Technical Proposal

Purpose

The purpose of this proposal is to describe a joint Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) initiative to produce a next generation of automated decision support system (DSS) that will enable government and food producers to prevent and, when necessary, enable highly focused responses to all hazards events involving the U.S. food supply while providing the government with a new capability to more efficiently focus their sampling and inspection efforts on areas of highest risk.

Identification and Significance of the Problem

The United States enjoys a plentiful and varied food supply that is generally considered to be safe; however, changes in the domestic and global environment are placing new stresses on our ability to assure that the foods we eat are safe. Changing demographics and food consumption habits, the growing number of food producers and suppliers, the occurrence of significant breakouts of food borne illnesses, the growth of globalization and many other factors underscore the need for effective risk-based approaches to food protection.[i]

76 million cases of food-borne illness occur in the United States annually. Each year, approximately 325,000 people are hospitalized with a diagnosis of food poisoning, and 5,000 die. In terms of medical expenses, lost wages and productivity estimates vary widely from $6.5 to $34.9 billion annually.[ii] Today, there are fifteen different federal agencies that administer at least 30 different laws relating to food safety. The two primary agencies charged with the protection of the food supply are the U.S. Department of Agriculture (USDA), which is responsible for meat, poultry, and processed egg products, and the Food and Drug Administration (FDA), which is responsible for virtually all other foods. Critics charge that the distribution of responsibility among different government agencies leads to inconsistent oversight, ineffective coordination, and the inefficient use of resources.[iii]

In November of 2007, the U.S. Food and Drug Administration (FDA) took the first critical step to address these and other challenges by creating a strategic framework to modernize and improve the safety of America's food supply. Among the key elements of the FDA's *Food Protection Plan* include efforts to more strategically inspect food production processes, enhance the ability to identify and react more quickly to outbreaks of food-borne illnesses, and place new emphasis on promoting the safety and integrity of the nation's food supply.[iv]

Core Element	Strategies	Purpose
Core Element #1: PREVENTION	Improved Outreach	Increase collaboration with industry to prevent food problems
	Formation of a Risk-Based Steering Committee	Prevent food problems through a systematic, comprehensive risk-based review of vulnerabilities
	Greater International Presence	Build foreign food management, scientific and technical capacity
Core Element #2: INTERVENTION	Targeted Inspections	Focus scarce human and technical resources where they will have the greatest impact
	Targeted Sampling	Focus scarce human and technical resources where they will have the greatest impact
	Food Field Examinations	Increase the number of inspections
	Independent Certification	Increase third-party inspections
	PREDICT Pilot	Develop new technical tools
Core Element #3: RESPONSE	Improved Product Tracing	Identify best practices
	Incident Command System (ICS) Training	Faster and more effective responses
	Formation of Rapid Response Teams	Faster and more effective responses
	Recall Templates	Faster and more effective responses

Table 1 Strategic Objectives of the FDA *Food Protection Plan*

Core to the vision of modernizing and improving the safety of food production in the United States, as set forth in the *Food Protection Plan,* is the use of risk-based management systems.[v] Thus, given the existing challenges to the nation's food supply system and the FDA strategic response as presented in the *Food Protection Plan*, any effective food protection risk-based management system must address the following five critical factors:

Requirement	Risk Management Considerations
1. Increase collaboration with industry to prevent food problems	Systems must allow for collaborative development and oversight of food production practices and distribution systems
2. Prevent food problems through a systematic, comprehensive risk-based review of vulnerabilities	Successful intervention relies on the early detection of the indicators and warnings of impending food problems in time to intervene and, when necessary effectively focus response efforts
3. Focus scarce human and technical resources where they will have the greatest impact	Requires the capability to identify and monitor in real time threats to the critical nodes of the food supply chain based on past experience and possible future events
4. Identify best practices	Must turn the lessons learned from past experiences, simulated future events and technology developments into the planning process of subsequent activities to maintain best practices
5. Promote faster and more effective responses	Enable on-the-fly simulations of food protection challenges across the entire threat continuum from deterrence, detection, prevention and response through mitigation at all levels from the factory floor to the corporate and government boardroom to guide the most effective responses

Table 2 Critical FDA Requirements and Risk Management Considerations

Within the above context, the development of any effective automated food safety risk management decision support system (DSS) represents a highly significant scientific and technical challenge. Among the principal characteristics of a solution are the requirements to integrate quantitative reality with qualitative social process, the large numbers of different systems and subsystems that must interact in specified ways to produce desired outcomes and the different food production environments in which the solution is expected to function. Moreover, the FDA *Food Protection Plan* places priority on collaboration with all stakeholders to prevent food problems from occurring, the use of targeted risk-based interventions and better coordinated rapid responses to food emergencies.[vi] But the science to support the evolution of next generation automated DSS systems capable of accomplishing these critical performance benchmarks have not been available until recently.[vii]

In 2000, we began a program of extensive research at National Defense University and The George Washington University on the nature of complex adaptive systems and the threats posed by accidents and attacks against the nation's critical infrastructures. One area of particular concern was the safety of the nation's food supply chain.[viii] The objective of this research was to identify, in tangible and scientifically defensible terms, the barriers standing in the way of developing the next generation of decision support systems capable of satisfying the FDA's vision of highly robust food protection risk management systems and much more.

First, our research confirmed that today's principle methods of scientific inquiry 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. Second, we found that effective methods to integrate quantitative scientific reality with qualitative human social process in the management of complex events and situations are illusory. Frequently, quantitative reality is misunderstood, ignored or simply denied as the result of qualitative social pressures. Third, 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.[ix]

In 2007, based on this extensive body of scholarly research, we filed an invention disclosure with the United States Patent and Trademark Office that provides a scientifically derived alternative to the continued reliance on deterministic methods as the best way to understand and manage complex systems. The invention disclosure describes a 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 also identifies 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.[x]

Working under a technical support agreement with Argonne National Laboratory, we have reduced the invention to practice and conducted early phase alpha testing of two functional decision support systems based on the novel technology. Argonne has provided one of a kind technical knowledge and capabilities in this new area of research that are not available elsewhere. One application relates to the risks affecting primary, secondary and post secondary schools including food safety. The second application deals with the risks associated with commercial airport operations. Both applications were built using a common architecture for scalability. Data sets related to these applications were validated in cooperation with the Army National Guard and the one of their kind facilities located at the Muscatatuck Urban Training Center in Jefferson County, Indiana.

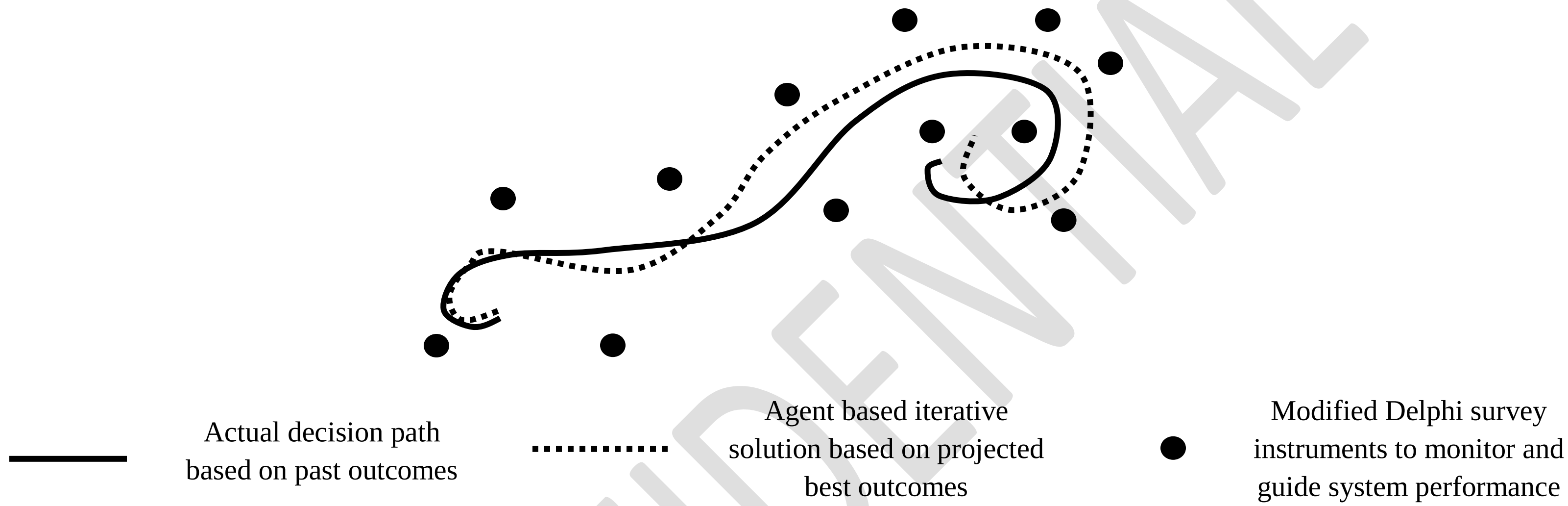

Figure 1 Decision Path Analysis™ to Enhance the Human Management of Complex Events and Situations

To develop our applications we bring together teams of multidisciplinary subject matter experts (SME's) and develop quantitative/computational social science (Q/CSS) models to reverse engineer past and projected events and their associated decision paths across different categories of events and situations. These SME's use a structured and repeatable process to determine and statistically weight the critical benchmarks of performance and to identify the indicators and warnings associated with deviations from optimum decision paths. Specially modified Delphi survey instruments are used to gather data inputs from designated network enabled systems users. The data is used to monitor progress along defined decision paths and determine the status of critical areas of performance at different locations in real time based on structured inputs from network enabled users.

