and Inspection

The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.

- **The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.**

The FDA Has Stolen the Following FQTQ Ideas

16. FQTQ Targeting of Resources

The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.

- **The FDA has stolen the process methods used by FQTQ to determine performance and "best investments" to mitigate risk.**

17. FQTQ Applications of Information Technology

The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as "tools."

- **The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.**

18. FQTQ Understanding Food Protection as a Science

The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.

- **The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA's understanding of the science of where food becomes contaminated and the associated risks.**

19. FQTQ Identification of Vulnerabilities and Risks

The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.

- **The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of "intervention", communication and response as a method for identifying vulnerabilities and associated food protection risks.**

20. FQTQ Food Risk Reduction Measures

The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.

- **The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA's understanding and use of effective food risk reduction measures.**

The FDA Has Stolen the Following FQTQ Ideas

21. Modeling, Science and Technical Applications

The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.

- **The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.**

22. Strengthen Risk Assessment

The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.

- **The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database;* the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.**

23. FQTQ Inspection and Assessment Strategies

The FQTQ systems model modernizes inspection and assessment strategies.

- **The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectiviity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.**

24. FQTQ Response Module

The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.

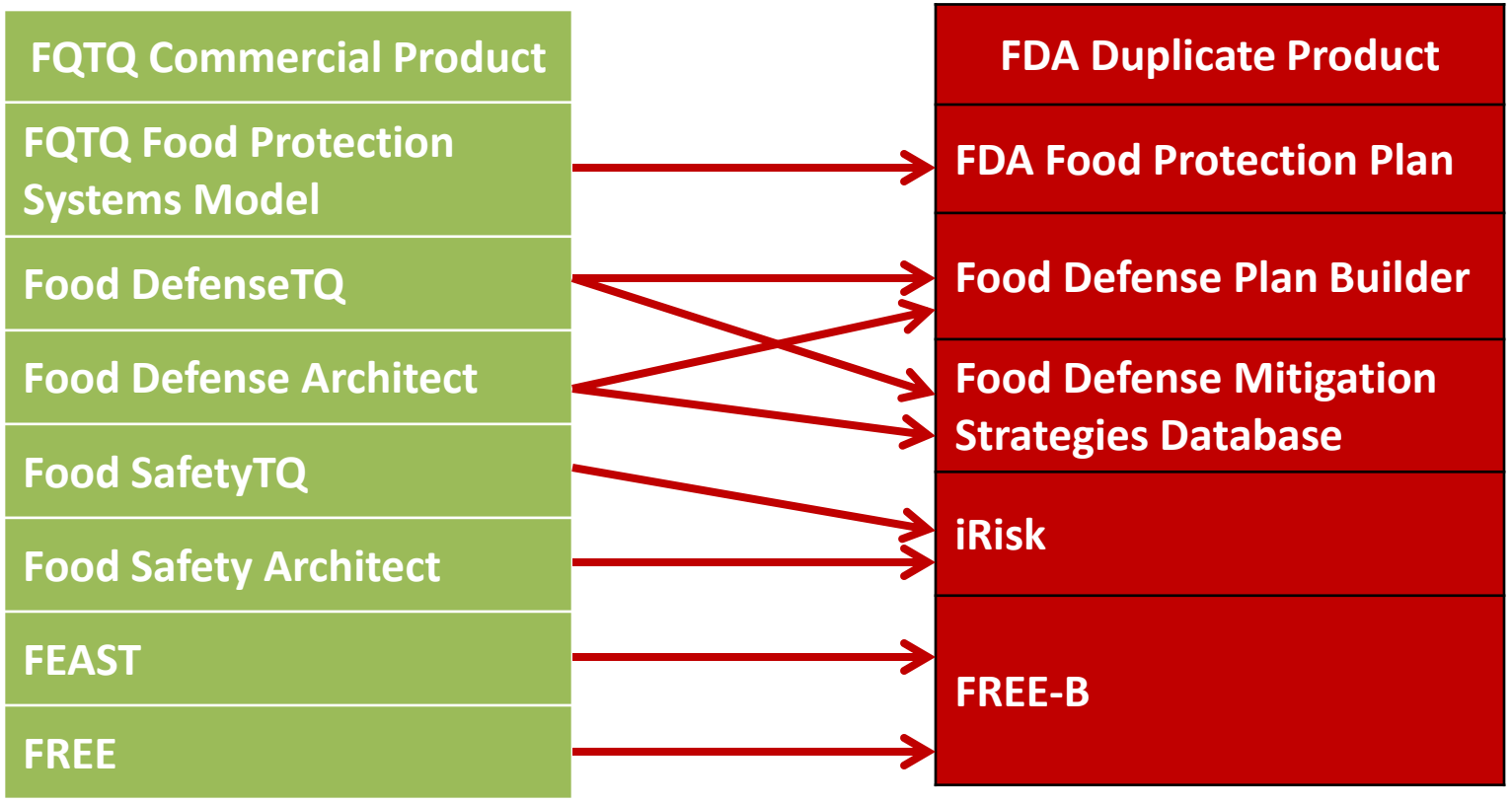
- **The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.**
- **The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.**

25. FQTQ Enhanced Risk Communications

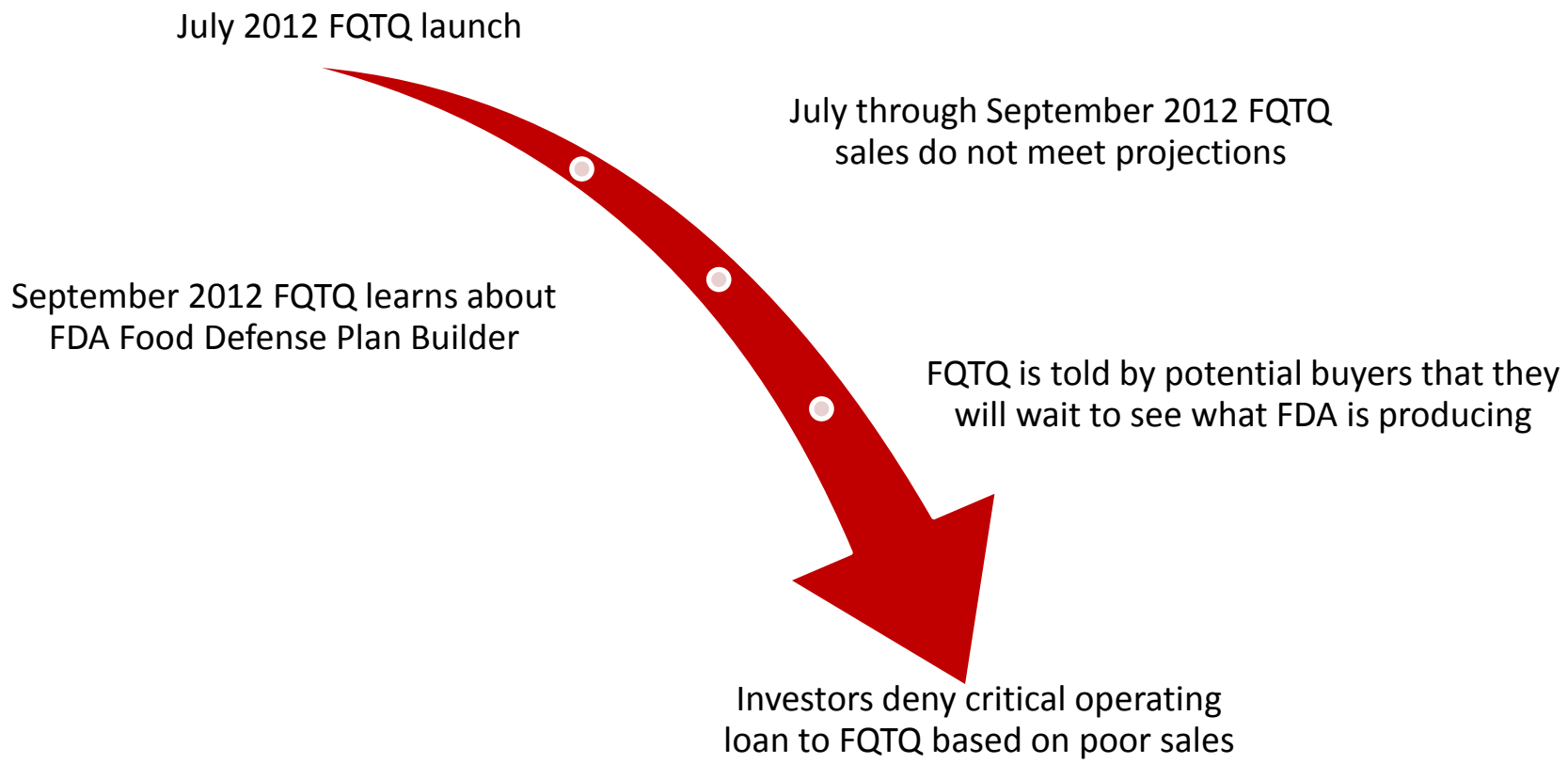
The FQTQ systems model for food protection improves risk communications.

- **The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.**

FDA Duplicates FQTQ Products



FQTQ Is Forced Out of Business



FDA Infringes on Patent US 8,103,601 B2

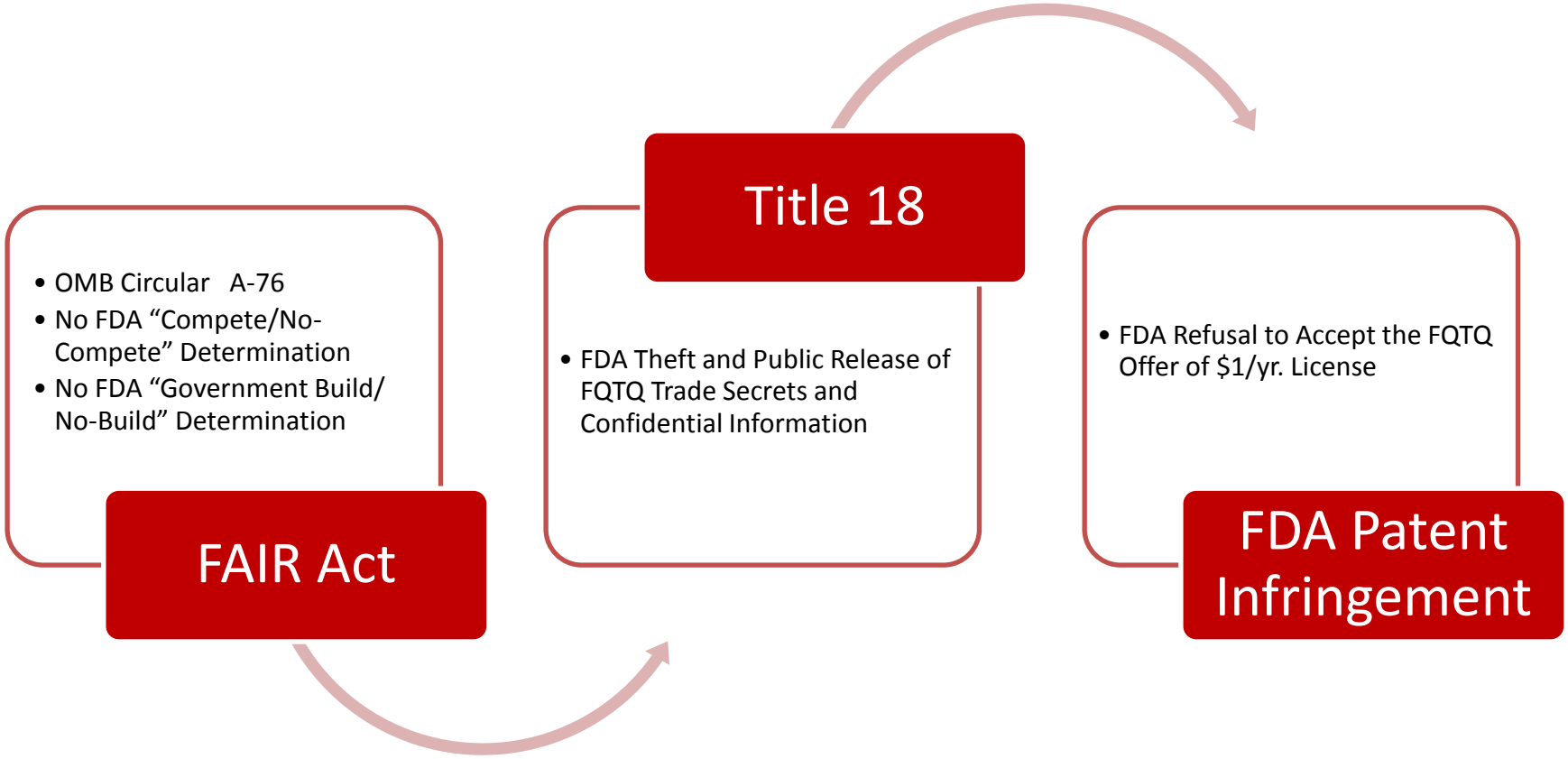
The patent has 20 claims and 101 associated objects of the invention

How FQTQ reduced the patent to use for food was FQTQ trade secret information until it was revealed by FDA in the FQTQ tools they duplicated and released to the public

FQTQ has prepared an extensive technical crosswalk that demonstrates flagrant infringement by the FDA on patent US 8,103,601 B2

FQTQ is prepared to share the results of the crosswalk with the National Small Business Ombudsman if it will assist in the timely resolution of this matter

FDA Unlawfully Competes with FQTQ



FDA-iRISK History and Key Contacts:

Key contacts:

1. FDA contact
   Sherri Dennis
   Email: Sherri.Dennis@fda.hhs.gov Office Phone: 240-402-1914
   Organization: FDA Center for Food Safety and Applied Nutrition

2. IFT prototype framework
   Rosetta Newsome
   Email: rnewsome@ift.org Office Phone: (312) 782-8424
   Organization: Institute of Food Technologists

3. Operationalized IFT prototype into Web-based format
   Greg Paoli
   Email: gpaoli@risksciencesint.com Office Phone: 613-260-1424
   Organization: Risk Sciences International

4. RTI inventory and evaluation
   Stephen Beaulieu
   Email: steveb@rti.org Office Phone: 919-541-7425
   Organization: RTI International

Journal of Food Protection, Vol. 76, No. 3, 2013, Pages 376–385
doi:10.4315/0362-028X.JFP-12-372

FDA-iRISK—A Comparative Risk Assessment System for Evaluating and Ranking Food-Hazard Pairs: Case Studies on Microbial Hazards

YUHUAN CHEN,[1] SHERRI B. DENNIS,[1]* EMMA HARTNETT,[2] GREG PAOLI,[2] RÉGIS POUILLOT,[1] TODD RUTHMAN,[2] AND MARGARET WILSON[2]

[1]*U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, Maryland 20740, USA; and* [2]*Risk Sciences International, Inc., 325 Dalhousie Street, Ottawa, Ontario, Canada K1N 7G2*

MS 12-372: Received 22 August 2012/Accepted 31 October 2012

ABSTRACT

Stakeholders in the system of food safety, in particular federal agencies, need evidence-based, transparent, and rigorous approaches to estimate and compare the risk of foodborne illness from microbial and chemical hazards and the public health impact of interventions. FDA-iRISK (referred to here as iRISK), a Web-based quantitative risk assessment system, was developed to meet this need. The modeling tool enables users to assess, compare, and rank the risks posed by multiple food-hazard pairs at all stages of the food supply system, from primary production, through manufacturing and processing, to retail distribution and, ultimately, to the consumer. Using standard data entry templates, built-in mathematical functions, and Monte Carlo simulation techniques, iRISK integrates data and assumptions from seven components: the food, the hazard, the population of consumers, process models describing the introduction and fate of the hazard up to the point of consumption, consumption patterns, dose-response curves, and health effects. Beyond risk ranking, iRISK enables users to estimate and compare the impact of interventions and control measures on public health risk. iRISK provides estimates of the impact of proposed interventions in various ways, including changes in the mean risk of illness and burden of disease metrics, such as losses in disability-adjusted life years. Case studies for *Listeria monocytogenes* and *Salmonella* were developed to demonstrate the application of iRISK for the estimation of risks and the impact of interventions for microbial hazards. iRISK was made available to the public at http://irisk.foodrisk.org in October 2012.

All stakeholders in the system of food safety would benefit from the availability of a tool that enables rapid, transparent, and rigorous evaluation of risks from foodborne hazards. The numerous combinations of foods and hazards make risk assessment across a broad mandate extremely challenging. In particular, federal agencies require evidence-based and transparent approaches to assess, compare, and evaluate the risk of foodborne illness from microbial and chemical hazards and the public health impact of interventions. Comparative risk assessment, sometimes called risk ranking, is integral to food safety decision making *(26)*. Given the multitude of potential foodborne hazards, limited resources should be focused on the greatest risks (and ideally, the greatest opportunities for risk reduction) among the many hazards, commodities, and farm-to-table stages in the food supply system. Assessing food safety risk over the product life cycle and over a large mandate requires the integration of science and state-of-the-art information technology to identify the food-hazard combinations posing the highest risks, to explore interventions to prevent harm, and to respond immediately when contamination and illness occur.

* Author for correspondence. Tel: 240-402-1914; Fax: 301-436-2641; E-mail: sherri.dennis@fda.hhs.gov.

As further evidence of the need for comparative risk assessment tools, an expert committee convened by the National Academy of Sciences *(26)* recommended that the U.S. Food and Drug Administration (FDA) develop tools for public health risk ranking as part of the iterative steps in a risk-based system for enhancing food safety decision making. The Academy panel recommended that the FDA create a model that is fit for purpose and ''scientifically credible, balanced, easy to use, and flexible'' *(26)* to conduct public health risk ranking in a systematic manner.

The FDA Food Safety Modernization Act, enacted in 2011 *(43),* emphasized the need for risk determination, including low versus high public health risk with regard to food products, production activities, and food facilities. For example, the designation of foods as high risk through risk assessment is needed for promulgating regulations pertaining to a product tracing system. In setting standards for produce safety, assessment is required to compare differences in risk associated with fruits and vegetables that are raw agricultural commodities. Risk analysis of on-farm manufacturing, processing, packing, or holding activities is needed for exempting from mandatory preventive controls certain facilities that engage in activities determined to be low risk and involving specific foods determined to be low risk. Implicit in each of these requirements is the need to

compare risks for many foods and hazards in parallel rather than evaluating one combination at a time.

Assessing the risk associated with various hazards and products can be challenging because of the complex and global nature of the food supply. Foods can be contaminated with microbial pathogens, microbial toxins, and chemical hazards at one or more points in the food supply system. Food safety hazards may be introduced from primary production on the farm, during processing, manufacturing, and retail distribution, and during food preparation at retail establishments or in homes. Control measures and interventions can also be identified and applied at various points in the system. A comparative risk assessment tool is needed to allow a systematic analysis of data for contamination, consumption, dose-response relationships, and health effects to identify the most significant risks and risk reduction opportunities based on public health metrics.

Identifying, comparing, and in some cases prioritizing food safety risks can involve a range of qualitative, semiquantitative, and quantitative methods. Various methods and their applications have been published. Qualitative decision trees or risk rules, such as a likelihood-severity grid for qualitative risk ranking *(4),* are examples of qualitative methods. Semiquantitative risk scoring includes the pathogen-produce pair attribution risk ranking model *(1),* the Risk Ranger *(32)* for determining relative risks for different product-pathogen-processing combinations, and the Food Safety Universe Database *(6, 26)* for ranking risks from food-hazard-location combinations in the food supply.

Many examples of quantitative risk assessment models have been published, notably the FDA and the Food Safety and Inspection Service (FSIS) risk assessments of *Listeria monocytogenes* in ready-to-eat foods *(41)* and *Vibrio parahaemolyticus* in raw oysters *(38).* The FDA and FSIS *L. monocytogenes* risk assessment included the development of a complex mathematical model with inputs of available exposure data for 23 ready-to-eat food categories and three dose-response models. The model predicted relative risk rankings among the 23 food categories based on outputs for two public health metrics (cases per serving and cases per year).

Both quantitative and qualitative methods of risk ranking can be useful for informing policy decisions, depending on the problem, the time frame, the specific risk management questions to be addressed, the availability and quality of the data, and the availability of resources. A readily accessible and structured system is desirable as both a risk assessment tool and a knowledge repository to inform food safety decision making, which often takes place in real time. Here, we describe the development and application of the FDA-iRISK (referred to in this article as iRISK) system, a Web-based database and quantitative risk assessment tool for storing evidence in a structured fashion and then assessing and comparing the health impact of microbial and chemical hazards in foods. To illustrate the capacity of iRISK, we present case studies for *L. monocytogenes* and *Salmonella* from an existing FDA library, including risk estimates for multiple food-hazard combinations and the impact of interventions.

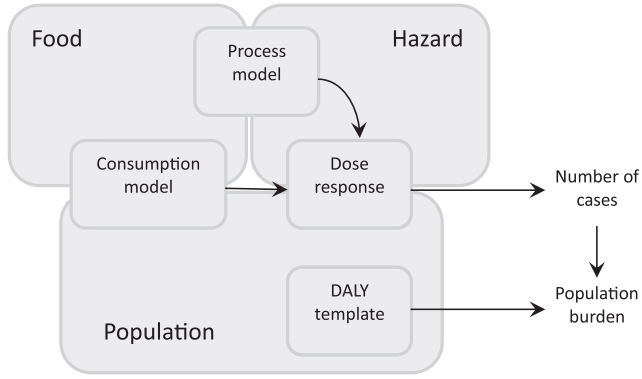


FIGURE 1. *Seven elements of a generic risk scenario in iRISK and their relationships.*

MATERIALS AND METHODS

iRISK development and peer review. The iRISK system was developed through partnership and collaboration with experts within and outside the government. iRISK originated from and built upon a risk ranking prototype developed through a cooperative agreement (grant) between the FDA and the Institute of Food Technologists (IFT). An expert panel with expertise in the food supply system, food safety, risk assessment and management, microbiology, toxicology, and other related areas was convened to develop the framework for the prototype *(29).* The FDA also commissioned a study conducted by RTI International (Durham, NC) to evaluate food safety risk ranking and prioritization models (at a later time RTI International also assisted with proof-of-concept testing of an earlier version of iRISK). Some of the models evaluated were published, but others were not available in the public domain. Based on the evaluation of the scope, strengths, and limitations of the available models, the FDA selected the IFT framework for further development. The IFT framework was operationalized into a series of quantitative risk assessment model elements by Risk Sciences International. The risk assessment model elements are combined with a relational database, a user interface, and report generation capabilities to form a Web-based program, designated iRISK. iRISK has undergone an external peer review for underlying algorithms and mathematical equations and the usability of the interactive Web interface, with a focus on microbial hazards. The FDA published a peer reviewed report describing efforts to expand the capacity of iRISK and enhance the user interface as suggested by the peer review panel *(39).*

iRISK model elements and their relationships. A risk scenario developed in iRISK is a quantitative risk assessment for a food-hazard pair to estimate the risk it poses to a population. The Web interface enables users to define the food and the hazard of interest, edit inputs, update references and assumptions, and store, view, and share data, information, and risk scenarios. Figure 1 illustrates the seven elements of a generic risk scenario: the food, the hazard, the population of consumers, a process model (i.e., food production, processing, and handling practices), consumption patterns in the population, dose-response relationships, and burden of disease measures associated with health effects (e.g., losses in disability-adjusted life years [DALYs]).

The iRISK model is consistent with the Codex risk assessment paradigm *(10, 11)*; hence, data inputs fall into two domains: exposure assessment and hazard characterization. Inputs in the exposure assessment domain focus on consumption patterns in the population, introduction of the hazard, and changes to the level and prevalence of the hazard through the farm-to-fork chain.

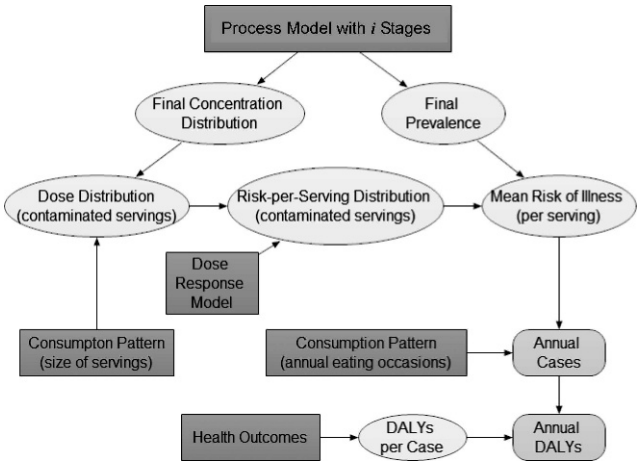


FIGURE 2. *iRISK model inputs and outputs for a food-hazard risk scenario (microbial hazards). User inputs are indicated by square nodes. Model outputs are indicated by oval nodes, with the ultimate risk output being the Annual DALYs for a food-hazard pair under evaluation. The data inputs as shown apply to a risk scenario in which the food is contaminated with a microbial hazard or a chemical hazard that causes acute effects. A risk scenario involving a chronic hazard includes the same inputs and outputs, except that consumption inputs are the amount consumed per day and the number of consumers.*

Inputs in the hazard characterization domain focus on the hazard pathogenicity or toxicity (expressed as a dose-response relationship) and the public health burden associated with infection or toxic effects of the hazard.

Structure of a generic model for microbial and chemical hazards. iRISK is designed to estimate risk associated with both microbial and chemical hazards. Figure 2 illustrates the inputs and outputs of a generic model for a food-hazard pair with a microbial hazard. This generic model also applies to a scenario in which the hazard is a chemical agent that causes an acute health effect. For a food-hazard pair in which the hazard is a chemical agent that causes chronic health effects, the overall underlying model structure is similar, but consumption patterns and doses are defined and measured differently. In this study, we focused on microbial hazards. The process model with multiple stages (Fig. 2) starts with the initial conditions of a pathogen in a food, i.e., the proportion of contaminated units (prevalence) and the distribution of the contamination in the contaminated units. The changes in contamination prevalence and levels as a result of food production, processing, and handling practices are modeled to estimate the final prevalence and concentration distribution of the hazard in contaminated units at the point of consumption. iRISK integrates the user-provided evidence inputs based on built-in templates and mathematical equations according to the biological and handling processes specified by the user. The outputs are generated by Monte Carlo simulations. The computations, including the Monte Carlo simulations, are conducted using the Analytica Decision Engine (Lumina Decision Systems, Los Gatos, CA). The mathematical architecture of iRISK has been peer reviewed *(39)*. Technical details on the models and equations employed are described in the technical documentation *(19)* available on-line with the iRISK tool.

Input elements for a food safety risk scenario. The user begins by specifying hazards, foods, and populations of interest and inputs data corresponding to the exposure assessment and hazard characterization domains. iRISK provides the model framework and templates, and the user chooses the template appropriate for a risk scenario and provides evidence (including the opportunity for providing a rationale for the selection of the evidence) for the seven elements (Fig. 1) within the framework.

Element I: foods. The definition of food affects the process model (e.g., the process model for peanut butter is different from that for soft ripened cheese). The granularity of the food classification (e.g., soft ripened cheese versus brie) depends on the specific purposes of the evaluation.

Element II: hazards. The type of hazard affects process model options (see description of process types below) and dose-response options provided within iRISK for the hazard. Risk ranking is done on the basis of the health burden for a food-hazard pair.

Element III: population groups. The choice of population group is linked to the choice of the dose-response model, specific patterns of health effects, and the consumption model. Depending on the risk scenario, one or more population groups (e.g., perinatal population or adults 60 years or older) and life stages of interest (e.g., early childhood or a duration of 5 years) can be defined.

Element IV: process models. The process model describes the impact of food production, processing, and handling on the level and prevalence of the hazard. The outputs from the process model are the probability distribution of the level of the hazard in the food at the time of consumption and the prevalence of contaminated servings; these data are used to predict ingested dose and the number of cases of illness. The data requirements for a process model include the initial conditions (i.e., initial prevalence, initial distribution of the hazard, and the unit mass), followed by process stages from farm to table (or a smaller scope) of the food supply chain up to the point of consumption.

Process models are defined as a succession of process stages, events, or steps along the farm-to-fork continuum. Each process stage is defined by a process type that describes the impact of the stage on the hazard and the unit size of the food. The process type describes what happens in an individual process stage, expressed as a fixed value or as a probability distribution representing variability. A process type may be selected from a menu of built-in process types that have been customized for this application. The process types and the associated mathematical equations describe the major process mechanisms that affect the prevalence, level, and spatial distribution of a microorganism. Mathematical equations describing the process types have been peer reviewed *(39)* and are similar to those previously published *(18, 27, 28)*. The process types and their data inputs are further described in Table 1.

Element V: consumption models. The consumption model is defined in relation to the specified population group. For microbial hazards, the distribution of the amount of food eaten (i.e., serving size) during each eating occasion and the number of eating occasions (i.e., number of servings) annually are required inputs. For chemical hazards, the distribution of the average amount of the food eaten daily (over a period of time or a lifetime) and the number of consumers are required.

Element VI: dose-response models. The dose-response relationship predicts the probability of a specific biological effect (response) at various levels of ingestion (doses) of a hazard. The

TABLE 1. *Process types and data inputs describing the impact of a process stage on microbial and/or chemical hazards*

Process type	Description of data inputs[a]
Increase by growth	This process type is applied to microbial hazards only. It describes the increase in level (a distribution or a fixed value on a log scale such as log CFU) due to growth of the bacterial pathogen, while prevalence is assumed to be unaffected.
Increase by addition	This process type represents the addition of the hazard in the amount of the specified addition to a unit of the food[b] (a distribution or a fixed value on a log scale such as log CFU or log PFU of a microbial hazard to a unit, or grams of a chemical hazard to a unit). The likelihood of such an addition occurring is also required (a fixed value from 0 to 1). This process type may be used to describe an increase in prevalence and/or concn or level as a consequence of cross-contamination, e.g., from the processing environment.
Decrease	This process type describes the removal or inactivation of some fraction of the hazard. For chemical hazards, the decrease is defined by a fixed value or a distribution that ranges from 0 (no decrease at all) to <1, because total elimination is assumed to be impossible. For microbial hazards, the decrease is defined usually by a distribution or by a fixed value of the log reduction in the level of contamination within the contaminated units. A reduction in prevalence is possible when the microbial hazard decreases because the individual microbes are discrete units. In contrast, chemical contamination is assumed to be continuous (i.e., distributed homogeneously throughout contaminated units); this process type leads to a diminution of the concn in contaminated units without change in the prevalence.
Pooling	When units of food are combined into larger units, some contaminated units may be mixed with some uncontaminated units, resulting in an increase in prevalence and a decrease in the concn or level of the hazard in each contaminated unit. Pooling reflects the simultaneous impact of cross-contamination and dilution. The input is the new unit mass (grams) of the food, and the iRISK model computes the associated changes to prevalence and concn or level of the hazard.
Partitioning	When units of food are subdivided, the result depends on the nature of the hazard. For chemical hazards, neither concn nor prevalence would be affected because the chemical is assumed to be spread sufficiently uniformly throughout the food that it would be expected to be in all partitions of the food. Microbial hazards exist as discrete units such as individual bacterial cells (at levels typically much lower than discrete molecules of chemicals) that cannot be divided among more units of food than their own number. The input is the new unit mass (grams) of the food as a fixed value, and the iRISK model computes the associated changes to prevalence and concn or level of the hazard.
Evaporation or dilution	This process type represents the proportional increase or decrease in hazard concn or level that results from varying the mass of the contaminated unit. Inputs fall between 0 and 1 for dilution and 0 and >1 for evaporation. For example, 2 would represent a doubling of the concn or level associated with a halving of the mass (such as in evaporation), and 0.25 would represent a fourfold decrease in the concn or level that results from increasing the mass by the same factor (such as in dilution).
Redistribution (partial)	This parameter describes the factor by which prevalence increases as a consequence of cross-contamination among food units; iRISK reduces the concn or level accordingly. Therefore, the input is a multiplier (≥ 1), either a distribution of values or a fixed value, to be applied to the current prevalence level. Using the number 1 implies no change in prevalence or no cross-contamination. This process type describes cross-contamination among food units but not from the processing environment.
Redistribution (total)	Selection of this process type automatically redistributes contamination evenly among all units. For chemical hazards, prevalence is set to 1.0. For microbial hazards, prevalence is set to 1.0 when there is a high enough level of organisms to redistribute to all units or is set to the maximum value possible when the level is not high enough. In both cases, the concn or level of the hazard for each unit is reduced accordingly by iRISK, keeping the total hazard load in the system (across all units) constant. No data input is needed. This process type describes cross-contamination among food units but not from the processing environment.
No change	The process does not affect prevalence, concn or level, or unit mass; no data input is needed. This designation is useful for describing the full processing system and for explicitly noting that no effect is expected at that stage. A ''placeholder'' process type is also available to be used in the initial stages of developing a process model before specific data are available.

[a] Usually the data input is defined by a distribution of values rather than a point value to represent the variability, such as in the levels of a hazard in food or in the growth, increase, and decline of a hazard in food over the product life cycle from production to consumption.

[b] A unit is a fixed quantity of food, which is key to maintaining a clear definition of prevalence because prevalence is described as the fraction of units that have one or more pathogens or any chemical contamination. Various processes in food production will change the functional unit of food because of, for example, pooling of milk from a farm tank into a bulk tank or partitioning milk from a processing plant to individual packages of milk. The change in the functional unit must be taken into account to adjust the estimates of prevalence and level or concentration of a hazard in response to these changes.

dose-response relationship is specific to the hazard type, either microbial or chemical (further broken down by acute versus chronic hazard). Dose-response relationships specific to population groups or foods can also be developed when data are available. One of the case studies (case study 2) provides population-specific dose-response models for *L. monocytogenes,* such as for the perinatal population and for adults 60 years of age or older. Currently, sufficient data are not available to develop dose-response relationships specific to the food matrix.

Element VII: health outcomes. Foodborne illness caused by a pathogen may have more than one health outcome among different individuals in the population *(2, 17, 21, 33).* For example, infection with *Salmonella* may result in mild diarrhea, severe

diarrhea requiring hospitalization, reactive arthritis, or death *(40)*. Different hazards will cause different frequencies of health outcomes, such as the proportion of illness cases resulting in hospitalization or death *(33)*. To compare the population health burden across different hazards, it is necessary to specify health endpoints of the illness in association with the hazard and translate the endpoints into a common metric. The DALY is one of several commonly used health impact metrics that integrate information on the severity and duration of illness to estimate disease burden *(2, 17, 21)*. A DALYs-per-case value (Fig. 2) is used as a measure of the averaged burden of disease per case of illness, taking into account the relative frequency of each potential health impact. Each health endpoint is defined in terms of its duration and severity, with the burden of disease being the product of these two factors. In the case of death, duration is expressed as years of life lost based on the age of the person affected, and severity is set to the maximum value of 1.0. Users can enter different health endpoints in iRISK to create a new DALY template. Through an expert elicitation *(39)*, the FDA has developed DALY templates for a number of hazards.

Case study data inputs. Case study 1 is a risk scenario for *Salmonella* (nontyphoidal) in peanut butter to illustrate the use of iRISK to estimate the population health burden for a single food-hazard pair. Through the use of built-in templates, inputs were entered for the elements of the *Salmonella* in peanut butter risk scenario (Table 2). Table 2 describes the iRISK template used for the various input parameters for the process model, the process type selected, and the input data, either as a fixed value (e.g., initial prevalence and unit mass) or as a distribution (e.g., initial level and log reduction during storage). For illustration purposes, the process model for peanut butter production was simplified, starting at the end of processing and including two stages: packaging and storage before consumption. At the end of processing, some units are contaminated, and the levels of *Salmonella* in the contaminated units are assumed to decline during storage before consumption. Data from the literature were used to estimate the initial contamination and log reduction during storage through the process model. Specific data inputs for the consumption model, dose-response model, and health effects are also shown Table 2. The iRISK templates provide the capacity to enter evidence that is required for the risk scenario in a consistent fashion and to document assumptions and sources of the data and references. These templates are described in greater detail in supplemental Tables IA, IB, and IC *(19)*. Having defined the food-hazard risk scenario by entering the evidence captured in Table 2, the scenario is available in a risk scenarios library within the individual user's iRISK database. The risk scenario is then selected for computation and reporting. iRISK constructs the model based on the evidence in the database and runs a Monte Carlo simulation while checking continuously for converging statistics of the output distribution. A report is generated as a portable document format file (Adobe Systems, San Jose, CA). The report includes a summary of the model outputs and risk scenario details, including all the input data, descriptions, and references, i.e., all the data and rationale entered by the user.

The second case study consists of risk scenarios for *L. monocytogenes* in soft ripened cheese for three population groups: the perinatal population, adults 60 years of age or older (adults 60+), and the general population (intermediate age). The perinatal population is defined as fetuses and neonates from 16 weeks after fertilization to 30 days after birth, the same definition used by the FDA and FSIS in the 2003 *L. monocytogenes* risk assessment *(41)*. Data and information inputs were the same for the hazard, the food, and the process model, whereas the three population groups were defined and the inputs were different for the dose-response model, consumption model, and DALY templates (Table 2). A more detailed description of the data, references, and rationale is provided in supplemental Tables IIA, IIB, and IIC *(19)*. The risk scenarios for the three population groups have different consumption patterns, dose-response relationships, and health effects. The model inputs for case studies 1 and 2 illustrate that although the food, hazard, and population of interest are different for the *Salmonella* risk scenario and the *L. monocytogenes* risk scenarios, the underlying model structure (Fig. 2) and the nature of the evidence required as inputs (Table 2) are the same for both pathogens. Case studies 3 and 4 included the evidence from case studies 1 and 2 to rank risks from multiple food-hazard pairs and to evaluate the effectiveness of interventions. Additional data were obtained from published studies *(23, 24, 30, 31)* and from an ongoing market basket survey to develop case study 3 on a risk scenario for *L. monocytogenes* in cantaloupes for adults 60+. The data inputs are shown in supplemental Tables IIIA, IIIB, and IIIC *(19)*.

Integration of model inputs through Monte Carlo simulations to estimate population health burden. The evidence entered for the seven elements of a risk scenario determine the level of exposure and the health impact of that exposure (Fig. 2). A risk-per-serving distribution (among contaminated servings) is generated taking into account the variability in the final distribution of the contamination (process model), the serving size distribution (consumption model), and the dose-response relationship (dose-response model). The mean risk of illness per contaminated serving is calculated from the distribution of risk (describing variability derived from any of the probabilistic inputs) generated through Monte Carlo simulation. The mean risk of illness per serving is the product of this mean and the prevalence of contaminated units at the time of consumption. The expected annual number of illness cases is calculated by multiplying the mean risk of illness per serving by the number of servings per year. The annual DALYs are calculated by multiplying the annual number of cases by the DALYs-per-case value. The iRISK Monte Carlo simulation is designed to address variability, and uncertainty can be explored by scenario analysis (e.g., changing parameters or changing distributions and comparing results).

The final result is the annual health burden, measured in DALYs lost per year, expected to result from the food-hazard combination given the assumptions for contamination, dose-response, health effects, and consumption pattern in the population in each scenario. Integration of data and information on duration and severity allow the comparison of different microbial pathogens associated with qualitatively different illness symptoms, severities, and health outcomes, including variations in the case complication (e.g., case fatality) rates among pathogens.

RESULTS AND DISCUSSION

iRISK 1.0 was used to develop the case studies reported here. These case studies are provided exclusively for illustrative purposes. The actual implementations of several of the case studies are available to users in the publicly released version of iRISK *(19)*.

Case study 1: a single food-hazard pair in one population group. The model results (Table 3) include final pathogen level (the mean of the distribution is reported), final prevalence, total illnesses, mean risk of

TABLE 2. *Examples of model inputs for food-hazard scenarios in iRISK*

Element of risk scenario	*Salmonella* in peanut butter, total population			*L. monocytogenes* in soft ripened cheese, three population groups		
	Input parameter, iRISK template	Model input	Reference(s)[a]	Input parameter, iRISK template	Model input	Reference(s)[a]
Food	Peanut butter	Description	*42*	Soft ripened cheese	Description	*41*
Hazard	*Salmonella*	Description	*34, 40*	*L. monocytogenes*	Description	*41*
Process model	Initial prevalence (manufacturing)	5.50E−06	*7–9, 36*	Initial prevalence (retail)	0.0104	*15*
	Initial concn	Uniform (−1.52, 2.55) log CFU/g	*5, 22, 34, 44*	Initial concn	Triangular (−1.39, −1.15, 0.699) log CFU/g	*15*
	Initial unit mass	6.85E+06 g		Initial unit mass	227 g	*15*
	Process stage 1: packaging, partitioning	Unit mass 250 g		Process stage 1: consumer storage, increase[b]	Triangular (0, 0.03, 5.79) (log CFU)	*12, 41*
	Process stage 2: storage, decrease	Uniform (0.49, 3.47) log CFU	*5*	NA		
Consumption model	Grams per eating occasion	30 g	*20, 37*	Grams per eating occasion[c]	(i) Triangular (10, 28, 85); (ii) Triangular (10, 28, 85); (iii) Triangular (10, 28, 168)	*41*
	Eating occasions per year	1.7E+10		Eating occasions per year[c]	(i) 1.2E+07; (ii) 1.8E+08; (iii) 1.7E+09	*41*
Dose-response model	Beta-Poisson model	$\alpha = 0.1324$; $\beta = 51.45$	*13*	Exponential[c]	(i) 4.51E−11; (ii) 8.39E−12; (iii) 5.34E−14	*14*
Health effects	DALY template (salmonellosis general population)	0.019 DALYs per case	*2, 33, 40*	DALY templates (listeriosis)[c]	(i) 14 DALYs per case; (ii) 2.6 DALYs per case; (iii) 5.0 DALYs per case	*21, 25*

[a] Detail description of rationale can be found in the supplemental Tables IA, IB, IC, IIA, IIB, and IIC *(19),* including assumptions made in using data and information from the listed references to derive the model inputs for the risk scenarios.

[b] The ComBase Predictor (http://www.combase.cc) was used to determine growth based on times and temperatures during consumer storage. See details in supplemental Table IIB *(19).*

[c] Inputs are defined separately for consumption, dose-response, and health effects for the three *L. monocytogenes* risk scenarios: (i) the perinatal population, (ii) adults 60 years of age and older, and (iii) the intermediate-age population (5 to 59 years of age). The three risk scenarios have the same food, hazard, and process model.

01028

TABLE 3. *iRISK output example: summary results for a single food-hazard pair*

Scenario	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Salmonella in peanut butter, total population	0.273	4.18E−06	3,380	1.99E−07	1.70E+10	63.5	3.74E−9

illness, total eating occasions, annual DALYs, and DALYs per eating occasion. The detailed report generated for each scenario contributes to the documentation, knowledge base development, transparency, and consistency that is key to the application of comparative risk assessment.

The mean risk of illness is the average probability of illness from one serving or eating occasion and was generated through Monte Carlo simulations from the mean of the risk-per-serving distribution among contaminated servings (an intermediate result not shown) and the final prevalence of contamination in the food. The results shown in Table 3 accounted for variability of all inputs for a food-hazard pair. When the final prevalence of the pathogen contamination in food is low (e.g., less than 1%), as is often the case, the majority (e.g., >99%) of the servings are not contaminated. The risk per serving for these noncontaminated servings is 0. The 5th, 95th, and 99th percentiles of the risk per serving (among all servings) is then 0. The mean risk of illness per serving (among all servings) will likely also be very low; nevertheless, it is not 0 because the risk for the <1% of contaminated products is not 0. This was the case for the risk scenario *Salmonella* in peanut butter (Table 3), where the final prevalence was approximately 4E−6 (approximately 4 in 1 million) and the mean risk of illness per serving was approximately 2E−7 (or 2 cases per 10 million servings). The Monte Carlo approach applied in iRISK, which focuses computation resources on only contaminated units, is much more efficient than simulation of both contaminated and noncontaminated units, given the low prevalence expected in the final servings for many food-hazard pairs.

Case study 2: a single food-hazard pair in three population groups. Based on the data inputs for *L. monocytogenes* in soft ripened cheese and the population groups, iRISK generated risk estimates through Monte Carlo simulations for each of the three risk scenarios (Table 4). The mean risk of illness was 7.1E−8 for the perinatal population, 1.3E−8 for adults 60+, and 1.4E−10 for the intermediate-age population. The difference was primarily driven by the difference in the assumed *L. monocytogenes* dose-response relationship among the three population groups (Table 2), given that the same process model was used, which resulted in the same final mean level and the same final prevalence of *L. monocytogenes* in the soft ripened cheese at the point of consumption. Combining the mean risk of illness output with the number of servings per year, the expected annual number of cases was determined (results not shown) and subsequently translated into annual DALYs loss of 11.7, 6.12, and 1.20 for the perinatal, adults 60+, and intermediate-age populations, respectively. The health metric (e.g., annual DALYs lost) formed the basis for risk ranking for multiple risk scenarios.

iRISK was further employed to characterize uncertainty about the annual DALYs, using the intermediate-age population as an example. The uncertainty analysis for the predicted annual DALYs was obtained through sensitivity analysis focused on the dose-response relationship. The inputs for the dose-response model were different r values (the single parameter of an exponential dose-response model) representing the 5th percentile (r = 1.42E−14), median (r = 5.34E−14), and 95th percentile (r = 1.02E−13) of the r value uncertainty distribution from the Food and Agriculture Organization of the United Nations and the World Health Organization *(14)*. The resulted annual DALYs were 0.320 (5th percentile), 1.20 (median), and 2.30 (95th percentile) for the uncertainty estimates. The median DALYs result was used in risk ranking.

Case study 3: risk ranking for multiple food-hazard pairs. From the FDA iRISK library, we selected five risk scenarios for ranking, including the food-hazard pairs developed in case studies 1 and 2 and a risk scenario for *L. monocytogenes* in cantaloupes for adults 60+. The case studies illustrate that iRISK allows risk ranking of population health burden across many different dimensions: multiple population groups (Table 4), multiple foods (Table 5), and multiple food-hazard combinations (Table 6). Table 4 shows risk ranking among three population groups: *L. monocytogenes* in soft ripened cheese for the perinatal population, intermediate-age population, and adults 60+. Table 5 shows an example of risk ranking for two different foods, soft ripened cheese and cantaloupe, for the same populations in a baseline nonoutbreak situation. All five risk scenarios can be

TABLE 4. *iRISK output example: risk ranking across multiple population groups*

Scenario of *L. monocytogenes* in soft ripened cheese	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Perinatal population	3.55	0.0104	0.850	7.08E−8	1.20E+07	11.7	9.77E−7
Adults 60 yr and older	3.55	0.0104	2.37	1.32E−8	1.80E+08	6.12	3.40E−8
Intermediate-age population	3.55	0.0104	0.242	1.42E−10	1.70E+09	1.20	7.08E−10

TABLE 5. *iRISK output example: risk ranking across multiple foods*

Scenario of *L. monocytogenes* in adults 60+	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Cantaloupe	2.32	0.0130	2.39	2.22E−9	1.08E+9	6.18	5.72E−9
Soft ripened cheese	3.55	0.0104	2.37	1.32E−8	1.80E+08	6.12	3.40E−8

selected for ranking (Table 6), although the food-hazard pairs are being compared for different population groups. In some cases, it may be important and more informative to make comparisons based on the same population. The health burden associated with *L. monocytogenes* in soft ripened cheese for the total U.S. population is the sum of that from the perinatal and intermediate-age populations and adults 60+. We used a risk scenario grouping option in iRISK to aggregate the total DALYs from the three population groups and compared the aggregate DALYs for *L. monocytogenes* with the annual DALYs for *Salmonella* in peanut butter in the total U.S. population (Table 6). These examples illustrate the flexibility of the iRISK system, which can be used to address different questions to meet different risk management decision-support needs.

Case study 4: evaluation of interventions. The predictive multistage process model is the means by which iRISK enables evaluation of control measures and potential interventions. For case study 2, the baseline risk scenario for *L. monocytogenes* in soft ripened cheese for the perinatal population included the amount of growth as having a Triangular probability distribution (minimum = 0, mode = 0.03, maximum = 5.79), with units of log CFU. The maximum growth of 5.79 log CFU was based on the assumption of 15 days of storage at 13.0°C (see supplemental Table IIB *(19)*). We conducted sensitivity analyses using iRISK to evaluate the impact of reduced storage temperature through interventions such as consumer education. When the maximum storage temperature is reduced from 13.0°C (supplemental Table IIB, mean temperature + 4 SD) to 10.6°C (mean + 3 SD) or 8.2°C (mean + 2 SD), the growth of *L. monocytogenes* (maximum level) during consumer storage would be reduced from 5.79 to 3.42 and 1.64 log CFU, respectively. The corresponding predicted annual loss in DALYs would decrease from 11.7 to 0.128 and 0.00817, respectively, keeping all other inputs in the model unchanged.

iRISK can be used to evaluate interventions at any of the stages in the process model. Using the *Salmonella* in peanut butter risk scenario, we evaluated the impact of interventions in the processing environment on predicted health burden in the total population. For example, food producers may implement measures such as controlling personnel and material movements, applying hygienic equipment design principles, and minimizing or eliminating moisture in the peanut postroasting area *(16)* to reduce the levels of *Salmonella* contamination in the postroasting stages of production. If such control measures decrease contamination from the baseline (uniformly distributed on the log scale between 1.52 and 2.55) for the initial level by reducing the maximum level by 1 or 2 log CFU, the predicted annual loss in DALYs would be reduced by 67 and 93%, respectively (Fig. 3).

The results presented in these case studies were based on the data inputs and assumptions made; the predicted mean risk of illness and annual DALYs will change as different inputs are used. The risk scenarios, risk estimates, and risk rankings presented in this study are primarily for illustration purposes. Because the data are stored in each user's unique registry within iRISK, the risk scenarios can be easily retrieved and updated with new data and updated assumptions.

Future considerations. Ongoing efforts are being made to further improve and validate the iRISK model, including further testing, adding functionalities such as more probability distribution options, and improving the capacity of iRISK to predict health burden of microbial toxins. iRISK is flexible; in addition to the DALY metric, other health impact metrics such as cost of illness *(3, 35)* may be added to the system. Ongoing efforts include increasing the library of food-hazard pairs. Like any quantitative risk assessment, development of a risk scenario in iRISK is data intensive. Data are needed from multiple sources, including the scientific literature, government

TABLE 6. *iRISK output example: risk ranking of population health burden across multiple hazards, foods, and population groups*

Scenario	Final mean level (log CFU/g)	Final prevalence	Total no. of illnesses	Mean risk of illness	No. of eating occasions	Annual DALYs	DALYs per eating occasion
Group 1: *Salmonella* in peanut butter, total population	0.273	4.18E−06	3,380	1.99E−07	1.70E+10	63.5	3.74E−9
Group 2: *L. monocytogenes* in soft ripened cheeses							
Total population						19.0	
Perinatal population	3.55	0.0104	0.850	7.08E−8	1.20E+07	11.7	9.77E−7
Adults 60 yr and older	3.55	0.0104	2.37	1.32E−8	1.80E+08	6.12	3.40E−8
Intermediate age population	3.55	0.0104	0.242	1.42E−10	1.70E+09	0.120	7.08E−10

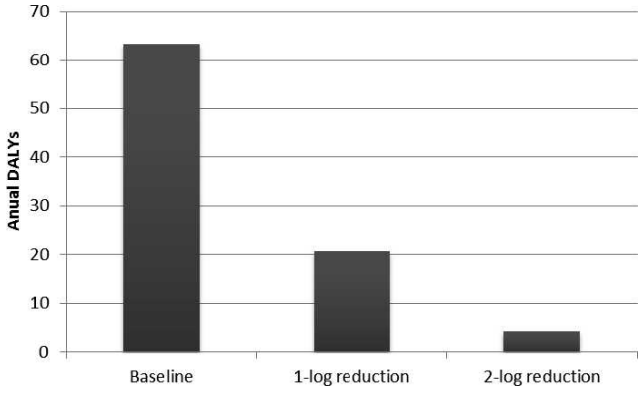


FIGURE 3. *iRISK output example: evaluation of intervention for the* Salmonella *in peanut butter risk scenario. Assuming improved control measures in the processing environment that reduces the maximum level of* Salmonella *contamination postroasting, the impact of the intervention on the annual DALYs was conducted using sensitivity analysis in iRISK. The inputs for the scenarios for the baseline and 1-log and 2-log reductions in the maximum level were distributions Uniform (−1.52, 2.55), Uniform (−1.52, 1.55), and Uniform (−1.52, 0.55), respectively.*

surveys (e.g., the National Health and Nutrition Examination Survey for consumption), publicly accessible databases (e.g., ComBase), expert elicitation and judgment (e.g., DALY-per-case estimates), and regulatory sampling and commissioned studies, as was shown in the case studies. Targeted data collection of prevalence and enumeration data for specific hazards in specific commodities at specific points throughout the food supply chain would help expand the library of food-hazard pairs. iRISK can be used to understand what takes place in a normal baseline situation and to explore an outbreak situation.

In conclusion, iRISK is an interactive, Web-based system that enables rapid, structured, quantitative risk assessment and serves as a knowledge repository due to the underlying relational database and reporting capability. iRISK has been designed to provide breadth and flexibility of calculations and computational features to simultaneously analyze data and estimate health burden in a manner that allows comparison across many dimensions with regard to hazards, foods and food commodities, food production, processing, and handling practices, and populations and the evaluation of interventions. iRISK calculates, through Monte Carlo simulation, the number of illness cases expected based on the contamination of the food by the hazard in question, the typical consumption pattern, and the dose-response relationship and then translates the number of cases into a public health metric to permit comparison of the public health burden across multiple food-hazard pairs. The FDA anticipates further enhancing the capacity and expanding the application of iRISK to support decision making to ensure food safety. iRISK version 1.0 was made available to the public in October 2012 *(19)*.

ACKNOWLEDGMENTS

The authors thank the many experts who provided invaluable input and critiques to assist the development of the iRISK system, including members of the IFT expert panel, RTI, and external peer reviewers. This work was supported in part by appointments (R. Pouillot) to the Research Participation Program at the Center for Food Safety and Applied Nutrition, administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the U.S. Food and Drug Administration.

REFERENCES

1. Anderson, M., L.-A. Jaykus, S. Beaulieu, and S. Dennis. 2011. Pathogen-produce pair attribution risk ranking tool to prioritize fresh produce commodity and pathogen combinations for further evaluation (P^3ARRT). *Food Control* 22:1865–1872.
2. Australian Institute of Health and Welfare. 2001. The burden of disease and injury in Australia 1996. Available at: http://www.aihw.gov.au/bod/bod_yld_by_disease/index.cf. Accessed 7 May 2012.
3. Batz, M. B., S. Hoffmann, and J. G. Morris, Jr. 2011. Ranking the risks: the 10 pathogen-food combinations with the greatest burden on public health. Emerging Pathogens Institute, University of Florida. Available at: http://www.epi.ufl.edu/sites/www.epi.ufl.edu/files/RankingTheRisksREPORT.pdf. Model available at: http://www.thefsrc.org/firrm.htm. Accessed 5 April 2012.
4. Bernard, D. T., K. E. Stevenson, and V. N. Scott. 2006. Hazard analysis, appendix 8-B, p. 57–68. *In* V. N. Scott and K. E. Stevenson (ed.), HACCP: a systematic approach to food safety, 4th ed. Food Products Association, Washington, DC.
5. Burnett, S. L., E. R. Gehm, W. R. Weissinger, and L. R. Beuchat. 2000. Survival of *Salmonella* in peanut butter and peanut butter spread. *J. Appl. Microbiol.* 89:472–477.
6. Cassidy, M. 2003. The food safety universe database: a risk assessment and risk ranking tool. Available at: http://www.aic.ca/conferences/pdf/Mike_Cassidy3.pdf. Accessed 27 July 2012.
7. Centers for Disease Control and Prevention. 2007. Multistate outbreak of *Salmonella* serotype Tennessee infections associated with peanut butter—United States, 2006–2007. *Morb. Mortal. Wkly. Rep.* 56: 521–524.
8. Centers for Disease Control and Prevention. 2009. Multistate outbreak of *Salmonella* infections associated with peanut butter and peanut butter–containing products—United States, 2008–2009. *Morb. Mortal. Wkly. Rep.* 58:1–6.
9. Chen, Y., V. N. Scott, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A. Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of *Salmonella* in low-moisture foods. II. Hygiene practices to minimize *Salmonella* contamination and growth. *Food Prot. Trends* 29:435–445.
10. Codex Alimentarius Commission. 1999. Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL-30. Available at: http://www.codexalimentarius.net/web/more_info.jsp?id_sta=357. Accessed 18 May 2011.
11. Codex Alimentarius Commission. 2007. Working principles for risk analysis for food safety for application by governments. CAC/GL-62. Available at: http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10751. Accessed 18 May 2011.
12. EcoSure. 2008. EcoSure 2007 cold temperature database. 2007 U.S. cold temperature evaluation design and summary pages. Available at: http://foodrisk.org/exclusives/EcoSure/. Accessed 24 October 2010.
13. Food and Agriculture Organization of the United Nations and World Health Organization. 2002. Risk assessments of *Salmonella* in eggs and broiler chickens. Technical report. Microbiological risk assessment series 2. Food and Agriculture Organization of the United Nations and World Health Organization, Rome. Available at: http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/salmonella0/en/. Accessed 7 May 2012.
14. Food and Agriculture Organization of the United Nations and World Health Organization. 2004. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods. Technical report. Microbiological risk assessment series 5. Food and Agriculture Organization of the United Nations and World Health Organization, Rome. Available at: http://www.fao.org/docrep/010/y5394e/y5394e00.htm. Accessed 9 May 2011.

15. Gombas, D. E., Y. Chen, R. S. Clavero, and V. N. Scott. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *J. Food Prot.* 66:559–569.
16. Grocery Manufacturers Association. 2009. Control of *Salmonella* in low-moisture foods. Available at: http://www.gmaonline.org/downloads/technical-guidance-and-tools/SalmonellaControlGuidance.pdf. Accessed 5 April 2012.
17. Havelaar, A. H., J. A. Haagsma, M.-J. Mangen, J. M. Kemmeren, L. P. B. Verhoef, S. M. C. Vijgen, M. Wilson, I. H. M. Friesema, L. M. Kortbeek, Y. T. H. P. van Duynhoven, and W. van Pelt. 2012. Disease burden of foodborne pathogens in the Netherlands, 2009. *Int. J. Food Microbiol.* doi:10.1016/j.ijfoodmicro.2012.03.029.
18. International Life Sciences Institute. 2010. Impact of microbial distributions of food safety. ILSI Europe report series. International Life Sciences Institute, Brussels. Available at: http://www.ilsi.org/Europe/Publications/Microbial%20Distribution%202010.pdf. Accessed 17 May 2011.
19. iRISK. 2012. iRISK, version 1.0. Technical documentation. Available at: http://irisk.foodrisk.org/SupportingDocumentation.aspx. Accessed 2 November 2012.
20. Jiang, R., J. E. Manson, M. J. Stampfer, S. Liu, W. C. Willett, and F. B. Hu. 2002. Nut and peanut butter consumption and risk of type 2 diabetes in women. *JAMA (J. Am. Med. Assoc.)* 288:2554–2560.
21. Kemmeren, J. M., M.-J. J. Mangen, Y. T. H. P. van Duynhoven, and A. H. Havelaar. 2006. Priority setting of foodborne pathogens. RIVM report 330080001/2006. Severity (Table 3) and duration (Table 18). Available at: http://rivm.openrepository.com/rivm/bitstream/10029/7316/1/330080001.pdf. Accessed 7 May 2012.
22. Kirk, M. D., C. L. Little, M. Lem, M. Fyfe, D. Genobile, A. Tan, J. Threlfall, A. Paccagnella, D. Lightfoot, H. Lyi, L. McIntyre, L. Ward, D. J. Brown, S. Surnam, and I. S. T. Fisher. 2004. An outbreak due to peanuts in their shell caused by *Salmonella enterica* serotypes Stanley and Newport—sharing molecular information to solve international outbreaks. *Epidemiol. Infect.* 132:571–577.
23. Leverentz, B., W. S. Conway, M. J. Camp, W. J. Janisiewicz, T. Abuladze, M. Yang, R. Saftner, and A. Sulakvelidze. 2003. Biocontrol of *Listeria monocytogenes* on fresh-cut produce by treatment with lytic bacteriophages and a bacteriocin. *Appl. Environ. Microbiol.* 69:4519–4526.
24. Leverentz, B., W. S. Conway, W. Janisiewicz, and M. J. Camp. 2004. Optimizing concentration and timing of a phage spray application to reduce *Listeria monocytogenes* on honeydew melon tissue. *J. Food Prot.* 67:1682–1686.
25. McLauchlin, J., R. T. Mitchell, W. J. Smerdon, and K. Jewell. 2004. *Listeria monocytogenes* and listeriosis: a review of hazard characterisation for use in microbiological risk assessment of foods. *Int. J. Food Microbiol.* 92:15–33.
26. National Academies of Sciences. 2010. Enhancing food safety: the role of the Food and Drug Administration. Committee on the Review of Food and Drug Administration's Role in Ensuring Food Safety, National Research Council. Available at: http://www.nap.edu/catalog/12892.html. Accessed March 2012.
27. Nauta, M. J. 2005. Risk assessment modelling of the food handling processes mixing and partitioning. *Int. J. Food Microbiol.* 100:311–322.
28. Nauta, M. J. 2008. The modular process risk model (MPRM): a structured approach for food chain exposure assessment, p. 99–136. *In* D. W. Schaffner (ed.), Microbial risk analysis of foods. ASM Press, Washington, DC.
29. Newsome, R., N. Tran, G. M. Paoli, L. A. Jaykus, B. Tompkin, M. Miliotis, T. Ruthman, E. Hartnett, F. F. Busta, B. Petersen, F. Shank, J. McEntire, J. Hotchkiss, M. Wagner, and D. W. Schaffner. 2009. Development of a risk-ranking framework to evaluate potential high-threat microorganisms, toxins, and chemicals in food. *J. Food Sci.* 74: R39–R45.
30. Penteado, A. L., and M. F. F. Leitao. 2004. Growth of *Listeria monocytogenes* in melon, watermelon and papaya pulps. *Int. J. Food Microbiol.* 92:89–94.
31. Pouillot, R., K. Hoelzer, Y. Chen, and S. Dennis. 2003. Estimating probability distributions of bacterial concentrations in food based on data generated using the most probable number (MPN) method for use in risk assessment. *Food Control* 29:350–357.
32. Ross, T., and J. Sumner. 2002. A simple, spreadsheet-based, food safety risk assessment tool. *Int. J. Food Microbiol.* 77:39–53.
33. Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M.-A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis.* 17:7–15. Available at: http://wwwnc.cdc.gov/eid/article/17/1/pdfs/p1-1101.pdf. Accessed 5 April 2012.
34. Scott, V. N., Y. Chen, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A. Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of *Salmonella* in low-moisture foods. I. Minimizing entry of *Salmonella* into a processing facility. *Food Prot. Trends* 29:342–353.
35. U.S. Department of Agriculture, Economic Research Service. 2010. Foodborne illness cost calculator. Updated date 28 December 2010. Available at: http://www.ers.usda.gov/Data/FoodborneIllness/. Accessed 27 May 2011.
36. U.S. Department of Agriculture, Economic Research Service. 2010. Peanut outlook. Impacts of the 2008–09 foodborne illness outbreak linked to *Salmonella* in peanuts. Available at: http://www.ers.usda.gov/Publications/OCS/2010/02Feb/OCS10A01/ocs10a01.pdf. Accessed 7 May 2012.
37. U.S. Department of Agriculture, Economic Research Service. 2010. Loss-adjusted food availability: spreadsheets. Available at: http://www.ers.usda.gov/Data/FoodConsumption/FoodGuideSpreadsheets.htm#fat. Accessed 7 May 2012.
38. U.S. Food and Drug Administration. 2005. Quantitative risk assessment on the public health impact of pathogenic *Vibrio parahaemolyticus* in raw oysters. Available at: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm050421.htm. Accessed 5 April 2012.
39. U.S. Food and Drug Administration. 2011. iRISK—a comparative risk assessment tool: peer review comment report. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD. Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm. Accessed 5 April 2012.
40. U.S. Food and Drug Administration. 2012. *Salmonella* species, p. 12–14; *Listeria monocytogenes*, p. 99–102. *In* Bad bug book—foodborne pathogenic microorganisms and natural toxins, 2nd ed. Available at: http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm. Accessed 7 May 2012.
41. U.S. Food and Drug Administration, and U.S. Food Safety and Inspection Service. 2003. Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. Available at: http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm. Accessed 27 December 2010.
42. U.S. Government. 1998. Code of Federal Regulations. Title 21. Food and drugs. Part 164. Tree nut and peanut products. Subpart B. Requirements for specific standardized tree nut and peanut products. Sect. 164.150. Peanut butter. Available at: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1972408731c5160cccff411f08afb2c9&rgn=div8&view=text&node=21:2.0.1.1.37.2.1.3&idno=21. Accessed 7 May 2012.
43. U.S. Government. 2011. An act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply. Public Law 111-353. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/content-detail.html. Accessed March 2012.
44. Zink, D. 2008. Environmental investigation and regulatory response: *Salmonella* Tennessee in peanut butter in the United States, 2007. IAFP Symposium S1, 2008 Foodborne disease update: *Salmonella* in processed foods. Presented at the Annual Meeting of the IAFP, Columbus, OH, 3 to 6 August 2008.

May 4, 2009

RTI Number 0211460.002

Tools and Methods for Ranking and Prioritizing Food and Feed Safety Risks

Submitted to:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Submitted by:

RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

RTI INTERNATIONAL

Table of Contents

List of Tables

List of Figures

Executive Summary

The results of this task order support the U.S. Food and Drug Administration's (FDA's) 2007 Food Protection Plan, which specifies the need to use risk-based approaches that integrate sound science with state-of-the-art information technology to appropriately manage food safety risks using a farm-to-fork approach. As such, the purpose of this study was twofold:

- To develop an inventory of available tools and methods for relative risk ranking and prioritization
- To evaluate the applicability of the identified tools and methods for use by the FDA to address food and feed safety risks.

In the first phase of the work, relevant sources of information about risk ranking and prioritization were identified. Information was garnered from government agencies, published literature, and the Internet. Specific information for food safety risk ranking was abundant; however, for risk prioritization, it was necessary to use more general information.

This report is divided into two major sections: **Section II** focuses on risk ranking and **Section III** covers risk prioritization. These are preceded by a section describing the purpose and approach to the work (**Section I**). Each major section presents reviews of specific models (risk ranking) or approaches (risk prioritization), including a description of the purpose and scope of each approach, its common uses, design and implementation considerations, and its strengths and limitations. Each risk ranking and risk prioritization method was also evaluated against a set of performance criteria (e.g., transparency, credibility, documentation, ease of use, flexibility, adaptability) for comparison purposes. Based on full consideration of the attributes of the candidate methods, a recommendation for future use is made.

We reviewed three qualitative and five semi-quantitative food safety risk ranking models in detail. Several other risk ranking approaches applied to other disciplines are also described briefly. Only models with food safety application were evaluated with respect to the specified performance criteria. These models were also evaluated for consistency with FDA-specified functional features (i.e., presence of two modules [a predictive, multistage, farm-to-fork process risk module and a hazard characterization module]; ability to rank and compare chemicals and microbiological agents in a single model; and transparency and adaptability). The relatively poor degree of resolution provided by qualitative methods suggested the need for a semiquantitative approach. The five semi-quantitative models (Risk Ranger, Food Sector Risk Ranking Model, Foodborne Illness Risk Ranking Model, Food Safety Universe Database Model, and Food Hazard Risk Registry [also called iRISK]) were compared. Although none of these models scored highly on all performance criteria, the Food Safety Universe Database Model and the iRISK model came close. After careful deliberation, we recommend that the FDA use iRISK for future risk ranking efforts because the model structure is most consistent with the FDA's specified functional features; it is more flexible than other reviewed models; and it is more sophisticated with respect to characterization of uncertainty, software, and documentation of inputs and outputs.

Multiple criteria decision analysis (MCDA), also referred to as risk prioritization, combines the tools of risk assessment and decision analysis to support complex decision making. We reviewed six general MCDA approaches:

- Elementary methods
- Decision trees and influence diagrams
- Multi-objective optimization
- Multi-attribute value/utility theory (MAUT)
- Outranking
- Analytic hierarchy process (AHP).

We also reviewed the two MCDA approaches (Multi-Factorial Risk Prioritization Framework for Food-borne Pathogens and an outranking approach) that have previously been applied to food safety; however these should be considered preliminary. Based on the implicit assumption that the MCDA approach to be chosen by the FDA should enable structured, well-justified, transparent decision-making from a wide variety of risk management options, and applicable to many different hazards and foods, we recommend MAUT or certain AHP methods. The major advantage of these approaches is the ability to quantify benefits through a single score representing the relative, proportional benefit of each alternative. We also recommend that aspects of fundamental resource allocation theory be incorporated into the FDA's decision-making process and that facilitated decision conferencing be implemented to aid in structuring the decision-making process and model construction.

I. Statement of Purpose and Methodological Approach

The results of this task order support the U.S. Food and Drug Administration's (FDA's) 2007 Food Protection Plan, which specifies the need to use risk-based approaches that integrate sound science with state-of-the-art information technology to appropriately manage food safety risks using a farm-to-fork approach. Taken together, these Food Protection Plan actions are best served using two common risk and decision analysis tools: risk ranking and risk prioritization. Therefore, the purpose of Task Order 2 was twofold:

- To develop an inventory of available tools and methods for relative risk ranking and prioritization
- To evaluate the applicability of the identified tools and methods for use by the FDA (including the Center for Food Safety and Applied Nutrition [CFSAN], the Center for Veterinary Medicine [CVM], and the Office of Regulatory Affairs [ORA]) to address food and feed safety risks.

Four specific objectives were identified:

- Conduct a comprehensive literature review and summary inventory of available methods and tools for risk ranking.
- Conduct a comprehensive literature review and summary inventory of available methods and tools for risk prioritization.
- Evaluate the available methods and tools for risk ranking for their ability to rank commodity/hazard pairs based on public health matrices and other relevant measures.
- Evaluate the available methods and tools for risk prioritization for their ability to be used in the following applications:
  - Prioritizing the use of investigation and sampling resources toward the areas of greatest public health concern for domestic, foreign, and/or imported products
  - Prioritizing future baseline studies
  - Prioritizing data collection efforts to resolve uncertainties
  - Focusing research, outreach, and prevention strategies on areas of greatest public health concern
  - Directing compliance and enforcement
  - Informing guidance and rulemaking
  - Prioritizing potential international activities.

