Annex 9B:

2008 Sector CIKR Protection Annual Report

for the Food (All Food, Except Meat, Poultry, and Egg Products) and Agricultural Sector

July 1, 2008

Homeland Security

Food and Drug Administration

This page intentionally blank

Contents

Foreword

The Food and Agriculture Government and Sector Coordinating Councils (GCC and SCC)[1] meet regularly to discuss Sector activities and requirements. These opportunities were used to share with the Sector partners the development of this Sector Annual Report (SAR). As the SAR was being drafted, it was sent out for review and comment to both the GCC and the SCC.

The chapter on funding priorities, investments, and gaps includes significant input from representatives across various federal departments and agencies that are concerned with the security of the Food and Agriculture Sector. The chapter on the progress of research and development initiatives in the Food and Agriculture Sector reflects the efforts of many relevant organizations, including private companies and trade organizations. The 2008 SAR development process included review by State and local government security partners in an effort to enable the report to reflect the status and progress of the entire Sector, but does not include much specific information from the non-Federal partners in the Sector.

1 A list of the acronyms used in this report can be found in attachment A.

This page intentionally blank

Executive Summary

Pursuant to Homeland Security Presidential Directive 7 (HSPD-7), the U.S. Department of Homeland Security (DHS) is responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the United States. Within DHS, this overarching responsibility has been delegated to the National Protection and Programs Directorate's Office of Infrastructure Protection (IP). The Food and Agriculture Sector-Specific Agencies (SSAs) have been assigned responsibility for overseeing protection efforts, serving as the SSA for the Food and Agriculture Sector, and overseeing the implementation of the Food and Agriculture Sector-Specific Plan (Food and Agriculture SSP). The Food and Agriculture SSAs are the United States Department of Agriculture (USDA) and the Department of Health and Human Services' Food and Drug Administration (FDA). USDA is responsible for the agriculture and food including meat, poultry, and egg products. FDA is responsible for all other food products.

Under HSPD-7 and the National Infrastructure Protection Plan (NIPP), each SSA is required to submit a Sector CIKR Protection Annual Report to DHS. The purpose of these reports is to communicate how CIKR protection is conducted in each sector, what priorities and requirements drive these efforts, and how such efforts are funded. This 2008 CIKR Protection Annual Report for the Food (All Food Except Meat, Poultry, and Egg Products) and Agriculture Sector includes updates on protective programs and initiatives being conducted or planned by the Food and Agriculture SSA, by DHS, or by other Sector partners.

The Food and Agriculture Sector has made significant progress in establishing positive relationships with Sector partners, which are necessary to implement Food and Agriculture SSP initiatives. A wide variety of assets, systems, and networks comprise the Food and Agriculture Sector, which has been divided into seven distinct subsectors, and the majority of facilities within the Food and Agriculture Sector are owned and operated by private companies. Establishing and maintaining these new relationships and developing trusted and protected information sharing between public and private security partners is a vital and ongoing component of Food and Agriculture Sector activities.

The Food and Agriculture Sector had many accomplishments during the past year, including:

- *Expansion of security partners.* The Food and Agriculture Government Coordinating Council continues to reach out across the Sectors in order to increase membership within the Sector (e.g., the Navajo Nation Veterinary Livestock Program). The Food and Agriculture Sector Coordinating Council has also examined which additional Subsector representatives could be added to its membership.

- *HSIN-FAS.* The Homeland Security Information Network-Food and Agriculture Sector (HSIN-FAS) site is functional. An Intergovernmental Personnel Act (IPA) employee from the State of Florida worked with all Sector members to identify requirements and make modifications to the HSIN-FAS site accordingly, as feasible.

The Food and Agriculture SSAs identified the following four Sector security priorities for 2008:

1. Review and revise the Food and Agriculture SSP to make it more applicable and useful to the entire Sector;

2. Identify additional support for a research and development identification and categorization process;

3. Develop a well-defined communication plan; and

4. Implement the Food and Agriculture Sector Criticality Assessment Tool (FAS-CAT).

These priorities align closely with the Food and Agriculture Sector's vision and goals as outlined in the Food and Agriculture SSP. The Food and Agriculture SSA is working with both public and private security partners in order to achieve the four priorities for 2008.

This Food (All Food Except Meat, Poultry, and Egg Products) and Agriculture Sector Annual Report describes the sector protective activities within the NIPP framework.

Section 1: Sector Security Goals and Priorities

1.1 Sector Security Goals

The National Strategy for Homeland Security and the Homeland Security Act of 2002 served to mobilize and organize our Nation to secure the Homeland from terrorist attacks. The U.S. Department of Homeland Security (DHS) goals to prepare for and respond to such events are set forth in Homeland Security Presidential Directives (HSPDs) 5, 7, 8, and 9. HSPD-9 represents a major step toward establishing a comprehensive national policy to defend the Food and Agriculture Sector against "terrorist attacks, major disasters and other emergencies." HSPD-7 focuses on issues concerning protection of all national Critical Infrastructure/Key Resources (CI/KR), the majority of which are owned and operated by the private sector. HSPD-5 ensures that all levels of Government that are responding to an incident of national significance have the capability to work efficiently and effectively together by using a common national domestic incident management approach. HSPD-8 provides guidance on how to prepare for such a response, including prevention activities.

Homeland security is not the responsibility of one Government department or agency; it is a partnership effort. Significant progress in the Food and Agriculture Sector regarding homeland security goals can only be accomplished through partnerships among all governmental levels and those who own the CI/KR. The Food and Agriculture Sector Coordinating Council (SCC) was formed as part of the private sector response. The SCC is a self-governing body representing the Food and Agriculture industry that provides a forum for the private sector to discuss infrastructure protection issues or to communicate with the Government through the Government Coordinating Council (GCC). The GCC, with representation from Federal, State, local, and tribal governments, is the public sector portion of the Food and Agriculture public-private partnership framework. The objective of the GCC is to provide effective coordination of food and agriculture security strategies and activities, policy, and communication across the Government and between the Government and the Food and Agriculture Sector to support the Nation's homeland security mission.

Early in the National Infrastructure Protection Plan (NIPP) process, the two councils agreed upon the following mission for the Food and Agriculture Sector:

> The mission is to prevent an attack on the food supply, including agricultural production, that would pose a serious threat to public health, safety, welfare, or the national economy, and to provide the central focus for a steadily evolving and complex industry/sector, with particular emphasis on the protection and strengthening of the Nation's capacity to supply safe, nutritious, and affordable food. In doing so, the sector is working to ensure that the industry has incorporated the concepts of HSPD-7 in its own critical asset protection plans, vulnerability/risk reduction plans, and Continuity of Operations Plans (COOPs). The sector will provide leadership on food, agriculture, natural resources, and related issues that is based on sound public policy, the best available science, and efficient management.

At the time, the GCC and SCC also established long-term sector security goals to support the mission. Note that the sector will revisit the sector strategy and goals in 2009 to ensure that they continue to be relevant and appropriate.

1.1.1 Long-term Security Goals and Priorities

Table 1-1: Food and Agriculture Sector Security Vision/Mission Statement and Security Goals

Sector Vision/Mission Statement	
To prevent an attack on the food supply and agricultural production that would pose a serious threat to public health, safety, welfare, or the national economy, and to provide the central focus for a steadily evolving and complex industry/Sector, with particular emphasis on the protection and strengthening of the Nation's capacity to supply safe, nutritious, and affordable food.	
Sector Goals	
Goal 1	**Work with State and local entities to ensure that they are prepared to respond to incidents.** The Food and Agriculture Sector will ensure that the combined Federal, State, local, and tribal capabilities are prepared to respond quickly and effectively to a terrorist attack, major disease outbreak, or other disaster affecting the national Food and Agriculture infrastructure.
Goal 2	**Improve Sector analytical methods to enhance and validate detection of a wide spectrum of threats.** Laboratory capabilities and capacities will be increased to address threat agents that could be used in an attack on food and agricultural products as well as traditional human pathogens that contaminate foods. This enhanced system will also accommodate requirements that could result from a bioterrorist attack on the food supply.
Goal 3	**Improve Sector situational awareness through enhanced intelligence communication and information sharing.** There will be more and better reporting of food and agriculture incidents and threats among industry security partners, law enforcement, and the intelligence community. Government-developed threat information will be shared expeditiously with the Food and Agriculture industry to facilitate threat-appropriate security measures.
Goal 4	**Tailor risk-based, performance-based protection measures to the Sector's physical and cyber assets, personnel, and customers' products.** Protection measures will be scalable to accommodate both the steady state and periods of heightened threat, as well as organizations of various sizes within the Sector. Specific security measures will address authentication of Sector personnel engaged in the Food and Agriculture industry.
Goal 5	**Address response and recovery at the sector level, not just as separate enterprises.** Standards and planning for Sector-wide continuity of operations should be developed. The Sector will facilitate a close partnership with the public health community to enable rapid identification and treatment of a bio-incident in the Food and Agriculture Sector. There will be advanced identification of protocols and resources to respond to and recover from an incident in the Sector.

Table 1-1 (Cont.)

Sector Goals (Cont.)	
Goal 6	**Expand laboratory systems and qualified personnel.** The ability to diagnose and treat animal disease outbreaks and crop contamination effectively will be strengthened to prevent, respond to, and recover from an incident in the Food and Agriculture Sector. State budgets for inspection, detection, and training protocols will be revisited to provide for such initiatives.

1.1.2 Goals for 2008

In calendar year 2008, the Sector Leadership is focusing on setting forth a defined set of achievable and worthwhile goals and priorities. The 2008 Food and Agriculture Goals are as follows:

- Food and Agriculture Sector Criticality Assessment Tool (FAS-CAT) Implementation.
- Sector Communications and the Homeland Security Information Network (HSIN), to include a metric defining the success of HSIN.
- Tabletop Exercise using DHS Homeland Security Exercise and Evaluation Program (HSEEP).
- Review of planned revision of the Sector-Specific Plan including, at a minimum, information on FAS-CAT, the Food Protection Plan, and the Import Safety Plan.

1.2 Sector CIKR Risk Profile

The Food and Agriculture Sector is composed of interdependent systems. Many defy traditional security practices because they are not "brick and mortar" entities, like buildings, bridges, or dams. Instead, they are open areas (i.e., farms, ranches, or livestock transport areas) and complex systems that span the globe. In addition, many of these systems face natural threats, including livestock and crop diseases and food-borne pathogens. As a result of these factors, preventing the introduction of threat agents into the systems within the Sector may not be feasible. Therefore, the Sector has acknowledged the importance of early awareness of any threat agents within its systems.

To support the ability of each CIKR sector to use risk to inform Sector security priorities, the DHS's Homeland Infrastructure Threat and Risk Analysis Center (HITRAC) produces a risk profile for each CIKR sector. HITRAC works closely with the U.S. Intelligence Community, as well as the SSAs, to integrate and analyze information on threat and to assess the potential vulnerabilities to and consequences from a terrorist attack on the Sector. Due to the sensitivity of the analysis, the report is classified "Secret, Not Releasable to Foreign Nationals." DHS encourages those infrastructure protection community partners with the appropriate security

clearance and need-to-know to use the assessments to inform their infrastructure protection activities, as appropriate.

