

Today's presentation

Outline











- 1. Who are we?
- 2. What is the technology?
- 3. How is it used?
- 4. How does it work?
- 5. What is Food DefenseTQ™?
- 6. Why is it important?
- 7. What does it do?
- 8. The Benefits
- The Proposal
- 10. Status



1. Who are we?

ThoughtQuest LLC







Raytheon Solipsys



- Hood College, Frederick, MD
- TEDCO company
 - John Hnatio, Ed.D., Ph.D.
 - 30 years as NBC risk manager
 - Barton Michelson, Ph.D.
 - 25 years JPME Leader
 - David Park
 - 30 years as food protection risk manger
- CSM Method®
- Significant collaborative development

2. What is the technology?

The CSM Method®

- Provisionally patented decision support architecture
 - Designed to enhance the human management of complex systems by turning data into knowledge
- Enables users to monitor their performance and manage the risk to their operations in real time
 - Compliance standards and best industry practices
 - Lessons learned
 - Changes in the strategic threat environment
- Prevents process anomalies, accidents, equipment malfunction and intentional attacks that can disable critical food protection operations
 - Identifies and alerts users to take effective countermeasures to avoid and prevent adverse events
 - When responses are necessary, it guides users to implement the most effective responses to incidents including natural events

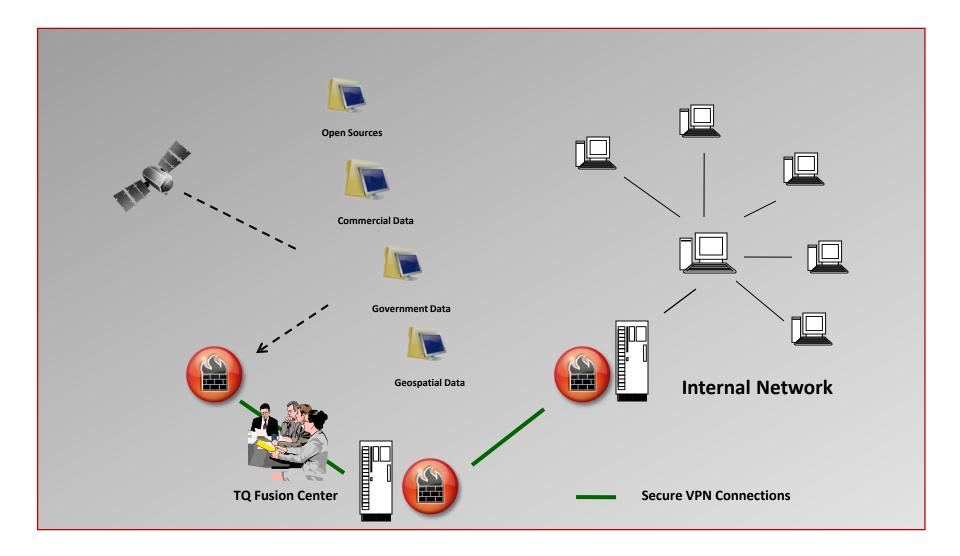


3. How is it used?



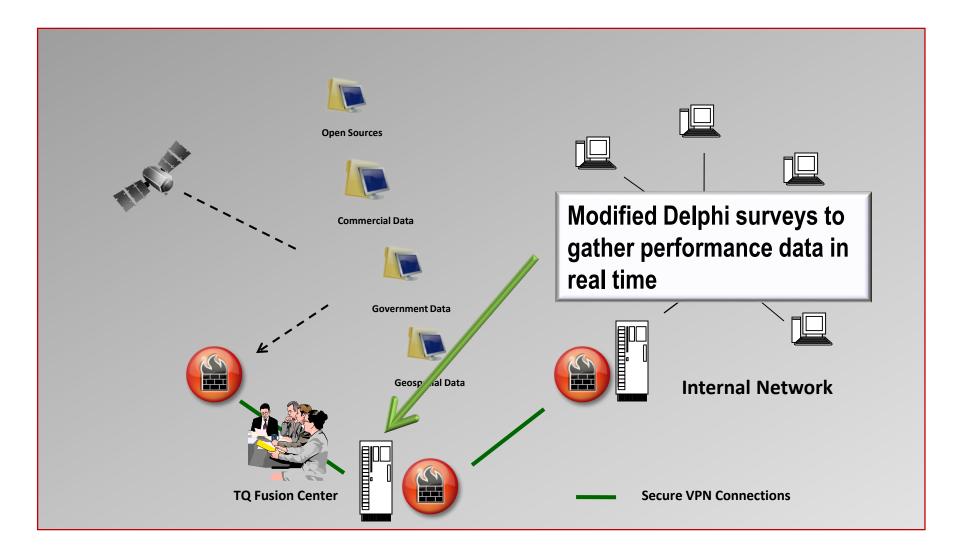


4. How does it work?



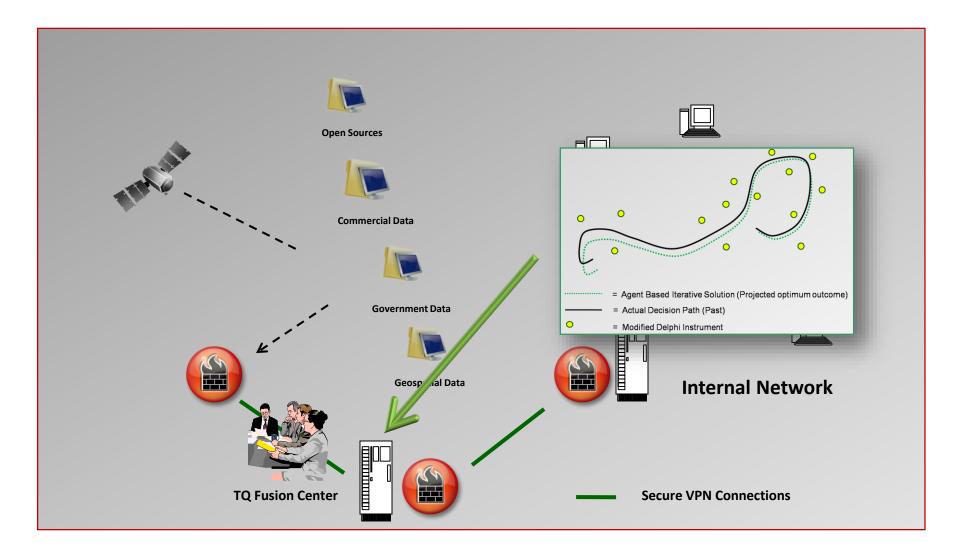


Modified Delphi Surveys



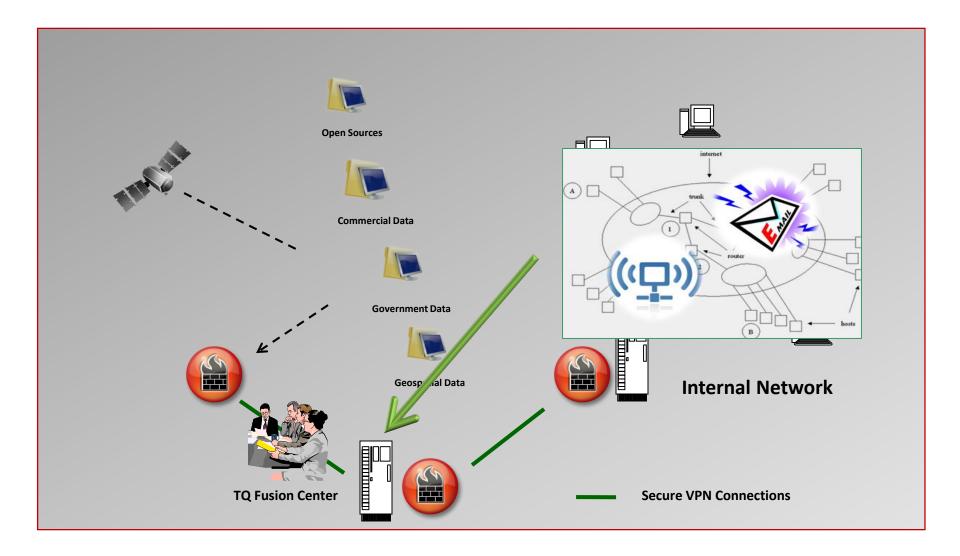


Decision Path Analysis TM



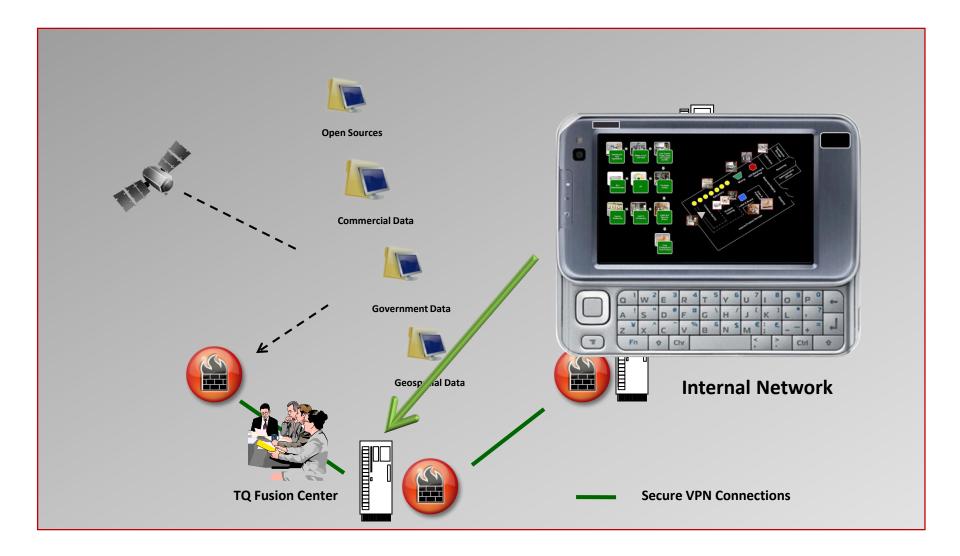


Leverages the web



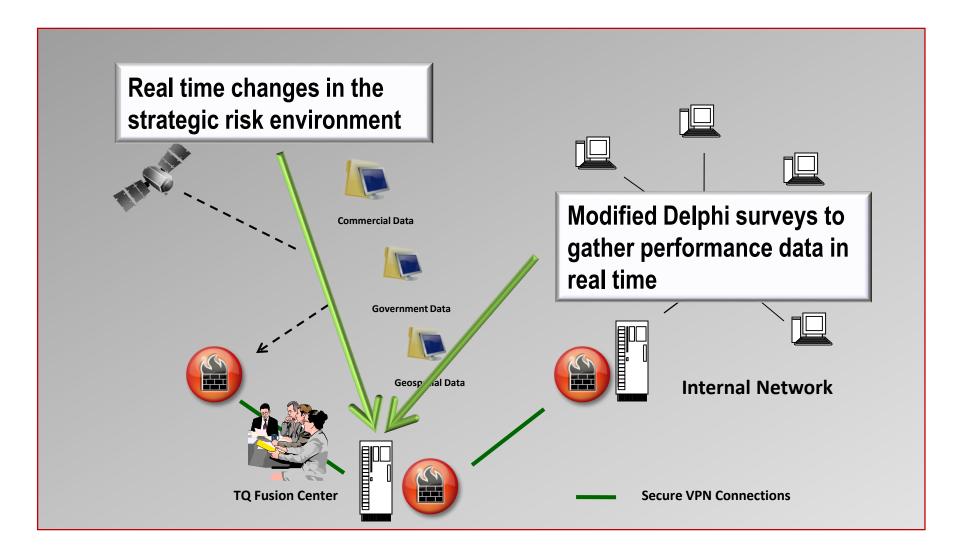


Leverages PDA technology