In the first phase of the work, we identified sources of information to identify candidate risk ranking and prioritization models that might be relevant to FDA needs. We used three information sources: government agencies, published literature, and the Internet. We conducted a comprehensive search of all relevant documents, including the grey literature. Our access to information sources included the libraries of North Carolina State University, the University of North Carolina at Chapel Hill, and Duke University. In addition, we used extensive in-house capabilities for conducting computerized literature searches. Databases searched included Chemical Information Systems (CIS), DIALOG, LEXIS/NEXIS, PubMed, TOXNET, Environmental Fate Database (Syracuse Research Corporation), and STN International. These database systems provide access to hundreds of bibliographic files. In addition to traditional online databases, we also searched for additional information on food risk ranking and

prioritization topics via Internet search engines and through personal contacts. Of the methods available, we found publicly accessible contract reports (available via the Internet) to be the most fruitful source of information for risk ranking. For risk prioritization, books and published journal articles provided the most information. A detailed description of our findings is provided in the body of this report.

II. Risk Ranking

II.1 Introduction

Risk ranking, sometimes called hazard ranking or comparative risk assessment, is applied to identify the most significant risks for a given situation. The method has a history of use in engineering, insurance, transportation, and environmental sciences and has been applied in both the private and public sectors. One important public sector interest is food safety, for which risk ranking can be used to guide policy development. Although somewhat later on the scene than other disciplines, the importance of risk ranking in food safety is now well established (Havelaar and Melse, 2003).

Most rankings are nowhere near as complete as a full quantitative risk assessment (except perhaps the FDA relative risk assessment of foodborne *Listeria monocytogenes*, U.S. FDA, 2003). Nonetheless, the process roughly follows the risk assessment paradigm and requires the sequential steps of hazard identification, risk evaluation, and development of a comparative ranking scale and list. Depending on the purpose of the ranking, the needs of the analyst, available resources, and availability of data, risk ranking can range from very simple to highly complex.

Because risk ranking will be used as a risk management tool, a critical first step is to identify the specific purpose or designated use of the ranking. Food safety risks, like risks in other sectors of society, are inherently complex and differ from one another in ways that make it difficult to compare one agent to another in any sort of simplified manner. Consequently, assumptions must be made, and all approaches to risk ranking include some degree of subjectivity and uncertainty. Certainly no one model can account for every important input or assumption, and risk ranking models differ substantially in basic approach.

Once the purpose of risk ranking is defined, the next step is to identify and define key inputs and risk attributes. In the case of food safety, the "risk" is usually related to the likelihood and severity of disease caused by a specific agent-food combination. The "agent" or "hazard" can be microbiological (pathogen) or chemical (toxic), while the "vehicle" or "food" may be categorized broadly (e.g., beef, poultry, fresh produce) or narrowly (e.g., ground beef, steak, roast). Risk ranking tools for use in food safety have been applied to a single hazard in multiple commodities, to a single commodity with multiple hazards, or to compare multiple commodity-hazard combinations.

A major consideration when initially categorizing agents and foods must be the degree of resolution. For agents, for example, does one categorize broadly (e.g., bacteria, viruses, parasitic protozoa) or more specifically (e.g., *Salmonella* and *Escherichia coli* [*E. coli*] O157:H7; norovirus and hepatitis A virus; *Cryptosporidium parvum* and *Cyclospora cayetanensis*). The same situation exists for foods (i.e., broad categories such as meat or produce vs. specific commodities such as ground beef or whole broilers). In most instances, a higher degree of resolution within agent and food categories is of greater value, but such resolution may not be possible given the limitations of supporting data sets used to estimate inputs.

Identification of the key risk attributes can also be complicated. Some risk attributes are specific to the agent (e.g., infectious dose), while others may be specific to the agent-food combination

(e.g., potential for the pathogen to grow in the product). In many instances, the attributes impacting overall public health are associated primarily with the agent or the food, and these may not necessarily influence one another, but on some occasions, they do. In addition, most public health risks are multi-attribute, meaning there is more than one way in which the hazard or vehicle can affect the outcome, making the ranking process that much more complex. Clearly, designing a good risk ranking method requires simplification, assumption, and subjectivity with respect to the choice of input variables, the choice of the data on which to characterize these inputs, and the weighting approach taken to express the relative importance of the different inputs. Uniformity and transparency are critical to providing a justifiable means by which to compare risks.

The simplest approach to risk ranking involves the use of personal judgment to create a "risk versus severity" table or matrix to assign rankings. A more complicated approach involves consideration of the body of scientific evidence about the risk(s) posed by the various agent-food combinations to inform values for input variables. These input variables serve as the basis for the creation of a mathematical model, frequently functionalized into a computer program. The mathematical algorithm assigns a rank based on the unique values or weights given to each input variable (criteria) for that specific agent-food combination. Often, risk ranking models involve the combination of personal judgment and scientific evidence to inform the outputs.

Another useful way to differentiate risk ranking approaches is based on the type of data used in model construction, in which case models are categorized as either surveillance-based (or "top-down") or prediction-based (or "bottom-up"). For microbial hazards, the top-down surveillance-based approaches infer the level of risk due to foods, hazards, or their combinations, based on information gathered by various observation systems such as active or passive disease reporting systems or outbreak databases, and a variety of other observations, including prevalence of pathogens in various commodities. Ideally, such databases are the best source of information for overall ranking because they reflect disease at the consumer (patient) level. However, these databases are invariably incomplete, meaning that quantitative linkages to particular foods are often difficult to justify from these data sources alone or might be estimated only for foods that account for a relatively high proportion of the risk.

The top-down approach has not been applied to chemical agents, largely because there is no systematic capacity to observe the health effects of food-associated chemical exposures in the human population. Therefore, when attempting to compare chemicals to microbes, a bottom-up approach is usually applied. This involves predictive modeling of the fate of microbes and chemicals in the food supply and their virulence or toxicity. The design of bottom-up risk ranking models requires the synthesis of both data and expert judgment to generate a prediction of the relative level of risk to human health. The approach may also be appealing because it can be used to investigate the potential for changes in the level of risk associated with possible interventions throughout the farm-to-fork chain. However, like all risk ranking models, predictive models are still simplifications of reality based on assumptions, and substantial uncertainty is associated with the results.

In **Section II.2**, we provide more detailed descriptions of qualitative risk ranking approaches that have been applied to food safety. The degree of detail in the narratives is determined by the information available in the public sector. In **Section II.3**, we provide detailed descriptions of

semi-quantitative risk ranking approaches that are well documented and have been previously applied to food safety (microbiological or chemical). For these models, a ranking attributes table is also included. This section also covers models with food safety applications but for which only minimal information is available. In **Section II.4**, we describe a number of risk ranking approaches that have been applied to disciplines outside food safety. In **Section II.5**, we provide synthesis comments and recommendations to the FDA.

II.2 Qualitative Food Safety Risk Ranking Approaches

II.2.1 The CFSAN Relative Risk Ranking

The Center for Food Safety and Applied Nutrition (CFSAN) relative risk ranking was conducted within the FDA with various scientists providing their expert consultation in assigning ranks. In this approach, relative risk rank is determined as the qualitative combination of two axes: (1) likelihood of an adverse event occurring from consumption or use of a product containing the hazard, and (2) the relative severity of that hazard. The term "likelihood" describes the relative probability that the hazard occurs in the food and causes illness, and "severity" describes the relative seriousness of symptoms consumers would experience.

Severity was determined for each hazard, irrespective of food source. The data used to determine severity ranks originated from a combination of expert opinion, the scientific literature, and estimates previously generated using the Food Handling Practices Model. Severity scores (expressed descriptively as Moderate, Serious, or Severe) reflect what would occur in a typical case with consideration of mitigating circumstances such as at-risk population. In instances of significant uncertainty or conflicting data, a higher severity category was chosen as a more conservative estimate. **Table II-1** describes the three severity categories and examples of agents included in each category.

Table II-1. Severity Ranking Descriptions

Severity Ranking	Description	Examples
Moderate	Not usually life threatening, no sequelae, normally short duration, symptoms are self-limiting, can include severe discomfort	Norovirus Histamine toxin *Clostridium perfringens*
Serious	Incapacitating but not life threatening, sequelae infrequent, moderate duration	Hepatitis A virus Ciguatera toxin *Salmonella* spp. *E. coli* O157:H7
Severe	Life-threatening or substantial chronic sequelae or long duration	*Listeria monocytogenes* *Enterobacter sakazakii* Undeclared or unapproved food or color additives Algal biotoxins

The second qualitative factor considered in the relative risk ranking was the likelihood that the hazard occurs in the identified product and will cause illness or death. This was estimated by taking into account the following:

- The epidemiological link between the hazard and illness due to consumption of the particular product (i.e., outbreaks)
- Data on the prevalence and level of the hazard in the product
- Frequency of consumption or use of product and amount consumed
- The effect of production, processing, and handling in terms of how they influence the hazard in the product at the point of consumption or use
- Impact of existing regulatory or non-regulatory management systems.

The data used to determine the likelihood ranks originated from a combination of expert opinion, the scientific literature, and consumption data available through the U.S. Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII) database. A likelihood rank was assigned for each product/hazard combination. **Table II-2** describes the three likelihood categories.

Table II-2. Likelihood Ranking Descriptions

Likelihood Ranking	Factors to Consider
Unlikely	§ Little or no evidence that the hazard has caused illness (i.e., no outbreaks) § Limited consumption or use of the commodity by the general population or consumption primarily restricted to a select sub-population § Limited or no data demonstrating presence of the hazard (i.e., no recalls)
Likely	§ Limited evidence that the hazard has caused illness (i.e., a few outbreaks) § Eaten or consumed periodically § Data demonstrating the presence of the hazard in product (i.e., recalls)
Very likely	§ Evidence that the hazard is associated with reported incidences of illness § Widely or frequently eaten or used by the general population § Data demonstrating the presence of the hazard in the product

The relative risk ranking was determined using the matrix shown in **Table II-3**. (The document describing this method was provided to RTI by the FDA; to our knowledge, it is not available in the public domain.) For example, if the severity rank was "serious" and the likelihood was "very likely," the relative rank for that product/hazard combination was "higher." For the same "serious" hazard in another product with a likelihood rank of "unlikely," the relative risk rank would be assigned "lower." Note that relative risk is described in three categories, such that there is overlap between certain combinations of severity and likelihood rank. This ranking scheme was applied to a wide variety of products and associated hazards under FDA jurisdiction.

Table II-3. Relative Risk Rank Matrix

		Likelihood		
		Unlikely	**Likely**	**Very likely**
Severity	**Moderate**	Lower	Lower	Medium
	Serious	Lower	Medium	Higher
	Severe	Medium	Higher	Higher

II.2.2 The FAO-WHO Risk Ranking for Fresh Produce

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) convened an expert consultation in October 2007 to consider how to adequately address the range of microbiological hazards associated with many different types of fresh produce (FAO-WHO, 2008). The intent was to use all the available information (which included review of the literature and unpublished data submitted by various countries) to establish the priority commodities of concern. The scope of the work was limited to produce that is marketed fresh or physically altered from its original form but that is commonly consumed raw. The experts considered the entire production-to-consumption continuum in their deliberations. Six major criteria were identified upon which to rank:

- Frequency and severity of disease
- Size and scope of production
- Diversity and complexity of the production chain and industry
- Potential for amplification of foodborne pathogens through the food chain
- Potential for control
- Extent of international trade and economic impact.

The rankings were qualitative, not quantitative. The commodities were placed into three general categories based only on the input of the experts:

- **Level 1 Priorities (leafy green vegetables):** The experts concluded that globally, leafy green vegetables presented the greatest microbiological food safety concern because (1) multiple outbreaks with large numbers of illnesses associated with these products have occurred in at least three regions of the world; (2) production and export volumes are high; and (3) the diversity of production and processing practices mean that post-harvest activities can contribute to amplification of pathogens.
- **Level 2 Priorities (berries, green onions, melons, tomatoes, seed sprouts):** The experts identified these commodities as being of intermediate concern. The first four products (berries, green onions, melons, and tomatoes) were considered to be similarly problematic, but they could not be prioritized one from another on a global scale, although the experts did conclude that such prioritization might be possible on a regional basis. Sprouted seeds were considered separately due their unique production issues and the availability of existing Codex Alimentarius guidelines for their production.
- **Level 3 Priorities (carrots, cucumbers, almonds, baby corn, sesame seeds, onions and garlic, mango, paw paw, celery, and maimai):** The experts considered these to be

of lowest priority because, although implicated in outbreaks of foodborne disease, the overall public health impact was considered minimal. However, limited data were available for many of these commodities and some of the problems have only recently been recognized, so these may be considered emerging problems.

Additional justification for the rankings is provided in Table 3 of FAO-WHO (2008).

The FAO-WHO ranking is the first ranking effort that was applied to fresh produce on a global scale. Critical factors that impacted the ranking resolution were identified as (1) limited and variable amount of information for most commodities; (2) limited understanding of hazards, routes of contamination, and controls; and (3) substantial differences in production systems both within and between countries. The experts concluded that prioritization of limited resources (e.g., research, risk assessment, controls) will be necessary to ensure that the issues of greatest concern are adequately and appropriately addressed.

II.2.3 The Carnegie-Mellon Risk Ranking Approach

This approach is based on initial work described by Florig et al. (2001) of Carnegie-Mellon University, which has since been applied to evaluate the differences between experts and the public when it comes to ranking the relative importance of food safety risks (Webster et al., 2008). The general approach is a five-step process:

1. Define and categorize the risks to be ranked
2. Determine risk attributes for each category identified in Step 1
3. Develop risk summary sheets for each risk that include the list of attributes from Step 2, characterizations for each attribute (as determined by experts; e.g., low, medium, or high factors), and a brief description of the risk and references for technical information, if needed (see **Table II-4** for the types of information captured in the risk summary sheets for different hazard attributes)
4. Select risk rankers and rank the risks
5. Assess the rankings and conduct statistical analysis.

Table II-4. Information Captured in Carnegie-Mellon Food Safety Risk Ranking Hazard Sheets

Risk Attributes	Risk Attribute Descriptions
Cases per year	Quantitative: estimated as unknown, worldwide, or U.S., depending on agent
Fatalities per year	Quantitative: estimated as unknown, worldwide, or U.S. based on number of cases or percentage of cases resulting in fatality
Likelihood of fatality	Qualitative: certain, low-medium, or rare or unknown; can also be estimated as percentage of cases likely to result in death
Likelihood of contracting disease	Qualitative: rare, low-medium, unknown
Chronic health effects	Descriptive
High risk groups	Descriptive
Types of food agent is found in	Descriptive
Geographic area agent is found	Descriptive but includes “ubiquitous”
Prevention measures in place	Descriptive

Risk Attributes	Risk Attribute Descriptions
Time between exposure and health effects	Descriptive for both acute and chronic effects
Scientific knowledge	Qualitative: estimated as medium or high
Ability to prevent exposure	Qualitative: estimated as medium or high

This approach was applied by Webster et al. (2008) to six food safety hazards: (1) bovine spongiform encephalopathy (mad cow disease); (2) *E. coli* O157:H7; (3) *Salmonella*; (4) botulism (*Clostridium botulinum*); (5) paralytic shellfish poisoning; and (6) acrylamide. Participants in the ranking exercise included both food safety experts and members of the lay public. Each participant was asked to read through the six risk summary sheets and rank the six hazards from highest risk (ranking of one) to lowest risk (ranking of six). Individual rankings from the lay public (n=29) and food safety experts (n=21) were summarized in frequency tables, and the Mann-Whitney statistical test was used to determine the significance of differences in ranking choices. Results for the food safety experts are summarized in **Table II-5**.

Table II-5. Public and Expert Rankings of Six Food Safety Issues

	Food Safety Issue											
	BSE[a]		E. coli		Salmonella		Botulism		PSP[b]		Acrylamide	
Rank	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)	Pub (n=29)	Exp (n=21)
1	3.4%	0.0%	41.4%	38.1%	20.7%	52.4%	0.0%	4.8%	0.0%	4.8%	34.5%	0.0%
2	13.8%	0.0%	41.4%	61.9%	34.5%	19.0%	6.9%	14.3%	3.4%	4.8%	0.0%	4.8%
3	27.6%	14.3%	6.9%	0.0%	13.8%	19.0%	41.4%	57.1%	3.4%	4.8%	13.8%	0.0%
4	20.7%	19.0%	10.3%	0.0%	6.9%	4.8%	17.2%	19.0%	31.0%	47.6%	17.2%	9.5%
5	13.8%	28.6%	0.0%	0.0%	20.7%	4.8%	24.1%	4.8%	20.7%	23.8%	20.7%	42.9%
6	20.7%	38.1%	0.0%	0.0%	3.4%	0.0%	10.3%	0.0%	41.4%	14.3%	13.8%	42.9%

[a] BSE = bovine spongiform encephalopathy (mad cow disease).
[b] PSP = paralytic shellfish poisoning.

The goal of this work was not merely to rank a variety of food safety concerns, but rather to characterize the differences between ranking scores provided by experts vs. the public and to try to understand the reasons for such differences. In this regard, the investigators were able to conclude that the Carnegie-Mellon Risk Ranking approach could be applied using subjects (rankers) with different backgrounds, both laypersons and technical, and that the results of both individual and group work had a strong correlation. However, this remains a highly subjective approach.

Perhaps the most useful feature of the Carnegie-Mellon method is the production of risk summary sheets that provide a snapshot of relevant information about the agent. A similar approach could be applied to foods or food-hazard combinations. Given the summary sheets, risk rankers can then individually decide if more weight should be given to one or more attributes relative to others.

II.3 Semiquantitative Food Safety Risk Ranking Models

This section describes five semi-quantitative food safety risk ranking models: Risk Ranger, the Food Sector Risk Ranking and Prioritization Model, the Foodborne Illness Risk Ranking Model (FIRRM), the Food Safety Universe Database (FSUDB), and the Food/Hazard Risk Registry (FHRR), also called iRISK. Each section includes Purpose and Objectives, Model Overview (including application and availability and intended users), Scope, Detailed Model Description, Platform, Uncertainty, Model Attributes, and Model Limitations. In addition, the developer, contacts, and references are provided for each model.

II.3.1 Risk Ranger

Developer/Sponsor
Australian Food Safety Centre of Excellence, based on the peer-reviewed work of Ross and Sumner (2002).

Contact
Dr. Mark Tamplin, Director, FSC
College Road, Private Bag 54, Room 320
Life Sciences Building
Tasmanian Institute of Agricultural Research
School of Agricultural Sciences
Hobart TAS 7001, Australia
Mark.Tamplin@utas.edu.au
Phone: +61 3 6226 6378
Mobile: +61 420 520 583,
Fax: +61 3 6226 7450
Website: www.foodsafetycentre.com.au

Documentation
Ross and Sumner (2002)
Sumner and Ross (2002)
Sumner et al. (2004)
Sumner et al. (2005)

Intended Users
Policy makers, risk managers, risk analysts, and others with specific expertise in foods safety. The limited number of inputs and relatively simple design makes this a very user-friendly platform. Designed specifically for food safety applications.

Availability
Available as a free download at http://www.foodsafetycentre.com.au/docs/RiskRanger.xls

Platform
Microsoft Excel

Purpose/Objectives

The purpose of this work was to develop a simple and accessible food safety risk calculation tool intended to be used as an aid to determine the relative risks from different product-pathogen-processing combinations. As such, this is probably the first real effort in semi-quantitative risk ranking, with model development done as early as 2000–2002.

Model Overview

Risk Ranger is a spreadsheet-based risk ranking tool that requires users to select from qualitative statements or to provide quantitative data concerning factors that affect the food safety risk of a specific population for selected product-hazard combinations. The general approach is bottom up, because it evaluates risk from harvest to consumption. A total of 11 inputs are grouped into three general categories. The spreadsheet converts the qualitative inputs to numerical scores, and using three different multiplicative algorithms, provides a risk ranking score (scaled logarithmically from 0 to 100) that approximates probabilities of disease or death. Risk estimates include predicted annual illnesses or probability of illness per day in the target population. Risk Ranger has been widely used internationally, largely because it is simple to use and publicly available as a free download. It has been applied to ranking hazards in the seafood and red meat industries and has also caught the attention of the FAO-WHO. Most of these applications have been vetted in the peer-reviewed literature.

Scope

The 11 inputs are grouped into three major categories: (1) susceptibility and severity; (2) probability of exposure to the food; and (3) probability of the food containing an infectious dose. The model is designed for ranking microbial agents in candidate foods, although it is also possible to rank microbial toxins. For a hazard-food combination, the user selects from a choice of qualitative responses to each question. Most of the responses were designed by experts based on the literature but are nevertheless somewhat arbitrary. About half of the questions allow user-specified responses under an "other" response, while the other half must be weighted using the given scales and their values. Inputs must be based on the judgment of the user, which may be based on experience, the literature, or any other means by which experts obtain information.

Detailed Model Description

The 11 inputs (which Risk Ranger calls questions, even though they are not all cast as questions) are detailed below, along with candidate responses. To make response as objective as possible and to maintain transparency, descriptions are provided and many of the weighting factors are specified.

Category 1: Susceptibility and Severity

The severity of the hazard is a function of the intrinsic features of the pathogen/toxin and the susceptibility of the consumer. These are addressed in Questions 1 and 2.

- **Question 1, Hazard severity:** The possible responses to this question, based on the severity of the symptoms caused by the hazard, are as follows; the weighting factors are arbitrary:

Response	Description	Score	Examples
Severe	Causes death in most cases	1.0	Tetrodotoxin, botulinum toxin
Moderate	Requires medical intervention in most cases	0.01	*Listeria monocytogenes*, *Vibrio vulnificus*, *Vibrio cholerae*, enterohemorrhagic *E. coli*
Mild	Sometimes requires medical attention	0.001	*Vibrio parahaemolyticus*, hepatitis A virus, noroviruses, histamine, ciguatera, algal biotoxins, *Salmonella*
Minor	Patient rarely seeks medical attention	0.0001	*Staphylococcus aureus*, *Clostridium perfringens*

- **Question 2, How susceptible is the population of interest?** Four populations that vary in their level of susceptibility are identified:

Response	Description	Score	Examples
General	All members of the population	1	
Slight	Slightly increased susceptibility	5	Young children, the aged

Response	Description	Score	Examples
Very	Very susceptible	30	Newborns; children under one year; and people with conditions such as diabetes, cancer, and liver damage
Extreme	Extremely susceptible	200	People with AIDS, transplant recipients

The various weightings (5, 30, and 200) are loosely based on the relative susceptibility of each population subgroup to *Listeria monocytogenes* and population estimates based on Australian health statistics. When the subpopulation is chosen, the program automatically makes changes in Questions 5 and 10, as detailed below.

Category 2: Probability of Exposure to Food

Absolute risk is based on the population size, the proportion of the population consuming the food, and how frequently people eat the food. These factors are addressed in Questions 3–5.

- **Question 3, Frequency of consumption:** This is scored on a simple algebraic weighting scale in absolute terms based on annual consumption, so the units are days and the selections and scores are as follows:

Response	Score
Daily	365
Weekly	52
Monthly	12
A few times per year	3
Other	user specified

- **Question 4, Proportion of population consuming the product:** The proportion consuming the product may be set as follows; this scale is considered arbitrary:

Response	Score
All (100%)	1
Most (75%)	0.75
Some (25%)	0.25
Very few (5%)	0.05

- **Question 5, Size of consuming population:** This is expressed as an absolute number. Risk Ranger has population estimates for Australia pre-programmed, but if a different country or region is desired, the user can simply input another population by selecting "Other" and specifying the size of that population. If a subset of the general population was chosen in Question 2, Risk Ranger automatically estimates the number in that category based on proportions specific for Australia, which is approximately the same as in most developed countries.

Category 3: Probability of Food Containing an Infectious Dose

The probability of exposure to an infectious dose depends on (1) the amount of food consumed; (2) the probability of contamination in the raw product and, if contamination is present, the initial level of contamination; (3) the probability of contamination at subsequent stages of the farm-to-fork continuum; and (4) changes in the level or concentration of the hazard that may occur during the transition from farm to fork (e.g., concentration, dilution, growth, or inactivation). These factors are addressed in Questions 6–11.

- **Question 6, What is the probability of contamination of raw product per serving?** Choices are as follows: (1) rare (0.1%); (2) infrequent (1%); (3) sometimes (10%); (4) common (50%); (5) all (100%); or (6) other. If "other" is chosen, the user can specify an estimate of probability of contamination.

Response	Score
Rare (0.1%)	0.001
Infrequent (1%)	0.01
Sometimes (10%)	0.1
Common (50%)	0.5
All (100%)	1
Other	user specified

- **Question 7, Effect of processing:** The following responses are possible; the weighting scale is arbitrary:

Response	Score
The process reliably eliminates hazards	0
The process usually (99% of cases) eliminates hazards	0.01
The process slightly (50% of cases) reduces hazards	0.5
The process has no effect on hazard	1
The process increases (10-fold) hazards	10
The process greatly increases (1000-fold) hazards	1,000
Other	user specified

- **Question 8, Is there a potential for recontamination after processing?** Four possible answers are possible; these are arbitrary values:

Response	Score
No	0
Yes, minor (1% frequency)	0.01
Yes, major (50% frequency)	0.5
Other	user specified

§ **Question 9, How effective is the post-processing control system?** Five answers are possible; again, the scaling is arbitrary:

Response	Description	Score
Well controlled	Reliable, effective systems in place	1
Controlled	Mostly reliable systems in place	3
Not controlled	No systems, untrained staff	10
Gross abuse occurs	[no description given]	1,000
Not relevant	Level of risk agent does not change	1

§ **Question 10, What level of increase in the post-processing contamination level would cause infection or intoxication in the average consumer?** Five answers are possible; these are also based on an arbitrary scale:

Response	Description	Score
None		1
Slight	10-fold increase	0.1
Moderate	100-fold increase	0.01
Significant	10,000-fold increase	0.0001
Other	NA	user input

To answer this question appropriately, the user must have some idea of the amount of the hazard that would be required to cause illness, and Risk Ranger provides a supporting table with benchmark infectious doses for relevant microorganisms. If a specific subgroup was identified in Question 2, Risk Ranger automatically adjusts the infectious dose down to take into account the increased vulnerability of subgroups.

§ **Question 11, What is the effect of meal preparation before serving?** The following answers form the basis for this weighting scale, which was determined arbitrarily:

Response	Score
Meal preparation reliably eliminates hazards	0
Meal preparation usually eliminates (99%) hazards	0.01
The process slightly reduces (50%) hazards	0.5
The process has no effect on hazards	1
Other	user specified

Risk Ranking

A simple mathematical model converts the answers to Questions 1–11 into a numerical value or "weighting." Risk Ranger then combines the scores to provide a risk ranking value that is scaled logarithmically between 0 and 100. A score of 0 represents a probability of foodborne illness of less than or equal to one case per 10 billion people (greater than current global population) per 100 years. At the upper limit (risk ranking = 100), every member of the population eats a meal

that contains a lethal dose of the hazard every day. A risk ranking change of 6 points corresponds to a 10-fold difference in the absolute risk. Therefore, an increase in risk ranking from 36 to 48 would be interpreted as a 100-fold increase in risk. Further details of the logic and equations are provided in Ross and Sumner (2002).

Outputs

In addition to the risk ranking score, Risk Ranger provides two other estimates of risk. The first of these is the predicted total number of illnesses in the population specified in Question 5. The higher the risk ranking, the greater the proportion of the population that is predicted to become ill. The other output is an estimate of the probability of illness per day in the target population, reflected by the answer to Question 2. Obviously, the risk ranking remains the same, irrespective of whether the general population or a highly susceptible subpopulation is considered; however, the probability of illness increases in the target population, allowing for representation of where illnesses may be focused.

Platform

The model was developed using Microsoft Excel with standard mathematical and logical functions. The listbox macro tool was used to automate much of the conversion from qualitative inputs to quantities for calculations, such that each selection made from the range of options is converted into a numerical value by the software.

Uncertainty

Neither uncertainty nor variability is addressed by Risk Ranger; questions are answered by scores given as point estimates.

Model Attributes

- Risk Ranger can theoretically be applied to compare risks of microbial hazards and microbial toxins
- It uses the same methodology to rank all agents and all commodities
- Simplicity in design and implementation has facilitated wide use
- The user is provided some choice (by using the “other” designation for some of the inputs)
- It produces multiple outputs, which include both risk ranking and risk estimates
- The method is well documented, has been subjected to performance evaluation and peer review, and has been applied in several risk management scenarios.

Model Limitations

- Risk Ranger may be considered a substantial oversimplification, hindering its use for discrimination of small but critical differences
- Weighting factors for most inputs are arbitrarily derived
- It does not address variability or uncertainty in any measurable way.

II.3.2 The Food Sector Risk Ranking and Prioritization Model

Purpose/Objectives

The Food Sector Risk Ranking and Prioritization Model (FSRRPM) is a combined risk ranking-risk prioritization model, the risk ranking component of which is based on the Australia-New Zealand Food Safety Authority priority classification system (NZFSA, 2006) and the Canadian Risk Characterization Model for Food Retail-Food Service Establishments (FAO-WHO, 2006).This project formed part of the Domestic Food Review of New Zealand, whose long-term (5+ years) goal was to put in place a food regulatory program across all sectors of the New Zealand domestic food industry. Because implementation of such a wide-reaching regulatory program could not be done in a short timeline, this model was intended to be used to prioritize which nonregulated food sectors should be targeted for immediate regulatory activity and which could be put off for efforts in future years. In short, the businesses estimated to provide the highest risk are slated to meet the Food Control Plan requirements first.

Developer/Sponsor
Australia-New Zealand Food Safety Authority

Contact
New Zealand Food Safety Authority
68-86 Jervois Quay, PO Box 2835
Wellington, NEW ZEALAND
Phone: +64 4 894 2500
Fax: +64 4 894 2501

Documentation
NZFSA (2006)

Intended Users
The model in its current format is only relevant to food safety authorities interested in ranking for purposes of regulatory oversight.

Availability
Unknown

Platform
Not described in current documentation.

Model Overview

The FSRRPM is intended to be applied only to those sectors of the industry not already under regulatory oversight. Food businesses are classified into 30 food sectors; the model ranks each sector according to the food safety risks posed by that sector. This is a farm-to-fork model and hence could be considered bottom-up in approach. The model consists of two different parts, each of which is subdivided into sections that consider different parameters that may affect risk. These two parts are described as follows: (1) Part One (Sections 1–4) applies the best available scientific information to provide an initial estimation of food safety risk associated with a food sector; and (2) using Part One as the basis, Part Two (Sections 5–7) considers the impact of the sector organization and business practices on food safety. The model output can serve as the basis for making management decisions about regulation or other control measures to be implemented.

Further information about specific applications of this model were unavailable.

Scope

The New Zealand Food Safety Authority obtained a list of sector groupings currently used in regulatory or nonregulatory settings, which served as the basis for the 30 food sector categories. The model is designed for ranking pathogens, not chemicals or toxins, in these commodities. Generally accepted information about pathogens, their disease outcomes and susceptible populations, and their entry and behavior in the food system were used to inform estimates of the

inputs. In cases where robust data were not available, opinion from recognized experts was elicited and used to parameterize parts of the model. The New Zealand Total Diet Survey Food List was used to inform consumption estimates. The weighting categories and subsequent scores are somewhat arbitrary in nature. Additional information on data sources are provided in the Detailed Model Description section below.

Detailed Model Description

Part One: Characterization of Risk title??

Part One of the model is divided into four sections, each of which is detailed below. In general, numerical values for each input in Part One were selected by considering a range that was sufficient to separate the sectors on the basis of risk. The relative risk weightings are comparable between sections and reflect the approximately equivalent impact of each section on overall food safety risk. Higher weights reflect greater risk.

Section 1: Food Type and Intended Use by Customer

This section is designed to capture the inherent risks associated with different types of foods. Factors considered include the following:

- The potential for any of three types of hazards (microbiological, chemical, physical) to occur in any of the foods produced by a food sector
- Whether the food supports the growth of microorganisms
- Whether or not the food is sold ready-to-eat
- The available foodborne illness, food complaint, and monitoring data from New Zealand, or international trend analysis highlighting specific or inherent risks associated with food types, which may include risks associated with food safety or suitability.

Briefly, foods are categorized in two domains, i.e., (1) based on three risk levels and (2) whether or not they are ready-to-eat (RTE). In the first domain:

- **High-risk** foods are defined as those associated with Group 1 biological hazards (detailed in an appendix to the original documentation, NZFSA [2006]) or associated with • 10% of complaints lodged in FoodNet since 1997
- **Medium-risk** foods are those associated with Group 2 pathogenic microorganisms or their toxins or associated with 1–9.99% of complaints lodged in FoodNet since 1997
- **Low-risk** foods are those associated with Group 3 pathogenic microorganisms or toxins and which were not previously captured in the high or medium risk categories above.

In the second domain, foods are categorized by whether or not they are ready to eat: a ready-to-eat food is one that is ordinarily consumed in the same state as that in which it is sold. For any one food product, the risk levels are combined with the ready-to-eat classification to create four overall food categories which are weighted as follows:

Category	Weight
High-risk foods that are ready-to-eat	20
Medium-risk foods that are ready-to-eat	15
High-risk or medium-risk foods that are not ready-to-eat	10
Low-risk foods that may or may not be ready-to-eat	5

A number of assumptions were necessary when functionalizing this section:

- For sectors that make multiple foods, the highest risk food is used to determine the weight
- Ready-to-eat foods are more likely to cause foodborne illness if they contain an uncontrolled hazard and are therefore given a greater weight
- No food is considered completely without risk; therefore, even low-risk foods are assigned a nonzero weight.

Section 2: Food Preparation and Processing

This section is designed to capture the additional risks introduced through food processing and handling based on consideration of the following factors:

- The number of processing steps that could increase the risk of contamination
- The amount of contact that occurs between the foods, the general environment in which the food is produced, or direct contact with humans
- Whether the food undergoes physical or chemical changes that affect its safety to the consuming public
- Whether the final processing step effectively controls any risks associated with prior steps in the farm-to-fork chain.

Based on these factors, the following risk weights are assigned:

Category	Weight
Extensive level of preparation/processing	20
Moderate level of preparation/processing	15
Low level of preparation/processing	10
No preparation/processing steps	0
Hazard reduction/elimination step at last point of process	–10

Inherent assumptions include the following:

- As the degree of processing increases, so does the likelihood of a food contamination event occurring; therefore, the highest weight is assigned to food sectors with the greatest number of processing or preparation steps
- Any business undertaking a hazard mitigation function as the final step in processing is given a lower weight, because this final step reduces risk

- If food has no preparation or processing steps (e.g., distribution or sale of shelf-stable prepackaged items) no additional risk is introduced, therefore a weight of zero can be assigned.

Section 3: Food Targeted for Vulnerable Populations

This section is designed to identify the additional risk food poses to vulnerable populations. It considers only foods made specifically for vulnerable populations, which are defined as children under the age of 5, adults over the age of 65, the sick and immunocompromised, and pregnant women. Specific assumptions made include the following:

- Disease can occur in the vulnerable populations after exposure to lower doses than would cause disease in normal people
- People within vulnerable populations may be susceptible to organisms that do not normally affect the general population.

Based on these assumptions, the following risk weights are assigned:

Category	Weight
Foods targeted specifically for vulnerable populations	20
All other foods	0

Section 4: Community Reach

This section is designed to account for the impact a food sector would have on the community if it produced unsafe food. Two major factors are considered: (1) the proportion of the population regularly consuming the food type (based on the 2003–2004 NZ Total Diet Survey Food List, provided in the source document appendix, NZFSA [2006]); and (2) the volume of food produced by the food sector. It is assumed that foods consumed by the majority of consumers or foods with wide distribution networks would impact more individuals and therefore should be assigned a higher risk weighting. On the other hand, foods with limited distribution or availability and consumption by a minority of consumers would present some risk, albeit lower. Risk weights are assigned as follows:

Category	Weight
Commodity/Wide Community Reach	20
Mid-range/Moderate Community Reach	10
Specialty food/Restricted Community Reach	5

Part Two: Potential for Control title

Part Two is divided into four sections, each of which is detailed below. The values assigned to each section in Part Two are lower than those applied in Part One, to reflect the more subjective nature of the inputs and associated data. As a result, the overall risk assigned to a sector will be more strongly influenced by factors in Part One of the risk ranking model than those in Part Two.

Section 5: Food Safety Systems/Structure in Place

The purpose of this section is to provide some indication of the level of business structure in which that food sector is operating. Factors considered include the following:

- Whether the food sector has a cooperative or industry association active in areas of food safety, and if so, the proportion of membership from within the sector
- Whether the food sector operates a voluntary Food Safety Code of Practice or similar tools, and if so, the proportion of businesses within the sector that have adopted the code or tools
- Whether the voluntary systems in place have been validated and verified for effectiveness in controlling food safety risks.

It is assumed that food sectors with recognized food safety risks that have voluntarily applied a structure or systems to self-regulate and control these risks will pose lower risk to food safety. Therefore, sectors are assigned a lower risk weighting when voluntary systems and structures to promote food safety are in place and adopted by a high proportion of businesses within the sector. Weights are assigned as follows:

Category	Weight
Poor systems/structure	10
Some systems/structure	5
Good systems/structure	0

Section 6: Appropriate Skill/Competency Levels Within the Sector

This section is designed to indicate the level of skill/competency of people operating within the food sector. It considers (1) the approximate average level of skill/competency of people working in the food sector; (2) whether New Zealand unit standards are available for training in appropriate skills for the food sector; and (3) the approximate proportions of attendance at such training courses.

It is assumed that food sectors that actively participate in food safety training or recruit highly trained individuals have a greater awareness of food safety requirements and therefore a lower food safety risk. In some food sectors, the level of food safety skill/competency required to effectively produce safe food is high. These sectors would receive an appropriate (good) weight; however, if a high skill level is required but not available, a weight corresponding to the poor category would be applied. In the case of food sectors for which the skill/competency required to produce or maintain safe food is low, an appropriate (good) weighting would be applied if skills/competencies are present. However, if absent, a low weight would be applied. The risk weights are assigned as follows:

Category	Weight
Poor skill/competency	10
Low skill/competency	5
Appropriate (good) skill/competency	0

Section 7: Regulatory Starting Point

This section is designed to indicate the level of regulation that is currently actively applied to the food sector. It considers the relevance of the regulation(s) for the sector and also takes into

consideration operational or administrative decisions in relation to application of that regulation. The following assumptions were made in describing this input:

- Where there are active, co-operative relationships between the regulator and the food sector, there is a greater awareness and understanding of food safety requirements, and it is assumed that the food sector has a lower food safety risk
- The regulatory starting point is considered poor if current regulations are not sufficient to provide food safety assurance
- The regulatory starting point is considered irrelevant for businesses with a level of exemption from the regulations or if the active enforcement of these regulations would have negligible impact on food safety assurance
- The regulatory starting point is considered good if the sector is currently actively regulated and the regulations provide a reasonable level of food safety; there is an inherent recognition here that food safety may be improved by the application of different or more appropriate regulatory requirements.

On the basis of these assumptions, there are two categories for weighting:

Category	Weight
Poor regulatory starting point	10
Irrelevant or good regulatory starting point	0

Calculating Risk Rank

An overall numerical score is determined additively, such that higher scores indicate higher risk. Once each food sector has an overall numerical value based on risk, it is possible to determine an initial priority of the food sector with regards to implementation of Food Control Plans.

Outputs

The current documentation does not specify outputs. However, the intention is to produce an initial relative risk ranking based on Parts 1 and 2 described above; hence, the individual results from Parts 1 and 2 can be viewed separately or combined. Apparently, a risk prioritization model can be run as an overlay to the risk ranking model, but little documentation is provided about the prioritization tool.

Uncertainty

It appears that scores are given as point estimates and then summed; therefore, neither uncertainty nor variability are addressed by this model.

Model Attributes

- The FSRRPM can theoretically be applied to compare risks of microbial hazards and microbial toxins
- It uses same methodology to rank all agents and all commodities
- Simplicity in design and implementation could facilitate wide use
- Strong emphasis on food safety control makes this model a good candidate for comparing control options across agents, commodities, or agent-commodity pairs

- The potential for linking the risk ranking directly with a companion risk prioritization model is appealing

Model Limitations

- Risk weighting is highly arbitrary and may not be justifiable in all cases
- The model does not address variability or uncertainty at all
- Application is limited by the question posed during design, i.e., it is limited to use as a risk ranking model specifically applied to food industry sectors not already under regulatory oversight for the purpose of making management decisions about future regulation or control
- All inputs are categorically specified; custom input is not possible
- The model produces only a single output (value), which has relevance to the risk ranking alone, thereby limiting the usefulness of the approach.

II.3.3 The Foodborne Illness Risk Ranking Model (FIRRM)

Purpose/Objectives

The Foodborne Illness Risk Ranking Model (FIRRM) was developed by Resources for Future under the advisement of the Food Safety Research Consortium, a multi-disciplinary collaboration of researchers from eight institutions with a common mission to improve public health by making food safety decision-making and priority-setting more science- and risk-based. The overall purpose of the FIRRM project was to develop a science-based tool for prioritization of food safety hazards which considers the distribution of risk across products and throughout the farm-to-fork chain. The outcome was an analytical software tool to facilitate the identification, comparison, and ranking of foodborne pathogens in multiple food types using several measures of public health impact.

Developer/Sponsor
Resources for Future under the advisement of the Food Safety Research Consortium, funded by the Robert Wood Johnson Fellowship Program and the USDA Cooperative State Research, Education, and Extension Service Integrated Food Safety Initiative

Contact
Sandra A. Hoffman
Resources for the Future
1616 P Street NW
Washington, DC 20036 hoffmann@rff.org

Documentation
Batz et al. (2004)
FSCR (2004)
Batz (2007)
Hoffmann et al. (2007)

Intended Users and Applications
Food Safety policymakers, risk managers, and risk analysts. Designed specifically for food safety applications.

Availability
Reputedly available as a free download at http://www.rff.org/fsrc/; however, attempting to access this website returns a page not available error. Appears to be currently available at http://www.thefsrc.org/firrm.htm.

Platform
Analytica

Model Overview

FIRMM takes a surveillance-based, top-down approach, using epidemiological surveillance data on pathogen illnesses and tracing those illnesses back to food origin (i.e., food source attribution). FIRRM consists of four modules. Module 1 (Disease Incidence Estimates) estimates the annual number of cases, hospitalizations, and

fatalities caused by each foodborne pathogen. Module 2 (Valuation of Health Outcomes) converts the results of Module 1 to two different metrics: economic costs and quality adjusted life year (QALY) losses. Module 3 (Attribution) determines the pathogen-specific illnesses and association with specific categories of food vehicles using one of three approaches (outbreak data, risk assessment, or expert judgment). Module 4 ranks pathogen-food combinations according to five different measures of social burden (estimated number of cases, hospitalizations, and deaths, as well as estimated economic impact and loss of QALYs). A general flow diagram for the model is provided in **Figure II-1**.

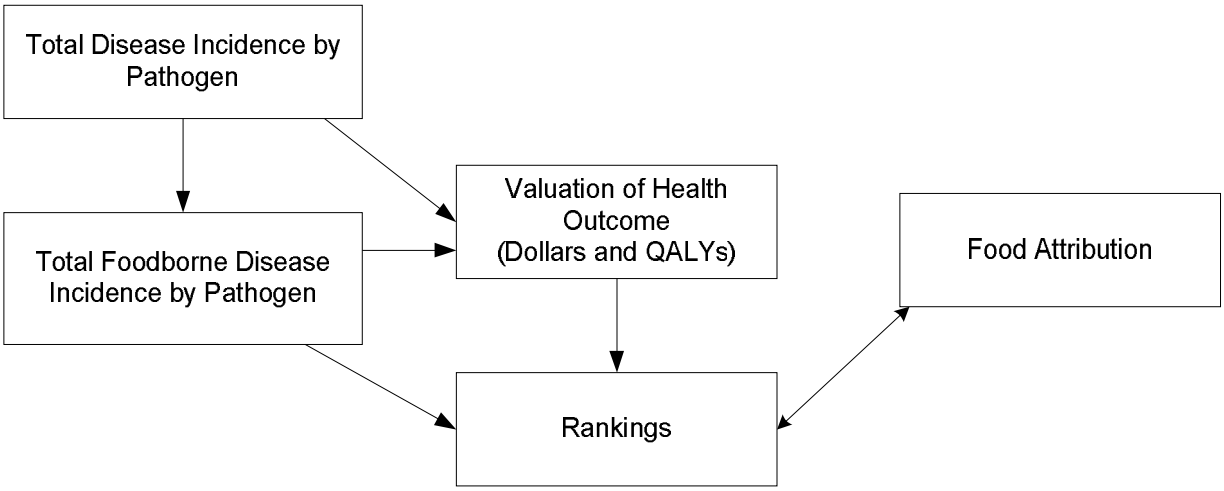


Figure II-1. Flow diagram of FIRRM model structure.

Many presentations of the model have been done and it is widely referenced on the Internet, including demonstration of outputs. However, to our knowledge, FIRRM has not yet been used by regulatory agencies for risk ranking.

Scope

The model covers the 28 bacterial, viral, and parasitic foodborne pathogens included in Mead et al. (1999). A complete list is shown in the box at right. Chemical agents are not ranked in FIRRM.

FIRRM Pathogens

Bacterial
Bacillus cereus
Botulism
Brucella
Campylobacter
Clostridium perfringens
E. coli O157:H7
E. coli non-O157 STEC
E. coli enterotoxigenic
E. coli other diarrheogenic
Listeria monocytogenes
Salmonella typhi
Salmonella nontyphoidal
Shigella
Staphylococcus toxin
Streptococcus
Vibrio cholerae toxigenic

Bacterial (cont'd)
Vibrio vulnificus
Vibrio other (*parahaemolyticus*)
Yersinia enterocolitica

Parasitic
Cryptosporidium parvum
Cyclospora cayetanensis
Giardia lamblia
Toxoplasma gondii
Trichinella spiralis

Viral
Norwalk-like viruses
Rotavirus
Astrovirus
Hepatitis A

The model covers the food categories described in the outbreak database managed by the Center for Science in the Public Interest (CSPI). Foods are identified by major food category and subcategory and are listed in **Table II-6**. Level of food categorization depends on attribution method chosen for application in Module 3. A major deviation from the CSPI

categorization is that FIRRM separates multisource outbreaks into their own major category and subcategories.

Table II-6. FIRRM Food Categories and Subcategories

Major Food Category	Food Subcategory	Major Food Category	Food Subcategory
Seafood	Finfish	Multi-ingredient	Salads
	Molluscan shellfish		Rice/beans/stuffing/hot pasta dishes
	Other seafood		Sandwiches
	Seafood dishes		Sauces/dressings/oils
	Seafood combo		Other foods
Eggs	Eggs		Multi-ingredient combo
	Egg dishes	Game	Game
	Egg combo	Poultry	Chicken
Produce	Fruits		Turkey
	Vegetables		Other poultry
	Produce dishes		Chicken dishes
	Produce combo		Turkey dishes
Beverages	Juices	Pork	Ham
	Other beverages		Other pork
	Beverage combo		Pork dishes
Dairy	Milk	Luncheon/ Other Meats	Luncheon meats
	Cheese		Other meats
	Ice cream		Other meat dishes
	Other dairy	Multisource	USDA
	Dairy combo		FDA
Breads and Bakery	Breads		USDA and FDA/Unknown
	Bakery	Unattributable	Unattributable
	Breads and bakery combo		

Detailed Description of Model

Module 1: Disease Incidence Estimates

The sources of data for this module are disease incidence and severity (hospitalization and death) estimates produced by Mead et al. (1999); in some instances, these data are supplemented with state-specific estimates from FoodNet and data from the USDA Economic Research Service (ERS) online foodborne illness cost calculator (USDA, 2003). This module is designed to produce estimates of the total annual number of cases of foodborne illness caused by each agent. In addition, the annual number of hospitalizations and deaths caused by that pathogen, attributable exclusively to the foodborne transmission route, are also estimated. **Figure II-2** provides an overview of the module.

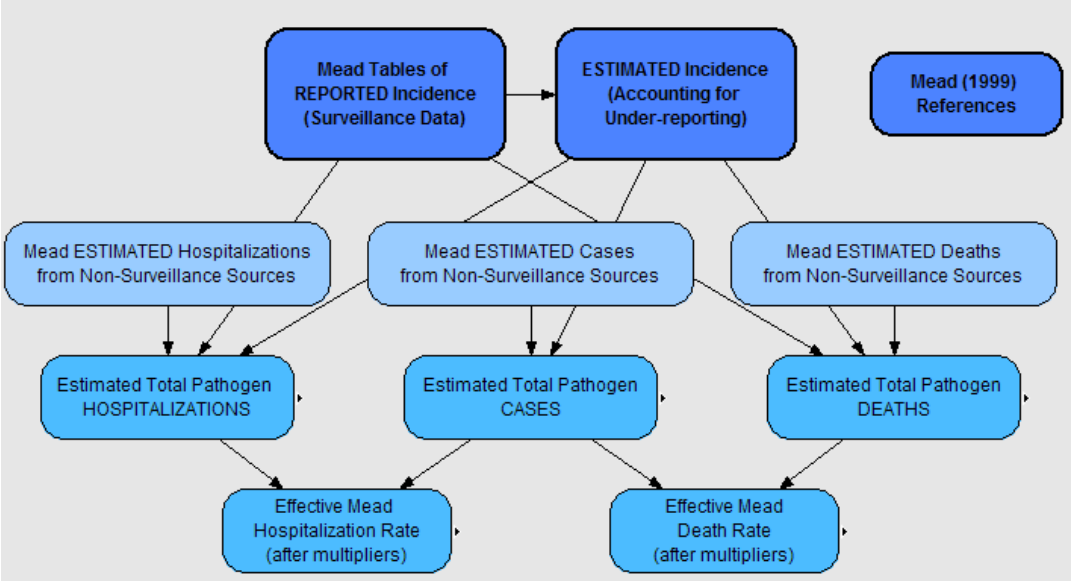


Figure II-2. Overview of FIRRM Module 1 disease incidence estimates using data from Mead et al. (1999).

Module 2: Valuation of Health Outcomes

Initially, all cases of disease for each pathogen are classified into various health outcomes. More specifically, for each pathogen, all cases are first divided into those who are hospitalized, those who visit a physician, and those who do not seek medical care. These three health states are further divided into subcategories (e.g., pregnant women, newborns) where appropriate. Cases of each health outcome subsequently recover or decline into a worse health outcome, such as chronic sequelae or premature death. This is referred to as the system-severity outcome tree approach. Economic valuation is calculated for each health outcome using two metrics (economic costs or QALY). Economic costs are calculated based on a combination of cost of illness (for morbidity) and willingness to pay (for mortality) using the general method applied by USDA (Buzby et al., 1996; USDA, 2003). Economic costs and QALY losses are summed to obtain totals for each pathogen. The overall scheme is detailed in **Figure II-3**, using non-typhoidal *Salmonella* as an example.

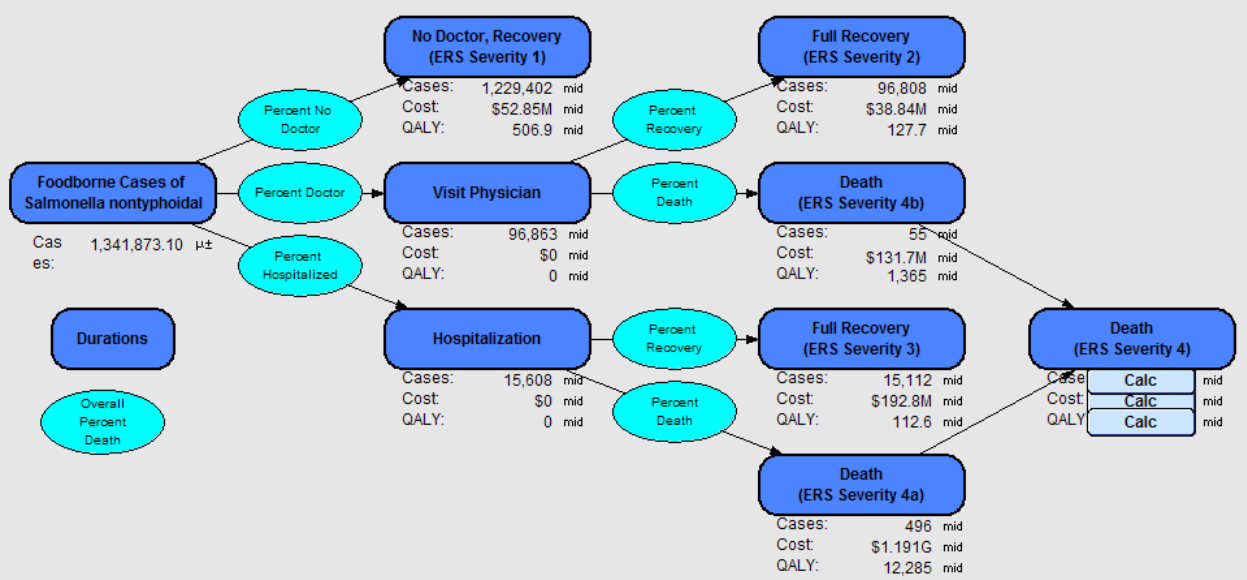


Figure II-3. Example of symptom-severity outcome tree using nontyphoidal *Salmonella*.

Module 3: Food Attribution

This module calculates pathogen-specific disease burden attributable to the different food categories using three different data sets and approaches. The user has the option of selecting which of these approaches to take. Each is briefly described below:

- **Food attribution using CSPI data:** CSPI maintains an outbreak database compiled from U.S. Centers for Disease Control and Prevention (CDC) line listings supplemented with information about documented outbreaks not included in the CDC database. For the 28 pathogens in the model, a total of 2,000 outbreaks representing over 83,000 cases of reported foodborne illness are included, dating from 1990 to present. This module is composed of two parallel computations: according to food subcategories and according to food major categories. Criteria are set (minimum of five outbreaks per pathogen) for inclusion in the attribution database to avoid misattribution, which might occur when the number of outbreaks is too low to give reasonable estimates of food attribution. Food attribution percentages are first calculated by pathogen and food subcategory, where the food attribution for each subcategory equals the number of cases associated with a selected pathogen for that specific subcategory divided by the total number of cases associated with that pathogen for all subcategories. The exercise is repeated for each major food category using the summation of the data for each subcategory in that major category. In this case, the food attribution for each major category equals the number of cases associated with a selected pathogen for that major category divided by the total number of cases associated with that pathogen for all major categories. Therefore, attributions are expressed as percentages.

- **Food attribution using risk assessment approach (also called consumption and contamination method):** This method uses publicly available information on the consumption of specific food products (ERS food consumption data system and CFSII data), probability of contamination (from the literature), dose-response relationship (from previous models), and information about consumer handling practices from U.S. FDA (2002) to estimate attributable disease for a particular pathogen as a function of food

category. Food attribution percentages are calculated from estimations of annual infections per person, by pathogen and major food category. The general approach is diagrammed in **Figure II-4**. The first three inputs are (1) annual per capita consumption by major food category; (2) total annual consumption (in kg), and (3) contamination rates (colony forming units [CFU]/kg) by pathogen and major food category. These are used to calculate contamination level experienced annually (CFU/yr). The contamination level experienced annually is multiplied by the percent of time consumers engage in "risky" behavior to provide an estimate of contamination level to which the consumer is exposed (CFU/yr). For each pathogen, the infectious dose (CFU/illness) is also specified. The ratio between the amount of the contaminant consumed and the infectious dose is estimated per pathogen and per major food category, providing a proxy for infections (illnesses/yr) by pathogen and food. To calculate food-pathogen percentages for use in food attribution, FIRRM simply sums the infections for each pathogen across all foods and divides by that total.

§ **Food attribution using expert judgment:** This method is based on expert elicitation of food attribution percentages for a subset of foodborne pathogens for all major food categories (as reported by Hoffmann et al., 2007).

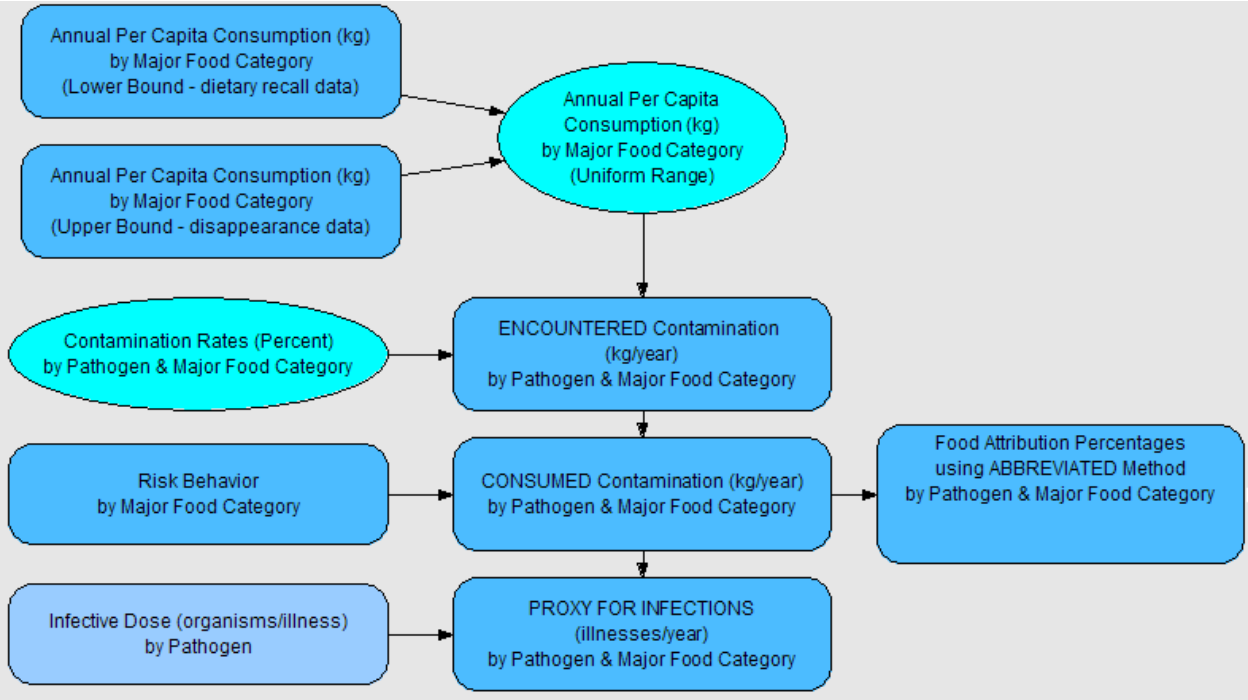


Figure II-4. Food attribution using a risk assessment method.

Module 4: Calculation of Rankings

Foodborne pathogen incidence (output of Module 1) and valuation of pathogen health outcomes (output of Module 2) are combined to provide pathogen-level measures of disease burden. Food attribution (output of Module 3) transforms pathogen-level estimates to estimates for pathogen-food combinations.

Outputs

The user selects which of the five measure of disease burden on which to rank. These include three disease incidence measures and two valuation measures:

- **Number of illness cases:** Rank disease burden according to estimated number of cases
- **Number of hospitalized cases:** Rank disease burden according to estimated number of hospitalizations
- **Number of deaths:** Rank disease burden according to estimated number of deaths caused by acute effects of disease, limited to deaths recorded in incidence data (i.e., does not include premature deaths due to chronic sequelae or latent complications)
- **Monetary valuation:** Rank disease burden according to estimated economic impact of health outcomes of disease based on cost of illness and willingness to pay
- **QALY valuation:** Rank disease burden according to estimated loss of quality of life due to health outcomes of disease, as measured by the QALY.

In addition to ranking pathogen-food combinations, the model also ranks pathogens (without attributing to food) and foods (by summation across all pathogens). Results are displaying in units appropriate to each measure or as a percentage of the total measure. Outputs can be viewed graphically.

Platform

FIRMM is designed in Analytica, a visual modeling and Monte Carlo simulation program in which mathematical models are developed using functional influence diagrams. The model is designed to be "point-and-click" for the user and includes built-in documentation and references. Uncertainty analysis is embedded in the program, and a "dashboard" interface allows the user to change some of the assumptions. It appears that significant training (~1 day) of user time would be required to become competent in model use.

Uncertainty

The model incorporates probabilistic uncertainty within a Monte Carlo simulation framework and produces intervals and statistics for outputs. To date, the primary driver of uncertainty bounds is associated with per-case valuation estimates.

Model Attributes

- The topdown approach has value because the rankings are based on final public health measure (i.e., product-specific attribution)
- FIRRM has a high degree of resolution in food categories if the CSPI method for food attribution is chosen
- It uses the same methodology to rank all pathogens and all commodities
- Valuation of health outcomes provides a well recognized metric for comparison/ranking of various public health outcomes
- It provides several measures of public health outcome(s) to facilitate comparison of different pathogens
- The user is provided some choice (e.g., method of attribution calculation, outcome metric, selecting specific data years to include in analysis, inclusion/exclusion of mixed products)

- It addresses uncertainty (to some degree) by using upper/lower bounds and probability distributions to describe some inputs (e.g., annual consumption, contamination rates, expert elicitation values) and uses Monte Carlo simulation
- Although it currently produces measures at the national level (United States), it could be refined to produce regional or country-specific rankings.
- It is relatively simple to update as new surveillance or attribution data become available.

Model Limitations

- FIRRM is based almost exclusively on epidemiological data, which can provide an incomplete picture of the true impact of the various pathogens and foods on disease burden and attribution
- Gaps in data, most importantly in regard to food attribution and the statistical uncertainty of disease incidence estimates, limit the utility of the model
- FIRMM does not consider the breadth of the farm-to-fork chain, because ranking is based solely on food source attribution; as a result, the model cannot be used to evaluate candidate mitigation strategies at various phases in the farm-to-fork continuum.
- Some (perhaps important) pathogen-product combinations are not subjected to attribution analysis because of relatively stringent criteria to prevent misattribution
- The model applies to microbiological agents only; chemical agents are not considered.

II.3.4 The Food Safety Universe Database (FSUDB)

Purpose/Objectives

The purpose of the Food Safety Universe Database (FSUDB) is to systematically assess and rank food safety risks for the ultimate purpose of optimizing the use of finite resources to best manage food safety issues.

Developer/Sponsor
Ontario Ministry of Agriculture and Food

Contact
Dr. Bruce McNab
Bruce.McNab@omaf.gov.on.ca

Documentation
OMAF (2003)

Intended Users
Food safety policymakers, risk managers, and risk analysts. Access is limited to a few authorized individuals within the sponsoring agency, likely due to inclusion of the impact of food-system sabotage or terrorism.

Availability
The database and associated algorithms are not available in the public domain.

Platform
Microsoft Access

Model Overview

This semi-quantitative food safety risk assessment tool ranks food safety hazards on two axes: likelihood (probability) and consequence (impact). The general model structure is a "universe" or cloud of likelihood and consequence data for every possible combination of food, hazard, and location along the farm-to-fork chain. Therefore, there are three dimensions to the model: (1) food; (2) hazard; and (3) location in the chain (e.g., production, processing, consumption). The two axes are further described as model components. Component A, Probability, includes the subcategories of (1) consumption; (2) proportion of the food contaminated with that hazard at a specified location; and (3) if contamination occurs, proportion of the food that would lead to exposure. Each subcategory is

scored at a value that can range from 0.01 and 10. Component B, Impact, also has three subcategories: (1) proportion who become ill; (2) severity of disease; and (3) difficulty to control. Each of these is scored between 1 and 10. For any one food-hazard-location combination, the scores for each of the subcategories from the Probability Component and the Impact Component are multiplied, resulting in a score ranging from 1 to 10^6. Note that all subcategory scores are ordinal and should not be construed as proportions in the strict mathematical sense.

Scope

The scope of the three dimensions is as follows:

- **Foods:** The food dimension is coded at several levels. The most basic level is the broad food category (e.g., meat, dairy, or plant origin foods). Within each category, subclassifications exist (e.g., chicken, pork, beef). For further detail, specific products within these subclassifications can be chosen (e.g., fresh whole beef, fresh ground beef, ready-to-eat beef).
- **Hazards:** Hazards are likewise coded with several levels of detail. The first level consists of broad categories of biological, chemical, or physical hazards. The broad categories are subdivided into subclassifications (e.g., bacteria, viruses, parasites). The third and most specific level of classification addresses specific hazards within each subclassification (e.g., *Listeria monocytogenes,* pathogenic *Salmonella*)
- **Location along the food chain:** The specific locations in the food chain include production, processing, distribution, and final food preparation.

Detailed Description of the Model

There are two components (Probability and Impact), both of which consist of three criteria each.

Component A, Probability

The Probability Component consists of three subcategories designated Pa, Pb, and Pc. Each subcategory in the Probability Component is given a score which may be as low as 0.01 to a high of 10. The subcategories and their scoring are described below:

- **Pa–Consumption:** The scale of consumption score reflects the amount of the selected food consumed per person per day. The scores are based on information reported in several Canadian and American studies. The score depends on the food in question and the segment of society being considered. For biological hazards, it is based on the number of servings consumed, whereas for chemical hazards, it is based on the number of grams of the food consumed per day. The more a food is consumed, the higher it is scored. Scoring definitions/details are as follows; note scaling is not linear. The original documentation provides examples of foods that fall into each category.

Score	Chemical Agents: Weighted Average Consumption (g/person/day)	Biological Agents: (servings/person/day)
1	<0.49	0-0.005
2	0.5-1.9	0.005-0.020

Score	Chemical Agents: Weighted Average Consumption (g/person/day)	Biological Agents: (servings/person/day)
3	2-4.9	0.020-0.05
4	5-9.9	0.05-0.1
5	10-19.9	0.1-0.2
6	20-39.9	0.2-0.3
7	40-59.9	0.3-0.4
8	60-79.9	0.4-0.5
9	80-100	0.5-0.6
10	>100	>0.6

§ **Pb–Contamination:** The proportion of food contaminated can be scored in one of two ways. The proportion accidentally contaminated (Pbi) is influenced by the food, the hazard, and the location in the food chain being considered. This score can be modified to reflect situations which span from extremely unlikely to extremely likely that contamination with a particular hazard will occur at a particular point along the food chain. The more likely the food in question is of being newly contaminated (or additionally contaminated) by the hazard at the particular point (including increased contamination due to hazard growth or concentration), the higher the score. The details of the scoring criteria are as shown below; for chemical contamination, the score is based on the frequency of chemical use; for biological agents, frequency of contamination. Scoring is not linear. The documentation provides examples of food-hazard-location combinations that fall into each score category.

Score	Chemical Contaminants: Used (tons/year) Treated batches (%) Environmental contamination (ppm)	Biological Agents: Proportion Accidentally Contaminated
0.01	Never intentionally used at this point Negligible probability of accidental contamination	Negligible
0.1	<0.5 t/yr No reason or incentive to use: negligible–0.01% <0.01 ppb	Negligible–0.01
1	0.5–1 t/yr Used on 0.01–0.1% of batches 0.01–0.5 ppb	0.01–0.1
2	1–5 t/yr Used on 0.1–1% of batches 0.5–5 ppb	0.1–1
3	5–10 t/yr Used on 1–5% of batches 5–50 ppb	1–5%

Score	Chemical Contaminants: Used (tons/year) Treated batches (%) Environmental contamination (ppm)	Biological Agents: Proportion Accidentally Contaminated
4	10–25 t/yr Used at least once on 5–15% of batches 50–250 ppb	5–15%
5	25–50 t/yr Used at least once on 15–30% of batches 250–500 ppb	15–30%
6	50–75 t/yr Used at least once on 30–50% of batches 500–750 ppb	30–50%
8	75–100 t/yr Used at least once on 50–90% of batches 750–1,000 ppb	50–90%
10	>100 t/yr Routinely used more than twice on the same batch on >90% of batches >1 ppm	>90%

For intentional contamination circumstances, the proportion contaminated by sabotage score (Pbii) is derived using the risk assessor's expert opinion of the sabotage appeal of contaminating that food with that hazard at that point along the food-chain. This is based on ease of logistics of acquisition and introduction of that hazard to the food at that point in the chain and the terror that such a deliberate introduction would cause. Detailed scoring information for Pbii is withheld from public access.