Table 1-2: Terrorist Attack Methods Addressed in the National CIKR Risk Profile

Aircraft as a Weapon	Food or Water Contamination
Assault	Improvised Explosive Device (IED)
Biological – Contagious Human Disease	Maritime Vessels as Weapons
Biological – Livestock and Crop "Disease"	Nuclear Explosive Device
Biological – Noncontagious Human Disease	Radiological Dispersal Device
Chemical	Standoff Weapons – Guided
Cyber – Directed Attack	Standoff Weapons – Unguided
Cyber – Nondirected Attack	Vehicle-borne IED (VBIED)

1.3 CIKR Protection Gaps

The Food and Agriculture Sector, composed of the SSAs (FDA and USDA), the GCC and the SCC, continues to examine the sector's infrastructure and the farm-to-fork continuum and find new areas that need to be protected. The following protection gaps have been identified over the past year by either FDA or the sector. Limits on time and resources have prevented the sector from addressing all of the following gaps, but some have begun to be addressed, as referenced in the text below.

- *Outreach and training within the food defense continuum*. To protect the food system from terrorist attacks or other emergencies, training is needed to enable appropriate individuals to develop an awareness of and recognize threats. While food defense awareness training has been provided to Federal, State, and local government employees and to industry, there is an ongoing need for updated training materials and improved dissemination. FDA, in cooperation with CDC, USDA, and state and local organizations representing food, public health, and agriculture interest, developed the ALERT and FIRST food defense awareness campaigns. In addition, because the Nation's food supply sources are global, food defense training for international trading partners has been conducted on a limited scale but more is needed.

- *Cyber security.* The Sector recognizes that cyber security is a critical area that needs to be addressed. The Sector partners, given limited resources and identified threats that would be more catastrophic to the Sector, have not focused directly on cyber protective measures. However, the Cyber Security Enhancement Act (CSEA) of 2002 (Title II, section 225 of the Homeland Security Act) requires all Federal agencies to protect automated IT systems under their control. Additionally, there is a value proposition for owner/operators to enhance their cyber security postures to prevent business interruption or loss or misuse of sensitive information.

1.4 Sector Priorities

The sector's priorities are described in section 1.1. Below are examples of sector activities that support these priorities. Note that the goals are not listed in order of importance.

1.4.1 Improve Sector Analytical Methods to Enhance and Validate Detection of a Wide Spectrum of Threats

USDA and FDA have active research programs to develop or improve laboratory methods for detection and validation of threat agents in foods and food animals. Specifically, in accordance with requirements in HSPD-9, they are working with several research partners to fill critical gaps in food defense research, including DHS' National Biodefense Analysis and Countermeasures Center (NBACC), DHS' Centers of Excellence, the Technical Support Working Group (TSWG), and the Australian Food Safety Center of Excellence (AFSCE), based at the University of Tasmania, Australia. In addition, FDA and USDA are co-chairs of the Food Emergency Response Network (FERN). This is a network of Federal and State laboratories that are committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist attack in this country. FDA has developed/validated methods for the detection of biological and chemical agents in a multitude of food commodities. These methods have been tested by the FERN laboratories to ensure that the methods work and that laboratory personnel are capable of running the method.

1.4.2 Expand Laboratory Systems and Number of Qualified Personnel

A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with USDA's Food Safety and Inspection Service (FSIS) to establish the Food Emergency Response Network (FERN) to include a substantial number of laboratories capable of analyzing foods for agents of concern. FERN will encompass a nationwide network of federal, state, and local laboratories working together to build the capacity to test the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

1.4.3 Improve Sector Situational Awareness through Enhanced Intelligence Communication and Information Sharing

HSPD-9 and HSPD-10, *Biodefense for the 21st Century*, directs DHS to establish a National Biosurveillance Integration System (NBIS) to provide early detection and situational awareness of biological events of potential national consequence by acquiring, integrating, analyzing, and disseminating existing human, animal, plant, and environmental biosurveillance system data into a common operating picture (COP) that represents a comprehensive depiction of the global biosurveillance security environment. FDA is working to interconnect their eLEXNET system

with NBIS information systems in order to forward food sector-specific eLEXNET data. NBIS is being developed to combine national health and intelligence data and information from multiple agencies at city, State, and Federal levels in order to improve situational awareness of potential terrorism against the Nation. The data exchange between these systems will be in both directions.

In addition, monthly meeting of the AgInt working group are held between food and agricultural defense representatives from multiple federal agencies (FDA, USDA, DoD, FBI, and DHS) to exchange information and to establish communication between each of these agencies.

1.4.4 Tailor Risk-based, Performance-based Protection Measures to the Sector's Physical and Cyber Assets, Personnel, and Customer Products

Assessing vulnerabilities of the food chain from farm-to-table allows FDA to determine the potential impacts of an intentional attack on the food supply and the resources and actions that can be taken to avoid and minimize the impact of such an attack. Vulnerability assessments have allowed FDA to determine those commodities that are of highest, medium, and low priority concern for intentional contamination as well as the points in the farm to table continuum that may serve as the most ideal location to add an agent. These vulnerability assessments facilitate the development of countermeasures for mitigating vulnerabilities, allow for the identification of research needs, and the development of additional guidance materials for consideration by the private sector.

FDA, USDA, DHS, and the Federal Bureau of Investigation (FBI) collaborated with private industry and the States in the Strategic Partnership Program Agroterrorism (SPPA) initiative. The SPPA was a joint program that involves Federal and State government agencies and private sector volunteers in providing governments and industry with a more complete sector-wide perspective of potential vulnerabilities. Under the initiative, vulnerability assessments were conducted using the CARVER+Shock tool. The SPPA provided a coordinated identification and assessment of possible vulnerabilities in the Food and Agriculture Sector. In so doing, the SPPA helps distinguish between real and perceived vulnerabilities and risks within the sector. It also helps identify potential mitigation measures and strategies that may be appropriate for the sector. In addition, the SPPA helps identify research needs and allocate research investments to address priority needs. A total of 36 different commodities and/or parts of the food and agriculture industry have been assessed as part of this initiative. Seventeen of those assessments were led by FDA. Attachment B has a list of completed SPPA assessments.

1.4.5 Address Response and Recovery at the Sector Level, Not Just As Separate Enterprises

The *2007 Intentional Animal Feed Contamination Tabletop Exercise* was conducted September 25 and 26, 2007 at the Pennsylvania Emergency Management Agency (PEMA), in Harrisburg, Pennsylvania and by teleconference with the West Virginia Division of Threat Preparedness, in Charleston, West Virginia. This two day exercise was conducted at the request of the Food and Agriculture Sector and was hosted by PEMA. The exercise was sponsored by

the states of Maryland, Ohio, Pennsylvania, and West Virginia, with development assistance from the U.S. Department of Agriculture and the U.S. Food and Drug Administration, and involved State and Federal agricultural and emergency management groups and representatives of private industry. This tabletop focused on the discussion of communications and information sharing between State and Federal agencies and private industry groups that would assume response roles during an intentional animal feed contamination incident resulting in human food contamination.

The *2007 Intentional Animal Feed Contamination Tabletop Exercise* was developed to test and evaluate communication and information flow plans, policies, procedures, and protocols between participating agencies. Early in the exercise planning process, the exercise planning team discussed scenario background, developed toxin agent information, and determined the geographical scope for the exercise. The primary areas focused on were regional collaboration, identifying vital triggers in agricultural incidents, and relating this investigation information to the appropriate agencies. These discussions would determine communication channel glitches between agencies and jurisdictions that may impede immediate detection, prevention and protection, response and recovery actions. The design of the tabletop allowed participants to discuss processes within their state's agencies and organizations related to the mission areas. A total of 122 participants participated at ten discussion tables.

The overall exercise was conducted appropriately and of value to participants, facilitators, evaluators, and exercise staff as a method to identify enhancements to the communication and information sharing processes that would occur during an agricultural feed contaminant (animal-based) incident leading to human illness from tainted-food consumption. The improvement plan at the end of the After Action Report (AAR) addresses the issues and recommendations submitted by players, facilitators, and evaluators and establishes follow-up actions designed to improve response capabilities for the States of Maryland, Ohio, Pennsylvania and West Virginia, Federal agencies, and private industry. The AAR will provide a reference for future animal-health/food contamination exercises or incidents to identify solutions that can be used to coordinate response and recovery activities in food and agricultural safety and defense.

1.4.6 Enhance and Improve Two-way Communication (Using HSIN)

The Food and Agriculture Sector, via the GCC and SCC, has opted to use the HSIN as the basis for its Sector-wide communications. Before the Sector centralized its communications at the network, it had to review the network to determine its capabilities and understand the needs of its users. To accomplish this review, the GCC collaborated with DHS leadership to acquire a State agriculture official who had a one-year assignment focused on the HSIN. This State official was brought to DHS to work for the period of one year beginning in February 2007. He finished his assignment in February of 2008. Through this combined effort of the GCC and the DHS state assignee, much was accomplished. The end goal was to have the Sector's HSIN portal used regularly for communications and collaborations. As of February 2008, the assignee had

completed numerous tasks with the interaction and collaboration of the GCC. The most important of these tasks were:

- Complete the redesign and reconfiguration of the HSIN-FA portal to make it more user friendly and relevant to Food and Agriculture Sector users;
- Produce a draft Sector Communications Plan to include incident communications; and
- Conduct outreach to solicit the Sector's new use of the portal. This outreach resulted in nearly doubling the number of Sector members signed up to use the site.

Another State official has been selected to continue the progress made this past year.

1.4.7 Work with State and Local Entities to Ensure That They Are Prepared to Respond to Incidents (GCC Specific)

FY 2008 Special Event Food Safety and Defense Assignment

Food safety and defense during special events are an important part of the FDA's mission to protect the food supply. In the past, the FDA has conducted assignments focused mainly at ensuring food protection at event venues. However, as the food supply chain grows more global than ever before, it becomes increasingly important to not only look at the vendors themselves but to also look at the production paths these foods have moved along before they reach the event venues. In 2008, a number of political special events will be taking place including the Republican and Democratic National Conventions. The FDA coordinated a "Special Event Food Safety and Defense Assignment" that was conducted from May 5 -16, 2008. Participants in this assignment included FDA; Department of Defense/Veterinary Service Activity and U.S. Army Veterinary Command; and selected State and local Departments of Health, Agriculture, and the Environment within Minnesota and Colorado that will be assisting with the Republican and Democratic National Conventions. The overarching goals of this assignment were to:

- Exercise the planning and implementation of a coordinated approach for food protection during high-profile special events among Federal, State and Local agency partners.
- Examine the traceability of higher risk foods served at special events.
- Create a template assignment for food safety and defense activities that can be used for other special events.

EPA Workshop

EPA co-sponsored a workshop with the DHS National Center for Food Protection and Defense, with participation from multiple Federal agencies, including FDA, USDA, and EPA, State

environmental agencies, the academic sector, and the food and waste management industry. The workshop's intent was to open a dialogue regarding disposal of food products deliberately contaminated with select chemical or biological agents. The workshop also included discussions of issues related to facility decontamination from such materials. The workshop highlighted the potential difficulties of disposing of materials contaminated with select agents, presented current research results, and emphasized the partnership between the public and private sector in the disposal process from such events.

1.4.8 Strengthen International Activities on Food Defense

On January 29-31, 2008, the Foreign Agricultural Service, in partnership with the Food Safety and Inspection Service, the Food and Drug Administration, the United States Environmental Protection Agency and the U.S. Department of State organized and implemented a conference in Cairo, Egypt titled "*Protecting the Middle East's Food Supply from Intentional Contamination.*" This conference was the first-ever food defense training activity conducted in the Middle East and was designed to encourage broader regional dialogue and engagement among the 17 Middle East Partnership Initiative (MEPI) countries on ways to protect the food supply from deliberate acts of contamination. Through expert presentations, examination of case studies, and exposure to other ongoing international food defense initiatives (e.g. APEC), participants learned to identify ways to individually and collectively assess vulnerability in the distribution chain, thereby preventing/mitigating the impact of possible intentional contamination of the food supply which may include attacks for personal, political, or economic motivation. This conference was funded by the State Department's Middle East Partnership Initiative (MEPI) economic pillar.