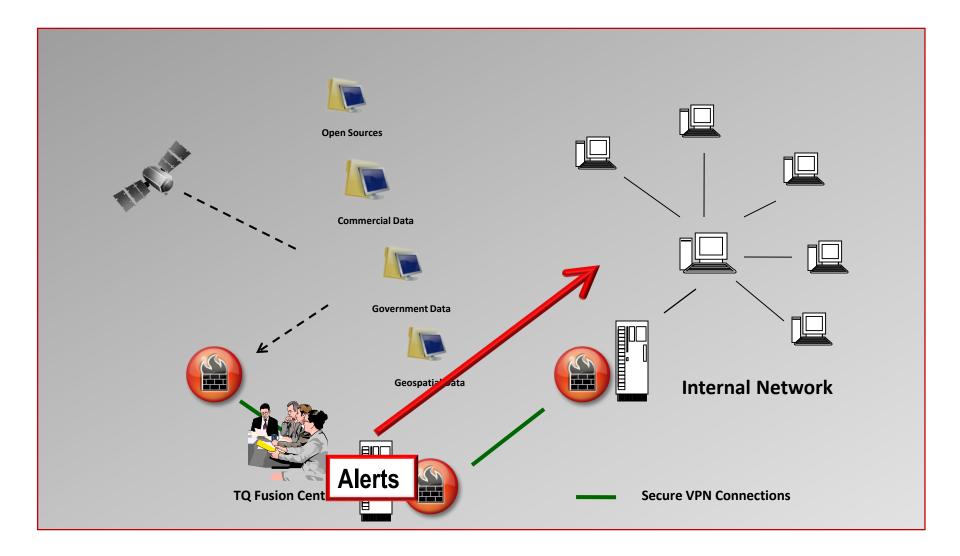


Monitors the strategic environment



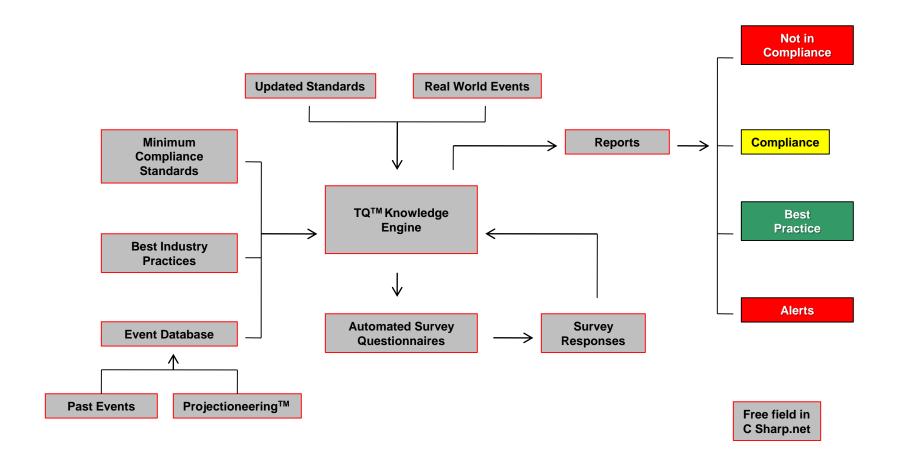


Alerts users of changing risks





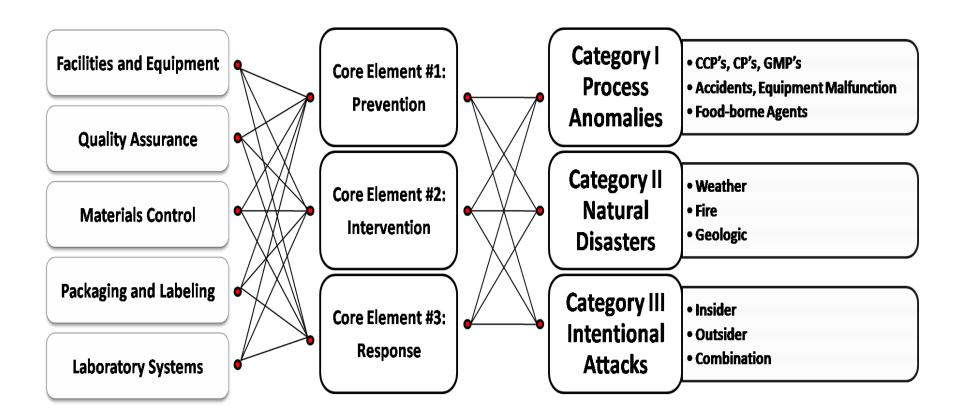
The System Architecture





5. What is Food DefenseTQTM?

Food DefenseTQ™ is an automated all hazards risk management tool



6. Why is the technology important?

The Big Picture



- 76 million cases of foodborne illness each year
 - 325,000 hospitalizations
 - 5,000 deaths
- ~\$35 billion in costs and lost productivity each year



Incidents and impact

Date	Producer	Incident Type	Cause	Estimated Losses	Incident Description
10/15/1982	Tylenol	Sabotage via adulteration	Suspected Insider	\$100,000,000+	Seven fatal Tylenol poisonings, code-named TYMURS by the FBI, took place in the Chicago area. The poisonings involved Extra-Strength Tylenol capsules laced with potassium cyanide.
6/1/1986	Excedrin	Tampering	Outsider	\$93,000,000+	Stella Maudine Nickell was sentenced to 90 years in prison for murdering her husband by deliberately poisoning his Excedrin capsules with lethal cyanide. She then poisoned five other people in order to make her husband's death appear to be the work of a serial killer.
3/1/1989	Heinz Baby Foods	Sabotage via adulteration	Suspected Insider	\$67,000,000+	In March of 1989 a bottle of Heinz baby food was reported containing glass; it was believed that the contamination was the result of an employee. Shortly after the report Heinz became the victim of an extortion plot when a former policeman began contaminating Heinz products. Heinz was forced to destroy 100 million jars of baby food.