Known by the registered trademark name of the CSM Method® we have developed a common architecture for a next generation of model-based decision support system that is highly scalable across many different applications.

1. Under the architecture we manage and assess human performance against several databases of standards. For example, in the case of a food safety DSS minimum compliance standards come from FDA, USDA and other food safety regulations. A second complimentary database of good management practices consists of complimentary topic specific policies, procedures and requirements.

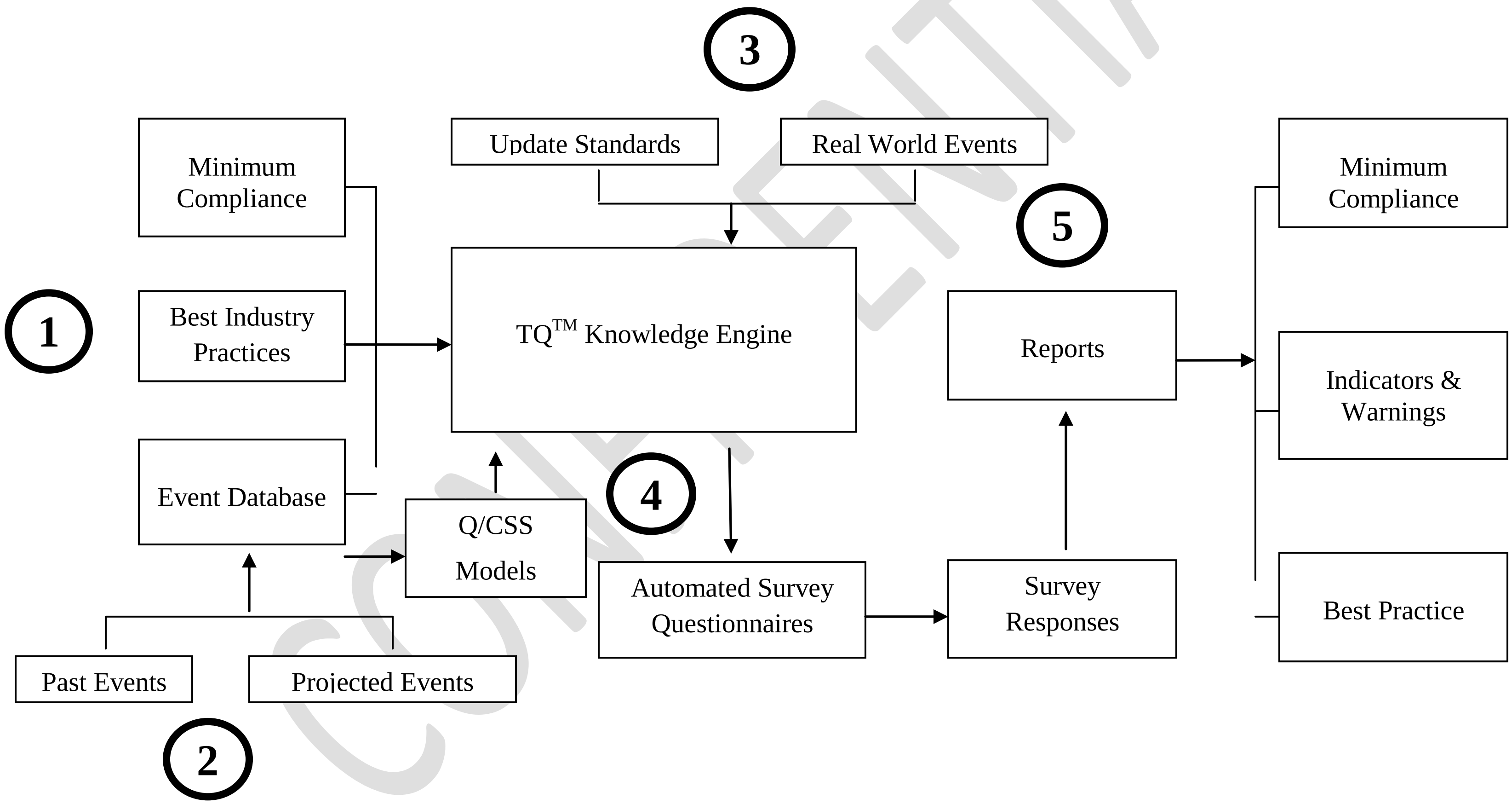

Figure 2 A Common CSM Method® Architecture for Many Commercial Applications

2. A third standard used to judge performance comes from a specially structured database of past and projected future events and their associated decision paths. We call this process Projectioneering™. For example, the *Food Protection Plan* envisions better coordinated and faster responses to breakouts of food borne illness. Under our architecture, past and projected responses to food related emergencies are analogously structured for repeatability as part of a supporting database.

3. Both minimum compliance and best practice standards are continuously updated. In addition, as real world events signal changes in the external food protection environment, the knowledgebase is updated with baseline values adjusted based on past, current experience and projected events.

4. Based on this information and the quantitative results from the Q/CSS models processing the events database the core knowledge engine generates and delivers to designated personnel, questions soliciting responses that are statistically scored to determine deviations from optimum decision paths and associated levels of performance.

5. Based on the scored and weighted results of survey data, the knowledge engine generates performance reports. When results indicate that levels of performance are below the minimum compliance or best practice levels, the reports indicate the specific actions that system users must be taken to improve performance. Based on the results of survey questionnaires, updated standards, real world events and past and projected events, the knowledge engine monitors the indicators and warnings of potential deviations from optimum decision paths and generates notification reports. These notification reports contain recommended user actions.

A critical aspect of any automated food protection risk management DSS must include the creation of system ontology. This is particularly significant because of the lack of a shared vocabulary or taxonomy of actions among the various data providers, system users and responders across the realm of all hazards events. Thus, under the FDA vision as set forth in the *Food Protection Plan*, we must integrate three otherwise independent or semi-independent domains, namely, a diverse federal governmental regulatory and oversight structure, state and local government authorities and private sector food producers. To accomplish this we must rely heavily on the development and integration of intuitive knowledge representation tools that emphasize the shared goals, and objectives of the different stakeholder domains in the context of the specific goals and objectives of the *Food Protection Plan*. In summary, our requirements include the development and representation of an all hazards food protection system ontology, modeling of past and projected food emergency event sequences and decision paths and the integration of geospatial and geographic visualization and robust collaboration and data collection capabilities. Under our proposed Phase I and Phase II efforts we will work closely with five strategic partners who will integrate the most advanced knowledge and technology solutions available as part of our common

CSM Method® architecture to produce a next generation DSS that will enable government and food producers to prevent and, when necessary, improve responses to all hazards events involving the U.S. food supply chain while giving the government the ability to more strategically focus their sampling and inspection efforts.