Over the last two years, the U.S. has led efforts to raise awareness of the issues and promote voluntary measures that can be taken by both the public and private sector to mitigate threat of an attack, protect public health, commerce, and the potential shock to APEC economies. At the 2007 Summit in Sydney, APEC Leaders endorsed the voluntary APEC Food Defense Principles. In February 2008, the U.S. introduced a follow-on, two-year initiative, "APEC Food Defense: Putting Principles to Practice," which aims to build a repository of case studies through pilot projects in APEC economies to demonstrate how to put the principles into practice. A U.S. interagency team completed an initial assessment in May 2008 in Peru. A series of follow-on workshops are being planned in Peru to be held in September 2008. An additional two to three pilot economies are being sought for 2008 and 2009 that can be highlighted at an APEC workshop on food defense in late 2009.

G-8 Food Defense Exercise — Demeter's Resilience

In 2004 and 2005, G8 leaders committed to defending against bioterrorism by; strengthening national and international biosurveillance capabilities, increasing protection of the global food supply, and improving bioterrorism investigation, response and mitigation capabilities. In 2005 the G8 Bioterrorism Experts Group (BTEX) agreed on a work plan for the development of a food defense tabletop exercise. Demeter's Resilience served to initiate a dialogue between G8

member nations on communication mechanisms during an intentional bioterrorist attack upon the G8 food supply. Demeter's Resilience took place on May 27–29, 2008, and was hosted by the National Center for Food Protection and Defense at the University of Minnesota, Minneapolis, Minnesota. The exercise provided an opportunity for G8 nations to strengthen lines of communication, which may enhance prevention, mitigation and recovery efforts on food system events. The simulated attack was based around a hypothetical food product that is widely exported to and/or imported from all G8 nations.

Demeter's Resilience was intended to accomplish the following primary objectives:

- Examine food defense communication and coordination procedures within and among G8 countries in response to a terrorist attack on the food supply.
- Discuss the roles and responsibilities of the various ministries, organizations, and sectors in responding to a terrorist threat or attack on the food supply (e.g. law enforcement, foreign affairs, food/agriculture/public health agencies, and the private sector).
- Through facilitated discussion and simulation, examine G8 countries' responses to a bioterrorism incident targeted at the food supply system.

1.4.9 Standardize CARVER+Shock (GCC Specific)

The Food and Agriculture Sector agreed that CARVER+Shock will be its main vulnerability/consequence/risk assessment tool. FDA, in collaboration with USDA, developed an interactive software version of this assessment tool to assist individual company representatives in assessing their manufacturing/processing operations. The CARVER+Shock software has a user-friendly interface that prompts the user to answer a series of questions, including multiple choice and short answer formats, and then offers a relative risk ranking of production steps and supporting information related to key vulnerabilities. Version 1 of the software was released in June 2007 and is primarily focused on manufacturing operations. Version 2 of the software is currently under development and will expand the scope of businesses addressed (retail, food service, and agriculture) and will be completed in 2009.

Section 2: Sector Programs, Activities, and Tools

2.1 CIKR Protection Programs and Initiatives

The Sector has a number of important programs underway to protect food and agricultural critical infrastructure. The focus of these programs ranges from preparedness, surveillance, and assessment activities to response and recovery activities.

Since cyber attacks on food and agriculture CIKR offer little financial gain and likely only minimal economic disruption, the Sector does not perceive itself as a target of such an attack. DHS as well has not identified the Food and Agriculture Sector as a target of cyber crime. Therefore, Sector partners agreed that addressing cyber security issues was not a top priority. However, the Sector will revisit the need to address cyber security. Cyber threats and attack tools evolve rapidly given the ingenuity of the cyber attacker community. Most can be blocked by continuously updated computer security programs. Such programs include adherence to procedural safeguards for the system; an effective, continuously adaptive firewall; the application of intrusion detection/intrusion prevention systems for detecting, reporting, and preventing external threats to the network and information systems; surveillance programs for detecting insider threats; continuing training of users of the system concerning proper security procedures; use of passwords resistant to hacker compromise; and related safeguards. Sector partners are employing cyber security measures as part of good business practices.

Highlights of the ongoing protective programs within the Sector are provided below.[2] Protective programs are listed in the order that they fall on the incident continuum: prevention, protection, response, and then recovery.

2.1.1 Food and Agriculture Sector Criticality Assessment Tool (FAS-CAT)

With guidance and direction from the Food and Agriculture Sector, the National Center for Food Protection & Defense has created FAS-CAT, an advanced Excel application, to help identify critical assets in the Food and Agriculture Sector and provide reporting mechanisms to DHS. The tool is designed to assist States, in partnership with both the private sector and other regional States as appropriate, in determining the most critical elements, nodes and sub-systems in the food and agriculture infrastructure. Specifically, FAS-CAT seeks to:

- Improve the overall process for food and agriculture critical system/sub-system identification.
- Provide greater equity in cross sector critical system identification for DHS.
- Enable the States to identify critical food and agriculture system components.

[2] Due to lack of resources, FDA was unable to complete the Risk Reduction Activity Questionnaires (RRQAs) for the protective programs listed here (so they are not in attachment C).

- Provide a common methodology to the process.
- Improve critical asset reporting to Homeland Security.

The tool was released to State Homeland Security Advisors in March 2008. The State HSAs were encouraged to use the tool to assist them in identifying food and agricultural assets for their state.

More information about FAS-CAT, including the tool itself and a video tutorial, can be found at www.foodshield.org or www.ncfpd.umn.edu.

2.1.2 Vulnerability Assessments

To help prevent attacks on the food supply, assessments are conducted to identify which food products are most vulnerable to attack, the potential sites of contamination along the food chain, and the threat agents that would be effective in attacking the food supply. In accordance with the HSPD-9 mandate to expand and continue conducting vulnerability assessments of the food sector, since 2004, FDA has completed assessments on 17 food and feed products by using the CARVER+Shock method.

Evaluation and Assessment of the Vulnerabilities of Incoming Ingredients/Additives in Regards to Food Defense

The FDA/CFSAN was provided funding by DHS/NBACC to evaluate the relative public health, economic and shock consequences (i.e., risk) of a range of product/ingredient/additive-agent scenarios. The project also involved an in-depth review of preventative controls and various processing or engineering technologies which may be used for eliminating or reducing the risk of an intentional act of terrorism or contamination. The project was completed in May 2008.

2.1.3 Raising Awareness

In order to protect the farm to table continuum, training is needed to raise awareness and enable appropriate individuals to recognize threats. Food defense awareness training has been provided to Federal, State, and local government employees and to industry, but there is an ongoing need to reach additional food and agriculture sector representatives and to update training materials. Also, the international community is another segment for which outreach is needed due to the global nature of the food supply. The ALERT campaign was and still is a major awareness initiative for FDA. The ALERT materials are available in multiple languages and a Web-based tool is available on FDA's Web site. There have been over 40,000 hits and downloads of materials from the ALERT website.

Development and Production of Food Defense Training Tool Kit for Food and Agricultural Industry Employees — Employees FIRST

The Employees FIRST tool kit will be used as part of ongoing employees training programs by management in the food industry. The tool kit will focus on the FIRST acronym and identify the five key points that industry and businesses can use to educate front line workers about the risk of intentional food contamination and provide measures to consider and implement to reduce these risks. Each of the letters in the FIRST acronym describes an action that a front line employee can take to mitigate risks of intentional contamination.

F – Follow company food defense plan and procedures.
I – Inspect your work area and surrounding areas.
R – Recognize anything out of the ordinary.
S – Secure all ingredients, supplies and finished product.
T – Tell management if you notice anything unusual or suspicious.

The tool kit will include a 10-15 minute DVD presentation that combines photos, context and video clips as well as a 4-color poster. The materials will be available in English and Spanish. The campaign will be introduced in August 2008.

The FBI, in collaboration with FDA and USDA hosted four Regional Agroterrorism Workshops (Houston, Chicago, Minneapolis, San Francisco) to enable the FBI, other Federal agencies, State and local law enforcement, food manufacturers, local farmers/ranchers, and local veterinarians and diagnosticians to gain an understanding of the issues they may face prior to, during, and after an agricultural terrorist attack. They are designed to be an open, thought-provoking exchange of ideas to help develop and expand existing knowledge of policies and procedures within the framework of responding to a terrorist attack. These workshops emphasized emergency response coordination, resource integration, and problem identification and resolution during the event. The workshops are usually two day events in which one and half day are lecture/presentations and a half day is used for a tabletop exercise.

2.1.4 Food Emergency Response Network

FDA's surveillance capacity will also be improved by increasing its laboratory capabilities to detect threat agents. The Food Emergency Response Network (FERN) is co-chaired by FDA and USDA and is a network of Federal, State, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity in case of emergencies. This network uses standardized procedures for the detection of threat agents. A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. Once the contaminant and food vehicle have been identified through food surveillance or outbreak investigation, FDA has primary responsibility for distinguishing contaminated food products from safe food products as quickly as possible to protect public health and mitigate disruption in distribution of important foods.

2.1.5 Emergency Response Exercises

HSPD-9 states that a coordinated response plan is to be developed that delineates the roles of federal, state, local, and private sector partners. In collaboration with State, local, tribal, and other partners, FDA has held a number of food defense exercises to validate communication and coordination procedures with stakeholders in managing food defense emergencies. Additional training and outreach is needed to assist states in developing their own response plans and to test those response plans.

FY 2008 Special Event Food Safety and Defense Assignment

Food safety and defense during special events are an important part of the FDA's mission to protect the food supply. In the past, the FDA has conducted assignments focused mainly at ensuring food protection at event venues. However, as the food supply chain grows more global than ever before, it becomes increasingly important to not only look at the vendors themselves but to also look at the production paths these foods have moved along before they reach the event venues. In 2008, a number of political special events will be taking place including the Republican and Democratic National Conventions. The FDA coordinated a "Special Event Food Safety and Defense Assignment" that was conducted from May 5 -16, 2008. Participants in this assignment included FDA; Department of Defense/Veterinary Service Activity and U.S. Army Veterinary Command; and selected State and local Departments of Health, Agriculture, and the Environment within Minnesota and Colorado that will be assisting with the Republican and Democratic National Conventions. The overarching goals of this assignment were to:

- Exercise the planning and implementation of a coordinated approach for food protection during high-profile special events among Federal, State and Local agency partners.
- Examine the traceability of higher risk foods served at special events.
- Create a template assignment for food safety and defense activities that can be used for other special events.

Exercise in a Box

FDA has initiated a project, in coordination with USDA, CDC, DHS, and State and local agency partners to develop a tool kit which will assist stakeholders in conducting food and agriculture emergency response related exercises. The kit will include materials (manuals, video clips, etc.) necessary to host an exercise. Multiple scenarios (unintentional food contamination, intentional food contamination, animal health, plant health, etc.) shall be developed in a modular format so that exercises may be scaled up or down depending on stakeholder needs. The target audience for the kits will be state regulators, but the kits will also be designed for local and private industry groups as well. The objective of the tool kit is to elicit discussion of emergency preparedness and response activities to ensure that all players have a common understanding of the communications plans and systems that could be utilized in response through scenario driven

exercises. The tool kit will allow stakeholders to test preparedness and response systems under their purview in a variety of settings from seminar to table top to full scale functional exercises. The tool kit is scheduled for completion in 2009.