8/1/1993	Diet Pepsi	Runaway Hoax	Unknown	\$5,500,000+	During the summer of 1993, PepsiCo managed to stave off a runaway hoax pertaining to alleged product tampering. Syringes were claimed to have been found in cans of Diet Pepsi throughout the U.S. With the arrests of several of the fraudulent claimants, reports of found hypodermic needles ceased.
9/11/1997	Arnott's Biscuits	Extortion	Unknown	\$22,000,000+	In 1997, Arnott's biscuits was forced to withdraw its entire Australian stock nationwide following an extortion threat.
7/4/2004	Gerber Baby Foods	Likely sabotage	Unknown	\$8,000,000+	Castor beans are found in three bottles of Gerber baby foods with notes indicating the food had been poisoned. The reports lead to copycat tampering of Gerber products.
5/1/2005	Heinz (Merion Plant)	Equipment Malfunction	Unknown: possibly operator error	Unknown	An undetermined quantity of anhydrous ammonia was released from malfunctioning equipment at the Heinz plant in Upper Merion Township, Montgomery County.
7/1/2005	MARS chocolate bars: Master Foods	Extortion	Likely Outsider	\$10,000,000+	Masterfoods lost an estimated \$7.5 million when an extortionist claimed to have contaminated Mars and Snickers bars with pesticide. Masterfoods removed the chocolate bars from 40,000 stores in the Australian state of New South Wales.
11/1/2005	Boca Foods (Hobbs Plant)	Fire Loading	Insider	\$8,000,000+	On Valentine's Day of 2005 the RMS Foods, Inc. plant, which makes organic Boca burgers, was almost entirely destroyed by a fire.
2/1/2005	Premier Foods	Adulteration	Inadvertent contamination	\$75,000,000+	Worcester sauce produced by Premier Foods was found to be contaminated by Sudan I carcinogenic dye. The origin was traced to adulterated chili powder. The sauce was used in hundreds of supermarket products such as pizzas and ready-made meals, and the contamination led to over 400 products being taken off the shelves.