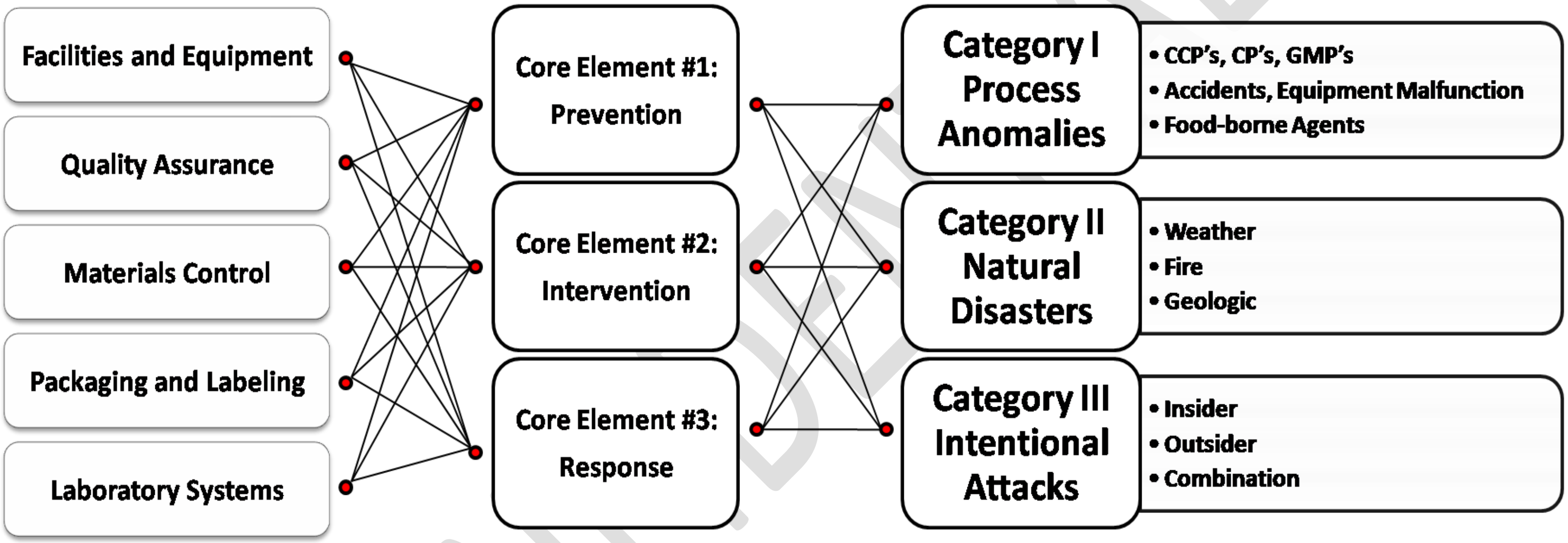

Figure 3 Creating a Shared All Hazards Ontology for Food Protection

Our integrated product team (IPT) includes the FDA-University of Maryland Joint Institute for Food Safety and Applied Nutrition (JIFSAN); the inventor of the CSM Method® and a cadre of highly experienced ThoughtQuest LLC information and organizational science personnel; the unique multi-disciplinary computational and social science modeling and social network analysis capabilities of National Security Innovations; the one of a kind scientific knowledge in this new area of research resident at the Argonne National Laboratory; the one-of-a-kind testing and validation capabilities of the Army

National Guard's Joint Maneuver Training and Simulation Center and the Muscatatuck Urban Training Center (MUTC), and; the world-class systems development and data visualization capabilities of Raytheon Solipsys.

JIFSAN will serve as the lead interface with the FDA's Risk –Based Steering Committee, USDA and industry leaders in coordinating the implementation of this proposed program. They will provide their significant subject matter and scientific expertise across all phases of program implementation. ThoughtQuest will provide their scientific knowledge and experience developing and field testing two previous applications of the CSM Method® risk management solution and will serve as the lead technology management provider under this proposal. National Security Innovations (NSI) will integrate their computational social science and social modeling and networking capabilities into the existing CSM Method® architecture to produce the next generation food protection risk management capability envisioned by the *Food Protection Plan*. MUTC will provide their unique skills and knowledge of national emergency contingency planning involving civil and military authorities including their interface with Northern Command and the Department of Homeland Security and the use of the Joint Simulation and Training Center at Camp Atterbury, Indiana, to support of food emergency event simulations.

Dr. Craig Swietlik of the Information Sciences Group of Argonne National Laboratory (ANL) will lead the effort to expand and modify the information system architecture by leveraging the existing CSM Method® operating system, to include data manipulation adjustments and the integration of highly robust data collection technologies into our existing architecture to produce the next generation automated food protection risk management capability envisioned by the *Food Protection Plan*. The secured web-based information system is hosted at Argonne and is based on current C# .net framework technologies. The system has been built to be highly scalable with a flexible architecture to support expansion. The knowledge engine will provide the minimum compliance standards, best practice standards, and confirmatory information together with dynamic weighting algorithms to provide a scoring and analysis of the results. In addition, ANL will provide subject matter experts in food protection.

Raytheon Solipsys will support the development and representation of food protection risk management system ontology, visual modeling of food emergency event sequences and decision paths and the integration of geospatial and geographic visualization technologies into our existing architecture through their Tactical Display Framework (TDF). TDF is a COTS visualization tool that enhances situational awareness based on an open plug-and-play architecture. The architecture and implementation of TDF makes it easily adaptable to specific users, classes of users, or multiple user applications. Because TDF is a framework, it can be customized to specific needs, notably that of the food industry and government. TDF supports interactive data visualization in a high update rate tactical situation, managing concurrently up to 20,000 composite tactical objects. The development of TDF is centered on real world applications in multiple mission areas with operator feedback and design input as an integral part of the development process. The look-and-feel of the display can be tailored for an individual and saved for repeated use. Short-cut, one-click application buttons can be defined to execute repetitive and time critical tasks efficiently, thereby reducing training time and increasing operator efficiency. It supports a wide variety of map, image, terrain and geo-spatial data that are fully integrated with 2D and 3D display features. TDF also provides a rule-based decision support engine for implementing operator doctrine. In addition to interfaces with TQ, TDF can display data from land-, sea-, air- and space-based sensors as well as user input. This allows the overall ThoughtQuest-Solipsys offering to increase capability as new requirements are formed. Written in Java, TDF operates on any COTS Laptop or work station that supports the Java Virtual Machine. TDF has been demonstrated on a variety of display devices to include a Panasonic *Toughbook* computer.

Phase I Tasks, Technical Objectives, Work Breakdown Flow, Schedule and Milestones

In this proposal we describe a two-phase program leading to a next generation of decision support system (DSS) that will enable government and food producers to prevent and, when necessary, enable improved responses to all hazards events involving the U.S. food supply chain while providing the government with a new capability to more efficiently focus their sampling and inspection efforts on areas of highest risk.

In Phase I we will develop the alpha prototype of a next generation DSS known as Food DefenseTQ™ with *TQ* standing for threat quotient. Food DefenseTQ™ will be based on the existing CSM Method® architecture and employ a comprehensive all hazards approach to managing the risks associated with food protection including process anomalies, natural disasters and intentional attacks. The Phase I system will include two fully integrated subsystems: a *Process Assurance Support System* (PASS) to address accidents, equipment malfunction, process anomalies and food-borne agents and a *Security Assessment and Facility Evaluation System* (SAFE) to address natural disasters and intentional attacks that may impact the food supply chain. The solution will be designed to support FDA and USDA regulatory and oversight responsibilities to include the application of control point (CP) and critical control point (CCP) technology solutions and the application of good management practices (GMP's). Food DefenseTQ™ will provide real time compliance monitoring and reporting of critical results in support of government targeted sampling and inspection efforts. The solution will be based on the use of FDA/USDA approved and standardized templates for specific classes of food processing activity and designed for maximum scalability for use by small, medium and large food enterprises and the government to more strategically focus scarce human and limited technical resources on those areas of highest risk.

Phase I tasks and technical objectives are designed to support the goals of the *Food Protection Plan* and include:

Phase I Task	Technical Objectives	Coordination & Data Sources
1 Identify and select a single focus area for alpha prototype of Food DefenseTQ™	1. Create a shared food protection ontology around all hazards events	FDA Risk-Based Management Committee; USDA, food industry; JIFSAN, ANL SME's; ThoughtQuest technical overview; NSI
2 Develop approved food template for alpha prototype that includes CP's, CCP's and GMP's; structure data using CSM Method®	2. Demonstrate the feasibility of using standardized templates to simplify the production, compliance and inspection process	FDA, USDA, food industry; JIFSAN & ANL SME's; ThoughtQuest technical overview; Raytheon Solipsys visualization of template
3 Develop FDA/USDA standards databases for regulatory and good management practices for approved process template	3. Structure CSM Method® standards database with data search and retrieval capability	ANL as technical lead with JIFSAN & ThoughtQuest technical overview; Raytheon Solipsys visualization and data representation
4 Identify and coordinate an industry partnership with food processor	4. Allow for collaborative development and oversight of food production practices and distribution systems	JIFSAN as lead in coordination with FDA/USDA; ThoughtQuest technical support