2.1.6 Research for Development of Detection Methods for Threat Agents in Food

The wide and complex food continuum from farm to table requires the vulnerability assessment of the multiple nodes in the food production systems within the continuum for potential vulnerabilities. The multitude of threat agents that may be used to attack the food supply requires a similar assessment to inform the development of countermeasures and inform research needs. Assessments of food systems and threat agents must be continued and completed ones must be updated based on the recent assessment results or new information on potential threat agents. FDA has developed or validated a limited number of detection methods for threat agents in foods. Additional methods need to be developed/validated for other identified threat agents that could be used to intentionally contaminate the food supply.

2.1.7 Research to Determine Threat Agent Characteristics in Foods

FDA has conducted research to determine the growth/survival characteristics of threat agents in foods and to determine to effect of various processing parameters on threats agents in foods. Further research is needed to examine the characteristics of additional threat agents and food processing effects of potential threat agents that could be used in the food supply.

2.1.8 Research to Determine Dose Response Relationships for Oral Ingestion of Threat Agents

Many of the threat agents that may be used to intentionally contaminate the food supply do not have information available for their lethal dose by oral ingestion. Much of the available information is for exposure by inhalation. Studies are underway for three agents that are of concern for the food and agriculture sector.

2.1.9 Research for Countermeasure Development

Mitigation strategies are developed to prevent, delay, minimize or detect an attack on the food supply. The development and implementation of countermeasures, informed by results of vulnerability assessments, is ongoing, particularly for imported foods.

Risk Mitigation Manual

FDA is working on a Risk Mitigation Manual by determining what technology, processing or other mitigation measures are known and effective against potential threat agents in order to

reduce the potential of intentional contamination of FDA regulated food products. This will lead to the development of a manual of options for risk mitigation strategies for various food production steps. FDA seeks to develop a valid, reliable, and user-friendly, electronic manual that builds off the CARVER + Shock vulnerability assessment methodology. The Manual shall include risk mitigation strategies such as physical, engineering, cyber, procedural, and processing options for moderate and high risk food production steps. The target audience for the Risk Mitigation Manual is federal, state, local government and industry stakeholders that have completed CARVER + Shock analyses and are now interested in implementing strategies to mitigate the areas of highest vulnerability. The project is scheduled for completion in 2009.

2.1.10 Development of Prion Surrogates

The objective of this EPA project is to develop an appropriate nonpathogenic surrogate for TSE-forming prions to be utilized in large-scale destruction and disposal studies. *Saccharomyces cerevisiae*, or budding yeast, is the system of choice for the ongoing research. Following the aggregation and purification of protein, methods are being developed for measurement and quantification of the protein aggregates in various environmental media, and the aggregates are being examined for their physical characteristics, such as thermostability and protease resistance.

2.1.11 Licensing Sale and Use of Additional Pesticides to Protect Food and Agriculture Sector

Under its statutory authorities and core regulatory programs, EPA continues to license, or register, additional pesticides to protect crops, livestock, and food products from select biological agents. This includes disinfectants for foreign animal diseases, including avian influenza and foot and mouth disease, and for public health diseases, such as human influenza, and fungicides for potentially major foreign crop diseases such as Asian soybean rust disease.

2.2 Coordination Groups and Security Partners

The Food and Agriculture Sector's main coordination mechanisms are the GCC and SCC. These councils facilitate security partners' abilities to communicate and collaborate.

The Food and Agriculture Sector GCC is made up of numerous Federal, State, local, and Tribal entities. The complete list of membership organizations is available in the Food and Agriculture SSP. Given the size and complexity of the Sector, current representation on the GCC is adequate, and reflects the breadth of the Sector. Membership is currently representative and will be reviewed as the sector and its risks change.

The GCC meets quarterly and has monthly conference calls to share information. Participation at the meetings and on the calls is strong, but leadership is working to determine what would make participation in these regularly scheduled events more meaningful to the participants and hopefully improve participation. Much of the meeting time is currently used to provide updates on DHS-IP requirements and activities, which often does not inspire meaningful discussion.

The Food and Agriculture SCC is divided into seven sub-councils:

1. Agriculture Production Inputs and Services.
2. Animal Producers.
3. Plant Producers.
4. Processors/Manufacturers.
5. Restaurant/Food Services.
6. Retail.
7. Warehousing/Logistics.

The SCC meets quarterly, in conjunction with the GCC. Some of the sub-councils are more active than others, therefore sub-council meeting frequency and member participation varies considerably. The SCC participates in monthly Partnership for Critical Infrastructure Security (PCIS) cross-sector calls and quarterly meetings and is part of the PCIS Steering Committee. The SCC has seen benefits from the partnership, including involvement in refining the Chemical Facility Anti-Terrorism Standards and increasing the number of industry members that have received clearances. Nonetheless, the joint leadership is looking to reinvigorate SCC participation in the partnership this year. The GCC and SCC chairs are discussing the value-proposition of the partnership and would like to focus activities and information sharing in areas that are more meaningful to all of the Food and Agriculture Sector partners.

Sector partners have worked together to create a draft Food and Agriculture Sector Incident Communications Standard Operating Procedure which includes a Food and Agriculture Incident Communications Flowchart. The purpose of the document is to provide a standard operating procedure to achieve a coordinated and effective communication and information exchange during catastrophic incidents or events. The goal is to achieve situational and operational awareness, of food and agriculture issues during an incident, for Sector GCC and SCC leadership, members and partner agencies and organizations. The councils hope to finalize the document this year. The councils have also partnered on, and are close to finalizing, a Food and Agriculture Sector Pandemic Influenza Planning Guidelines Annex.

Sector partnership success has been most apparent in the joint exercise that the Sector hosted this year. The *2007 Intentional Animal Feed Contamination Tabletop Exercise* was conducted September 25 and 26, 2007 at the Pennsylvania Emergency Management Agency (PEMA), in Harrisburg, Pennsylvania and by teleconference with the West Virginia Division of Threat Preparedness, in Charleston, West Virginia. The exercise was sponsored by the states of Maryland, Ohio, Pennsylvania, and West Virginia, with development assistance from USDA and FDA, and involved State and Federal agricultural and emergency management agencies, public health agencies, law enforcement, and representatives of private industry. This tabletop focused on the discussion of communications and information sharing between State and Federal agencies and private industry groups that would assume response roles during an intentional animal feed contamination incident resulting in human food contamination. The overall exercise was conducted appropriately and of value to participants, facilitators, evaluators, and exercise staff as a method to enhance the communication and information sharing processes that would occur during an agricultural feed contaminant (animal-based) incident leading to human illness

from tainted-food consumption. Sector partners have agreed to work together on a similar exercise in 2008 to build upon the success of the 2007 exercise.

Sector partners have worked together in many additional areas recently. For instance, in November 2006, the U.S. and Thailand co-hosted the first-ever Asia-Pacific Economic Cooperation (APEC) Food Defense Workshop in Bangkok, Thailand. The workshop included technical and policy experts from 17 of the 21 economies and examined the goal of identifying critical areas of vulnerability in the food supply and how to mitigate the terrorist threat. APEC economies' participation was robust and lively – and an added highlight was the active involvement of several global private sector food supply industries, bringing a valuable and much needed additional perspective to the productive discussion. While the U.S. routinely brings together policy officials, technical experts, and the private sector to address food defense concerns domestically, the meeting in Bangkok was the first time these stakeholders came together in an international context. The commitment made in the APEC Leaders' statement, a week and a half later, reflects the success of the work and the importance of having such a discussion within the region. Building on 2006 efforts, the U.S. and Vietnam co-hosted the follow-on workshop in Hanoi in June 2007, which focused on building appropriate infrastructure, developing risk communication strategies, and building partnerships between governmental bodies and the private sector. Fifteen APEC economies participated in the Hanoi workshop with even more economies solidly on board with the APEC Food Defense Initiative. In addition to building on the work from the Bangkok workshop, the experts in Hanoi prepared a draft set of "APEC Food Defense Principles". These principles put APEC in the forefront of international thinking on critical issues in protecting the food supply against deliberate terrorist contamination and help pave the way for sustained APEC counterterrorism efforts on food defense.

The members of the Food and Agriculture GCC and SCC also met with members of the Transportation GCC in May 2008 to discuss security of the food supply in the transportation portion of the supply chain. Several issues were addressed at the meeting, including the need to review existing vulnerability assessments, the possibility of using existing models to determine consequences of terrorist attacks on the food supply while being transported, and opportunities for future collaboration on protective programs. Follow up meetings are planned.

Please see the Food and Agriculture SSPs for a detailed description of the sector's GCC and SCC, including authority, membership, and objectives.

Section 3: CIKR R&D Progress and Updated Capability Gaps

3.1 Progress

In July 2006, the Food and Agriculture Sector, mandated by HSPD-7 to coordinate critical infrastructure protection (CIP) activities across the spectrum of systems and activities that move agricultural and food products from "farm-to-fork," established an owner-operator led Critical Infrastructure Partnership Advisory Council (CIPAC) working group known as the Joint Committee on Research (JCR). Reflective of the entire Sector, the JCR includes representatives from Federal, State, and local government, and the private sector.

Created to establish priorities and commonalities in Sector security shortcomings and to identify applicable recent or ongoing research initiatives, the Sector charged the JCR with collecting information to identify and study potential gaps in agricultural security and food defense ("security/defense") research and development (R&D) efforts.

As reported in the 2007 JCR Annual Report (appended to the 2007 Sector Annual Report), the JCR proposed a number of recommendations to address both short-term and long-term deliverables regarding R&D for the Sector. In addition to these R&D recommendations, the JCR also recommended improving its own efficiency and productivity. Specifically, JCR members felt the lack the fiscal and personnel resources necessary to collect, review, and categorize relevant information in a timely, thorough manner. To that end, the JCR recommended expanding support for the JCR, to include staff and software-supported data collection.

This past year, the JCR determined that this recommendation to seek support for the JCR is of utmost importance in order to achieve any further success with its R&D goals. Data management challenges have proven prohibitive to JCR progress without investment in functional methods to review and quantify incoming information. Additionally, the JCR has neither the internal resources, such as dedicated staff or analytical tools, nor monetary wherewithal to fund the support needed to move forward. Moreover, the JCR is reluctant to engage in soliciting industry for their identified research gaps until the capacity exists to do something useful with the collected information.

The JCR's first year revealed both the complexities of its mission as well as JCR's inability to successfully complete mission given operational support levels and the Sector's R&D integration with the overall DHS priorities at the time. This situation resulted in a second year marked by relative inactivity of the JCR as a group while JCR leadership attempted to follow up on first year recommendations and consider a redirection of effort to allow for more progress towards the accomplishment of the critical mission originally envisioned for the Committee. The JCR has recently prepared and finalized a White Paper requesting resources/support from DHS to accomplish some of its identified priority tasks. Please see the 2008 JCR Annual Report in attachment G.

3.1.1 FDA Center for Food Safety and Applied Nutrition

The FDA/CFSAN research plan for counterterrorism focuses on four broad research areas that are critical for FDA's mission to safeguard the country's food supply:

- *New methods.* The rapid and accurate detection of chemical, microbiological, and radiological agents that could be intentionally introduced into the food supply.
-
- *Prevention technologies*. The acquisition of information about new prevention technologies and/or technology enhancements that help protect the food supply against potential exposure to nontraditional pathogens, toxins, and chemicals during possible high-threat situations.