§ **Pc–Exposure:** This subcategory characterizes the likelihood that consumers will be exposed to the hazard given that contamination occurs. For biological hazards, this is based on the likelihood of an organism surviving to consumption, given the location of its introduction relative to inactivation steps (e.g., thermal or chemical treatments). For chemical hazards, the ranking is based on processing steps that would reduce concentration, chemical half-life, pre-harvest intervals, and drug withdrawal periods. The greater the likelihood of exposure, the higher the score. Subscores are not directly proportional to their nonlinear definitions. Probability of exposure to chemical hazards is scored as follows:

Score	Processing factors reduce residue by:	Half-life of chemical (days)	Bioaccumulation BCF Log Kow	Pre-harvest interval or withdrawal period (days)
0.01	>99%	<1	<100 <3	<0.25
0.1	>99%	1–3	100–150 <3	<0.25
1	>99%	3–5	150–200 3–3.25	0.25–0.5

Score	Processing factors reduce residue by:	Half-life of chemical (days)	Bioaccumulation BCF Log Kow	Pre-harvest interval or withdrawal period (days)
2	95–99%	5–8	200–300 3.25–3.5	0.5–1
3	90–95%	8–12	300–500 3.5–4	1–2
4	80–90%	12–20	500–750 4–4.5	2–5
5	60–80%	20–40	750–1,000 4.5–5	5–10
6	40–60%	40–60	1,000–2,000 5–5.5	10–20
8	5–40%	60–100	2,000–5,000 5.5–6.5	20–40
10	<5%	>100	>5,000 >6.5	>40

Probability of consumer exposure to biological hazards is scored as follows; for microbiological agents, the documentation provides examples of applicable foods:

Score	Subsequent Contamination Reduction	Contamination occurs PRIOR to:
0.01	>5 log	Thermal processing Pasteurization Commercial cooking
0.1	3–5 log	Commercial non-thermal processing (e.g., smoking, curing, fermentation, long aging period)
1	2–3 log	Commercial non-thermal processing (e.g., smoking curing, fermentation, aging period)
2	95–99%	Consumer cooking: pathogens not distributed internally and product has small surface area
3	90–95%	Commercial non-thermal processing: medium aging period Long-term exposure in the environment
4	80–90%	Consumer cooking: pathogens distributed internally and consumer may prefer product undercooked; or product has large surface area
5	60–80%	Washing: easy-to-wash produce Commercial nonthermal processing: minimal aging period
6	40–60%	Washing: moderately difficult-to-wash produce Commercial nonthermal processing: minimal aging period
8	5–40%	Washing: hard-to-wash produce Commercial nonthermal processing: minimal or no aging period
10	<5%	All foods contaminated at point of consumption (ready-to-eat) or post-cooking or pasteurization

Component B, Impact

The Impact Component consists of three subcategories designated Ia, Ib, and Ic. Each subcategory in the Impact Component is given a score from 1 to 10. The subcategories and their scoring are as follows:

- **Ia–Proportion of Exposed Consumers That Become Ill:** The proportion of exposed consumers that become ill as a result of exposure to a specific hazard is influenced by the toxicity or virulence of the hazard and the amount to which the consumer is exposed relative to the critical amount required to cause illness. For chemicals, the rankings are based on exposure concentrations relative to maximum residue limits (MRLs). For biological agents, ranking is based on available data on the dose required to cause infection and consideration of the fraction of that infective dose to which consumers are likely to be exposed given the particular hazard-food-point-of-contamination scenario. The greater the exposure, the greater the impact score. Scoring criteria are as follows; for microbiological agents, the documentation provides examples:

Score	Frequency of Violations Observed in Surveys or Expected Concentrations Relative to MRL	Fraction of Infectious Dose at Point of Consumption
1	<10 MRL	$<1/10^8$
2	<1% and 10–100 MRL	$1/10^8$–$1/10^6$
3	1–10% and 10–100 MRL	$1/10^6$–$1/10^5$
4	<1% and 100–1,000 MRL	$1/10^5$–$1/10^4$
5	>10% and 10–100 MRL	$1/10^4$–$1/10^3$
6	1–10% and 100–1,000 MRL	0.001–0.01
7	<1% and >1,000 MRL	0.01–0.1
8	>10% and 100–1,000 MRL	0.1–1
9	1–10% and >1,000 MRL	1–2
10	>10% and >1,000 MRL	>2

- **Ib–Severity of Illness:** This impact factor is evaluated based on the severity of illness among consumers who become ill. For chemicals, this is based on both acute and chronic toxicity data; in this case, a score for a particular agent may be calculated using the combined impact of these factors, so-called sub-sub-scoring. For biological agents, the ranking is based on data describing the average cost per case for specific illnesses, including treatment, hospitalization, lost time, and statistical value of life as expressed in the disability adjusted life years (DALY) metric. Scoring criteria are as follows; for microbiological agents, the documentation provides examples:

Score	Oral LD_{50} (mg/kg)	Oral Reference Dose/ Acceptable/Tolerable Daily Intake (mg/kg/day)	Cancer potency, Factor q1, TD_{50} (mg/kg/day), IARC Classification	Health-Related Cost per Case ($$ Canadian)
1	>5,000	≥10	• 0.0001 • 1000 4 = probable not carcinogen	Impact unknown or unproven
2	500–5,000	5–10	0.0001–0.001 100–1,000 3 = not classifiable as carcinogen	<1,200
3	100–500	1–5	001–0.01 10–100	1,200–2,500
4	50–100	0.5–1	0.01–0.1 1–10	2,500–5,000
5	25–50	0.1–0.5	0.1–1 0.1–1	5,000–20,000
6	10–25	0.05–0.1	1–10 0.01–0.1	20,000–50,000
7	5–10	0.01–0.05	10–100 0.001–0.01	50,000–200,000
8	2–5	0.005–0.01	100–1,000 0.001–0.01 2B = possible human carcinogen	200,000–1 million
9	0.5–2	0.001–0.005	1,000–10,000 0.001–0.01 2A = probable human carcinogen	>1 million
10	<0.5	≤0.001	• 10,000 • 0.001 1 = known human carcinogen	>50% mortality regardless of cost/case

§ **Ic–Difficulty to Limit Impact:** This score reflects how difficult it is to reduce or limit the impact of the hazard in the food. Ranking is based on factors such as time to realize the problem, size of the distribution network, the ease with which recall may be initiated, the ease with which the hazard can be identified and eliminated, and indirect economic effects. For biological agents, the potential for secondary spread is also considered. Because multiple factors are considered in scoring, the combined impact of these factors is calculated using so-called sub-sub-scoring. Final scores are ordinal from 1 to 10; the more difficult it is to limit impact, the higher the score. The scoring descriptions are as follows.

Score	Time to realization of problem (days)	Extent of Required Recall, Difficulty to Eliminate Source of Contamination	Secondary Spread (biohazards), Indirect Economic Impacts
1	0.5	Small defined source, no recall Easy to identify and eliminate source	No secondary infection No indirect economic impacts
2	1	Local distribution, small recall Easy to identify and eliminate source	No secondary infection No indirect economic impacts

Score	Time to realization of problem (days)	Extent of Required Recall, Difficulty to Eliminate Source of Contamination	Secondary Spread (biohazards), Indirect Economic Impacts
3	1–2	Regional distribution, moderate recall Easy to identify and eliminate source	No secondary infection No indirect economic impacts
4	3	Provincial distribution, moderate to large recall Can identify source with investigation and eliminate at some cost	No secondary infection No indirect economic impacts
5	4	2–3 Province distribution Can identify source with investigation and eliminate at some cost	No secondary infection No indirect economic impacts
6	5	National distribution, national recall Can identify source with investigation and eliminate at some cost	Some secondary spread of infection Some indirect economic impacts
7	5–10	North American but good tracing and specific product recall Can identify source with investigation and eliminate at some cost	Some secondary spread of infection Some indirect economic impacts
8	10–15	Trans continental but good tracing and specific product recall Very difficulty to identify source and very difficult to eliminate	Some secondary spread of infection Some indirect economic impacts
9	15–30	North American but poor tracing and Imprecise recall Very difficulty to identify source and very difficult to eliminate	Significant secondary infection Significant indirect economic impacts
10	>30	Trans continental but poor tracing and imprecise recall Very difficult to identify source and very difficult to eliminate	Significant secondary infection Significant indirect economic impacts

Risk Ranking

The overall risk score for any one food-agent-location trio is calculated multiplicatively as the product of the six subscores (three probability and three impact); the range is 1 to 1,000,000:

$$Risk\ score = Pa \times Pb \times Pc \times Ia \times Ib \times Ic$$

Outputs

Outputs are produced in two forms, designated per-serving risk and societal risk. These two outputs are influenced by the scale of consumption and the proportion of food servings contaminated. This is done very simply by including or excluding the scale of consumption (Pa) in the calculation of the overall risk score. Including Pa in the calculation gives a risk rank range of 1 to 1,000,000 and reflects societal risk. Excluding Pa from the calculation provides a risk ranking range of 1 to 100,000 and expresses risk from a per-serving perspective.

The FSUDB can also be manipulated to produce scores as applied to specific segments of society (e.g., susceptible subpopulations, age-related differences in consumption patterns) by maintaining separate data records for very specific food-hazard-location combinations. Information is also captured to allow comparison of risk scores by food source, type of establishment, and regulatory authority responsible for the food. Furthermore, notes on references, explanations of scoring, and who assigned or changed scores and when and why are also captured in the FSUDB. Similarly, notes on potential tools to control risks for that hazard-food-location combination may also be recorded.

Platform

The FSUDB database program was developed in Microsoft Access. A primary data-entry screen allows the user to enter the data, which in most cases is facilitated by pick-lists. The left-hand side of the screen prompts the user to enter different types of data. The middle part of the screen provides pop-up pick-lists from which the user picks appropriate available codes. The description of each code is provided in the pick-list and appears on the right side of the screen once a code has been selected. Pick-lists and descriptions are stored in tables in the background of this relational database. The database administrator controls any changes to the code tables. The overall risk score is calculated automatically by an algorithm programmed into the system. This algorithm may be changed or weighted differently by the database administrator, if appropriate. Training requirements appear to be moderate, about 4–6 hours.

Uncertainty

Risk assessors' uncertainties about probability and impact subscores are captured in uncertainty scores of 1 to 10. An uncertainty score of 1 represents no or negligible uncertainty. A score of 10 represents extreme uncertainty about probability or impact scores. These uncertainty scores are used in algorithms programmed into the database to place a type of confidence interval on the calculated risk-scores. However, because the database is not publicly available, it is not clear how these uncertainty scores are reflected in the associated outputs.

Model Attributes

- FUSDB can be applied to compare risks of microbial hazards and chemical hazards
- It uses the same methodology to rank all agents and all commodities
- User-friendly interface could facilitate wide use
- Production of two risk measures (risk per serving and societal risk) provides flexibility
- The model is applicable to both accidental and intentional contamination scenarios
- The documentation is straightforward and in most instances, specific examples are provided to help the user in choice of scaling values for the different inputs
- The evidence base for the model is relatively transparent; however, scoring criteria might be considered arbitrary by some and justification/definitions for specific scores are simply designated as "developed by the authors and used for internal consistency."

Model Limitations

- There is limited consideration of uncertainty
- As currently designed, each of six individual criteria (subcategorizations) have equal importance (or weight), although this could probably be remediated by minor coding changes
- The tool is not publicly available
- Although the approach allows for ranking within specific sectors of the food chain (e.g., production, processing), it currently does not have a simple means by which to allow aggregation of results so that one could follow the combined impacts of each phase of the farm-to-fork continuum for risk ranking purposes.

II.3.5 The Food/Hazard Risk Registry (FHRR) or iRISK

Purpose/Objectives

The purpose of this project was to support the development and implementation of a risk ranking framework to evaluate potential high-threat microbiological agents, toxins, and chemicals in food. The framework was to include a model for quantitatively or semi-quantitatively comparing and determining the potential threats of these agents and the ability to evaluate interventions or control points (e.g., manufacturing/processing, warehouses, transport, retail) at various places in the farm-to-fork chain. In the development of this model, FDA specifically requested the use of criteria that, at a minimum, addressed compatibility of a hazard with food as a vehicle, toxicity (or dose necessary to result in disease), accessibility, and likelihood of effect (illness).

Developer/Sponsor
FHRR developed by the Institute of Food Technologists and FDA CFSAN and operationalized as iRisk by Risk Sciences International (formerly Decisionalysis). Funded by FDA CFSAN.

Contacts

Rosetta Newsome
Institute of Food Technologists
525 W. Van Buren, Ste. 1000
Chicago, IL 60607
rlnewsome@ift.org
Phone: 312.782.8424
Fax: 312.782.8348

Greg Paoli
Risk Sciences International
1831 Yale Ave
Ottawa, ON Canada K1H 6S3
gpaoli@analyzerisk.com
Phone: (613) 260-1424

Documentation
Newsome et al. (In press)
Paoli (2008a,b)

Intended Users and Applications
Policy makers, risk managers, risk analysts, and others with specific expertise in foods safety. Designed specifically for food safety applications.

Availability
The iRISK model is meant to be accessible on-line with FDA-CFSAN permission, although at the time of this writing, permission for on-line access had not yet been granted.

Platform
Visual Basic (web-based user interface)
Analytica

Model Overview

The iRISK model is designed to analyze data concerning hazards (both chemical and biological) in food and return an estimate of the resulting health burden on a population level. This is a bottom-up, or predictive modeling approach to risk ranking that requires the application of data and expert judgment to assemble sufficient information to predict

the fate of the hazards in the food supply through the farm-to-fork chain. These results are combined with food intake data and information on hazard virulence or toxicity to produce a prediction of the relative level of risk to human health of the particular hazard-food pair. The model produces a semi-quantitative characterization of the disease burden, which can be used for comparison (ranking) purposes and can facilitate the evaluation of the impacts of hazard control measures.

The model is organized into two major modules, Exposure (farm-to-table) and Hazard Characterization (health impacts), and one sub-module. The Exposure module is subdivided into three major sections representing the farm-to-fork continuum: (1) primary production; (2) processing; and (3) distribution, storage, retail, foodservice, and home. The Hazard Characterization module addresses (1) agent pathogenicity or toxicity and (2) potential public health burden. The submodule addresses consumption/food intake. The overall model structure is provided in **Figure II-5**.

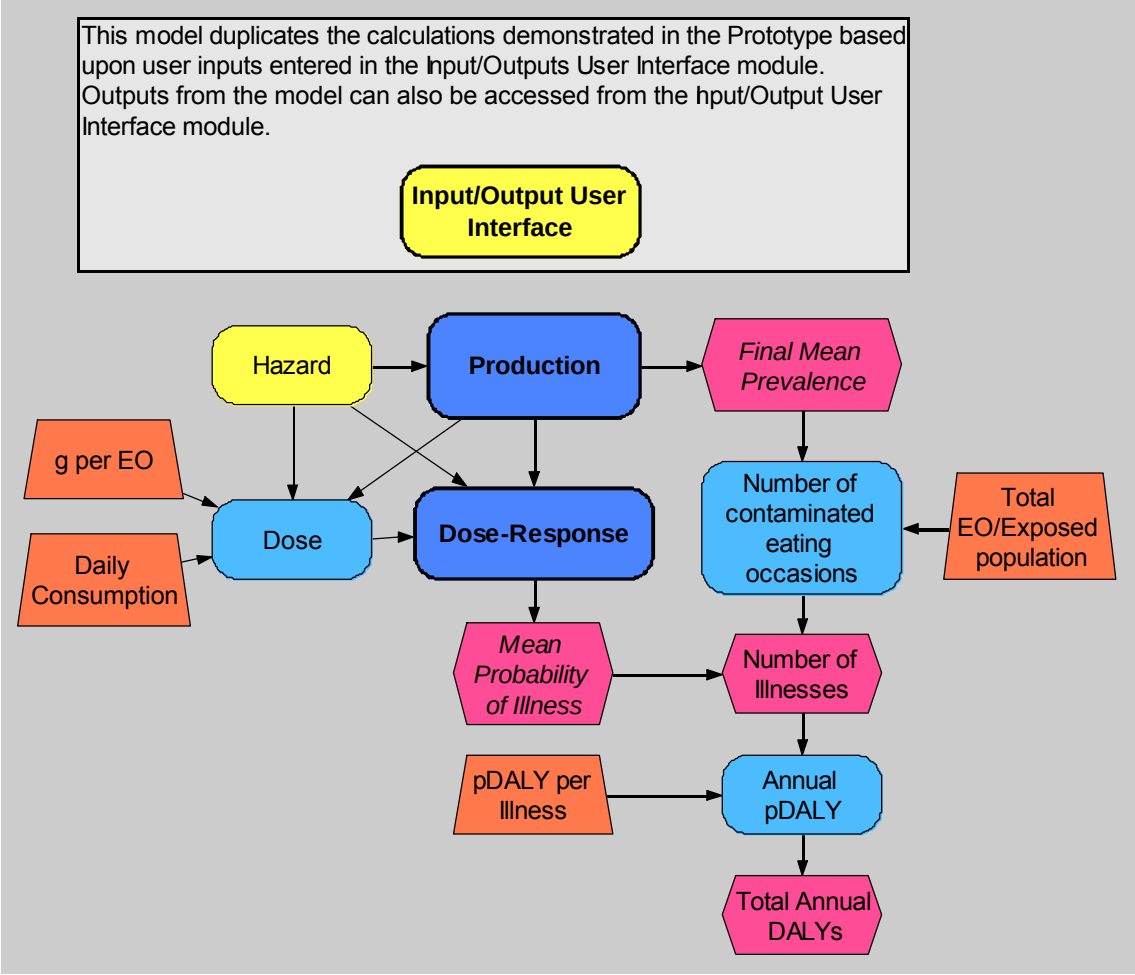


Figure II-5. Overview of iRISK model (in Analytica).

The metric used for reporting risk is a modification of the DALY, designated the "pseudo-DALY or pDALY; this metric allows for a semi-quantitative characterization of the disease burden of disparate health impacts. The usual approach to measuring the DALY is to assign a severity

weight and duration weight to discrete, relatively well-characterized health outcomes. The pDALY approach allows for the characterization of a standard health outcome (such as a mild illness) without further definition of the exact impact. This was developed primarily to facilitate risk ranking of chemical substances which may present a risk of diverse, poorly characterized outcomes (e.g., noncancer toxicity) that may not be easily assigned individual weights and durations. In short, the pDALY method allows the impact of the hazard, whether cancer, infectious, or toxic, to be put on a relative scale.

To date, 24 food-hazard pairs have been used to test the prototype. No other applications are known at this time.

Scope

The data required to execute iRISK includes information about the food (which foods, along with the associated consumption data and processing/preparation methods) and the hazard (hazard-specific dose-response curve and anticipated health effects in humans). The user can specify any combination of these elements, providing capability to evaluate a broad range of risk scenarios. For example, risk can be compared for the same food contaminated with different hazards; the same hazard present in multiple foods; multiple agent-food combinations; or a single hazard-food combination processed or prepared in different ways.

Detailed Description of the Model

Input Variables and Data Sources

The Institute of Food Technologists convened a panel of experts having expertise in the farm-to-fork food system, food safety, risk assessment and management, microbiology, chemistry, toxicology, predictive microbiology, and computer modeling to develop the risk-ranking framework prototype. The panel's expertise and efforts were supplemented with additional developmental assistance by other experts, as needed. Hence, the evidentiary base for the model development was the expert elicitation framework supplemented by expert panel judgment and publicly available peer-reviewed scientific information.

The experts identified potential input variables or risk criteria which would be critical to a risk ranking tool:

- Initial prevalence
- Initial concentration before processing
- Change in concentration at primary production
- Likelihood of introduction at primary production
- Introduced concentration at primary production
- Change in prevalence during primary production
- Change in concentration at processing
- Likelihood of introduction at processing
- Introduced concentration at processing
- Change in prevalence (processing)
- Change in concentration at distribution, storage, retail, foodservice, and in the home

- Likelihood of introduction at distribution, storage, retail, foodservice, and in the home
- Introduced concentration at distribution, storage, retail, foodservice, and in the home
- Change in prevalence at distribution, storage, retail, foodservice, and in the home
- Total eating occasions/exposed population
- Grams per eating occasion
- pDALY per illness
- Daily consumption
- Dose-response model
- Dose.

The panel then designed a series of key questions that could be answered by the user to provide a predicted value or description for each of the risk criteria. The format for answering these questions depends on the particular question, but can be qualitative (e.g., high, medium, low, likely/not likely), quantitative (metric/scale), objective (available data), subjective (expertise), or rationale-based. Metrics (values assigned to individual risk input criteria) for the risk criteria in the Exposure and Hazard Characterization modules were systematically developed by the panelists. The panelists also developed decision logic (supporting rationale and guidance), including pertinent examples, to define the answer options and guide users in answering the questions and entering data. The decision logic and supporting rationale define the answer options for each question, provide intellectual justification for the relevance to the metrics for each question, and provide the necessary user interface.

Module 1: Exposure

Users first determine the hazard-food category for which they wish to enter information. They are then prompted by specific questions for pertinent details on hazard prevalence and hazard concentration, and the predicted changes in hazard prevalence and concentration at each of the three food system stages (i.e., primary production; processing; and distribution, storage, retail, foodservice, and home) for that product.

- **Hazard Prevalence (Introduction and Changes):** The model addresses the likelihood of hazard introduction at each of the three stages, the change in prevalence that might occur during each stage, and the predicted prevalence after each stage. This results in a final prevalence estimate. Initial prevalence is expressed on the basis of percentage of total units in which the hazard is present (contaminated units/total units, 0–100%). Within each of the three food system stages, hazard presence is considered on a bulk lot or truck load type basis rather than by individual consumer or retail units. Change in prevalence (occurring independently of initial concentration, change in concentration, or introduced concentration within each of the three food system stages) is represented using multipliers, where 1 corresponds to unchanged prevalence, values <1 represent reduction in prevalence, and values >1 represent relative increases in prevalence.

- **Hazard Concentration (Introduction and Changes):** Hazard concentration is expressed as initial concentration (in $\log_{10}$ CFU/g for microbes and g/g for chemicals) at the earliest point of contamination, and subsequent concentration as a result of any increases, decreases, or additions occurring during the three stages of the farm-to-fork continuum. Monte Carlo simulation computes final estimated concentration of the agent

from triangular distributions (minimum, most likely, or maximum concentration values). The simulation engine examines each possible pathway of contamination explicitly, and the resulting concentrations are weighted (because not all concentrations are equally likely) by their respective probability of occurrence calculated in concentration weights. As a result, 16 pathways track probabilities for concentration throughout each of the three food system stages.

Submodule for Consumption/Food Intake

This submodule estimates the proportion of the population that is exposed to the hazard and how much of a given food is eaten. Using the USDA's CSFII 1994–1998 database, an aggregate approach was taken in terms of grouping the food products. CSFII data are compiled for four population groups (entire United States, women 16–49 years of age, children 1–6 years of age, and the elderly [65+ years of age]). The user may specify what percentage of a given population is at risk (e.g., percentage of pregnant women). The consumption of foods contaminated with various chemicals is based on the mg/kg body weight/day measure. Population size is based on Census estimates for each population group in the database to compute population risk for chemicals. Microbial risk is calculated using mean serving size and total number of servings (eating occasions). For chemical hazards, risk (probability of illness) is calculated on the basis of the 90th percentile for consumption.

Module 2: Hazard Characterization

This module addresses (1) agent pathogenicity or toxicity and (2) potential public health burden. The user first specifies the agent and the hazard outcome type(s) to be considered (see list under Input Variables and Data Sources, above). When selecting a specific health impact, space is provided in boxes to provide rationale and supporting references.

- **Dose-Response Relationships:** Multiple dose response models are available for each potential hazard outcome type (i.e., threshold linear, non-threshold linear, step-threshold, beta-Poisson, or exponential). Templates for each of the dose-response models in association with each of the health outcomes are part of the software and cannot be changed by the user. Therefore, the dose-response section of the module specifies appropriate parameters for each model as applied to each outcome. All dose-response pages allow consideration of probability of illness given response, addressing the question of what proportion of infections would result in illness. Dose-response curves are incorporated into the risk calculations.

- **Potential Public Health Burden:** Users create pDALY templates by assigning a fraction of cases to appropriate health impacts. Hence, the results of exposure are captured semi-quantitatively on two dimensions—impact severity (mild, moderate, severe, and death) and duration (short, medium, long). Basically, the user assigns a fraction of cases to appropriate health impacts so that there are up to 12 ways of describing a health impact:

  - Mild illness, with short, medium, or long term impacts (3 combinations)
  - Moderate illness with short, medium, or long term impacts (3 combinations)
  - Severe illness with short, medium, or long term impacts (3 combinations)
  - Mortality in child, adult, or the elderly (depending on population)

- Specific syndromes including hemorrhagic colitis, hemolytic uremic syndrome, enteric fever, reactive arthritis/Reiter's' syndrome
- New health impact(s).

pDALY templates available to date are as follows:

- Acute (chemicals)
- Blood target organ (chemical)
- Cancer (chemical)
- *E. coli* O157:H7
- Gastroenteritis only (rare fatality)
- Hepatitis A virus
- Neural tube defect
- Neurodevelopmental (chemical)
- Reproductive (chemical)
- *Salmonella*
- Severe pathogen
- New pDALY template.

Calculation of Rankings

Monte Carlo simulation computes a range of doses based on the concentration of the hazard in the food and average serving size. The computed doses are then applied to hazard dose-response models to compute mean probability of illness for distinct population groups. Prevalence values are used to determine the number of contaminated servings. Combining the consumption estimates with probability of illness and the burden of disease (pDALY) values generates a final risk characterization metric in the form of annual pDALYs. Risks that are inferred based on lifetime exposures (for chemical hazards) are prorated to an annual risk estimate (by dividing by an arbitrary lifetime value of 70 years) to allow for compatible timeframes for comparison between disparate agents.

Outputs and Reports

The major outputs are as follows:

- Final mean concentration in positive lots
- Final mean prevalence
- Mean probability of illness
- Number of illnesses
- Annual pDALY

The prototype is coded such that there is an option to include or exclude any foods, hazards, or specific hazard-food combinations, as chosen by the user. The prototype also provides a basic mechanism that reports back selected contents of the database (the evidence) according to foods, hazards, processes, and their combinations.

A risk-ranking summary report can be generated that lists (in ascending or descending order) the results, aggregated by hazard or food and ordered by total risk, expressed as pDALY. The

summary report also provides a list of currently excluded foods, hazards, and combinations and summarizes the following:

- The dose-response model and parameters
- Grams consumed and number of eating occasions
- Mean hazard prevalence (%)
- Number of contaminated servings from once contaminated lots
- Mean concentration in food
- Mean dose
- Mean probability of illness
- Number of illnesses
- pDALY per illness
- Annual pDALY.

Platform

The FHRR model is available in two platforms: an Analytica (Lumina Decision Systems, Los Gatos, Calif.) which constitutes the prototype; and a web-based user interface implemented in Visual Basic (Microsoft, Redmond, Wash.). The latter is now referred to as iRISK. The Analytica model (Figure II-5) was built initially to facilitate the development of calculations and computational features, for visualization of logic flow and interrelationships between input and output variables, and to serve as the basis for further development, discussion, and review of the algorithms. The Analytica model allows calculations based on only a single hazard-food pair and does not allow relative risk rankings of different hazard-food pairs.

The web-based platform was developed to provide a user-friendly input/output interface that facilitates concurrent use and data sharing without significant time delay by multiple individuals (**Figure II-6**). This tool begins as something of a "blank slate" such that the user must identify the hazard, food, population group, and at least one health effect, as well as some other user-specified inputs (e.g., parameters for the Exposure module). However, other aspects are fixed and cannot be changed by the user (e.g., hazard-specific dose response parameters, food consumption and intake). The web-based platform has advantages in that it allows users to explore the complex ranking hierarchy, view the current evidence, edit evidence, and update assumptions. Calculations are performed using Visual Basic; a relational database (Microsoft Access) stores the relationships between variables (foods, hazards, processes, and evidence) individually, and in their many combinations. It appears that significant training (~1 day) of users would be required.

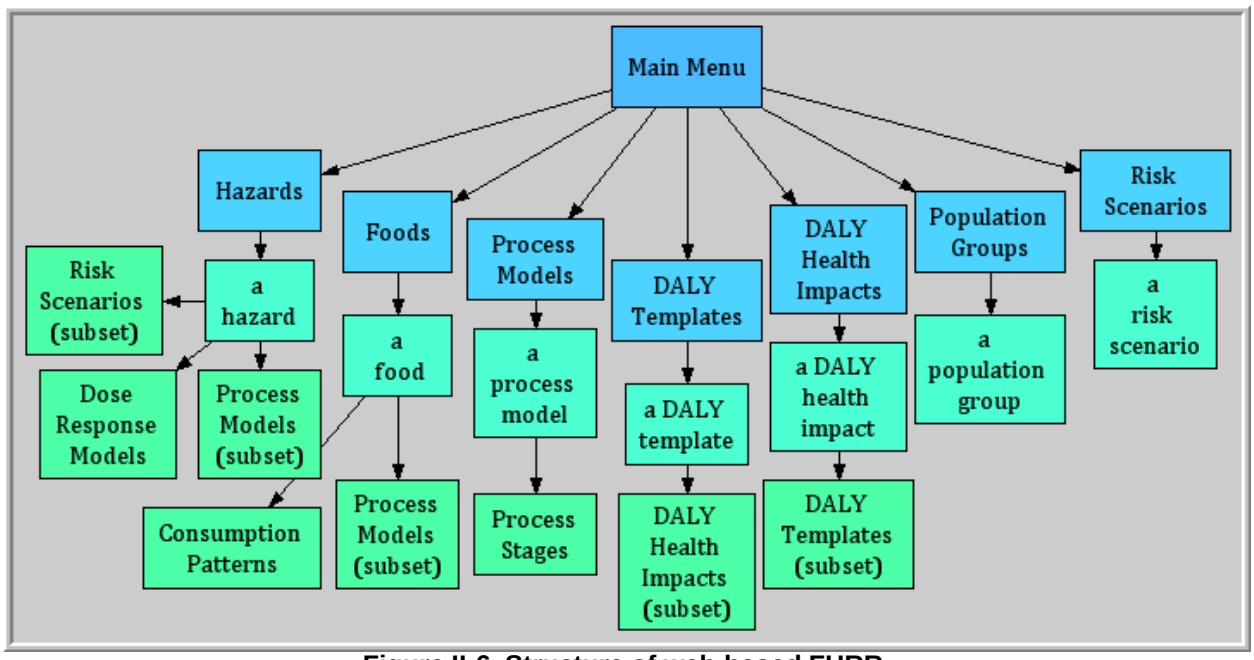


Figure II-6. Structure of web-based FHRR.

Uncertainty

The web-based version (iRISK) uses Monte Carlo simulation to compute a range of doses based on the concentration of the hazard in the food and the average serving size. Triangular distributions were chosen for characterization of agent concentration; other distributions (e.g., Beta Pert) could readily be used in future iterations of the model.

Model Attributes

- FHRR/iRisk has specific application to food safety, including both microbiological and chemical (including microbial toxins) risks
- The model is based on the classic microbial risk assessment paradigm
- The bottom-up farm-to-fork approach is amenable to the evaluation of candidate mitigation strategies
- The model uses the same methodology to rank all agents and all commodities
- It provides a novel measure of public health outcome (pDALY) to facilitate comparison of disparate agents; the pDALY is proposed as a harmonization of burden of disease measures given that the spectrum and relative frequency of health outcomes varies widely among hazards
- The user is provided some choice (dose-response model, combinations of disease endpoints)
- The model addresses (to some degree) uncertainty by using triangular distributions for many inputs and using Monte Carlo simulation to compute a range of doses
- The model is flexible, theoretically allowing its use for considering the impact of regional, seasonal, or geographic inputs on risk
- The evidence base for the model is relativity transparent and the documentation is good

- The production of risk summary reports for hazard-food pairs provides a synopsis of the inputs used for the ranking of each hazard-commodity pair
- The prototype can accommodate any number of possible modifications, including improved scientific documentation, incorporation of additional data, accounting for data quality or strength of judgment, or the addition of a feature that accommodates the input of confidence intervals for input and output estimates.

Model Limitations

- FHRR/iRisk may be considered by some as an oversimplification of the farm-to-fork chain
- Gaps in many of the data inputs may limit reliability of the risk estimates
- The uncertainty bounds of the model are inherently large given the simplified, three-category representation of the food system and reliance on expert opinion to develop the inputs; the current model does not overcome any fundamental uncertainty and right now, there is no quantitative way to measure uncertainty and variability in the inputs and outputs
- Requires substantial scientific expertise and training on the part of the user.
- The web-based version (iRISK) is not populated with defined data sets (such as consumption or dose-response relationships), meaning that the user must personally enter all data into the database; this is a time-consuming process.

II.4 Risk Ranking Examples in Other Disciplines

Other disciplines have taken a variety of approaches to risk ranking. This section discusses the application of risk ranking to evidence-based medicine (Section II.4.1) and the impact of pharmaceuticals on the aquatic environment (Section II. 4.2). We also describe a recent application of the Delphi technique to food safety (Section II. 4.3), a risk ranking approach to compare the environmental impact of veterinary pharmaceutical substances (Section II. 4.4), and correspondence analysis (Section II. 4.5). Additional approaches are summarized in Section II. 4.6.

II.4.1 Evidence-Based Medicine Approach

Björkstén et al. (2008) used an evidence-based medicine approach to rank (and prioritize) a list of allergenic foods that are of sufficient public health importance to be included in allergen lists. The attributes include clinical issues (diagnosis, potency of allergen, severity of reactions), population elements (prevalence, exposure), and modulating factors (food processing). In the process, the investigators developed a set of criteria on which to evaluate the scientific literature based on quality, relevance, and statistical power. Each piece of evidence was given a relative weight ranging from 1 (strong, associated with several well designed studies) to 5 (weak, an expert opinion based on limited data or theoretical considerations). Thereafter, a systematic process was applied to (1) determine whether the allergen in question caused immunoglobulin E (IgE)–mediated food allergy; (2) evaluate all the other criteria (e.g., potency, severity of reaction, prevalence of the allergen in the population, and exposure to the allergen in the population characteristics) and weight the strength of evidence; and (3) determine if the allergen is of public health concern. Björkstén et al. use the example of ranking the quality of evidence for egg as a

food allergen of public health importance. Several clinical studies have proven the IgE-mediated mechanism or allergenicity (rank of 1). Scores for prevalence of the food allergy across the population based on severity (rank of 1), potency (rank of 2), and exposure (rank of 1) were assessed and plotted on a graph, where the x-axis represents the potency (as a ratio of the severity of the adverse reaction to the potency of the dose required to elicit reaction) and the y-axis represents the likelihood of an adverse reaction. Based on such graphs, foods can then be categorized as "minor allergenic foods" (those with low severity and likelihood), "emerging allergenic foods" (those with moderate severity and likelihood), or "major allergenic foods requiring risk management measures" (those with high severity and likelihood). Based on the outcome of the ranking scheme, and because eggs are a well characterized and fairly common allergenic food, they were recommended for mandatory labeling.

Björkstén et al.'s evidence-based medicine approach has several appealing features. First, it is based on the classic risk assessment paradigm to identify a hazard (allergenic foods), assess the hazard (prevalence, severity of reactions, allergenic potency), assess the exposure (e.g., use of food, form of allergen in food, evidence of impact of processing), and perform risk characterization. Second, it provides a concrete set of criteria by which to evaluate the strength and quality of scientific evidence associated with the inputs. However, the division of allergens into the three possible groups is based on the ranks in each category for each specific allergen, and there is no mathematical model to combine these scores. Therefore, the assigning of allergens into one of the three potential outcomes is arbitrary. This approach was developed to support decision making as to which allergenic foods are of sufficient public health importance through a systematic and consistent evaluation of the evidence to help facilitate dialog among stakeholders and risk managers from different geographical jurisdictions. The framework developed in this approach may be applicable and useful in other aspects of food safety.

II.4.2 Risk Ranking of Pharmaceuticals Based on Aquatic Environmental Impacts

Cooper et al. (2008) ranked (and prioritized) pharmaceuticals on the basis of their aquatic environmental impacts using a two-step process: (1) compilation of a preliminary risk assessment database for common pharmaceuticals; and (2) risk ranking based on five different combinations of the physical-chemical and toxicological data. The database was built from the scientific literature, various online sources, and regulatory and drug manufacturer information. The drugs were ranked for potential environmental exposure and risk-based combinations of the following attributes:

- Annual prescriptions dispensed
- Surface water concentrations
- Effluent concentrations
- Environmental and biological half-lives
- Mammal, fish, and crustacean toxicity
- Octanol-water partition coefficient (K_{ow})
- Solubility
- Toxicity values in the Ecological Structure Activity Relationship (ECOSAR) online database (U.S. EPA, 2009).

Five different combinations of the physical-chemical and toxicological data sets were used to do five rankings of the pharmaceuticals (e.g., ECOSAR data only, All data categories, All data minus the ECOSAR data, Most data [pharmaceuticals with the most data to minimize uncertainty], and Aquatic Environment data [drug categories that best describe environmental transport, fate, and aquatic toxicity]). The values of each individual attribute were compiled and converted to the same units (e.g., all aquatic toxicity values were converted to mg/L), and then active pharmaceutical ingredients were ranked in each attribute category. All values for each attribute for each active pharmaceutical ingredient were then summed to create an overall ranking value. An uncertainty value was calculated for each active pharmaceutical ingredient to estimate the amount of missing data for each drug. The main finding of the study was that central nervous system, cardiovascular, and anti-infective drugs were heavily represented in the top 100 ranked drugs, and that anti-infective agents appeared to pose the greatest overall risk based on environmental transport, fate, and aquatic toxicity.

This is a very simple risk ranking model in which the investigators included only pertinent variables for which ample data were available. Although the model is data driven, the exclusion of agents for which data are lacking may bias the rankings (because an absence of data does not necessarily mean an agent poses little risk). The approach does not translate literally to microbiological food safety issues because of differences in the environmental behaviors of microbes and chemicals. However, the concept of creating a database of pertinent microbial information and then using a simple summation ranking scheme to prioritize according to highest risk could be applicable to food safety.

II.4.3 Delphi Technique

Hillers et al. (2003) applied a four-round Delphi technique to rank consumer food handling behaviors associated with the transmission and potential prevention of illnesses caused by 13 foodborne pathogens. Briefly, the Delphi method is a systematic, interactive forecasting method that relies on a panel of independent experts. The experts answer questionnaires in two or more rounds, and after each round, a facilitator provides a summary of the experts' responses. In the next round, the experts rank the issues at hand with knowledge of how the entire panel ranked everything in the first round. The intent is that the large range of responses will decrease with each round and that the group will eventually converge towards a consensus answer. The process stops after a predefined criterion (e.g., number of rounds, consensus, or stability of results), and the mean or median scores of the final rounds determine the results.

Hillers et al. (2003) used a panel of nationally recognized food microbiology experts. In the first round, the experts were asked to edit (by adding to or deleting from) a list of food handling behaviors compiled from a literature search. In the second round, they ranked these behaviors for each of the 13 pathogens according to the importance of that behavior in preventing illness, with the most important behavior scored at 1, and the least important given the highest score. The third round focused on the classification of food handling behaviors into five major categories: personal hygiene, adequate cooking, avoidance of cross-contamination, maintenance of foods at safe temperatures, and avoidance of food from unsafe sources. This round was also used to identify the behaviors most likely to be associated with reducing the risk of foodborne illness among high-risk populations. In the fourth and final round, the experts ranked the combinations of food handling behavior and pathogen again, and a mean rank score was calculated by averaging the rankings, using the same importance scales described above. By way of example,

the study found that the use of a thermometer during cooking was of primary importance in preventing illness caused by *Campylobacter jejuni*, *Salmonella* spp., *E. coli* O157:H7, *Toxoplasma gondii*, and *Yersinia enterocolitica*.

The Delphi technique does not require empirical data per se, which has its strengths and weaknesses; it may be appropriate in situation where limited data are available, but it suffers from the inherent disadvantages of expert elicitation. However, by careful design of the expert panel, the investigator can get a full range of opinions (estimates) on inputs; total agreement is not necessarily expected, and without it, one can obtain some estimate of uncertainty. The method is a highly structured and a transparent means by which to compile expert knowledge for use in risk ranking.

II.4.4 Risk Ranking of Veterinary Pharmaceutical Substances for Environmental Impact

Kools et al. (2008) developed a risk-based ranking tool to rank (and prioritize) European veterinary pharmaceutical substances that have potential environmental impacts and should therefore be considered as candidates for more complex risk assessments. The approach consisted of four steps: (1) compilation of active pharmaceutical substances (usage estimation); (2) exposure characterization (dung, soil, surface water, and aquatic organisms); (3) effects characterization (based on therapeutic doses); and (4) risk characterization (ratio of exposure to effects, or risk index). The agents were ranked according to four exposure scenarios: intensively reared animals, pasture animals, companion animals, and aquaculture. A total of 233 active veterinary medical products that had sufficient information for the four exposure scenarios were compiled from European Union databases.

The predicted environmental concentrations (PECs) of the veterinary medical products were calculated for the four different exposure scenarios using straightforward models and formulas. For example, the PEC in surface water (µg active substance (a.s.)/L) was calculated as follows:

$$PEC_{sw} = \frac{PEC_{soil}}{(K_{oc} \times f_{oc} \times 10)}$$

where

PEC_{soil}	=	predicted environmental concentration in soil (µg a.s./kg soil)
K_{oc}	=	organic carbon normalized soil sorption coefficient (L/kg soil)
f_{oc}	=	fraction of organic carbon in the soil (kg oc/kg soil)
10	=	default dilution factor when runoff enters surface water after a rain event.

Next, lowest therapeutic doses (TD_{low}) were used as a surrogate for ecotoxicological effects, where biological concentration factors (BCFs) were normalized for therapeutic dose–based ecotoxicity predictions (TD_{low}/BCF). Finally, risk indices were calculated (e.g., RI_{soil} = PEC_{soil}/TD_{low}) for each pharmaceutical in soil, dung, surface water or aquatic organisms. A frequency of use index was also determined to reflect the likelihood of widespread use (in tonnage). The risk index and frequency of use indices were used to rank the veterinary medical products. In general, the top-ranked substances were antibiotics and parasiticides. Distinct

differences appeared between intensively reared animals, where anticoccidia are used as feed additives in large doses over a long time (ranked higher), versus pastured animals, where anticoccidia are seldom or rarely used (ranked lower).

This risk ranking approach was particularly simple, using concepts that can be easily applied to a large number of veterinary pharmaceuticals without requiring extensive expert knowledge. It was also applicable to situations in which ecotoxicological data were absent. However, the approach is not directly applicable to microbiological food safety because the equations used to estimate chemical concentrations and dosage will not translate to microbes. However, the conceptual model could be used by modifying the equations to reflect microbial prevalence, growth and inactivation schemes, and other factors relevant to microbes. Nonetheless, the concepts behind the equations used for chemicals may be too simple to capture the complex processes of microbes in animals and the environment.

II.4.5 Correspondence Analysis

Salguerio et al. (2008) used correspondence analysis as a qualitative prediction tool to assess the risk of large-scale spills in mine tailing dams. The method relies on a historical database containing two sets of qualitative data: 1) variables that are observable before an "event" or dam failure (e.g., type and size of dam, location), and 2) variables that concern the consequences of the "event" (e.g., dam failure type, sludge characteristics, downstream range of damage). The approach consists of four steps:

1. Extract a set of observable "predictor" variables (in this case, size, type of dam, dam fill material, location, failure type, fatalities, downstream range of damage) for a new case for which the investigator intends to estimate risk of failure and place them in a complete disjunctive (or indicator) matrix

2. Select a set of qualitative variables from the database that are linked to the failure episode and resulting damage and place in a similar matrix

3. Establish a specific graphical relationship between the two matrices by projecting the qualitative matrix onto factorial axes resulting from the eigenvalue decomposition of the predictor matrix through the corresponding analysis algorithm (factorial axes are a transfer function between the two matrices)

4. Use the relationship given by Step 3 to forecast the modalities in which the quantitative variables fall, giving a new matrix that will outline the levels of risk.

This method uses three mathematical equations: (1) correspondence analysis of one matrix onto another under the complete disjunctive format; (2) the relative contribution of one axis to modality, which is parallel to a correlation coefficient in regression analysis; and (3) the new, or generated, matrix that is then projected onto the previously obtained axes with a third equation. Using this method, the investigators were able to prioritize Mediterranean mines for review to prevent future breakages.

The approach is mathematically rigorous but based on empirical data. Salguerio et al. found their results to be robust and were able to validate them at actual test sites and by expert knowledge.

The method might be applicable to food safety if a historical database of certain observable qualitative variables existed or could be compiled (e.g., farm location, farm size, type of produce, frequency and type of irrigation) and if there were existing data on the same input variables for which outbreaks have occurred in the past. The correspondence analysis method could then be used to generate an empirical scale of risk from which guidelines for prioritizing further data collection might be derived. In this way, past history could potentially be used to predict future behavior of, for instance, an emerging pathogen or chemical agent that had features similar to better characterized agents.

II.4.6 Other Approaches

An overview of recent applications of risk ranking in a variety of other fields is provided in **Table II-7**, including the five discussed above. This is not a full inventory, as that is beyond the scope of this document.

Table II-7. Candidate Risk Ranking Methods/Models and Their Applications

Method/Model	Applications	Variables	References
Ranking from evidence-based medicine: allergenic foods	Used to decide which allergenic foods are of sufficient public health importance to be included in allergen lists	Clinical (diagnosis, potency of allergen, severity of reactions), population (prevalence, exposure), modulating factors (food processing)	Björkstén et al. (2008)
Risk ranking: pharmaceuticals	Preliminary risk assessment database of pharmaceuticals used to prioritize those that threaten the environment and aquatic life	Five different combinations of physical-chemical and toxicological data	Cooper et al. (2008) http://www.chbr.noaa.gov/peiar/
Delphi technique for risk ranking: food-handling and consumption	Expert elicitation technique used to identify and rank food-handling and consumption behaviors associated with 13 major foodborne pathogens	Safe temperatures, thermometer use, avoidance of cross-contamination, hand washing	Hillers et al. (2003)
Risk-based ranking: veterinary pharmaceuticals	Used to assess the potential for environmental risks of active substances of veterinary medicinal products	Four exposure scenarios (soil, surface water, aquatic organisms), i information on drug usage and dose	Kools et al. (2008)
Correspondence analysis (qualitative prediction tool)	Used to determine risk of breakage in mine tailings dams	Historical qualitative data (size, type of dam, location, failure type, fatalities, downstream range of damage)	Salgueiro et al. (2008)
Multicriteria decision analysis: toilet selection	Used to evaluate the use of NoMix urine separating toilets for managing environmental risk and postponing expensive upgrades to a large wastewater treatment plant	Ranking of alternative technology pathways on the basis of technical, financial, and social concerns	Borsuk et al. (2008)

Method/Model	Applications	Variables	References
Risk ranking: chemical release	New index used for environmental risk management considering both toxicity and release amount of chemicals	Toxicity data; reference concentrations; toxicity-weighted release amount for human health protection in water, atmosphere, and aquatic life	Nakamura et al. (2008)
Risk ranking: transgenic plants	Used to prioritize nontarget invertebrates for risk analysis regarding transgenic plants	Risk presented by plant to invertebrate species; environmental impact; economic, social, and cultural values for each species	Todd et al. (2008)

II.5 Comments and Recommendations

II.5.1 Criteria for Risk Ranking Model Selection

The first consideration in recommending a candidate risk ranking model is that its analytical framework is appropriate or "fit for purpose." The model recommended from the information gathered in this task order will be used as the basis for Task Order #3 (*Public Health Risk Assessment for FDA-Regulated Commodity/Hazard Combinations Using Risk Ranking Methodology and Tools*). The specific goal of Task Order #3 is to critique and implement a systematic public health risk assessment for FDA-regulated products that considers the relative ranking of commodity-hazard pairs. The FDA has identified the following functional features upon which to base the choice of a recommended risk ranking approach:

1. Consists of two modules: a predictive, multistage (farm-to-fork) process risk module and a hazard characterization module
2. Can rank and compare chemicals and microbiological agents in a single model
3. Readily adaptability to multiple agents or commodities without the need to change modeling approach or code
4. Can group agents or commodities consistent with the Domestic Priorities List
5. Clearly documents assumptions
6. Considers/characterizes uncertainty in the modeling approach.

In Task Order #2, we operationalized these general functional features into a set of criteria (i.e., specific model attributes) with which we could compare and contrast all of the candidate risk ranking models that have been specifically applied to food safety. The models were scored on the following criteria:

- **Scientific credibility (Sci Cred):** The model is scientifically sound and supported by high-quality data
- **Characterization of uncertainty (CoU):** The model provides uncertainty analysis in both model design and in model output
- **Transparency (Trans):** Both the structure and the data incorporated in the model are readily discernible and explained to the analyst
- **Documentation (Doc):** The model software allows the user to input comments or documentation to support rankings for any input or factor

- **Balance (Bal):** The model has the appropriate balance of resolution and dimensionality such that it is both detailed enough while maintaining a relatively simple structure
- **Ease of use (EoU):** The model can be used with a minimal amount of training on the part of the user
- **Flexibility (Flex):** The analyst can choose from among several ranking parameters and data sets and can alter many of the assumptions underlying the model and data
- **Adaptability (Adapt):** The model can be updated readily as new data become available
- **Accessibility (Access):** The model is readily available and can be designed to be web accessible or downloaded to PCs without the need for extensive additional software
- **Usefulness (Use):** The model provides information which facilitates ranking or prioritization in a systematic manner
- **Applicability (Appl):** The model is applicable to the desired use, which includes comparison of hazard-commodity pairs over a wide range of food products, considering the complete farm-to-fork continuum, and including both microbial and chemical hazards

The criteria were scored as follows:

– Poor
0 Unknown or neutral
+ Good
++ Excellent
NA Not applicable.

Table II-8 presents the specific scores for each of the candidate food safety models; the abbreviations of the criteria used in the header row are shown above in the list of criteria.

Table II-8. Evaluation of Risk Ranking Strategies for Applicability for Intended Use

Method	Sci Cred	CoU	Trans	Doc	Bal	EoU	Flex	Adapt	Access	Use	Appl
Semiquantitative Food Safety Risk Ranking Approaches											
FIRRM	++	+	++	++	++	–	++	+	++	++	–
FSUDB	++	0	++	+	++	0	+	+	–	++	+
FHRR/iRISK	++	+	++	++	++	–	++	+	++	++	++
Risk Ranger	+	–	+	0	++	++	–	+	++	+	0
FSRRPM	+	–	+	–	0	+	–	+	+	+	–
Qualitative Food Safety Risk Ranking Approaches											
FAO-WHO	0	–	+	–	–	+	–	–	NA	+	–
CFSAN	0	–	+	–	–	+	–	–	NA	+	0
Carnegie-Mellon	+	–	+	–	0	++	–	–	NA	+	+

II.5.2 Justification for Recommendation

None of the models scored good (+) or excellent (++) for all of the attributes listed above. Three models came close: FIRRM, FSUDB, and FHRR/iRISK. Therefore, the justification for our final recommendation will focus on a comparison of these three top-ranked models.

The first means by which to judge these models was by whether they meet all six functional features. FIRRM does not meet functional features 1 and 2: it does not contain either a predictive, multistage process risk model, nor does it have a hazard characterization module (thus, it gets a score of poor [–] for applicability). Rather, as a topdown epidemiological model, FIRRM infers the level of risk due to foods, hazards, or their combinations based on information gathered by epidemiological observation systems, such as active or passive disease reporting systems and outbreak databases. Although this approach may be considered advantageous because it reflects risk at the consumer (patient) level, it does not allow the user to take into consideration the product's life cycle from production to consumption. In addition, because of the principle reliance on epidemiological surveillance data (which is not broadly available for chemical agents), the topdown epidemiological approach is not well suited for comparing risks associated with microbes and chemical agents in a single model. This is apparent in the absence of a chemical ranking component in FIRRM.

The two remaining models, FSUDB and iRISK, ranked identically on scientific credibility, transparency, balance, adaptability, and usefulness. For example, both are able to rank chemical and microbial hazards against one another and should be applicable to evaluation of both accidental and intentional contamination scenarios. Both models have high resolution within hazard and food categories; in other words, both are designed to allow for categorization of the hazards and foods into logical subcategories that are relevant from control and regulatory standpoints. The description of inputs and scoring for each of the models is relatively transparent and based on sound scientific justification. Likewise, both models are theoretically adaptable upon the availability of new data and accessible via the web. Both are coded in Microsoft Access and allow for the creation of databases. In addition, both make ample use of pull-down screens and point-and-click icons, which facilitate use. Both models are appropriately balanced, although iRISK is somewhat more complicated than FSUDB.

There are, however, a number of differences between the models that can be used in making a recommendation. Perhaps most important is the issue of applicability. iRISK is obviously a predictive process risk model that considers the three phases in the farm-to-fork continuum (production, processing, and distribution/end user) and includes a hazard characterization module, corresponding to functional feature 1. As such, this approach is in keeping with the classic microbial risk assessment paradigm (which includes separate exposure assessment and hazard characterization). FSUDB has roughly the same structure if one considers the Probability module as addressing exposure and the Impact module as a form of hazard characterization. However, FSUDB modules do not provide the degree of resolution that iRISK does. For example, FSUDB does not have a dose-response function.

Another major difference is in the dimensionality of the two models. The iRISK model works in two dimensions, such that the user specifies the agent and the food and then proceeds with modeling across the continuum. FSUDB works in three dimensions: agent, food, and location in the food chain. Therefore, the FSUDB output is specific for location in the food chain.

According to the FSUDB documentation, the user can compare the impacts of the various phases in the farm-to-fork continuum because the model is coded to allow the user to average and sum scores across hazards, foods, and locations along the food chain. The user is, however, cautioned to scrutinize this function so that a "biased view is avoided" (OMAF, 2003).

FSUDB and iRISK also differ with respect to flexibility, documentation, and accessibility. From a flexibility standpoint, iRISK is coded so that the user has the option to include or exclude any foods, hazards, or specific hazard-food combinations. This allows the user to consider a full range of comparisons, including a single agent transmitted by multiple foods, a single food contaminated with different agents, or user-designed specified combinations of agent-food pairs. It would also facilitate comparisons between agent-hazard pairs to compare seasonal, temporal, or geographic impacts on hazard prevalence or total number of contaminated servings. iRISK also allows the user to compile consumption data for four population groups, and users may specify what percentage of a given population is at risk for a particular simulation. On the other hand, FSUDB captures information that allows comparison of risk scores by food source, type of establishment, and regulatory authority responsible for the food. FSUDB can be manipulated to produce scores as applied to specific segments of society (e.g., susceptible subpopulations, age-related differences in consumption patterns); however, in its current state, this can only be done by maintaining separate data records for very specific food-hazard-location combinations.

With respect to documentation, the software associated with FSUDB allows the user to capture notes on references; explanations of scoring; and who assigned or changed scores, when, and why. FSUDB also allows the user to record potential tools to control risks for that hazard-food-location combination, as well as the type of establishment and regulatory authority responsible for the food. Although the prototype (FHRR) of iRISK does not necessarily provide for such detailed documentation, the web-based iRISK model has been upgraded to allow the user to input substantial documentation and justification for parameter estimates entered into the model.

The iRISK model is web-accessible as long as the user has received appropriate clearance. The user creates his/her own personal database, but users can share their databases with others by providing the appropriate specifications within their workspace. The FSUDB database and associated algorithms are not available in the public domain and availability to the agency would need to be negotiated with the developer/sponsor.

While both models consider uncertainty, FSUDB is somewhat less sophisticated. For example, FSUDB collects user uncertainties about probability and impact subscores using an uncertainty score of 1 (negligible uncertainty) to 10 (extreme uncertainty); these uncertainty scores are used in algorithms programmed into the database to place a type of confidence interval on the calculated point estimates of risk. On the other hand, iRISK allows the user to specify distribution type for several inputs in the process section of the exposure module. Further, in risk ranking, iRISK is coded to use Monte Carlo simulation to compute a range of doses based on the concentration of the hazard in the food and the average serving size. The embedded use of Monte Carlo simulation provides for a more rigorous consideration of uncertainty by iRISK that is not captured by FSUDB. Nonetheless, in an ideal world, both parameter and user uncertainty would be captured by the recommended model. In point of fact, the creators of iRISK do acknowledge the need to further develop uncertainty characterization in future versions of the model.

The models also differ in a few ways not captured by the scoring criteria. One of these is described as differences in outputs and reporting capabilities.. Specifically, FSUDB produces only two outputs (per-serving risk and societal risk), while the iRISK model has a much more sophisticated reporting system. Specifically, iRISK provides a basic mechanism that reports back selected contents of the database (the evidence) according to foods, hazards, processes, and their combinations. The iRISK also produces much more detailed outputs in the form of risk summary reports for hazard-food pairs; these reports provide information on the pertinent dose-response model(s) and parameters and the impact on hazard concentration and prevalence of primary production, processing, and the combined steps of distribution, storage, retail, food service, and home. In short, the iRISK output is more in keeping with what might be produced by a traditional quantitative risk assessment model.

Another difference that makes the iRISK model particularly appealing is the inclusion of a public health metric (in the form of the pDALY). Although we recognize the need to further evaluate the appropriateness of the pDALY approach, the production of a public health metric (instead of a simple rank or risk estimate, as is produced by FSUDB) adds value to the risk ranking exercise. Specifically, the pDALY approach allows for harmonization of the burden of disease across a broad spectrum and frequency of health outcomes, which vary widely among hazards. It also provides an output more in keeping with the traditional risk assessment paradigm.

II.5.3 Recommendation

Food safety risks, like risks in other sectors of society, are inherently complex and differ from one another in ways that make it difficult to compare one agent to another in any sort of simplified manner. Consequently, assumptions must be made and all approaches to risk ranking include some degree of subjectivity and uncertainty. This was common to all the models reviewed in this report, as was a general lack of available scientific data, or at the very least, gaps in the science. Nonetheless, based on our analysis, we recommend that the FDA give preference to the iRISK model for future risk ranking efforts for the following reasons:

- The iRISK model is currently available to the FDA in both formats (Analytica and web-based); access to some of the other models (particularly FSUDB) may be more difficult due to restrictions imposed by their sponsoring agencies.

- Of all the models evaluated, iRISK excels on applicability because it is the only model that consists of two distinct modules representing both a predictive, multistage (farm-to-fork) process risk module and a hazard characterization module.

- iRISK also excels in adaptability. Its creators state that the prototype can accommodate any number of possible modifications, including improved scientific documentation, incorporation of additional data, accounting for data quality or strength of judgment, or the addition of a feature that accommodates the input of confidence intervals for input and output estimates.

- The iRISK scores are equal to or better than the scores of all other models with respect to scientific credibility, characterization of uncertainty, transparency, flexibility, balance, accessibility, and usefulness. Particularly strong features of iRISK are its scientific

grounding, use of a public health metric for estimation of risk, excellent software features, and the provision of a full range of details in the reporting phases.

§ Although iRISK (and the FIRMM and FSUDB models, for that matter) require more extensive user training than do some of the simpler risk ranking models, the added value provided by iRISK justifies the more rigorous training requirements.

II.6 References

Batz, M. 2007. *An approach to ranking microbial foodborne hazards*. Presented at the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) Workshop, Tools for Prioritizing Food Safety Concerns, Greenbelt, MD. June 4–6. Available at www.jifsan.umd.edu/presentations/tools_2007/PDF/6.Batz_JIFSAN_Food_Safety.pdf (accessed December 9, 2008).

Batz, M., S.A. Hoffmann, A.J. Krupnik, J.G. Morris, D.M. Sherman, M.R. Taylor, and J.S. Tick. 2004. *Identifying the most significant foodborne hazards to public health: a new risk ranking model.* The Food Safety Research Consortium Discussion Paper Series (1). Available at http://www.thefsrc.org/Discussion%20Papers/FRSC-DP-01.pdf (accessed December 9, 2008).

Björkstén, B., R. Crevel, C. Hischenhuber, M. Lovik, F. Samuels, S. Strobel, S.L. Taylor, J.M. Wal, and R. Ward. 2008. Criteria for identifying allergenic foods of public health importance. *Regul. Toxicol. Pharmacol.* 51(1):42–52.

Borsuk, M.E., M. Maurer, J. Lienert, and T.A. Larsen. 2008. Charting a path for innovative toilet technology using multicriteria decision analysis. *Environ. Sci. Tech.* 42(6):1855–1862.

Buzby, J.C., T. Roberts, C.T.J. Lin, and J.M. Macdonald. 1996. *Bacterial Foodborne Disease: Medical Costs and Productivity Losses.* AER-741. U.S. Department of Agriculture, Economic Research Service, Washington, DC.

Cooper, E.R., T.C. Siewicki, and K. Phillips. 2008. Preliminary risk assessment database and risk ranking of pharmaceuticals in the environment. *Sci. Total Environ.* 398(1–3):26–33.

FAO-WHO (Food and Agriculture Organization of the United Nations and World Health Organization). 2008. *Microbiological hazards in fresh fruits and vegetables*. Microbiological Risk Assessment Series, Meeting Report (prepublication version). Available at www.who.int/entity/foodsafety/publications/micro/MRA_FruitVeges.pdf (accessed January 13, 2009).

Florig, H.K., M.G. Morgan, K.M. Morgan, K.E. Jenni, B. Fischhoff, P.S. Fischbeck, and M.L. DeKay. 2001. A deliberative method for ranking risks (1): Overview and test bed development. *Risk Anal.* 21:913–921.

FSCR (Food Safety Research Consortium). 2004. *Methodology primer for the Foodborne Disease Risk Ranking Model*. Available at www.card.iastate.edu/food_safety/papers/FIRRM_Primer_for_Conf.pdf (accessed December 9, 2008).

Havelaar, A., and Melse, J.M. 2003. *Quantifying Public Health Risk in the WHO Guidelines for Drinking-Water Quality: A Burden of Disease Approach.* Rijkinstituut voor Volskgezondheid en Milieu (RIVM), Bilthoven, Netherlands. RIVM Report 734301022

Hillers, V.N., L. Medeiros, P. Kendall, G. Chen, and S. DiMascola. 2003. Consumer food-handling behaviors associated with prevention of 13 foodborne illnesses. *J. Food Prot.* 66(10):1893–1899.

Hoffmann, S., P. Fischbeck, A. Krupnick, and M. McWilliams. 2007. Using expert elicitation to link foodborne illness in the U.S. to Food. *J. Food Prot.* 70:1220–1229.

Kools, S.A., A. Boxall, J.F. Moltmann, G. Bryning, J. Koschorreck, and T. Knacker. 2008. A ranking of European veterinary medicines based on environmental risks. *Integr. Environ. Assess. Manag.* 4(4):399–408.

Mead, P.S., L. Slutsker, V. Dietz, L.F. McCraig, H,S, Bresee, C. Shapiro, P.M. Griffin, and R.B. Tauxe. 1999. Food-related illness and death in the United States. *Emerg. Infect. Dis.* 5:607–625.

Nakamura, J., N. Azuma, T. Kameya, T. Kobayashi, and K. Urano. 2008. Analysis of the toxicity-weighted release amount ranking of PRTR chemicals in Japan. *J. Environ. Sci. Health. Part A, Tox. Hazard Subst. Environ. Eng.* 43(5):452–459.

Newsome, R., N. Tran, G.M. Paoli, L.A. Jaykus, B. Tompkin, M. Miliotis, T. Ruthman, E. Hartnett, F.F. Busta, B. Petersen, F. Shank, J. McEntire, J. Hotchkiss, M. Wagner, and D.W. Schaffner. In press. Development of a Risk Ranking Framework to Evaluate Potential High Threat Microorganisms, Toxins, and Chemicals in Food. Submitted to *J. Food Sci.*, December 8, 2008.

NZFSA (New Zealand Food Safety Authority). 2006. *Food Sector Risk Ranking and Prioritization Model: The Methods. Domestic Food Review.* Available at www.nzfsa.govt.nz/policy-law/projects/domestic-food-review/risk-ranking/riskranking-methods.pdf (accessed November 5, 2008).

OMAF (Ontario Ministry of Agriculture and Food). 2003. *Food Safety Universe Database: A Semi-Quantitative Risk Assessment Tool.* Draft. V7, November 3. Available at https://ospace.scholarsportal.info/bitstream/1873/6231/1/10318750.pdf (accessed November 17, 2008).

Paoli, G. 2008a. *Introductory workshop on the web-based tool to evaluate food risk.* Decisionalysis Risk Consultants, Inc., Ottawa, Ontario, Canada. Presented in Washington DC, October 24.

Paoli, G. 2008b. *Risk Registry User Manual*. Decisionalysis Risk Consultants, Inc., Ottawa, Ontario, Canada. September. Available at http://foodrisk.org/exclusives/iRISK/index.cfm (accessed December 9, 2008).

Ross, T. and J. Sumner. 2002. A simple, spreadsheet-based, food safety risk assessment tool. Int. *J. Food Microbiol.* 77:39–43.

Salgueiro, A.R., H.G. Pereira, M.-T. Rico, G. Benito, and A. Diez-Herreo. 2008. Application of Correspondence Analysis in the Assessment of Mine Tailings Dam Breakage Risk in the Mediterranean Region. *Risk Analysis* 28(1):13–23.

Sumner, J and T. Ross. 2002. A semi-quantitative seafood safety risk assessment. *Int. J. Food Microbiol.* 77:55–59.

Sumner, J., T. Ross, and L. Ababouch. 2004. *Application of risk assessment in the fish industry*. FAO Fisheries Technical Paper 442, FAO-WHO, Rome, Italy. Available at http://www.fao.org/docrep/007/y4722e/y4722e00.htm.

Sumner, J., T. Ross, I. Jenson, and A. Pointon. 2005. A risk microbiological profile of the Australian red meat industry: Risk ratings of hazard-product pairings. *Int. J. Food Microbiol.* 105:221–232.

Todd, J.H., P. Ramankutty, E.I. Barraclough, and L.A. Malone (2008). A screening method for prioritizing non-target invertebrates for improved biosafety testing of transgenic crops. *Environ Biosafety Res.* 7(1):35–56.

USDA (U.S. Department of Agriculture). 2003. *Foodborne Illness Cost Calculator. USDA Economic Research Service.* Available at http://www.ers.usda.gov/data/foodborneillness (accessed December 9, 2008).

U.S. EPA (Environmental Protection Agency). 2009. *Ecological Structure Activity Relationships (ECOSAR)*. Version 1.00a. Available at http://www.epa.gov/oppt/newchems/tools/21ecosar.htm.

U.S. FDA (Food and Drug Administration). 2002. *Food Safety Survey: Summary of Major Trends in Food Handling Practices and Consumption of Potentially Risky Foods.* Center for Food Safety and Applied Nutrition, Consumer Studies Branch. Available at http://www.cfsan.fda.gov/~dms/fssurvey.html.

U.S. FDA (Food and Drug Administration). 2003. *Quantitative Assessment of Relative Risk to Public Health from Foodborne* Listeria Monocytogenes *Among Selected Categories of Ready-to-Eat Foods.* U.S. FDA Center for Food Safety and Nutrition with the U.S. Department of Agriculture's Food Safety and Inspection Service and the Centers for Disease Control and Prevention. September. Available at http://www.foodsafety.gov/ ~dms/Lmr2-toc.html.

Webster, K.D., C.G. Jardine, L. McMullen and S.B. Cash. 2008. *Risk Ranking: Investigating Expert and Public Differences in Evaluating Food Safety Risks.* Department of Agricultural, Food and Nutritional Science and Department of Rural Economy, University of Alberta, Alberta, CA. Available at http://ageconsearch.umn.edu/bitstream/6378/2/pr080002.pdf (accessed January 13, 2009).

III. Risk Prioritization

III.1 Introduction

Risk prioritization uses tools of both risk assessment and decision analysis to determine the importance of one risk relative to another, usually in the context of mitigation. Risk prioritization is multifactorial in that it considers a whole cadre of factors (in addition to public health) that might influence prioritization. For example, the Food and Agriculture Organization of the United Nations (FAO)–World Health Organization (WHO) guidelines on microbial risk assessment in food safety (FAO-WHO, 2006) identify factors such as economic burden and facilitation of fair trade as key prioritization considerations. Others factors might include food attribution, risk perception, social sensitivity, and practicality of control (Henson et al., 2008). It should be apparent that there is a role for other disciplines such as economics and social psychology in the design and implementation of risk prioritization models. Unlike risk ranking, which is more of a risk assessment exercise, risk prioritization is inherently used as a risk management tool. This document evaluates tools and their potential application to risk prioritization with a focus on the comparative evaluation of mitigation alternatives and the allocation of resources to support those alternatives.

Many decisions are influenced by multiple potentially competing objectives. For example, in its mission to protect the public food supply, FDA may consider the following:

- Minimizing negative public health impact
- Minimizing negative economic consequences of actions
- Minimizing cost (budgetary limitations)
- Considering the concerns of various stakeholder (e.g., the public, farmers, food processing industry)
- Increasing the understanding and characterization of uncertain food safety issues.

Potential alternative actions, such as facility inspections, public outreach, and research, achieve these various objectives to differing degrees, and a single alternative typically will not outperform other alternatives with respect to all objectives. Therefore, decision making can become quite complex, with many competing objectives and alternatives.

The field of multiple criteria decision analysis (MCDA) provides tools to support complex decision making. MCDA approaches are used to systematically structure and model decision problems in multiple dimensions. In so doing, MCDA aids decision making by integrating value judgments, as well as objective, quantitative measurements, within a transparent and systematic framework so that decision makers can achieve a preferred course of action. A primary goal is to achieve a well considered and justified decision and to provide a transparent explanation of the decision's basis (an audit trail). Within this context, it is important to emphasize that MCDA cannot provide an objective "right" answer (Belton and Stewart, 2002), but rather provides enhanced understanding, the explicit weighting of different objectives (e.g., stakeholder concerns), a decision-making structure, and transparency that enable well justified and systematic decisions to be made. One of the particular strengths of MCDA methods is the transparent incorporation of qualitative value judgments into the decision and the ability to consider the influence of alternative value preferences.

The following sections provide a general overview of MCDA (Section III.2), a more detailed review of specific MCDA approaches (Section III.3), example risk prioritization as applied specifically to food safety (Section III.4), and finally, a recommended approach for FDA to develop tools to better enable prioritization of food safety mitigation measures (Section III.5).

III.2 MCDA Overview

This section presents a basic overview of MCDA techniques, including characteristics shared by different approaches. The general MCDA procedural framework, which involves problem structuring and preference modeling, is presented. The next section discusses some common analytic components of MCDA methods, including the development of a performance matrix. Finally, the application of MCDA methods to resource allocation problems and the importance of benefit/cost ratios in maximizing potential benefits for available resources are discussed.

III.2.1 MCDA Procedural Framework

The general procedural framework for decision analysis has several common elements, even though the specific approaches may differ in details. The problem is generally divided into components, which are then analyzed independently. For example, criteria are defined to describe different dimensions of the problem. Once analyzed independently, the components are then aggregated in some way to give insights about the problem as a whole. The MCDA process consists of three basic phases: problem structuring, preference modeling, and sensitivity analysis.

Problem structuring includes defining the decision problem and identifying objectives, stakeholders, alternatives, criteria, and attributes. Alternatives are the potential actions to be compared in the analysis. Criteria are the categories/perspectives from which to compare the alternatives. Attributes measure the performance of a given alternative with respect to each criterion.

In defining the decision-making problem, there is a difference between situations with predefined alternatives and situations with undefined or infinite alternatives. “Discrete” MCDA methods are used in situations with clearly defined alternatives, whereas “continuous” MCDA methods are used in situations with poorly defined or infinite alternatives. An example of discrete alternatives would be the evaluation of specific research grant applications. An example with continuous alternatives would be deciding the percentage of available funds to allot to different investments, where the percentage can vary continuously. Multi-objective optimization methods such as goal programming (discussed further below) have been developed to address continuous MCDA decision problems directly.

Criteria and attributes define the measures that will be used to compare the alternatives. A useful approach for structuring objectives, criteria, and attributes is a value tree (also known as an objectives hierarchy). The high-level objectives within the hierarchy are fundamental objectives that define general goals for the decision makers (e.g., protecting public health, minimizing negative socio-economic impacts). The hierarchy also includes “means” objectives that influence the parent fundamental criteria. The objectives become more concrete at lower levels of the objectives hierarchy and can be thought of as criteria for comparing alternatives. The lower-level objectives/criteria within the hierarchy should be characterized by attributes associated with the

performance of specific alternatives. **Figure III-1** shows an example of a value tree for evaluating stream rehabilitation projects (Hostmann, 2005).