5 Develop and statistically analyze past and projected events including process anomalies, intentional attacks and natural events; structure data using Projectioneering™ methodology	5. Incorporate lessons learned from past and simulated future events into the planning process of subsequent activities to maintain a comprehensive library of best practices	FDA, USDA, food industry with JIFSAN lead & ANL SME's; ThoughtQuest technical overview; Raytheon Solipsys visualization & data representation; NSI
6 Use CSM Method® architecture to populate Food DefenseTQ™ decision support system (DSS)	6. Identify the indicators and warnings of impending food problems in time to intervene and enhance responses; monitor in real time the critical nodes of the food supply chain based on past experience and possible future events	FDA, USDA, food industry representatives with JIFSAN lead & ANL SME's; NSI; ThoughtQuest technical overview
7 Build Food DefenseTQ™ visualization platform including event, decision path and "on the fly" scenario generation capability	7. Simulate food protection challenges across the entire threat continuum from deterrence, detection, prevention and response through mitigation at all levels from the factory floor to the corporate and government boardroom	FDA, USDA, food industry with JIFSAN & ANL and ThoughtQuest SME's; ThoughtQuest technical overview; Raytheon Solipsys visualization & data representation; NSI; MUTC to imbed technology visualization capability at JSTEC
8 Conduct Phase I alpha demonstration for government and industry leaders; solicit recommendations for Phase II	8. Allow for collaborative development and oversight of food production practices and distribution systems	FDA, USDA, food industry representatives; demonstration supported by entire integrated product team at Camp Atterbury

Table 3 Phase I Tasks, Technical Objectives and Coordination and Data Sources

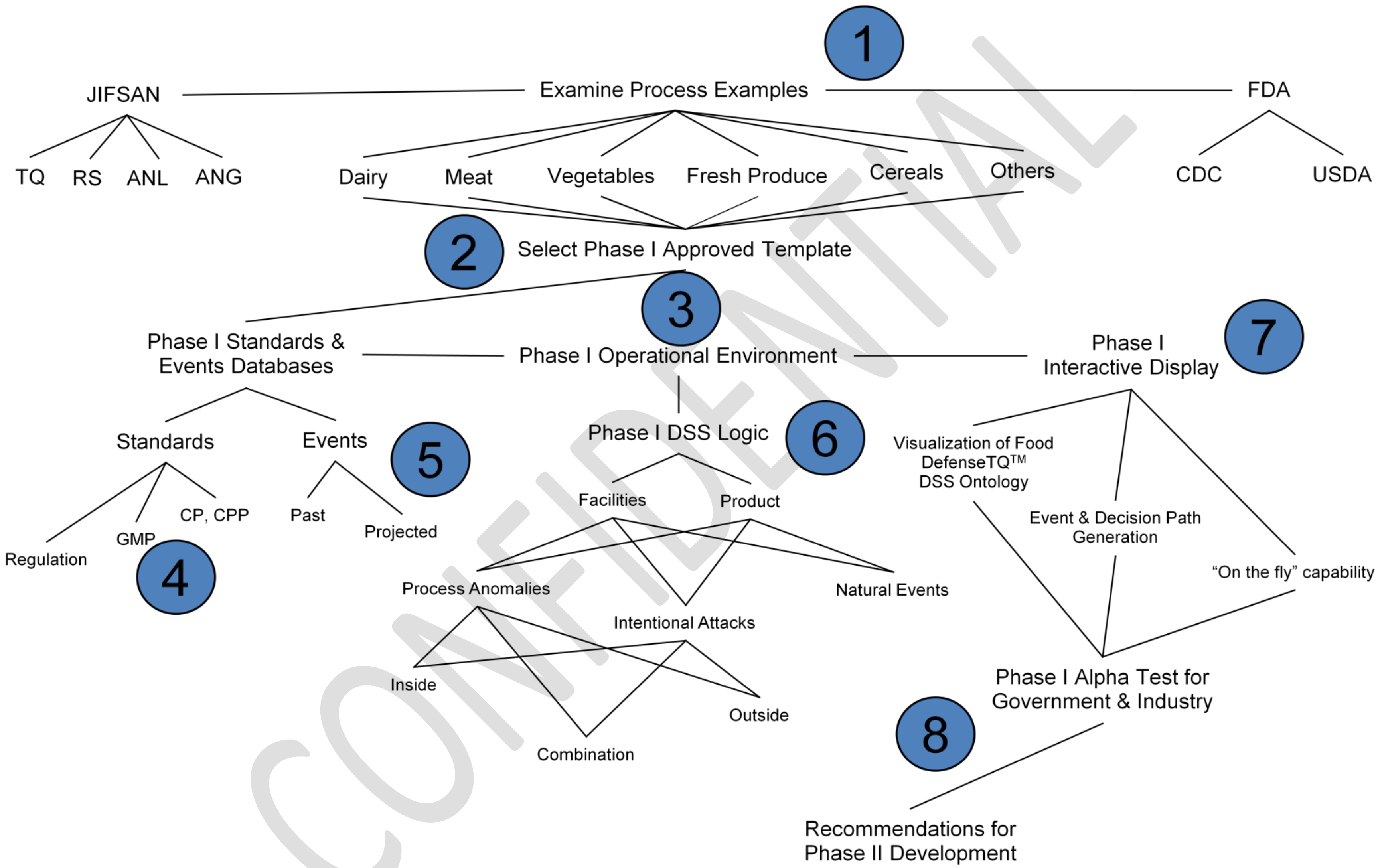

Figure 4 Phase I Work Breakdown Flow

Phase I Task	Objective	What	How	Who/Where	When	Deliverable
1. Identify and select a single focus area for alpha prototype of Food DefenseTQ™	Create and all hazards food protection ontology	System ontology	Structure and conduct interviews; data gathering and analysis	JIFSAN, ANL, ThoughtQuest and Raytheon Solipsys	Q-1	Organizational, contextual and visual map of Food DefenseTQ™ taxonomy
2. Develop approved food template for alpha prototype	Demonstrate the feasibility of using standardized templates	Identification of Phase I focus area	Develop and obtain approval initial template	JIFSAN, ANL and ThoughtQuest and Raytheon Solipsys	Q-1	Initial food process template for alpha demonstration
3. Develop standards databases for approved template	Structure CSM Method® standards database	Standards database	Structure and analyze FDA/USDA requirements	JIFSAN, ANL and ThoughtQuest	Q-1	CSM Method® standards database
4. Create industry-government collaborative partnership	Form collaborative government-industry partnership	Public-private partnership for program	Recruit food industry champion	US industry participant, JIFSAN, ANL and ThoughtQuest	Q-2	Industry environment for Food DefenseTQ™ alpha demonstration
5. Develop and statistically analyze past and projected events	Structure CSM Method® database of past and projected events	Events database	Lessons learned from past and simulated events for library of best practices	US industry participant, JIFSAN, ANL, ThoughtQuest and NSI	Q-2	Structured CSM Method® events database

6. Populate Food DefenseTQ™ decision support system (DSS) with data	Identify indicators and warnings (I&W's) of impending food problems; monitor the critical nodes of the food supply chain using standards and events databases	Earliest possible detection of I&W's and focused responses via real time monitoring	Use of CSM Method® to identify I&W's as actionable intelligence	US industry participant, JIFSAN, ANL and ThoughtQuest	Q-2	Food DefenseTQ™ DSS logic
7. Food DefenseTQ™ visualization platform	Capability to simulate food protection challenges across the threat continuum at different levels from the factory floor to the corporate and government boardroom	Visualization of Food DefenseTQ™ DSS	Integration of CSM Method® DSS logic with Tactical Display Framework	US industry participant, JIFSAN, ANL, ThoughtQuest, Raytheon Solipsys, NSI and the Army National Guard (ANG)	Q-3	Food DefenseTQ™ DSS for alpha demonstration imbedded at the JSTEC
8. Phase I alpha demonstration of Food DefenseTQ™ for government and industry leaders	Encourage a collaborative government-industry partnership	Solicit industry and government inputs to improve Food DefenseTQ™	Alpha demonstration of Food DefenseTQ™	US industry participant, JIFSAN, ANL, ThoughtQuest, Raytheon Solipsys, NSI and the Army National Guard (ANG)	Q-4	Government interagency and industry demonstration at JSTEC with suggestions for improvement