- *Agent characteristics*. The acquisition of scientific information on the behavior of chemical (stability) and microbiological (survival, growth) agents in foods during processing and storage, which will improve FDA's ability to detect, quantify, and control pathogens, toxins, and chemicals that threaten the food supply.

- *Dose response relationships*. The acquisition of knowledge related to the number of pathogenic microorganisms and level of toxic chemicals ingested that lead to adverse reactions in humans and the factors that would either increase or decrease the population's susceptibility in relationship to foods as a vehicle.

3.1.1.1 New Methods

Effective methods for the preliminary detection of foods, purposefully contaminated with chemical and microbiological agents, are critical components of the Center for Food Safety and Applied Nutrition's (CFSAN's) ability to detect and respond rapidly to acts of terrorism. This approach includes both field and laboratory methods. Some of the priority sub-areas include:

- *Validation of field methods for the detection of microbiological and chemical agents in foods:* A number of rapid field methods have been developed for environmental and clinical samples for different chemical and microbiological agents. However, there is little assurance that these methods will work effectively in foods, particularly at the levels likely to be encountered. Furthermore, these methods often have an unacceptable incidence of false positives. Thus, the methods need to be validated for a number of food groups, including assessing the lower limit of detection.

  Priority microbial agents include *Bacillus anthracis, Yersinia pestis, Francisella tularensis,* and *Brucella abortus*. Priority chemical agents include abrin, alpha-amanitin, *Clostridium botulinum* neurotoxin, staphylococcal enterotoxin, ricin, strychnine, T-2 toxin, and tetrodotoxin. Additionally, where methods for agents that have been traditionally associated with food safety concerns (*e.g., Salmonella,* enterohemorraghic *Escherichia coli*) are considered too insensitive for regulatory work, these methods should be reviewed for potential applicability for rapid screening.

- *Development of new field methods for the detection of chemical and microbiological agents in foods:* For those agents and/or foods where existing field methods are either not available, found to be too insensitive, or have too high a rate of false positives, new field methods should be developed or current methods should be modified to overcome current limitations. This work should be initiated in a manner that is phased with the completion of the validation of currently available methods.

  Additionally, the development of portable methods for screening of food samples for the presence of elevated levels of relatively low-energy beta emitters is needed. For these radionuclides, current field instrumentation is generally considered only semi-portable.

- *Technology transfer of field methods:* The development of prototype field methods is only the first step in making improved methods available to field investigators, Federal and State laboratories, and the food industry. Scale-up and commercialization have their unique problems and are often the stumbling block that has prevented the realization of many analytical approaches. Promising field methods should be identified and opportunities for technology transfer, including the delivery of test units for testing by FDA investigators, should be included as an active component of the research and development plan.

- *Development of laboratory-based confirmation methods:* Effective laboratory based methods are needed to confirm the results of field trials and/or provide information of the presence of agents that are potentially harmful at levels that could not be detected using field methods. This approach includes the development of both improved genomic-, proteomic-, or immuno-based rapid methods and the enhancement of culture techniques. Tests should be validated in a variety of foods. Multi-agents assays are desirable.

  Priority microbial agents include *B. anthracis, Y. pestis, F. tularensis, Vibrio cholerae, B. abortus*, and *Shigella dysenteriae*. Priority chemical agents include abrin, aconitine, colchicine, fluoracetic acid, and picrotoxin. Emphasis should be placed on methods that are capable of detecting multiple agents.

- *Development of techniques for fingerprinting agents of terrorism:* Key to the criminal investigations that would follow any attack on the food supply is the ability to determine if the presence of an agent is related to an act of terrorism or is accidental in nature. Techniques for "fingerprinting" agents (forensics) are an important tool for such determinations. For microbiological agents, this approach typically involves sub-speciation, while chemicals are usually identified by profiling of chemical contaminants. Available techniques are limited for many of the microbiological and chemical agents.

- *Sampling techniques*: Often, the limiting factor in the assessment of foods for chemical or microbiological contamination is the ability to take a sample of sufficient size, such that it is representative. Techniques for the nondestructive sampling of large volumes of foods and the subsequent concentration of the sample to a manageable volume would greatly impact the effectiveness of the agency's analytical program for both food safety and food defense.

3.1.1.2 Prevention Technologies

The food industry is focused on finding a means for reducing the risk of acts of terrorism through both the implementation of security measures and the utilization of intervention technologies that are simultaneously capable of controlling chemicals and microorganisms from both a food safety and food defense perspective. The food industry relies heavily on CFSAN to be a source of the guidance on what methods are effective for controlling various potential agents. This situation is particularly true for the small- to medium-sized food companies; however, even large food companies are hesitant to initiate research with the agents of concern. The development of such guidance is dependent upon having detailed information on the behavior of the agents in various foods and in response to different processing technologies. However, information on the behavior of a substantial percentage of the agents is minimal. For example, even though *C. botulinum* has been long recognized as a food safety concern, there is surprisingly little quantitative information available on the thermal inactivation kinetics of the neurotoxin in foods. This lack of information is even more critical when it comes to the efficacy of some of the newer food-processing technologies, such as high-pressure treatment of juices and seafood.

Priority microbial agents include *B. anthracis, F. tularensis, B. abortus, Y. pestis, Cryptosporidium parvuum*, and *S. dysenteriae*. Priority chemical agents include abrin, amanitin, aconitine, colchicine, digoxin/digitalis, fluoroacetic acid, nicotine sulfate, picrotoxin, ricin, strychnine, and tetrodotoxin. Prevention technologies must be evaluated in a number of foods, with priority given to foods that vulnerability assessments have indicated are at greatest risk of intentional contamination. Priority intervention technologies and related factors include thermal treatments, ionizing radiation treatments, ultraviolet radiation treatments, acidification, dehydration/water activity, disinfectant/biocides, temperature, freezing, and fermentation. Prevention technology assessment must be done both at laboratory and pilot plant scale to provide meaningful information to the food industry. The assessment and development of in-line sensors that could be used to monitor food-processing lines for contamination on a continuing basis is a priority area of interest.

3.1.1.3 Characteristics of Microbiological and Chemical Agents in Food

Additional assessments of the abilities of nontraditional microbial pathogens to survive and grow in foods during processing and storage, or the stability and activity of chemical agents while present in foods, and the potential for their inactivation during food processing are essential to improving CFSAN's ability to detect, quantify, and control food-borne pathogens, toxins, and chemicals that threaten the food supply. Priority areas for research include:

- Examining the effect of food characteristics and processing conditions on the stability of biologically derived toxins (e.g., ricin, abrin, amanitin) and toxic chemicals (e.g., nicotinic acid, organophosphates, fluoroacetic acid) that could be used as agents for terrorism with foods.

- Determining the growth and survival kinetics of *Y. pestis* and *F. tularensis* in foods as affected by temperature, pH, water activity, and the presence of commonly used antimicrobials.

- Determining the growth and survival characteristics of *Burkholderia mallei* and *Burkholderia pseudomallei* in foods.

- Characterizing the radiation resistance of *B. anthracis* spores in selected foods.

- Determining the effects of food composition parameters on the radiation doses needed to inactivate vegetative cells of microorganisms that have potential as WMD.

- Characterizing the stability of biologically derived toxins and toxic chemicals during lactic acid fermentations of the type used to produce fermented dairy products.

- Establishing partition coefficient values needed to develop solvent extraction methods for the separation of various biologically derived toxins and toxic chemicals from foods.

3.1.1.4 Dose Response Relationships for the Transmission of Microbiological and Chemical Agents by Ingestion

Key data needed for an effective threat assessment are the levels of probably agents that would be needed to produce adverse reactions in exposed populations (i.e., per os or intraoral). However, for a number of the nontraditional agents, the information on infectious or toxic doses is either limited to other routes of entry (e.g., intravenous, intraperitoneal, intramuscular, inhalation) or via vehicles that do not take into account the complex nature of food matrices. For example, while there are dose response studies done with *B. anthracis* for inhalation and cutaneous routes of entry, there is virtually no information available concerning gastrointestinal anthrax. Moreover, the relative infectivity of *B. anthracis* spores versus vegetative cells for the induction of gastrointestinal anthrax is not known. Research should be undertaken to provide information on appropriate animal models, the levels of priority microbiological and chemical agents needed to produce adverse health effects, and/or the lethality via a gastrointestinal route of entry. Additionally, studies must be undertaken to determine how these levels are influenced by factors associated with the food matrices or the health status/immune status of the host.

3.1.2 Environmental Protection Agency (EPA)

EPA has the following food and agriculture defense R&D projects ongoing:

- *Development of transportable gasifier for animal carcasses.* The U.S. Department of Defense (DoD) Technical Support Working Group (TSWG), in collaboration with EPA and USDA, funded the construction of a transportable gasifier capable of processing large quantities of animal carcasses and plant material resulting from agricultural emergency events. This gasifier converts the biomass material into an inert ash and a combustible

synthesis gas that is burned in a secondary combustion chamber. Testing of a full-scale prototype occurred in March 2008 at an agricultural industry site in North Carolina. During these tests, the gasifier was operated on a mixture of poultry/swine and on bales of wheat straw. A final report on the testing is in preparation and further refinements and testing are planned in Canada this winter in collaboration with the Canadian Food Inspection Agency.

- *Development of prion surrogates.* The objective of this EPA project is to develop an appropriate nonpathogenic surrogate for transmissible spongiform encephalopathy (TSE)-forming prions to be utilized in large-scale destruction and disposal studies. *Saccharomyces cerevisiae*, or budding yeast, is the system of choice for the ongoing research. Following the aggregation and purification of protein, methods are being developed for measurement and quantification of the protein aggregates in various environmental media, and the aggregates are being examined for their physical characteristics, such as thermostability and protease resistance.

- *Investigation of persistence and wide area decontamination methods for avian influenza (AI) virus.* This work, a natural extension to ongoing EPA work on decontamination after biological contamination events, was initiated in response to the heightened awareness of potential impacts from highly pathogenic avian influenza (HPAI). The work began with a detailed literature search of prior AI studies, and indicated HPAI persistence under some environmental conditions, as well as suggesting data gaps on persistence in some environmental media. This literature search was used as a basis for an interagency-reviewed EPA public Q&A document on AI, and subsequent laboratory studies on persistence of HPAI on outdoor materials, chicken feces, unpainted wood, glass, and soil under varying ambient conditions including temperature, relative humidity, and UV exposure levels. Based on the results from the persistence studies, selected conditions will be examined for efficacy of viral inactivation using widely available, inexpensive, low environmental impact chemicals.

- *Efficacy of common chemicals for decontamination of HPAI.* In 2007-8, EPA and USDA worked collaboratively with the University of Delaware on research to determine the efficacy of some commonly available chemicals, including citric acid, acetic acid, and detergent, against avian influenza virus (AIV) on porous and nonporous surfaces. USDA funded the two-phase research project, EPA reviewed the test protocols and results, and the University of Delaware carried out the testing and drafted a report that has been submitted for publication. The completed study provides a basis for USDA use recommendations for disinfectants to be used against AIV and for USDA requests for emergency exemptions from Federal pesticide registration for use of one or more generic chemicals against AIV.