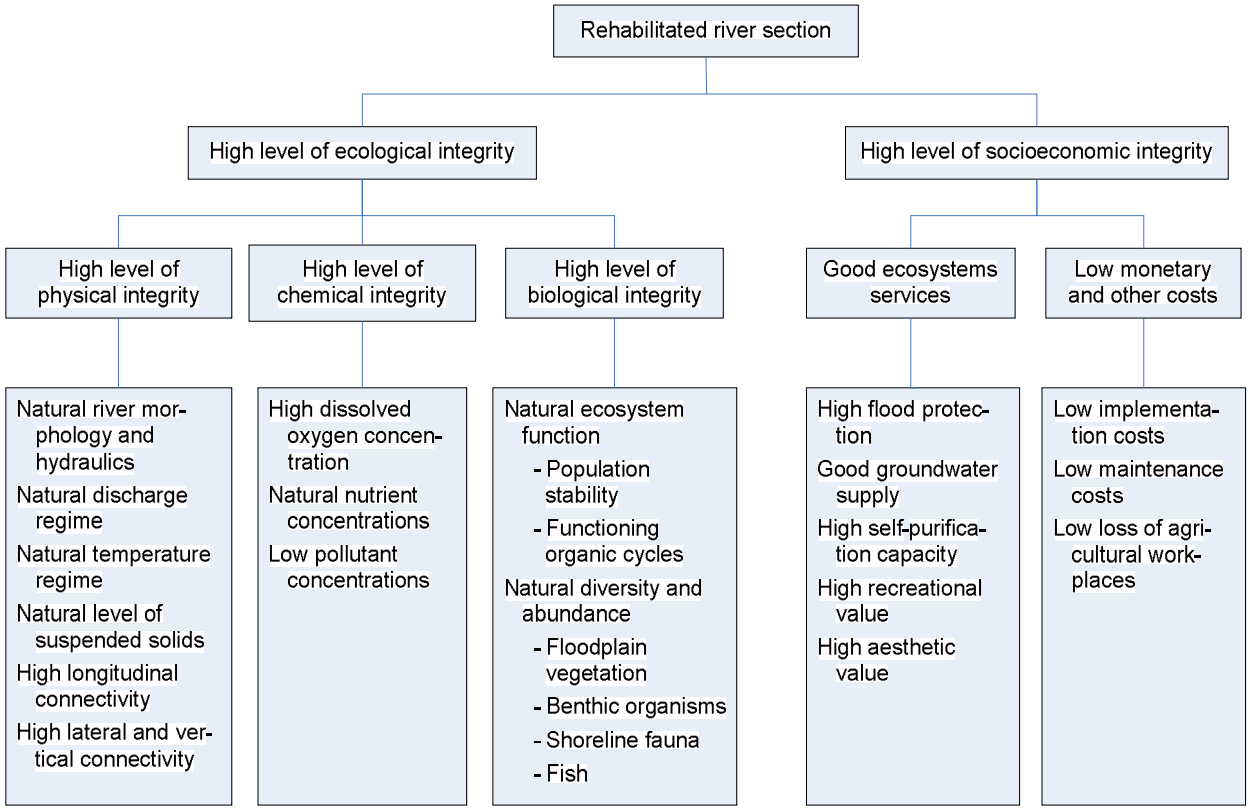


Figure III-1. Example objectives hierarchy (value tree) for evaluating stream rehabilitation projects. Source: Hostmann (2005)

Preference modeling is the next phase in MCDA. As described by Belton and Stewart (2002), preference modeling contains two primary components: evaluating preferences relative to each criterion and developing an aggregation model that combines preferences across criteria and allows comparison of alternatives.

The first component of preference modeling relies on the lowest level/most specific criteria (e.g., as developed in a value tree). These criteria should be defined such that a relatively unambiguous ordering of the alternatives can be developed with respect to each criterion; this ordering should adequately express the preferences of the decision-maker (Belton and Stewart, 2002). The ordering may be based on observable, quantitative measures or value judgments elicited from the decision-makers and stakeholders. If such an ordering is not possible, the decision problem may need to be redefined (e.g., splitting of criteria). The detailed approach for eliciting preferences and ordering the alternatives relative to each criterion varies widely for different MCDA methods.

In the second component of preference modeling, decision-makers specify how important criteria are relative to each other. The relative importance of different criteria may be expressed, for

example, by a weight parameter, with more important criteria having greater weight values. The specific approach for aggregating preferences varies for different MCDA methods.

Sensitivity analysis to analyze the robustness of the results is the final phase of MCDA. Sensitivity analysis identifies the most influential criteria and attributes (objective and value based). Sensitivity analysis also can evaluate the influence of different preference judgments, which may lead to different ranking of the alternatives. In other words, if one criterion were considered more important, then another alternative may exhibit superior performance. The sensitivity analysis phase is critical to fully evaluate the underlying assumptions, uncertainties, and the results of the decision analysis.

The MCDA process is inherently iterative and exploratory. For example, the problem may be restructured (additional alternatives, modified criteria) as understanding is enhanced through later stages of the MCDA process.

III.2.2 MCDA Fundamental Elements and Characteristics

This section describes some of the analytic elements and comparative characteristics of many MCDA approaches. The discussion provides insight into the kinds of information and decisions required by an MCDA analysis and some basic differences between approaches.

The problem structuring phase of the analysis generates a set of n alternatives, a_i ($i = 1, \ldots, n$) and m criteria, Z_j ($j = 1, \ldots, m$). Note that criteria may also be called attributes in some contexts. The criteria should be measurable in the sense that the alternatives can be ordered relative to each criterion (Seppälä et al., 2002). The measurement scale may be based on an inherently quantitative measure (e.g., an estimated health outcome), or it may be based on some ordinal scale representing qualitative judgments of the decision-maker (e.g., strongly preferred, preferred, not preferred). The score for alternative i relative to criterion j can then be expressed as $z_j(a_i)$, with all scores represented in the following performance matrix:

		Criteria			
		Z_1	Z_2	L	Z_m
Alternatives	a_1	$z_1(a_1)$	$z_2(a_1)$	L	$z_m(a_1)$
	a_2	$z_1(a_2)$	$z_2(a_2)$	L	$z_m(a_2)$
	M	M	M	L	M
	a_n	$z_1(a_n)$	$z_2(a_n)$	L	$z_m(a_n)$

Once the various alternatives are scored relative to each criterion, the values for all criteria are aggregated in some way to allow comparison of alternatives. Many of the MCDA approaches require the criteria values to be transformed into some normalized scale so that inter-criteria values can be compared. For example, the common dimension might be monetary value or a dimensionless scale between zero and one, with one representing the highest scoring alternative.

Results of the aggregation model vary with the MCDA approach. The results may be a complete ranking of alternatives ($a_i > a_j > \ldots > a_n$), the best alternative ($a_i > a_j, a_k, \ldots, a_n$), a set of

acceptable alternatives (a_i, a_j, $a_k > a_l$, a_m, a_n), or an incomplete ranking of alternatives (Seppälä et al., 2002).

A general classification of preference modeling divides MCDA approaches into two groups: performance aggregation methods and preference aggregation methods (Guitouni and Martel, 1998).

In **performance aggregation**, the various criteria scores for a given alternative are aggregated into a single performance function, which is then compared between alternatives. For example, in multi-attribute utility theory (MAUT) methods, an additive value function may be developed that is simply the sum of attribute values multiplied by criteria weights.

Preference aggregation typically involves pair-wise comparison of alternatives relative to each criterion. Preference information is aggregated to determine which alternatives can be regarded as better than others. For example, the outranking MCDA approach uses the following relations presented by Roy (1973):

- Alternative "a" is indifferent to alternative "b"
- Alternative "a" is strictly preferred to "b"
- Alternative "a" is weakly preferred to "b."

Thus, rather than computing an aggregate function to compare alternatives, preference information is aggregated to determine the preferred alternatives. The specific approaches for preference aggregation vary.

Another important concept differentiating MCDA methods is the degree to which they are compensatory. This characteristic refers to whether poor performance in one criterion can be compensated by good performance in other criteria. If poor performance in one criterion will automatically lead to poor overall performance, the method is noncompensatory. Most methods are partially compensatory. However, there are relative differences whereby, for example, MAUT is relatively more compensatory than the outranking approach.

III.2.3 MCDA Application to Resource Allocation

When MCDA methods are used for resource allocation problems, many organizations simply score and then sort the available projects (alternatives) from highest to lowest performance. Projects are then funded in that order as allowed by the available budget. Although this approach may appear rational, it ignores fundamental relationships between costs and benefits and does not ensure that the greatest value is obtained from the available resources (Phillips and Bana e Costa, 2005).

In contrast, resource allocation approaches that consider the benefit/cost ratio can maximize the potential benefit for given available resources, as illustrated by the example benefit/cost triangle in **Figure III-2**. A benefit/cost triangle can be constructed for each available project by comparing a measure of costs with a measure of benefits. In contrast to traditional cost/benefit analysis, MCDA approaches can include multiple factors in the evaluation of costs and benefits. Accordingly, an MCDA estimate of benefits can incorporate both quantitative information (e.g., financial values, risk) and qualitative information (e.g., value judgments). The benefit/cost ratio indicates the relative value for money provided by the project.

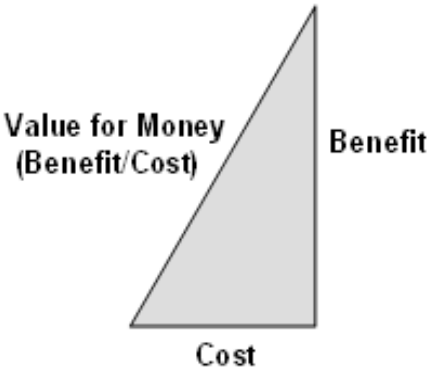


Figure III-2. A benefit/cost triangle expresses the relative value for money provided by a project. Source: adapted from Phillips and Bana e Costa (2005)

Projects can be sorted by their benefit/cost ratios and then plotted on a graph of cost (x axis) versus benefit (y axis). Such a graph represents the "efficient frontier" where project portfolios provide the maximum benefit for a given available budget (cost). **Figure III-3** shows an example of the efficient frontier (Phillips and Bana e Costa, 2005). The graph shows the cumulative cost versus benefit for projects prioritized according to two different schemes: maximum benefit only (green curve) and maximum cost versus benefit (red curve). The graph shows cumulative costs and benefits, whereby the incremental cost and benefit for a given project are added to the cumulative total cost and benefit for the portfolio. The current cumulative total value is plotted for a given project, so that the placement of projects on the graph depends on their rank ordering and the associated prioritization scheme. Accordingly, the left-most projects on the graph have the highest priority, while the lowest priority projects appear on the far right. It can easily be seen in the graph that prioritizing projects by benefit alone does not generate portfolios on the efficient frontier, because projects may be funded even though they provide less relative benefit per unit of cost. By funding projects providing the maximum benefit per cost, an organization can achieve the maximum aggregate benefit for available resources.

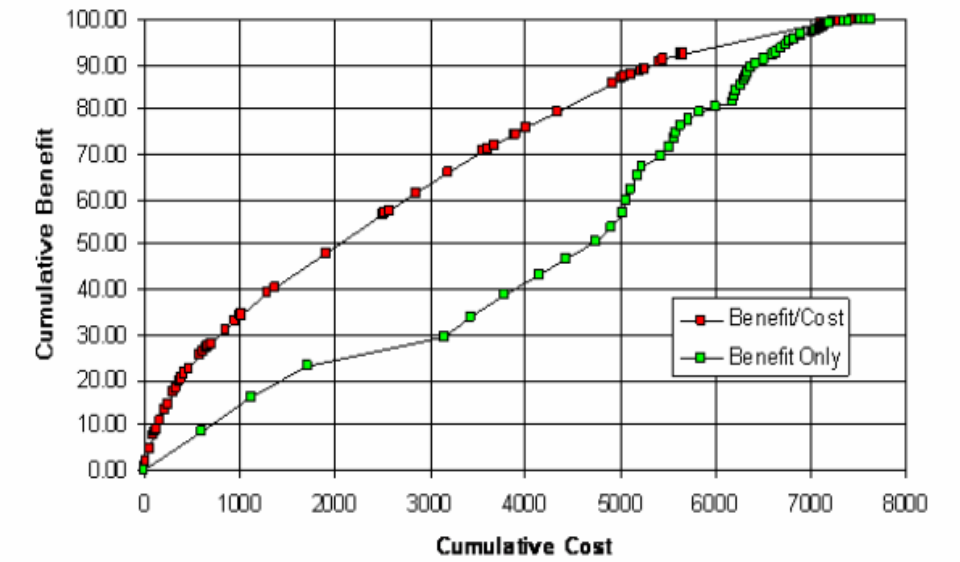


Figure III-3. Example of prioritizing projects by benefit/cost ratio (red line, the efficient frontier) vs. benefit only (green line).
Source: Phillips and Bana e Costa (2005)

Once the efficient frontier is calculated, an existing project portfolio can be plotted as shown in **Figure III-4**. Point P represents the existing portfolio. The light green shaded area in the figure shows all of the possible portfolios for the available projects. Point B represents a portfolio available for approximately the same cost that provides greater overall benefit. Point C represents a portfolio providing approximately the same benefit at lower cost.

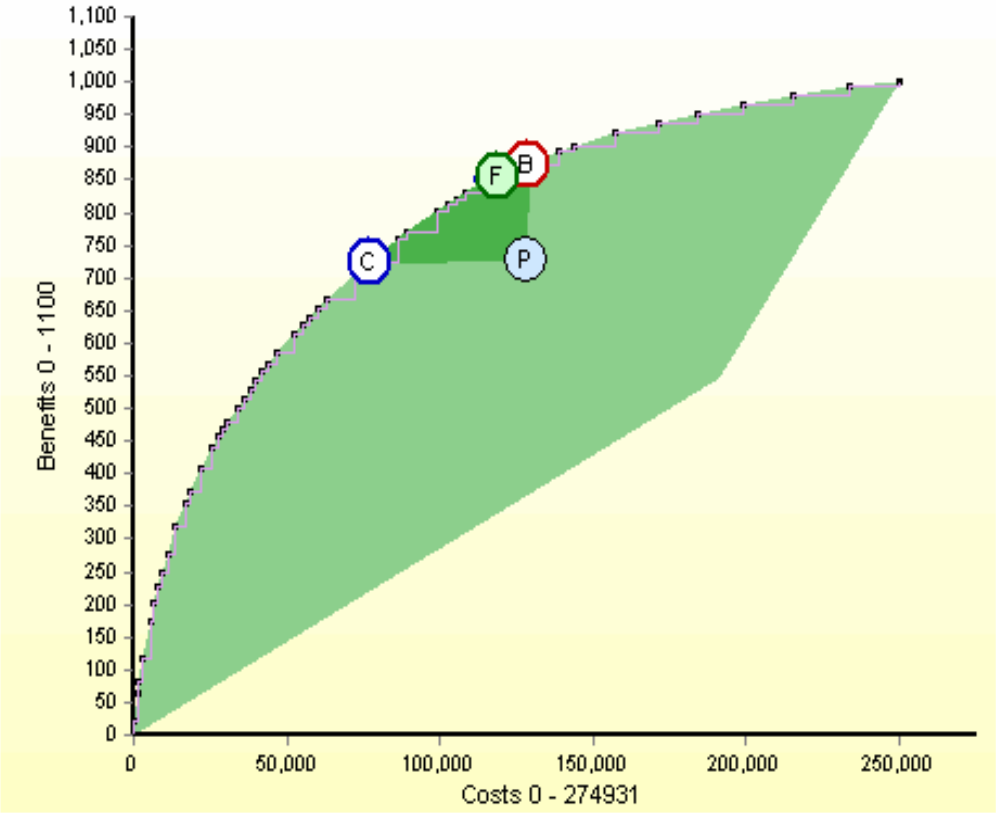


Figure III-4. Example comparing an existing portfolio (P) to the efficient frontier. Source: Phillips and Bana e Costa (2005)

To support resource allocation based on benefit versus cost considerations, a proportional measure of relative benefit must be calculated for each project. The result of some MCDA approaches (outranking and most analytic hierarchy process [AHP] implementations) is a rank ordering of alternatives, and the MCDA score associated with these methods is not meaningful outside of this ranking. The associated quantitative result is not a proportional estimate of benefits and thus not useful for resource allocation based on benefit/cost ratios. In contrast, MAUT-based methods (including some AHP implementations) provide a quantitative result that estimates benefit, and the associated MCDA score does reflect the relative, proportional benefit associated with alternatives. In addition, methods rooted in multi-objective optimization have been developed to allocate resources and develop project portfolios on the efficient frontier.

III.3 MCDA Method Descriptions

This section provides more detailed descriptions of specific MCDA approaches, including elementary methods, decision trees and influence diagram analysis, MAUT, AHP, and outranking. **Table III-1** provides a summary comparison of the reviewed MCDA approaches with respect to the following measures:

- **Transparency (Trans):** The method is readily discernible to the decision-maker (straightforward) and provides a clear audit trail to justify decision-making
- **Ease of Use (EoU):** The method is relatively simple to implement
- **Uncertainty (Unc):** The method supports uncertainty analysis

- **Adaptability (Adapt):** The method easily allows updates as new projects or data become available
- **Applicability (Appl):** The method is applicable to the desired use (resource allocation)
- **Software Support (Software):** Software packages that implement the method are readily available.

Each of these measures was scored as follows:

–	Poor
0	Unknown or neutral
+	Good
++	Excellent.

Table III-1. Summary Comparison of MCDA Approaches for Resource Allocation

Approach	Trans	EoU	Unc	Adapt	Appl	Software
Decision trees and influence diagrams	++	+	++	0	0	++
Multi-objective optimization	–	–	+	+	+	+
Multi attribute value theory (MAUT)	++	+	+	+	++	++
Analytic hierarchy process (AHP)	+	++	+	0	0	++
Outranking	–	++	+	0	–	++

III.3.1 Elementary Methods

Several MCDA methods are described as elementary, in that their required calculation procedures are relatively simple and straightforward. It is important to keep in mind that most comprehensive MCDA applications are based on a more involved approach, but results from these elementary methods are relatively less labor and resource intensive and can provide valuable insights to the decision-maker.

In the **maximin** method, each alternative is scored based on the performance of its weakest attribute. The analogous **maximax** method scores each alternative based on the performance of its strongest attribute. Comparison of the alternatives requires that all attributes be scored on comparable scales.

The **conjunctive method** is designed to screen alternatives based on whether they exceed minimum performance thresholds for all criteria. One useful application of the conjunctive approach is to decrease a large number of alternatives to allow more detailed evaluation of a subset. The conjunctive method does not require attributes to be scored on a common scale, thereby limiting the effort needed for the analysis. In the analogous **disjunctive method**, alternatives pass the screening test if they exceed the minimum performance threshold for at least one attribute (as opposed to all attributes in the conjunctive method).

In the **lexicographic method**, the criteria are ordered in terms of importance. The alternative with the best performance is the alternative with the strongest performance for the most important criterion. If multiple alternatives are tied with respect to the most important criterion,

these alternatives are compared for the next criterion, and so on, until the highest performing alternative is selected.

In the **TOPSIS method** (technique for order preference by similarity to ideal solution), the selected alternative should be as close to the ideal as possible and as far from the negative ideal as possible. The ideal is defined as a hypothetical alternative with the highest individual criteria scores. The negative ideal is the combination of minimum scores.

III.3.2 Decision Trees and Influence Diagram Analysis

General Description

A **decision tree** is a graphical representation of a sequential decision-making problem. It consists of decision nodes (squares), chance nodes (circles), and end nodes (triangles). The order of the nodes (from left to right) represents the progression of the decision, whereby information is revealed and decisions are made sequentially. Branches emanating from decision nodes represent the available alternatives, and branches emanating from chance nodes represent possibilities and their associated probabilities.

An **influence diagram** is generally more compact than a decision tree, in that it represents the structure of a decision rather than each possible outcome explicitly. Decision trees can usually be converted into influence diagrams and vice versa. Influence diagrams may contain several types of nodes: a decision node (rectangle), an uncertainty node (oval), a deterministic node (double oval), and a value node (octagon or diamond). The arcs connecting the nodes can be categorized as follows: functional arcs ending in value nodes, conditional arcs ending in uncertainty nodes, and informational arcs ending in decision nodes. Generally, alternatives are represented by decision nodes with incoming informational arcs. Information is represented by uncertainty nodes, deterministic nodes, and conditional arcs. Preferences are represented by value nodes and incoming functional arcs.

Example Applications

Lasry et al. (2008) used influence diagrams within the context of MCDA to estimate the effectiveness of various funding priorities for HIV/AIDS prevention.

The Analytica software package includes an example application for portfolio analysis that evaluates the cost versus benefit of potential projects as calculated using a MCDA-based scoring approach.

Advantages

Decision trees and influence diagrams provide powerful tools to evaluate uncertainty. Formalized methods are available for “solving” these diagrams and generating probability distributions for the potential outcomes (Clemen and Reilly, 2001).

Available influence diagram software (e.g., Analytica) can be used to develop sophisticated and powerful models, including standalone user interfaces that do not require the user to own the software.

As described below, graphical analysis methods can be cumbersome for large, complex decision problems. However, these methods can be useful for analyzing components of larger decisions. For example, a decision tree or influence diagram could be used to estimate the performance of alternatives for specific criteria.

Limitations

Because these graphical analysis methods can become quite large and cumbersome, they have not been used as extensively as other MCDA methods for complex decisions with many criteria and alternatives. However, some software platforms (e.g., Analytica) provide significant flexibility and power (e.g., nested influence diagrams, embedded algorithms) to analyze more complex problems. Many of the multicriteria methods (e.g., MAUT) can be implemented within such a software environment.

Software Tools

Several decision tree analysis software packages are available, including TreeAge (http://www.treeage.com/) and Precision Tree (http://www.palisade.com/). Available software for developing influence diagrams includes Analytica (http://www.lumina.com/index.html) and Netica (http://www.norsys.com/netica.html).

III.3.3 Multi-Objective Optimization

General Description

Multi-objective optimization refers to a class of approaches derived from linear (and nonlinear) programming that were developed primarily in the operations research field. Multi-objective optimization has been applied in many disciplines, particularly in engineering and finance. Multi-objective optimization involves the design of alternatives from continuously varying options rather than selection from discrete, preselected options. In multi-objective optimization, several objective functions are optimized simultaneously, as opposed to traditional linear programming, in which a single function is optimized. The approach explicitly accounts for trade-offs between competing objectives, such as maximizing effectiveness while minimizing cost.

Many multi-objective optimization methods require the decision-maker to specify performance goals (or “aspiration levels”) for each criterion, defined in terms of the corresponding attribute values (Belton and Stewart, 2002). Three types of performance goals can be described: the minimum level of performance considered satisfactory, the maximum level of performance considered satisfactory, or a target level of performance. Some of the multi-objective optimization approaches (e.g., goal programming) will search for a solution within a minimum distance from the specified goals.

Multi-objective optimization approaches typically do not achieve a single, optimal solution. Rather, the analysis produces a range of options that achieve different goals to differing degrees. Some multi-objective optimization tools are interactive and allow the user to specify adjustments to the aspiration levels and, for example, generate solutions that fall between different specified goals.

Multi-objective optimization is a broad field with many different specific methodologies and several supporting software tools (see below). Example methodologies include data envelopment analysis (Mohan et al., 2008), goal programming (Chaerul et al., 2008), the normal boundary intersection method (Das and Dennis, 1998), the normal constraint method (Messac et al., 2003), and the Pareto surface generation for convex multiobjective instances method (Craft et al., 2006).

Example Applications

Chaerul et al. (2008) used goal programming to evaluate alternative healthcare waste management strategies considering multiple objectives, budget constraints, and different priorities.

Advantages

The multi-objective optimization approach is typically customized to specific problems. When the performance of alternatives can be expressed in equation form, multi-objective optimization can be a powerful approach to achieve optimal solutions with a formal mathematical basis.

Limitations

The multi-objective optimization approach generally involves more complex mathematical algorithms than do discrete MCDA methods, and multi-objective optimization requires explicit quantification of the decision problem. Accordingly, functions must be specified to capture the performance of alternatives relative to the criteria. In many situations, particularly those involving qualitative judgments, such formal mathematical relationships are difficult to achieve. In some cases, the objective function can be developed based on a discrete MCDA formulation.

Fewer user-friendly supporting software tools are available to support multi-objective optimization than for some of the other MCDA methods, and custom tool development is often required. Although some software packages are available to support multi-objective optimization methods, they still require the development of equations describing the problem.

Software Tools

Multi-objective optimization-based decision support tools are often customized and developed in standard programming languages, such as C++, or mathematical programming software, such as MATLAB. Specialized software implementing specific multi-objective optimization techniques is also available, including NIMBUS (http://nimbus.mit.jyu.fi/) and DecisionPro (http://www.decisionpro.biz/).

III.3.4 Multi-Attribute Utility Theory (MAUT)

General Description

The MAUT approach provides a transparent and defensible means of quantifying and comparing the value of alternatives in terms of both quantitative and qualitative judgment criteria. In MAUT, the term “utility” refers to a measure of the desirability or relative satisfaction derived from something. MAUT calculates the utility of the various alternatives based on multiple criteria.

The term MAUT is used in this discussion to refer collectively to MAUT and multi-attribute value theory (MAVT). MAVT refers to decision analysis without formal uncertainty analysis, while MAUT refers to methodologies that formally account for uncertainty. In the literature, MAVT is typically treated as a subset of MAUT, and the more general term (MAUT) is more commonly used.

Within the MAUT framework, the decision-makers establish utility functions that capture the relative performance of alternatives. A single-attribute utility function describes the performance for a particular attribute, whereby the utility is maximum for the most preferred alternative and minimum for the least preferred alternative. Generally, the utility is scaled between 0 and 1, as shown in the hypothetical utility function in **Figure III-5**.

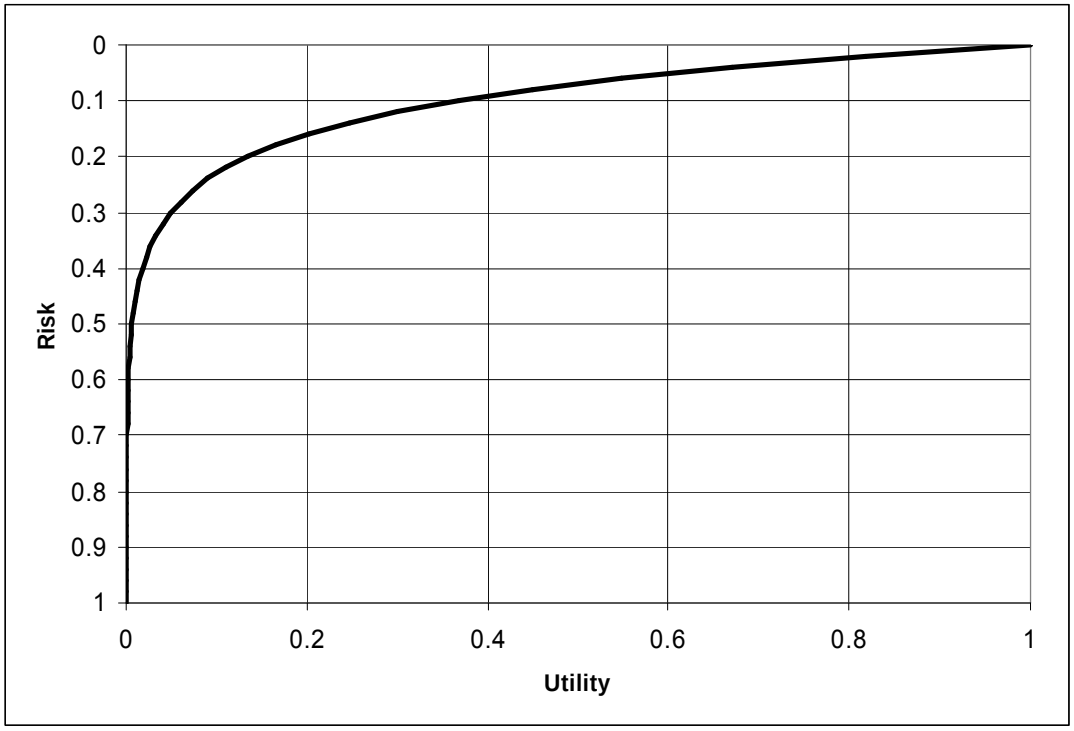


Figure III-5. Example utility function describing increasing utility with decreasing risk.

In this figure, the maximum utility occurs at the minimum risk, and the utility decreases exponentially as risk increases. Approaches are available to simplify the development of these utility functions (e.g., MACBETH) in terms of quantitative and judgment-based information (Bana e Costa and Vansnick, 1999). MACBETH involves pair-wise comparison of alternatives similar to other MCDA approaches (AHP and outranking); however, it produces a function that proportionally measures utility across criteria.

Once single-attribute utility functions are developed, the information for multiple criteria is aggregated using a multi-attribute utility function (MAUF). This produces a single number expressing the utility of each alternative. Development of the MAUF includes the assignment of relative weights to the criteria that express their relative importance. This process requires explicit value judgments from the decision-makers. Although the process can be challenging and controversial, it provides transparency and consistency to the decision-making process.

Approaches are available to simplify the development of weights for the MAUF (e.g., the simple multi-attribute rating technique [SMART] and swing weighting).

The MAUF is often an additive function of the weights multiplied by the attribute values; however, other forms (e.g., multiplicative) are possible. The simple additive form requires preferential independence between criteria, so that each criterion has no dependence on the performance relative to other criteria. If preferential independence is not established, the problem often can be restructured (e.g., by splitting criteria) to achieve it. Alternatively, aggregation functions can be developed to capture criteria interdependence; however, this can significantly increase the complexity of the analysis.

The performance of each alternative relative to each criterion is measured through values of the attribute(s) characterizing each criterion. Thus, each alternative is evaluated for each attribute. In some cases, this may involve an independent model (e.g., a risk ranking or risk assessment result). In other cases, it may be a qualitative judgment that is measured on an ordinal scale (e.g., strongly agree, agree, neutral, disagree, strongly disagree) and then converted to a quantitative measure.

Once all attribute values for each alternative are established, the alternatives can be given a comparative score. The alternatives can be compared based on their overall score, as well as relative to their performance for specific criteria. If the problem was structured using a value tree, the results may be aggregated at any level of criteria aggregation.

Example Applications

MAUT and MAVT are among the more widely applied methods of MCDA, accounting for the many practical applications in a broad range of fields such as energy, manufacturing, medical, military, and public policy (Belton and Stewart, 2002). Some examples in the field of environmental management include nuclear emergency management (Hämäläinen et al., 2000), climate change policy evaluation (Keeney and McDaniels, 2001), energy policy analysis (Jones et al., 1990), and regional forest resource planning (Ananda and Herath, 2003). Specific example applications relative to resource allocation are described below.

Bana e Costa (2001) used MAUT to evaluate the allocation of public resources for proposed road projects. The project considered multiple criteria, including effectiveness, as well as environmental, social, and economic measures, to develop a plan within the fixed available budget.

Bana e Costa et al. (2006) also used a MAUT approach to allocate public investments for social services to children, the elderly, and the disabled. Objectives of the decision analysis were increased transparency, "rationality," and making the best use of limited resources. The effort included decision conferencing to elicit preferences from multiple stakeholders and build consensus.

Phillips and Bana e Costa (2005) describe how a pharmaceutical company used MAUT to evaluate research and development projects in terms of multiple criteria, including cost, medical need, and strategic objectives. The company evaluated the projects in terms of their value for the

money (the cost to benefit ratio). Over a period of a few funding cycles, they then managed their resource allocation into a portfolio of projects that provided increasing benefits relative to costs.

Advantages

The MAUT approach is relatively straightforward, transparent, and intuitive. Decision-makers generally can easily understand the underlying algorithms, particularly when the alternatives are scored based on a weighted average across criteria (the typical approach). The logic behind the algorithms is explicit, and can readily be reviewed and modified. For example, criteria weights can be modified explicitly to evaluate the implications of specific alternative value judgments and assumptions.

MAUT provides a detailed record and basis for decision-making. The audit trail is a particularly attractive feature of the method for many decision-makers, especially in government applications, where public policy decisions can be controversial. Clearly, MAUT provides transparency and consistency to the decision-making process.

A distinct advantage of MAUT for resource allocation problems is that the method provides a single number expressing the overall benefit of an alternative. This number is a proportional, scaled measure of benefits; in other words, doubling of the benefit score implies an estimated doubling of the benefit. Using the benefits measure, projects can be evaluated in terms of their relative value for money, thus maximizing the potential benefit for a given amount of resources. This advantage is in contrast to other MCDA approaches (the standard AHP approach and outranking), which provide a rank ordering of alternatives rather than a proportional measure of benefits.

Limitations

The MAUT approach can require more time and effort to implement compared with some of the other MCDA methods. MAUT requires the development of utility functions describing the performance of alternatives for each criterion, whereas some other approaches have less demanding preference elicitation methods (e.g., pair-wise comparison in AHP and outranking). However, approaches have been developed to simplify the processes of developing single-attribute utility functions (e.g., MACBETH) and intercriteria weighting (e.g., SMART).

Software Tools

The algorithms associated with the most common MAUT implementations are relatively straightforward and can be developed using spreadsheets. However, specialized applications developed specifically for MAUT provide distinct advantages through user-friendly interfaces, graphical presentation tools, sensitivity and uncertainty analysis capabilities, and other features. Many software packages are available that support standard MAUT approaches, such as Criterium Decision Plus (http://www.infoharvest.com) and Web HIPRE (http://www.hipre.hut.fi/). Several other applications provide MAUT capabilities specifically designed for resource allocation problems, including Equity (http://www.catalyze.co.uk), HiPriority (http://www.krysalis.co.uk/), and Logical Decisions Portfolio (http://logicaldecisions.com/).

III.3.5 Analytic Hierarchy Process (AHP)

General Description

The AHP method is closely related to MAUT; however, it has a unique preference scale and elicitation procedure. In addition, the underlying algorithm uses eigenvalues and eigenvectors rather than a simple weighted average as in the typical MAUT implementation. Elicitation of preferences is done through pair-wise comparison of alternatives relative to each criterion using a nine-point preference scale. Once scores are established for each pair, the algorithm provides a rank ordering of the alternatives.

Example Applications

Britten et al. (2006) used AHP to identify appropriate amounts from each food group that together will meet nutritional goals for various age/gender groups based on Dietary Reference Intakes and Dietary Guidelines.

Febriamansyah (2006) used AHP to evaluate water allocation scenarios within a river basin in Sumatra considering multiple stakeholder interests, physical limitations, and socio-institutional factors.

Advantages

The AHP approach is relatively simpler to implement than many MAUT methods because it does not require the performance of alternatives to be evaluated explicitly (only through pair-wise comparison). AHP has been a very popular approach, likely due to strong software support and relatively straightforward implementation procedures.

Limitations

The AHP approach has been criticized because the ranking of alternatives may be affected by the addition of new alternatives or new criteria (the rank reversal problem). In addition, because the performance of alternatives is not predicted explicitly, the alternatives' scores in AHP provide only limited information about the relative benefits of one alternative compared to another (e.g., a score of 10 versus 5 does not necessarily indicate a doubling of estimated benefit). This characteristic limits the potential of fully evaluating the benefits versus costs for resource allocation problems. Cost can be included in AHP as an additional criterion for evaluation; however, the results do not provide scores for alternatives that proportionally represent their benefits.

Alternative AHP implementations are available that address this problem through elicitation procedures similar to MAUT; these help ensure that quantitative measures for alternatives proportionally represent their benefits. The level of effort required is similar to MAUT approaches, so the advantages of this AHP approach versus MAUT are not clear.

Because the AHP approach is based on pair-wise comparison of alternatives relative to all criteria, the number of required comparisons can become large if many alternatives and criteria are considered. Also, the addition of a new alternative requires comparative evaluation relative to all other alternatives (as opposed to scoring the new alternative independently as in MAUT).

Software Tools

The software packages Expert Choice (http://www.expertchoice.com) and Decision Lens (http://www.decisionlens.com) are widely used, standard implementations of AHP.

III.3.6 Outranking

General Description

Outranking methods involve the aggregation of preferences between alternatives. The decision-maker assigns preference (strict preference, weak preference, or indifference) between alternatives and relative to each criterion. The "outranking relation" applies when alternative "a" is at least as good as alternative "b," considering all criteria. Using the terminology associated with outranking, alternative "a" is then "dominant" relative to "b." Through pair-wise comparison of alternatives for all criteria, the method determines whether one alternative is better than another. In one example outranking method (ELECTRE II), the dominance relation is expressed through a concordance index and a discordance index. The concordance index represents the superiority of alternative "a" relative to alternative "b." The discordance index represents the inferiority of alternative "a" relative to "b." The decision-maker must assign concordance and discordance thresholds (e.g., representing minimum allowable performance) through which to calculate concordance and discordance indices. Different outranking approaches calculate these indices in different ways and with different levels of complexity. In addition to ELECTRE, example outranking methods include PROMETHEE (Brans and Vincke, 1985), ORESTE (Roubens, 1980), and MELCHIOR (Leclerc, 1984). All of these methods share the general idea that poor performance on one criterion (below a specified threshold) cannot be compensated for by good performance on other criteria. Thus, the methods are noncompensatory.

Example Applications

Roussat et al. (2009) used ELECTRE to assess the sustainability of alternative demolition waste management strategies considering criteria such as economics, environmental consequences, and social issues.

The PROMETHEE outranking approach was also used to evaluate food safety intervention alternatives (Fazil et al., 2008; see details in Section III.4.2). Measurement criteria included effectiveness, cost, weight of evidence, and practicality.

Advantages

Outranking approaches are generally easier to implement than MAUT. Preference elicitation involves pair-wise comparison of alternatives, which can reflect the natural decision-making process. Furthermore, preferences do not have to be quantified; for example, performance can be based on ordinal scales. In addition, outranking approaches are noncompensatory, whereby minimum threshold performance levels for specific criteria must be exceeded for sufficient overall performance.

Limitations

The algorithms underlying outranking methods are less intuitive and transparent than the standard MAUT approach. In addition, it can be challenging to develop performance thresholds specifying, for example, the minimum allowable performance.

For resource allocation problems, a particular disadvantage of outranking methods is that the result is not a single score that proportionally represents the benefit of a given alternative. Instead, outranking provides a rank ordering of alternatives. Some of the methods generate quantitative results (e.g., concordance and discordance indices in ELECTRE). However, the values do not provide a proportional measure of benefit. Without such a measure of benefit, project prioritization cannot be based on the maximum potential benefit per cost.

Because outranking is based on pair-wise comparison of alternatives relative to all criteria, the number of required comparisons can become large if many alternatives and criteria are considered. Also, the addition a new alternative requires comparative evaluation relative to all other alternatives (as opposed to scoring the new alternative independently, as in MAUT).

Software Tools

Many outranking implementations are based on custom applications developed using other software platforms (e.g., spreadsheets). Decision Lab (http://www.visualdecision.com/) is commercial software supporting the PROMETHEE outranking approach.

III.4 Food Safety Examples

III.4.1 Multi-Factorial Risk Prioritization Framework

The Multi-Factorial Risk Prioritization Framework for Food-borne Pathogens (MFRPF), developed by the Food Safety Research Consortium and Canadian Public Health agencies provides an approach for prioritizing food-pathogen pairs in terms of several criteria in addition to public health (Hensen et al., 2007). In this framework, four factors are considered as important to risk managers:

- **Public health:** This criterion considers the impact and burden of disease as quantified by disability adjusted life year and cost of illness measures.

- **Market-level impacts:** This criterion considers the potential economic losses from disease and outbreaks.

- **Consumer risk perception and acceptance:** This criterion considers differential consumer acceptance of foodborne risks. A Delphi-based rating system based on five criteria is proposed to measure consumer risk perception and acceptance:

  - The degree to which risk is perceived as uncontrollable by consumers
  - The degree to which risk is perceived as unknown to the individual
  - The degree to which risk is perceived as unknown to scientists
  - The degree to which exposure to the hazard is perceived as involuntary
  - The degree to which consumers perceive the outcome(s) as severe.

- **Social sensitivity:** This criterion is intended to capture increased societal sensitivity to risk for particular groups, from the perspective of both consumers and industries/firms. Sensitive consumer groups may include, for example, the elderly or children. The industry/firm side may include, for example, groups with historical or cultural significance, particularly in marginal or rural areas. Note that the social sensitivity criterion does not measure health impacts to these groups (as measured by the public health criterion), but rather the increased societal sensitivity associated with potential impacts. A Delphi-based rating system is also proposed for measuring social sensitivity.

Operationalizing the MFRPF framework includes the generation of information cards and cobweb diagrams. Information cards summarize the basic data for each criterion for a given pathogen-food pair. There are several information cards for each pathogen-food pair, including one card per criterion and a summary card. The cobweb diagrams graphically summarize the results for a given pathogen-food pair presenting the quantitative results for each criterion on a separate axis, as illustrated in the example in **Figure III-6**.

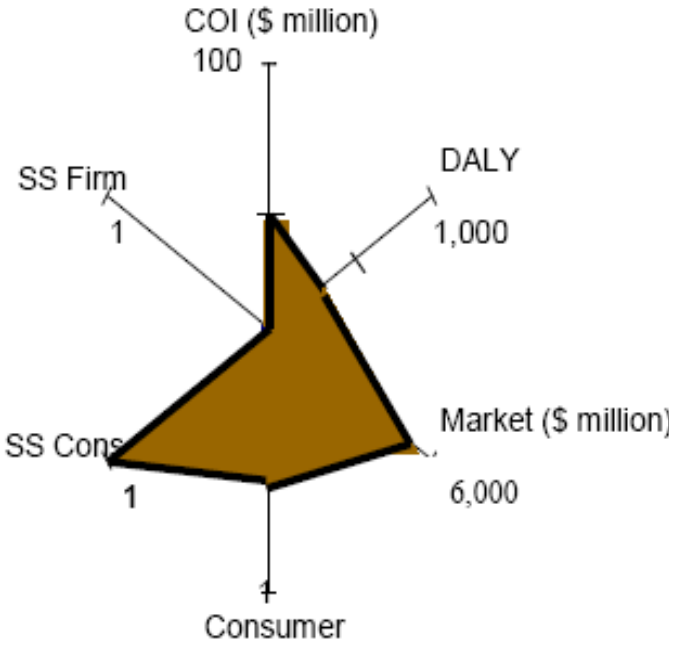


Figure III-6. Example cobweb diagram from the MFRPF approach for *E.coli* O157/beef
Source: Hensen et al. (2007)

An MCDA approach is then proposed to aggregate the performance across criteria for each pathogen-food pair. The authors discuss the potential use of MAUT and outranking to compare and prioritize the food-pathogen pairs. The MCDA approach chosen is intended to allow comparative evaluation of different stakeholder priorities through alternative weighting of different criteria. The result should be an ordered ranking of food-pathogen pairs based on their aggregated performance as measured through MCDA. To our knowledge, the MCDA implementation had not yet been completed for the model described by Hensen et al. (2007).

The authors discuss potential ways to incorporate uncertainty and feasibility of interventions into the analysis. The MCDA approach would generate an "A" list of ordered food-pathogen pairs. A "B" list would be a prioritized list of those food-pathogen pairs with reasonably feasible interventions. The authors mention the importance of considering the ease of implementation and the benefits associated with a given intervention; however, a specific approach is not presented. A "C" list would include the food-pathogen pairs without known feasible interventions and ordered to reflect the need for further information characterizing the food-pathogen pair. No specific approaches for prioritization based on information needs are presented.

The MFRPF approach provides some significant advances in the prioritization of food-pathogen pairs for food safety applications. Specifically, the approach considers several different criteria besides public health, provides innovative approaches for presenting data (information cards and cobweb diagrams), and is perhaps the first specific application of MCDA techniques to food safety risk prioritization. However, explicit approaches for comparing intervention alternatives are not provided, even though the authors do recognize the importance of benefits and feasibility. The method also does not explicitly consider the costs of interventions. For these reasons, the framework is not directly applicable to FDA resource allocation problems; nevertheless, some aspects of the approach may be useful (e.g., criteria, information cards, cobweb diagrams).

III.4.2 Outranking MCDA Approach for Food Safety Risk Prioritization

Fazil et al. (2008) recently presented an example of evaluating food safety interventions using an outranking MCDA approach that considered the following criteria:

- **Weight of evidence:** This criterion is intended to capture the scientific evidence supporting a given intervention. The authors used a strength-of-evidence index based on available research studies. This index compares and weighs research studies of different types with positive and negative evidence of the intervention's effectiveness. Weights assigned to different types of studies include the following: randomized clinical trials (weight=5), randomized field trials (weight=5), nonrandomized field trials (weight=4), cohort (weight=2), and cross-sectional (weight=1).

- **Effectiveness:** This criterion measures how well an intervention works. The authors consider two dimensions to effectiveness: effectiveness at the point of application (e.g., the farm or transport truck) and effectiveness at other points of interest (e.g., when the consumer receives the product, impact on public health outcome). The first dimension can often be quantified by direct evidence in the literature, while the latter will generally require modeling.

- **Cost:** This is considered as an additional criterion in this MCDA analysis. The authors discuss three cost components: capital costs (initial and depreciated costs over time), material costs, and labor costs. They note that obtaining cost information may require reference to the grey literature and expert opinion.

- **Practicality:** This criterion considers the relative ease of implementation of a given intervention. This is a more subjective measure that would require input from stakeholders and experts.

The authors propose four additional potential criteria, including trade implications, consumer perception, unintended positive consequences, and unintended negative consequences. The example analysis does not consider these additional criteria because they are more difficult to measure and are less generally applicable.

Fazil et al. (2008) adopted the PROMETHEE outranking approach. This includes criteria weighting and the assignment of preference functions based on indifference and preference thresholds (similar to concordance and discordance thresholds discussed in Section III.3.5). The approach involves pair-wise comparison of alternatives relative to each criterion. The results include a "positive flow," measuring the degree to which an option dominates (outperforms) others; a "negative flow," measuring the degree to which an option is dominated; and a "net flow," measuring the overall preference for each alternative.

The Fazil et al. (2008) approach provides an excellent framework for evaluating potential food safety intervention alternatives. The criteria appear well thought out and effective. Additional criteria, such as trade implications, may be important in many cases, a fact the authors acknowledge. The primary drawbacks of the method are related to inherent limitations of the outranking approach and the treatment of cost. Outranking results (e.g., net flow) are meaningful only in a relative sense and for purposes of ordering the alternatives. Unlike MAUT and some implementations of AHP, outranking does not provide a proportional measure of benefits, whereby, for example, a doubling of the MCDA score implies an estimated doubling of the benefits. Without a proportional measure of benefits, the approach cannot consider the relative cost versus benefit, which is a critical consideration for resource allocation problems. Fazil et al. (2008) consider cost only as an additional criterion. Their approach does not allow calculation of the cost/benefit ratio through which overall benefit can be maximized for available resources. Nevertheless, Fazil et al. (2008) provide criteria and approaches for evaluating criteria that appear very applicable and useful for FDA resource allocation problems.

III.5 Recommendation

In this section, we synthesize our findings and make a recommendation for approaches to be used by FDA for allocating resources to be used for potential food safety intervention alternatives. Clearly, the desired approach would be rooted in MCDA methods, thus enabling structured, well-justified, and transparent decision-making. In addition, the approach should be based on fundamental resource allocation techniques in an effort to maximize benefits for available resources.

Specifically, we recommend the use of MCDA approaches, such as MAUT or certain AHP methods, that can quantify benefits through a single score representing the relative, proportional benefit of each alternative. These approaches do require performance evaluation of alternatives relative to each criterion, which can be more time consuming than the preference elicitation used for some of the other MCDA methods (e.g., standard AHP, outranking). However, the power of the information provided by proportional benefits lies in the ability to fully evaluate cost versus benefits and maximize the potential benefit for available resources.

Although the evaluation of costs versus benefits may be reminiscent of standard cost/benefit analysis, there are fundamental differences. The proposed approach is based on the evaluation of multiple criteria, including both qualitative judgment and directly measurable criteria.

Cost/benefit analysis is restricted to quantifiable measures that can be converted into monetary values. One of the more significant criticisms of cost/benefit analysis is the attribution of monetary value to seemingly nonquantifiable factors and the associated operational and stakeholder perception challenges. In contrast, an MCDA-based measure of benefits allows performance evaluation in terms of metrics that are more naturally associated with the criteria. Furthermore, each criterion may be associated with its own measurement scale (not just monetary value, as in cost/benefit analysis). The benefits include the potential inclusion of additional relevant, value judgment–based criteria and a transparent scoring system without many of the pitfalls of standard cost/benefit analysis.

A critical component of MCDA is the structuring of the decision problem, including the development of objectives, alternatives, criteria, and attributes. In an organizational setting, one of the most effective and productive approaches of MCDA problem structuring is decision conferencing. A decision conference is a facilitated workshop where the decision-makers and stakeholders meet to brainstorm and collaboratively develop a decision analysis model. An impartial facilitator with MCDA expertise provides the structure for the meeting, guides discussion, and captures the group's thinking (typically using interactive, computer-based tools). Bana e Costa et al. (2006) and Phillips (2006) provide useful references for decision conferencing. The emphasis during the workshop is on the process, increased understanding, collaboration, insights, and creative thinking. Decision conferencing helps organizations develop a shared understanding, common purpose, and commitment to the adopted approach across the organization. This benefit can be in contrast to decision support tools developed independently, which may not have collective organizational support and may not adequately reflect all perspectives. Following a decision conference, the facilitator's organization will typically finalize the MCDA model for later presentation to the decision-makers and potential further refinement using an iterative process. Given its distinct advantages, we recommend that FDA consider decision conferencing to structure their resource allocation issues and to develop a decision-making model.

As described in Section III.3.4 under Software Tools, several software packages are available to support MCDA-based resource allocation approaches, including Equity, HiPriority, and Logical Decisions Portfolio. We recommend that FDA evaluate these software options in more detail, as well as the option of developing a custom implementation.

In summary, we recommend that FDA consider the following options to further evaluate and develop an approach to assist in resource allocation for food safety problems:

- Use an MCDA approach that results in a single measure that proportionally represents benefit. Both MAUT and some implementations of AHP provide this capability.

- Incorporate fundamental resource allocation theory into the decision-making process. Specifically, evaluate alternatives in terms of their benefit/cost ratio, thus allowing maximum potential cumulative benefit for available resources (having a project portfolio on the efficient frontier).

- Consider a facilitated decision conference to structure the decision-making problem and develop a decision-making model. Such a facilitated workshop allows decision-makers to

brainstorm and discuss the problem and collaboratively develop objectives, alternatives, criteria, and measurement attributes through which to develop a decision-making model.

§ Evaluate available software supporting MCDA-based resource allocation and consider the potential benefits of developing a custom tool.

III.6 References

Ananda, J., and G. Herath. 2003, Incorporating Stakeholder Preferences into Forest Planning: A Value Function Approach. *Ecological Economics* 45(1):75–90.

Bana e Costa, C.A., and J.-C. Vansnick. 1999. The MACBETH Approach: Basic Ideas, Software, and an Application. In *Advances in Decision Analysis* (*Mathematical Modelling: Theory and Applications 4*), edited by N. Meskens and M. Roubens. Kluwer Academic Publishers. pp. 131–157.

Bana e Costa, C.A. 2001. The Use of Multi-Criteria Decision Analysis to Support the Search for Less Conflicting Policy Options in a Multi-Actor Context: Case Study. *Journal of Multi-Criteria Decision Analysis* 10(2):111–125. Available at http://dx.doi.org/10.1002/mcda.292

Bana e Costa, C.A., T.G. Fernandes, and V.D.P. Correia. 2006. Prioritisation of Public Investments in Social Infrastructures Using Multicriteria Value Analysis and Decision Conferencing: A Case Study. *International Transactions in Operational Research* 13(4):279–297.

Belton, V., and T.J. Stewart. 2002. *Multiple Criteria Decision Analysis: An Integrated Approach.* Kluwer Academic Publishers: Boston.

Brans, J.P., and P. Vincke. 1985. A Preference Ranking Organization Method (the PROMETHEE Method for Multiple Criteria Decision-Making). *Management Science* 31(6):647–656.

Britten, P., K. Marcoe, S. Yamini, and C. Davis. 2006. Development of food intake patterns for the MyPyramid Food Guidance System. *Journal of Nutrition Education and Behavior* 38(6 Suppl.):S78–92.

Chaerul, M., M. Tanaka, and A.V. Shekdar. 2008. Resolving Complexities in Healthcare Waste Management: A Goal Programming Approach. *Waste Management and Research* 26(3):217–232.

Clemen, R.T., and T. Reilly. 2001. *Making hard decisions with DecisionTools.* Duxbury Press: Pacific Grove, CA.

Craft, D., T. Halabi, H. Shih, and T. Bortfeld. 2006. Approximating Convex Pareto Surfaces in Multiobjective Radiotherapy Planning. *Medical Physics* 33:3309–3407.

Das, I., and J.E. Dennis. 1998. Normal-Boundary Intersection: A New Method for Generating the Pareto Surface in Nonlinear Multicriteria Optimization Problems. *SIAM Journal on Optimization* 8(3):531–657.

FAO-WHO (Food and Agriculture Organization of the United Nations–World Health Organization). 2006. *Food Safety Risk Analysis: A Guide for National Food Safety Authorities.* Food and Nutrition Paper 87. Available at ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf.

Fazil, A., A. Rajic, J. Sanchez, and S. McEwen. 2008. General Interest Choices, Choices: The Application of Multi-Criteria Decision Analysis to a Food Safety Decision-Making Problem. *Journal of Food Protection* 71(11):2323–2333

Febriamansyah, R. 2006. *The Use of AHP (the Analytic Hierarchy Process) Method for Irrigation Water Allocation in a Small River basin (Case Study in Tampo River Basin in West Sumatra, Indonesia)*. Presented at the 11th Conference of the International Association for the Study of Common Property (Survival of the Commons: Mounting Challenges and New Realities), Bali, Indonesia. June 19–23.

Florig, H.K., M.G. Morgan, K.M. Morgan, K.E. Jenni, B. Fischhoff, P.S. Fishbeck, and M.L. DeKay. 2001. A Deliberative Method for Ranking Risks (1): Overview and Test Bed Development. *Risk Analysis* 21:913–921.

Guitouni, A. and J.-M. Martel. 1998. Tentative Guideline to Help Choosing an Appropriate MCDA Method. *European Journal of Operational Research* 109:501–521.

Hämäläinen, R.P., M. Lindstedt, and K. Sinkko. 2000. Multiattribute Risk Analysis in Nuclear Emergency Management. *Risk Analysis* 20(4):455–467.

Henson, S.J., J.A. Caswell, J.A.L. Cranfield, A. Fazil, V.J. Davidson, S.M. Manders, and C. Schmidt. 2007. A Multi-Factorial Risk Prioritization Framework for Food-Borne Pathogens. University of Massachusetts Amherst, Department of Resource Economics, Working Paper No. 2007-2008. Available at http://www.umass.edu/resec/workingpapers.

Hostmann, M. 2005. Decision Support for River Rehabilitation. Dissertation. Swiss Federal Institute of Technology Zurich. Available at http://www.wsl.ch/land/products/rhone-thur/entscheidung/docs/hostmann_2005.pdf.

Jones, M., C. Hope, and R. Hughes. 1990. A Multi-Attribute Value Model for the Study of UK Energy Policy. *Journal of the Operational Research Society* 41:919–929.

Keeney, R. L., and T.L. McDaniels. 2001. A Framework to Guide Thinking and Analysis Regarding Climate Change Policies. *Risk Analysis* 21(6):989–1000.

Lasry, A., M.W. Carter, and G.S. Zaric. 2008. S4HARA: System for HIV/AIDS Resource Allocation. *Cost Effectiveness and Resource Allocation* 6:7. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2386442.

Leclerc, J.P. 1984. Propositions d'extension de la notion de dominance en presence de relations d'orde sur les pseudocriteres: MELCHIOR. [Proposals to Extend the Notion of Dominance in the Presence of Orders Based on Pseudocriteria: MELCHOIR.] *Mathematical Social Science* 8:45–61.

Messac, A., A. Ismail-Yahaya, and C.A. Mattson. 2003. The Normalized Normal Constraint Method for Generating the Pareto Frontier. *Structural and Multidisciplinary Optimization* 25(2):86–98.

Mohan, S.V., B.P. Reddy, and P.N. Sarma. 2008. Ex Situ Slurry Phase Bioremediation of Chrysene Contaminated Soil with the Function of Metabolic Function: Process Evaluation by Data Enveloping Analysis (DEA) and Taguchi Design of Experimental Methodology (DOE). *Bioresource Technology* 100(1):164–172.

Phillips, L.D. 2006. *Decision Conferencing*. London School of Economics and Political Science Working Paper LSEOR 06.85.

Phillips, L.D., and C.A. Bana e Costa. 2005. *Transparent Prioritisation, Budgeting, and Resource Allocation with Multi-Criteria Decision Analysis and Decision Conferencing*. London School of Economics and Political Science Working Paper LSEOR 05.75.

Roubens, M. 1980. Analyse et aggregation des preferences: Modelisation, adjustement et resume de donnees relationelles. [Analysis and Aggregation of Preferences: Modeling, Adjustment and Summary of Relational Data.] *Revue Belge de Statistique d'Informatique et de Recherche Operationelle* 20(2):36–37.

Roussat N., C. Dujet, and J. Méhu. 2009. Choosing a Sustainable Demolition Waste Management Strategy Using Multicriteria Decision Analysis. *Waste Management* 29(1):12–20.

Roy, B. 1973. How Outranking Relation Helps Multiple Criteria Decision Making. In *Multiple Criteria Decision Making*, edited by J.L. Cochrane and M. Zeleny. Columbia, SC: University of South Carolina Press.

Seppälä, J., L. Basson, and G.A. Norris. 2002. Decision Analysis Frameworks for Life Cycle Impact Assessment. *Journal of Industrial Ecology* 5(4):45–68.

THE Society for Food Science & Technology

Journal of Food Science

A Publication of the Institute of Food Technologists

Development of a Risk-Ranking Framework to Evaluate Potential High-Threat Microorganisms, Toxins, and Chemicals in Food

R. Newsome, N. Tran, G.M. Paoli, L.A. Jaykus, B. Tompkin, M. Miliotis, T. Ruthman, E. Hartnett, F.F. Busta, B. Petersen, F. Shank, J. McEntire, J. Hotchkiss, M. Wagner, and D.W. Schaffner

ABSTRACT: Through a cooperative agreement with the U.S. Food and Drug Administration, the Institute of Food Technologists developed a risk-ranking framework prototype to enable comparison of microbiological and chemical hazards in foods and to assist policy makers, risk managers, risk analysts, and others in determining the relative public health impact of specific hazard–food combinations. The prototype is a bottom-up system based on assumptions that incorporate expert opinion/insight with a number of exposure and hazard-related risk criteria variables, which are propagated forward with food intake data to produce risk-ranking determinations. The prototype produces a semi-quantitative comparative assessment of food safety hazards and the impacts of hazard control measures. For a specific hazard–food combination the prototype can produce a single metric: a final risk value expressed as annual pseudo-disability adjusted life years (pDALY). The pDALY is a harmonization of the very different dose–response relationships observed for chemicals and microbes. The prototype was developed on 2 platforms, a web-based user interface and an Analytica® model (Lumina Decision Systems, Los Gatos, Calif., U.S.A.). Comprising visual basic language, the web-based platform facilitates data input and allows use concurrently from multiple locations. The Analytica model facilitates visualization of the logic flow, interrelationship of input and output variables, and calculations/algorithms comprising the prototype. A variety of sortable risk-ranking reports and summary information can be generated for hazard–food pairs, showing hazard and dose–response assumptions and data, per capita consumption by population group, and annual p-DALY.

Keywords: food safety, risk, risk ranking

Introduction

Risk analysis is an essential part of science-based policies for food safety and public health protection today (Jaykus and others 2006). Food safety risk assessments completed to date typically focus on a single food product-pathogen pair such as *Salmonella* in eggs (USDA-FSIS 1998), a single agent such as mercury (Carrington and Bolger 2002), or a pathogen such as *Listeria monocytogenes* (FDA-CFSAN and others 2003) in one or a few specific food products. Food safety risk assessments today are not typically designed to quantitatively compare and rank risks of different food safety hazards (for example, microbiological hazards compared with chemical ones) because of the complexity of the calculations and comparisons required. A well-conceived strategic approach to public health protection that quickly and accurately identifies different types of hazards, ranks them by level of importance, and identifies approaches with the greatest potential to reduce hazards is critically needed (IFT 2002).

Risk ranking has been applied previously in a variety of settings, but very little activity has been applied to rank different types of risks in food systems. Havelaar and Melse (2003) maintained that to reduce the risk of foodborne illness, the relative risk across the different types of hazards should be compared. The U.S. Food and Drug Administration (FDA) awarded the Institute of Food Technologists (IFT) a 2-year cooperative agreement grant that supported development and implementation of a risk-ranking framework to evaluate potential high-threat microbiological agents, toxins, and chemicals in food. The framework was to include a model for quantitatively or semi-quantitatively comparing and determining potential threats and the ability to evaluate interventions or control points (for example, manufacturing/processing, warehouses, transport, retail) at various places in the farm-to-fork chain. Implementation of the framework would include use of existing and newly developed lists of hazardous agents for systematic ranking. Further, the FDA desired use of criteria in the risk ranking that at a minimum pertained to compatibility of a hazard with food as a vehicle, toxicity (or dose necessary to result in disease), accessibility, and likelihood of effect (illness). While many risk-ranking approaches are possible, the approaches fall into 2 main groups: surveillance-based "top-down" approaches and prediction-based "bottom-up" approaches.

Top-down and bottom-up approaches to risk ranking

With respect to microbial hazards, surveillance-based approaches attempt to infer the level of risk due to foods, hazards,

Authors Newsome and McEntire are with the Inst. of Food Technologists, Chicago, IL 60607, U.S.A. Authors Tran and Petersen are with Exponent, Inc., Washington, DC 20036, U.S.A. Authors Paoli, Ruthman, and Hartnett are with Decisionalysis Risk Consultants, Inc., Ottawa, Ontario, Canada K1H653. Author Jaykus is with North Carolina State Univ., Raleigh, NC 27695, U.S.A. Author Tompkin is retired from ConAgra, La Grange, IL 60525, U.S.A. Author Miliotis is with the Food and Drug Administration/Center for Food Safety and Applied Nutrition College Park, MD 20740, U.S.A. Author Busta is with the Natl. Center for Food Protection and Defense and Univ. of Minnesota, Minneapolis, MN 55455, U.S.A. Author Shank is retired from the Inst. of Food Technologists, Washington, DC 20036, U.S.A. Author Hotchkiss is with Cornell Univ., Ithaca, NY 14853, U.S.A. Author Wagner is with Mars Symbioscience, Rockville, MD 20850, U.S.A. Author Schaffner is with Rutgers Univ., New Brunswick, NJ 08901, U.S.A. Direct inquiries to author Newsome (E-mail: rlnewsome@ift.org).

doi: 10.1111/j.1750-3841.2008.01042.x

or their combinations based on information gathered by various observation systems such as active or passive disease reporting systems, outbreak databases, and a variety of other observations such as prevalence of pathogens in various commodities. Such information sources may be best for overall ranking of pathogens, but quantitative linkages to particular foods are often very difficult to justify from these sources alone and are typically estimated only for foods that might be attributed to a relatively high percentage of the attributable risk. The Foodborne Illness Risk Ranking Model (FIRRM), initiated in 2003 by the Food Safety Research Consortium, is an example of such top-down approaches to risk ranking (FSRC 2005). The FIRRM integrates data on foodborne illness surveillance; food–pathogen combinations; medical symptoms, complications, and outcomes; economic impact; and social values relevant to judging the significance of a potential hazard to population health.

In most cases, there is no systematic capacity to observe the effects of food-associated chemical exposures in the human population. This is because of a number of challenges, including the many potential causes of symptoms, the sheer number of chemicals that have common outcomes, and the long latency between exposure and outcomes. In addition, many chemical exposures occurring as a consequence of food consumption are at levels believed to be so low that there may not be any readily observable effects for a vast majority of exposed consumers.

The other main group of ranking approaches is based on predictive modeling of the fate of microbes and chemicals in the food supply together with their virulence or toxicity. The FDA's charge to the IFT panel included the capability to deal with a variety of microbial and chemical hazards. Given this and the inherent difficulties associated with top-down approaches for both microbial and chemical hazards noted previously, a bottom-up or predictive model of risk was used as the underlying framework for the ranking application described here. This requires the application of data and expert judgment to assemble sufficient information to predict the fate of the hazards in the food supply, together with their virulence and toxicity characteristics, to generate a prediction (which may be, of necessity, quite crude) of their relative level of risk to human health and the potential for changes to level of risk associated with possible interventions throughout the farm-to-fork chain.

The Process

IFT convened a panel of individuals with expertise in the farm-to-fork food system, food safety, risk assessment and management, microbiology, chemistry, toxicology, predictive microbiology, and computer modeling to develop the risk-ranking framework prototype. IFT staff experts in food safety and project management helped support the initiative. IFT supplemented the panel's expertise and efforts with additional developmental assistance by experts affiliated with risk, food, and chemical consultancies with expertise in food safety, biochemistry, environmental health science, public health, risk analysis, computer programming, and Web technology. The initial concept for the framework, which contributed to deliberations and subsequent prototype development, included an expert elicitation framework, tools, and envisioned information from several sources: expert panel judgment, evidence databases, value models, assessment assumptions, and policy options. This concept would feed into methodological research summary reports that were envisioned to aid the risk-ranking activities of the FDA and other possible users.

Model Components

The panel developed 2 main risk criteria modules: exposure (farm-to-fork) and hazard characterization (health impacts). The exposure module contained questions grouped into 3 food system stages: primary production; processing; and distribution, storage, retail, foodservice, and home. Questions comprising the hazard characterization module addressed agent pathogenicity or toxicity and potential public health burden. Formats for the answers to the explicit questions were qualitative (for example, high, medium, low, likely/not likely), quantitative (metric/scale), objective (available data), subjective (expertise), and rationale based.

Metrics (values assigned to individual risk input criteria) for the factors in the 2 modules were systematically developed. Metrics for levels of consumption of the identified food types of primary concern were compiled using the U.S. Dept. of Agriculture's 1994–1998 CSFII food intake database. The risk criteria comprising the 2 modules were integrated via an algorithm approach.

User inputs

Prototype users are prompted by specific questions for pertinent details on hazard prevalence, concentration, and changes in concentration at each of the 3 food system stages. Monte Carlo simulation computes mean final log concentrations from triangular distributions (minimum, most likely, or maximum log concentration value). To address health impacts, users are prompted to describe and assign importance to health impacts through pseudo-disability adjusted life years (pDALY). The pDALY concept is modified slightly from the general use of DALY (IOM 2005) to allow for a semiquantitative characterization of the disease burden of health impacts. The usual approach to measuring DALY is to assign a severity weight and duration weight to discrete relatively well-characterized health outcomes. The pDALY approach allows for the characterization of a standard health outcome (such as mild illness) without further definition of the exact impact. This was developed primarily to facilitate risk ranking of chemical substances that may present a risk of diverse, poorly characterized outcomes (for example, noncancer toxicity), which may not be easily assigned individual weights and durations.

Users create pDALY templates by assigning a fraction of cases to appropriate health impacts, such as mild, moderate, or severe pathogen, and short-term, adult, elderly, or childhood mortality. Some questions have predefined answers connected with predefined weights for risk-ranking calculations. Guidance exists in the form of help files that facilitate user responses to questions. Users can assign one or more dose–response functions to hazard outcome types, such as cancer or chronic noncancer. Users select the functional form of the dose–response relationship and record appropriate parameters for the chosen dose–response function.

Hazard–food pairs

IFT identified and incorporated into the prototype a number of hazard–food pairs (Table 1) to test the questions developed for the modules and the respective decision logic and to evaluate the metrics, ranking processes, and outcomes. The hazards for the pairs were chosen on the basis of participant knowledge of the hazard. To ensure that the prototype could address the full range of possible outcomes of varying severity and uncertainties, the chemical hazards were also chosen on the basis of conveniently available residue data, comparability to selected microbial hazards, and presence of multiple potential toxic endpoints. The prototype can accommodate additional pathogens and chemical toxicants and other hazard–food pairs, such as combinations involving food

canning and post-lethality processing of ready-to-eat (RTE) product or scenarios involving home food storage or preparation (for example, *L. monocytogenes* and temperature-abused RTE luncheon meat).

Prototype characteristics and functionality platforms

The prototype exists on 2 platforms: a web-based user interface, implemented in Visual Basic language and an Analytica® model. The web-based platform was developed to provide a user-friendly input/output user interface that facilitates concurrent use and data sharing without significant time delay. More specifically, the web-based platform (Figure 1) allows users to explore the complex ranking hierarchy, view the current evidence, edit evidence, and update assumptions. Calculations are performed in the web-based implementation using Visual Basic. Microsoft Access, a relational database, stores the relationships between variables (foods, hazards, processes, and evidence) that apply to each individually and their many combinations.

The Analytica model (Figure 2), which complements the web-based prototype application, facilitates visualization of the logic flow and interrelationship of input and output variables. It also allows inspection and auditing of the calculations comprising the prototype. Appropriate consumption measures with census-based population size estimates pulled from the database serve as the basis for risk calculations. Although the Analytica model reproduces the web-based calculations exactly, it allows only calculations based on a single hazard–food pair and does not allow relative risk rankings of different hazard–food pairs. The Analytica model was designed for the initial development of the calculations, given the visualization and computational features of the software, to facilitate further development, discussion, and review of the algorithms. The web-based implementation was then compared with the Analytica-based calculations to ensure that the implementation was sound.

Table 1 — Hazard–food pairs used for prototype testing.