Table 4 Phase I Work Breakdown Schedule

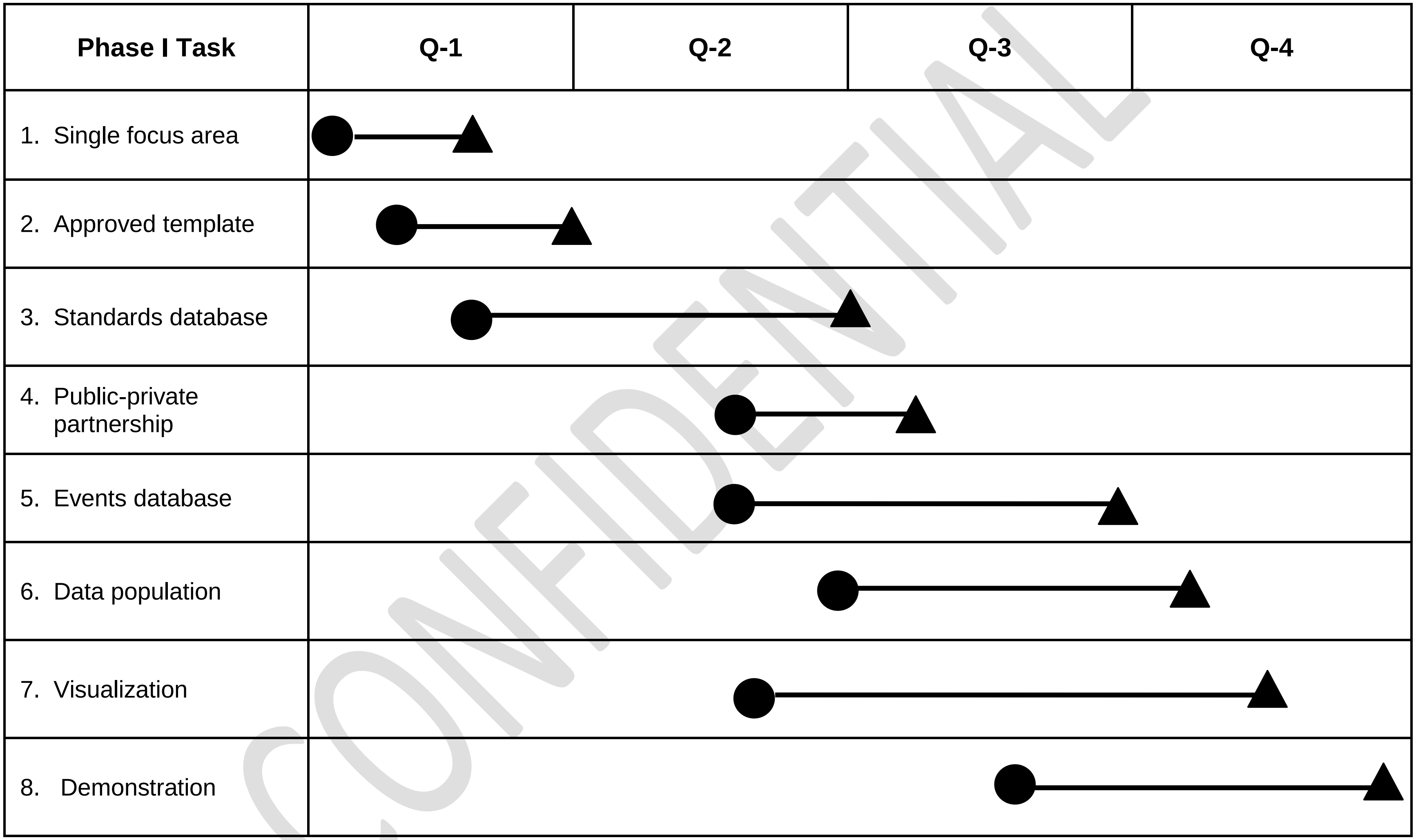

Figure 5 Phase I Milestone Schedule

Phase II Tasks, Technical Objectives, Work Breakdown Flow, Schedule and Milestones

The purpose of the Phase II work plan is to demonstrate the horizontal and vertical scalability of Food DefenseTQ™ across different food processing areas of concern and at different organizational levels from the growing field and factory floor to the corporate and government boardroom.

In Phase II we will integrate interagency and industry recommendations arising from the Phase I alpha demonstration into our Phase II work plan. We will examine and work with FDA and USDA to identify two additional high priority food processing areas of concern and develop two additional approved process templates that will be used for Phase II scaling. We will identify and coordinate a broadened industry partnership with two additional industry food processors that will collaborate with us on Phase II development of Food DefenseTQ™. For each of the two additional high priority food processing areas of concern we will develop standards databases for regulatory and good management practices, identify CP, CCP's and GMP's and structure data using CSM Method®. We will develop and statistically analyze past and projected events to include process anomalies, intentional attacks and natural events for the two additional areas of concern. The data will be structured and visualized using the integrated ThoughtQuest CSM Method® and Raytheon Solipsys Tactical Display Framework solution. Phase II ends with the industry deployment of three modular products for field testing and evaluation.

Phase II Task	Technical Objectives	Coordination & Data Sources
1 Integrate interagency and industry recommendations into the Phase II development plan	1. Allow for collaborative development and oversight of food production practices and distribution systems	FDA Risk-Based Management Committee; USDA, food industry; JIFSAN, ANL SME's; ThoughtQuest technical overview; NSI
2 Identify and select two additional focus areas for prototyping of Food DefenseTQ™	2. Demonstrate scalability	FDA Risk-Based Management Committee; USDA, food industry; JIFSAN, ANL SME's; ThoughtQuest technical overview; NSI

3 Develop approved food templates for Phase II application that include CP's, CCP's and GMP's; structure data using CSM Method®	3. Demonstrate the scalability of standardized templates to simplify the production, compliance and inspection process	FDA, USDA, food industry; JIFSAN & ANL SME's; ThoughtQuest technical overview; Raytheon Solipsys visualization of template
4 Develop FDA/USDA standards databases for regulatory and good management practices for approved process templates	4. Structure CSM Method® standards database with data search and retrieval capability	ANL as technical lead with JIFSAN & ThoughtQuest technical overview; Raytheon Solipsys visualization and data representation
5 Identify and coordinate an industry partnership with two additional food processors	5. Allow for collaborative development and oversight of food production practices and distribution systems	JIFSAN as lead in coordination with FDA/USDA; ThoughtQuest technical support
6 Develop and statistically analyze past and projected events including process anomalies, intentional attacks and natural events for selected processing activities and at partner site; structure data using Projectioneering™	6. Incorporate lessons learned from past and simulated future events into the planning process of subsequent activities to maintain a comprehensive library of best practices	FDA, USDA, food industry with JIFSAN lead & ANL SME's; ThoughtQuest technical overview; Raytheon Solipsys visualization & data representation; NSI
7 Use CSM Method® architecture to populate Food DefenseTQ™ decision support system (DSS)	7. Identify the indicators and warnings of impending food problems in time to intervene and enhance responses; monitor in real time the critical nodes of the food supply chain based on past experience and possible future events	FDA, USDA, food industry representatives with JIFSAN lead & ANL SME's; NSI; ThoughtQuest technical overview
8 Build Food DefenseTQ™ visualization platform including event, decision path and "on the fly" scenario generation capability	8. Simulate food protection challenges across the entire threat continuum from deterrence, detection, prevention and response through mitigation at all levels from the factory floor to the corporate and government boardroom	FDA, USDA, food industry with JIFSAN & ANL and ThoughtQuest SME's; ThoughtQuest technical overview; Raytheon Solipsys visualization & data representation; NSI; MUTC to imbed technology visualization capability at JSTEC
9 Industry deployment of three Food DefenseTQ™ modular systems for field testing and evaluation	9. Allow for collaborative development and oversight of food production practices and distribution systems	FDA, USDA, food industry representatives; demonstration supported by entire IPT