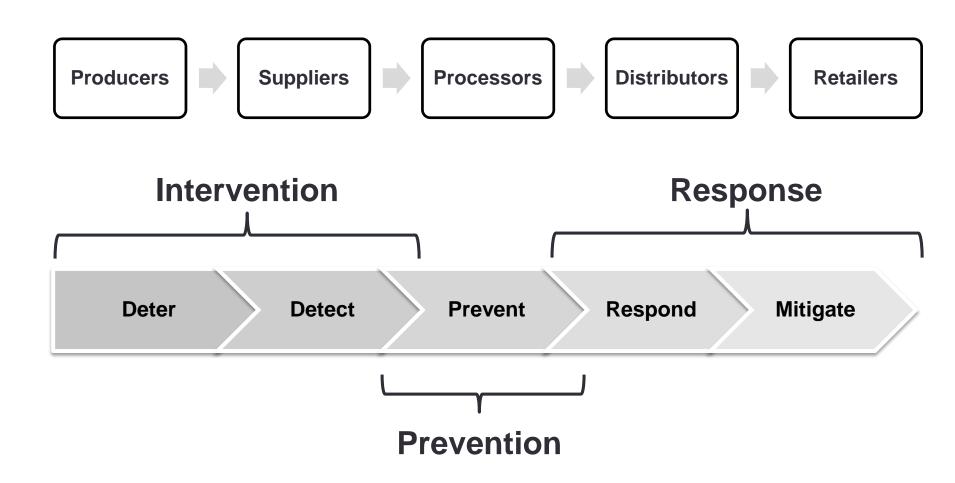
Incidents and impact

Date	Producer	Incident Type	Cause	Estimated Losses	Incident Description
9/26/2006	Tyson's Chicken (Heflin Plant)	Accidental Fire	Maintenance contractor	\$100,000,000+	In September 2006, a fire broke out at Tyson's Heflin, Alabama plant. The fire started over the weekend while a contractor was repairing a roof. Insulation caught fire and the plant was completely destroyed. Tyson's was subsequently forced to abandon the chicken commodity market to Kochs Foods.
10/12/2006	Natural Selection Foods LLC	E. coli 0157:H7 contamination	Poor sanitary practices: cattle feces and growing fields	\$160,000,000+	FDA and the State of California announced that the test results for samples collected during a field investigation were positive for <i>E. coli</i> O157:H7 in spinach. Samples of cattle feces on one of the implicated ranches tested positive for the same strain of <i>E. coli</i> O157:H7 that sickened 204 people. The outbreak affected 26 states with 204 confirmed illnesses,104 hospitalizations and 3 deaths.
9/25/2007	Topps Meat Company	E. coli O157:H7 contamination	Poor safety practices	\$144,000,000+	21.7 million pounds of frozen ground beef products produced between September 25, 2006, and September 25, 2007 by the Topps Meat Company were recalled in September 2007 due to <i>E. coli</i> O157:H7 contamination. At the time, this was the second-largest beef recall in U.S. history, after Hudson Foods Company's recall of 25 million pounds of ground beef in 1997. The outbreak affected 8 states with 29 confirmed serious illnesses.
1/30/2008	Hallmark- Westland Meat Packing Company	Animal cruelty	Non- compliance with USDA regulations	\$132,000,000+	On February 17, 2008 Hallmark/Westland Meat Packing Company was forced to recall over 143 million pounds of beef products, considered the largest meat recall in the United States, following an investigation into animal cruelty. Workers were videotaped using forklifts to move downed animals unable to walk into the kill pens.
4/10/2008	Not confirmed	Salmonella enterica in produce	Likely poor sanitary practices: cattle feces and growing fields	\$98,000,000+	At least 203 reported hospitalizations were linked to the outbreak that caused at least one death, and may have been a contributing factor in at least one additional death. CDC states that "it is likely many more illnesses have occurred than those reported." By applying the CDC estimated ratio of non-reported salmonellosis cases to reported cases (38.6:1), one would arrive at an estimated 40,273 illnesses from this outbreak.
8/24/2008	Maple Leaf Foods	Listeria monocytogenes in deli meats	Poor safety practices	\$122,000,000+	Several products were recalled for meats processed by Maple Leaf. The recall was later extended to include Schneider's, McDonald's, and other products. Since the time of the initial outbreak, there have been: 38 Confirmed cases of listeriosis; 30 Suspected cases; 9 Confirmed deaths caused by the outbreak and 11 suspected deaths.
1/17/2009	Peanut Corporation of America	Salmonellosis in peanut butter	Poor safety practices	\$200,000,000+	Salmonella was reported to be found in 46 states in at least 3,419 peanut butter-based products. At least 683 people became sick claiming at least nine lives as of March 10th. Peanut butter and peanut paste manufactured by PCA were distributed to hundreds of firms for use as an ingredient in thousands of different products, such as cookies, crackers, cereal, candy and ice cream, all of which were recalled. Some products were also sold directly to consumers in retail outlets like dollar stores.