Arsenic and smoked salmon
Bacillus cereus and liquid, extended-shelf-life coffee creamer in individual serving units
Benomyl and apple juice
Clostridium perfringens and beef broth-based gravy prepared in a restaurant
Cyclospora cayetanensis and fresh raspberries
Dioxin and lettuce
Dioxin and fresh green onions
Dioxin and cheddar cheese
Dioxin and whole milk
Escherichia coli O157:H7 and apple juice
E. coli O157:H7 and sprouts
Enterobacter sakazakii and powdered infant formula
Fumonisin and canned corn
Hepatitis A virus and fresh strawberries
Hepatitis A virus and raw oysters
Listeria monocytogenes and whole milk
Methyl mercury and smoked salmon
Nitrate and smoked salmon
Nitrite and smoked salmon
Norovirus and raw oysters
Salmonella spp. and powdered milk
Salmonella spp. and raw oysters
Shigella dysenteriae and fresh green onions
Staphylococcus aureus enterotoxin and natural cheddar cheese

Characteristics and functionality

Two main components make up the key conceptual features of the risk-ranking prototype: computer programming code integrating exposure and hazard characterization modules and risk information data. The framework characterizes the burden of disease for health impacts associated with hazards through illness duration and severity. It also links health impact categories to hazards through the pDALY, a simplified way of addressing burden of

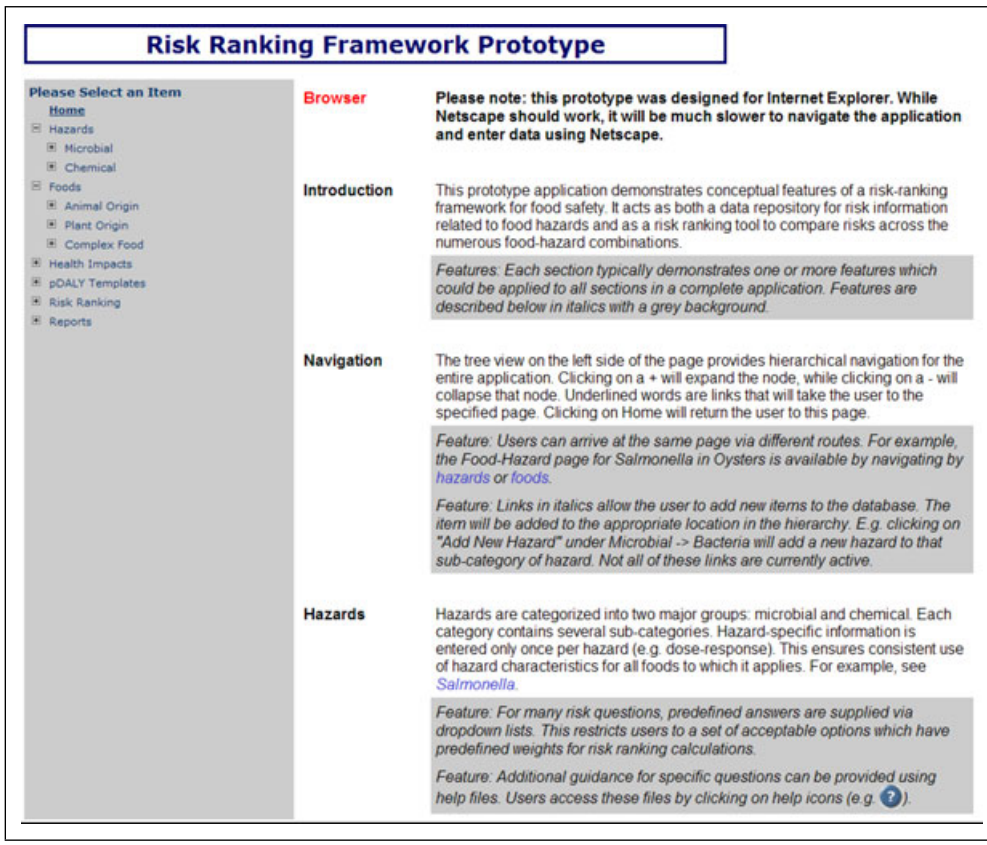


Figure 1 — Initial view: main page of web-based prototype implementation.

disease. CSFII 1994–1998 data were used to estimate the proportion of the population(s) potentially exposed to the hazard and the amount of food eaten.

The prototype generally incorporates empirical evidence (CSFII food intake data, dose response data, and residue data), expert rationale, and module integration algorithms (via Visual Basic language) and provides output in the form of risk-related evidence, assumptions, and risk-ranking reports. Thus, while the product is a prototype for a risk-ranking framework, there is inherent value in the knowledge comprising the prototype.

The framework is not intended to replace or substitute for more complex single hazard–food pair risk assessments since the level of detail is limited in the interest of allowing comprehensive and rapid ranking of many hazard–food pairs. Instead, the framework can provide a comparative risk rank for hazard–food pairs, expressed as annual pDALY. The risk-ranking section of the web-based version uses Monte Carlo simulation to compute a range of doses based on the concentration of the hazard in the food and the average serving size. The doses are used in conjunction with the dose–response model(s) for the hazard to compute a mean probability of illness for each population group. Prevalence values are then used to determine the number of contaminated servings. Triangular distributions were chosen for simplicity and ease of change; other distributions could readily be utilized in future iterations of the model. Combining the number of contaminated servings with the probability of illness and the pDALY template value for the hazard generates a final risk measure (annual pDALY). For chemical hazards, risks that are inferred based on lifetime exposures are prorated to an annual risk estimate by dividing by an arbitrary lifetime value of 70 y (consistent with the value used by the FDA and the Environmental Protection Agency) to allow for compatible timeframes for ranking. Alternatively, acute hazards (primarily microbial hazards) can be multiplied by the same factor to estimate compatible lifetime burden of disease measures. Tables 2 and 3 show the input and output variables of the prototype.

Another advantage of the prototype is its flexibility. For example, one could consider seasonal and geographic impacts on hazard prevalence, contaminated servings, and subsequent risk rank by addressing the appropriate number of suitably defined hazard–food pairs in the web-based implementation. An example of this would be *Vibrio vulnificus* in raw oysters harvested from the Gulf Coast during summer compared with winter. Similarly, the risk rank of a hypothetical intentional contamination event could be considered by incorporating the hypothetical hazard prevalence, concentration, and locations within the food chain in which contamination occurs.

Exposure module

The panel chose the 3 main food system stages—primary production (includes harvesting); processing (includes post processing); and distribution, storage, retail, foodservice, and home—to enable representation of key points at which hazard prevalence and concentration could change throughout the food system. In the future, the capability exists to address transport of source materials or animals prior to processing or food product subsequent to processing at any of the food system stages. Within each of these 3 food system stages, hazard presence is considered on a bulk lot or truckload type basis rather than by individual consumer or retail units.

The prototype addresses hazard concentration via initial concentration, in log units/g for microbes and g/g for chemicals, at the earliest point of primary production before any known production, processing, distribution/storage-related changes might occur. Subsequent concentration as a result of any increases or decreases or additions (introduction of contamination) occurring during the 3 food system stages is also addressed. The simulation engine examines each possible pathway of contamination explicitly, and the resulting concentrations are weighted by their respective probability of occurrence calculated in concentration weights. As a result, 16 pathways track probabilities for concentration throughout each of the 3 food system stages.

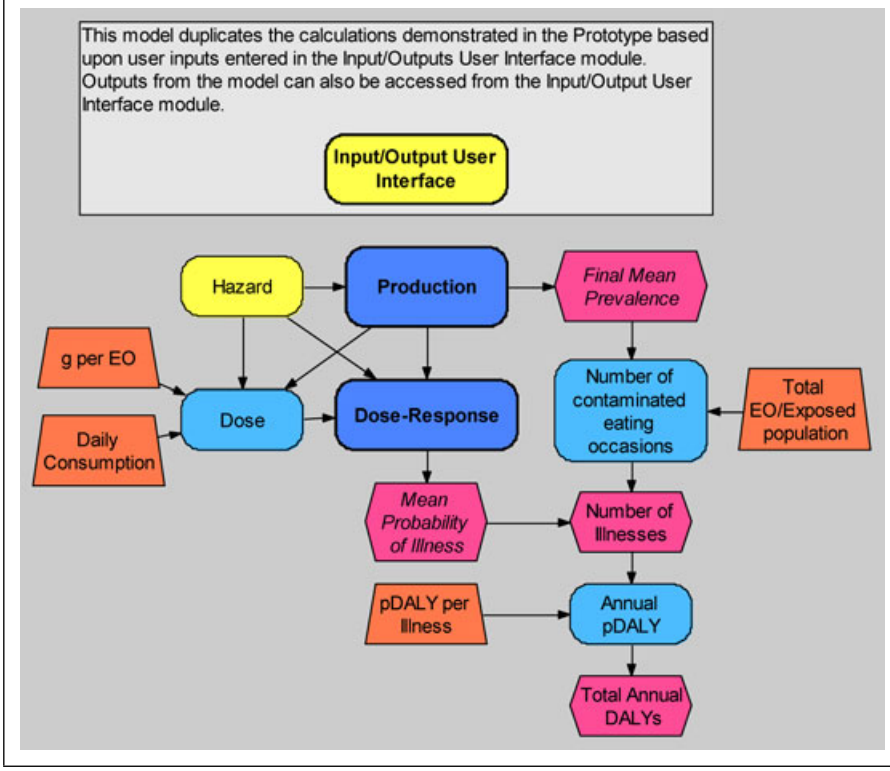


Figure 2—Initial view of Analytica model.

The prototype addresses hazard prevalence more simply by estimating the likelihood of hazard introduction at each of the 3 stages, changes in hazard prevalence during each stage, prevalence at the end of each stage, and final prevalence at the end of the continuum. The calculations for prevalence estimate the concentration of the agent at the end of the farm-to-fork chain based upon the changes in concentration (increases or decreases) and additions that occur throughout the food system as defined by the user. Initial prevalence is expressed on the basis of percentage of total units in which the hazard is present (contaminated units/total units, 0% to 100%). Change in prevalence (occurring independently of initial concentration), change in concentration, or introduced concentration within each of the 3 food system stages is addressed with values between 0 and 1 reducing the prevalence by that factor, values greater than 1 increasing the prevalence by that factor, and a value of 1 leaving the prevalence unchanged.

In allowing the user to address likelihood for introduction or addition of a hazard during each of the stages, the prototype has placeholders for future developmental efforts to address controllability efficacy and controllability compliance. This is based on the understanding that the existence of guidance or regulation to describe how a hazard enters the food chain and the ability to control a hazard is a relevant consideration in risk ranking. For example, if a hazard were controllable, then a risk-rank metric could be used for mitigation, or if not controllable, then the rank could be used in considering the need for research. These considerations, which are managerial in nature, do not currently lend themselves to an obvious numeric or ranking, but this may change with future iterations of the prototype.

Table 2—Risk-ranking prototype input variables.[a]

Initial prevalence
Initial concentration before processing
Change in concentration at primary production
Likelihood of introduction at primary production
Introduced concentration at primary production
Change in prevalence during primary production
Change in concentration at processing
Likelihood of introduction at processing
Introduced concentration at processing
Change in prevalence (processing)
Change in concentration at distribution, storage, retail, foodservice, and in the home
Likelihood of introduction at distribution, storage, retail, foodservice, and in the home
Introduced concentration at distribution, storage, retail, foodservice, and in the home
Change in prevalence at distribution, storage, retail, foodservice, and in the home
Total eating occasions/exposed population
Grams per eating occasions
pDALY per illness
Daily consumption
Dose–response model
Beta-Poisson
Exponential
Linear
Chemical cancer
Chemical noncancer
Noncancer method
Threshold
Linear model threshold
Linear model nonthreshold
Hazard
Microbial or chemical/toxin
Dose
RfD
Threshold

[a]As shown in the input/output user interface Analytica node.

Table 3—Risk-ranking output variables.[a]

Final mean concentration in positive lots
Final mean prevalence
Mean probability of illness
Number of illnesses
Annual pDALY

[a]As shown in the input/output user interface Analytica node.

Consumption (food intake) submodule

The consumption/food intake submodule addresses the proportion of the population that is exposed to the hazard and the amount of a given food that is eaten. Due to the large number of as-eaten foods in the U.S. Dept. of Agriculture's 1994–1998 CSFII 8-digit food-code database, expert panel members determined that an aggregate approach based on 3- and 5-digit levels of food intake data would be sufficient and effective for developing quantitative metrics for risk-ranking purposes. CSFII data are based on 4 population groups: the entire United States, women 16 y to 49 y of age, children 1 y to 6 y of age, and individuals 65 y of age and older. Users may also specify what percentage of a given population is at risk.

Chemical risks are computed using the mg/kg bw/day consumption measure (in which bw = body weight). Population size based on census estimates for each population group is in the database to compute population risk for chemicals. Microbial risk is calculated using mean serving size and total number of servings. For chemical hazards, risk (probability of illness) is calculated on the basis of 90th percentile for consumption.

Hazard characterization (health impacts) module

Multiple dose responses can be assigned to hazard outcome types (for example, cancer, acute or chronic noncancer [for chemicals] and infectious or toxigenic [for microorganisms]). Each dose response option subcategory offers a subset of appropriate dose–response models. When users address a hazard and corresponding dose–response models, they will encounter the question "What is the strength of judgment that this hazard causes adverse health effects?" for which there are 4 possible responses: no studies available, not well established, moderate evidence, or well established. Because the responses to the question do not readily lend themselves to numeric expression, they are not currently factored into the risk ranks. Nevertheless, the information is pertinent and provides justification which, at some future time, may lead to a more quantitative expression of strength of supporting evidence.

For toxicological dose–response relationships (chemical and toxin-producing microbial hazards), 5 models are available: step threshold, threshold linear, nonthreshold linear, beta-Poisson, and exponential. For infectious dose responses, 4 models are available: beta-Poisson, exponential, threshold linear, and nonthreshold linear. The dose–response templates cannot be changed by users. The dose–response section of the prototype shows appropriate parameters for the selected model; changing the model changes the parameters for the options provided. All dose–response pages allow consideration of probability of illness given response, addressing the question of what proportion of infections would result in illness. All dose–response curves are incorporated into the risk calculations. Users may choose from any number of health impacts, which basically represent a DALY approach (Table 4) and then link them with one or more of the pDALY templates (Table 5).

The pDALY template allows the impact of the hazard to be placed on a relative scale. The results of exposure are captured semi-quantitatively in 2 dimensions: impact severity (mild, moderate, severe, or death) and duration (short, medium, or long), allowing up to 12 ways to describe a health impact. In addition, when selecting a specific health impact, users may indicate and provide support for their choice of health impact, duration, and severity.

Other prototype characteristics

The prototype addresses microbial risk as represented by colony forming units at the point of consumption and does not track toxin production occurring throughout the food chain (for example, staphylococcal enterotoxin formation). Strain-to-strain differences in virulence of microorganisms are not included nor are differences in immunity among individuals because of innate or acquired immunity, such as resistance to certain pathogens (such as norovirus and hepatitis A virus).

Additionally, the model is very sensitive to situations where a microbial hazard has a toxigenic response characterized by a threshold linear model, as observed for *C. perfringens* and beef gravy. This sensitivity exists because the dose–response model contains a threshold below which a response does not occur and above which it does. Thus, when the predicted concentration of the pathogen is close to the threshold, very slight increases in the concentration of the pathogen can result in very large changes in health effects. The prototype has the capability of accommodating a number of possible modifications:

- Inserting additional scientific documentation;
- Allowing assignment of a relative estimate of data quality;
- Adding more inputs for multiple hazard reductions;
- Considering factors that contribute to a decrease or increase of a food hazard (as might occur during in-home preparation or storage);
- Integrating the web-based implementation with the Analytica model (allowing users to view and address more than one hazard–food pair at the same time);
- Allowing answers to the strength of judgment and hazard controllability questions to be factored into the risk-ranking output to address uncertainty associated with these factors;
- Accommodating the input of confidence intervals for input and output estimates;
- Considering the benchmark dose lower confidence limit as a risk measure rather than the reference dose;
- Standardizing the dose–response modeling for different categories of chemical hazards;
- Incorporating consumption data (for example, data from the National Health and Nutrition Examination Survey data); and
- Including additional data that would enhance the strength of the exposure and hazard characterization modules (for example, data pertaining to dose response).

Table 4—Health impacts.

Mild, short-term impacts
Mild, medium-duration impacts
Mild, long-term impacts
Moderate, short-term impacts
Moderate, medium-duration impacts
Moderate, long-term impacts
Severe, short-term impacts
Severe, medium-duration impacts
Severe, long-term impacts
Childhood mortality
Adult mortality
Elderly mortality
Hemorrhagic colitis
Hemolytic uremic syndrome
Enteric fever
Reactive arthritis/Reiter's syndrome
New health impact

Table 5—pDALY templates.

Acute (chemicals)
Blood target organ (chemical)
Cancer (chemical)
Escherichia coli O157:H7
Gastroenteritis only (rare fatality)
Hepatitis A virus
Neural tube defect
Neuro-developmental (chemical—below BmD)
Reproductive (chemical)
Salmonella
Severe pathogen
New pseudo DALY template

Risk-Ranking Output

The prototype provides a basic reporting mechanism that reports selected contents of the database (the evidence) according to foods, hazards, processes, and their combinations. A risk-ranking summary report can be generated, grouped by hazard or food; ordered by total risk or name; and produced in ascending or descending order. Total risk (pDALY) is aggregated by hazard or food depending on the grouping selected. The application sums the pDALY measures as a total risk for a particular food or hazard, depending on the grouping selected. In addition, users have the option to specify foods, hazards, or hazard–food combinations that are to be excluded from rankings due to incompleteness of data or development of assumptions. Checking the pertinent box on the food, hazard, and hazard–food pages determines whether they are included in the ranking. The individual food and hazard settings take priority over the combination of settings.

For the dose–response relationship, the risk-ranking summary report summarizes the type, model, and parameters of the dose–response; grams per eating occasion; total number of eating occasions; mean hazard prevalence; number of contaminated servings from once contaminated lots; mean concentration in food; mean dose; mean probability of illness; number of illnesses; pDALY per illness; and annual pDALY. By default, the risk-ranking summary report prints the 1st dose–response chart, but other charts are included. The "print summary" function produces a summary of the evidence entered and is distributable for discussion and holistic consideration.

Conclusions

In cooperation with the FDA, IFT participants in this study developed a functional semi-quantitative risk-ranking framework prototype—a flexible tool that enables relative comparison and ranking of microbial food-related risks with chemical risks via a single metric: annual pDALY. Specific approaches taken in developing the prototype enabled resolution of some broad challenges faced in risk-ranking efforts. The successful production of this risk-ranking prototype holds tremendous potential as a unique tool capable of comparing microbial hazards and chemical hazards not only separately but also comparatively by using a common metric.

Acknowledgments

This study was supported under FDA cooperative agreement grant number FD-U-002255-01 and by additional funding from the Food Risk Analysis Initiative of Rutgers Univ.

References

Carrington CD, Bolger MP. 2002. An exposure assessment for methylmercury from seafood for consumers in the United States. College Park, Md.: U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition: Available from: http://www. cfsan.fda.gov/~acrobat/mehgra2.pdf. Accessed Sept 4, 2008.

FDA-CFSAN, USDA-FSIS, CDC. 2003. Quantitative assessment of relative risk to public health from foodborne Listeria monocytogenes among selected categories of ready-to-eat foods. U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition, U.S. Dept. of Agriculture/Food Safety and Inspection Service, Centers for Disease Control and Prevention. Available from: http://www.foodsafety.gov/~dms/lmr2-toc.html. Accessed Sept 4, 2008.

[FSRC] Food Safety Research Consortium. 2005. Prioritizing opportunities to reduce the risk of foodborne illness: a conceptual framework. Available from: http://www.card.iastate.edu/food_safety/national_conference/FSRC_Conceptual_Framework_final.pdf. Accessed Sept 4, 2008.

Havelaar AH, Melse JM. 2003. Quantifying public health risk in the WHO guidelines for drinking-water quality. RIVM report nr 734301022/2003. Available from: http://www.who.int/water_sanitation_health/dwq/rivmrep.pdf. Accessed Dec 1, 2008.

[IFT] Institute of Food Technologists. 2002. Emerging microbiological food safety issues: implications for control in the 21st century. An expert report. Chicago, Ill.: Institute of Food Technologists. Available from: http://www.ift.org/cms/?pid=1000379. Accessed Nov 20, 2008.

[IOM] Institute of Medicine. 2005. Estimating the contributions of lifestyle-related factors to preventable death: a workshop summary. Washington, D.C.: National Academies Press, 80 p.

Jaykus L, Dennis S, Bernard D, Claycamp HG, Gallagher D, Miller AJ, Potter M, Powell M, Schaffner D, Smith MA, Ten Eyck T. 2006. Using risk analysis to inform microbial food safety decisions. Issue paper nr 31. Ames, Iowa: Council for Agricultural Science and Technology.

Murray CJL, Lopez AD, Mathers CD, Stein C. 2001. The global burden of disease 2000 project: aims, methods and data sources. Global programme on evidence for health policy discussion paper nr 36. Geneva, Switzerland: World Health Organization. Available from: http://www.who.int/healthinfo/paper36.pdf. Accessed Nov 8, 2007.

[USDA-FSIS] U.S. Dept. of Agriculture, Food Safety and Inspection Service. 1998. Salmonella Enteritidis risk assessment: shell eggs and egg products. Final report. Washington, D.C.: U.S. Dept. of Agriculture, Food Safety and Inspection Service. Available from: http://www.fsis.usda.gov/ophs/risk/. Accessed Sept 4, 2008.

DATE: 2-25-2013

FAX To: Ms. Elizabeth Dickinson, Esq.

Chief Counsel
Rm. 4536
Food and Drug Administration
Silver Spring, MD 20993-0002
(T) 301-796-8540
(F) 301-847-8637
E-mail: Elizabeth.Dickinson@fda.hhs.gov

SUBJECT: YOUR LETTER OF FEBRUARY 22, 2013, TO MR. JOHN HNATIO AT FOODQUEST TQ, LLC

NOTE:

Dear Ms. Dickinson:

We received your letter of February 22, 2013, asking for a response to your letter of January 28, 2013. On February 12, 2013, we faxed our response directly to your office. I have made direct contact with your office to make certain that you receive the attached copy of our original response. Thank you very much for your willingness to look into this matter. If you have any questions, please feel free to contact me at 240-439-4476 x-11. You can also reach me at e-mail: jhnatio@thoughtquest.com Best regards, John.

FROM:

John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702
240-439-4476 X-11
E-mail: jhnatio@thoughtquest.com

COPY

DATE: 2-12-2013

FAX TO:

Ms. Elizabeth Dickinson, Esq.
Chief Counsel
Rm. 4536
Food and Drug Administration
Silver Spring MD 20993-0002
(T) 301-796-8540
(F) 301-847-8637
E-mail: Elizabeth.Dickinson@fda.hhs.gov

SUBJECT: RESPONSE TO YOUR LETTER OF JANUARY 28, 2013 TO MR. JOHN HNATIO, FOODQUESTTQ, LLC

FROM:

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702
240-439-4476 x-11
E-mail: jhnatio@thoughtquest.com

COPY

ORIGINAL SENT ON: 2-12-21013 COPY PROVIDED ON 2-25-2013

Elizabeth H. Dickinson, Esq.
Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

February 12, 2013

Dear Ms. Dickinson:

Thank-you very much for your letter of January 28, 2013. In your letter you refer to the letter that we wrote to Senator Barbara Mikulski on December 19, 2012. We truly appreciate your help and we are looking forward to working with you as we move forward together to fairly resolve this matter.

In the Fall of 2012, our company became concerned that the Food and Drug Administration (FDA) Food Defense Team may be improperly using FoodQuestTQ LLC generated trade secrets and other business proprietary information to duplicate several of our products.

We have since learned that members of the FDA's Food Defense Team have taken our FoodQuestTQ LLC product descriptions and our proprietary commercial and trade secret information and duplicated three of our products. Other new products that duplicate our pre-existing commercial offerings may also be in development by the FDA that we are not yet aware of at this time.

1. The new ***FDA Food Defense Plan Builder*** tool takes our pre-existing **Food DefenseTQ** tool, which is used to build food defense plans (just recently upgraded to become **Food Defense Architect**) and duplicates it.

2. The new ***FDA FREE-B*** tool takes elements of our pre-existing **FREE** and **FEAST** computer software tools, which are used to simulate and manage food emergencies, and duplicates them.

In your letter you refer to our December 19, 2012, letter to Senator Mikulski and you ask us to "identify the patents to which you are referring in your letter and the FDA software system which you allege uses your ideas." The patent upon which the entire FoodQuestTQ integrated Food Protection computer software tool suite is based is:

- USPTO Patent No.: US 8,103,601 B2, DOI: January 24, 2012.

The patent describes methods and techniques that are an expression of the Complexity Systems Management Method or CSM Method®. The CSM Method® is a registered trademark business process and data transformation patent for dealing with complex and evolving risks and risk countermeasures across all critical infrastructures including food and agriculture. It consists of 92 objects of invention that are integrally tied to each of the 20 claims granted by USPTO under the patent.

It is important to note, however, that our company's concerns go well beyond the possibility that the FDA may have infringed on our patent to include the more immediate concern that the Food Defense

ORIGINAL SENT ON: 2-12-21013 COPY PROVIDED ON 2-25-2013

Team has improperly taken FoodQuestTQ LLC product information and company proprietary commercial and trade secret information to duplicate our products.

Attached please find a brief description of some specific topics that you may wish to discuss directly with the FDA Food Defense Team. We wanted to provide this information to you now in order to make our upcoming meeting as productive as possible.

Again, thank you very much for looking into our concerns. We are still very interested in building a cooperative relationship with the FDA so that we can work together to make the food we all eat safer. We very much look forward to meeting with you personally to lay out a plan on how we can work together to fairly resolve this issue in a mutually beneficial way.

Please feel free to contact me at my office telephone of 240-439-4476 x-11 to arrange for a meeting or if we can be of any further help to you in resolving this matter.

Sincerely yours,

John H. Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
(T) 240-439-4476 x-11
(M) 301-606-9403
E-mail: jhnatio@thoughtquest.com

COPY OF ORIGINAL DATED 2/12/201 FOR YOUR EYES ONLY

Informal Note for: Elizabeth Dickinson

From: John Hnatio J. H.

Date: 2/12/2013

For many years prior to my retirement from government service, I had the great privilege of serving in senior positions in both the Executive and Legislative Branches of our government where I dealt directly with technology transfer issues and the vital relationship between the government and industry in achieving national objectives. For example, I was the leader of the technology transfer program for the nuclear weapons program that included all ten of the national laboratories where I oversaw billions of dollars of cooperative work between the government and the private sector. I also served as a loaned Executive from the White House to the Senate to spearhead efforts to strengthen the defense industrial base and promote greater cooperation between government and industry. Suffice it to say that I have "lived and breathed this stuff" for well over 30 years.

Based on my significant expertise in this area, there may be several specific aspects of this situation that you may wish to explore directly with the FDA Food Defense Team before we have the opportunity to meet.

First and foremost, is the requirement that federal employees protect and keep as confidential proprietary commercial information provided to them by the private sector. In all of our interactions with the FDA Food Defense Team we clearly advised them whenever we were sharing proprietary commercial information. In addition, all of the proprietary commercial information we provided to the FDA Food Defense Team was clearly marked as containing proprietary information. The FDA Food Defense Team used this proprietary information and other publicly available descriptions of our product to duplicate three of our products.

Second, are the numerous laws and statutes that dictate when the government can and cannot internally "build" products. Here the rules are very clear. Among these important rules is a documented "build-no build" determination by a government agency based on the notion that the activity involved is an "inherently government function." While the authority to regulate the food industry certainly is an inherently government function, food defense and food safety undertakings to assist the food industry implement and comply with those regulations are not. Rather, they represent a shared responsibility between the government and the private sector. The FDA Food Defense Team did not make a good faith "build-no build" determination before they decided to duplicate our products.

Another important government determination requires that no government agency or its subcontractors, including Battelle Memorial Institute in this case, be permitted to compete with the private sector. Here the rules are also very clear. Before and as part of any funding decision by a federal agency to contract with a Federally Funded Research and Development Center (FFRDC) the agency must make a "compete-no compete" determination. This requires that each federal agency systematically consider and reach a considered determination that the activity they are funding will not compete with the same, similar or better product offering that is already available in industry. In many federal

agencies this responsibility is shared by the Head Contracting Official and is basis to the procurement process. The FDA Food Defense Team did not make a good faith "compete-no compete" determination before they decided to duplicate our products.

There are several other issues that raise serious concerns about the integrity of the FDA Food Defense Team's actions that are disturbing that their supervisors should be made aware of.

On October 6, 2012, we briefed the FDA Food Defense Team. During that briefing we attempted to discourage them from pursuing a course of action that would only result in a waste of taxpayer dollars to duplicate pre-existing commercial products. At that meeting, we offered the FDA Food Defense Team a one dollar a year license to use our tools for all FDA personnel across the Food and Agricultural industry vertical. The FDA Food Defense Team never responded to our offer. But they did tell us that our company's products were far better than the ones that the FDA was developing under their contract with Battelle Memorial Institute.

In December 2012, we were invited by the Grocery Manufacturer's Association (GMA) to attend an FDA Food Defense Team sponsored workshop. Before the meeting we were told by the FDA Food Defense Team that the principal purpose of the workshop was to discuss the use of a food defense targeting tool originally developed by the military Special Forces that has been converted by the FDA Food Defense Team for use by food facilities. After speaking personally with a member of the FDA Food Defense Team about the "true purpose" of the meeting, FoodQuestTQ created a web based survey to reach out to industry to obtain their inputs on the usefulness of the FDA targeting tool.

Just days before the scheduled Food Defense Team sponsored workshop at GMA, we published an article giving the preliminary results of the industry survey. The results of the survey raised serious questions about the utility of the FDA targeting tool by industry. This article received very significant notoriety within the FDA Food Defense Team as evidenced by the fact that the FoodQuestTQ article was "opened" for reading and further distribution by the leader of the FDA Food Defense Team more than 40 times.

A few days before the FDA Food Defense Team sponsored workshop was scheduled to take place on December 12, 2012, we were provided with a copy of the FDA Food Defense Team agenda for the workshop by GMA. We realized at this time that the Food Defense Team intentionally misled us about the true purpose of the workshop. The agenda made it clear that the real purpose of the workshop was for the FDA Food Defense Team to demonstrate and receive inputs from the food industry on the FDA's new Food Defense Plan Builder tool. A representative of Battelle Memorial Institute wrote the company an e-mail stating that the FDA Food Defense Team industry workshop to demonstrate their new Food Defense Plan Builder tool could only be attended by food processing companies.

Late in the evening of December 11, 2012, we were informed by GMA that the FDA had prohibited our company from attending the following day's workshop to demonstrate our FoodQuestTQ food defense plan builder tool (known as Food Defense Architect). The GMA advised us that the FDA Food Defense Team prohibited us from attending the workshop because they (the FDA Food Defense Team) did not want to give our company any unfair competitive advantage. After the workshop, we were able to

verify that we were again misled by the FDA Food Defense Team when we found that attendees at the workshop included many other non-food processing companies including competing software companies.

COPY

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

Senator Barbara Mikulski
Washington, DC
503 Hart Senate Office Building
Washington, D.C. 20510

February 12, 2013

Dear Senator Mikulski:

We would like to thank-you very much for your help in arranging a meeting with Ms. Dickinson at the Food and Drug Administration. We would like to extend our particular thanks to Mr. Barton Kennedy of your staff for his diligent efforts working through the federal bureaucracy on our behalf. We express our personal thanks to Bart.

We recently received a letter from Ms. Dickinson asking for background information on our concerns. We have responded to her request and hope to meet with her very soon to resolve the matter. We feel confident that when Ms. Dickinson gets the opportunity to review the materials she will take the appropriate actions necessary to resolve our concerns.

With your permission, we will keep you apprised of our progress in working with the Food and Drug Administration to resolve our concerns. Again, thanks to you and your staff.

Sincerely,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC

cc: Elizabeth Dickinson, FDA-OGC

COPY

Representative John Delaney
1632 Longworth House Office Building
Washington, DC 20515

FQTQ
Powered by FoodQuestTQ
TQ stands for threat quotient

February 12, 2013

Dear Representative Delaney:

We wanted to thank-you for your assistance in obtaining the opportunity to meet with Ms. Elizabeth Dickinson at the Food and Drug Administration. We realize that without your help such a meeting would never have been possible.

There is one particular person on your staff who worked diligently on our behalf. Kevin Mack deserves our special thanks. You must be proud to have him as a member of your staff.

We recently received a letter from Ms. Dickinson asking for background information on our concerns. We have responded to her request and hope to meet with her very soon to resolve the matter. We feel confident that when Ms. Dickinson gets the opportunity to review the materials she will take the appropriate actions necessary to resolve our concerns.

With your permission, we will keep you apprised of our progress in working with the Food and Drug Administration to resolve our concerns. Again, thank-you for all of your help.

Sincerely,

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC

cc: Elizabeth Dickinson, FDA-OGC

Pages 836 through 837 redacted for the following reasons:
- -
Entire page withheld under (b)(5).

Rec'd in OL: 12/19/12
Referred to CFSAN for draft response: 12/21/12
Conference call: EWortman, MStringfellow, and RDurkin, JGuenther, and JMenikheim (CFSAN/OFDCER): 1/4/13
R/D: JMenikheim, OAO: 1/7/13
Cleared EOS: SBerndt: 1/7/13
Cleared CFSAN: SMusser: 1/7/13
Edits: MStringfellow: 1/8/13

Control #: 2012-10062

G:\WP\STRINGFELLOW\Food Defense\2012-10062 Mikulski (c) food defense FoodQuestTQ.doc

File Copy	**Office**	**Surname**	**Date**	**Office**	**Surname**	**Date**

US008103601B2

(12) **United States Patent**
Hnatio

(10) **Patent No.: US 8,103,601 B2**
(45) **Date of Patent: Jan. 24, 2012**

(54) **COMPLEXITY SYSTEMS MANAGEMENT METHOD**

(75) Inventor: **John Harris Hnatio**, Union Bridge, MD (US)

(73) Assignee: **Projectioneering, LLC**, Frederick, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1178 days.

(21) Appl. No.: **11/808,580**

(22) Filed: **Jun. 12, 2007**

(65) **Prior Publication Data**

US 2011/0173146 A1 Jul. 14, 2011

Related U.S. Application Data

(60) Provisional application No. 60/812,591, filed on Jun. 12, 2006.

(51) **Int. Cl.**
G06N 5/00 (2006.01)

(52) **U.S. Cl.** **706/14**; 706/45

(58) **Field of Classification Search** 706/14, 706/45

See application file for complete search history.

(56) **References Cited**

PUBLICATIONS

Kohn, et al., Advanced Nonlinear and Hybrid Systems Control Technology, Technical Progress Report, U.S. Army, Armaments Research Development and Engineering Center, Picatinny Arsenal, Aug. 1996, pp. 1-75.*

Hvass, et al., Condition Based Maintenance for Intelligent Electromechanical Actuators, Mechanical Engineering Department, University of Texas at Austin, 2004, pp. 1-249.*

* cited by examiner

Primary Examiner — Wilbert L Starks

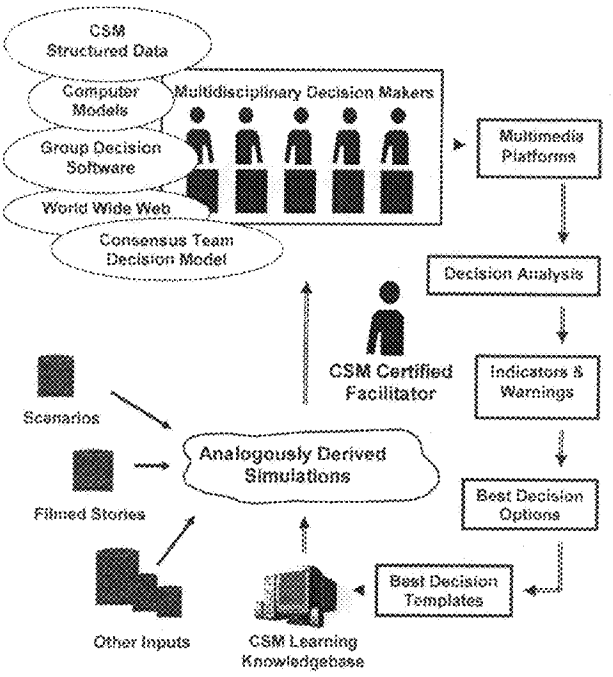
(74) *Attorney, Agent, or Firm* — Miles & Stockbridge P.C.; David R. Schaffer, Esq.

(57) **ABSTRACT**

The Complexity Systems Management (CSM) Method is a scientifically derived business process method for managing complex events and situations. The CSM Method™ is based on new scientific evidence that explains the behaviors of complex adaptive systems. This same scientific evidence gives rise to a new method of science, known as a priori optionality. A priori optionality is based on six scientifically derived tenets that are systematically applied using the CSM Method™ to more accurately characterize the behaviors of complex adaptive systems and manage complex events and situations. Applications of the CSM Method are integrally tied to specialized knowledgebases and a plurality of automated software applications.

20 Claims, 25 Drawing Sheets

CSM PHASE 2 Immersion Environment



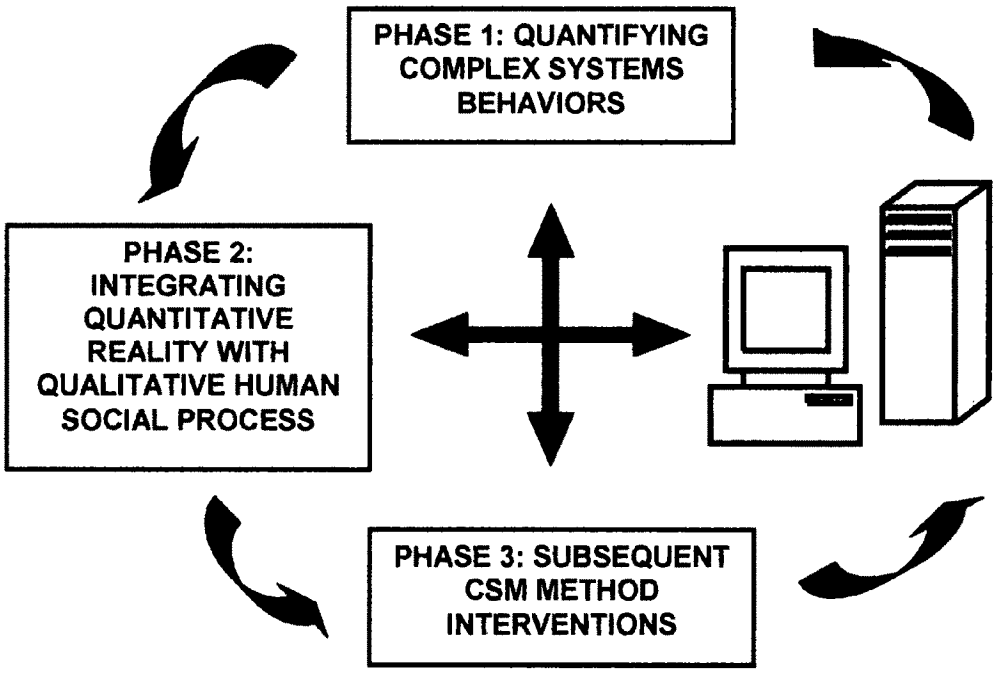

PHASE 1: QUANTIFYING COMPLEX SYSTEMS BEHAVIORS
PHASE 2: INTEGRATING QUANTITATIVE REALITY WITH QUALITATIVE HUMAN SOCIAL PROCESS
PHASE 3: SUBSEQUENT CSM METHOD INTERVENTIONS

FIGURE 1

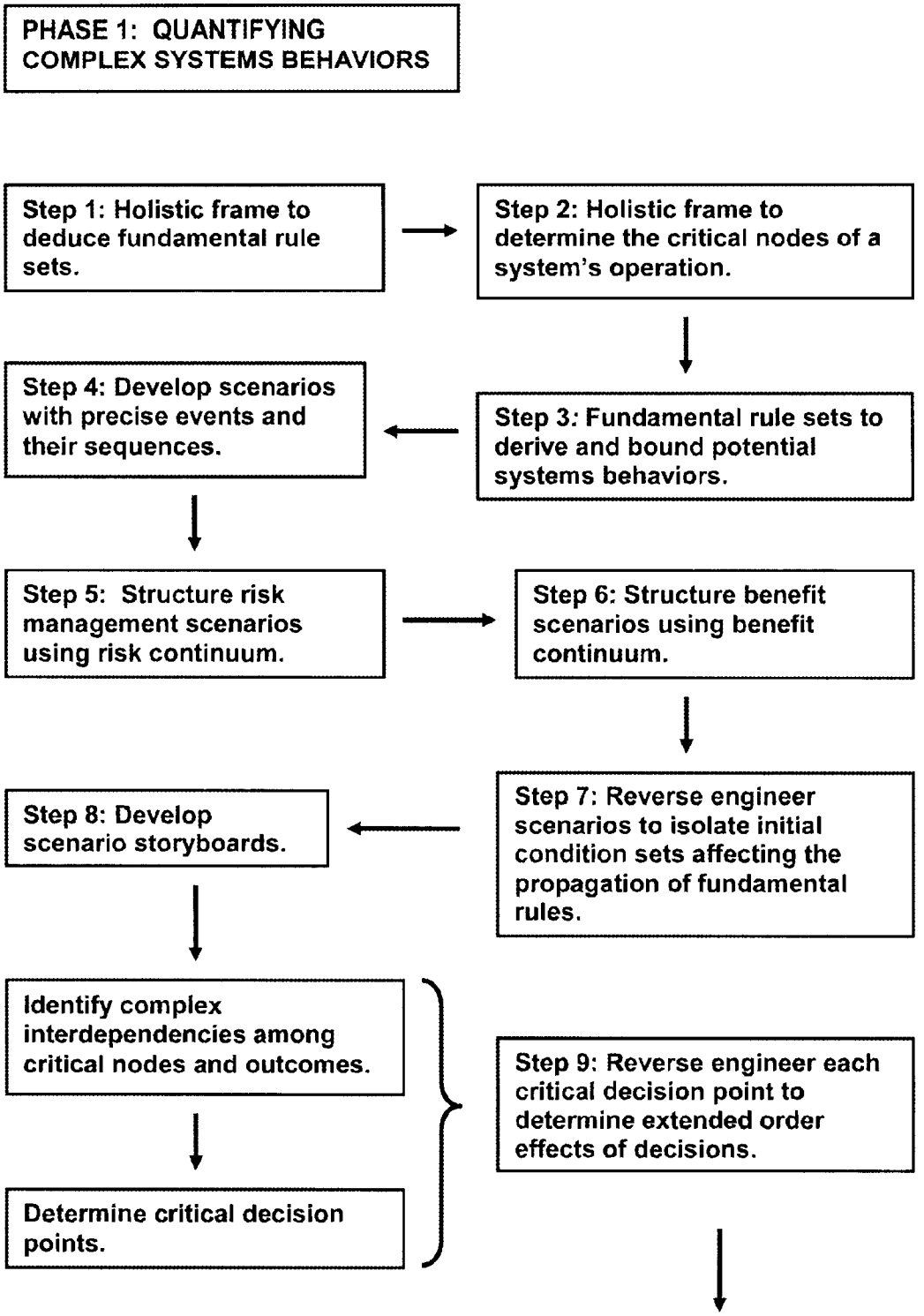

PHASE 1: QUANTIFYING COMPLEX SYSTEMS BEHAVIORS
Step 1: Holistic frame to deduce fundamental rule sets.
Step 2: Holistic frame to determine the critical nodes of a system's operation.
Step 3: Fundamental rule sets to derive and bound potential systems behaviors.
Step 4: Develop scenarios with precise events and their sequences.
Step 5: Structure risk management scenarios using risk continuum.
Step 6: Structure benefit scenarios using benefit continuum.
Step 7: Reverse engineer scenarios to isolate initial condition sets affecting the propagation of fundamental rules.
Step 8: Develop scenario storyboards.
Identify complex interdependencies among critical nodes and outcomes.
Determine critical decision points.
Step 9: Reverse engineer each critical decision point to determine extended order effects of decisions.

FIGURE 2A

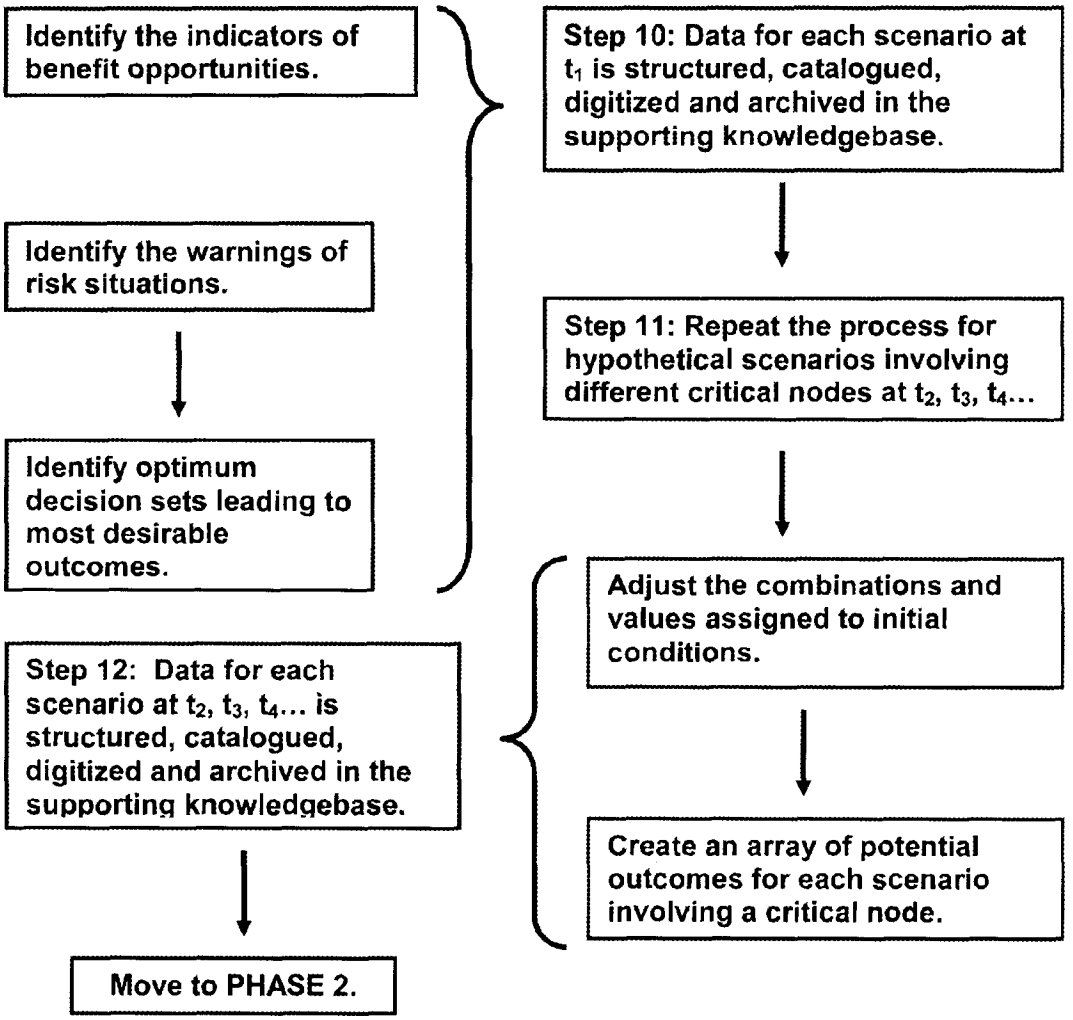
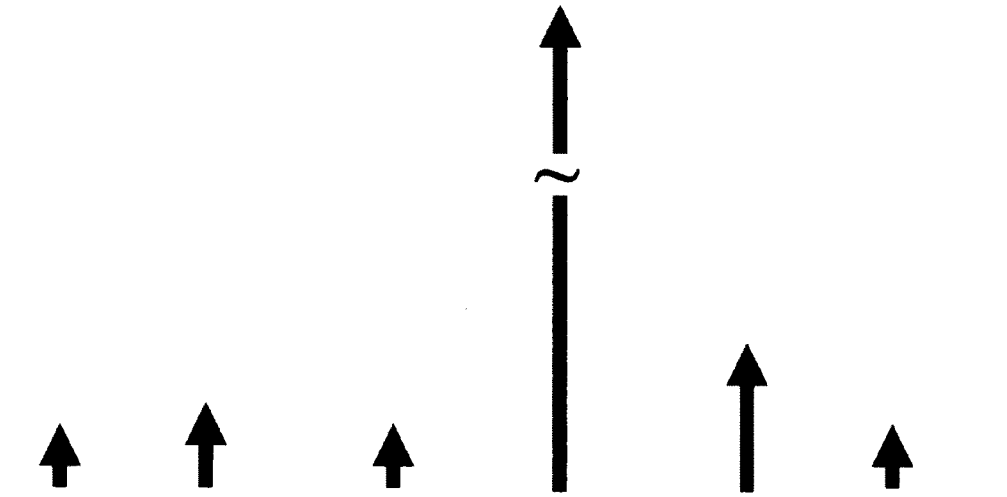

Identify the indicators of benefit opportunities.
Identify the warnings of risk situations.
Identify optimum decision sets leading to most desirable outcomes.
Step 10: Data for each scenario at t_1 is structured, catalogued, digitized and archived in the supporting knowledgebase.
Step 11: Repeat the process for hypothetical scenarios involving different critical nodes at t_2, t_3, t_4...
Adjust the combinations and values assigned to initial conditions.
Create an array of potential outcomes for each scenario involving a critical node.
Step 12: Data for each scenario at t_2, t_3, t_4... is structured, catalogued, digitized and archived in the supporting knowledgebase.
Move to PHASE 2.

FIGURE 2B

Moving in the direction of effective *risk management* requires the reallocation of intellectual capital and resources...

Moving from this:

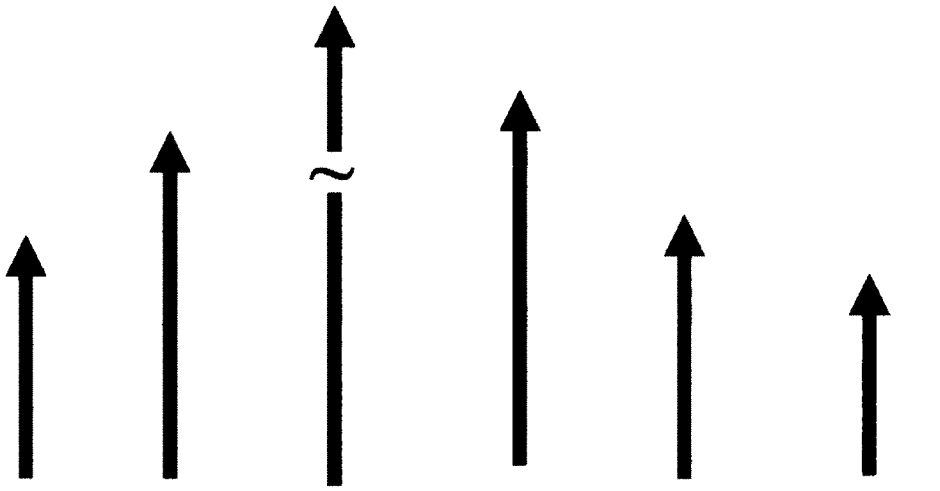


By the time you are forced to react it may already be too late

FIGURE 3 A

Moving in the direction of effective *risk management* requires the reallocation of intellectual capital and resources...

To this:

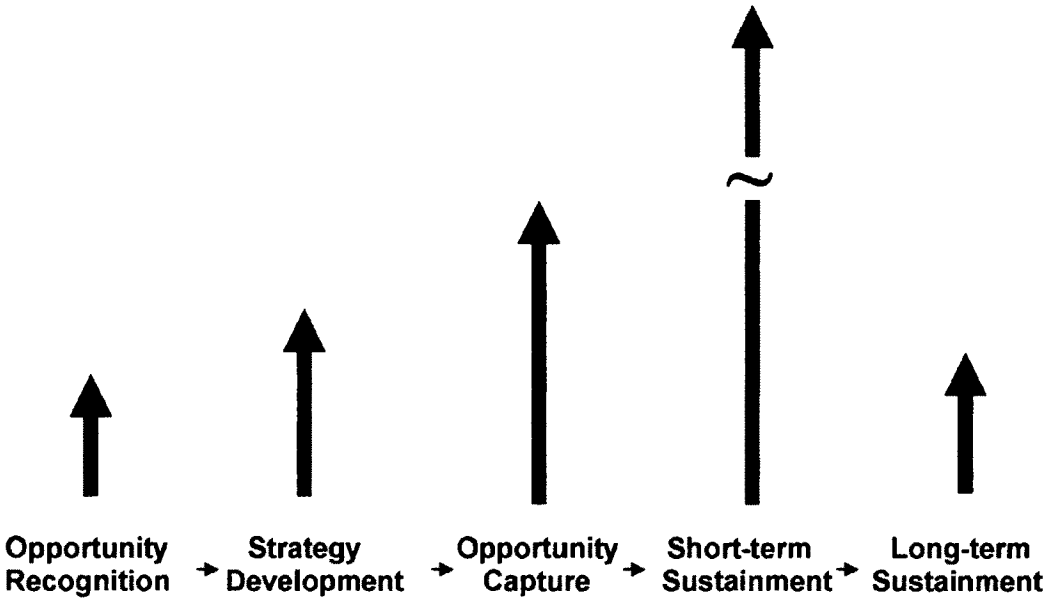


It's all bout preventing catastrophes before they happen

FIGURE 3 B

Moving in the direction of effective *benefit management* requires the reallocation of intellectual capital and resources...

From this:

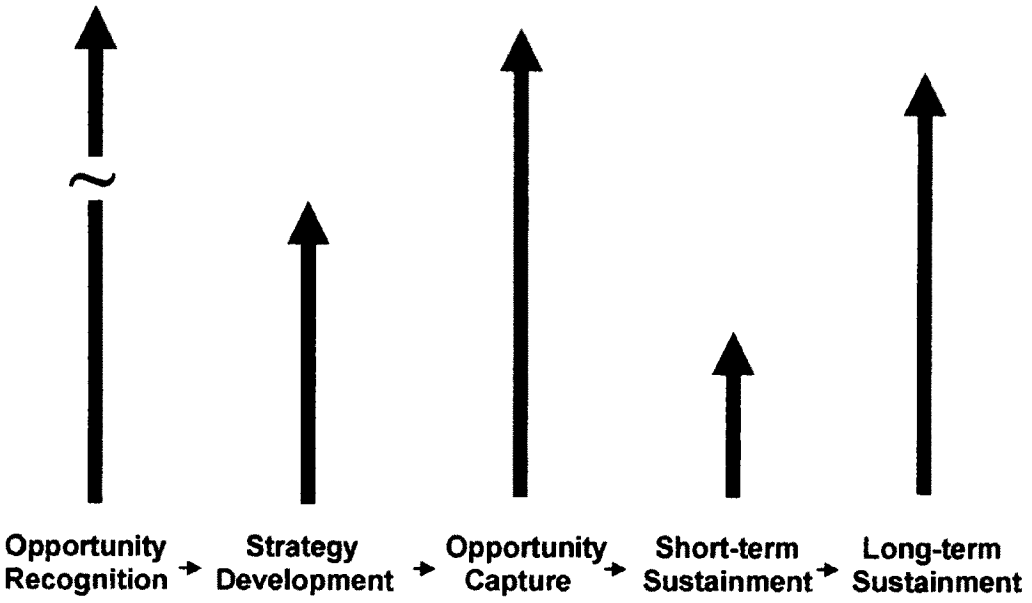


If you don't recognize opportunity, act on it before the competition, and sustain long-term benefit you will lose your competitive advantage

FIGURE 4 A

Moving in the direction of effective *benefit management* requires the reallocation of intellectual capital and resources...

To this:



It's all about recognizing, acting upon, and sustaining opportunities in order to beat the competition

FIGURE 4 B

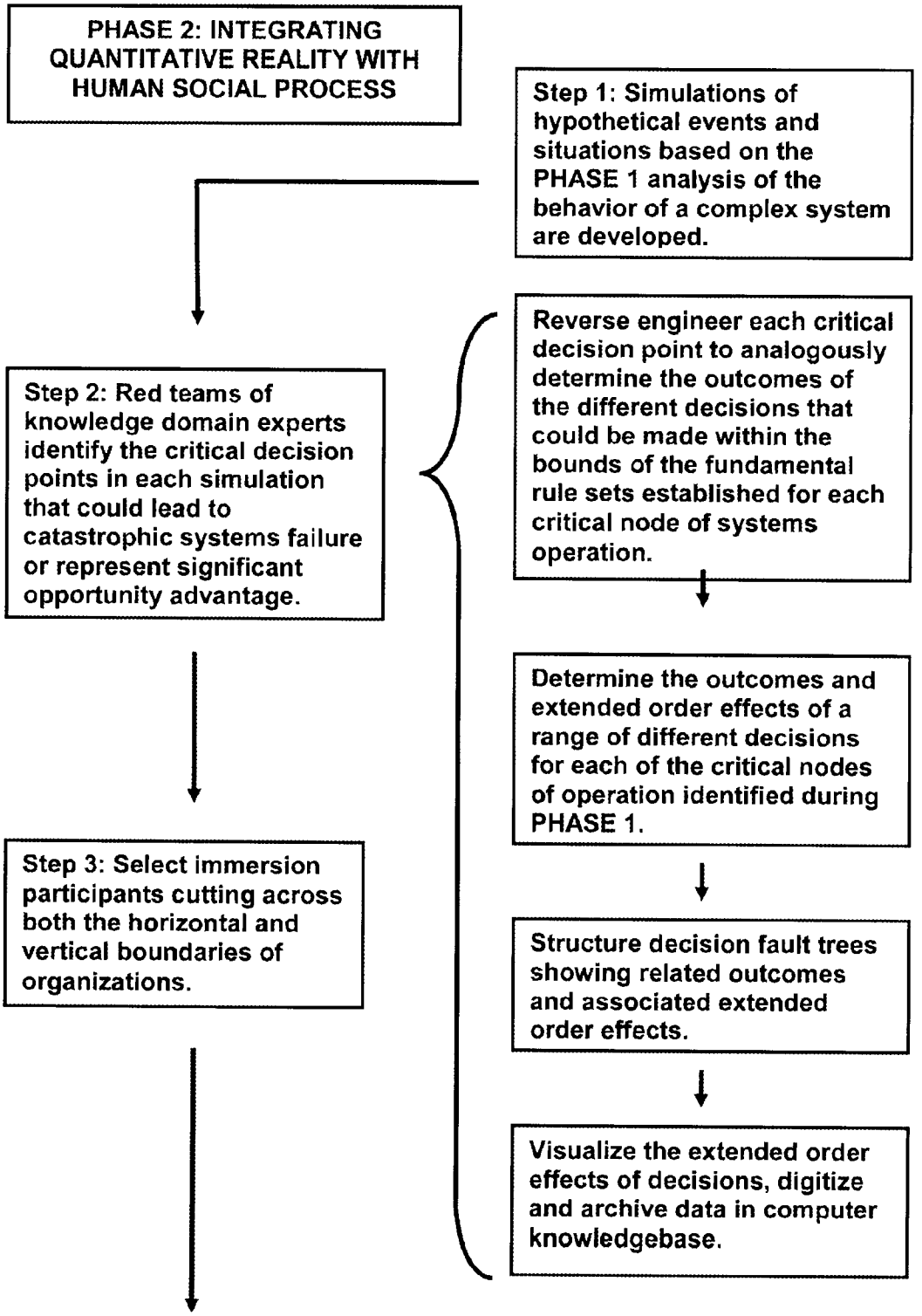

PHASE 2: INTEGRATING QUANTITATIVE REALITY WITH HUMAN SOCIAL PROCESS
Step 1: Simulations of hypothetical events and situations based on the PHASE 1 analysis of the behavior of a complex system are developed.
Step 2: Red teams of knowledge domain experts identify the critical decision points in each simulation that could lead to catastrophic systems failure or represent significant opportunity advantage.
Reverse engineer each critical decision point to analogously determine the outcomes of the different decisions that could be made within the bounds of the fundamental rule sets established for each critical node of systems operation.
Determine the outcomes and extended order effects of a range of different decisions for each of the critical nodes of operation identified during PHASE 1.
Step 3: Select immersion participants cutting across both the horizontal and vertical boundaries of organizations.
Structure decision fault trees showing related outcomes and associated extended order effects.
Visualize the extended order effects of decisions, digitize and archive data in computer knowledgebase.

FIGURE 5A

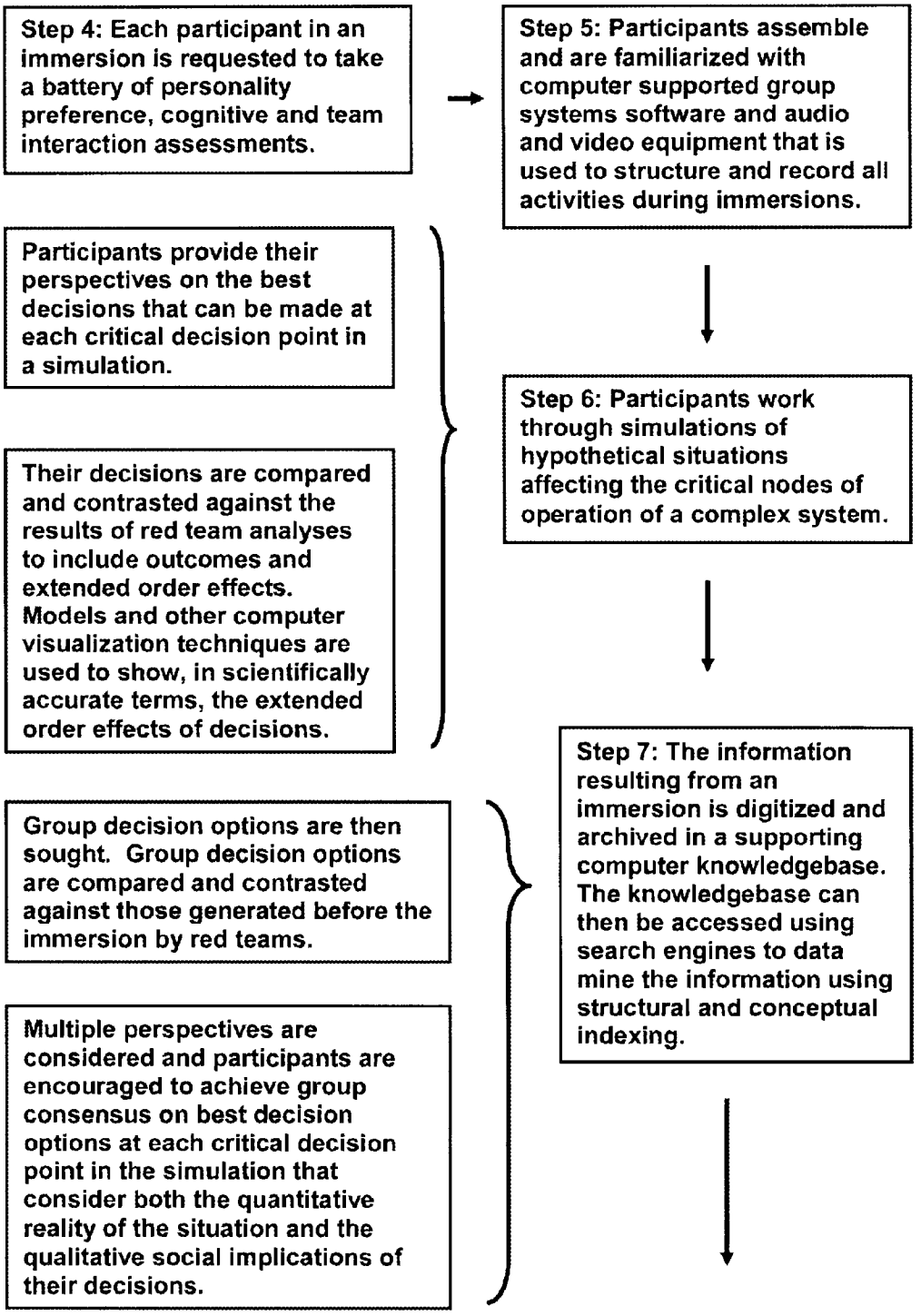

Step 4: Each participant in an immersion is requested to take a battery of personality preference, cognitive and team interaction assessments.
Step 5: Participants assemble and are familiarized with computer supported group systems software and audio and video equipment that is used to structure and record all activities during immersions.
Participants provide their perspectives on the best decisions that can be made at each critical decision point in a simulation.
Step 6: Participants work through simulations of hypothetical situations affecting the critical nodes of operation of a complex system.
Their decisions are compared and contrasted against the results of red team analyses to include outcomes and extended order effects. Models and other computer visualization techniques are used to show, in scientifically accurate terms, the extended order effects of decisions.
Step 7: The information resulting from an immersion is digitized and archived in a supporting computer knowledgebase. The knowledgebase can then be accessed using search engines to data mine the information using structural and conceptual indexing.
Group decision options are then sought. Group decision options are compared and contrasted against those generated before the immersion by red teams.
Multiple perspectives are considered and participants are encouraged to achieve group consensus on best decision options at each critical decision point in the simulation that consider both the quantitative reality of the situation and the qualitative social implications of their decisions.

FIGURE 5B

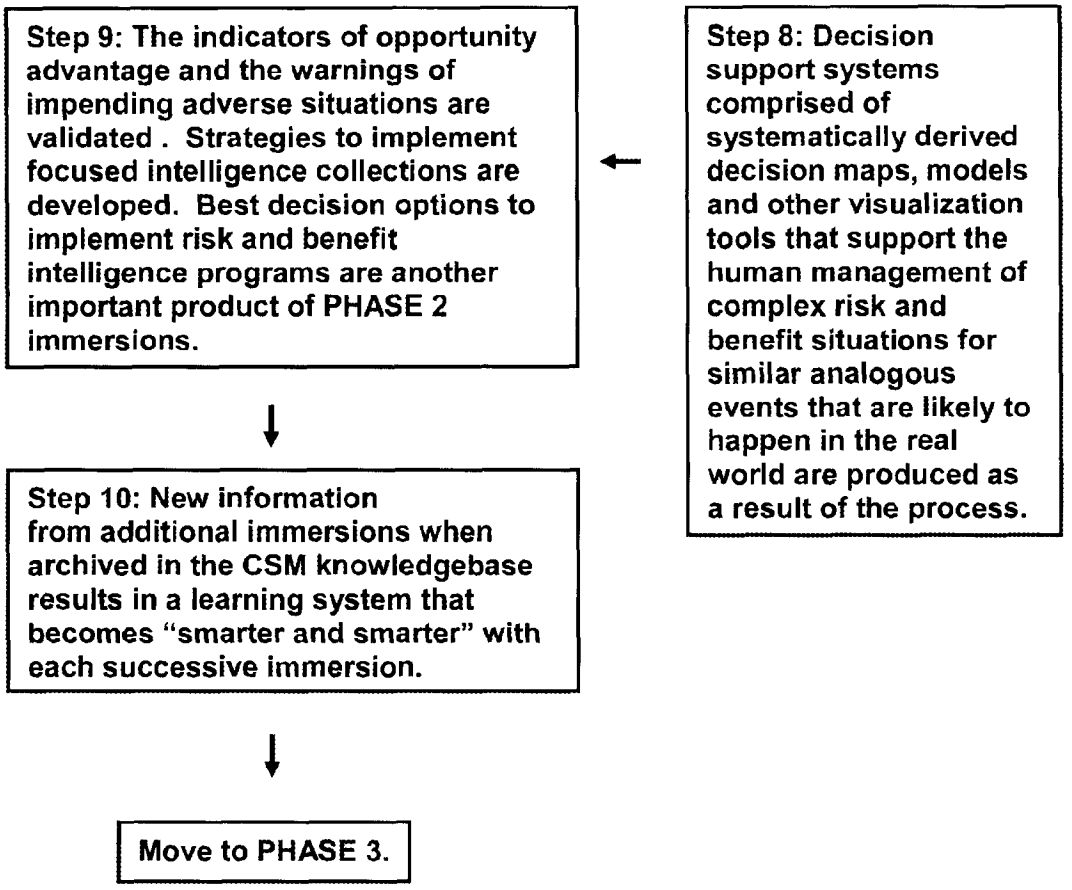
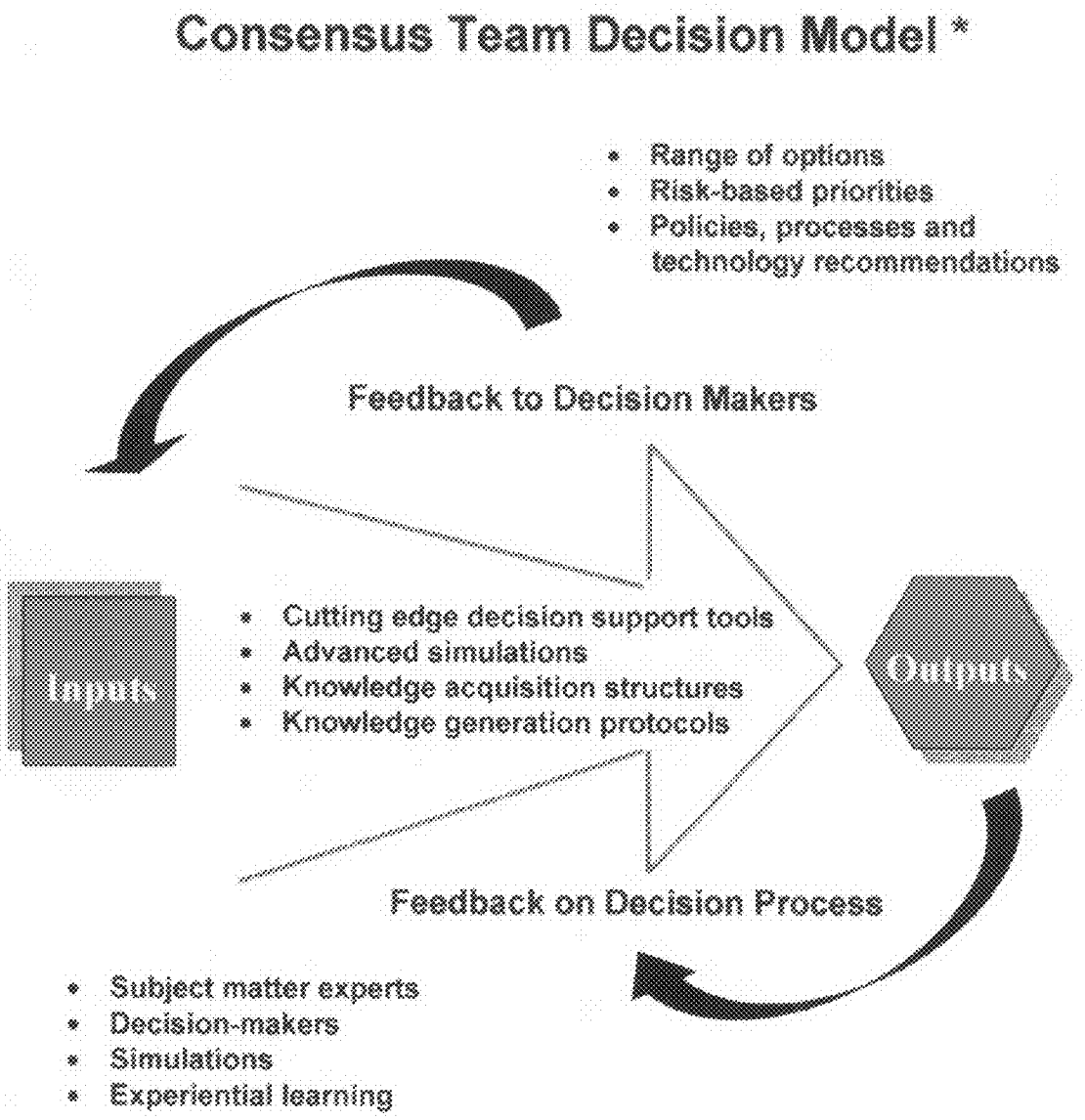

Step 9: The indicators of opportunity advantage and the warnings of impending adverse situations are validated . Strategies to implement focused intelligence collections are developed. Best decision options to implement risk and benefit intelligence programs are another important product of PHASE 2 immersions.
Step 8: Decision support systems comprised of systematically derived decision maps, models and other visualization tools that support the human management of complex risk and benefit situations for similar analogous events that are likely to happen in the real world are produced as a result of the process.
Step 10: New information from additional immersions when archived in the CSM knowledgebase results in a learning system that becomes "smarter and smarter" with each successive immersion.
Move to PHASE 3.