- *Disinfectant efficacy testing for foreign animal disease (FAD) agents.* In 2008, EPA and USDA initiated an Interagency Agreement (IAG) for conducting a research program for testing the ability of selected antimicrobial disinfectant chemicals/products to inactivate high consequence Foreign Animal Disease (FAD) agents on inanimate surfaces. Under this IAG, the EPA is tasking to the USDA's Plum Island Animal Disease Center (PIADC)

to conduct this research with the following goals: (1) Develop disinfectant efficacy test methods that will be acceptable to USDA and EPA for the purpose of carrying out research studies covered by this IAG; (2) Determine the effectiveness of selected antimicrobial pesticides for inactivating priority Foreign Animal Disease (FAD) agents on hard, nonporous and porous surfaces and to provide scientific data that may support USDA use recommendations, FIFRA section 18 exemptions and USDA deliberations with respect to the National Veterinary Stockpile; and (3) test the resistance of less virulent agents to inactivation by antimicrobial pesticides to determine their suitability for use as surrogates for FAD agents in disinfectant efficacy testing. The intent of this research is to fill substantial data gaps that exist with respect to the efficacy of various disinfectants against high consequence FAD agents.

3.1.3 DHS Science and Technology Directorate (S&T)

Select R&D programs that the Chem/Bio Division of the DHS Science and Technology Directorate (S&T) is invested in for food and agriculture defense are listed below.

- *FAD vaccines & diagnostics program.* In a project funded from 2007–2013, USDA and Plum Island Animal Disease Center have committed to develop improved veterinary countermeasures for foreign animal diseases (FADs) and transition them to the National Veterinary Stockpile. To accomplish this, investigators will complete animal challenge testing of current Foot and Mouth Disease (FMD) vaccine to determine onset of protection; develop marked FMD vaccines for each of the major viral serotypes and subtypes to allow distinction between infected and vaccinated animals (critical for trade issues to prevent economic loss) and to provide improved onset of protection, and develop vaccines for Rift Valley Fever (RVF) and Classical Swine Fever (CSF). The countermeasures are currently undergoing testing, evaluation, and scale-up for next generation differentiate infected from vaccinated animals (DIVA) FMD vaccines and antivirals.

- *FAD modeling.* The main thrust of this effort is to develop epidemiological, economic, and transportation network models that can be used to support strategic decision/policy making and provide support to the main players in the agriculture defense area (e.g. USDA). Within this program, notable projects are the Multi-scale Epidemiological Simulation and Analysis (MESA) tool, which is being used to support systems studies on FMD and Highly Pathogenic Avian Influenza (HPAI) (for APHIS); as well as several activities initiated by the Foreign Animal Disease Threat (FADT) subcommittee (described below). Additionally, Lawrence Livermore National Labs, National Institutes of Health (Fogarty International Center) and the National Science Foundation seek to improve countermeasures through the development of FAD modeling. Their goal is to develop national scale, coupled disease spread-economic impact models to support decision makers in evaluating outbreak prevention and mitigation measures and in formulating agro-defense strategies and requirements. Researchers will begin by transitioning extant, version-controlled, epidemiological and economic models for FMD and HPAI into a USDA/DHS Joint Operational Modeling Center (JMOC). Working in

collaboration, the USDA/DHS JMOC will coordinate data acquisition and develop and maintain operational models for domestic livestock and wildlife disease analysis. Currently, the first set models resident in the JMOC Scenario Bank V1 will be exercised to develop and store a set of baseline FMD and AI reference scenarios to be used by decision makers and analysts. In addition, research into integrating an underlying transportation network model into existing epidemiological models is underway. In parallel, an academic research center focused on supporting fundamental research in mathematics and biology will address longer-term modeling challenges confronting animal disease modelers. This Center will provide the insights, tools, and training for successive generations of models and modelers. Another program known as the Research and Policy for Infectious Disease Dynamics (RAPIDD) forum is a joint effort between DHS and the NIH-Fogarty International Center, the purpose of which is to address the highest priority knowledge gaps identified by a renowned international group of modeling experts and train next-generation modelers through its Distinguished Fellows element.

- *Systems studies.* Every year S&T selects a number of high priority topics/questions that require deep, comprehensive "system-wide" study. Traditionally there have always been food and agricultural studies that analyze the Nation's defensive architecture [Past full and final reports can be provided upon request].

- *Food Biological Agent Detection System (FBADS).* The FBADS program was developed to fill a need identified by DHS and in partnership with FDA and industry representatives. The goal of the program is to develop new detectors and concept of operations for the protection of the Nation's critical food infrastructure that are compatible with extant food processing operations. The FBADS program entered into Phase I testing at the start of FY 2008 working in partnership with one of the National Center for Food Protection and Defense's industrial partners for the testing of a single representative agent in milk.

- *National Biodefense Analysis and Countermeasures Center (NBACC).* The NBACC has a sub-Center called the Biological Threat Characterization Center (BTCC) which is responsible for two efforts: (1) the bi-annual Bioterrorism Risk Assessments (BTRA), and (2) conducting laboratory studies to close key knowledge gaps in the bio/ag defense area. The previous iteration of the BTRA [2006] also included assessments on food and water events. The 2008 BTRA, which is getting ready for delivery to the White House homeland Security Council, includes food, water and agriculture scenarios within its Probabilistic Risk Assessment process. The food lab studies performed at the NBACC were used to close any priority knowledge gaps here.

- *Plum Island Animal Disease Center and National Bio & Agro-Defense Facility (NBAF).* These facilities have the operations side, which is managed by the S&T Office of National Labs whereas the R&D/program aspects exercise the FAD Vaccines & Diagnostics program (above). The NBAF currently does not have a research program at this stage.

- *Consequence Management System (CMS).* The CMS is a tool developed by the National Center for Food Protection and Defense (NCFPD) and BT Safety LLC and in partnership with multiple industry partners. The CMS is a computerized simulation model that depicts

the evolution of food-borne bioterrorism events involving selected agents and food products. The tool has been developed to support policy decision making and bioterrorism event planning, to provide assessments for the food industry, and for use as a training tool. NCFPD and BT Safety began creating the browser-based CMS back in 2004 at the request of the Food and Drug Administration, which wanted an advanced visual model for predicting, tracking, and assessing the public health and economic impact of a catastrophic food contamination incident. The CMS has since undergone significant changes, augmenting its capabilities. Of its accomplishments, the tool has been deployed to FDA for food safety events and used to provide the consequence calculations for the food aspects of the DHS 2008 Bioterrorism Risk Assessment (BTRA). Currently, the CMS team is developing an educational/training version that can be taken to state and local authorities. This work will be completed through this funding year ending June 1st 2008, with a no-cost extension to June 1st 2009.

Additionally, progress reports from DHS S&T Centers of Excellence (the National Center for Foreign Animal and Zoonotic Disease Defense (FAZD) and the National Center for Food Protection and Defense (NCFPD)) regarding information modeling and analysis, supply chain and information management, public health response and epidemiology, economic analysis, detection and diagnosis, inactivation and food processing, decontamination disposal, risk communication and education activities can be found in attachment D.

3.2 Capability Gaps

3.2.1 R&D Gaps

As discussed above, the Sector's JCR is actively working to establish a mechanism to identify research and development needs from the private sector. As that process becomes established, this section will be able to be more comprehensive.

The following R&D gaps have been identified as critical by FDA:

- Biological and Chemical Agent Detector for Use with a Multitude of Food Matrices.
- Mitigation of Biological Threat Agent Contamination of High Risk Foods.

Please see attachment E for the Capability Gap Statements for each of these FDA identified gaps above.

Further, over the past two years, the Sector has partnered in the SPPA program, described in section 2 above. Through the SPPA assessments, participants identified numerous research gaps that would help them plan, mitigate, and respond to threats or actual incidents of terrorist attacks or natural disease outbreaks. The identified research gaps included (but are not limited to):

- *Identifying feasible threat agents.* What threat agents are applicable to the industry assessed? Are possible/feasible ranges of threat agent production by terrorists known?

- *Using threat agents at industry location.* Which are stable in various components of the industry — identify whether agents can survive in different stages of the industry's process. Are agent inactivation temperatures, suitable environmental/physical conditions, persistence, etc. known? What threat agents may be removed, inactivated, or minimized by processing conditions (e.g., contact with ambient air (freezing and heat), pH of secondary solutions). How will threat agents interact with vaccines? Are threat agents compatible with pharmacological materials?

- *Infectious doses.* Identify infectious doses of top threat agents.

- *Testing for threat agents.* Support development of validated methods to test for threat agents in agriculture products. Are detection methods available for all threat agents? If so, what methods are available? What methods have been validated against industry components? To whom are the methods/materials available (industry or emergency responders)?

- *Laboratory capacity and capability.* Support methodologies for laboratory surge capacity for negative testing to allow for movement of nonexposed animals or noncontaminated product. Continue to expand pre-approved lab network partners that may test samples for threat agents.

- *New technologies.* Support development of rapid field screening tests to quickly and easily test for known threat agents. Support development of tests to determine exposure/infection of an individual animal to the threat agent.

- *Emergency contacts.* Work with industry to develop a system and protocols to ensure timely and accurate communication with the agriculture industry to alert them should an attack occur. Need Government clarification of communication channels regarding agriculture defense. Want specific names, not just "call your local representative (FBI, USDA, State health department, State agriculture department, law enforcement, etc.)" If an event occurred, whom would the USG contact at each industry? How will threats be communicated to the industry or a specific company?

- *Information sharing.* What is the plan for CARVER+Shock best practice sharing? How will the knowledge gained from SPPA assessments be disseminated to industry? Continue to migrate towards a single web portal to deliver food and agriculture defense related information to all partners within the food and agriculture defense spectrum. Goal is to have a single source information point for industry, for example the Homeland Security Information Network, AgriGard, etc. Would allow user to enter a zip code and website returns contact information for nearest key Federal contacts (e.g., FBI WMD Coordinator, State Veterinary Office/Livestock Commissioner, FDA Office of Criminal Investigation (OCI), DHS Protective Security Advisor (PSA), Trade organizations etc.) Need standard operating procedures for using the web portal.

3.2.2 Modeling Gaps

- There is a critical need for economic modeling and estimates of the impacts that would result from the response to and recovery from an intentional food contamination event. Specific economic estimates are needed with regard to the cost of:
  - Human illness from exposure to biological and chemical agents through oral ingestion.
  - Human death from exposure to biological and chemical agents through oral ingestion.
  - Decontaminating the
    - Food manufacturing facility.
    - Food distribution warehouse.
    - Grocery store.
    - Transportation vehicle (truck, rail car, etc.).
    - Consumer refrigerator/freezer.
  - Disposing of food, food ingredients, contaminated equipment, or consumer refrigerator/freezer.
  - Destroying food manufacturing facility(ies).
  - Losing the employee base as a result of illness, death, or inability to report to work.
  - Losing the market for contaminated product.
  - Losing the market for entire commodity.
  - Losing the market for entire brand.
  - Losing international trade.
  - Transporting food into affected area.
  - "Marketing" to reassure the public that the food supply is safe .

- There is a critical need for elaboration of social science issues in order to facilitate a better understanding of the public's psychological and sociological response to an intentional food contamination event. This effort would include but not be limited to a determination of the:
  - Degree of the loss of confidence in the food supply.
  - Desire/need for parents to keep their children home (not send them to school).
  - Desire/need for the public to stay at home (not go to work).
  - Loss of productivity across other sectors because people have not gone to work.
  - Degree of loss of confidence in the U.S. Government.

  A range of scenarios would need to be considered. The Food and Agriculture Sector would provide the scenario parameters to be considered, such as the food that was contaminated; agent that caused the illness; range of illnesses and deaths; geographic area of exposure (city, state, region); and number of manufacturing facilities, distribution facilities, and grocery stores involved. The Sector could also provide subject matter experts to ensure the integrity of the scenario being considered.