Table 5 Phase I Tasks, Technical Objectives and Coordination and Data Sources

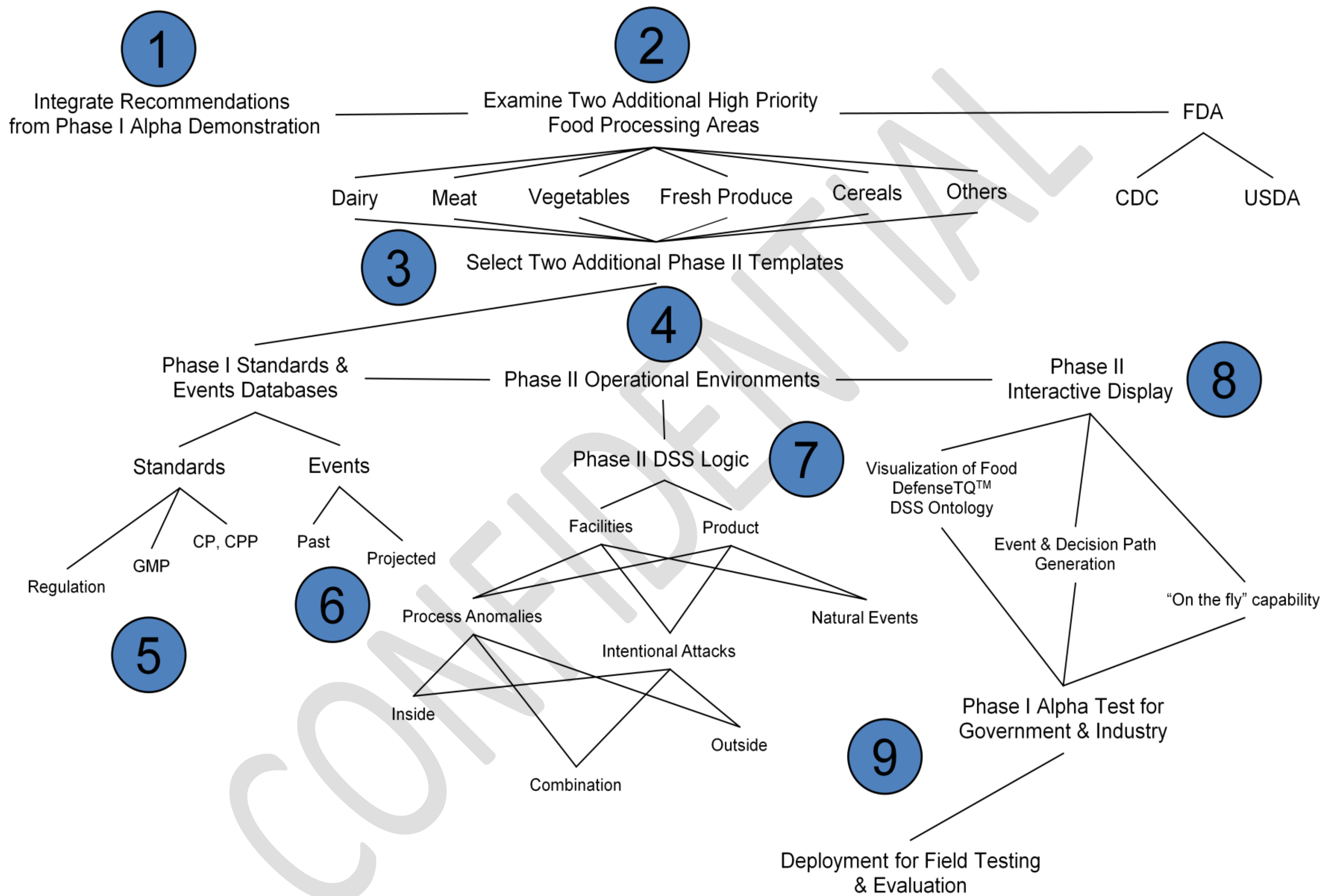

Figure 6 Phase II Work Breakdown Flow

Phase II Task	Objective	What	How	Who/ Where	When	Deliverable
1. Integrate interagency and industry recommendations	Allow for collaborative development and oversight	Industry-government solution	Revise Phase II program plan with suggestions	JIFSAN, ANL, ThoughtQuest, NSI and Raytheon Solipsys	Q-5	Revised Phase II program plan
2. Identify and select two additional focus areas for prototyping of Food DefenseTQ™	Create and all hazards food protection ontology	System ontology	Structure and conduct interviews; data gathering and analysis	JIFSAN, ANL, ThoughtQuest and Raytheon Solipsys	Q-1	Organizational contextual and visual map of Food DefenseTQ™ taxonomy
3. Develop approved food templates for Phase II effort	Demonstrate the scalability of standardized templates	Identification of Phase II focus areas	Develop and obtain approval two additional templates	JIFSAN, ANL and ThoughtQuest and Raytheon Solipsys	Q-5	Two additional food process templates to demonstrate scalability
4. Develop standards databases for two additional approved templates	Structure CSM Method® standards databases	Standards database	Structure and analyze FDA/USDA requirements	JIFSAN, ANL and ThoughtQuest	Q-6	CSM Method® standards database
5. Broaden industry-government collaborative partnership	Solidify public-private partnership for food protection	Expanded public-private partnership for food protection	Recruit two additional food industry champions	US industry participants, JIFSAN, ANL and ThoughtQuest	Q-7	Industry environment for Food DefenseTQ™ alpha demonstration

6. Develop and statistically analyze past and projected events	Structure CSM Method® database of past and projected events	Events database	Lessons learned from past and simulated events for library of best practices	US industry participants, JIFSAN, ANL, ThoughtQuest and NSI	Q-8	Structured CSM Method® events database
7. Populate Food DefenseTQ™ decision support system (DSS) with data	Identify indicators and warnings (I&W's) of impending food problems; monitor the critical nodes of the food supply chain	Earliest possible detection of I&W's and focused responses via real time monitoring	Use of CSM Method® to identify I&W's as actionable intelligence	US industry participants, JIFSAN, ANL and ThoughtQuest	Q-6	Food DefenseTQ™ DSS logic
8. Food DefenseTQ™ visualization platform	Capability to simulate food protection challenges across the threat continuum at different levels	Visualization of Food DefenseTQ™ DSS	Integration of CSM Method® DSS logic with Tactical Display Framework	US industry participants, JIFSAN, ANL, ThoughtQuest, Raytheon Solipsys, NSI and the Army National Guard (ANG)	Q-7	Food DefenseTQ™ DSS for alpha demonstration imbedded at the JSTEC
9. Industry deployment of three Food DefenseTQ™ modular systems for field testing and evaluation	Encourage a collaborative government-industry partnership	Obtain industry and government operational experience	Industry deployment at three selected field locations	US industry participants, JIFSAN, ANL, ThoughtQuest, Raytheon Solipsys, NSI	Q-8	Industry and Government tested Food DefenseTQ™

Table 6 Phase II Work Breakdown Schedule

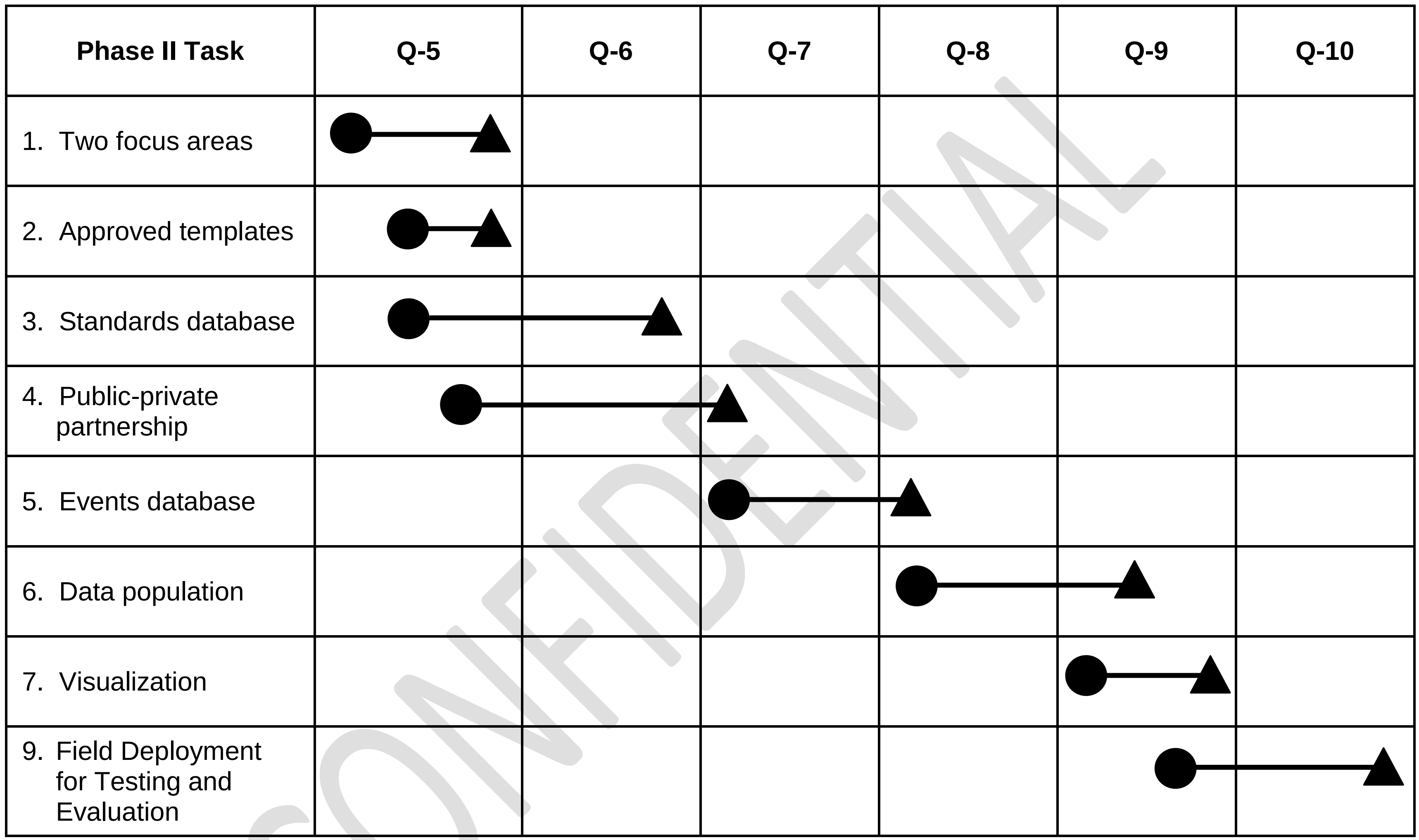

Figure 7 Phase II Milestone Schedule

Supporting Work

ThoughtQuest LLC, the University of Maryland, Argonne National Laboratory (ANL), NSI Inc., and the Muscatatuck Urban Training Center (MUTC) have worked together to develop and alpha test two functional systems using the CSM Method® common architecture. We are currently conducting research to develop Food DefenseTQ™.