FIGURE 5C



* As adapted from Michelson, McGee & Hawley, 1994

FIGURE 6

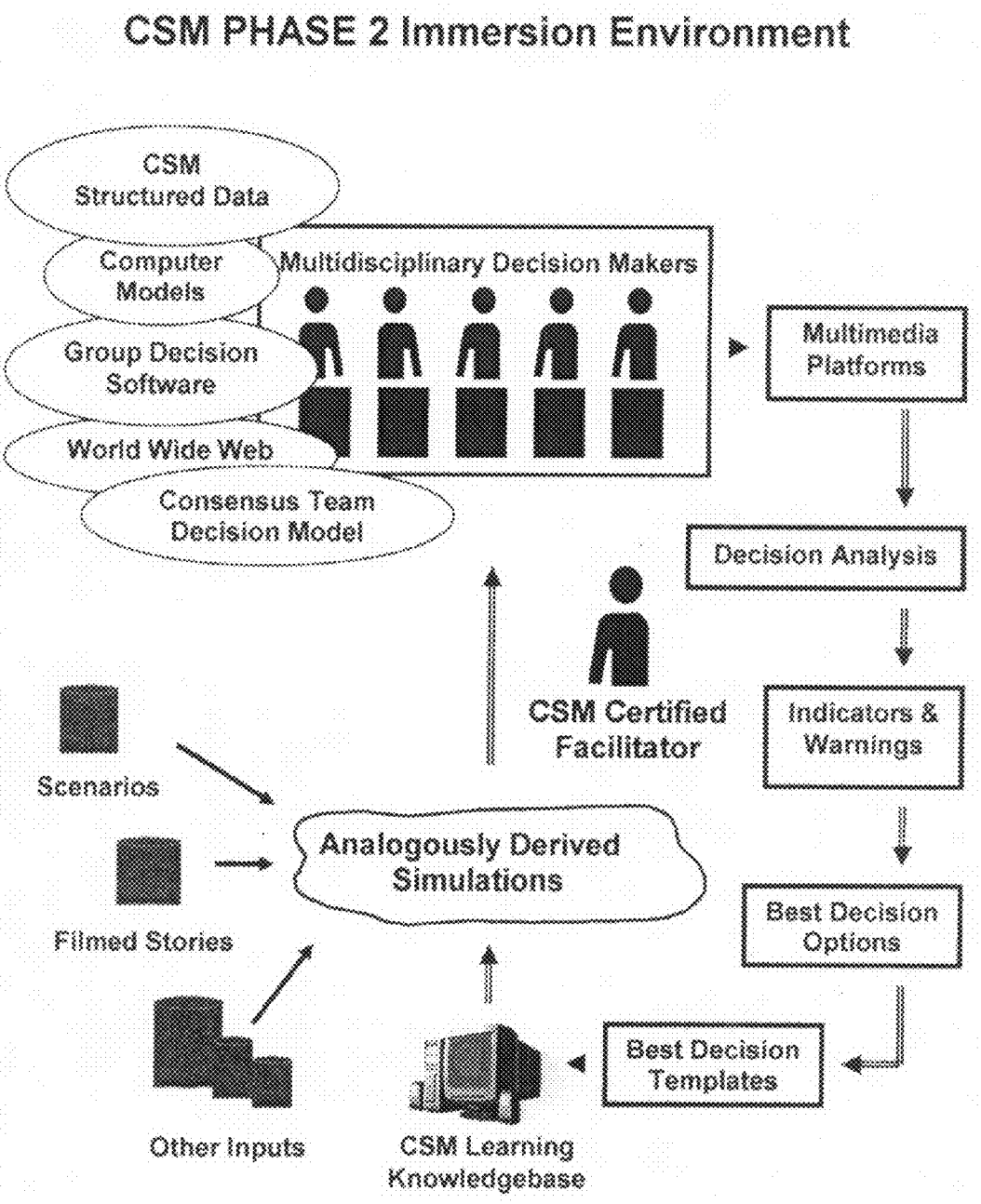

CSM PHASE 2 Immersion Environment
CSM Structured Data
Computer Models
Group Decision Software
World Wide Web
Consensus Team Decision Model
Multidisciplinary Decision Makers
Multimedia Platforms
Decision Analysis
Indicators & Warnings
Best Decision Options
Best Decision Templates
CSM Certified Facilitator
Scenarios
Filmed Stories
Other Inputs
Analogously Derived Simulations
CSM Learning Knowledgebase

FIGURE 7

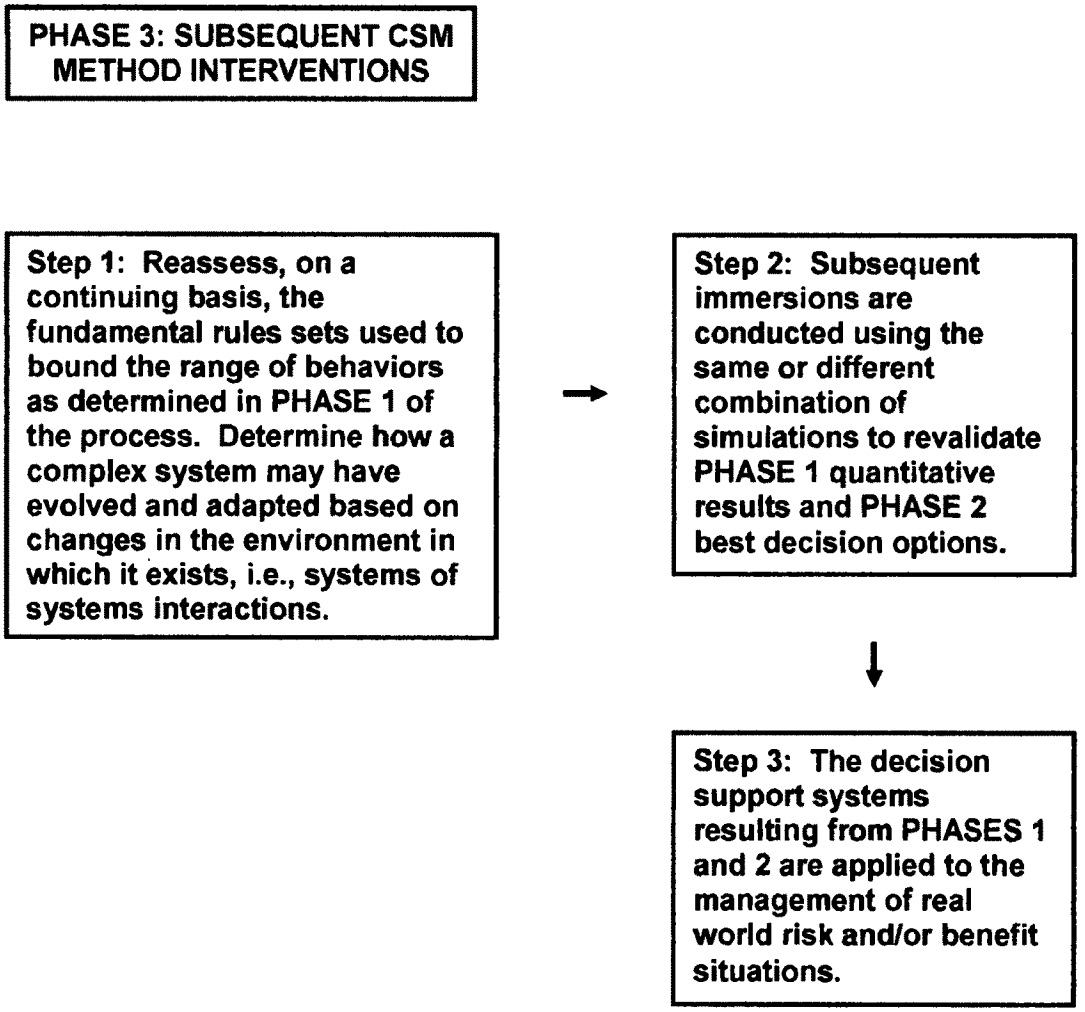

PHASE 3: SUBSEQUENT CSM METHOD INTERVENTIONS
Step 1: Reassess, on a continuing basis, the fundamental rules sets used to bound the range of behaviors as determined in PHASE 1 of the process. Determine how a complex system may have evolved and adapted based on changes in the environment in which it exists, i.e., systems of systems interactions.
Step 2: Subsequent immersions are conducted using the same or different combination of simulations to revalidate PHASE 1 quantitative results and PHASE 2 best decision options.
Step 3: The decision support systems resulting from PHASES 1 and 2 are applied to the management of real world risk and/or benefit situations.

FIGURE 8

PHASE 1: Quantitative Analysis	PHASE 2: Integrating Quantitative Reality with Qualitative Human Social Process	PHASE 3: Subsequent Interventions
Scientific Ground Truth 12 Process Steps	Consensus on Best Decisions 10 Process Steps	Re-validate Assumptions 3 Process Steps

FIGURE 9

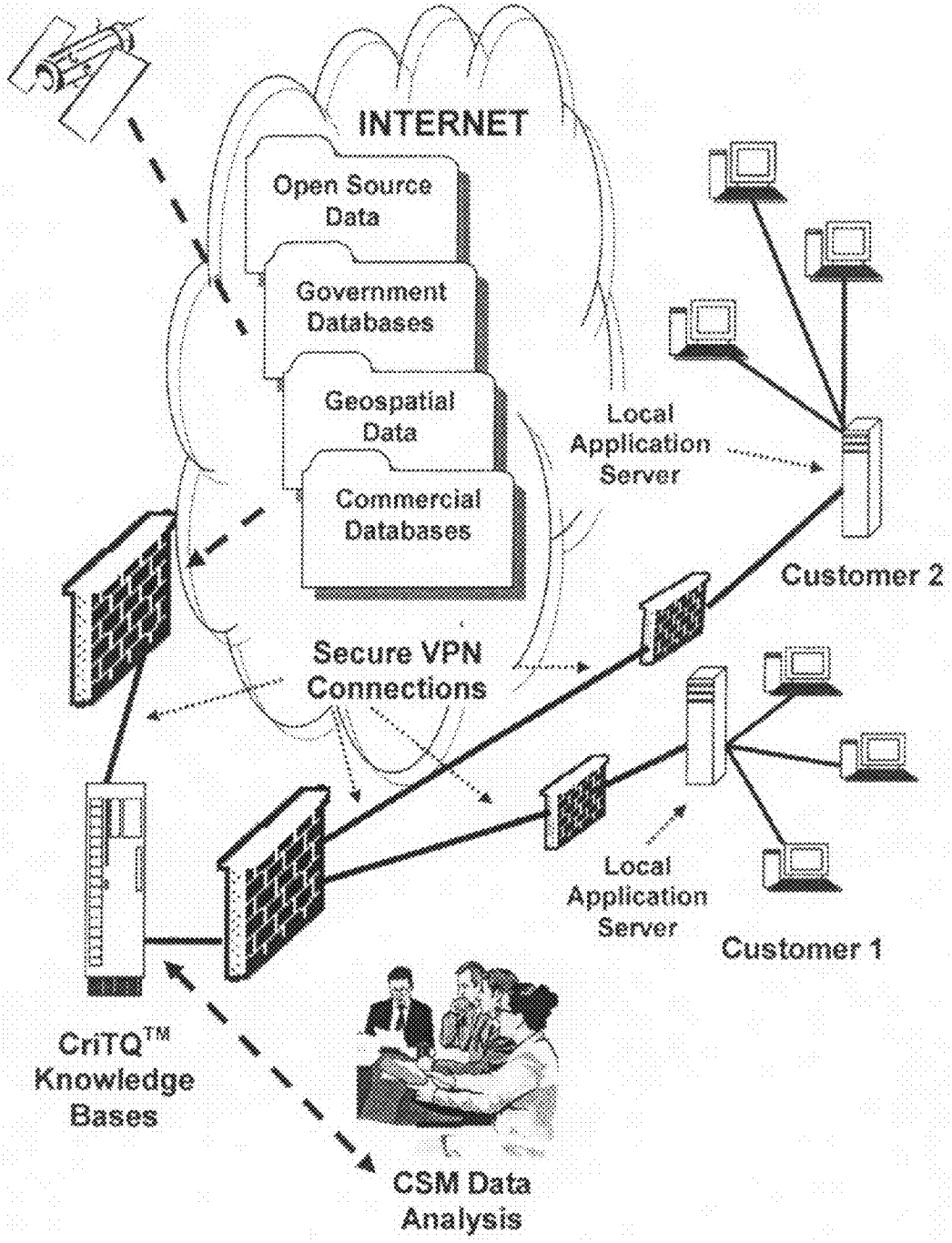
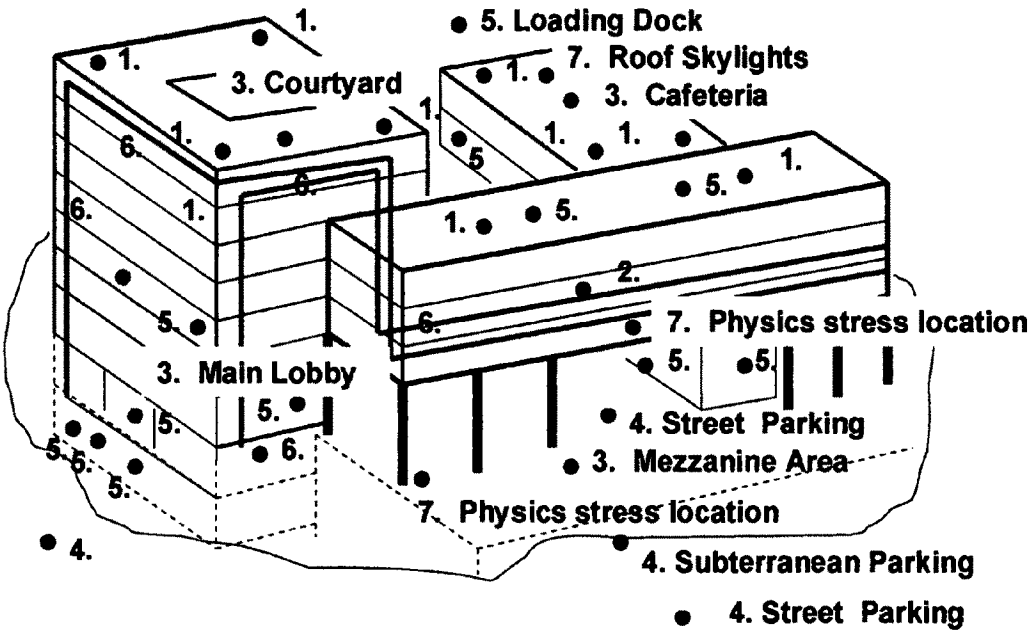
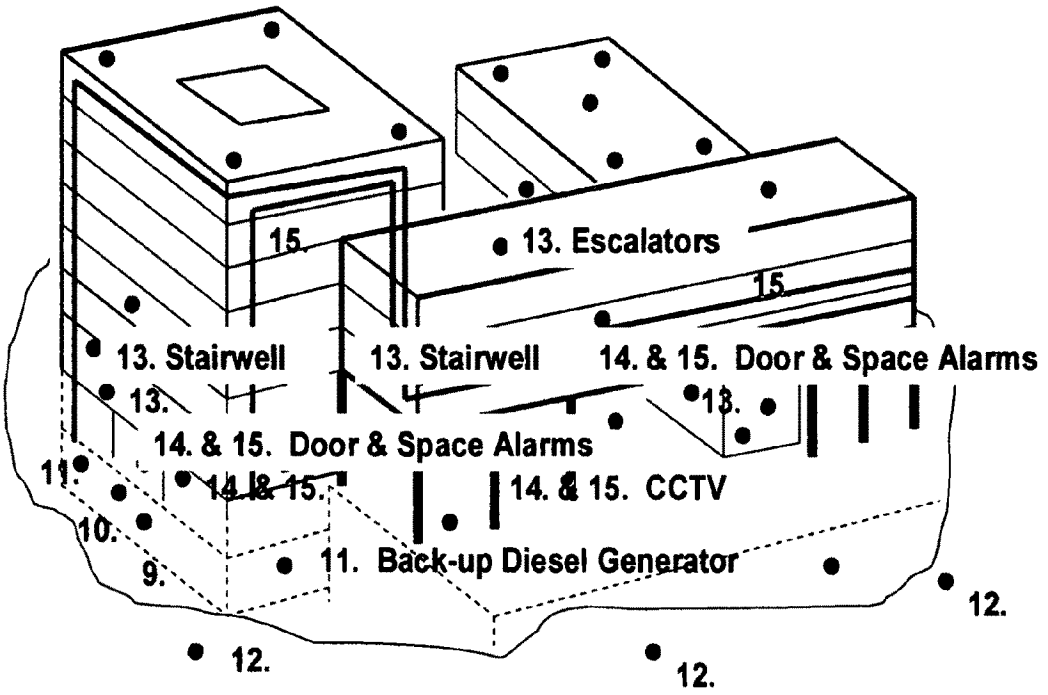

INTERNET
Open Source Data
Government Databases
Geospatial Data
Commercial Databases
Local Application Server
Customer 2
Secure VPN Connections
Local Application Server
Customer 1
CriTQ™ Knowledge Bases
CSM Data Analysis

FIGURE 10



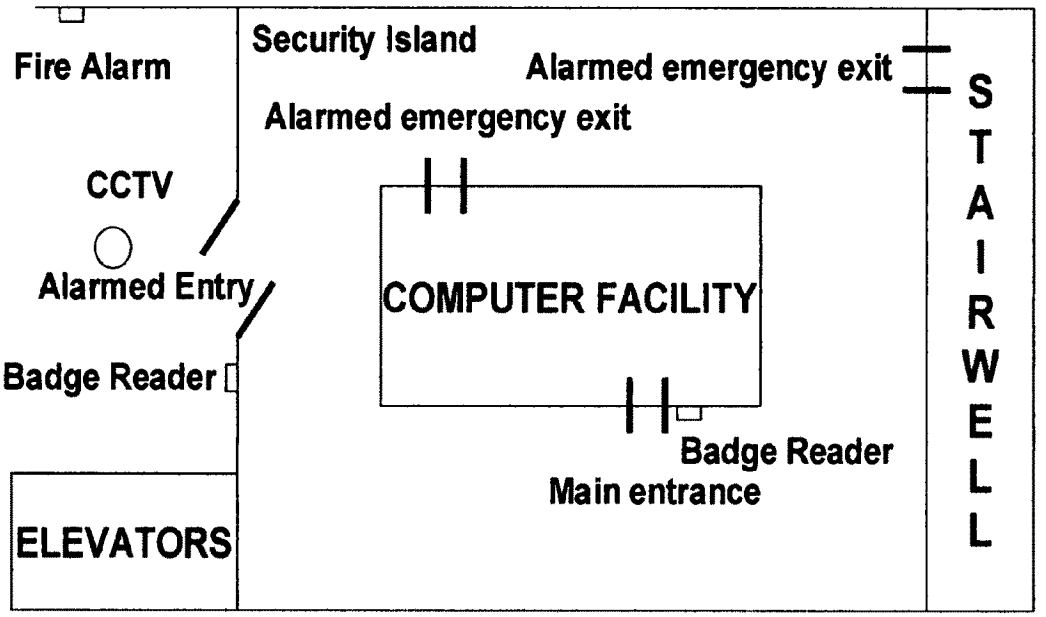
1. Heating & Ventilation Systems
   a. Roof based
   b. At-ground intake
2. SCADA Rooms & Controls
3. Mass Gathering Areas
   a. Cafeterias
   b. "Open design areas"
   c. Courtyards
4. Parking
   a. Perimeter parking
   b. Subterranean parking
5. Ingress & Egress Points
   a. Roof access
   b. Utility tunnels
   c. Main entrances & exits
   d. All other doorways
   e. Loading Dock & Storage
6. Cabling & Communications
   a. Electrical
   b. Communications
   c. Computer cabling
7. Physics Stress Locations

FIGURE 11 A



8. Water
   a. Water intake
   b. Water distribution systems
9. Sanitation & Sewer
10. Power
   a. Back-up power
   b. Immediate power for critical systems
11. Perimeter Buffer Zones
12. Elevators & Stairways
13. Security Systems
14. Safety Systems
   a. Fire suppression systems
   b. Fire and other emergency alarms
15. Other

FIGURE 11 B



Average guard force response to an alarm for this area = 4.2 minutes

FIGURE 12

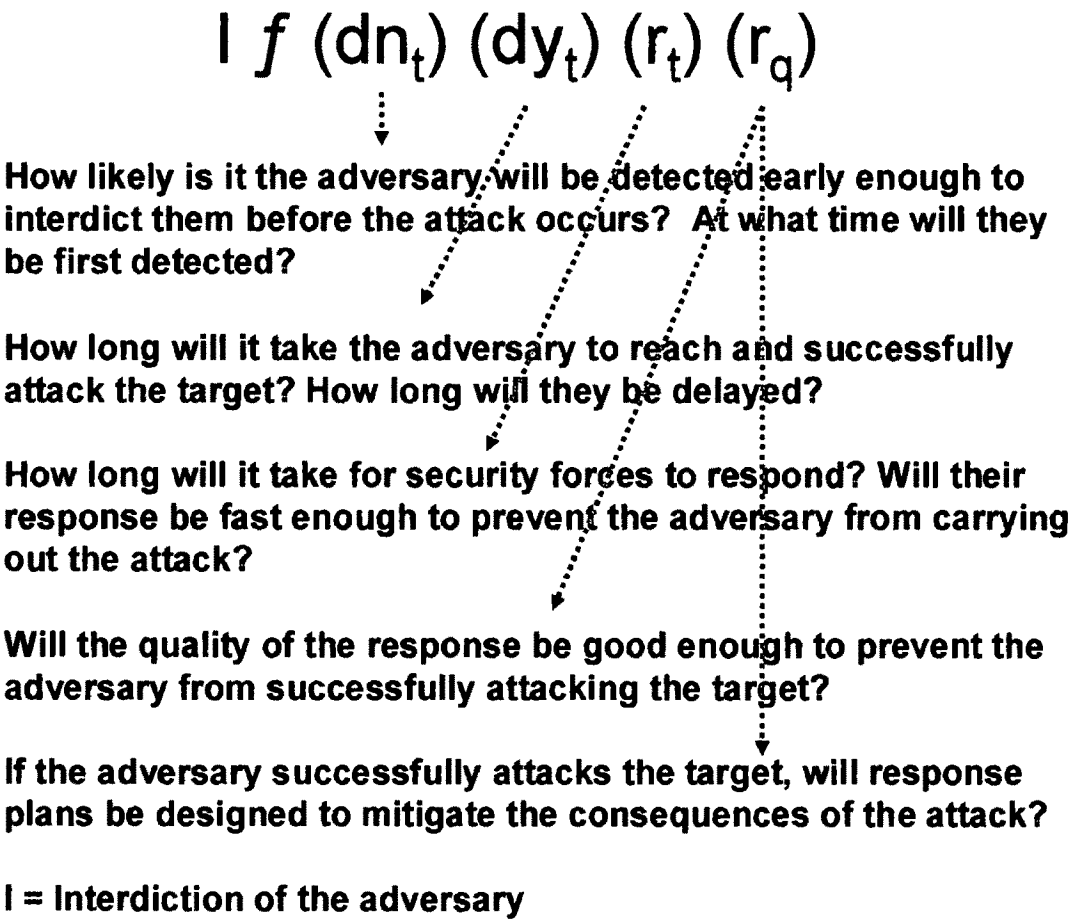

I f (dn$_t$) (dy$_t$) (r$_t$) (r$_q$)
How likely is it the adversary will be detected early enough to interdict them before the attack occurs? At what time will they be first detected?
How long will it take the adversary to reach and successfully attack the target? How long will they be delayed?
How long will it take for security forces to respond? Will their response be fast enough to prevent the adversary from carrying out the attack?
Will the quality of the response be good enough to prevent the adversary from successfully attacking the target?
If the adversary successfully attacks the target, will response plans be designed to mitigate the consequences of the attack?
I = Interdiction of the adversary

FIGURE 13

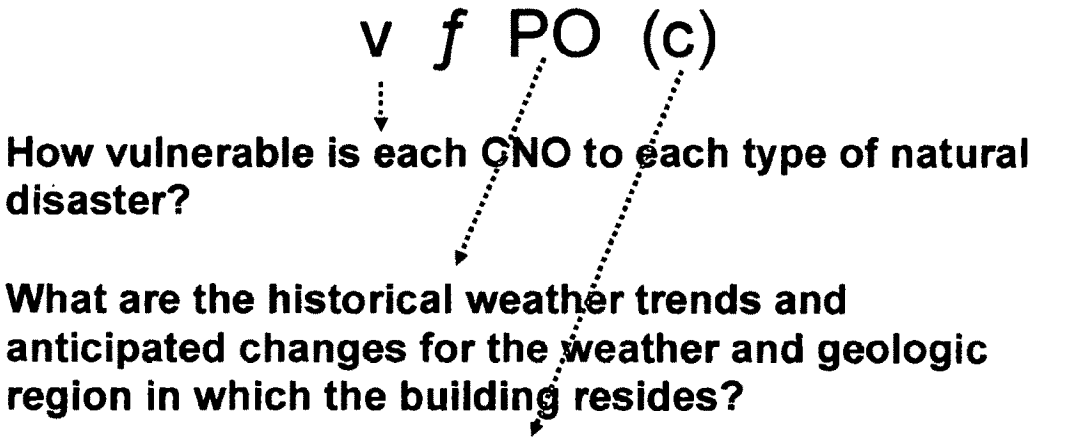

v f PO (c)
How vulnerable is each CNO to each type of natural disaster?
What are the historical weather trends and anticipated changes for the weather and geologic region in which the building resides?
What are the "worst case" consequences to each critical node should it be subjected to the worst case historical trend or anticipated natural event?

FIGURE 14

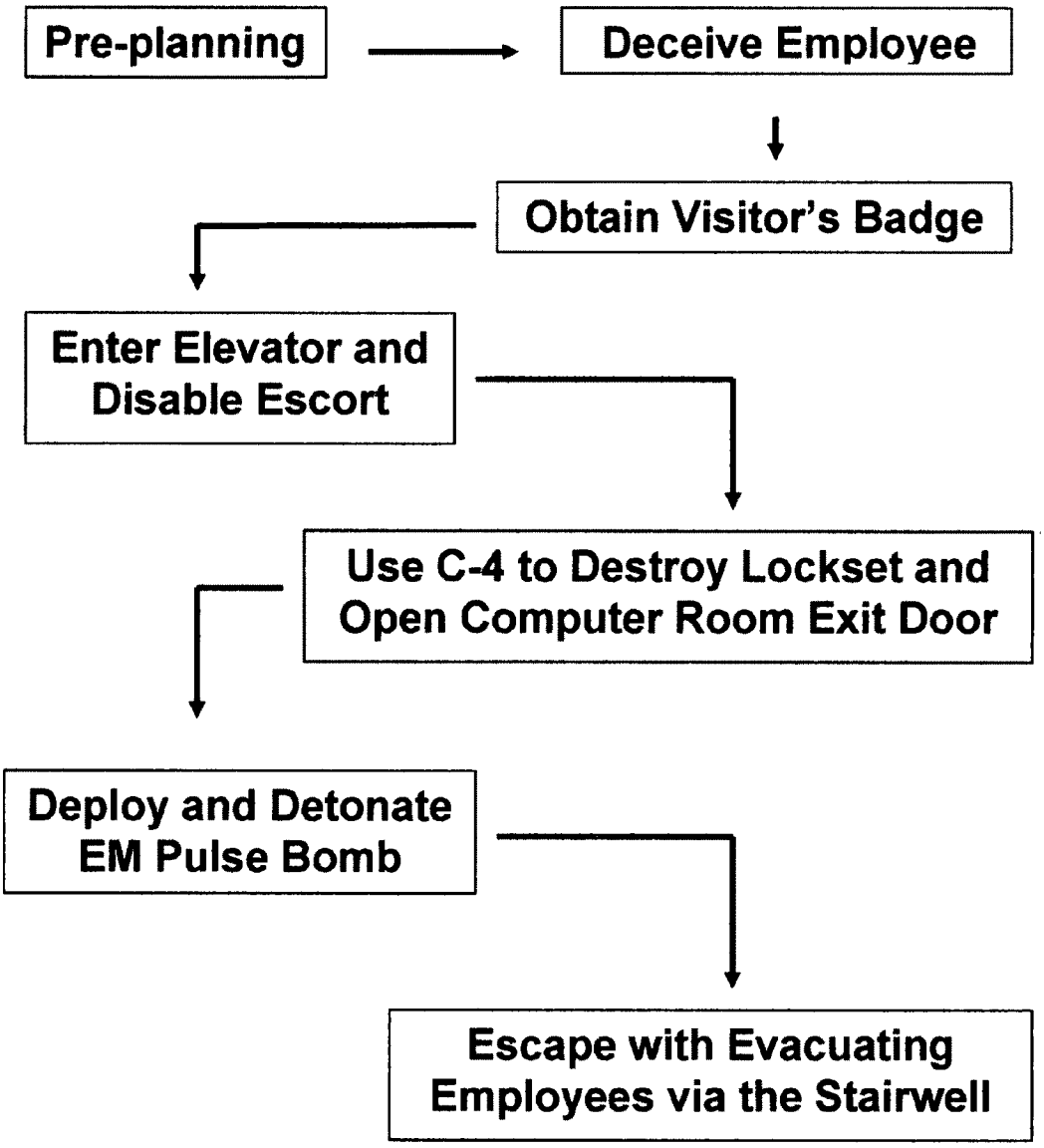

Pre-planning
Deceive Employee
Obtain Visitor's Badge
Enter Elevator and Disable Escort
Use C-4 to Destroy Lockset and Open Computer Room Exit Door
Deploy and Detonate EM Pulse Bomb
Escape with Evacuating Employees via the Stairwell

FIGURE 15

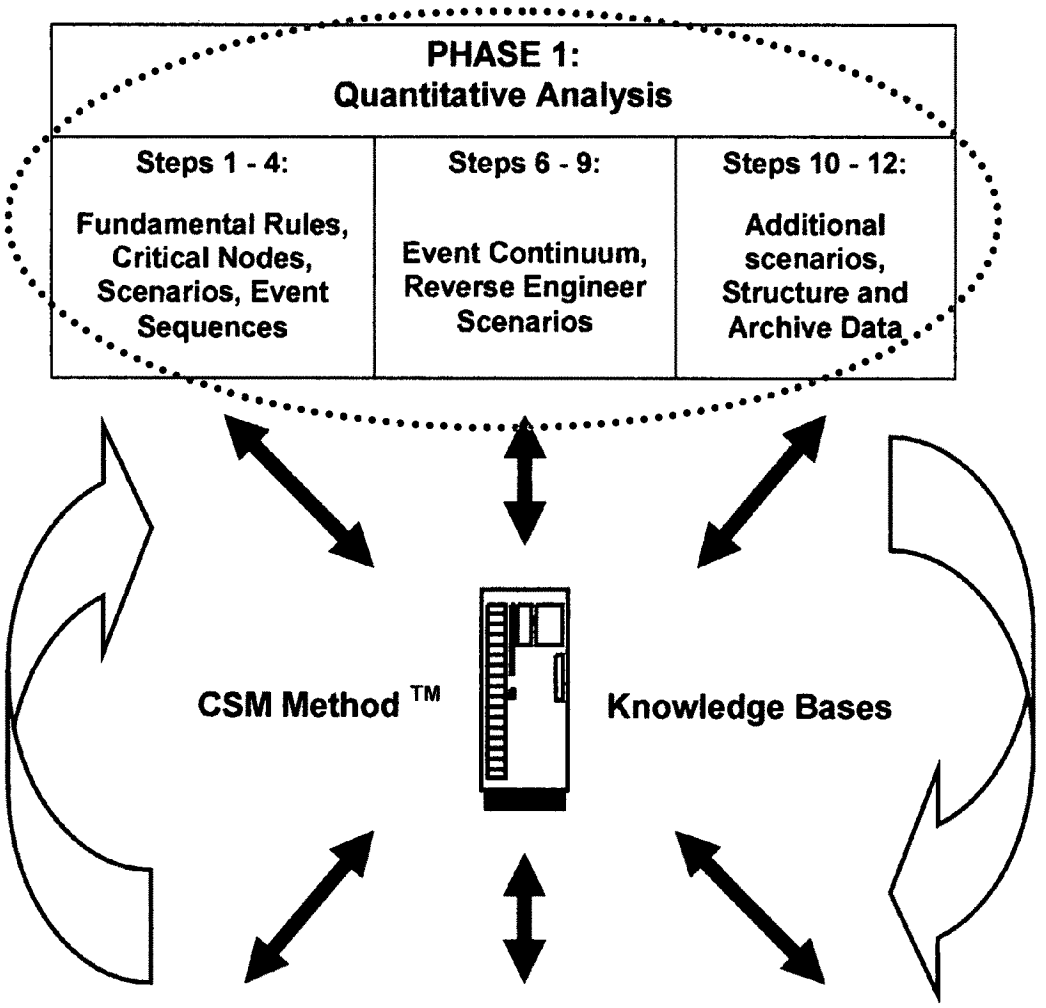

PHASE 1:
Quantitative Analysis
Steps 1 - 4:
Fundamental Rules, Critical Nodes, Scenarios, Event Sequences
Steps 6 - 9:
Event Continuum, Reverse Engineer Scenarios
Steps 10 - 12:
Additional scenarios, Structure and Archive Data
CSM Method ™
Knowledge Bases
PHASE 3:
Subsequent CSM Interventions
Steps 24 - 25:
Additional Immersions, Use Decision Templates
Step 23:
Reassess Fundamental Rules
PHASE 2:
Qualitative Analysis
Steps 13 – 22:
Integrate Quantitative Reality with Human Social Process

FIGURE 16

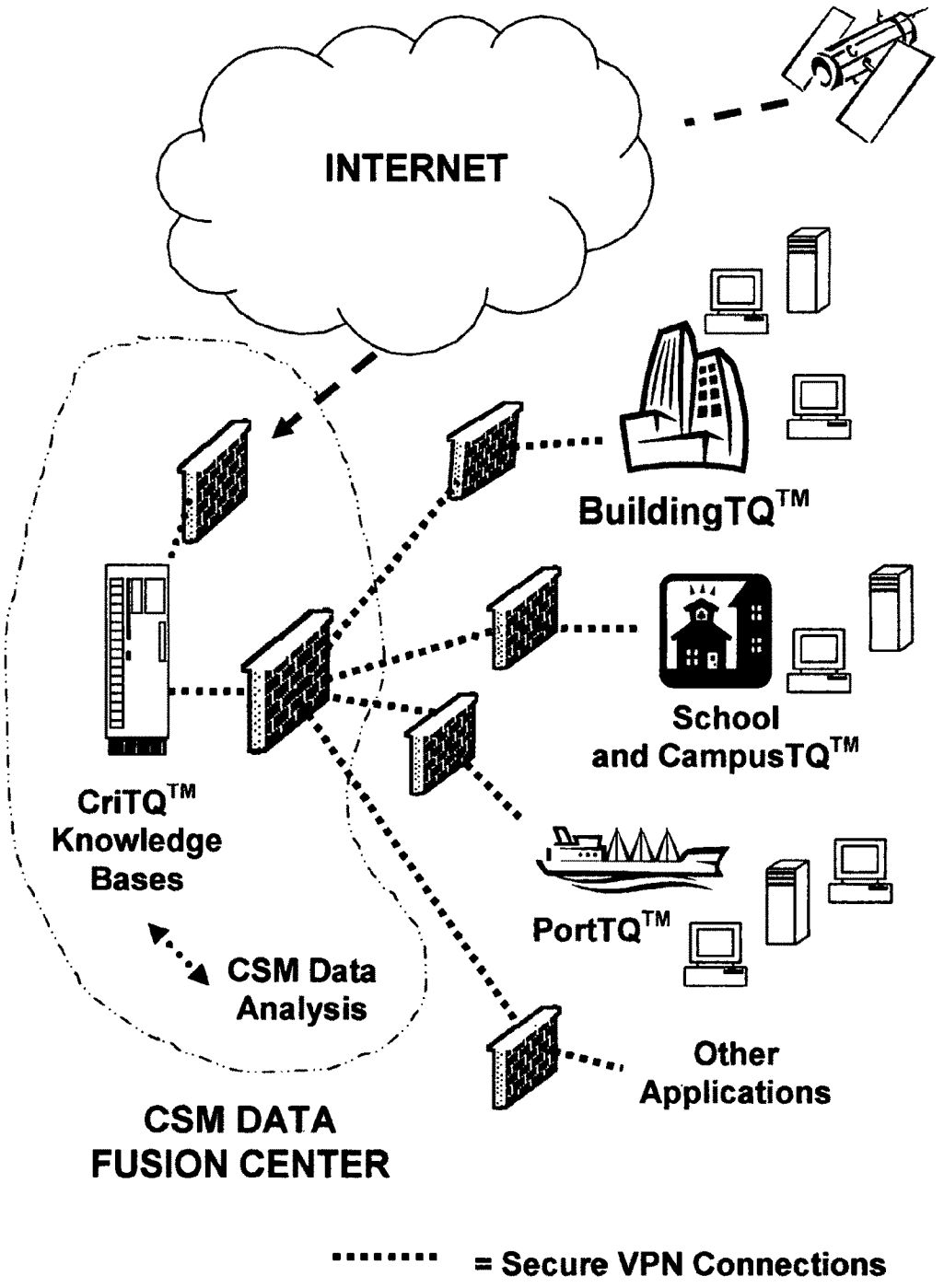
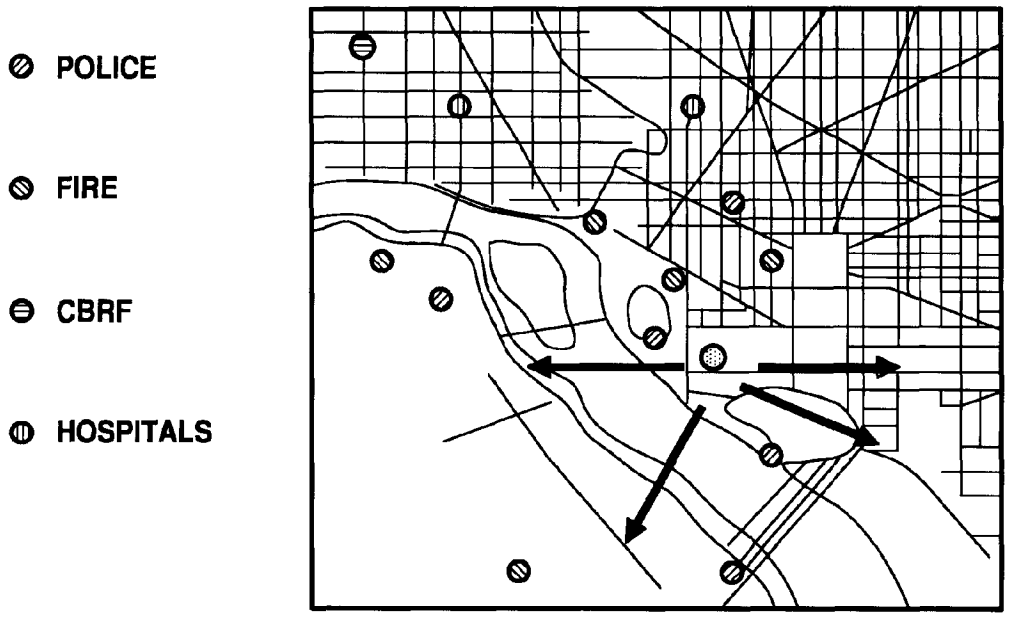

INTERNET
BuildingTQ™
School and CampusTQ™
PortTQ™
Other Applications
CriTQ™ Knowledge Bases
CSM Data Analysis
CSM DATA FUSION CENTER
= Secure VPN Connections

FIGURE 17



POLICE: 8 Minutes earliest response
CBRF: 30 minutes earliest response
Fire: 11 minutes earliest response
HOSPITAL: 23 minutes distant

FIGURE 18

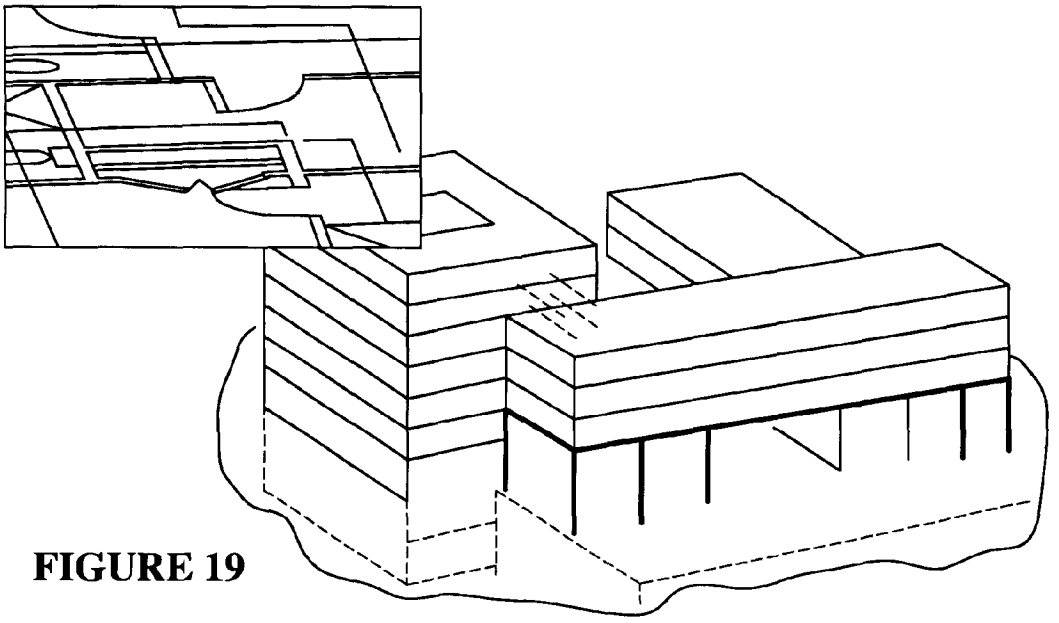
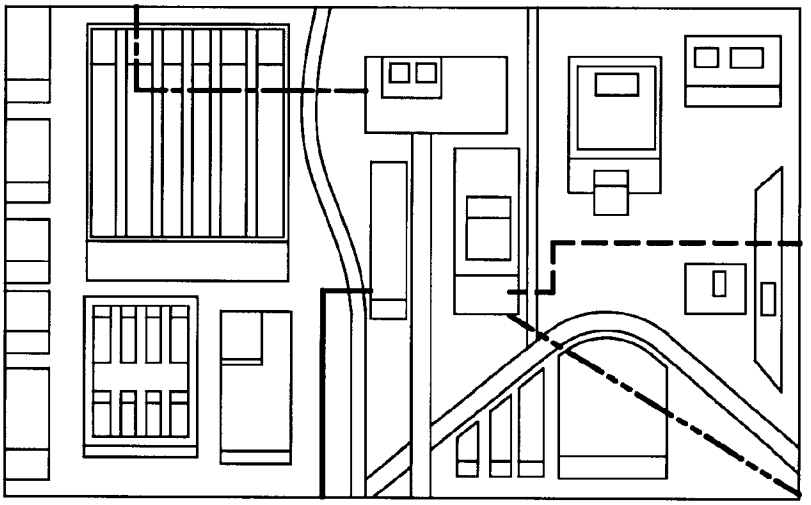


FIGURE 19



Sanitation

Main Potable Water Line

Power

Primary Communications Trunk Line

FIGURE 20

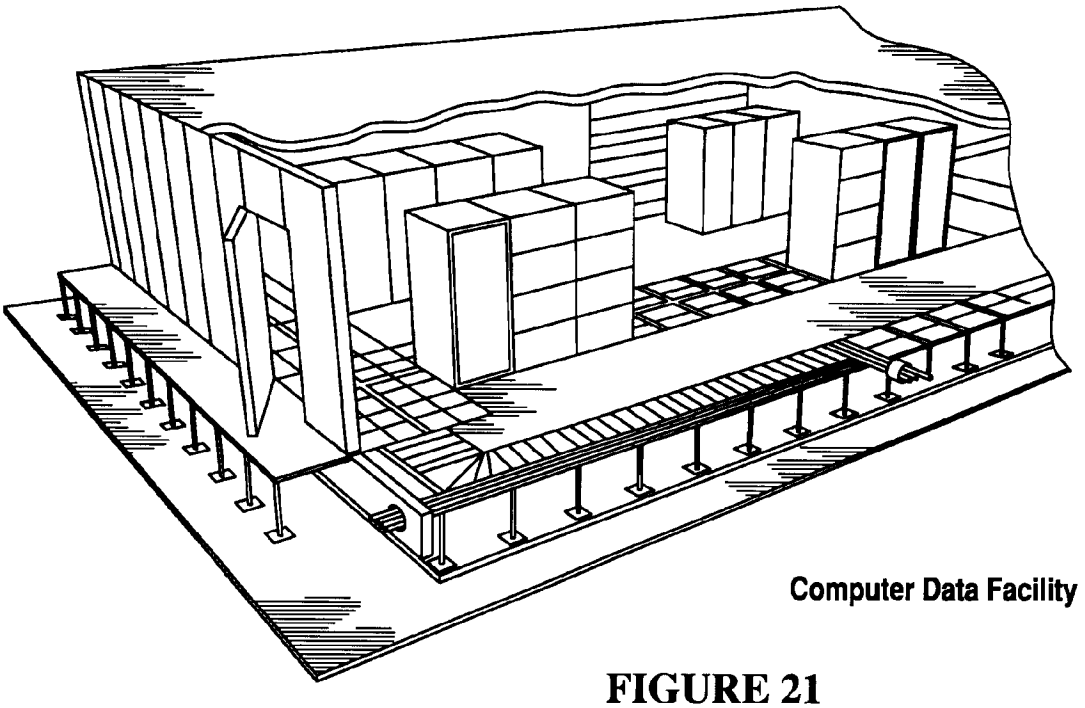


FIGURE 21

COMPLEXITY SYSTEMS MANAGEMENT METHOD

Priority is claimed to provisional U.S. Patent Application No. 60/812,591 filed on Jun. 12, 2006.

BACKGROUND OF INVENTION

Today's principle methods of scientific inquiry continue to rely heavily on the linearity of systems, reductionism, certainty of measurement, the reversibility of systems and induction as the best way to understand and manage complex systems. This reliance on deterministic methods of scientific inquiry continues in spite of overwhelming scientific evidence that when systems reach certain thresholds of complexity deterministic methods of inquiry are no longer effective.

Effective methods to integrate quantitative scientific reality with qualitative human social process in the management of complex events and situations are illusory. Frequently, scientific reality is misunderstood, ignored or denied as the result of qualitative social pressures. For example, overwhelming scientific evidence that human generated emissions of green house gasses into the atmosphere were contributing in a significant way to global warming has existed for many decades. But only with the rapid and highly visible melting of the polar ice caps and rapidly rising sea levels, has the world community begun to take the potentially catastrophic consequences of global warming seriously.

While computer technology has greatly influenced our ability to store, gather and share data, it is utilized in ways that continue to rely heavily on deterministic methods of scientific inquiry. The use of computer technology to support deterministic methods of scientific inquiry continues in spite of overwhelming scientific evidence that when systems reach certain thresholds of complexity deterministic methods of inquiry are no longer effective.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a scientifically derived alternative to the continued reliance on the linearity of systems, reductionism, certainty of measurement, the reversibility of systems and induction as the best way to understand and manage complex systems.

It is an object of the present invention to provide an effective science-based method for analogously integrating quantitative scientific reality with qualitative human social process in ways that allow for the more effective management of complex events and situations.

It is an object of the present invention to provide a systematic process for deriving, structuring and manipulating data using computer technology that accounts for the non-deterministic behaviors of complex adaptive systems, supports the integration of quantitative reality with human social process, and assists human beings in the more effective management of complex events and situations.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1**. depicts the CSM Method as a three phase, multi-step, computer supported business process method.

FIGS. **2**.A. and **2**.B. present a detailed process flow diagram of Phase 1. of the CSM Method.

FIG. **3**. A. presents the current center of gravity for risk management as a function of reaction and response and illustrates the risk event continuum.

FIG. **3**. B. shows that under the complexity systems management method the new center of gravity for risk management shifts from reaction and response to anticipation and prevention and illustrates the risk event continuum.

FIG. **4**. A. shows the current center of gravity for benefit management as a function of reaction and short-term sustainment and illustrates the benefit event continuum.

FIG. **4**. B. shows that under the complexity systems management method the new center of gravity for benefit management shifts from reaction and short term sustainment to anticipation and long-term sustainment of benefit.

FIGS. **5**.A., **5**.B. and **5**.C. present a detailed process flow diagram of Phase 2. of the CSM Method.

FIG. **6**. presents a diagram of the CSM Method Consensus Team Decision Model.

FIG. **7**. presents a diagram of a CSM Method immersion.

FIG. **8**. presents a detailed process flow diagram of Phase 3. of the CSM Method.

FIG. **9**. presents the CSM Method as using a common approach by depicting that all applications of the CSM Method systematically implement the six tenets of a priori optionality.

FIG. **10**. presents a diagram of the common CSM Method IT enterprise architecture.

FIG. **11**. A. presents a notional example of a BuildingTQ computer visualization of critical nodes 1. through 7. of building operations.

FIG. **11**. B. presents a notional example of a BuildingTQ computer visualization of critical nodes 8. through 14. of building operations.

FIG. **12**. presents a schematic diagram of the sensitive computer facility in the building that is the target of the adversary attack.

FIG. **13**. presents the Estimate of Event Sequence Interruption (EESI) algorithm.

FIG. **14**. presents the Weather and Geological Events (WGE) algorithm.

FIG. **15**. presents a computer visualization of a risk event sequence for the surreptitious entry and destruction of computer data facility.

FIG. **16**. illustrates that the automation of the CSM Method focuses on the systematic implementation of the tenets of a priori optionality and Phase 1. of the CSM Method.

FIG. **17**. illustrates that the supporting CSM Method CriTQ architecture is securely connected over a virtual private network (VPN).

FIG. **18**. illustrates a geographical plot of the time and quality of external response and evacuation routes.

FIG. **19**. illustrates Cad-cam or dedux renderings of building plans.

FIG. **20**. illustrates a geographical plot of a building's supportive infrastructures.

FIG. **21**. illustrates an example of a critical mode rendered as a 3-D image.

DETAILED DESCRIPTION OF INVENTION

The Complexity Systems Management (CSM) Method is a scientifically derived business process that enhances the human understanding of complex adaptive systems and the improved management of complex events and situations.

The CSM Method is based on scientific evidence that systems are continuously evolving based on systems of systems interactions, i.e., systems are complex and adaptive. The CSM Method is based on scientific evidence that the exact predictability of outcomes when systems reach certain thresholds of complexity is not possible. The CSM Method

uses a new scientifically derived business process method to project, versus predict, a range of potential outcomes including non-linear excursions and counter intuitive events that may occur in complex adaptive systems. The projection of a range of potential outcomes, versus exact predictability of outcomes is an object of the present invention.

The CSM Method is based on new scientific evidence that renders obsolete the principle methods of scientific inquiry hitherto used to manage complex systems. The scientific process of triangulation has identified the specific frames of reference used to conceive the predominant methods of scientific inquiry into the behaviors of complex systems and four proven scientific breakthroughs of science. Triangulation is the application and combination of several research methodologies in the study of the same phenomenon. As opposed to relying on one single form of evidence or perspective as the basis for findings, multiple forms of diverse and redundant types of evidence are used to check the validity and reliability of the findings. This is of great importance in said invention because hitherto abstract concepts, notions and subjective views are now, for the first time, rendered in concrete and tangible form suitable for scientific analysis. The identification of specific frames of reference for conceiving the predominant methods of scientific inquiry into the behaviors of complex systems and four proven scientific breakthroughs of science is an object of the present invention.

When the existing frames of reference for today's principal methods of scientific inquiry are compared and contrasted, the scientific evidence shows that they are not sufficient to explain the behaviors of complex adaptive systems. With the emergence of complexity science, a new set of frames of reference emerges rendering obsolete previous methods of scientific inquiry into the behaviors of complex adaptive systems. This is highly significant because the frames of reference for complexity science render obsolete today's predominant methods of scientific inquiry used to explain the behaviors of complex adaptive systems. The discovery of scientific evidence revealing that today's principal methods of scientific inquiry are not sufficient to explain the behaviors of complex adaptive systems is an object of the present invention.

Using the scientific process of triangulation, the specific frames of reference for the two principal methods of scientific inquiry and each of the four breakthroughs of science are identified through the process of triangulation. With the emergence of complexity science five frames of reference predominate, namely, non-linearity, holism, uncertainty (of measurement), irreversibility (of systems) and deduction. The scientific derivation of the specific frames of reference for the two principal methods of scientific inquiry and four breakthroughs of science in concrete and tangible form suitable for scientific analysis is an object of the present invention.

A Priori Optionality is Based on Six Tenets

The five frames of reference of non-linearity, holism, uncertainty (of measurement), irreversibility (of systems) and deduction form a new principle of science called a priori optionality. A priori optionality systematically applies these five frames of reference to enhance the understanding of complex adaptive systems and the management of complex events and situations. Based on these five frames of reference, six tenets were scientifically derived to create a new method of scientific inquiry to guide the systematic implementation of the CSM Method business process, namely:

1. The application of linear deterministic methods, when coupled with the imprecise mathematical constructs we use to measure large complex systems, contribute to the inability to predict with precision the future behavior of any complex system.
2. Because of the irreversibility of systems, systems of systems interactions, i.e., interdependencies, and randomness, there can be no single exact prediction of the future behavior of a complex system or system of systems.
3. There exist no absolute bounds of certainty in a complex system within which different behaviors may occur. This is because the bounds within which different behaviors, i.e., events, occur change based on the evolving adaptations of the system itself resulting from continuous systems of systems interactions with the environment in which it exists. In such environments, nothing is ever exactly predictable because nothing ever stays exactly the same.
4. The irreversibility of systems, systems of systems interactions and randomness show that nothing that has happened in the past will ever occur again exactly as it occurred initially. Only by thinking about a range of potential events that may occur within the bounds of the patterns of behavior we observe in complex systems can we predict, albeit in inexact terms, a possible range of future behavior of any complex system.
5. Because of the compounding effects of systems of systems interactions and randomness, as systems become larger and larger the validity of the assumptions upon which we explain the behavior of complex systems must be continuously assessed to revalidate the fundamental rule sets that define the patterns of behavior we observe in large complex systems.
6. While the exact prediction of the future behavior of complex systems is not possible, the potential future behaviors of a complex system can be imprecisely projected. In complex systems, fundamental rule sets bound how initial conditions propagate to produce different systems behaviors. Because of systems of systems interactions, i.e., system interdependencies, we must continuously revalidate the fundamental rule sets we use to define the bounds of a system's behavior.

The scientific derivation of the six tenets of a priori optionality to form a new method of scientific inquiry into the behaviors of complex adaptive systems is an object of the present invention.

The CSM Method is a Computer Supported Three Phase, Multi-Step Process that Systematically Implements the Six Tenets of a Priori Optionality

As depicted in FIG. **1**., the CSM Method is a computer assisted, three-phase, multi-step process that systematically implements the six tenets of a priori optionality to produce a new business process method for managing complex adaptive systems and complex events and situations. Specified data produced by the process is structured for repeatability, digitized and archived in a CSM Method knowledgebase that is updated as an integral part of the CSM Method business process. The unique means of structuring data for repeatability under the CSM Method business process is an object of the present invention.

Phase 1: Quantifying Complex Systems Behaviors

FIGS. **2**.A. and **2**.B. present a process flow diagram of the Phase 1: Quantifying Complex Systems Behaviors multi-step process used to systematically implement the CSM Method based on the six tenets of a priori optionality. Phase 1. of the CSM Method consists of twelve distinct process steps. Each step of Phase 1. of the CSM Method is described in detail below. The purpose of Phase 1. of the CSM Method business process is to quantitatively examine the behavior of a complex system. During Phase 1., complex systems are examined

from the holistic frame of reference to identify patterns of interest, i.e., behaviors, exhibited by a complex system or systems of systems.

During phase 1., selected patterns of complex systems behavior are quantified and "reverse engineered." For example, a traffic system is one example of a complex adaptive system that may exhibit many different patterns of behavior. A traffic jam at a particular location is just one example of a traffic system exhibiting a pattern of behavior that can be quantified and reverse engineered.

Complexity scientists hold that a holistic perception of a system (or interacting systems of systems) beginning with deduction can lead to the observation of simplicities or patterns that can provide insights about the behavior of complex systems or systems of systems.

Scientific evidence shows that the behavior of complex interdependent systems can be understood by identifying the underlying rule sets, i.e., fundamental rule sets that define their patterns of behavior. For example, all traffic jams can be explained, at their most fundamental level, in terms of three simple rules. First, the driver of an automobile by applying foot pressure on the accelerator can choose to speed up a vehicle. Second, the driver of an automobile by relieving foot pressure on the accelerator can choose to slow down a vehicle. Third, the driver by applying foot pressure on the brake can slow down or completely stop a vehicle.

Scientific evidence shows that variations in initial conditions, e.g., volume of traffic, number of lanes, weather conditions, the aggressiveness of individual drivers, enforcement of speed limits and many other factors can influence in what combinations individual drivers exercise these three basic rules and how the effects of their individual behaviors multiply. Thus, the right combination of driving conditions and how this influences the exercise of these basic rules by drivers can either cause or prevent traffic jams. But, of course, the wild card in all of this is the assumption that drivers will act rationally and respond in a consistent fashion to initial and subsequent changes in driving conditions. All of us know too well that human beings do not always act rationally—some drink while driving, pass in violation of double yellow solid lane markings, engage in acts of road rage, enter into high speed chases with the police and otherwise behave in ways that defy rational explanation—at least in quantitative analytical terms.

In complex systems we are also confronted with the notion of randomness as a fundamental characteristic of nature. In complex systems this means that even minor deviations in initial conditions due to random deviation can produce unimaginably different end states. The notion of randomness renders obsolete the positivist reliance on linear cause and effect, certainty of measurement, the reversibility of systems, reductionism and induction as the best way to understand the behaviors of complex systems. Scientific evidence that the notion of randomness renders obsolete the positivist reliance on deterministic methods to best understand complex systems is an object of the present invention.

Fundamental rule sets that bound patterns of behavior in complex systems are deduced using analogous scientific methods. Science tells us that metaphor is a figure of speech that we transfer to something that is not directly applicable in order to illuminate by highlighting or providing a unique interpretation. For example, we often hear politicians and economists say things such as "we need to put the brakes on inflation" or "we need to step on the accelerator to speed up the economy." But while metaphors help to illuminate, politicians and economists do not really mean that we should design a macroeconomic policy or system based on the parts of a car. Scientists go on to say that analogy is different because it asserts some level of direct similarity or difference between the elements of two or more different domains and the causal relationships driving them. Analogies are usually used to connect one well-understood domain to one less well understood by extrapolating similarities. Science tells us that using analogy to extrapolate between domains one can then devise empirical tests to prove or disprove similarities or differences as one moves from one well-understood domain to another less understood domain. For example, one leading scientist on the behavior of complex systems reminds us that Huygens extrapolated the wave theory of light based on the better-understood and empirically tested notions of sound waves. Similarly, he tells us that Fourier's theory of heat conduction was based on better-known laws associated with the flows of liquids (Rosenhead, 1998). The use of analogous methods for scientific extrapolation using the CSM Method is an object of the present invention.

Care is taken to discriminate between initial conditions and fundamental rule sets. In complex systems, fundamental rules sets bound the manner in which initial conditions propagate to produce different behaviors of systems. Multidisciplinary expertise is used to assure that a variety of perspectives and knowledge are brought to bear in deducing fundamental rule sets that define the behavior of a complex system versus the initial condition sets that can affect how the observed behavior may propagate in the complex system. This includes recognition of significant qualitative social process factors that can affect the manner in which human beings exercise the fundamental rule sets defining and bounding the propagation of patterns of complex systems behavior that are addressed as part of Phase 2. of the CSM Method business process. The systematic integration of quantitative reality with human social process is an object of the present invention.

Based on the fundamental rule sets defining the behavior being observed, the critical nodes of system operation are determined. The critical nodes of a complex system are those core interrelationships within the system itself that are particularly sensitive to changes in initial conditions. The critical nodes of a complex system, if significantly affected, upset the equilibrium of a system and result in its evolution or devolution. This is akin to the scientific findings that the stability of a turbulent gaseous system is a function of energy gain or loss as described in dissipative structure theory (Prigogine, 1998). It is also akin to the deduction of rule sets that discriminate between initial conditions and fundamental rule sets as exemplified by traffic systems and the occurrence of traffic jams (Resnick, 1999). The characterization of critical nodes as those core interrelationships within the system itself that are particularly sensitive to changes in initial conditions, is an object of the present invention.

Since the application of linear deterministic methods, when coupled with the imprecise mathematical constructs we use to measure complex systems contribute to our inability to precisely predict the future behavior of any complex system, a range of potential scenarios of potential future systems behaviors are developed. Using fundamental rule sets to define and bound potential systems behaviors, a range of possible scenarios using different combinations of initial conditions that affect the critical nodes of the system are derived. These scenarios reflect the different ways in which human beings can exercise fundamental rule sets to propagate an array of potential outcomes. Abandoning the notion of exact predictability in complex systems due to randomness and the imprecision of the mathematical constructs we use to measure complex systems is an object of the present invention.

Each potential scenario that could affect a critical node of system operation is reverse engineered. During the process of reverse engineering each critical node of system operation, the initial conditions that affect the critical node of system operation are identified. The specific series or sequence of events for each scenario that would have to occur to significantly affect each critical node of operation is identified. This is known as an "Estimate of Event Sequence Interruption (EESI)". This is accomplished using real or imaginary combinations of initial conditions and assessing their relative impact on the manner in which fundamental rules sets are exercised to propagate a pattern of behavior in a complex system. The development and application of the EESI algorithm is an object of the present invention.

As scenarios are reverse engineered, great care is taken to identify and structure the precise events and the sequence in which they must occur for a given event to take place in the real world. For risk applications, scenarios are structured along a time continuum that begins with earliest possible detection of an adverse event moving sequentially through deterrence, prevention, response and the mitigation of consequences should the event occur. The structuring of exact event sequences along a time continuum using the CSM Method is an object of the present invention.

Structured responses to the following two questions are developed for each hypothetical risk scenario: 1) what information had it been known before the adverse situation happened could have been used to prevent it from happening in the first place? and; 2) what information had it been known before the adverse situation occurred could have used to mitigate its consequences? These become the warnings of impending adverse events and the subject of structured intelligence data collection strategies designed to identify warning signals as early as possible to interrupt event sequences in order to prevent adverse outcomes before they occur. Specific warnings of impending adverse events and structured intelligence data collection protocols to proactively identify these warning signals is an object of the present invention.

For benefit applications, scenarios are structured along a time continuum that begins with earliest possible recognition of an opportunity moving sequentially through strategy development to take advantage of the opportunity, specific actions to capture the opportunity and short and long-term sustainment of beneficial outcomes. Structured responses to the following two questions for each real or hypothetical benefit scenario are developed: 1) what information had it been known before the opportunity was first recognized could have been used to recognize and act on it sooner? and; 2) what information had it been known beforehand could have been used to sustain the benefits of the opportunity longer? These become the indicators of impending opportunities and the subject of structured intelligence data collection strategies designed to identify opportunities as early as possible and sustain optimum event sequences, i.e., those of greatest benefit, in both the short and long term. The derivation of specific indicators of impending opportunity and structured intelligence data collection to identify these indicators as early as possible is an object of the present invention. Quantitative, i.e., science-based, models are used to analogously extrapolate the extended order effects of the outcomes of possible decisions that could be made to manage each scenario. This is significant because the CSM business process discriminates between the uses of metaphor in favor of science-based analogical rigor. The application of analogical rigor (versus metaphorical fancy) as a scientific tool to extrapolate from one well known knowledge domain to another is an object of the present invention. Computer supported collaborative tools such as Group Systems and Meeting Works® are used to guide and consistently structure knowledge generation and capture.

Consistent with the tenets of a priori optionality, the relative impacts of initial conditions expressed as mathematical values are imprecise because of the irreversibility of systems, continuous systems of systems interactions and the imprecision of the mathematical constructs we use to measure complex systems. In other words, the CSM business process is based on the fundamental premise that there exist no single correct answers to explain complex system behaviors. For this reason, specific sequences of events and different combinations of initial conditions (in a real or imagined system) are considered in terms of a range of potential outcomes as bounded by fundamental rule sets. The fundamental premise that there exist no single correct answers to explain complex system behaviors and the requirement to analyze a plurality of potential event outcomes within the bounds of fundamental rules is an object of the present invention.

Consistent with the tenets of a priori optionality we recognize that the bounds within which patterns of systems behavior arise are inexact and ever-changing because of systems of systems interactions that affect fundamental rule sets. The fundamental rule sets, initial conditions, sequence of events and the potential outcomes for each scenario involving a critical node of operation, the warnings of adverse situations and the indicators of opportunity situations are structured, catalogued and archived in a supporting CSM Method computer knowledgebase. Utilizing the same rule sets initially deduced, an array of future system behaviors can then be simulated by adjusting the relative values of initial conditions affecting the manner and degree to which fundamental rule sets are exercised to propagate system behaviors that can, in turn, affect critical nodes of systems operation. The scientific finding that initial conditions affect the propagation of fundamental rules to produce different systems behaviors is an object of the present invention.

The assumptions, upon which fundamental rule sets are initially deduced, however, must be continually reassessed based on systems of systems interactions. For example, significant step advances in technology development can change the fundamental rule sets upon which complex systems behave. In the case of a traffic system and the application of analogy, imagine a future time; say 150 years from today, when personal vehicles operate on the principle of magnetic levitation via centrally controlled computer secure automated data acquisition (SCADA) networks in order to optimize safe, efficient and very large volume traffic flows in highly complex traffic systems. While the observed behavior of speeding up, slowing down and stopping a vehicle remains the same, the fundamental rule sets defining and bounding the behavior of the traffic system would have significantly changed. In such a different traffic system, the notion of a driver putting their foot on the brakes to stop the vehicle would no longer represent a fundamental rule of the behavior of the traffic system. The fundamental rule set guiding the behavior of the complex traffic system has changed and with it, the relative importance of initial conditions that propagate how system behaviors will multiply. The scientific finding that the assumptions upon which fundamental rule sets are deduced must be continually reassessed based on systems of systems interactions is an object of the present invention.

Phase 1. of the CSM Method business process is concluded by developing simulations that portray a projected range of systems behavior based on interactions among critical nodes using the data previously developed and archived in the supporting CSM Method knowledgebase. These simulations are

designed to reflect complex interdependencies among different critical nodes and their effects on outcomes. As depicted in FIGS. **3**. A. and **3**.B., for risk applications, storyboards follow an event continuum from earliest possible detection of an adverse event through deterrence, prevention, response and mitigation of consequences. Special attention is paid to the relationships between and among deterrence, detection, prevention, response, mitigation and recovery. For example, actions taken to respond to a given event can have a major effect on mitigating the consequences of an event. Mitigating the consequences of an adverse event can positively affect long term recovery. The creation of risk event continuum from earliest possible detection of an adverse event through deterrence, prevention, response and mitigation of consequences is an object of the present invention.

FIG. **3**. A. illustrates that the current center of gravity for risk management rests on reaction with principal attention focused on ex post facto response to events. Scientists remind us that if organizations fail to prevent adverse events that can quickly escalate from contingencies to disasters to catastrophes, they lose competitive advantage.

FIG. **3**. B. illustrates the shift in the center of gravity from react and respond to the anticipation and prevention of adverse events under the CSM Method business process. If organizations can prevent adverse events before they happen or more effectively mitigate their consequences they gain competitive advantage. The systematic method used under the CSM Method to prevent adverse events before they happen or, when necessary, more effectively mitigate their consequences is an object of the present invention.

As depicted in FIGS. **4**. A. and **4**. B., for benefit applications, storyboards follow an event continuum from the earliest possible recognition of opportunity, through the development of a strategy to exploit the opportunity, the implementation of a strategy to capture the opportunity, the short-term sustainment of the opportunity to the long-term sustainment of the opportunity. Special attention is paid to the relationships between and among opportunity recognition, strategy development, opportunity capture and short and long-term sustainment. For example, strategies used to capture an opportunity may affect both short and long-term sustainment.

FIG. **4**. A. illustrates that the current center of gravity for benefit management rests on reaction with principal attention focused on short-term sustainment of opportunity. Scientists remind us if organizations do not recognize opportunity and act to capture and sustain it for the long-term, they can lose their competitive advantage.

FIG. **4**. B. illustrates the shift in the center of gravity from react and short term sustainment to the earliest possible anticipation of opportunity, capture, and long-term sustainment of the benefits of the opportunity under the CSM Method business process. In this way, the organizations of the future will achieve and maintain competitive advantage. The early identification of opportunity events before they happen and their sustainment is an object of the present invention.

Those critical points within a simulation where decisions must be made to exploit the evolution or avoid the uncontrolled devolution of a system are identified. These are called critical decision points. Multidisciplinary teams reverse engineer each critical decision point in a simulation carefully considering the risk and/or benefit continuum and the outcomes and extended order effects of different decision options. The method of identifying critical decision points and the systematic method of reverse engineering them is an object of the present invention.

Out of the range of possible decisions, the optimum decision sets in a simulation that lead to the most desirable outcome(s) are identified. The supporting rationale for selected decisions, in both quantitative and qualitative terms is structured, digitized and indexed using consistent methods to assure repeatability, i.e., understanding the meaning of the data for re-use at t_2, t_3, t_4 and so on, and archived in the supporting knowledgebase. The systematic, science-based process for determining best optimum decision sets is an object of the present invention.

The consequences of decisions and the warnings and indicators of risk or benefit applications, respectively, are identified and structured. Computer supported collaborative tools such as Group Systems and Meeting Works® are used to guide and consistently structure knowledge generation and capture during this process. These computer supported collaboration tools also help to assure the repeatability by organizing both structured and unstructured information as data to a supporting CSM Method knowledgebase in ways that the data can be readily understood by subsequent users, i.e., repeatable information. The methods used to structure data for repeatability is an object of the present invention.

Computer graphic representations of critical nodes of operation, models visualizing systems and systems behaviors, decision outcomes and the extended order effects of decisions to include decision maps, decision fault trees, and other computer visualization techniques are developed in preparation for Phase 2. of the complexity systems method. The use of tailored computer visualization platforms to guide the implementation of the CSM Method and structure data for repeatability is an object of the present invention.