- The Sector needs to have a better understanding of the costs and benefits of preparedness and mitigation strategies. Specifically, the various response measures that could be taken to address a food contamination incident or the introduction of a FAD or plant pest need to be analyzed. This information needs to be considered along with the savings to the industry that would result from taking that action. To determine whether it would be in the

Sector's best interest to take that action, the long-term costs of no action (e.g., allowing the disease to spread) need to be analyzed too for comparison.

This information will enable decision makers to determine if and when to invest in preparedness, response, and mitigation activities. In addition, this information may also help private industry determine when to invest in preparedness/protective measures versus enduring response and recovery activities.

-
- The Sector needs to understand the most effective places to apply countermeasures within the farm-to-table continuum. Dynamic models could help the Sector determine which technologies need to be developed or implemented, would be cost-effective, and would provide sufficient benefits to justify the expenditures.

  Time is of the essence during the initial spread of a human, crop, or animal disease or the distribution of a contaminant in the food supply chain. Dynamic models could help the Sector make decisions about countermeasures by helping it determine where in the supply chain the deployment of technologies would be likely to have the biggest impact for the investment. The same models could be used to explore response and recovery strategies to help determine what strategy would be most likely to mitigate the consequences of a natural event in a cost-effective manner.

  The models could select key points in the farm-to-table continuum to determine the effectiveness of applying countermeasures there. For example, in the food processing continuum, the models could examine incoming ingredients, finished products before they left the manufacturing facility, and distribution warehouses.

- There is a critical need to share sensitive Sector data and surrogate data methods. All of the modeling efforts require certain base data sets to allow the models to provide the best information possible. Some of the data are very sensitive to the Sector; however, researchers need to have access to these data so that appropriate analysis and response evaluations (synthetic experience) can take place. A particular unintentional scenario (and there are quite a few) could harm the Sector just as badly as an intentional one. Researchers need to determine how to make the sensitive data available to investigators or operational managers so that proper planning can take place in peace time. If this planning cannot be done, there is an inherent weakness in the Sector's response planning, because data will only be available at the time of an event or for certain perceived terror threats.

Section 4: Funding Priorities

4.1 Planned SSA Investments

FDA's food defense program supports HSPD-9 on safeguarding the American public by defending America's food supply against terrorist attacks. HSPD-9 lays out a framework for augmenting the nation's food safety protections and establishing a partnership among the various organizations responsible for protecting the nation's food supply. The food supply is part of the Nation's critical infrastructure and contributes about 20% to the U.S. gross national product. A terrorist attack on the food supply could have catastrophic public health and economic consequences. The funds requested would continue to improve laboratory preparedness and food defense field operations, food defense research, surveillance, and incident management capabilities. Through this initiative, FDA will enhance its capacity to prevent, prepare for, respond to, and mitigate the effects of a terrorist attack, a major disaster or other emergency on the food supply.

The funds requested will allow FDA to:

- Continue to establish the FERN, a national network to increase analytic surge capacity in the event of terrorist attack. FERN is designed to ensure adequate laboratory testing capacity for biological, chemical and radiological threats.
- Continue field support of food defense operations.
- Conduct targeted food defense research efforts by focusing on food counterterrorism technologies, laboratory methods development, and infectious dose thresholds for food contaminated with bioterror agents.
- Improve coordination and integration of food surveillance capabilities with DHS under the government-wide Bio-Surveillance Initiative.
- Upgrade Crisis Incident Management capabilities.

See table 4.1 for FDA's food defense investments.

Table 4-1: Sector Annual Report on Budget

Sector:	Food and Agriculture Sector						
Agency:	Food and Drug Administration						
					Budget		
Program/ Investment Title	Priorities Addressed	Program/Investment Description: How Program/Investment Supports CI/KR Protection	OMB Account	Included in the HSDB?*	FY07 Actual	FY08 Enacted	FY09 Estimate
Food Emergency Response Network		FERN is a nationwide laboratory network that integrates existing federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products.	009-10-9911	Y	34.38	36.483	42.645
Food Defense Research		Investing in research, through an integrated program of intramural, extramural, and consortia-based initiatives, is needed to “shield” the food supply from terrorist threats.	009-10-9911	Y	14.787	15.167	19.238
Inspections/Risk Based – Imports Monitoring Related Activities		High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. FDA’s Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S.	009-10-9911	Y	101.658	97.062	121.209
Food Registration and Listing System		The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) required FDA to issue a regulation that requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA. FDA established an online registration system.	009-10-9911	Y	10.314	11.242	12.794

Table 4-1 (Cont.)

Sector:	Food and Agriculture Sector						
Agency:	Food and Drug Administration						
					Budget		
Program/ Investment Title	Priorities Addressed	Program/Investment Description: How Program/Investment Supports CI/KR Protection	OMB Account	Included in the HSDB?*	FY07 Actual	FY08 Enacted	FY09 Estimate
Crisis Management		Improvements increase FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products.	009-10-9911	Y	2.626	2.608	6.135
Bio-Surveillance		This interagency improves Federal surveillance capabilities in human health, food, agriculture, and environmental monitoring and establishes An integration capability at the Department of Homeland security (DHS), to rapidly compile these streams of data and integrate them with threat information. in FDA, these funds are used to coordinate existing food surveillance capabilities to establish the appropriate connectivity with the integration and analysis function at DHS.	009-10-9911	Y	4.934	4.934	8.004
Field Support for Food Defense Operations		FDA field staff allows FDA to increase its border presence by doing more field exams, sample collections and analysis, domestic inspections and laboratory analysis. This supports the compliance, policy and enforcement actions anticipated from the more than doubling of Field import staff and the corresponding inspections, sampling, testing, and field exams to match the current mix of employees in the review process. The Agency is making optimal use of every method available to quickly identify applicants and reduce the time to hire.	009-10-9911	Y	3.2	3.2	3.2
Agency Totals:					**137.519**	**170.696**	**213.225**

*HSDB = Homeland Security Data Base

4.2 Non-SSA Investments

Several Federal departments and agencies have invested in Food and Agriculture defense activities, including DHS, EPA, and the Federal Bureau of Investigations (FBI). Funding that DHS has provided to States for Food and Agriculture defense-related grants can be found in attachment F.

DHS has also invested in training in the area of food and agriculture defense. For instance, DHS awarded $700,000 in FY 2007 to the University of California-Davis (UC-Davis), and their Western Institute for Food Safety and Security (WIFSS) in Continuation Funds for the Agroterrorism Preparedness Curriculum for Frontline Responders. The original award in FY 2004 funded a series of six courses related to Food Safety and Defense, including a series in Awareness, Preparedness, Detection and Diagnosis, National Incident Management Systems (NIMS) and Risk Communication, Response and Recovery. This curriculum is referred to as the Agroterrorism Preparedness Curriculum for Frontline Responders. In FY 2008, DHS is considering providing Continuation Funds to the University of Tennessee for their Food and Agriculture Vulnerability Assessment Training Program, as well as additional funds for UC-Davis and their Agroterrorism Preparedness Curriculum for Frontline Responders.

In addition to the initiatives described above, DHS also sponsors these Food and Agriculture Safety and Defense Initiatives:

1. The Center for Domestic Preparedness and their WMD Basic Agriculture Emergency Response Training (AgERT) Course.

2. The Center for Domestic Preparedness and their Pandemic Influenza Planning and Preparedness Course.

3. The Louisiana State University and their Preparedness and Response to Agriculture Terrorism.

EPA has also spent funds from FY 2006-2008 and utilized FTEs to complete or make progress in its Food and Agriculture Sector activities. For example, EPA spent $750K of FY 2006-2008 funds on activities to develop technologies and tools for disposal of animal carcasses and other biomass. EPA also spent $640K of FY 2006-2008 funds for research activities to improve the understanding and capabilities for decontamination of select animal bio-agents including prions, avian influenza virus, and other high consequence bio-agents. Also in FY 2007-2008 EPA used FTEs to collaborate with USDA and other Federal and State agencies and industry on research and development for decontamination and training of on-scene coordinators and responders.

The FBI has funded many food and agriculture defense initiatives. Highlights of those initiatives are below and more information is available upon request:

- *FBI regional joint conferences.* The FBI's Agroterrorism Program has initiated a series of cross training conferences with USDA and FDA, focusing on criminal and terrorist incidents within the food and agriculture sector. The trainings will serve to open a

dialogue between FBI, USDA, and FDA and to foster a greater understanding of roles and responsibilities in connections with a criminal or terrorist incident.

- *International Symposium on Agroterrorism (ISA)*. FBI hosted the third ISA in April 2008. The main mission of the ISA is to protect the food supply worldwide while illustrating the importance of a coordinated effort. More than 1,000 individuals from 21 different countries have attended past ISAs, participating in break-out education sessions and case studies, hearing world-renowned experts discuss agroterrorism, and interacting with each other.

- *Agroterrorism Working Groups (AWG)*. FBI initiated AWG in June 2005 to enhance the FBI's ability to detect, deter, assess, and respond to potential terrorist threats or attacks targeting the food and agriculture sectors. FBI mandated that all FBI field divisions develop and lead an AWG in each division under the direction of the filed WMD Coordinator(s). The AWG should at a minimum comprise Federal, State, and Local government counterparts in food and agriculture, appropriate local, county, state, and/or Federal law enforcement personnel, and appropriate public health officials.

- *SPPA Initiative*. FBI funded the SPPA from FY 05 through FY 08. Details on the SPPA initiative are provided in section 2 of this document.

- *Food and Agriculture InfraGard*. The FBI's Food-Agriculture InfraGard Special Interest Group (SIG) is a resource dedicated to safeguarding the food and agriculture sectors of both private industry and government through information-sharing networks and a private secure portal of communication. This SIG intends to enhance the sharing of information among private sector stakeholders who can assist the FBI in detecting, deterring, assessing, and preventing threats and attacks targeting the agriculture and food processing industries within our nation.

- *Joint US/AUS/CAN/UK agroterrorism meeting*. In January 2007, FBI hosted the first bi-annual Agroterrorism Conference including representatives from the FBI as well as the Law Enforcement, Agriculture, and Intelligence entities of Australia, Canada, and the United Kingdom. The conference goals include the sharing and evaluation of agroterrorism response protocols, comparison of agroterrorism investigative efforts, discussion of prevention/detection/mitigation strategies, and the establishment of long-term liaison ties to assist in future agroterrorism prevention efforts.

4.3 Gaps

Not funding this initiative also diminishes FDA's ability to prevent or respond to a terrorist attack or a public health emergency related to food. Not providing sufficient resources will have far-reaching consequences:

- Imported foods will remain a safety and security threat. Products from countries with high-risk food production, manufacturing, and distribution systems will continue to enter U.S. commerce without appropriate surveillance.

- FDA and our industry partners will not achieve the ability to rapidly trace the origin of foods implicated in intentional or unintentional adulteration.

- The confidence of American consumers in the safety and security of the food supply will be low.

Gaps that have been identified are also described in section 1.3, CIKR Protection Gaps, and in section 2.1, CIKR Protection Programs and Initiatives.