7. What does Food DefenseTQ[™] do?

Looks Across the Entire Risk Continuum



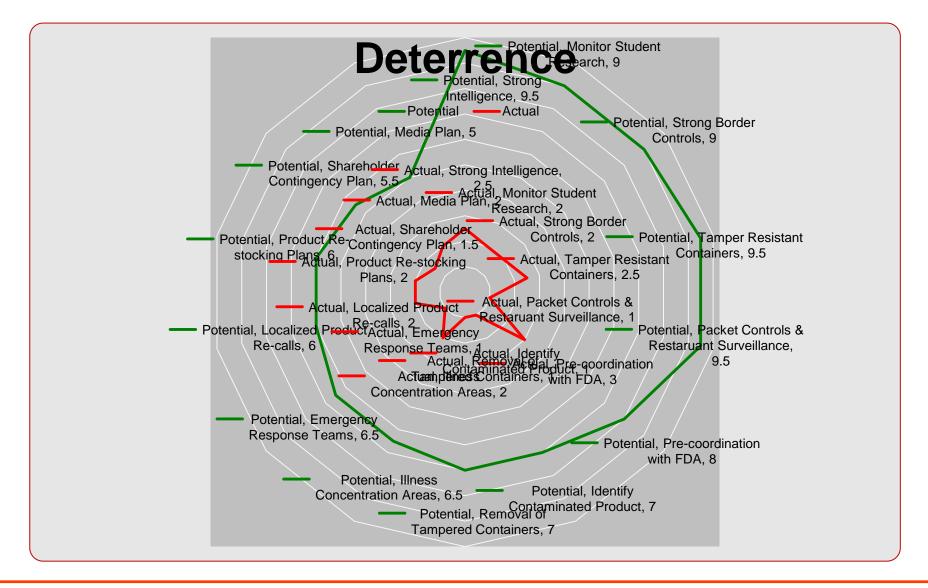


Monitors the critical nodes of system performance

National Incident Management System Cat: 1,2 & 3	Liaison with First Responders Cat: 2 & 3	Alerts Cat: 1, 2 & 3	Records and Investigations Cat: 1, 2 & 3	Preventive Maintenance Cat: 1 & 2	First Responder Communications Cat: 1, 2 & 3	Personnel Account- ability Cat: 1, 2 & 3	Integrity of Alarm, Computer & Communications Systems Cat: 1, 2 & 3
Immediate Medical Assistance	Medical Triage Plan	Medical Transportation	Product Recall	Media Protocol	After Action Reviews	Protocol for Correcting Deficiencies	Community Relations
Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3
Prohibition of Weapons	Reliability of Vendors	Diagnosis of System Abnormalities	Anonymous Reporting	Recognizing Threatening Behaviors	Employee Referrals	Safety Training & Certifications	Pre-employment, Criminal Background Checks
Cat: 1 & 3	Cat: 1 & 3	Cat: 1, 2 & 3	Cat: 1 & 3	Cat: 1 & 3	Cat: 1 & 3	Cat: 1, 2 & 3	Cat: 1 & 3
Facility Lockdown	Facility Hot Spots	Marking of Roads & Boundaries	Site Maps, Building Plans & Systems Drawings	Access Control	Personnel Identification	Visitor Control	Traffic Management
Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3
Facility Shutdown	Evacuation	Emergency Drills	Emergency Notification	Emergency Awareness Training	Assignment of Safety & Security Personnel	Protocol for Notifying Authorities	Product Integrity: Tampering
Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1, 2 & 3	Cat: 1 & 3

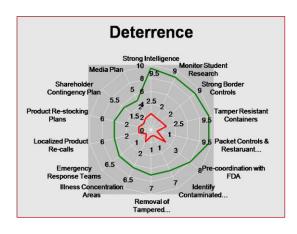


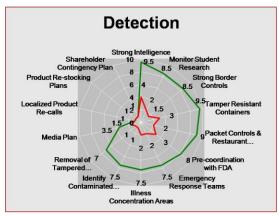
Measures performance continuously

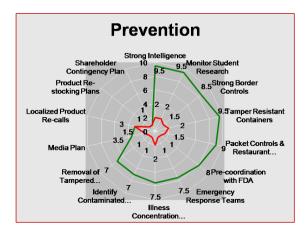


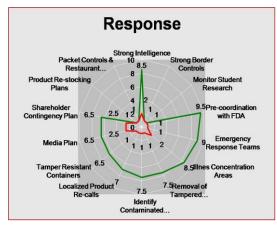
Measures performance continuously

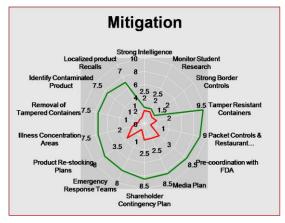
Across the Entire Risk Continuum

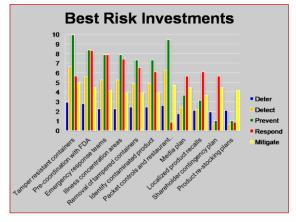












Visualizes the process

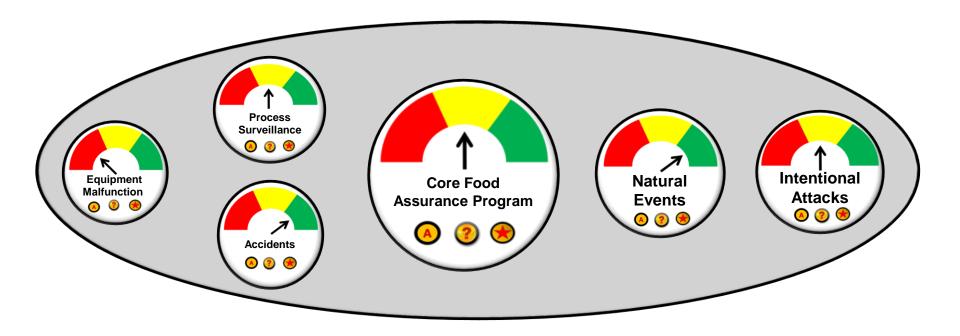
The Tactical Display Framework

- 100% Java proven DoD display solution
- HMI provides a common look and feel
- Geospatial map engine for realtime tracking and imagery display anywhere on Earth
- Optimized for high performance
- Operationally tested and mature
- Dynamic, flexible, and modern design allowing extreme configurability
- Very interactive with multiple selections, rollovers, and tags
- 3-D capability