Summary of the Twelve CSM Method Phase 1. Business Process Steps

1. Complex systems are examined from the holistic frame of reference to deduce the fundamental rule sets that define and bound the propagation of a real (or imaginary) system's behavior being observed at t_1. For example, in the case of scientific research on traffic systems, the fundamental rule sets that result in a traffic jam would be deduced using analogous scientific methods. The initial conditions and the fundamental rules sets that bound how initial conditions propagate to produce different systems behaviors are isolated. For example in our traffic system analogy the rule sets bounding the system's behavior to produce a traffic jam, i.e., press your foot down on the accelerator, take your foot off the accelerator and put your foot on the brakes, are discriminated from the initial conditions that affect how the rules are exercised by human beings driving cars, e.g., weather conditions, drunken drivers, road rage, road construction, broken down cars, etc.
2. The complex system is viewed holistically to determine the critical nodes of a system's operation, i.e., those core interrelationships or activities unique to a given system that are particularly sensitive to changes in initial conditions. For example, in the case of a traffic system we could view a geospatial image of a specified geographic area and look for major population centers, the convergence of major roadways where large amounts of traffic must flow and other factors. In a traffic system, such areas would be especially sensitive to the types of initial conditions described in Step 2. because people would be more likely to exercise the three fundamental rule sets in a different combination to produce traffic jams. In this case, an adverse event would lead to more people taking

their foot off the accelerator, applying the brakes and accelerating less frequently and to a lesser degree thus producing a traffic jam.

3. Using fundamental rule sets to define and bound potential systems behaviors, a range of possible scenarios using different combinations of initial conditions that affect the critical nodes of the system at t_1 are derived. For example, in a large traffic system we might consider a severe rainstorm that floods major roadways, a dramatic increase within a specified time period of incidents of road rage, a major accident involving a gasoline fuel truck or other initial conditions that may occur either singly or in combination involving a critical node(s) of a traffic system.
4. Scenarios are developed which identify and structure the precise events and their sequence that must occur for a given event to occur in the real world. See Table 11. and FIG. **15**. For example, in our traffic system example, what initial conditions would have to occur and in what sequence to result in the long term closure of a major interstate highway in relation to the fundamental rules bounding the system?
5. For risk applications scenarios are structured along a time continuum that begins with earliest possible detection of an adverse event moving sequentially through deterrence, prevention, response and the mitigation of the consequences of an event. Structured responses to the following two questions are developed for each hypothetical risk scenario: a) what information had it been known before the adverse situation happened could have been used to prevent it from happening in the first place? and; b) what information had it been known before the adverse situation occurred could have used to mitigate its consequences? These become the warnings of impending adverse events and the attention of structured intelligence data collection strategies designed to interrupt event sequences as early as possible to prevent adverse situations. See Table 11.
6. For benefit applications, scenarios are structured along a time continuum that begins with earliest possible recognition of an opportunity moving sequentially through strategy development to take advantage of the opportunity, specific actions to capture the opportunity and short and long-term sustainment of benefit. Structured responses to the following two questions for each hypothetical benefit scenario are developed: a) what information had it been known before the opportunity was first recognized could have been used to recognize and act on it sooner? and; b) what information had it been known beforehand could have been used to increase and sustain the benefits of the opportunity longer? These become the indicators of impending opportunities and sustainment and the subject of focused intelligence data collection strategies designed to identify opportunities as early as possible and sustain optimum event sequences, i.e., those of greatest benefit in the short and long term. See FIGS. **4**. A. and **4**. B.
7. Each scenario is reverse engineered to isolate how potential i would affect the manner in which people exercise the fundamental rule sets that in combination serve to propagate systems behaviors that, in turn, affect the critical nodes of a system's operation. For example, using the traffic system analogy how might a snowstorm leading to the jack-knifing of gasoline tanker on a major interstate at mile marker 7 during rush hour affect the manner in which people would exercise the three fundamental rule sets that result in traffic jams? Values representing the relative effect of one or a combination of initial conditions on the manner in which fundamental rule sets are exercised to propagate a systems behavior observed at t_1 are derived and considered in terms of their potential outcomes. For example, suppose the snowstorm alluded to above was only minor relative to normal snowfalls during a storm and average seasonal weather conditions for the area. But the jack-knifing of the gasoline fuel tanker resulted in a rupture of the tank requiring road closure and the dispatch of special environmental response teams for clean up. And, suppose that an intersection with another feeder interstate roadway known for its very heavy traffic volumes during rush hour was located at mile marker 7 and the tanker jack-knifed at the height of rush hour. What would be the relative importance and sequence of these initial conditions in affecting how people would exercise the three fundamental rules bounding the occurrence of a traffic jam? Clearly, conditions such as these would affect the manner in which people exercise fundamental rule sets leading to traffic jams. More time spent with your foot on the brake instead of on the accelerator. The immediate effect would be a traffic jam. Extended order effects could include delays in clean up because of weather conditions, blockage of emergency shoulder response routes because of the confluence of multiple first responders such as police, fire, and hazardous materials team (HAZMAT) responders, ambulances and other first responders trying to access the scene using the limited capacity of the shoulders of the roadway, etc. The systematic derivation of the extended order effects for a range of potential scenarios and decision outcomes is an object of the present invention.
8. Based on the results of reverse engineering scenarios involving critical nodes of systems operation, storyboards are developed to produce simulations of risk or benefit situations that can affect the system. These simulations are designed to reflect complex interdependencies among different critical nodes and their effects on outcomes. The critical decision points within each simulation, i.e., those points where decisions must be made to avoid the uncontrolled evolution or devolution of a system, are identified. For example, using our traffic system analogy suppose our fuel tanker spill at mile marker 7 has resulted in a complete closure of all four lanes of traffic and a traffic backup along the highway is building at a rate of approximately one mile every two minutes (stopping approximately 1450 cars and trucks per mile). The previous exit off of the interstate is at mile marker three. The next previous exit is 22 miles farther back up the interstate. Based on a quantitative analysis of the situation, a critical decision point in an accompanying simulation would occur four minutes from the time the interstate was closed at mile marker 7. If a decision is not made to detour traffic at the mile marker 3 exit within four minutes, traffic will continue to back up for at least another 22 miles potentially placing up to 32,000 cars in gridlock.
9. Each critical decision point in a simulation is reverse engineered carefully considering the risk and/or benefit continuum, the outcomes and extended order effects of different decision options, and the identification of warnings and/or indicators of risk and benefit situations. Out of the range of possible decisions, the optimum decision sets in a simulation that lead to the most desirable outcome(s) are identified. In our example above, the optimum decision could be to immediately close the

roadway at mile maker 3 and detour traffic off the interstate to secondary roadways in order for traffic to bypass the accident at mile marker 7.

10. The fundamental rule sets, associated initial conditions, the sequence of events associated with different scenarios, arrays of potential outcomes for each scenario involving a critical node of operation and the warnings and/or indicators or risk or benefit situations for t_1 are structured, catalogued and archived in a supporting CSM Method business process knowledgebase.
11. The process is repeated for hypothetical scenarios involving the same and other critical nodes at t_2, t_3, t_4 and so on by adjusting the combinations and values assigned to initial conditions to create an array of event paths with different potential outcomes for each of the critical nodes of system operation that are bounded by the fundamental rule sets deduced during Step 1. of the CSM Method business process. Outcomes are derived for each scenario based on the relative affect of one or a combination of initial conditions and the manner in which associated fundamental rule sets are exercised to propagate a systems behavior observed at t_2, t_3, t_4, and so on.
12. The fundamental rule sets, associated initial conditions, the sequence of events associated with different scenarios, arrays of potential outcomes for each scenario involving a critical node of operation and the warnings and/or indicators of risk or benefit situations for additional scenarios are structured for repeatability, catalogued and archived in a supporting knowledgebase.

Phase 2: Integrating Quantitative Reality with Qualitative Human Social Process

FIGS. **5**.A., **5**.B. and **5**.C. present a process flow diagram of the Phase 2: Integrating Quantitative Reality with Qualitative Human Social Process multi-step process used to systematically implement the CSM Method based on the six tenets of a priori optionality. Phase 2. of the CSM Method consists of ten distinct process steps designed to analogously bridge the gap between quantitative reality, i.e., ground truth, as determined during Phase 1. and qualitative human social process. Each step of Phase 2. of the CSM Method is described in detail below.

The purpose of Phase 2. of the CSM Method business process is to address the current lack of a science-based methodology that analogously integrates quantitative technology factors with qualitative social process factors in the context of complex interdependent systems and the human management of complex events and situations. Phase 2. of the complexity systems method focuses on the systematic integration of the quantitative reality of complex interdependent systems as developed during Phase 1. with the qualitative social processes that affect the human management of complex events and situations. The systematic integration of quantitative reality with human social process is an object of the present invention.

Phase 2. of the process uses what are called immersions to bring select groups of decision makers and subject matter experts who would be involved in managing an event in the real world together to manage hypothetical simulations of complex events and situations based on the scenarios developed and reverse engineered during Phase 1. of the CSM Method and the six tenets of a priori optionality. The scientific method of a priori optionality and its integration throughout all phases of the CSM Method business process is an object of the present invention.

Phase 2. immersions allow policy makers and subject matter experts to consider complex situations before they happen in the real world. They are provided with the opportunity to systematically consider and plan in advance for complex contingencies and create risk and benefit decision support templates that can be used to guide decision making when similar analogous events happen in the real world. The creation of pre-agreed risk and benefit decision support templates that can be archived in the CSM Method knowledgebase and readily retrieved for use by human beings to manage real world events is an object of the present invention.

During phase 2. of the complexity systems management method, subject matter experts and decision makers, cut across both the horizontal and vertical boundaries of organizations, are brought together in an immersion. This is done to encourage shared situational awareness from the policy to the operational level. Cutting across organizations both vertically and horizontally to identify immersion participants to increase situational awareness and diversity of inputs is an object of the present invention.

Analogously derived science-based simulations of hypothetical events and situations involving systems relationships among critical nodes of operation of a complex system are used during immersions. As noted previously, these simulations reflect the earlier thinking of the multidisciplinary experts who developed and reverse engineered scenarios for the critical nodes of systems operations during Phase 1. of the CSM Method business process. Analogously derived science-based simulations of hypothetical events involving systems interrelationships among critical nodes of operation of a complex system is an object of the present invention.

During Phase 2. immersions, decision makers and subject matter experts who would be involved in managing an event in the real world are brought together to manage a range of hypothetical simulations of complex events and situations based on the scenarios developed and reverse engineered during Phase 1. They are asked to identify the decisions they would make, consider the outcomes and the extended-order effects of their decisions as they work through simulations involving the behavior of complex systems and their associated critical nodes of systems operation. Including decision makers and technical subject matter experts as participants in immersions to support multidisciplinary problem solving is an object of the present invention.

The decisions made by participants and the outcomes and extended order effects of their decisions are compared and contrasted against the results of the Phase 1. structured data already archived in the supporting CSM Method computer knowledgebase. This data includes the critical decision points, i.e., those points in a simulated event where decisions must be made in order to avoid system failure or to take advantage of opportunity. The notions of opportunity advantage and system failure are akin to dissipative structures, i.e., systems that evolve or devolve based on energy gain or loss, respectively. The comparison and contrast of the results of the Phase 1. structured data already archived in the CSM Method knowledgebase against the decisions of immersion participants is an object of the present invention.

A special consensus team decision tool is used during Phase 2. immersions to help achieve consensus among the participants on the "best" decision options to pursue as they manage their way, as a team, through hypothetical simulations of situations involving the critical nodes of a systems operation based on the scenarios developed in Phase 1. Michelson, McGee and Hawley describe consensus as a term that connotes something more than simple agreement (1994). As part of the CSM Method business process, the term consensus connotes that participants in a group develop "best" decision options based on a structured process of "give and take" that

takes into account the different knowledge and perspectives of other multidisciplinary members of the team. The process is structured to assure repeatability of data. FIG. **6**. depicts the consensus team decision process i.e., the Consensus Team Decision Model. The use of a structured and repeatable consensus model tailored for application as part of the CSM Method to achieve consensus on best decision options is an object of the present invention.

Using the process of compare and contrast with Phase 1. data, participants in an immersion are provided an opportunity to see and experience the outcomes and extended order effects of both good and bad decisions. During immersions, decisions are structured using group collaborative tools such as Group Systems or Meeting Works® to combine the thinking of all immersion participants to produce an analogously derived optimum solution. The opportunity for immersion participants to see and experience the outcomes and extended order effects of both good and bad decisions is an object of the present invention. The result is called a best decision option. Best decision options reflect the "best" combined elements of the ideas of the immersion team to produce solutions with the most desirable outcomes and extended order effects. The derivation, digitization and computer archiving of a plurality of scenarios and pre-generated and agreed-upon best decision options and associated decision templates is an object of the present invention.

Best decision options, outcomes and extended order effects are visually mapped for use during immersions, digitized and archived in the supporting CSM Method knowledgebase. The process allows participants to achieve consensus on best decision options in a way that the lessons learned from the experience can be captured in a computer knowledgebase to build a body of repeatable knowledge that establishes reference points for further simulations. This data form the basis of risk and benefit decision support systems that can be used to assist in the management of analogous events as they occur in the real world. FIG. **7**. depicts the structure of a Phase 2. complexity systems management immersion environment. Building a body of repeatable knowledge that establishes reference points for further simulations that serve as the basis for risk and benefit decision support systems is an object of the present invention. A CSM Method knowledgebase capable of "learning" based on structured CSM Method data inputs is an object of the present invention.

Phase 2. of the CSM Method business process begins with the development of analogously derived, i.e., science-based, simulations. Before an immersion takes place, inputs are sought from the entire system both vertically and horizontally to gather subject matter knowledge at every level. The critical nodes of systems operation for the complex systems behavior under examination as identified during Phase 1. are reverse engineered by immersion participants. Results of Phase 1. reverse engineering of scenarios is used as a tool to compare and contrast the decisions of immersion participants with those developed during Phase 1. Analogous science-based simulations based on CSM Method futures driven event scenarios is an object of the present invention.

For risk applications, the precursor warning signals that can lead to adverse events or cause disasters to escalate to become catastrophes are identified. For benefit applications, the precursor indicators of opportunity that can be exploited to increase the competitive advantage of the organization are identified. Depending on the nature of the application, the critical decision points to prevent and/or respond to simulated adverse events or to exploit impending opportunities are identified. The immersion process examines the range of possible decisions that could be made and their extended order effects. Science-based models are used to show participants the extended order effects of their decisions. Based on this extensive preliminary work, a select combination of decision makers, operational responders and multidisciplinary subject matter experts who would be responsible for managing similar events in the real world are brought together to manage risk and/or benefit simulations. Using analogous science-based methods to extrapolate the extended order effects and consequences of events and decisions is an object of the present invention.

The tools and techniques described below are used to help immersion participants reverse engineer critical decisions and reach consensus on best decision options under differing sets of circumstances, i.e., changing initial conditions.

As described previously, a team decision process is used for participants to achieve consensus on the best decisions to make. This team decision process is designed to address the concerns raised by Janis in *Groupthink* (1982). The Consensus Team Decision Model, as modified for use as part of the CSM Method, is an object of the present invention. "Best" decision templates based on these inputs are structured for repeatability, digitized and archived in a supporting computer knowledgebase that gets "smarter and smarter" as successive groups run through the same or similar simulations. The creation of CSM learning knowledgebases that use structured data derived from the methodical application of a priori optionality is an object of the present invention. The creation of optimum decision templates structured for repeatability and immediately accessible from digitized computer data stored on a CSM knowledgebase is an object of the present invention. The resulting knowledgebase can be used for educational, strategic and tactical operational uses as a planning and operational response tool to manage analogous events that confront decision makers in the real world. The creation of pre-agreed upon decision templates that are structured for repeatability and immediately available to decision makers by querying the CSM Method knowledgebase is an object of the present invention.

Summary of the Ten CSM Method Phase 2. Process Steps

1. Simulations of hypothetical events and situations based on the Phase 1. analysis of the behavior of a complex system are developed. These simulations of different situations reflect the interrelationships among the critical nodes of a complex system and the fundamental rule sets, associated initial conditions, the sequence of events and means and methods associated with different scenarios and arrays of potential outcomes for each scenario involving a critical node of systems operation as developed during Phase 1. These simulations are digitized and archived in a supporting knowledgebase. CSM Method simulations of the critical interdependencies among critical nodes is an object of the present invention.
2. Teams of knowledge domain experts identify the critical decision points in each simulation that could lead to systems failure or represent significant opportunity advantage. Multidisciplinary teams reverse engineer each critical decision point to analogously determine the outcomes of the different decisions that could be made within the bounds of the fundamental rule sets established for each critical node of systems operation. The same multidisciplinary teams determine the outcomes and extended order effects of a range of different decisions for each of the critical nodes of operation identified during Phase 1. Care is taken to assure that the range of possible decisions reflect the fundamental rule sets bounding the behavior of the system. The analogous

determination of decision outcomes and the extended order effects of different decisions for a range of potential outcomes within the bounds of fundamental rule sets is an object of the present invention. This data is visually structured as decision fault trees showing related outcomes and associated extended order effects. Scientific models are developed to assist immersion participants visualize the extended order effects of their decisions. This information is digitized and archived in a supporting CSM Method computer knowledgebase.

3. Immersion participants are selected from across both the horizontal and vertical boundaries of organizations. They are intentionally selected to horizontally cut across "stovepipes" of organizations and to vertically cut from the operational to the senior decision making levels. Included within the group of immersion participants are multidisciplinary experts familiar with the type of system and systems behavior under study. The selection of immersion participants to include senior decision makers, operational personnel and subject matter experts is an object of the present invention.
4. Phase 2. of the CSM Method business process pays special attention to the human social process aspects of individual preferences and group behavior. Each participant in an immersion is requested to take a battery of personality preference, cognitive and team interaction assessments. The results of these tests can provide significant insights on how individuals think, learn, and behave differently in a group or as a member of a team. Behavioral testing of immersion participants for the reasons outlined herein is an object of the present invention. The results of human assessments are provided in confidence to each participant. Human assessment feedback results are used to:
   a. Determine how different immersion participants think, learn and behave, especially in group settings. This allows the information and data presented during immersions to be tailored based on how participants think and learn. This type of human social process knowledge allows for the systematic examination of ways to bring the right information, in the right form, at the right time to decision makers based on different thinking, learning and behavior styles.
   b. Examine a broad range of human characteristics and different behaviors that can affect the quality of both individual and group decision making including individual decision styles and a person's likely reaction under stress, individual and group openness and willingness to accept new ideas, a group's conceptual capacity to see the "big picture", group patterns of motivation, an individual's social assertiveness and other factors.
   c. Facilitate effective team interactions among immersion participants by providing information that can be used to manage potential conflicts that can arise among individuals with different personality traits. Effective team interactions are essential to achieve group consensus around best decision options and to avoid the dangers of "groupthink" (Janis, 1982).
5. Participants in immersions are familiarized with computer supported group systems software, e.g., Meetings Works®, Group Systems, etc., and audio and video equipment that is used to structure and record all activities during immersions. This information is structured, digitized and input to the CSM Method knowledgebase. The digitization of all CSM Method immersion data, i.e., audio, visual and presentation materials for repeatability is an object of the present invention.
6. Participants take part in simulations of hypothetical situations affecting the critical nodes of operation of a complex system. A start and stop process is used to examine and reverse engineer each critical decision point in a simulation (as previously reverse engineered by multidisciplinary teams during Phase 1. before the immersion). Participants are asked to provide their individual perspectives on the best decisions that can be made at each critical decision point in a simulation. Their decisions are compared and contrasted against the results of multidisciplinary team analyses and the results of Phase 1. to include outcomes and extended order effects. Models and other computer visualization techniques are used to show, in scientifically accurate terms, the extended order effects of decisions. Group decision options are then sought. Group decision options are compared and contrasted against those generated during Phase 1. of the CSM Method business process. Multiple perspectives are considered and participants are encouraged to achieve group consensus on best decision options at each critical decision point in the simulation that consider both the quantitative reality of the situation and the qualitative social implications of their decisions. The integration of individual and group perspectives, the comparison and contrast of these perspectives against Phase 1. data archived in the CSM knowledgebase, and group consensus on best decisions is an object of the present invention. Great care is taken to structure and record participant feedback in ways that the reasons and supporting rationale for combining elements of different ideas to achieve consensus around best decision options can be captured in a repeatable way.

   Digitizing and structuring data to create repeatability for the rationale upon which immersion participants reach consensus on best decision options is an object of the present invention. Repeatability is made possible by structuring the information and data acquisition process, using group systems software and by audio and visual recording of all individual inputs and group interactions during the immersion. All information is digitized and archived in a supporting CSM Method computer knowledgebase that can be data mined by structural and conceptual indexing techniques. The integration of quantitative scientific reality with qualitative human social process is an object of the present invention.
7. The information resulting from an immersion is digitized and archived in a supporting computer knowledgebase. The knowledgebase can then be accessed using search engines to mine data using structural and conceptual indexing. In this way, a group's reasons and rationale for combining elements of different ideas to achieve consensus around best decision options at a critical decision point in a simulation can be structured and captured in a repeatable fashion so that the results can be understood by others after the immersion takes place, i.e., repeatability.
8. Decision support systems comprised of systematically derived decision maps, models and other visualization tools that support the human management of complex risk and benefit situations for similar analogous events that happen in the real world are produced as a result of the process. The creation of CSM Method libraries of a

plurality of analogously derived events and situations based on the tenets of a priori optionality is an object of the present invention.

9. The indicators of opportunity advantage and the warnings of impending adverse situations are validated by immersion participants and strategies for intelligence data collection are developed. Best decision options to implement risk and benefit data collection strategies is another important product of Phase 2. immersions. The scientific derivation of the specific indicators of opportunity and specific warnings of risk events is an object of the present invention. The mining of open source data to find as early as possible the indicators of opportunity and warnings of adverse events as derived using the CSM Method is an object of the present invention.
10. Additional immersions can be conducted using the same or different combination of simulations with different participants. Different participants in the process bring new perspectives and ideas as critical decision points are reverse engineered. Using the same immersion processes to structure and acquire information and data in combination with group systems software and audio and visual recording of individual inputs and group interactions during the immersion repeatability is assured. Thus, the addition of new data from additional immersions when archived in the supporting CSM Method computer knowledgebase results in a learning system that becomes "smarter and smarter" with each successive immersion. The addition of new data from additional immersions when archived in the supporting CSM Method computer knowledgebase to establish a learning system that becomes "smarter and smarter" with each successive immersion is an object of the present invention.

Phase 3: Subsequent CSM Method lnterventions

The purpose of Phase 3. of the CSM Method business process is to reassess, on a continuing basis, the fundamental rule sets upon which complex systems are characterized and the optimum risk and benefit decision options and accompanying decision support systems are based. One of the scientifically derived tenets of a priori optionality is that there exist no absolute bounds of certainty in any complex system within which different behaviors may occur. Scientific evidence that there exists no absolute bounds of certainty in any complex system within which different behaviors may occur is an object of the present invention. A priori optionality posits that the bounds within which different behaviors occur in a complex system change based on the evolving adaptation of the system itself resulting from continuous systems of systems interactions with the environment in which it exists. Scientific evidence that all systems evolve based on systems of systems interactions is an object of the present invention. Thus, no system ever stands alone or remains unaffected by the space, i.e., environment, in which it exists. Scientific evidence that no system ever stands alone or remains unaffected by the space is an object of the present invention.

The reassessment of the fundamental rule sets bounding the behavior of a complex system is accomplished through the use of continuing multidisciplinary team analysis, the conduct of subsequent immersions, the use of computer modeling and the real world operational use and testing of the risk and benefit applications of the decision support systems resulting from the Phase 1. and 2. CSM Method business process. Scientific evidence that the fundamental rule sets of complex systems must be continually reassessed based on systems of systems interactions is an object of the present invention.

Summary of the Three CSM Method Phase 3 Process Steps

1. Teams of multidisciplinary experts reassess, on a continuing basis, the fundamental rules sets used to bound the range of behaviors as determined in Phase 1. of the CSM Method business process. They consider how a complex system may have evolved and adapted based on changes in the environment in which it exists, i.e., systems of systems interactions. The continual reassessment of the fundamental rules sets which bound the behaviors of complex systems is an object of the present invention.
2. Subsequent immersions are conducted using the same or different combinations of simulations to revalidate Phase 1. quantitative results and Phase 2. best decision options. Subsequent immersions can be conducted with different groups or combinations of participants. Establishing CSM learning knowledgebases by conducting subsequent CSM immersions and structuring data using the CSM Method business process is an object of the present invention.
3. The decision support systems resulting from Phases 1. and 2. are applied to the management of real world risk and/or benefit situations. The use of CSM knowledgebases to guide analogous real world events is an object of the present invention. The performance of management teams using these decision support systems is benchmarked against previous performance. Declines in performance over time using decision support systems resulting from Phases 1. and 2. lead procedurally to multidisciplinary team Phase 1. quantitative reassessments and the conduct of subsequent immersions to re-achieve desired levels of performance. The benchmarking of performance and the conduct of subsequent Phase 1. quantitative reassessment of fundamental rules sets is an object of the present invention.

Deliverables Resulting from Phases 1., 2., and 3. of the CSM Business Process Method

Table 1., below, summarizes the key deliverables resulting from the CSM Method business process achieved through the systematic implementation of the six tenets of a priori optionality.

TABLE 1

Significant deliverables resulting from the CSM Method business process

CSM METHOD PHASE 1.	CSM METHOD PHASE 2.	CSM METHOD PHASE 3.
1. Fundamental rule sets at t_1 driving a complex system's behavior 2. Initial conditions affecting the fundamental rule sets at t_1	1. Simulation of real and hypothetical events 2. The outcomes of different decision at critical decision points 3. Decision fault trees showing outcomes and extended order effects	1. Continuing reassessment of fundamental rules 2. Subsequent immersions to revalidate and update best decision options 3. Decision templates and results of Phase 1. and 2. to manage analogous real

TABLE 1-continued

Significant deliverables resulting from the CSM Method business process

CSM METHOD PHASE 1.	CSM METHOD PHASE 2.	CSM METHOD PHASE 3.
3. Identification of the critical nodes of systems operation 4. Range of scenarios at t_2, t_3, t_4 and so on using different combinations of initial conditions to disturb system equilibrium and observe outcomes and determine event sequences 5. For risk applications, an Estimate of Event Sequence Interruption (EESI) 6. For benefit applications, the early indicators of impending opportunity 7. The early warnings of impending adverse events 8. Data collection strategies including data mining to look for the early indicators of opportunity and the early warnings of adverse events. 9. Critical Decision points for scenarios 10. Optimum Decision sets 11. Best decision templates 12. All data structured for repeatability in a CSM Method business process knowledgebase	4. Multidisciplinary analysis during immersions 5. Participant cognitive assessments of learning styles, team interaction styles, conflict handling 6. Multidisciplinary consensus on best decision options 7. Consensus on best decision options and supporting rationale 8. Computer archive of repeatable data 9. Decision maps, models, computer visualization tools to support the Mangment of analogous real world events 10. Validation of indicators of benefit and warnings of adverse impending events 11. Consensus decisions on data collection strategies to look for the early indicators of opportunity and the early warnings of adverse events. 12. A CSM Method business process knowledgebase of repeatable information and data that becomes "smarter" with successive immersions.	world events.

Automation of the CSM Method Business Process Model

Phase 1. of the CSM Method business process is the focus of significant computer automation. Phase 1. structured and digitized data contained in the CSM knowledgebase is used for Phases 2. and 3. of the CSM Method business process. To demonstrate the present invention, a prototype capability was designed to show in concrete and tangible form how the CSM Method business process model can be applied to structure data and create a CSM knowledgebase that supports Phases 2. and 3. of the CSM Method business process. The example presented here demonstrates only one of many potential automated applications of the CSM Method. As depicted in Table 11., below, all applications of the CSM Method business process are designed to systematically structure data using an analogous methods consistent with the six tenets of a priori optionality. The example presented herein is our BuildingTQ (with TQ standing for threat quotient) risk management application of the CSM business process method.

The network architecture used is common to all CSM Method automated applications. Tailored risk management software applications dealing with a range of critical infrastructures ranging from energy, transportation, communications, public health and safety, etc. use CSM Method "productized" software packages that are installed on each client's own internal network subject to their network security requirements. These "productized" software packages are designed to systematically implement the six tenets of a priori optionality. These software packages provide functionality for the client to: 1) geospatially and otherwise to visualize the external and internal critical nodes of their operations; 2) gather and structure data concerning these critical nodes; 3) as appropriate, determine compliance with safety, security, regulatory and best business practices for each critical node; 4) simulate modifications to existing system design to reduce the risks associated with man-made and natural events affecting their critical nodes; 5) use visualization platforms to monitor in real time changes to the risks associated with their critical nodes. Using "productized" software to structure data consistent with the tenets of a priori optionality and for repeatability to support Phases 2. and 3. of the CSM Method business process is an object of the present invention.

The core of the system is the CriTQ™ CSM Method business process knowledgebase which resides in a secure environment at a Data Fusion Center (DFC). It is here that the critical nodes of different critical infrastructure systems are identified and subjected to deep systems analysis and reverse engineered using the CSM Method risk management business process. Consistent with Phase 1., a range of scenarios of potential adversary attacks and natural events are developed for each critical node of a selected infrastructure. The data is structured and archived in the CriTQ knowledgebase. For example, the means and methods associated with different attack scenarios and the consequences associated with a successful attack or natural event involving a critical infrastructure system and a system behavior are structured and archived in the knowledgebase. The indicators of benefit opportunities and warnings of an impending attack or natural event are analogously determined using the CSM Method. The use of analogous methods to derive the indicators of benefit opportunities and warnings of an impending adverse or natural event is an object of the present invention. The data is structured and archived in the CriTQ knowledgebase.

For benefit applications, the CriTQ knowledgebase constantly scans the open source environment for the indicators of impending opportunity and provides real time "data bursts" to clients to advise them of opportunity. The use of data mining techniques to continuously scan open sources for the indicators of opportunity as derived using the CSM

Method is an object of the present invention. These indicators of business opportunity are actively displayed on computer visualization platforms. The "active" versus "passive" method of searching out and relaying the indicators of impending opportunities is an object of the present invention.

For risk management applications the CriTQ knowledgebase constantly scans the open source environment for the warnings of adverse events as scientifically derived using CSM Method business process. Clients are provided with real time "data bursts" to warn them of impending adverse events. These threat warnings are actively displayed on computer visualization platforms. See FIGS. **11**. A. and **11**. B. The use of data mining techniques to continuously scan open sources for the warnings of adverse events as derived using the CSM Method is an object of the present invention. These warnings of adverse events are actively displayed on computer visualization platforms. The "active" versus "passive" method of searching out and relaying the warnings of adverse events is an object of the present invention.

BuildingTQ™ as One Example of a Risk Management Application of the CSM Business Process Method

The following example demonstrates the use of the CSM Method business process in a Phase 1. risk management application involving large modern buildings. The application is known as BuildingTQ with "TQ" as an acronym for threat quotient. In this case, the risk management concern involves the potential for malevolent attacks by adversaries against modern commercial buildings and the range of natural phenomenon that can affect building operations and safety.

Today's modern commercial buildings are examples of complex adaptive systems of systems. From heating, ventilation and air conditioning systems that must respond to changes in temperature and weather conditions, to wind dampening systems to prevent the excessive swaying of tall buildings, to power loading for the most efficient use of electricity, to fire suppression systems and so on, modern buildings represent a complex interweaving web of systems of systems that must continuously respond to changing conditions.

examine a selected building from the holistic frame of reference to deduce the fundamental rule sets that define and bound the propagation of a real (or imaginary) system's behavior being observed at t_1. First, the fundamental rules that bound the range of potential malevolent attacks against the building are derived.

Ask yourself the following question: What causes a traffic jam? Most of us would quickly respond with answers like, poor weather conditions, too many cars, those "idiot Maryland drivers," rubber-necking, accidents or some other similar response. But scientists think about things like traffic jams quite differently. To a complexity scientist there are three and only three things that cause a traffic jam. You put your foot on the accelerator to speed up your car. You take your foot off the accelerator to slow down the car. And, you put your foot on the brake to stop the car. To complexity scientists, how people exercise these three rules determines whether or not a traffic jam will occur. For example, if it snows heavily most people will spend more time with their foot off the accelerator and on the brake causing traffic to slow down and back up.

In the application of the CSM Method these are called fundamental rules. In the case of a large building ask yourself the question: How can an adversary attack it? Many people would quickly respond by saying things like break through the glass, shut off the alarm system or shoot the guards. All reasonable things to say, of course, but they are not what a scientist would characterize as fundamental rules.

As Table 2. shows, when the tenets of a priori optionality are applied under the CSM Method business process, three, and only three, ways an adversary can attack a building emerge. First, an adversary force can use forced entry. Second, they can use stealth. Third, they can use a range of improvised destructive devices (IDD). When you think in these terms, breaking through doors, sneaking past the guards, shutting off alarm systems, blowing up the lobby with a bomb and much more all become initial conditions affecting theses three, and only these three, fundamental rules: forced entry, stealth and use of IDD.

TABLE 2

The Three fundamental rules for attacking a building

Forced Entry	Surreptitious Entry	Improvised Destructive Devices (including radiological dispersal devices)
Unauthorized access to a site or building using force. During business and non-business hours armed assault and takeover of a building or critical node of operation by a coordinated group armed loner	Unauthorized access to a site or building using stealth During business hours use of false credentials insider or insider assistance impostor unnoticed access During non-business hours break-in using stealth avoid detection infrared e-field Israeli-type fence CCTV electromagnetic sensors other	During business and non-business hours vehicle bomb suicide bomber pre-placement of IDD w/remote detonation shielding of radiological sources

Phase 1. Step 1. Deducing Fundamental Rule Sets and Systematically Extrapolating Adversary Means and Method for Buildings

In Phase 1. Step 1. of the BuildingTQ application, multidisciplinary experts use the tenets of a priori optionality to

Tables 3. and 4., below, illustrate how CSM Method fundamental rules are used to analogously extrapolate and systematically structure initial conditions such as the type of pre-planning and the actions that must be taken by an adversary to successfully conduct "forced entry" attack against a

building. Care is taken to discriminate between the fundamental rules and the initial conditions. Because the data is systematically structured it can be embedded as part of the BuildingTQ software logic system and archived in the CSM Method CriTQ knowledgebase in a manner that allows for repeatability, i.e., easily understood by subsequent users. The use of the CSM Method to derive fundamental rules, analogously extrapolate and systematically structure initial conditions is an object of the present invention.

TABLE 3

Adversary pre-planning for forced entry into a building

Fundamental Rule: Forced Entry	Adversary Means and Methods
Unauthorized access to a site or building using force. During business and non-business hours armed assault and takeover of a building or critical node of operation by a coordinated group armed loner	Armed assault and takeover of a building or critical node of operation Pre-planning Adversary cell structure for coordination Safe house for adversary planning activities Adversary "casing" of existing buildings (or buildings under construction) physical or remote observation to determine: building security routines communications intercepts guard locations and duties guard training and armament perimeter and access ways (including loading dock, vehicle and personnel) routines perimeter detection capability critical nodes of building operations (especially security) local response capability law enforcement fire special event response teams (NEST, HAZMAT, CBRF, RRT's, etc.) hospitals triage capacity ambulances EMT squads access to public or controlled records building security plans building blueprints intrusion detection capability geospatial and photographic images building and site supporting critical infrastructures power feeds and internal systems water feeds and internal systems sewage system (internal, external) communication feeds and internal systems local emergency response capability recruitment or "assistance by force" of a knowledgeable insider to obtain critical information monetary remuneration blackmail coercion

TABLE 4

Adversary forced entry into a building

Fundamental Rule: Forced Entry	Adversary Means and Methods
Unauthorized access to a site or building using force. During business and non-business hours armed assault and takeover of a building or critical node of operation by a coordinated group armed loner	Armed assault and takeover of a building or critical node of operation Conduct of attack Armed assault and takeover of a building or critical node of operation Number of attackers as a function of surveillance of security routines and planning information Adversary coordination cells safe houses communications equipment

TABLE 4-continued

Adversary forced entry into a building	
Fundamental Rule: Forced Entry	Adversary Means and Methods
	Adversary equipment hand guns automatic weapons gas to disable or kill opposing force gas masks burst bombs vehicle penetration stand-off weapons (sniper/mortar/other) Tactics and techniques "de-sensitization" of security routines "de-sensitization of alarm systems impostor tactics knowledgeable insider assistance hacking/MP attack of SCADA use of gas to kill disable opposing force burst bombs initiate negotiations

Tables 4. and 5., below, illustrate how CSM Method fundamental rules are used to analogously extrapolate and systematically structure initial conditions such as the type of pre-planning and the actions that must be taken by an adversary to surreptitiously gain access to a building. Care is taken to discriminate between the fundamental rules and the initial conditions. Because the data is systematically structured it can be embedded as part of the BuildingTQ software logic system and archived in the CSM Method CriTQ knowledgebase in a manner that assures repeatability, i.e., easily understood by subsequent users.

TABLE 5

Adversary pre-planning for surreptitious entry into a building	
Fundamental Rule: Surreptitious Entry	Adversary Means and Methods
Unauthorized access to a site or building using stealth During business hours use of false credentials insider or insider assistance impostor unnoticed access During non-business hours break-in using stealth avoid detection infrared e-field Israeli-type fence CCTV electromagnetic sensors other	Unauthorized access to a site or building using stealth. Pre-planning Adversary cell structure for coordination Safe house for adversary planning activities Adversary "casing" of building physical or remote observation to determine: building security routines communications intercepts guard locations and duties guard training and armament perimeter and access ways and perimeter detection capability ingress and egress routes critical nodes of building operations (especially security) hacking of SCADA or communications local response capability law enforcement fire special event response teams (NEST, HAZMAT, CBRF, RRT's, etc.) hospitals triage capacity ambulances EMT squads access to public or controlled records building security plans building blueprints intrusion detection capability geospatial and photographic images building and site supporting critical infrastructures power feeds and internal systems water feeds and internal systems sewage system (internal, external) communication feeds and internal systems local emergency response capability recruitment or "assistance by force" of a knowledgeable insider to obtain critical

TABLE 5-continued

Adversary pre-planning for surreptitious entry into a building	
Fundamental Rule: Surreptitious Entry	Adversary Means and Methods
	information
	monetary remuneration
	blackmail
	coercion

TABLE 6

Adversary surreptitious entry into a building	
Fundamental Rule: Surreptitious Entry	Adversary Means and Methods
Unauthorized access to a site or building using stealth	Unauthorized access to a site or building using stealth
During business hours	Conduct of break-in by stealth
use of false credentials	Timing is likely to be a function of reducing the possibility of adversary detection (non-business hours; night time)
insider or insider assistance	
impostor	Avoid perimeter detection
unnoticed access	e-field
During non-business hours	Israeli-type fence
break-in using stealth	perimeter/exterior doorway CCTV
avoid detection	Bypass or circumvent secondary detection
infrared	internal infrared
e-field	internal CCTV
Israeli-type fence	electromagnetic door sensors
CCTV	window vibration/e-continuity detectors
electromagnetic sensors	Adversary equipment
other	handguns or automatic rifles
	standoff weapons (sniper/mortar/other)
	radio equipment to intercept security communications
	specialized equipment to penetrate doorways
	non-hardened doorways
	card slide at jamb
	standard lock picking techniques
	micro-charge at lockset
	"pop the pins"
	counter doorway e-magnetic detection
	physically break through door
	hardened doorways
	standard lock picking techniques
	pressure jaws at jamb to defeat lock or remove exposed
	"spot weld" hinges
	torch to penetrate metal clad door
	counter doorway e-magnetic detection
	remove door casing from surrounding non-hardened materials, e.g., cement block, non-protected concrete framing, etc.
	glass exposures
	low vibration glass cutting equipment
	traditional sash lock defeat
	counter window sash e-magnetic detection
	Tactics and techniques
	"de-sensitization" of security routines
	"de-sensitization" of alarm systems
	impostor tactics
	knowledgeable insider assistance
	hack SCADA or communications

Tables 7. and 8., below, illustrate how CSM Method fundamental rules are used to analogously extrapolate and systematically structure initial conditions such as the type of pre-planning and the actions that must be taken by an adversary to successfully conduct an "improvised explosives attack" on a building. Care is taken to discriminate between the fundamental rules and the initial conditions. Because the data is systematically structured it can be embedded as part of the BuildingTQ software logic system and archived in the CSM Method CriTQ knowledgebase in a manner that allows for repeatability, i.e., easily understood by subsequent users.

TABLE 7

Adversary pre-planning for an IDD attack against a building

Fundamental Rule: Improvised Destructive Devices (including radiological dispersal devices)	Adversary Means and Methods Improvised Destructive Device (including radiological dispersal and improvised nuclear devices)
Unauthorized access to a site or building using stealth. During business hours use of false credentials insider or insider assistance impostor unnoticed access During non-business hours break-in using stealth avoid detection infrared e-field Israeli-type fence CCTV electromagnetic sensors	Pre-planning Adversary cell structure for coordination Safe house for adversary planning and preparation activities Adversary "casing" of building physical or remote observation to determine: building security routines communications intercepts guard locations and duties guard training and armament perimeter and access ways and perimeter detection capability nitrogen "sniffers" searches ingress and egress routes critical nodes of building operations (especially security) defensive vehicle barriers Jersey barrier hydraulic barrier swerve and slow roadway controls vehicle traps (at loading docks and other truck entry locations) local response capability law enforcement (response time & capability) fire (response & capability) emergency event response teams (NEST, HAZMAT, CBRF, RRT's, etc.) hospitals triage capacity ambulances EMT squads Other medical transportation Access to public or controlled records building security plans building blueprints intrusion detection capability geospatial and photographic images building and site supporting critical infrastructures water feeds and internal systems power feeds and internal systems sewage system (internal, external) communication feeds and internal systems local emergency response capability Recruitment or "assistance by force" of a knowledgeable insider to obtain critical information monetary remuneration blackmail coercion

TABLE 8

Conduct of an IDD attack against a building

Fundamental Rule: Improvised Destructive Devices (including radiological dispersal devices)	Adversary Means and Methods
Unauthorized access to a site or building using stealth. During business hours use of false credentials insider or insider assistance impostor unnoticed access During non-business hours break-in using stealth avoid detection infrared e-field	Conduct of IDD (s) attack Timing is likely to be a function of reducing the possibility of adversary detection and the specific characteristics of the IDD or IDD's to be used Avoid early detection physical search identification of IDD (if remotely placed) Adversary equipment vehicle explosive material(s) C-4 fertilizer-fuel oil

TABLE 8-continued

Conduct of an IDD attack against a building	
Fundamental Rule: Improvised Destructive Devices (including radiological dispersal devices)	Adversary Means and Methods
Israeli-type fence CCTV electromagnetic sensors	radiological laced IDD improvised nuclear device (IND) Adversary coordination cells safe houses communications equipment Tactics and techniques "de-sensitization" of security routines "de-sensitization of alarm systems false credentials impostor tactics Stand-off delivery of IDD MP bombs Knowledgeable insider assistance recruitment or "assistance by force" of a knowledgeable insider to obtain critical information or credentials monetary remuneration blackmail coercion initiate negotiations (if motive of attack)

Phase 1. Step 2. Identifying the Critical Nodes of Building Operations

In accordance with the tenets of a priori optimality, the building is viewed holistically to determine the critical nodes of systems operation, i.e., those core interrelationships or activities unique to a commercial office building that are particularly sensitive to changes in initial conditions. As Table 9. illustrates, there are fourteen critical nodes of systems operation most frequently associated with modern buildings each of which is supported by other subsystems. Many of these subsystems are interdependent. For example, water fire suppression systems depend on the availability of sufficient water supplies provided under adequate pressure. The following list of critical nodes was developed based on analysis by building subject matter experts and a "word cluster analysis" of General Services Administration, the National Building Code and a broad cross section of state building codes and standards.

TABLE 9

The fourteen critical nodes of a commercial office building
1. Heating and Ventilation Systems
a. Roof based
b. At-ground
c. Other
2. SCADA Rooms & Controls
3. Mass Gathering Areas
a. Cafeterias
b. "Open design areas"
c. Courtyards
d. Auditoriums
e. Others
4. Cabling and Communications Systems
a. Electrical
b. Communications
c. Computer cabling
d. Other
5. Physics Stress Locations
a. Load bearing pillars
b. Structural steel and support cabling
c. "Undampened" locations
d. Other
6. Water Systems
a. Water intake
b. Water distribution systems
c. Valves
d. Water pressure systems including pumps
e. Other
7. Sanitation and Sewer Systems
a. Supporting water systems
b. Sewer lines
c. Free flow
d. Pumps
e. Other
8. Parking Areas
a. Perimeter parking
b. Subterranean parking
c. Others
9. Building Ingress & Egress Points
a. Roof access
b. Utility tunnels
c. Main entrances & exits
d. All other doorways
e. Loading Dock & Storage
10. Power
a. Back-up power
b. Immediate power for critical systems
c. Power cabling runs
d. Substations
e. Transformers
f. Breakers
f. Other
11. Perimeter Buffer Zones
a. Open zones
b. Fenced perimeters
c. Other
12. Elevators, Escalators, "People Movers", Stairways
13. Security Systems
a. Alarms
b. Remote surveillance systems
c. Security personnel
d. Credentialing
e. Other
14. Safety Systems
a. Fire suppressant systems
b. Fire and other emergency alarms
c. Other

Automated applications of the CSM Method make extensive use of computer visualization tools. For example, each of the fourteen critical nodes of a modern commercial office

building as identified above are rendered by location on a computer generated dedux diagram, i.e., wire frame representation of the building as shown in Table 27. These platforms when integrated with the building's secure control automated data acquisition (SCADA) system of sensors for applicable critical nodes and incoming data on threats become "active." This means that a critical node or combinations of critical nodes begins to "blink" based on real time data inputs to the BuildingTQ software logic system. See FIGS. **11**. A. and **11**. B. This "active" versus "passive" method of relaying on data concerning CSM Method derived indicators and warnings is an object of the present invention.

Automated applications of the CSM Method use a host of other computer visualization tools such as geospatial imagery. In the case of the BuildingTQ application, a geospatial "pan, zoom and scan" capability allows users to view the unique characteristics of their own buildings and the regional area in which the building is located. This provides users with visual data on their building's exterior critical nodes and other visual data on the locations of power, sewer, water, communications and other infrastructures unique to the geographic area that are critical to the functioning of the building. This data provides important information on the locations of critical infrastructures that might be the target of attacks, the locations, times of response and capabilities of law enforcement, fire and medical responders and other data. See Tables 23. and 31. This analogously derived data is structured for use by the BuildingTQ software logic system and archived in the CriTQ knowledgebase.

Phase 1. Step 3. Fundamental rule sets are used to define and bound potential systems behaviors to derive a range of possible scenarios that display different combinations of the initial conditions that can affect the critical nodes of the system.

In this example, a team of multidisciplinary experts consider the fundamental rule of surreptitious entry and a potential set of initial conditions that will upset the equilibrium of a critical node in the building. A potential scenario is developed. In this case, an adversary team of four individuals, armed with handguns that have communications and small C-4 explosive "lock-set" charges have carefully planned an attack of a particularly sensitive computer facility in a large headquarters building of a national merchandise retailer and food store. The team will attack during a normal business hours and intends to rely on surreptitious entry to destroy data on the computer hard drives using a small powerful suit case size electro-magnetic pulse (EMP) capacitor-type device. The fundamental rule is surreptitious entry. Initial conditions include time of attack, method of entry, adversary motivation and objective, equipment and other factors.

FIG. **12**., represents a schematic diagram of the sensitive computer facility in the building that is the target of the adversary attack.

Schematic diagrams for each critical node of a building showing the location of surveillance equipment, alarms, doorways, elevators, stairwells, are digitized and archived in the CriTQ knowledgebase. As part of the active software platform, clients validate and change if necessary schematic layouts, provide details about construction, provide average guard force response times, type of response (if applicable) and other data that can be used to calculate earliest point of detection, the adversary delay time provided by different security and construction barriers, length of time for response and quality of response.

Phase 1. Step 4. Scenarios are developed which identify and structure the precise events and their sequence that must occur for a given event to take place in the real world. In this example, the precise sequence of events used by the adversaries to surreptitiously enter the building, destroy data in the computer facility and escape consists of a sequence of seven actions as set forth in Table 10., below. This is known as an event sequence. The analogous derivation of event sequences using the CSM Method is an object of the present invention.

TABLE 10

An event sequence for the surreptitious entry and destruction of a computer data facility by an adversary group

1. The team is escorted into the building by an employee who has been lead to believe that the four men are visiting a senior company official with offices on the sixth floor of the building. They are given visitor badges.	→ Check in time is 10 minutes. Detection highly unlikely.
2. Upon entering the elevator the adversaries disable their escort and any others on the elevator and proceed directly to the computer area on the fourth floor.	→ Average time for elevator to traverse four floors is 1.8 minutes. Detection is highly unlikely.
2. Adversaries trigger nearby fire alarm and proceed to computer area.	→ Takes less than one minute. Detection of adversaries or intent remains highly unlikely.
4. Adversaries break through the glass encasing the entryway to the security island and proceed to the emergency exit of the computer facility.	→ First potential detection of adversaries by CCTV in the computer facility lobby area. Response clock begins. Time to break glass and enter area is less than 30 seconds.
5. Adversaries use a charge of C-4 explosive to penetrate the steel class A fire door.	→ Explosive charges placed and detonated. Time to penetrate door is approximately one minute.
6. Adversaries deploy and detonate the EMP devices.	→ Thirty seconds to deploy and remotely detonate EMP capacitor-type device.
7. Adversaries shed gear and proceed to escape through stairwell mixing with other employees evacuating the building.	→ Less than 30 seconds. Detection and capture is highly unlikely.

Multi-disciplinary teams reverse engineer a range of potential scenarios to determine the exact sequence of events that must occur for the adversary to "beat the system." A plurality of scenarios for each generic critical node of a building are structured, digitized and archived in the CriTQ knowledgebase.

Special attention is paid to earliest possible detection, security and construction barrier delay times, response times and the quality of responses. The goal is early detection, sufficient barrier delay time, and effective security interdiction of the adversary force before an attack can be successfully com-

pleted. If prevention fails and response is still necessary, the BuildingTQ software application assists the client by identifying mitigating actions as further described below.

Event sequences support an embedded algorithm known as the Estimate of Event Sequence Interruption (EESI™). As depicted in FIG. **13**. the EESI algorithm states that interdiction (I) of the adversary is a function of detection time (dn_t), delay time (dy_t), response time (r_t) and response quality (r_q) or: I f (dn_t) (dy_t) (r_t) (r_q). The Estimate of Event Sequence Interruption (EESI) algorithm is an object of the present invention.

In our sample scenario described above, the running of the EESI algorithm indicates that the adversary is likely to successfully destroy data in the computer facility and escape based on the following:

- For the sample scenario, the total elapsed time is 15.3 minutes.
- 12.8 minutes elapses before first possible detection of the adversaries.
- This leaves response force with less than 3 minutes to prevent the attack during the chaotic period of a potential fire and building evacuation.
- Since average response time to an alarm at the computer facility during normal periods is 4.2 minutes, prevention of the attack and capture of the adversaries is highly unlikely.

Based on a range of scenarios bounded by fundamental rules for each critical node of a building, win or lose values are calculated. EESI calculations produce a numerical value known as a Threat Quotient (TQ) for each critical node. Using the results of EESI calculations another algorithm, known as the Event Probability Algorithm (EPA), is applied to prioritize the relative risk of different scenarios where the probability of an attack occurring (PO) is a function of the vulnerability of the critical node (v) and the consequences that would result if that critical node were successfully attacked (c) or: PO f (v) (c). The Event Probability Algorithm (EPA) is an object of the present invention.

Based on EESI calculations and TQ scores, ways to prevent or mitigate the consequences of an attack are considered. In our sample scenario for example, more rigorous visitor control procedures would result in the earlier detection of the adversaries and the interruption of the event sequence. In similar fashion, a concrete wall in lieu of a glass enclosure leading to the computer facility would provide additional barrier delay time slowing the adversaries down long enough for security forces to respond and interrupt the event sequence. By taking mitigating actions, the relative risk of a critical node can be reduced. An algorithm known as the Adjusted Threat Quotient (ATQ) is applied where the vulnerability of a critical node (v) and the consequences if it were successfully attacked (c) become a function of the mitigating actions taken to prevent or limit the consequences of the attack depicted as m or: (v) (c) f m. The application of the ATQ algorithm to account for m results in an adjusted threat quotient for the critical node. The Adjusted Threat Quotient (ATQ) algorithm is an object of the present invention.

Another critical risk management concern for commercial buildings involves natural phenomenon such as weather and geologic events. For natural phenomenon, BuildingTQ applies what is known as the Weather and Geological Events (WGE) algorithm. WGE states that for natural events the vulnerability of a critical node (v) is a function of the probability of the event occurring (based on frequency, trends analysis and modeling projections) PO and the consequences (c) should a critical node be subjected to a natural event or (v) f PO (c) as depicted by FIG. **14**. Natural events addressed by BuildingTQ include fire, earthquakes, hurricanes, tornadoes, floods, tsunamis, windstorms, heavy snowfalls, ice storms, etc. The Weather and Geological Events (WGE) algorithm is an object of the present invention.

Threat quotient (TQ) scores for different weather and geologic events are generated. TQ scores are weighted based on frequency, trends analysis and modeling projections and the consequences should a critical node be subjected to a natural event. Like man-made events, weather and geologic events can then be subjected to the WGE algorithm. If, for example, a hospital has significant back up power capability at above flood grade for a major hurricane hitting the region this becomes a significant mitigator. By taking mitigating actions, the relative risk of a critical node can be reduced. The Adjusted Threat Quotient (ATQ) is applied where the vulnerability of a critical node (v) and the consequences if it were subject to a natural event (c) become a function of the mitigating actions taken to prevent or limit the consequences of the event depicted as m or: (v) (c) f m. The application of the ATQ algorithm to account for m results in an adjusted threat quotient for the critical node.

Phase 1. Step 5. For risk applications scenarios are structured along a time continuum that begins with earliest possible detection of an adverse event moving sequentially through deterrence, prevention, response, immediate mitigation of consequences, and long term recovery. As part of this process, structured responses to the following question are developed for each hypothetical risk scenario: what information had it been known before the adverse situation happened could have been used to have prevented it from happening in the first place? The method in which the indicators of benefit and the warnings of adverse events are derived is an object of the present invention. These become the warnings of impending adverse events and the attention of focused data collection strategies designed to produce actionable intelligence that can be used to interrupt event sequences as early as possible to prevent adverse situations.

To address mitigation m in the ATQ algorithm, structured responses to the following question are developed for each hypothetical risk scenario: what information had it been known before the adverse situation occurred could have been used to mitigate its consequences? The method in which the consequences of adverse events are derived using the CSM Method is an object of the present invention.

FIG. **15**. represents a computer visualization of the event sequence analyzed at Table 11., below.

Each risk event sequence is then systematically evaluated against a threat continuum beginning with deterrence and moving through detection, prevention, response and mitigation. For each specific event sequence, responses to the following five questions are systematically structured for repeatability and archived as part of the CSM knowledgebase.

1. What specific actions would deter an adversary from committing the act?
2. What specific actions would facilitate the earliest possible detection of the adversary?
3. What specific information had it been known before the event occurred could have been used to prevent it from happening in the first place? (These specific factors are of great significance because they represent the warnings of an impending attack.)
4. If the adversary is successful in reaching the critical node, i.e., target of the attack, what would be the most effective methods of response?
5. If the adversary is successful in reaching the critical node, i.e., target of the attack, what would are the most

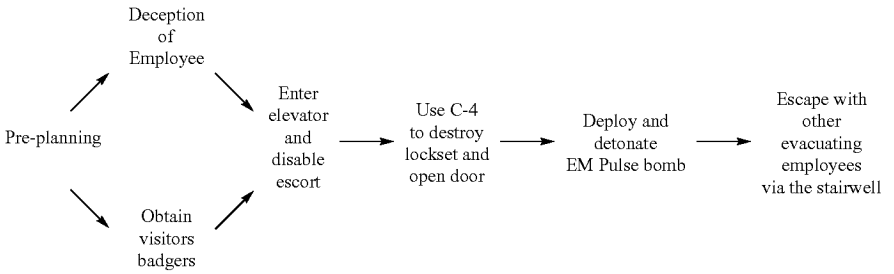
effective methods of mitigating the consequences, i.e., extended order effects of a successful attack?

The systematic evaluation of event sequences against benefit and threat continua is an object of the present invention.

Table 11., below, represents a computer visualization of the product—a structured analogous evaluation of an event sequence against the CSM Method threat continuum.

TABLE 11

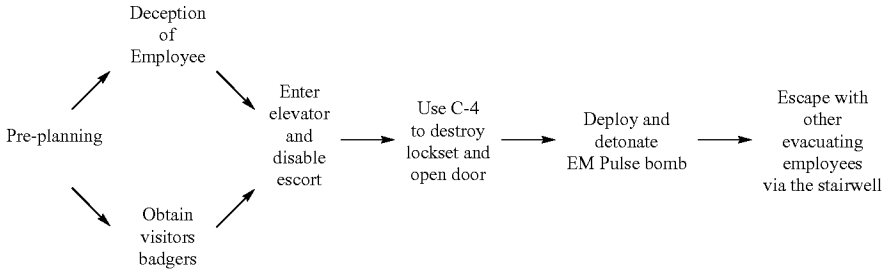
A computer visualization of a structured evaluation of an event sequence against the CSM Method threat continuum



Deter	Detect	Prevent	Respond	Mitigate
Targeted employee awareness programs re: visitor control and other adversary deception tactics	Targeted employee awareness programs re: visitor control and other adversary deception tactics including a "hot-line" for reporting unusual incidents	Unauthorized attempts to circumvent visitor control procedures; investigate all reports	Immediate notification of all security, local, state and federal authorities of a successful attack on computer data facility	Determine how access control system was circumvented and make necessary modifications
Strong access control procedures by visitor validation prior to entry; maintain and hold visitor identification	Visitor validation by host; use of two forms of photo identification one of which is an authorized government issued picture ID, e.g., state driver's license	Attempts to use false credentials; investigate all reports	Building shut down with access allowed only by positive identification including security and first responders	Implement business continuity plan (BCM) for an attack; re-route all communications to back up location; if no data back-up work with authorities to preserve as much data as possible; shut down computer data facility access points to absolutely preclude any unauthorized or accidental access to damaged system ; recover available data
Proactive monitoring "casing" activities especially those related to physical security and access controls	Establish "hot-line" for reporting suspicious activities with monetary rewards for providing information leading to the arrest and successful conviction of perpetrators	"Hot-line" or other information indicating a possible attack on the computer data facility or related critical nodes; investigate all such reports	Raise security alert level and implement emergency security plans	Work with corporate management, security, all levels of law enforcement and other first responders to prepare a coordinated press release; prepare for press conference
Maintain close liaison with local, state and federal authorities re: possible threats	Improve physical security and surveillance of computer data facility; CCTV directly at each entranceway; lockset protection against explosives; use of "Lexan" or other unbreakable see through barrier protection at computer data security island	Earlier detection of adversary force Increased barrier delay time to slow adversary down long enough for an effective security interdiction Determination of "false alarms" for fire	Seal off computer data facility as a potential crime scene and physical danger area; determine type of devices (EMP devices may also be Improvised Destructive Devices intended to kill those who attempt to move them).	Determine adequacy of detection, barrier delay and procedures for detecting false alarms to fire incidents
Searches at all ingress points for contraband to include all visitors and random searches of employees	Effective searches will include explosives nitrogen "sniffers" , metal detection, radiography of all packages, briefcases, back packs, etc. for contraband	Identification and confiscation of contraband; investigate	Investigate how perpetrators defeated security search procedures	Investigate and upgrade search protocols
Communications protocols with local, state and federal authorities to report suspicious sales or purchases of weapons and explosives	Reporting of suspicious sales or purchases of weapons and explosives	Reports of suspicious sales or purchases of weapons and explosives; investigate	Contact law enforcement to inform them of event; request an investigation to assure that no information of suspicious sales or purchases of weapons and explosives may not	Investigate what information, if any, could have been used to detect the perpetrators before they could have successfully completed their attack; upgrade procedures

TABLE 11-continued

A computer visualization of a structured evaluation of an event sequence against the CSM Method threat continuum



Deter	Detect	Prevent	Respond	Mitigate
			have been reported; if not reported-investigate	
Targeted security force, employee and local, state federal awareness programs to recognize, report and investigate "casing" or other suspicious activity	Targeted security force, employee and local, state federal awareness programs and reporting protocols	Proactive security, employee and law enforcement recognition, reporting and investigation of "casing" or other suspicious activity;	Determine if there were signs of "casing" that went unrecognized and include this information as part of a formal after action review (AAR)	If there were unrecognized signs of casing, e.g., hacking, unauthorized access to the building/computer systems, records, etc.; upgrade procedures
Active security and law enforcement monitoring of the warnings of adversary pre-planning including unusual purchases of equipment and materials, e.g., high voltage capacitors.	Communications protocols for reporting on warnings of adversary pre-planning	Other reports of possible adversary pre-planning including unusual purchases of equipment and materials, e.g., high voltage capacitors; investigate	When rendered safe, "reverse engineer" weapons; to include a "forensic shopping list" for all components to aid investigation	If means and methods of device construction are different from data previously archived in CSM knowledgebase, update the information
Emergency preparedness plans that include post evacuation assembly of all evacuated occupants	Effective implementation of emergency plans through formalized testing programs including post evacuation assembly of all evacuated occupants	Credentials checks to identify unauthorized individuals attempting to escape using evacuation as a "cover"	Conduct credentials checks to identify unauthorized individuals attempting to escape using evacuation as a "cover"	If emergency evacuation procedures do not include "control and assembly" provisions make necessary upgrades to plans, procedures and testing programs

Based on the analysis of the risk scenario event sequence against the threat continuum, a series of structured questions are developed. The questions fall into five general categories, namely, deterrence, detection, prevention, response and mitigation. This method of analogously deriving and structuring these questions is an object of the present invention. The questionnaires that result are imbedded as a part of the BuildingTQ software logic and used by clients to obtain Threat Quotients (TQ) for each critical node of building operation.

For example, in this case the critical nodes of building operation are the main lobby of the building a primary ingress/egress point and the computer data facility. Table 12., below, provides an example of ipsitive, i.e., "yes" or "no", question sets analogously derived from Table 11., above, showing how the resulting data is systematically derived and structured for repeatability prior to being archived in the CSM Method knowledgebase.

TABLE 12

A BuildingTQ example of an ipsitive question set derived from a scenario-threat event risk continuum analysis

DETERRENCE
1. Does your building security program include a targeted employee awareness program on the importance of visitor control?
2. Does the program address adversary deception tactics to surreptitiously gain access to your building?
3. Does security validate visitor meetings by contacting the host of the visit prior to allowing visitor access to your building?
4. Does your visitor badging process require that visitor's to your building provide two forms of photo ID?
5. Is one form of identification required to be a government issued ID such as a driver's license?
6. Do your procedures call for a badge exchange, i.e., a visitor's badge issued in exchange for a government issued ID and held by security for pick-up at the end of the visit?
7. Has your security force been trained in the proactive monitoring of possible "casing" activities by adversaries, especially those related to physical security and access controls?

TABLE 12-continued

A BuildingTQ example of an ipsitive question set derived from a scenario-threat event risk continuum analysis

8. Have your employees been trained in the proactive monitoring of possible "casing" or other suspicious activities by adversaries?
9. Have you coordinated the need for proactive monitoring of possible "casing" activities by adversaries, with local, state and federal law enforcement authorities?
10. Do your building managers and the security office maintain close liaison with local, state and federal authorities regarding possible threats to your building?
11. Do you have communications protocols in place with local, state and federal authorities to report suspicious sales or purchases of weapons and explosives that may? Affect the security of your building?
12. Do your security procedures include searches at all ingress points for contraband including weapons, explosives and other contraband?
13. Are specialized metal, explosives and x-ray equipment used?
14. Do you have a listing of suspicious or unusual activities that may indicate your building is being "case?"
15. Does law enforcement monitoring these warnings of possible adversary pre-planning activities including unusual purchases of equipment and materials that could be used to build Improvised Destructive Devices?
16. Are all evacuees, including visitors, accounted for following an evacuation?

DETECTION

1. Do you have a targeted employee awareness programs that include the importance of visitor control and adversary deception tactics?
2. Do you have an employee "hot-line" for reporting unusual or suspicious activities?
3. Do you offer monetary rewards for employees and others who provide information leading to the arrest and successful prosecution of perpetrators?
4. Do each of the critical nodes of your building include a survey by security engineers using the EESI algorithm, i.e., interdiction (I) of the adversary is a function of detection time (dn_t), delay time (dy_t), response time (r_t) and response quality (r_q) or: I f (dn_t) (di_{nt}) (r_t) (r_q)
5. Do you consistently conduct thorough searches of all visitors who enter your building?
6. Do you conduct searches of employees?
7. Do employees who are exempt from searches have background checks?
8. Are briefcases, backpacks, packages, purses and other hand carried items subject to search?
9. Are there specific protocols in place to assure that suspicious sales and illicit purchases or theft of weapons and explosives occurring in your region are reported to you by local authorities?
10. When you receive such reports, do you impose special security precautions?
11. Do federal, state and local law enforcement in your geographic region maintain a specific list of pre-planning activities that an adversary must undertake to attack your building?
12. Do federal, state and local law enforcement proactively use this list to identify and investigate potential attacks against your building?
13. Are there specific written communications protocols with federal, state and local law enforcement to report suspicious activities that may include "casing" to building security management?
13. Are there specific written communications protocols with other first responders including medical, fire and other personnel?
14. Do you have a formalized program of testing and training of your building's emergency response plan?

PREVENTION

1. Are all unauthorized attempts to circumvent visitor control procedures immediately pursued and investigated?
2. Are all attempts to use false credentials immediately pursued and investigated?
3. Are employee and building management and staff credentials tamper-resistant?
4. Are all continuously badges accounted for?
5. Do you have a published "hot-line" number for employees and others to report suspicious activities?
6. Have you computed an EESI analysis for your data computing facility I f (dn_t) (dy_t) (r_t) (r_q)?
7. Have you computed an EESI analysis for all other critical nodes of your building's operations I f (dn_t) (dy_t) (r_t) (r_q)?
8. Do you have procedures or technical means for determining false fire alarms?
9. Do you have security response procedures in place in the event you discover weapons, explosives or other contraband during searches?
10. Do you immediately pursue and investigate all reports of suspicious sales, purchases, loss or theft of weapons and explosives?
11. Does your security office and local law enforcement have a list of pre-planning and other suspicious activities that an adversary would have to undertake in order to plan a surreptitious assault on your building?
12. Does your security office make proactive use of the list?
13. Does your regional law enforcement make proactive use of the list?
14. Does federal law enforcement make proactive use of the list?
15. Do your security personnel have basic training in the management of IDD events?
16. Does local law enforcement have a bomb squad ready to respond to your request for assistance?
17. Are there procedures in place with law enforcement, military medical and other first responders in the event of an attack on your building?
18. Does your security office, local, state and federal law enforcement have knowledge of the construction and the materials required to build an improvised destructive device including an electro-magnetic pulse bomb or and Improvised Destructive Device?

TABLE 12-continued

A BuildingTQ example of an ipsitive question set derived from a scenario-threat event risk continuum analysis

19. Do they maintain a watch list for such items?
20. Do your regional law enforcement authorities report suspicious purchases, sales, losses or thefts of the materials necessary to construct an EMP?
21. Do your regional law enforcement authorities report suspicious purchases, sales, losses or thefts of the materials necessary to construct an IDD?
22. In the event of a building evacuation or lock down, does your emergency plan include procedures for assembly and the positive identification of all personnel?
23. When an evacuation involves a suspected false alarm or other potential illegal activity, do your security procedures change?

RESPONSE

1. Do you have written investigative procedures requiring the immediate investigation of potential or actual breaches of building security?
2. Do you have formal written policies and procedures for immediately contacting local, state and federal law enforcement, as appropriate, of any attack on your building?
3. Do you have an automatic emergency notification call list?
4. Do you have an automated emergency notification call system?
5. Do you have back-up communications capability in the event of loss of primary communications systems and the power that supports them?
6. Do you have written building lock down procedures?
7. Do you have a building wide emergency notification system?
8. Do you have a system of varying security alert levels?
9. Does each successive security level have added security conditions and procedures that must be followed for specific types of incidents that could impact each critical node of your building's operation?
10. In the event of an attack on your data computing center do you have written procedures to Seal off computer data facility as a potential crime scene and physical danger area?
11. Do you have written procedures to determine the type of devices (EMP devices may also have secondary Improvised Destructive Devices intended to kill those who attempt to move them)?
12. Do you have written "render-safe" procedures for devices or suspicious objects or packages left unattended in your building?
13. Do you have written policies in effect that require the investigation to determine how perpetrators circumvented security procedures and equipment?
14. Do these policies require that deficiencies discovered during these investigations are corrected?
15. Do you contact law enforcement to request an investigation?
16. Do you request assurances that no information of suspicious sales, purchases, thefts or losses of weapons and explosives have been reported
17. If you learn that information was not provided to you do you request an investigation as to why not?
18. In the aftermath of an attack on your computer data facility, do you determine if there were signs of "casing" that went unrecognized?
19. Do you have a formal system for conducting after action reviews following security and safety incidents involving each critical node of your building's operations?
20. Is this information included as part of a formal after action review (AAR)?
21. Do these procedures require positive identification using tamper resistant photo ID?
22. When rendered safe are the devices left behind in the computer data facility "reverse engineered" to include a "forensic shopping list" for all components to aid in the investigation?
23. Are security forces trained to recognize the configurations of different types of improvised weapons?
24. Do you have emergency procedures in place that require, in the event of a building evacuation, that all personnel including visitors are accounted for?

MITIGATION

1. In the aftermath of an attack on your computer data facility do you determine how the access control system was circumvented and make necessary modifications?
2. Are there written procedures requiring that this be done?
3. Do you have a business continuity plan in the event that your computer data facility is attacked and data destroyed?
4. Does your BCM plan Implement business continuity plan require re-routing of all communications to a back up location?
5. If you have no data back-up facility do you have plans to work with authorities to preserve as much data as possible?
6. Do lock down your computer data facility access points to absolutely preclude any unauthorized or accidental access to damaged system?
7. Do you have a data recovery plan?
8. In the aftermath of the event, do you work with corporate management, security, all levels of law enforcement and other first responders to prepare a coordinated press release and prepare for a press conference?
9. Are there written procedures requiring that this be done in the event the building is attacked?
10. In the aftermath of the attack, do you determine the adequacy of detection, barrier delay and response times?
11. Are there written procedures requiring that this be done?
12. Is the CSM knowledgebase updated to reflect new data, if any?
13. Do you have procedures for detecting false alarms to fire and security systems?