Description	Client	Contact Information	Date Completed
School and CampusTQ™ is an all hazards risk management and continuous performance assessment tool that looks across all aspects of primary, secondary and post secondary school safety and security including school violence, the control of communicable disease, food safety, fires, natural disasters, chemical, biological and nuclear emergencies, improvised explosive devices and other threats.	State of Maryland	Maryland Research and Applied Sciences Consortium Jason A. Harris Program Manager (410) 715-4180 email: jharris@marylandtedco.org	Successfully alpha tested in February 2007.
AirportTQ™ is an all hazards risk management and continuous performance assessment tool that looks across all aspects of commercial air transport including equipment malfunction, accidents, natural disasters and intentional attack.	*	*	Successfully alpha tested in August 2008.
Food DefenseTQ™ is an all hazards risk management and continuous performance assessment tool that looks across all aspects of food safety and security including equipment malfunction, accidents, natural disasters and intentional attack.	H.J. Heinz Company	Dennis J. Kolsun Associate Director for Regulatory Affairs Heinz World Headquarters (412) 736-7123 email:Dennis.Kolsun@us.hjheinz.com	We are now conducting research with H.J. Heinz Company to formulate this application.

*Indicates that we are bound by the terms of non disclosure agreements not to reveal the identity of the client.

Table 7 Leveraging the Significant Investments Already Made to Produce a Next Generation Food Protection DSS

Relationship with Future Research and Development

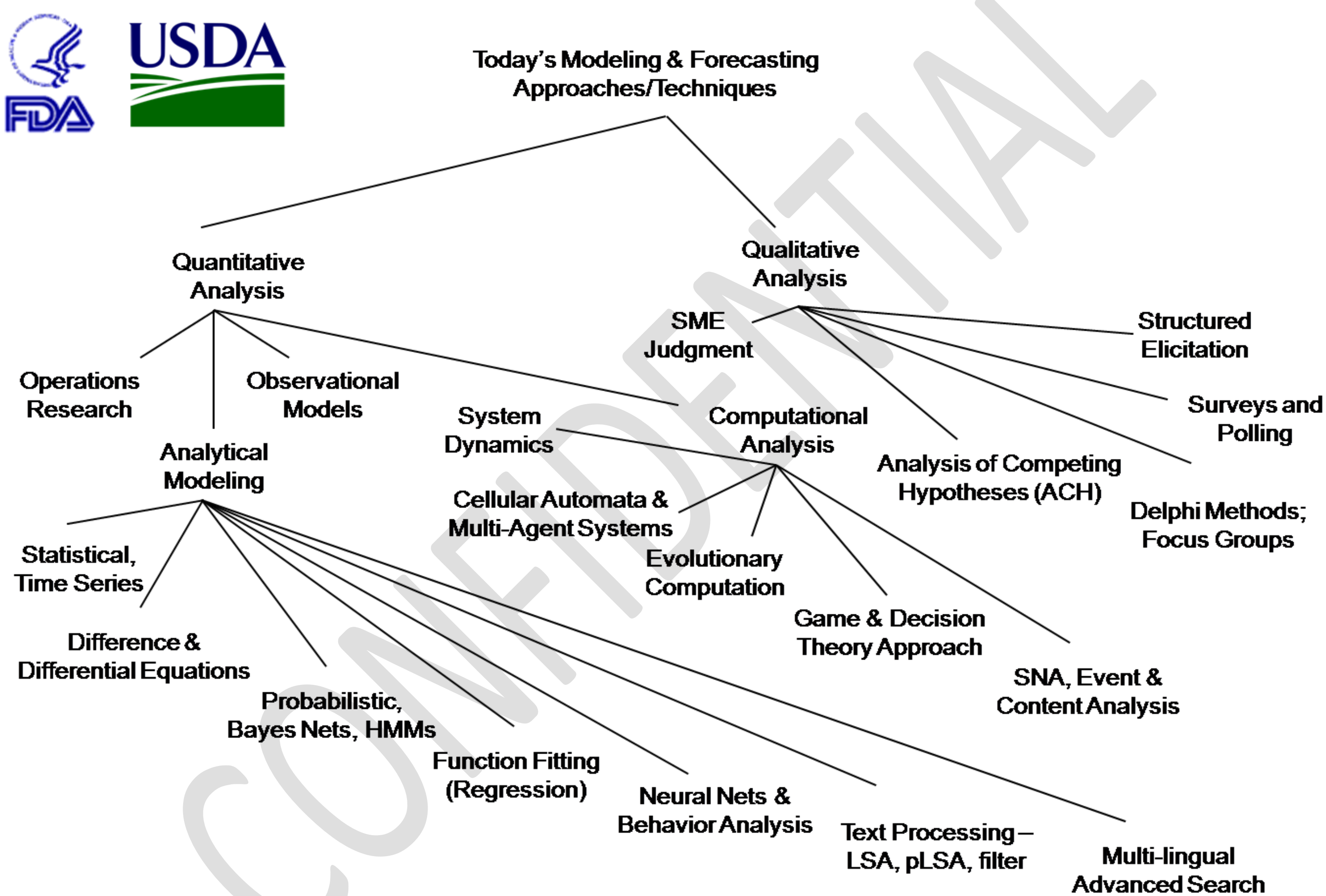

Figure 12 Any Next Generation Food Protection DSS Must Leverage Today's Tools in New Ways to Meet Tomorrow's Needs

The development of next generation DSS such as Food DefenseTQ™, requires new approaches and methods for deriving, structuring and manipulating information and data that accounts for the non-deterministic behaviors of complex adaptive systems, supports the more effective integration of quantitative reality with human social process, and assists human beings in the more effective management of complex events and situations. Our Phase I applied research efforts will focus on the application of our CSM Method® architecture via a food protection DSS alpha demonstration that will form the scientific and technical foundation for the Phase II objective of building a fully functional Food DefenseTQ™ all hazards risk management DSS.

Research Area	Phase I Anticipated Results	Significance to Phase II
Advanced methods of knowledge representation	Food protection ontology, taxonomy and integration of geographic/geospatial information to support Food DefenseTQ™	Visualize and re-visualize the behaviors of complex adaptive systems on the fly as they evolve
More robust machine learning and Q/CSS modeling and analysis capabilities to support continuously self learning systems	Identify and quantify food protection event and decision paths in a systematic and repeatable manner	Adjust baseline weighting values of performance benchmarks based on lessons learned and by the projection of " rare events" to produce learning knowledgebases, i.e. machine learning/reasoning
Human cognitive "framing"	Validation of previous research on the management of complex contingency operations that indicates the predominance of deterministic framing	New method to schematically frame problem solving in the context of the non-deterministic behaviors of complex adaptive systems
On the fly Q/CSS modeling and visualization of event and decision paths	Modeling and visualization of food protection event and associated decision paths	On the fly modeling, visualization and monitoring of events and associated decision paths
Q/CSS modeling of organizational and human conflict resolution paths	The identification of "best" decision paths that avoid and, when necessary, resolve uncertainty among a diverse groups of stakeholders	The use of decision templates to guide more effective intervention, prevention and response modalities
Technology supported consensus and conflict resolution techniques	Consensus building and conflict resolution based on event and Decision Path Analysis™	Identification of the indicators and warnings of potential events among stakeholders in time to intervene and guide responses

Table 8 Rigorous Phase I Scientific and Empirical Research as the Foundation for Phase II and Future Research and Development

Commercialization Strategy

ThoughtQuest LLC has reduced to practice a pending process patent known commercially under the registered trademark name as the CSM Method®. The CSM Method® enhances the human management of complex events by preventing and, when necessary, improving responses to events that can adversely impact the complex and continuously evolving critical infrastructure systems upon which modern society depends.