We Use Performance Dashboards



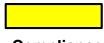
A = Corrective Actions

🕐 = Help

Alerts



Best Practice



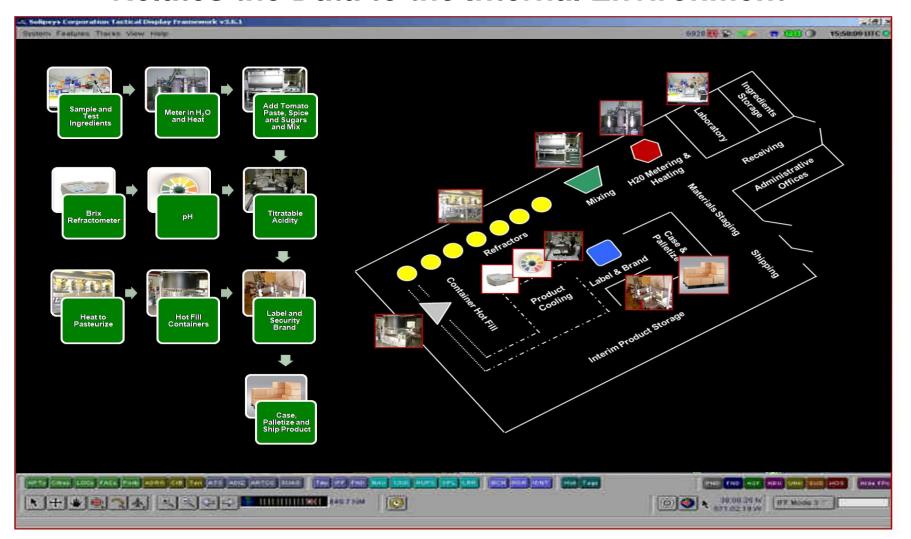
Compliance



Creates Actionable Intelligence

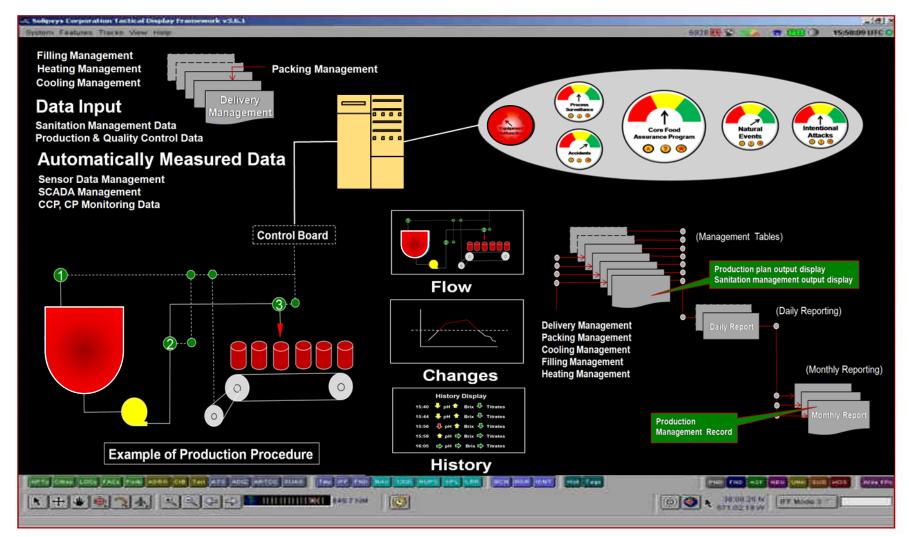


Relates the Data to the Internal Environment





Relates the Data to the Internal Environment



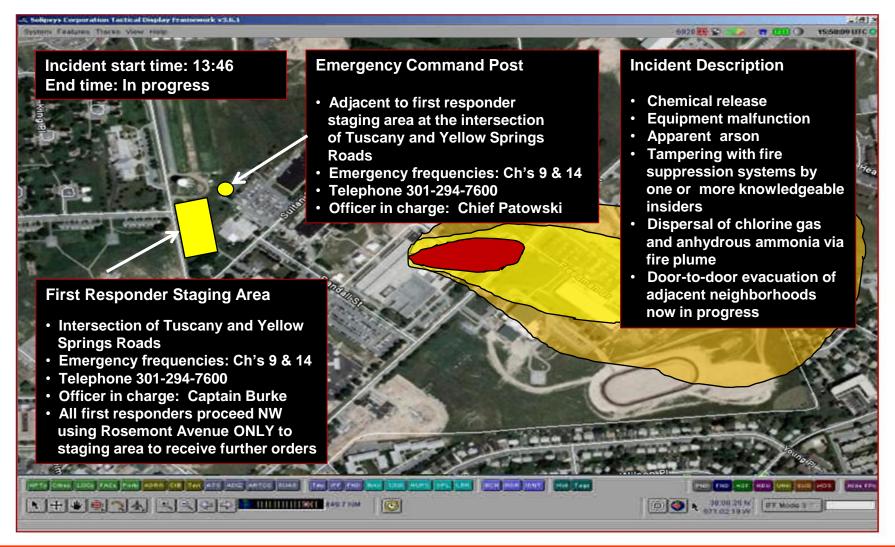
PDA Enabled Solution for Process Monitoring and Inputs



Relates the Knowledge to External Environment



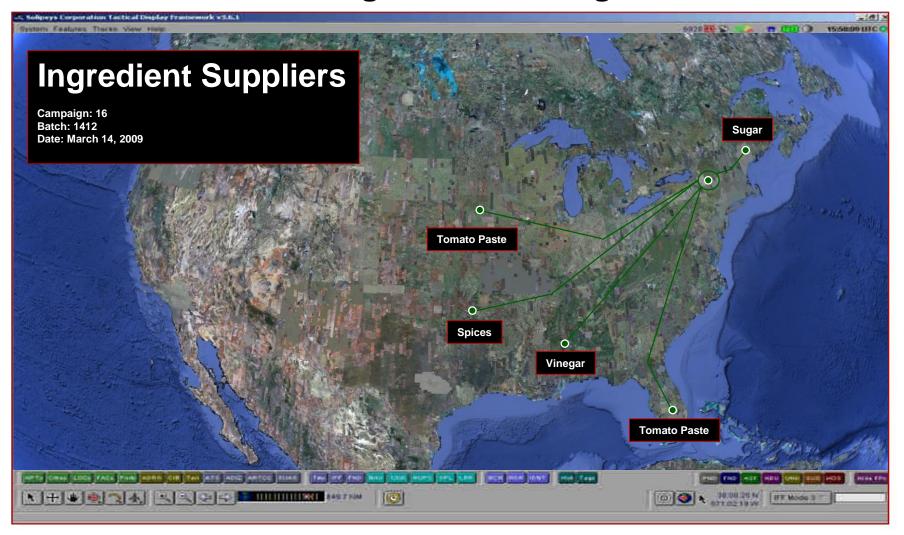
Creates Shared Situational Awareness



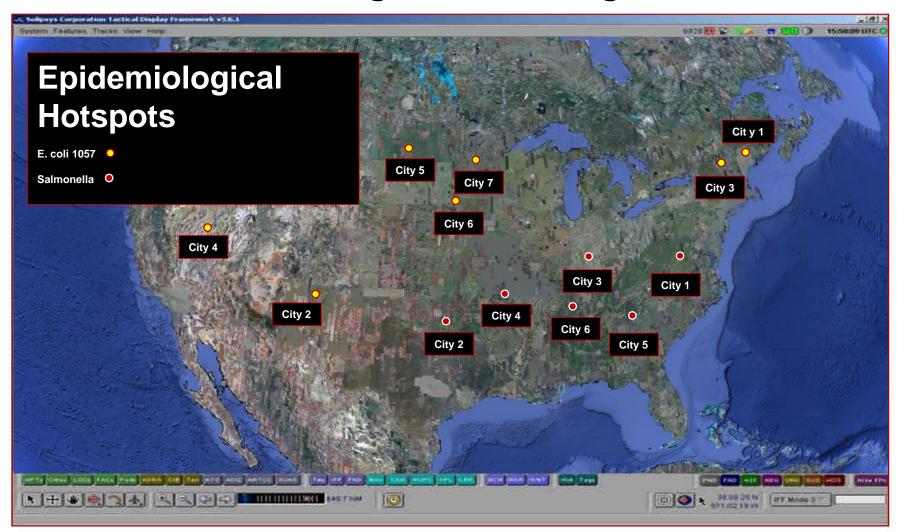
PDA Enabled Solution for Awareness, Reconnaissance & Intelligence