TABLE 12-continued

A BuildingTQ example of an ipsitive question set derived from a scenario-threat event risk continuum analysis

14. Do you investigate why search procedures failed?
15. Do you upgrade search protocols accordingly?
16. Do you have written procedures requiring that this be done?
17. Do you investigate what information, if any, could have been used to detect the perpetrators before they could have successfully completed their attack?
18. Do you upgrade procedures accordingly?
19. Are there written requirements that numbers 3. and 4., above, must be conducted?
20. In the aftermath of the attack on the computer data facility, do you investigate_if there were unrecognized signs of casing, e.g., hacking, unauthorized access to the building/computer systems, records, etc.
21. Do you upgrade security policies, procedures and equipment to "close holes" in your security systems?
22. Are there written requirements that numbers 6. and 7., above, must be conducted?
23. If the adversary means and methods of device construction are different from data previously archived in CSM knowledgebase do you update the data to include new information?
24. Do your emergency evacuation procedures include "control and assembly" provisions?
25. Do they include positive identification of all personnel including visitors?
26. Is positive ID assured using photo tamper-resistant ID?
27. Are evacuation and control and assembly procedures tested?
28. Are evacuation plans and procedures upgraded accordingly?
29. Do you have written requirements that evacuation drills be conducted?
30. Has it been more than twelve months since the last evacuation test at your building?

The use of ipsitive questions allows the BuildingTQ software to provide scores based on a "yes" or "no" answer to the question set. Clearly a "yes" response receives a lower TQ value (less risk) than a "no" answer.

Phase 1. Step 6. (Benefit applications only). Benefit applications use the same systematic approach to structure data as risk scenarios do. In the same fashion, benefit scenarios are structured along a time continuum, but one that begins with earliest possible recognition of an opportunity moving sequentially through strategy development to take advantage of the opportunity, specific actions to capture the opportunity and short and long-term sustainment of benefit. Structured responses to the following two questions for each hypothetical benefit scenario are developed: a) what information had it been known before the opportunity was first recognized could have been used to recognize and act on it sooner? and; b) what information had it been known beforehand could have been used to increase and sustain the benefits of the opportunity longer? As with risk scenarios, this data represents the indicators of impending opportunities and sustainment and the subject of data collection strategies designed to search out and identify opportunities as early as possible and sustain optimum event sequences, i.e., those of greatest benefit in the short and long term. In this case, benefit (B) is a function of the probability of an event (good or bad) happening (PO) times the consequences that result (c) or: B f PO (c). This is known as the Opportunity Benefit Algorithm (OPA). The Opportunity Benefit Algorithm (OPA) is an object of the present invention.

Phase 1. Step 7. Each scenario is reverse engineered to isolate how potential initial conditions would affect the manner in which people exercise the fundamental rule sets that in combination serve to propagate system's behaviors that, in turn, affect the critical nodes of a system's operation. How potential initial conditions affect the manner in which people exercise fundamental rule sets is an object of the present invention.

In our Building TQ example of an adversary attack on the computer data facility, the fundamental rule is represented by the nature of the attack—in this case surreptitious entry. As discussed previously, a priori optionality, tells us that there are three and only three ways a building can be attacked: 1) armed assault; 2) surreptitious entry, and; 3) improvised chemical, biological or nuclear devices including explosives, "dirty bombs", EMP devises, "bio bombs", fire bombs, etc. Reverse engineering our BuildingTQ scenario we quickly see the difference between a fundamental rule and initial conditions. In this example, initial conditions would be things such as time of day, the results of adversary casing of the building with special emphasis on things like the effectiveness of the access control system, detection capabilities, construction features, the consequences that will result from a successful attack and other factors.

Take as an example the initial condition that the attack on the computer data facility occurred during a normal business day? Ask yourself the question, how did a daytime attack during normal business hours affect the way people behave to propagate a system's behavior? In the BuildingTQ example the answer is clear. A daytime attack was critical to the successful escape of the adversaries by creating the circumstances necessary for a mass evacuation of the building. The adversary's means and methods depended upon being able to mingle with large numbers of people evacuating the building in order to make good their escape. A fire alarm late at night or on a weekend would not result in a mass evacuation because the building would be occupied with too small a population of people to provide the necessary "cover" for a successful escape.

Another initial condition is the effectiveness of the building's access control system. Ask yourself the question how did the performance of the access control system propagate a system's behavior? In the Building TQ example the answer is clear. A weak easily circumvented access control system created a huge "hole" in the security system that could be easily exploited by the adversary. Even though the building had been infiltrated by an adversary force, the access control and security system continued to operate on a business as usual basis because there was no detection. Ask yourself how the adversary's means and methods would have to change in our BuildingTQ scenario had they been confronted with a strong access control system. The incident would likely have been prevented.

Isolating initial conditions from fundamental rules is essential for the systematic generation of new scenario event paths that can then be subjected to EESI and a threat continuum analysis. The analogous, systematic and repeatable methods used under the CSM Method to isolate initial conditions from fundamental rules are an object of the present

invention. The systematic generation of a plurality of new scenario event paths that can be subjected to EES1 and a threat continuum analysis is an object of the present invention.

Phase 1. Step 8. Based on the results of reverse engineering scenarios involving critical nodes of systems operation, storyboards are developed to produce simulations of risk or benefit situations that can affect the system. These simulations are designed to reflect complex interdependencies among different critical nodes and their effects on outcomes. They identify the critical decision points within each hypothetical simulation, i.e., those points where decisions must be made to avoid the uncontrolled evolution or devolution of a system. The use of CSM Method derived simulations that reflect complex interdependencies between and among critical nodes of systems operation is an object of the present invention. The identification of CSM Method derived critical decision points is an object of the present invention.

In our BuildingTQ example, a story board is developed based on the event sequence scenario for the adversary attack against the computer data facility. The application of the of EES1 algorithm and a threat event continuum analysis allows us to easily isolate critical decisions that would have prevented the event or otherwise diminished the extended order effects of a successful adversary attack on the computer data facility. Isolating critical decisions that would have prevented an adverse event or otherwise diminished the extended order effects of a successful adversary attack is an object of the present invention. A few examples of critical decision points in our Building TQ scenario include:

- The initial employee decision to "validate" the adversary team as "legitimate" visitors to the building even though he had no confirmation of a meeting by the host.
- The decision by access control personnel not to require positive identification of the "visitors."
- The decision by access control personnel not to call the alleged host of the meeting to confirm the legitimacy of the visit.
- Decisions to ignore or avoid quantitative analysis showing the true capability of the security system in terms of early detection, barrier delay time, time for security response and the quality of the security response.
- Decisions to avoid or ignore a broader range of potential scenarios that could impact the computer data facility (and likely other critical nodes of building operation).

Phase 1. Step 9. Each critical decision point in a simulation is reverse engineered carefully considering the risk and/or benefit continuum, the outcomes and extended order effects of different decision options, and the identification of warnings and/or indicators of risk and benefit situations. Out of the range of possible decisions, the optimum decision sets in a simulation that lead to the most desirable outcome(s) are identified. The derivation of optimum decision sets using the CSM Method is an object of the present invention.

In our BuildingTQ example, an unknown group approaching an employee to help them gain access to the building for an unconfirmed meeting is a warning signal of a possible attack. During this step, the critical "what if" question is addressed: suppose the initial employee decision had been different? Say the employee remembered from the company's new hire orientation program that it was important to assure that only legitimate visitors with positive identification be allowed to enter the building. The employee would likely have done one of two things; 1) recognize the approach by strangers as suspicious and report it to security, or 2) if properly trained to do so, play along with the adversaries and clandestinely work with security to identify and capture the suspects.

Clearly, either of these two actions would have served to prevent the attack on the data computing facility as it was originally planned. But if the employee decided to "play along" with the adversaries and clandestinely coordinate his actions with security, the perpetrators would not only have been prevented from attacking the computer data facility as planned, but also removed as a potential future threat. In this case, decision number two is the clearly the preferred option. The question then becomes, do current employee security orientations include such things as describing suspicious behaviors? What to do? How to do it? And, so on. Different decisions are mapped showing their extended order effects. Storyboards are expanded around different decision sets and outcomes, i.e., extended order effects, systematically structured in decision fault tree formats for repeatability and archived in the CSM knowledgebase. Suspicious approaches to employees by strangers could be a warning signal of an impending attack and is archived in the knowledgebase. The derivation and structuring of the extended order effects of a range of possible decisions using the CSM Method is an object of the present invention.

Phase 1. Step 10. The fundamental rule sets, associated initial conditions, the sequence of events associated with different scenarios, arrays of potential outcomes for each scenario involving a critical node of operation and the warnings and/or indicators or risk or benefit situations for t_1 are structured, catalogued and archived in a supporting knowledgebase. In our BuildingTQ example additional scenarios involving critical nodes and combinations of critical nodes are systematically examined in Phase 1. Steps 1.-9. with all data structured for repeatability in the CSM knowledgebase as described previously. Scenarios developed in this step include complex interdependencies between critical nodes. For example, in our BuildingTQ computer data facility, computer operations are also highly dependent on other critical nodes and infrastructures including back-up power, effective fire suppression systems, cabling and communications systems, etc.

Phase 1. Step 11. The process is repeated for hypothetical scenarios involving the same and other critical nodes at t_2, t_3, t_4 and so on by adjusting the combinations and values assigned to initial conditions to create an array of event paths with different potential outcomes for each of the critical nodes of system operation that are bounded by the fundamental rule sets deduced during Step 1. of the process. Outcomes are derived for each scenario based on the relative affect of one or a combination of initial conditions and the manner in which associated fundamental rule sets are exercised to propagate a systems behavior observed at t_2, t_3, t_4, and so on. The production of a plurality of CSM Method analogously derived futures driven scenarios is an object of the present invention.

Using our BuildingTQ example, this step creates a data library of different scenarios based on a range of possible attacks involving the computer data facility and the fundamental rule of surreptitious entry. New scenarios at t_2, t_3, t_4 and so on are systematically created by changing initial conditions as described in Phase 1. Step 10. are structured using the Phase 1. CSM Method business process to generate a range of different scenarios involving the fundamental rule of surreptitious entry. The data library possible attack scenarios is archived in the CSM Method knowledgebase.

Phase 1. Step 12. The fundamental rule sets, associated initial conditions, the sequence of events associated with different scenarios, arrays of potential outcomes for each scenario involving a critical node of operation and the warnings and/or indicators of risk or benefit situations for t_2, t_3, t_4,

t_5 and so on are structured for repeatability, catalogued and archived in the supporting CriTQ knowledgebase.

Using our BuildingTQ example, Phase 1. Steps 1.-12. are repeated for different critical nodes of building operations using the remaining two fundamental rules of armed assault and improvised destructive devices (IDD's) including chemical, biological and biological weapons. This creates an extensive data library of structured, repeatable data that is archived for use and analysis in the CSM CriTQ knowledgebase. The development of analogously derived futures driven scenario event libraries based on the CSM Method and the six tenets of a priori optionality is an object of the present invention.

Automating Phase 1. of the CSM Method Business Process: Building TQ as One of Many Possible Applications

Data gathered and structured in Phase 1. Steps 1.-12. is archived in the CSM CriTQ knowledgebase, is analyzed using an intelligent system that applies values to ipsitive question sets on a scale of 1 to 10 with 1 being the lowest threat quotient or TQ (smallest level of risk) and 10 being the highest TQ (highest level of risk). The intelligent system weights assigned values based on numerous factors including the type of building, its function, number of critical nodes, demographic data for the city and region in which the building is located and other factors further described below. The methods of deriving threat quotient (TQ) scores and values is an object of the present invention.

At the core of each CSM Method business process application is a tailored software logic architecture. Software logic architectures are unique to the subject area involved. For purposes of demonstration and explanation this claim uses an existing risk management application for buildings known as BuildingTQ. The BuildingTQ CSM Method business process application is used here as only one of many representative examples of how Phase 1. of the CSM Method can be automated. Tailored CSM Method software logic architectures that are designed to address the range of risk management applications is an object of the present invention.

In structuring the software logic architecture for Building TQ eight distinct steps are involved that build on Phase 1. Steps 1.-12. of the CSM Method business process. Each of the eight steps for structuring the software logic architecture for the Building TQ application is consistent with the six tenets of a priori optionality. Each step is described below.

The BuildingTQ Software Logic Architecture

Step 1. involves the creation of a "building type" taxonomy that allows for the identification of generic types of buildings and facilities. For example, a representative list of different building types includes:

1. School and college campuses
2. Banks
3. Hospitals
4. Multi-story commercial office buildings
5. Multi-story apartments and condominiums
6. Commercial retail buildings
7. Manufacturing facilities
8. Water and sewage treatment facilities
9. Hospitality industry including hotels, malls, theme parks, etc.
10. Casinos
11. Computer data centers
12. Emergency response centers
13. Stadiums
14. Convention centers
15. Warehouses
16. Others

Step 2. involves the identification of generic critical nodes for each generic class of building and facility. For example, a representative list of the critical nodes generic to all building types includes:

1. HVAC Systems
2. SCADA rooms, control and sensor systems
3. Mass gathering areas
4. Parking facilities including above ground and subterranean
5. Ingress/egress points including roof, utility tunnels, main entrances and exits, loading docks, and all other doorways
6. Communications systems including cabling runs
7. Blast physics stress locations
8. Water (intake and distribution)
9. Sanitation and sewer systems
10. Power supplies and distribution systems including wiring
11. Perimeter security including physical barriers and buffer zones
12. All human transit systems, e.g., elevators, escalators, stairwells
13. Security systems including alarm systems and guard force response capabilities
14. Safety systems especially those relating to fire prevention and management
15. Others

Step 3. involves the prioritization of the relative importance of generic critical nodes based on specific building/facility type. Numerical weighting factors are applied to the generic critical nodes of different types of buildings and facilities. For example, university, college and K-12 school campuses are unique from other building configurations based on the purpose of their use. Table 13., below, illustrates how the CSM Method business process analysis and weighting model is used to prioritize examples of the different critical nodes of a college campus and building safety. Numerical weighting values are the result of the multidisciplinary inputs of subject matter experts, computer modeling, and data gathered during Phase 1. of the CSM Method business process and other specific threat data. The prioritization of the importance of critical nodes using the Event Probability Algorithm (EPA) is an object of the present invention. The CSM Method business process analysis and weighting model is an object of the present invention.

TABLE 13

How the CSM Method business process analysis and weighting model is used to prioritize examples of the different critical nodes of college campus and building safety

Critical Node	Weight*	Rationale
1. Secure Control Automated Data Acquisition (SCADA) system	SCADA equipped structures 8.0 TQ Non-SCADA equipped structures 1.0 TQ	In many modern school buildings SCADA may play an important role in controlling HVAC, communications, security, safety surveillance and alarm systems and other critical nodes of building operations.
2. HVAC systems	Roof based air intakes 8.0 TQ Ground-based air intakes	HVAC systems and attendant air intakes, whether roof or ground based, are highly susceptible to the

TABLE 13-continued

How the CSM Method business process analysis and weighting model is used to prioritize examples of the different critical nodes of college campus and building safety

Critical Node	Weight*	Rationale
	9.0 TQ	introduction and distribution of deadly chemical gasses and biological agents; improperly maintained HVAC systems can also pose serious health risks.
3. Security Systems	9.5 TQ	Security systems represent the first line of defense for college campus and building security and are essential for deterrence, early detection, prevention and effective response to both man-made events and natural phenomenon.
4. Parking facilities	9.5 TQ	In-building or subterranean parking areas are particularly susceptible to the use of an Improvised Destructive Device (IDD). The detonation of an IDD (s) can cause catastrophic structural failure if properly placed. Secondary fires fueled by gasoline can burn plastics and other materials from vehicles to emit toxic gases. Open parking lots located close to buildings can also be the target of a serious threat posed by a car bomb.
5. Mass gathering areas	9.0 TQ	Students massed in large numbers can represent a highly attractive target for mass killings by malevolent actors; large scale evacuations may become problematical in the event of an emergency.
6. Blast physics stress locations	New construction TQ 7.5 Old construction TQ 8.5	The construction of modern buildings makes them less susceptible to complete structural failure using IDD's. The use of larger "truck bombs" similar to the Murrah Federal Building bombing, however, must be addressed by effective perimeter security including barriers and buffer zones that prevent unauthorized "close-in" truck access.
7. Ingress and egress points	Campus access 7.0 TQ Unauthorized building ingress/egress 9.0 TQ	By nature, centers of learning are considered open access areas. Unauthorized access to campus buildings, however, represents a much greater threat to the security and safety of students.
8. Communications systems	9.5 TQ	In the event of emergency, it is imperative to have effective means of communicating quickly to large populations of students, law enforcement, public safety personnel and the families of students.
9. Water intake and distribution systems	7.0 TQ	Water supplies may be vulnerable to the introduction of poisonous or toxic materials; widespread contamination is a function of water usage and the resultant dispersion of poisonous or toxic substances introduced into the water supply system at key locations.
10.-14. Remaining Critical Nodes	Value	Rationale

*Based on a scale of 1 to 10 with 1 being least important and 10 being most important

Step 4. Build a taxonomy that rates the importance of each critical node of operation (CNO) by generic building/facility type in terms of probability of occurrence (based on past trends, future modeling) and potential consequences relative to natural phenomenon using a scale of 1 to 10 with 1 being the lowest consequence to 10 being the highest threat quotient (TQ) based on today's standard building practice. This becomes the BuildingTQ initial TQ default rating for each CNO. The derivation of default TQ starting values for different types of buildings, facilities and other infrastructure systems using the CSM Method is an object of the present invention.

As described previously, for natural phenomenon (v) f PO (c). Table 14., below, applies TQ values to a large commercial bank building geographically located in Omaha, Nebr. In this example, we are assessing the risk associated with the heating, ventilation and air conditioning (HVAC) system, a critical node of the building's operations. For example, the Omaha region is known for its frequency of damaging tornadoes. On large commercial buildings HVAC systems are fre-

quently located of roof areas making them unusually susceptible to the type of high wind conditions that can be generated by tornadoes. Because tornadoes are a relatively common weather phenomenon affecting the region, a probability of occurrence (PO) value of 9 on a scale of 1 to 10 is applied. We also know that HVAC systems affect all building operations and are one of the systems most critical to the safe operation of a modern commercial office building. A tornado holds the potential of completely disabling the bank's HVAC system and thus a consequence value of 9 is assigned. The resulting threat quotient (TQ) results from multiplying the probability of occurrence (PO) value of 9 times the consequence (c) value of 9 to produce a TQ of 81%.

Earthquakes in the Omaha region, on the other hand, are a relatively rare geological phenomenon. For this reason a low PO value of 2 is assigned. However, in the unlikely event of a major earthquake, there is good reason to conclude that major commercial office buildings would sustain major damage including the destruction of their HVAC systems. Thus a high (c) value of 9 is assigned. The PO value of 2 times the (c) value of 9 results in a TQ of 18%. The process is repeated for the range of natural phenomenon that could affect a modern commercial bank building located in Omaha, Nebr.

TABLE 14

The CSM Method BuildingTQ Model for applying TQ values for natural phenomenon

Building Type	Natural Disaster	Location	Critical Node	Probability of Occurrence	Consequence	TQ
Bank	Tornado	Omaha	HVAC Systems	9	9	81%
	Earthquake			2	9	18%
	Flooding			2	5	10%
	High Winds			6	9	54%
	Lightning			7	9	63%
	Hurricane			2	9	18%
	Tsunamis			2	9	18%
	Snowfall			9	6	54%
	Fire			8	9	72%

Step 5. involves the identification and rating of the significance of mitigating actions (m) by generic building/facility type and critical node that will reduce the potential consequences relative to natural phenomenon using a scale of 100 percentage points.

As described previously, for natural phenomenon consequence (c) minus mitigating actions (m) equals Adjusted TQ or (c)−(m)=ATQ. Table 15., below, applies mitigating values for natural phenomenon for the same bank building located in Omaha, Nebr., to produce an ATQ.

As illustrated by Table 15., above, the existing TQ value for a tornado occurring (PO) and causing devastating damage to the building's HVAC systems initially stands at 81%—a high TQ value. But stronger "bolt-down" systems for roof based HVAC units make them much more wind resistant and provide a mitigating (m) value of 21%. The existing TQ value of 81% is reduced (−) by 21% to establish a new ATQ of 61% closer to the average expected for a building of this type located in the Omaha region.

Step 6. creates the taxonomy for rating the importance of CNO's by generic building/facility type in terms of vulnerability and potential consequences relative to attack types, i.e., BuildingTQ fundamental rules, using a scale of 1 to 10 with 1 being the lowest consequence to 10 being the highest threat quotient (TQ) based on today's standard building and security practice. This becomes the BuildingTQ initial TQ default rating for that building type. As described previously, for threat events the probability of a risk event occurring (PO) is a function of the vulnerability of the CNO (v) times the consequences that would result from a successful attack (c) or: PO f (v) (c).

Table 16., below, applies TQ values for the HVAC systems against armed assault, surreptitious entry and the use of an improvised destructive device for the same bank building located in Omaha, Nebr. As noted above, these values become the BuildingTQ initial TQ default rating for a modern bank building geographically located in the Omaha, Nebr. region.

TABLE 15

The CSM Method BuildingTQ model for applying ATQ values for natural phenomenon

Building Type	Natural Disaster	Location	Critical Node	Current TQ	Mitigating Action	% Value	ATQ
Bank	Tornado	Omaha	HVAC Systems	81%	Stronger Boltdown	20%	61%
	Earthquake			18%	WB Earthquake Resistance	60%	1%
	Flooding			10%	Pumping System for below grade	40%	1%
	High Winds			54%	Stronger Boltdown	20%	34%
	Lightning			63%	Increased Grounding	40%	23%
	Hurricane			18%	WB Hurricane Resistance	40%	1%
	Tsunamis			18%	WB Tsunami Resistance	20%	1%
	Snowfall			54%	Increased Roof Load Construction	25%	29%
	Fire			72%	Primary and Secondary Fire Safety Design & Evacuation Plan	60%	12%

TABLE 16

The CSM Method BuildingTQ Model for applying TQ values for risk events

Building Type	Attack Type	Location	Critical Node	Vulnerability	Consequence	TQ
Bank	Armed Assault	Omaha	HVAC Systems	8	9	72%
	Surreptitious Entry			6	9	54%
	Improvised Device			8	9	72%

As Table 16. illustrates, the results of the Phase 1. CSM Method business process show that under certain scenarios, attacks that include HVAC systems can substantially increase the risks of a bank to successful attack. Consequently, a relatively high TQ value of 8 is assigned to the bank in Omaha. The use of HVAC systems to aid surreptitious entry, while still a significant concern, is assigned a lower TQ value of 6. The use of an improvised destructive device, especially a biological or chemical weapon is assigned a TQ value of 8. Multiplying the assigned vulnerability value (v) times the consequence (c) value produces a TQ value. For example, the vulnerability of the bank's HVAC system (v) to attack using an improvised destructive device 8, when multiplied by the consequences of a successful attack against the HVAC system (c) result in a TQ score of 72% on a scale of 1 to 100 percentage points.

Step 7. Build a taxonomy that rates by CNO's and generic building/facility type, mitigating actions (m) that will interdict attacks and reduce the consequences of attempted attack types on a scale of 1 to 100 percentage points. Weight the elements of detection, delay, response and quality of response to reflect the greater value of anticipation and prevention versus reaction and response. For example, the vulnerability of the CNO (v) times the consequences of a successful attack (c) minus mitigating actions (m) weighted in favor of interdiction where early detection time (dn_t) is assigned a 40% weighting factor (on a scale of 1 to 100 percentage points); delay time (dy_t) is assigned 25%; response time (r_t) is assigned 20% and quality of response (rq) is assigned 15% or: (v)(c)−(m) where m=[(dn_t) (40%)] [(dy_t) (25%)] [(r_t) (20%)] [(r_q) (15%)].

Table 17., below, applies mitigating values and associated weights for armed assault, surreptitious entry and improvised destructive devices for the same bank building located in Omaha, Nebr.

As Table 17. illustrates, initial default TQ scores for armed assault, surreptitious entry and the use of an improvised destructive device for specific building types are adjusted based on mitigating factors that are weighted in favor of anticipation and prevention in order to interdict the adversary before a successful attack can be perpetrated. In the BuildingTQ example involving the bank in Omaha, an initial TQ value of 72% was assigned to the risk posed by an improvised destructive device being used against the HVAC CNO of the bank building. However, with the introduction of perimeter protection for HVAC air intakes, the use of chem.-bio sensors and drop down baffles to immediately halt further convection flow of contaminated air into the building is given a very significant mitigating value of 50%. This is because the underlying mitigation weighting scale gives more relative value to mitigating factors that provide for early detection and increased delay time that, in turn, would lead to the successful interdiction of the event before it happens and before consequences can result. Use of weighting factors to give more relative value to mitigating factors that provide for early detection and increased delay time that, in turn, lead to successful interdiction before events is an object of the present invention.

Step 8. Create the taxonomy for natural phenomenon and provide the heuristic rationale for natural phenomenon and malevolent attack questionnaires.

For Natural Phenomenon

$$vfPO(c)$$

$$(c)-(m)=\text{ATQ}$$

For Malevolent Attacks

$$POf(v)(c)$$

$$If(dn_t)(dy_t)(r_t)(r_q)$$

$$(v)(c)fm$$

TABLE 17

CSM Method BuildingTQ model for applying ATQ values for risk events

Building Type	Attack Type	Location	Critical Node	Current TQ	Mitigating Actions	% Value*	ATQ
Bank	Armed Assault	Omaha	HVAC Systems	72%	Perimeter protection of intakes; chem-bio sensors/ baffle	50%	22%
	Surreptitious Entry			54%	Alarm man-size ducts	35%	19%
	Improvised Destructive Device			72%	Blast resistant design and construction; explosives searches	35%	37%

*(v)(c) − (m) where m = (dn_t) (40%) (dy_t) (25%) (r_t) (20%) (r_q) (15%)

Phase 1. Steps 4. and 5. of the CSM Method business process creates the taxonomy and provides the heuristic rationale and a sample questionnaire for a surreptitious entry malevolent attack. The CSM Method taxonomy and heuristic rationale for natural phenomenon and malevolent attack questionnaires is an object of the present invention.

The CSM Method™, CriTQ™ and the BuildingTQ™ Automated Software System

The CSM Method business process uses a three-phased, multi-step process for analyzing and improving performance within complex systems. The CSM Method uses a science-based process to help clients better understand their complex environments.

Data gathered in all phases of the process is captured in an intelligent knowledgebase. This powerful platform incorporates semantic search and data retrieval capabilities and the ability to graphically display data. This enables users to easily model the behavior of their system—for example, to see the impact of changes to a compensation plan on sales, or to see how the failure of a critical radio network in Albany would impact airport operations in New York City.

The focus of CSM method software systems is on the automation Phase 1: Quantitative Analysis of the CSM Method business process in order to serve as the foundation for the implementation of Phases 2. and 3. of the process. Structured Phase 1. data archived in the CSM Method knowledgebase is integrated with and used to support the Phase 2: Qualitative Analysis and Phase 3: Subsequent CSM interventions Phase 3. of the CSM business process.

Phase 1: Quantitative Analysis

The growing complexity of today's world environment mandates a new approach to threat analysis. The CSM Method supports products and services in targeted markets. We are developing a series of products based on the CSM Method. These products are marketed as the CriTQ™ product family. The CriTQ architecture consists of three parts, securely connected over a virtual private network (VPN).

1. The centralized CriTQ knowledge engine, i.e., CSM Method knowledgebase. This server stores all common data, including satellite imagery, geospatial data, current threats, regulatory information libraries, vulnerabilities and risks, warnings and indicators of impending events, and "best practices" for risk mitigation This data is refreshed on a continuing basis from open Internet sources using automated search and retrieval tools. The CriTQ engine is housed in a manner to provide effective continuity of operation support.

2. An application-specific server located on the customer's premises (or optionally hosted at another secure location). This server stores the individual user's proprietary data (user information, building plans, risk mitigation strategies, etc), to prevent unauthorized access.

3. A solution-specific interface application, built to run under a standard web browser (Internet Explorer, Firefox, etc). This application provides users a real-time interface into both servers, seamlessly blending common data and proprietary data in response to user requests.

BuildingTQ™

Modern buildings are made up of a mix of interdependent components. HVAC systems rely on utility power and commercial water, include complex distribution systems, and employ SCADA (Supervisory Control and Data Acquisition) applications to automate control processes. Traditional risk assessment products look at each of these components individually. In contrast, BuildingTQ uses a system-wide approach to threat assessment, analyzing how threats to one critical component will impact other components and the building as a whole.

BuildingTQ is a comprehensive vulnerability assessment and risk management tool targeted at owners and managers of commercial properties. BuildingTQ enables users to identify and resolve critical vulnerabilities arising from multi-hazard threats. This includes both natural threats (e.g. fire, hurricanes, and earthquakes) and man-made threats (terrorist actions, criminal activities). It is based on a business process model known as the CSM Method.

The results of this assessment—what we call the ThreatQuotient™—is displayed in graphical format using a combination of geospatial data and 3-D building diagrams. BuildingTQ also suggests possible strategies for mitigating risks based on "best practices" in our knowledgebase. As mitigation strategies are selected (or new ones are defined by the user), changes to the ThreatQuotient (TQ) are displayed in real time. This enables users to model their actions to determine the most effective solution based on their individual business, security and safety model.

Competing approaches rely on historical threat data, i.e., the law of large numbers, which by definition do not reflect real time changes in the threat environment. In contrast, BuildingTQ's threat data maintained in the CriTQ knowledge engine is continuously refreshed as it scans the environment for the warnings of impending attacks based on data provided using the CSM Method business process.

As depicted in Tables 18. and 19., the CriTQ knowledgebase continuously scans the internet and other sources for open source data identified by the CSM Method business process. The data mining of open sources for data on CSM Method derived indicators and warnings is an object of the present invention.

The BuildingTQ Automated System Requirements Specification

TABLE 18

Continuous scan of open source data

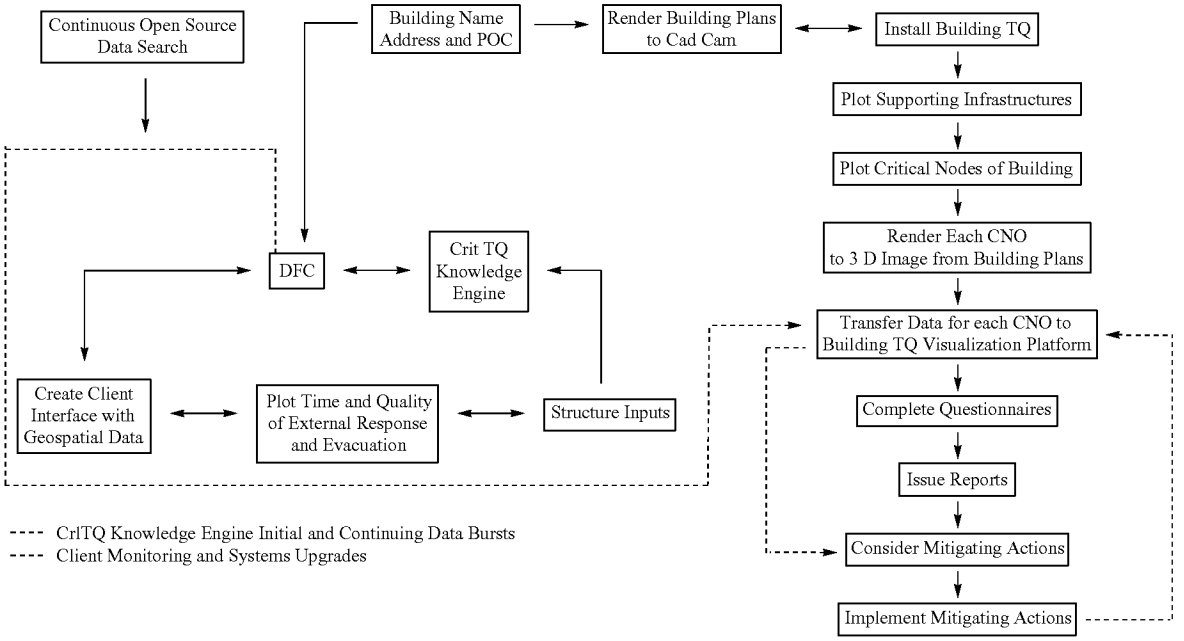


TABLE 19

The CriTQ knowledge engine uses search technology to continuously scans the internet and other sources for open source data identified by the CSM Method business process

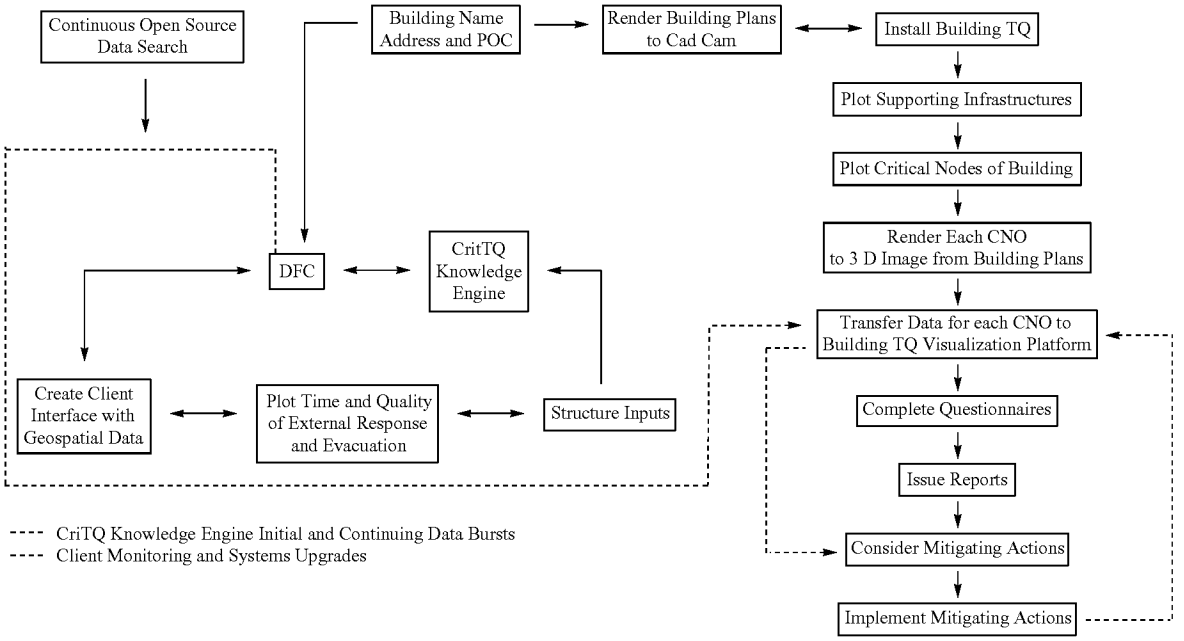
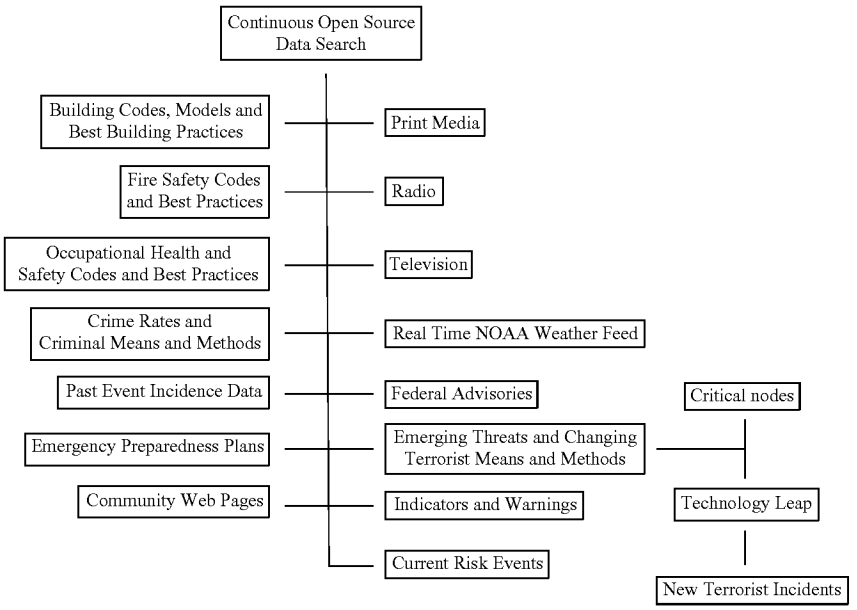


TABLE 20

Examples of CSM Method open source data gathering

Open source data includes data harvested from open sources such as:

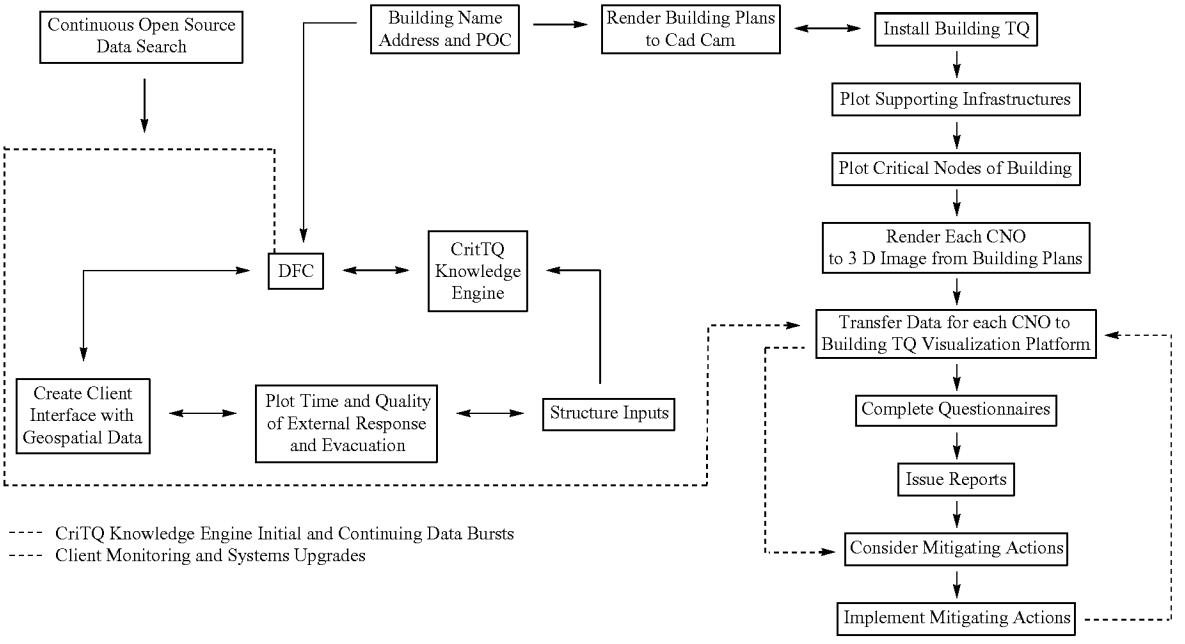


30

The software logic system then asks the client to input data regarding the name and address of the building.

TABLE 21

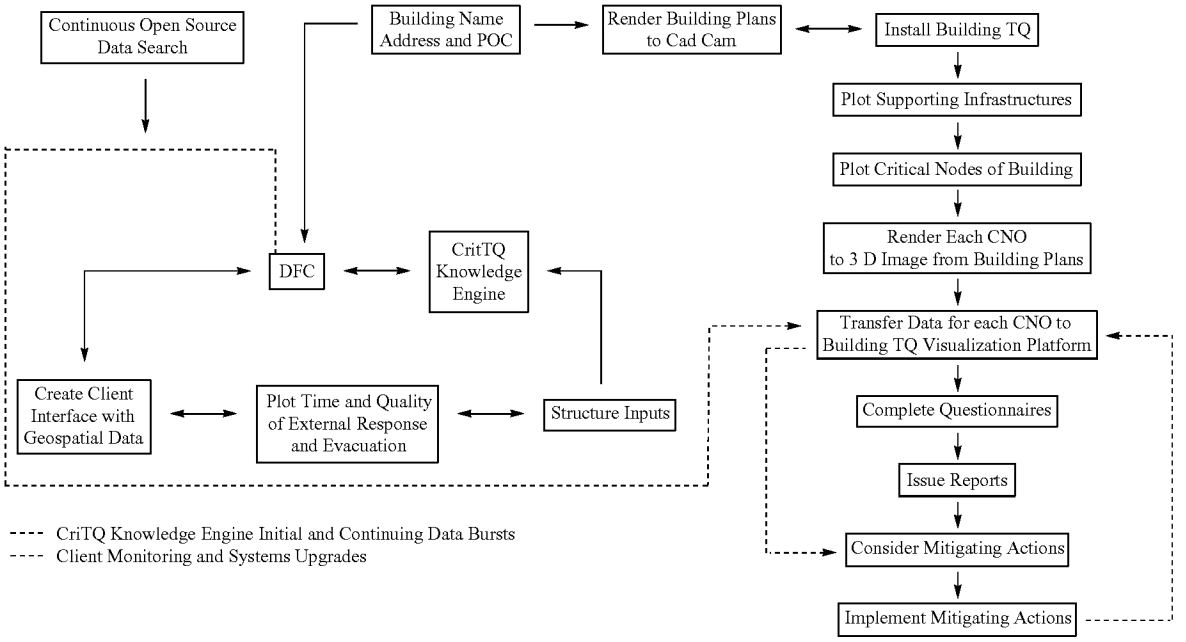
Client inputs data regarding the name and address of their building



The software logic system validates client identity then directs the data to personnel at the data fusion center (DFC) over the secure VPN network.

TABLE 22

Data regarding the location is directed to the DFC

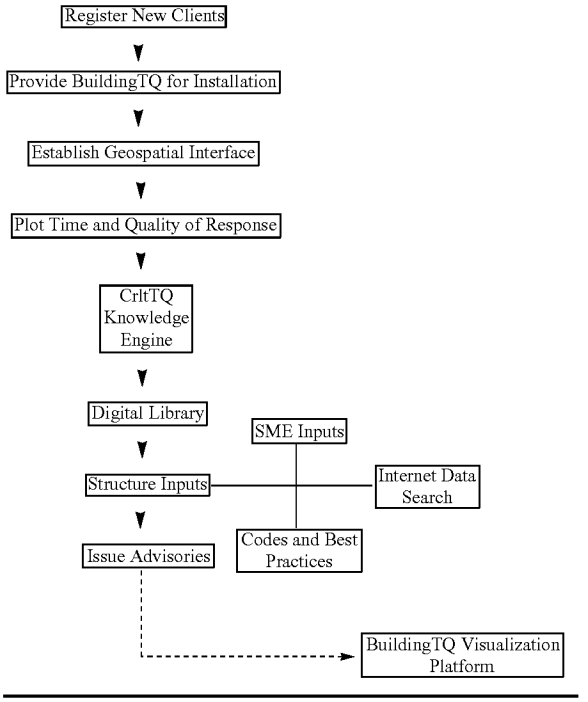


Upon receipt of locator data from the client, personnel at the DFC register the new client and establish a geospatial interface. As depicted FIG. **18**, below, the time and quality (in this instance the type) of response and evacuation routes are geospatially plotted. For example, in the plot in FIG. **18**, the earliest Police responce to the client is 8 minutes, the earliest Fire response to the client is 11 minutes.

Data developed as a result of the CSM Method Phase **1**. business process is structured and input to the CriTQ knowledgebase where it is integrated with other data.

TABLE 23

Client registration at the DFC



Data input to the CriTQ knowledgebase is developed and structured consistent with Phase 1. of the CSM Method business process and input to the CriTQ knowledge engine. This data includes:

1. The development and reverse engineering of a range of scenarios for each critical node of building operation consistent with Phase 1. of the CSM Method business process.

2. Catalogue adversary means and methods for each scenario consistent with Phase 1. of the CSM Method business process.

3. Identify the warnings of possible attack by individual and combinations of critical nodes consistent with Phase 1. of the CSM Method business process.

4. Develop exact event sequences for each scenario and apply EES1 algorithm to create BuildingTQ threat quotients consistent with Phase 1. of the CSM Method business process.

5. Create ipsitive conditional logic questionnaires for each critical node of building operation that address safety, security and continuity of building operations consistent with Phase 1. of the CSM Method business process.

6. Develop and structure consequences of each scenario by critical node consistent with Phase 1. of the CSM Method business process.

7. Identify and structure generic mitigation methods for each scenario by critical node consistent with Phase 1. of the CSM Method business process.

8. Create a data library of structured generic scenarios for each critical node consistent with Phase 1. of the CSM Method business process.

9. Conduct and structure generic cross-systems analysis of all critical nodes to catalogue systems interdependencies in order to derive Whole BuildingTQ values consistent with Phase 1. of the CSM Method business process.

10. Develop best decision templates for each scenario and combinations of scenarios consistent with Phase 1. of the CSM Method business process.

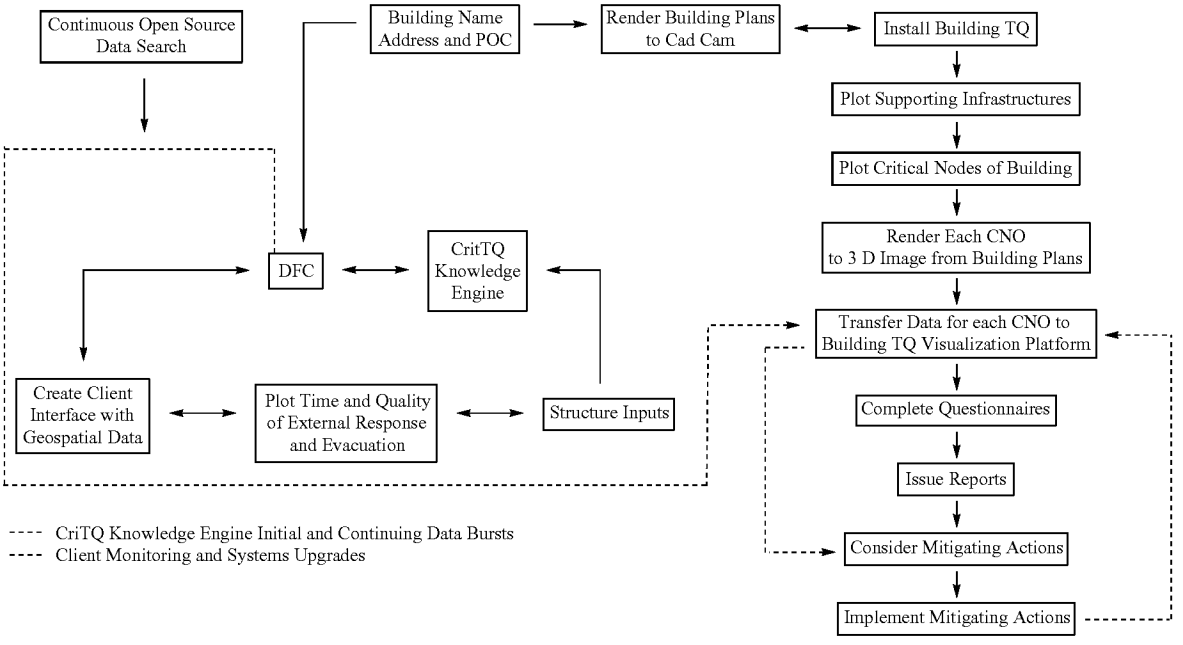
11. Issue threat advisories to clients based on continuous monitoring of open source data including the warnings of possible attack and weather or geologic phenomenon. The warnings of possible attack are systematically derived consistent with Phase 1. of the CSM Method business process.

12. Generate data libraries of international, national, state and municipal building codes and building construction best practices using "word clustering" and semantic driver capabilities.

Data for items 1. through 12., above, is input to the CriTQ knowledge engine as depicted by Table 24, below.

TABLE 24

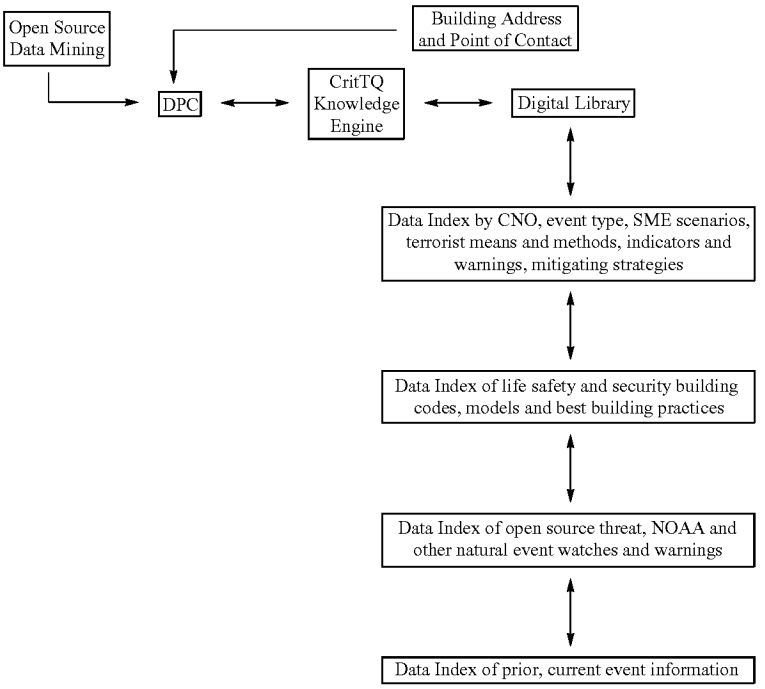
Structured CSM Method data is input to the CriTQ knowledge engine



Data necessary to produce matrices of building codes, models, scenarios, adversary means and methods, warning signals and consequences and mitigating actions by critical node is indexed. All data pertaining to scenarios, adversary means and methods, warning signals and consequences and mitigating actions by critical node are derived consistent with Phase **1**. of the CSM Method business process. Data indexes are created to speed access and pre-format data as depicted in Table 25, below.

TABLE 25

Data indexes are created to speed access and pre-format data

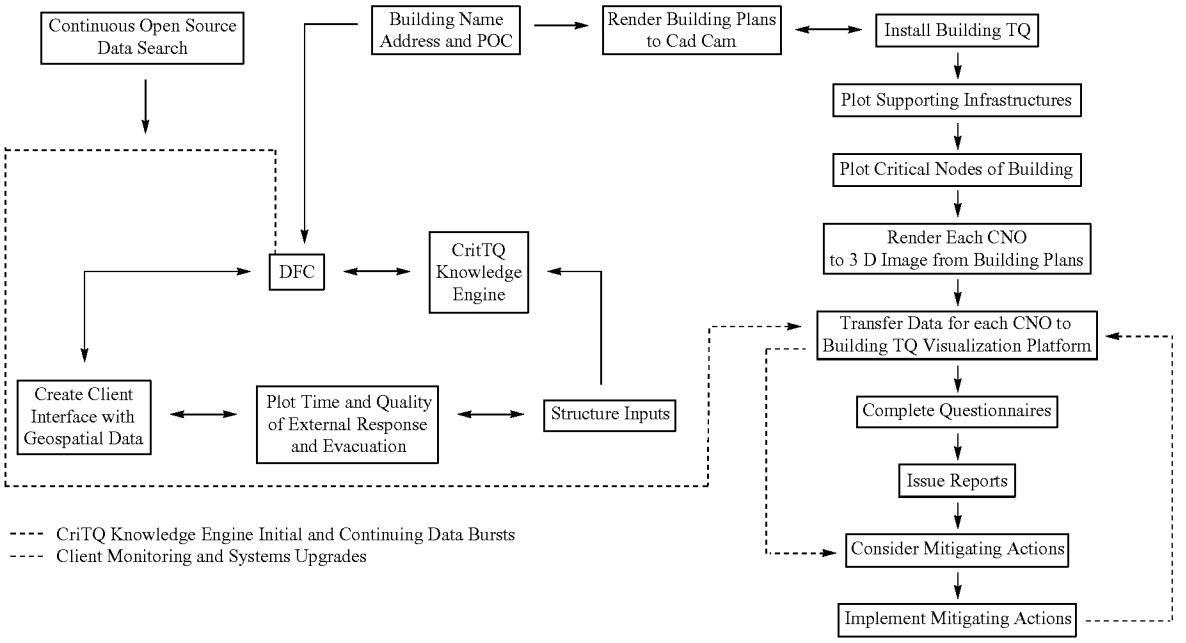


Building plans are then rendered to cad cam or dedux renderings for computer visualization as depicted in Table 26, below and FIG. **19**.

own network behind their system's firewall. This is done to assure that data specific to the building remains the sole proprietary property of the client.

TABLE 26

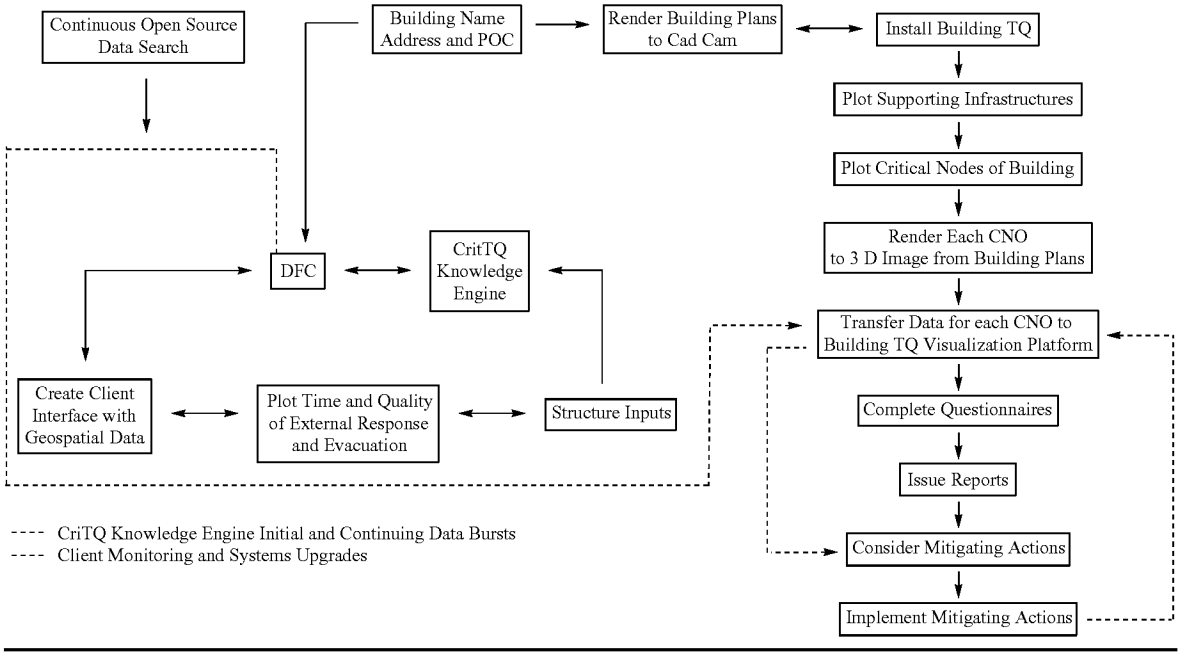
Building plans are rendered into cad-cam or dedux form



As depicted in Table 27, below, the data fusion center then provides the client with the "customized" BuildingTQ software over the secure network for installation on the client's

TABLE 27

The BuildingTQ software is installed at the client's location

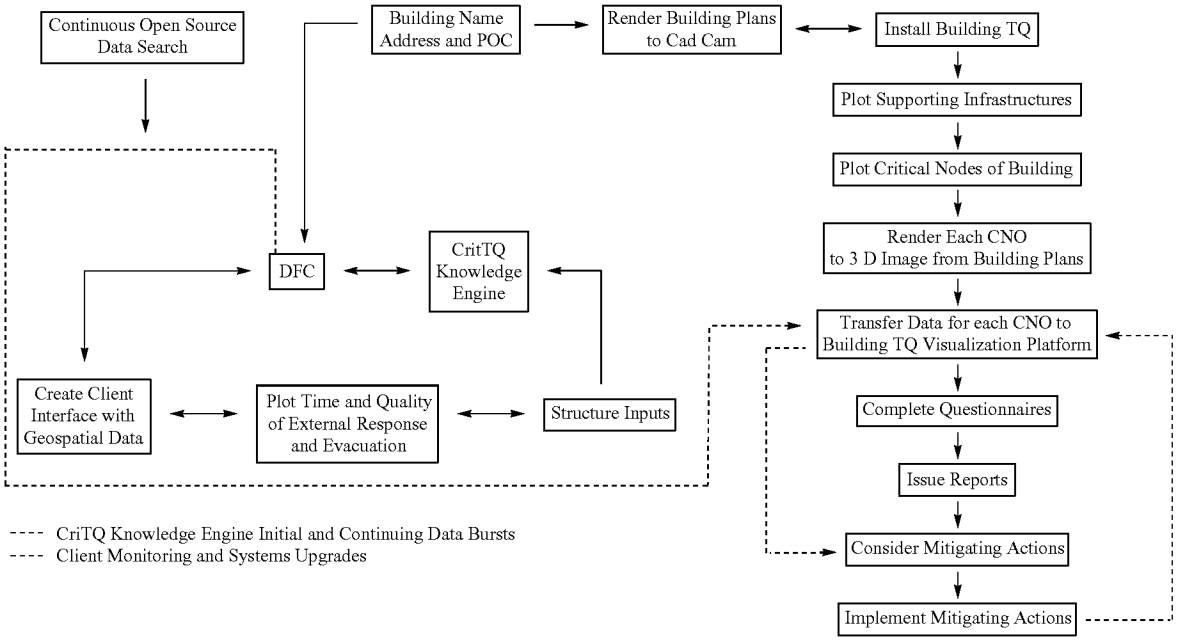


As depicted in Table 28, below, and FIG. **20**, the building's supporting infrastructures including external power supplies, sewer and water lines and communications are geospatially plotted. The critical nodes of building operation as derived by the Phase **1**. CSM Method are plotted on a computer visualized platform. An example of this visualization is provided at FIGS. **11**. A. and B. Each critical node of the building is rendered in building plan format as appearing in the example of a data computer data facility at FIG. **12**. As depicted in FIG. **20**, each critical node is also rendered as a three dimensional image.

and **11**. B.) and to augment the BuildingTQ software installed on their system. From this point forward all data flow becomes unidirectional from the DFC to the client in what are called "data bursts" as represented by the red dotted line appealing in Table 29, below. With a fully operational BuildingTQ platform, clients complete ipsitive questionnaires developed during Phase 1. An example of a CSM Method analogously derived questionnaire was presented earlier at Table 12. The BuildingTQ software computes the structured

TABLE 28

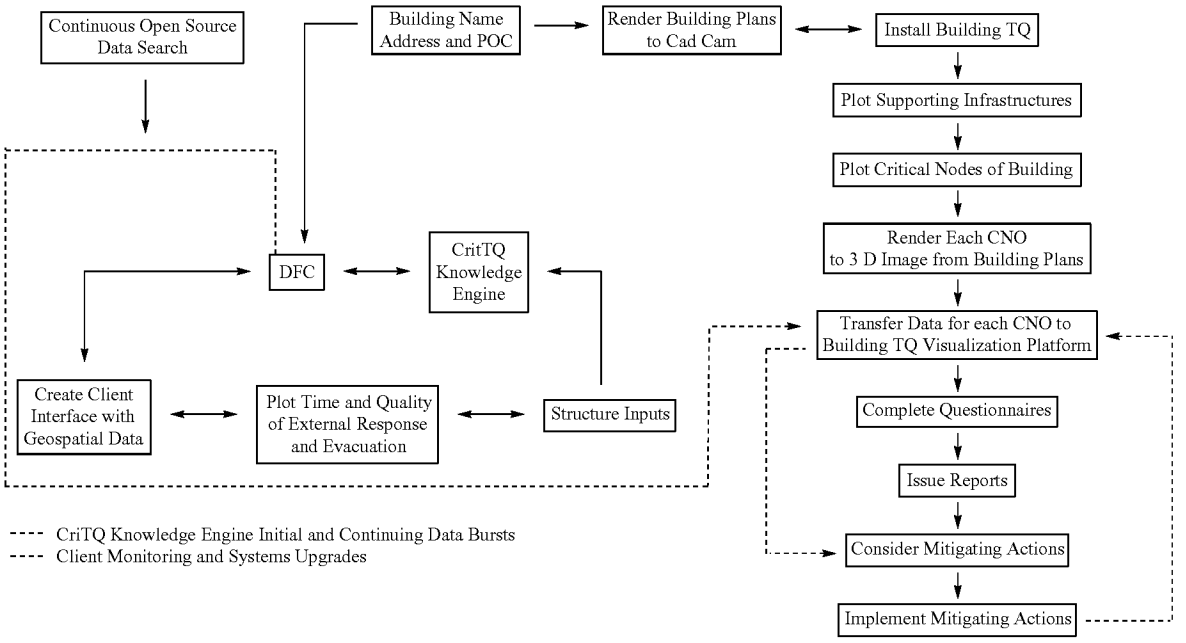
Critical aspects of the building's operations are plotted and visualized



As depicted in Table 29, below, structured data is directed via the secure network from the CriTQ knowledgebase to the clients Building TQ visualization platform (See FIGS. **11**. A. data consistent with the CSM Method business process using the algorithms, numerical values, weighting factors using data archived in the CriTQ knowledgebase.

TABLE 29

Visualization, questionnaires, reports and mitigation



Phase 1. (Quantitative Analysis) Serves as the Foundation for Phase 2. (Integrating Quantitative Reality with Human Social Process) and Phase 3. (Subsequent Interventions) of the CSM Method Business Process

Phase 1. of the CSM Method serves as the foundation for Phases 2. and 3. of the process.

Scientific evidence shows that no body of knowledge or method exists for integrating quantitative reality with human social process in the context of managing complex events and situations. This is highly significant because the failure of human beings to act on quantitative reality can have disastrous consequences. For example, the scientific community has known for many years that the accumulation of green house gases in the atmosphere is resulting in a rapid unnatural warming of the earth. For many years, scientists have been modeling the devastating consequences of the melting of the polar ice caps and subsequent rises in sea level. Although the scientific evidence of global warming because of the emission of green house gases was overwhelming, the problem is largely ignored in favor of the continued industrialization of the underdeveloped countries including Indonesia, India and China and the global economy.

The purpose of the CSM Method Phase 2. process is to provide a science based method, i.e., analogous process, to bridge the gap between quantitative reality and human social process in the management of complex systems, events and situation. Phase 2. of the CSM Method business process serves as the catalyst for human attention and action in the more timely and effective management of otherwise intractable challenges. The CSM Method as a scientifically derived tool for integrating quantitative reality with human social process in the context of the more effective management of complex events and situations is an object of the present invention.

Data derived and structured during Phase 1. using the CSM Method is the basis upon which Phase 2. and Phase 3. of the CSM process is implemented. Use of Phase 1. data helps assure the consistent application of the six tenets of a priori optionality throughout all phases of the CSM Method. For example, Phase 1. data is used to:

1. Develop Phase 2. simulations used during immersions based on Phase 1. data.
2. Identify the critical decision points (CDP's) in simulations.
3. Determine the qualitative human social consequences of simulated events based on Phase 1. quantitative data.
4. Portray the range of potential outcomes, i.e., extended order effects, for CDP's in simulations based on Phase 1. data.
5. Compare and contrast Phase 1. data against the actions taken by decision makers as they attempt to manage simulations during an immersion.
6. Reassess on a continuing basis the fundamental rules upon which complex systems are characterized and the optimum risk/benefit decision options.

Why the CSM Method Business Process is Different from Current Methods to Assess Risk and Take Advantage of Opportunity

Table 30. compares the CSM Method with other risk assessment tools currently in use. The chart serves to illustrate only a sampling of the differences between the CSM Method and a small number of tools currently in use that are used as risk assessment tools. Of course, one fundamental difference between the CSM Method and all other risk and benefit management tools is that it is based on the tenets of a priori optionality—a whole new way of understanding, systematically analyzing and presenting solutions for managing complex systems. The use of a priori optionality to undergird the CSM Method is an object of the present invention. Another fundamental and overarching difference is the analogous means by which the indicators of benefit and the warnings of adverse events are systematically derived and monitored by data mining. The analogous means by which the indicators of benefit and the warnings of adverse events are systematically

derived and data mined is an object of the present invention. A third fundamental and overarching difference is that the CSM Method business process produces a CriTQ knowledgebase that learns over time and contains best decision templates that can be used in the actual management of real world events. CSM Method knowledgebase that learn over time and contain best decision templates for use in the management of real world events is an object of the present invention.

TABLE 30

A sampling of the differences between the CSM Method and other risk assessment tools

	CSM	Carver + Shock	Operational Risk Management (ORM)	Table Top Exercises (TTE's)	Probabilistic Risk Assessment (PRA)	RAMCAP
Human in the loop and simulations	✓	X	X	✓	X	X
Reverse engineering of science-based scenarios	✓	X	X	X	✓	X
Scientific analysis of extended order effects of decisions	✓	X	X	X	X	X
Structured use of Multidisciplinary SME's and Red Teams	✓	X	X	X	X	X
Six-sigma Standard	✓	✓	✓	X	✓	✓
Analogously derived scenarios and simulations	✓	X	X	X	✓	X
Systematic focus on anticipate and prevent and, as opposed to react and respond	✓	X	X	X	✓	X
Focuses on decision makers at all levels vertically and horizontally across the system	✓	X	X	X	X	X
Critical infrastructure systems seen as complex and adaptive	✓	X	X	X	X	X
Systematic analysis of actual terrorist means and methods	✓	X	X	X	X	X
Identification of vital systems of system interdependencies	✓	X	X	X	X	X
Systematic isolation of triggers to produce "actionable" intelligence	✓	X	X	X	X	X
Systems analysis across entire threat continuum including deterrence, detection, prevention, response, short and long term consequences	✓	X	X	X	X	X
Consensus decisions on priorities and actions before events happen	✓	X	X	X	X	X
Best decision templates to guide actual operational responses	✓	X	X	X	X	X
Knowledge base of repeatable information to support emergency planning, education, testing and actual operational responses	✓	X	X	X	X	X

What is desired to be claimed:

1. A method of assessing and managing behavior of a complex adaptive system, comprising the steps of:

inputting a first plurality of data defining parameters of said complex adaptive system;

defining a plurality of fundamental events which determine behavior of said complex adaptive system;

modifying at each of a plurality of times at least ones of said first plurality of data to define a plurality of initial conditions;

testing each of said first plurality of data to determine a first subset of said first plurality of data which are most relevant to said plurality of fundamental events for each of said plurality of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system;

measuring an effect of each one of said plurality of initial conditions of each respective one of said developed plu-

rality of scenarios on said first subset of data to provide status information which is capable of being tested to indicate likelihood of an event occurring in said complex adaptive system.

2. The method of claim **1** further including the steps of;

testing each of said scenarios to determine for each scenario precise events which must occur to cause said complex adaptive system to exhibit said scenario; and determining for each tested scenario critical decision points.

3. The method of claim **2** further including the steps of:

modifying said first plurality of data to simulate predetermined events occurring in said complex adaptive system;

determining the effects from said simulated events on said critical decision points; and

forming decision fault trees from said determined effects.

4. The method of claim **3** further including forming decision maps and computer models to manage said predetermined events.

5. The method according to claim **1** including the further step of applying to said status information a first algorithm providing an estimate of an event sequence interruption.

6. The method according to claim **5** wherein values obtained from said applying of said first algorithm provide an event quotient for each of said first subset of data.

7. The method according to claim wherein said event quotient further includes a functional relationship based on an algorithm related to occurrence of natural events and an effect of said natural events on said first subset of data.

8. The method according to claim **5** further including the step of modifying said first plurality of data as a function of a result of said application of said first algorithm.

9. The method of claim **1** wherein said first subset of data are critical nodes of the complex adaptive system.

10. A method of increasing the likelihood of behavior of a complex adaptive system, comprising the steps:

defining fundamental elements which control the functioning of the complex adaptive system;

assigning a plurality of sets of initial values at a respective plurality of times to a plurality of features of the complex adaptive system;

determining which ones of said plurality of features of the complex adaptive system are most directly related to said fundamental elements for each of said plurality of sets of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system;

measuring an effect of each one of said plurality of sets of initial conditions of each respective one of said developed plurality of scenarios on said ones of said plurality of features most directly related to said fundamental elements to generate sets of data functionally related to the likelihood of a particular occurrence in said complex adaptive system.

11. The method of claim **10** further including the steps of;

testing each of said scenarios to determine for each scenario precise events which must occur to cause said complex adaptive system to exhibit said scenario; and

determining for each tested scenario critical decision points.

12. The method according to claim **11** further including the step of modifying said plurality of features as a function of a result of said application of said first algorithm.

13. The method of claim **11** further including the steps of:

modifying said plurality of features to simulate predetermined events occurring in said complex adaptive system;

determining the effects from said simulated events on said critical decision points;

and forming decision fault trees from said determined effects.

14. The method of claim **13** further including forming decision maps and computer models to manage said predetermined events.

15. The method according to claim **10** including the further step of applying to said set of data a first algorithm providing an estimate of an event sequence interruption.

16. The method according to claim **15** wherein values obtained from said applying of said first algorithm provide an event quotient for each of said ones of said plurality of features most directly related to said fundamental elements.

17. The method according to claim **16** wherein said event quotient further includes a functional relationship based on an algorithm related to occurrence of natural events and an effect of said natural events on said ones of said plurality of features most directly related to said fundamental elements.

18. A computer program product for use with a digital computer for assessing and managing behavior of a complex adaptive system, said computer program product including a computer usable medium having a plurality of computer readable program code means embodied in said medium, comprising;

a first computer readable program code means containing a first plurality of data defining parameters of said complex adaptive system and a plurality of defined relationships which control the functions of the complex adaptive system;

a second computer readable program code means causing a modification at each of a plurality of times at least ones of said first plurality of data to define a plurality of initial conditions;

a third computer readable program code means for testing each of said plurality of data to determine a first subset of said first plurality of data which are most relevant to said plurality of defined relationships for each of said plurality of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system;

a fourth computer readable program code means for determining an effect of each one of said plurality of initial conditions of each respective one of said developed plurality of scenarios on said first subset of data to provide status information which is capable of being tested to indicate likelihood of an event occurring in said complex adaptive system.

19. The computer program product according to claim **18** including a fifth computer readable code means for testing each of said scenarios to determine for each scenario precise events which must occur to cause said complex adaptive system to exhibit said scenario; and determining for each tested scenario critical decision points.

20. The computer program product according to claim **19** including a sixth computer readable code means for applying to said status information a first algorithm providing an estimate of an event sequence interruption.

* * * * *