Market Size	Technology Need	Product	Status
$1.6 trillion dollars to be spent over the next five years to upgrade and build new U.S. infrastructure[xi]	Next generation risk assessment and continuous performance assurance decision support systems (DSS)	TQ™ line of products	CSM Method® invention reduced to practice

Table 10 Markets, Technology Need, Product and Status

Our commercialization strategy leverages government and private investments in the development of Food DefenseTQ™ to speed the integration of state of the art (SOA) technologies into our existing highly scalable CSM Method® architecture to further demonstrate the utility of our TQ™ line of products and speed market penetration into three major industry verticals over the next five years. A key part of our commercialization strategy is the granting of a government free use license for Food DefenseTQ™ and the licensing of the product to the food industry.

Vertical	Product	Technology Need	Market/5yrs[xii]	Status
Public Safety	School & CampusTQ™	Next generation risk assessment and continuous performance assurance DSS	$0.47 billion	$75,000.00 TEDCO funding; $500,000.00 basic and applied investment; product successfully alpha tested; co-development negotiations in progress; scalability leveraged to support alpha testing of other products
	BuildingTQ™	Ibid.	$0.96 billion	Primary data sets developed; system designed with an alpha test in preparation; co-development negotiations in progress

Agriculture	Food DefenseTQ™	Ibid.	$2.30 billion	Primary data sets developed; research now being conducted with global food manufacturer; co-development discussions are now in progress
Transportation	AirportTQ™	Ibid.	$1.25 billion	Primary data sets developed; system successfully alpha tested with one of the world's largest commercial air carriers; discussions are continuing

Table 11 Vertical, Product, Technology Need; Market over 5 years and Status

Key Personnel

Name	Technical Role	Telephone and email	Special Qualifications	Education, Institution, Academic Honors & Year
JIFSAN principal	Leader of IPT and Principal Investigator	???	???	???
John Hnatio[xiii] ThoughtQuest U.S. Citizen	CSM Method®	(301) 644-3907 jhnatio@thoughtquest.com www.thoughtquest.com	President and CSO of ThoughtQuest; recognized authority in the development of nuclear and biological risk based management and oversight systems; inventor of CSM Method®; extensive experience developing and managing generic enabling technology government-industry consortia	EdD-Higher Education Administration-George Washington University-2006 PhD-Physics, Russian Academy of Sciences -*honoris causa*-1995 MLS-Georgetown University-*scholae studorium superiorum-1992* BS-St. University of NY College at Buffalo-*summa cum laude*-1974 First student recipient of the *Navigator Award* for doctoral research on complex adaptive systems and next generation decision support systems at GWU-2004

David Park ThoughtQuest U.S. Citizen	Senior food defense SME and technical program lead	(540) 338-8186 Dkpark72@aol.com	Food process assurance authority; co-developer of first FDA & USDA regulatory accepted computer control for thermal pasteurization and sterilization of acidified and low-acid canned foods; co-founder of the Institute of Thermal Processing Specialists (IFTPS)	BS-Food Science-Purdue University-1972 Purdue University-*Outstanding Food Service Alumni Award*-2007 Purdue University-Purdue/KS DACUM Food Safety/Defense Team, USDA CSREES
Craig Swietlik[xiv] ANL U.S. citizen	Senior Technical Advisor: Advanced Information Technology Systems	(630) 252-8912 Swietlik@anl.gov www.anl.gov	Group Leader of the Argonne National Laboratory Information Sciences Group; extensive expertise in large-scale information and knowledge management systems, Internet systems, and cyber security	PhD Computer Science/Applied Mathematics, Northwestern University MS, BS Mathematics, Loyola University of Chicago

Barton Michelson[xv] ThoughtQuest U.S. citizen	Human and Organizational Behavior	(301) 518-9908 bmichelson@goeaston.net www.thoughtquest.com	Extensive teaching, consulting and research on organizational systems development and organizational behavior and decision making	PhD, MA & BA, The Ohio State University (1972, 1970 & 1962)
Jason Brooks Raytheon Solipsys U.S. Citizen	Advanced simulation, modeling and visualization	(240) 554-8352 Jason.brooks@solipsys.com	Expertise in high-performance, interactive data visualization, 2D and 3D user interfaces, time-critical workflow optimization, Command and Control (C2) HMI development	M.Sc., Computational Design, Carnegie Mellon University B.Arch., School of Architecture, Carnegie Mellon University
Robert Popp[xvi] NSI U.S. citizen	Computational Social Science Modeling	(781) 864-1347 rpopp@natlsec.com www.natlsec.com	Extensive expertise in quantitative/ computational social science modeling and analysis; former DARPA Deputy Director for IAO and IXO offices; Founder, President & CEO of NSI, Inc.	PhD, Electrical Engineering University of Connecticut BA/MA-*summa cum laude*, Phi Beta Kappa), Computer Science, Boston University

Lt. Colonel Jere Riggs- Indiana Army National Guard U.S. citizen	MUTC Army Point of Contact	(317) 247-3483 Cell: (317) 508-8251 LTC, GS, JFHQ-IN-J5 jere.j.riggs@us.army.mil	Director of Strategic Plans and Policy (J-5) IANG; extensive experience in all phases of contingency planning and civil-military coordination	Command and General Staff Officer's College (1997) MS, Oakland City University (2007)

Table 12 Key Personnel

Facilities and Equipment

Requirement	Location	Justification	Regulatory Compliance
University of Maryland JIFSAN	College Park, MD	Main offices; conduct research	Yes-Federal, Maryland
ThoughtQuest Headquarters facilities	ThoughtQuest, Frederick, MD	Main offices; conduct research	Yes-Federal, Maryland
NSI Headquarters facilities	Boston, MA	Main offices; conduct research	Yes-Federal, Massachusetts
Host server	Argonne	Main offices; conduct research	Yes-Federal, Illinois
TDF data manipulation & visualization	Raytheon Solipsys	Storage and manipulation of S&RO DSS Phase I & II TDF platform	Yes-Federal, Maryland
JSTEC	MUTC	MUTC/JSTEC/Camp Atterbury; demonstration	Yes-Federal, Indiana

Table 13 Regulatory Compliance of Facilities to Conduct Work

Prior, Current, or Pending Support of Similar Proposals or Awards

On January 15, 2009, ThoughtQuest LLC submitted a proposal to the Defense Advanced Research Projects Agency (DARPA) under SB091-003 to develop the Geospatial Inference System for Stability and Reconstruction Operations or GISARO. The proposal involves the use of the CSM Method® architecture to build a novel decision support system to guide and measure the performance of civil-military efforts in the conduct of stability and reconstruction operations in foreign lands. The award under the solicitation is currently pending.

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[iv] U.S. Department of Health and Human Services (2007, November). *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply.* Washington, DC: Food and Drug Administration. Retrieved from the World Wide Web on March 25, 2009, at: http://www.fda.gov/oc/initiatives/advance/food/plan.html

[v] U.S. Food and Drug Administration (2008, December). *Food Protection Plan: One Year Progress Summary.* Retrieved from the World Wide Web on March 25, 2009 at: http://www.fda.gov/oc/initiatives/advance/food/progressreport1108.html

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[vii] Hnatio, J. (2006). The Complexity systems management method: A next generation decision support tool for the management of complex challenges at institutions of higher education (doctoral dissertation). Washington, DC: The George Washington University.

[viii] Hnatio, J. (2000). The management of complex contingency operations: Course syllabus. Industrial College of the Armed Forces, Elective No. 5166. Washington, DC: National Defense University.

[ix] Hnatio, J. (2006). The Complexity systems management method: A next generation decision support tool for the management of complex challenges at institutions of higher education (doctoral dissertation). Washington, DC: The George Washington University.

[x] Hnatio J. (2007, July 20). Invention disclosure: *Complexity systems management method*, [application no. 11/808,580]. United States Patent and Trademark Office, Washington, D.C.

[xi] Reid, R.L. (2008, January). The infrastructure crisis: Special report. *Civil engineering: The on-line magazine of the American Society for Civil Engineers.* Reston, VA: The American Society of Civil Engineers.

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[xiv] See for example: Orlandic, R., Lukaszuk J. & Swietlik C. (2001). *The design of a retrieval technique for high dimensional data on tertiary storage.* Argonne, IL: Argonne National Laboratory.

[xv] See for example: Michelson, B. J. et. al. (1999). Hawley, L.; McGee, M. & Michelson, B., (1993). Consensus team decision making for strategic leaders. Washington, DC: Industrial College of the Armed Forces, National Defense University Press, and; Michelson, B. (2001). *Leadership and power base development: Using power effectively to manage diversity and job-related interdependence in complex organizations,* as appearing in AU-24 Concepts for Air Force leadership (4th ed.), Maxwell AFB, AL: Air University.

[xvi] See in particular: Popp R. & Yen J. (eds.). (2006). Emergent information technologies and enabling policies for counter-terrorism. *Chapter 1: Utilizing information and social science technology to counter the twenty-first century strategic threat*, by R. Popp. New Jersey: Wiley & Sons.