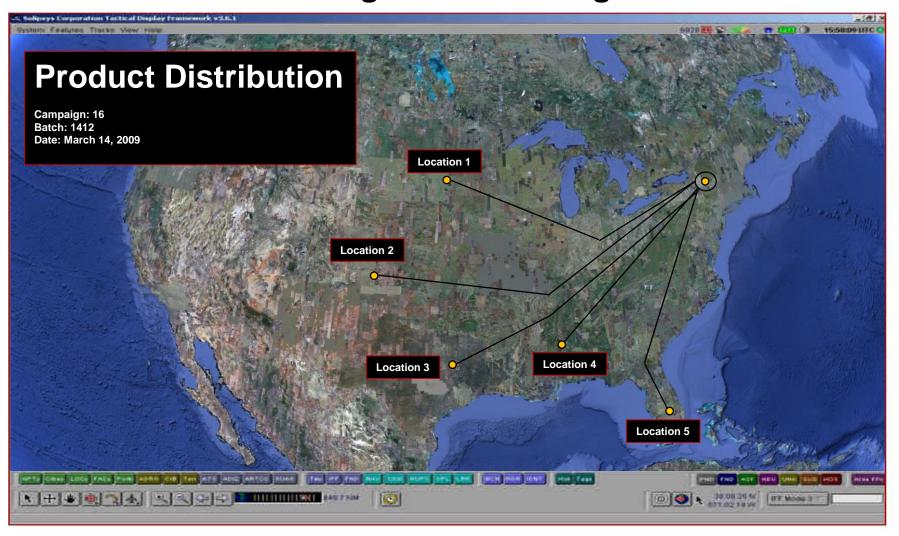
Relates the Knowledge to the Strategic Environment



Relates the Knowledge to the Strategic Environment



Relates the Knowledge to the Strategic Environment





8. The benefits

Capability	TQ™	Carver + Shock	PRA	Ramcap Plus™	BT Safety
Statistical Drivers				1	
Consolidate and update standards					
Adjust to changes in the threat environment based on real world and projected incidents	1				
Monitor indicators and warnings of incidents					
Issue alerts to prevent incidents					
Specific criteria to guide all-hazards responses					
One time assessment capability		1			
Law of Large Numbers		√		/	
Projectioneering™					
Continuous performance assessment					
Use of net based questionnaires					
Performance reports by critical category					
Specific criteria to correct problems					

Contributions to Strategic Food Protection

Core Element	Strategies	Purpose	Food Defense TQ™
Core Element #1: PREVENTION	Improved Outreach	Increase collaboration with industry to prevent food problems	1
	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	1
	Independent Certification	Increase third-party inspections	/
	PREDICT Pilot	Develop new technical tools	
Core Element #3: RESPONSE	Improved Product Tracing	Identify best practices	1
	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	/

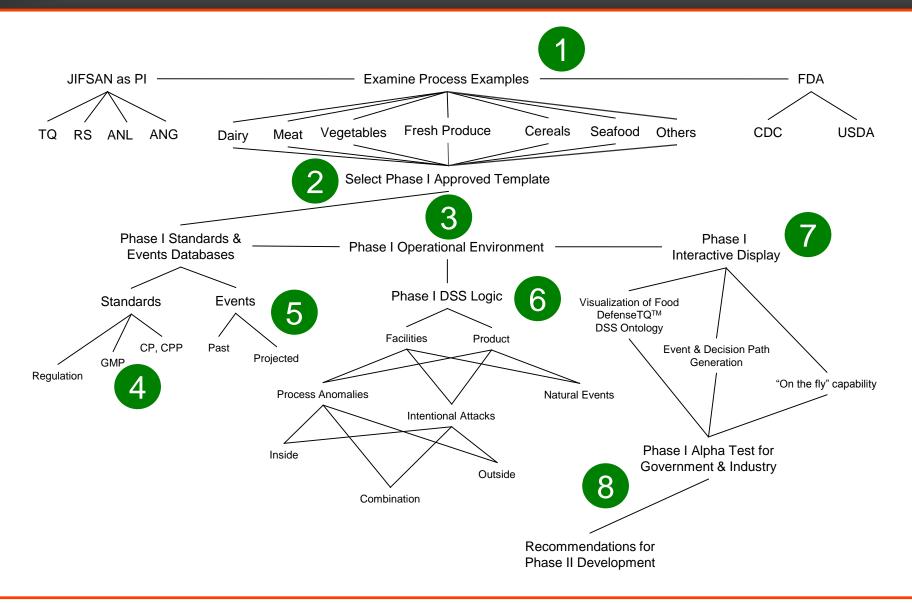
9. The Proposal

Build: Food DefenseTQ™

- Uses an "all hazards" approach to managing risk
 - Process assurance for CCP, CP, accident and equipment management (including sensors and SCADA)
 - Natural events
 - Intentional attacks
- Supports the FDA compliance and reporting process
 - Allows for real-time compliance monitoring and reporting of critical results
 - More efficient quality assurance, compliance and inspection
- Inexpensive and easy to use
 - Uses a modular approach based on product and approved FDA process templates
- Highly scalable
 - Small, medium and large enterprises
 - FDA oversight



Phase I Work Breakdown Flow



Phase I Work Breakdown Flow

Primary Phase I Tasks

- Examine and identify high priority food processing area of concern to FDA; coordinate with USDA and CDC
- In coordination with FDA, USDA and CDC select approved process template for use as Phase I example
- 3. Develop standards databases for regulatory and good management practices; identify CP, CCP's and GMP's and structure data using CSM Method®
- 4. Identify and coordinate an industry partnership with food processor for collaboration
- 5. Develop and statistically analyze past and projected events to include process anomalies, intentional attacks and natural events; structure data using ProjectioneeringTM methodology
- 6. Use CSM Method® architecture to populate Food DefenseTQ™ decision support system (DSS)
 - a. Process Assurance Support System (PASS)
 - 1) Accidents
 - 2) Equipment Malfunction
 - 3) Process Anomalies
 - b. Security Assessment and Facility Evaluation System (SAFE)
 - 1) Natural Events
 - 2) Intentional Attacks
- 7. Build Food DefenseTQTM visualization platform to include event, decision path and "on the fly" scenario generation capability
- Conduct Phase I alpha demonstration for government and industry; solicit recommendations for Phase III development

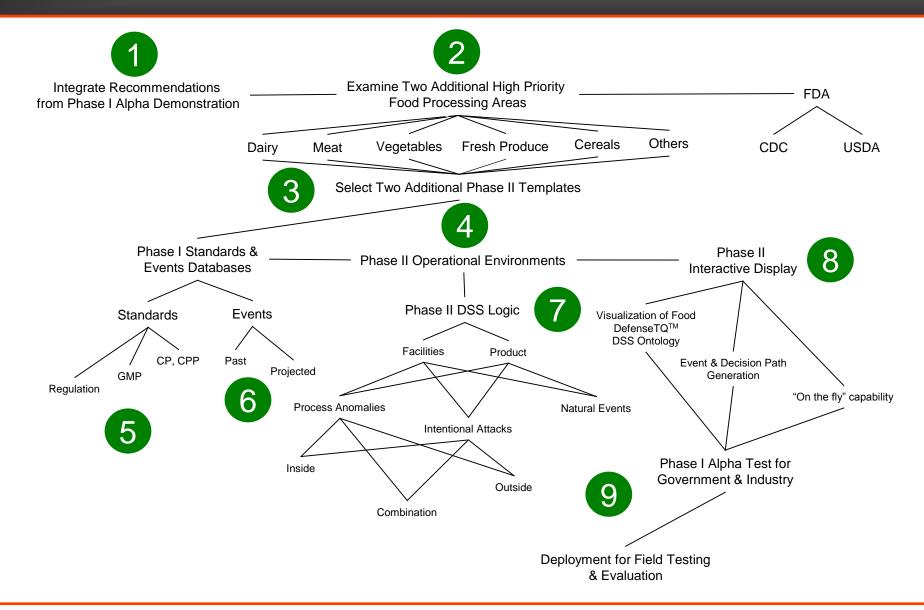


Phase I Work Plan

TASK	DESCRIPTION	TEAM MEMBERS	ROLE
Phase-I, Task-1	Examine Areas of Food Processing Concern	JIFSAN, TQ, ANL	JIFSAN: Interagency coordination TQ; ANL: Technical support
Phase-I, Task-2	Select Approved Process Template	JIFSAN, TQ, ANL	JIFSAN: FDA approved template TQ, ANL: Technical support
Phase-I, Task-3	Develop Standards Databases	JIFSAN, TQ, ANL	JIFSAN: SME knowledge TQ: CSM Method® and Food DefenseTQ TM architecture ANL: SME knowledge, information technology expertise
Phase-I, Task-4	Develop and analyze events databases	JIFSAN, ANL, TQ	JIFSAN: SME knowledge ANL: SME knowledge, information technology expertise TQ: CSM Method® and Food DefenseTQ TM architecture
Phase I, Task-5	Operational environment for collaboration	JIFSAN, TQ	JIFSAN: FDA sponsored center TQ: Industry interface
Phase-I, Task-6	Phase I DSS Logic	JIFSAN, ANL, TQ	JIFSAN: SME knowledge ANL: SME knowledge, information technology expertise TQ: CSM Method® and Food DefenseTQ [™] architecture
Phase-I, Task-7	Phase I interactive display	Raytheon Solipsys, TQ, ANL, JIFSAN	RS: Tactical Display Framework (TDF) TQ: CSM Method® and Food DefenseTQ™ architecture ANL: SME knowledge, information technology expertise JIFSAN: SME knowledge
Phase I, Task-8	Phase I alpha demonstration for government and industry	JIFSAN, TQ, ANL, RS	JIFSAN: Interagency coordination TQ, ANL, RS: Technical support



Phase II Work Breakdown Flow



Phase II Work Breakdown Flow

Primary Phase II Tasks

- 1. Integrate interagency and industry recommendations into the Phase II development plan
- Examine and identify two additional high priority food processing areas of concern to FDA; coordinate with USDA and CDC
- In coordination with FDA, USDA and CDC select two additional approved process templates for Phase II scaling
- 4. Identify and coordinate an industry partnership with tow food processors for collaboration
- Develop standards databases for regulatory and good management practices; identify CP, CCP's and GMP's and structure data using CSM Method®
- 6. Develop and statistically analyze past and projected events to include process anomalies, intentional attacks and natural events; structure data using Projectioneering™ methodology
- 7. Use CSM Method® architecture to populate Food DefenseTQ™ decision support system (DSS)
 - a. Process Assurance Support System (PASS)
 - 1) Accidents
 - 2) Equipment Malfunction
 - 3) Process Anomalies
 - b. Security Assessment and Facility Evaluation System (SAFE)
 - 1) Natural Events
 - 2) Intentional Attacks
- 8. Build Food DefenseTQTM visualization platform to include event, decision path and "on the fly scenario generation capability fro two additional processes
- 9. Deploy Phase II modular products for field testing and evaluation



Phase II Work Plan

TASK	DESCRIPTION	TEAM MEMBERS	ROLE
Phase-II, Task-1	Integrate Recommendations from Phase I Alpha Demonstration	JIFSAN, TQ, ANL	JIFSAN: Interagency coordination TQ; ANL, RS: Integrate recommendations
Phase-II, Task-2	Examine Two Additional High Priority Food Processing Areas	JIFSAN, TQ, ANL	JIFSAN: Interagency coordination TQ; ANL: Technical support
Phase-II, Task-3	Select Two Additional Approved Process Templates	JIFSAN, TQ, ANL	JIFSAN: FDA approved templates TQ, ANL: Technical support
Phase-II, Task-4	Two Phase II operational environments for collaboration	JIFSAN, TQ	JIFSAN: FDA sponsored center TQ: Industry interface
Phase-II, Task-5	Develop Phase II Standards Databases	JIFSAN, TQ, ANL	JIFSAN: SME knowledge TQ: CSM Method® and Food DefenseTQ™ architecture ANL: SME knowledge, information technology expertise
Phase-II, Task-6	Develop and analyze Phase II events databases	JIFSAN, ANL, TQ	JIFSAN: SME knowledge ANL: SME knowledge, information technology expertise TQ: CSM Method® and Food DefenseTQ™ architecture
Phase-II, Task-7	Phase II DSS Logic systems	JIFSAN, ANL, TQ	JIFSAN: SME knowledge ANL: SME knowledge, information technology expertise TQ: CSM Method® and Food DefenseTQ [™] architecture
Phase-II, Task-8	Phase II interactive display	Raytheon Solipsys, TQ, ANL, JIFSAN	RS: Tactical Display Framework (TDF) TQ: CSM Method® and Food DefenseTQ™ architecture ANL: SME knowledge, information technology expertise JIFSAN: SME knowledge
Phase II, Task-9	Deployment for field testing and evaluation	JIFSAN, TQ, ANL, RS	JIFSAN: Interagency coordination TQ, ANL, RS: Technical support



10. Next Steps



Technical proposal is drafted

- Purpose
- Identification and Significance of the Problem
- Description of Technical Solution
- Members and Roles of IPT
- Phase I Technical Objectives
- Phase I Work Plan
- Phase I Tasks and Milestones
- Phase II Linkage
- Phase II Tasks and Milestones
- Related Work
- Relationship with future R&D
- Research Objectives and Significance to Phases I and II
- Commercialization Strategy
- Resumes of Key Personnel and Qualifying Experience
- Key Personnel Contact List
- Facilities and Equipment
- Subcontractors and Consultants
- Prior, Current or Pending Support of Similar Effort
- Proposal End Notes

Now Coordinating with UMD and JIFSAN