Section 5: CIKR Protection: Security Practices and Obstacles

5.1 CIKR Protection Security Practices

The Food and Agriculture Sector partners have said that they do not expect or desire the Government to implement or mandate security practices. The overriding concern is one of liability. Thus, as security guidelines and practices are developed in collaboration between government and industry, they are shared with appropriate security partners as voluntary security guidance materials; an example are FDA's Food Security Preventive Measures Guidance documents available at http://www.cfsan.fda.gov/~dms/defguids.html. Updated versions of these documents were released in November 2007. An example of similar industry-developed guidance is the "Grocery Manufacturers Association (GMA) Food Supply Chain Handbook," a comprehensive guide to selecting safe and reliable ingredient, packaging, and service suppliers throughout the supply chain. This document is available on the GMA website (http://www.gmabrands.com/).

5.2 Obstacles

5.2.1 Defining the Role for and Utilizing the Extension Professional

The role that Extension takes in food emergencies lacks definition and is often not properly documented and supported system wide in a proper emergency management procedure that improves interagency cooperation, such as the Incident Command System. Extension programming is locally driven. In some states there are agreements between statewide Extension and health departments to cooperate during a food emergency, but the proper MOUs or MOAs are not spelled out and lead to random participation and messages from Extension to their clientele. As a locally trusted source of science based information, the cooperative extension service has the potential to bolster and supplement information that consumers receive through the media. The net result will be increased consumer food safety and less economic impact on the food production and distribution system.

However, in order to provide the clearest and most impactful messages, extension professionals must clearly define their own role, understand the roles of other agencies and organizations, understand and use emergency communication techniques before, during, and after an advisory that affects consumer food products. These roles will vary from state to state, so there is a need to help agencies and organizations to fully understand the capacity to which Extension can serve in this arena. In addition, it must allow flexibility for state- and county-extension teams, but provide clear guidelines as to what emergency management procedures reduce the impact of a potential food disaster.

5.2.2 Communication on DHS Sector-Specific Initiatives

As stated in the 2007 Food and Agriculture SAR, DHS has initiated projects and distributed grant money for projects in the area of food defense and agriculture protection. However, information about these projects is still not always provided to the SSAs (USDA and FDA) in a timely manner, if at all. To properly coordinate all of the activities within the Sector, USDA and FDA should be made aware of, at a minimum, all of the DHS activities related to food defense and agriculture protection. Ultimately, DHS should be coordinating all projects with the SSAs to minimize duplication, fill in gaps, and leverage resources. Currently, the SSAs provide this information to DHS via reports such as this one. A two-way mechanism for this information sharing is needed.

5.2.3 Concerns Related to Cyber Security

Information security and assurance exists at all levels of Sector protection efforts. However, since cyber attacks on the food and agriculture infrastructure offer minimal national-level impact, the Sector does not perceive itself as a target of such an attack. DHS as well has not identified the Food and Agriculture Sector as a target of cyber crime. Given the recent focused attention on this particular area of CIKR protection, it would be useful to have DHS National Cyber Security Division or the FBI provide a threat analysis and characterization for the Sector to better understand whether a Sector-centric program is needed to support cyber security.

Section 6: Program Effectiveness and Continuous Improvement

6.1 CIKR Protection Mission Progress

This section provides a summary of the overall progress of the Food and Agriculture Sector's CIKR protection efforts. The information is based on metrics that were developed collaboratively with the DHS/Office of Infrastructure Protection (DHS/IP) to assess the status of the Food and Agriculture Sector's CIKR protection effort. This summary of overall progress covers two key facets of CIKR protection – the status of activities, projects, and tools developed to meet the goals and objectives identified in the Food and Agriculture Sector-Specific Plan (FASSP) and the implementation of the NIPP Risk Management Framework. In addition, the consolidated metrics also emphasize the role of Sector partnerships in successfully executing the NIPP.

The Food and Agriculture Sector has made significant progress in completing Sector-specific actions and milestones in pursuit of advancing the nine goals laid out in its SSP. The Sector accomplished this by aligning existing CIKR protective programs and risk management priorities with its goals and collaborating with Sector security partners. Because CIKR protection cannot be accomplished unilaterally, significant progress in the Food and Agriculture Sector is contingent on partnerships among Federal, State, local, tribal and territorial partners and CIKR owner/operators. The Food and Agriculture SCC continues to provide an essential forum for the private sector to discuss infrastructure protection issues. It also communicates with the public sector through the Food and Agriculture GCC.

As discussed earlier in this document, USDA and FDA, the SSAs for the Sector, and their industry partners have set goals and priorities for the year that align with the ongoing threats to the Sector: livestock and crop disease and food and water contamination. One of their highest priorities in 2008 focused on the long-term security goal of working with State and local entities to ensure preparedness to respond to incidents. Two notable examples are:

- Development of the Food and Agriculture Sector Criticality Assessment Tool (FAS-CAT).
- Launch of the ALERT initiative.

Also described earlier, the Sector partnered with the National Center for Food Protection and Defense (NCFPD), a DHS Center of Excellence, to develop the Food and Agriculture Sector Criticality Assessment Tool (FAS-CAT). This assessment tool is provided to each State to assist in determining and documenting the most critical State-level elements and systems/subsystems within the Food and Agriculture infrastructure. FAS-CAT also provides a method of prioritization for further assessments of State or private sector vulnerability and development of potential protective measure(s) or mitigation strategies, documentation and improved characterization of a State's Food and Agriculture Sector risk profile, and creation of an effective

response to future DHS National Data Calls for information on critical Food and Agriculture infrastructure components.

Consistent with Sector efforts to expand partnerships, the Food and Agriculture SSAs have collaboratively launched the ALERT initiative to raise the awareness of State and local government agency and Sector representatives regarding food defense issues and preparedness. This tool is broad enough to apply to all aspects of the farm-to-table supply chain, and is designed to engage a variety of stakeholders. ALERT seeks to decrease the risk of intentional food contamination at industry and business facilities. For business and trade purposes, many of the Sector partners have traditionally focused on reducing the risk of food contamination or preventing an animal or plant disease outbreak. The protection of the Sector's critical infrastructure is a natural outgrowth of those more traditional efforts.

In 2008, the Food and Agriculture Sector has been able to narrow key gaps identified in its 2007 Sector Annual Report. For example, the Sector is working to enhance and improve two-way communication by modifying the HSIN portal, to better serve as a primary means of communication and collaboration for the Sector. The Sector has also improved standardization of the CARVER+Shock, in order for it to serve as the Sector's main vulnerability/consequence/risk assessment tool. The CARVER+Shock assessment methodology has been established to meet the NIPP baseline criteria, and achieve this year's milestone.

The Food and Agriculture Sector continues to make considerable progress in accomplishing the long-term security goals and priorities outlined in the NIPP and the FASSP. The set of activities undertaken demonstrate the robust CIKR protection approach adopted by the Food and Agriculture Sector. In addition, the proposed initiatives will enable the Food and Agriculture Sector to build on its success and continue engaging State, local, and territorial governments in the CIKR protection process.

6.2 Path Forward

Sector-Specific Metrics ideally comprise a set of measures that are tailored to the unique risk profile and characteristics of the food and agriculture sector as well as provide meaningful information about the status of the security posture of the owners and operators in the sector. However, the food and agriculture sector is very broad and complex. Therefore, identifying one valuable sector specific metric, let alone a set of metrics questions that are relevant across the sector, will be a true challenge.

The SCC has decided to focus the initial sector specific metric development effort on one subsector — the Processors and Manufacturers (PM). Over the next 12 months, the PM subcouncil will begin to brainstorm possible metrics questions that will be relevant to all of their members and descriptive of progress made on protective efforts throughout the PM subsector.

The real test of the sector partnership is whether all of the participants find value in it. Over the next year, the sector leadership will work to make the partnership as valuable as possible to the GCC and SCC council members, as well as the overall sector membership. Cross-cutting and

value-added protective programs can only be implemented if there is trust between partners and recognition of the need for a united sector effort. That is the path forward that sector leadership is striving toward.

This page intentionally blank

Attachment A: Acronym List

AAR	after action report
ADM	Archer Daniels Midland Company
AFSCE	Australian Food Safety Center of Excellence
AgERT	Agriculture Emergency Response Training
AI	avian influenza
AIV	avian influenza virus
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service (USDA)
ASM	Agricultural Sector Model
AWG	Agroterrorism Working Group
BoNT	botulinum neurotoxin
BSL	bio-safety level
BTA	Bioterrorism Preparedness Act of 2002
BTEX	Bioterrorism Experts Group (G8)
BTCC	Biological Threat Characterization Center
BTRA	bioterrorism risk assessment
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention (HHS)
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CIKR	critical infrastructure and key resources
CIP	critical infrastructure protection
CIPAC	Critical Infrastructure Partnership Advisory Council
CMS	Consequence Management System
COOP	continuity-of-operations plan
CSEA	Cyber Security Enhancement Act (2002)
CSF	classical swine fever
DHS	U.S. Department of Homeland Security
DIVA	differentiate infected from vaccinated animals
DoD	U.S. Department of Defense
EPA	U.S. Environmental Protection Agency
FAD	foreign animal disease
FADT	Foreign Animal Disease Threats (Subcommittee) (NSTC)
FAD-ZD	foreign animal disease and zoonotic disease
FAS-CAT	Food and Agriculture Sector Criticality Assessment Tool
FAZD	National Center for Foreign Animal and Zoonotic Disease Defense (DHS)
FBADS	Food Biological Agent Detection System
FBI	Federal Bureau of Investigation

FDA	U.S. Food and Drug Administration
FERN	Food Emergency Response Network
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMD	foot-and-mouth disease
FMDV	foot-and-mouth disease virus
FSIS	Food Safety and Inspection Service
FTE	full-time equivalent
FY	fiscal year
G8	Group of Eight
GCC	Government Coordinating Council
GMA	Grocery Manufacturers Association
GRAS	generally recognized as safe
HHS	U.S. Department of Health and Human Services
HITRAC	Homeland Infrastructure Threat and Risk Analysis Center
HPAI	highly pathogenic avian influenza
HSA	Homeland Security Advisor
HSDB	Homeland Security Data Base
HSEEP	Homeland Security Exercise and Evaluation Program
HSIN	Homeland Security Information Network
HSIN-FAS	HSIN Food and Agriculture Sector (portal)
HSPD	Homeland Security Presidential Directive
HUB	historically underutilized business
IAG	interagency agreement
ICS	Incident Command System
IED	improvised explosive device
IIT	Illinois Institute of Technology
IP	Office of Infrastructure Protection (DHS)
ISA	International Symposium on Agroterrorism
IT	information technology
JCR	Joint Committee on Research
JMOC	Joint Modeling Operations Center (USDA/DHS)
LANL	Los Alamos National Laboratory
MEPI	Middle East Partnership Initiative
MESA	Multi-scale Epidemiological/Economic Simulation and Analysis (tool)
MIPT	Memorial Institute for the Prevention of Terrorism
MOA	memorandum of agreement
MOU	memorandum of understanding
NBACC	National Biodefense Analysis and Countermeasures Center (DHS)
NBAF	National Bio & Agro-Defense Facility

NBIS	National Biosurveillance Integration System
NCFPD	National Center for Food Protection and Defense
NCFST	National Center for Food Safety and Technology
NIH	National Institutes of Health
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NSF	National Science Foundation
OLFIA	oligonucleotide-based lateral flow immunoassay
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy (White House)
PCIS	Partnership for Critical Infrastructure Security
PCR	polymerase chain reaction
PEMA	Pennsylvania Emergency Management Agency
PIADC	Plum Island Animal Disease Center (USDA)
PM	Processors/Manufacturers (Subsector)
PNC	Prior Notice Center (FDA)
PRA	probabilistic risk assessment
PSA	Protective Security Advisor (DHS)
Q&A	question and answer
R&D	research and development
RAPIDD	Research and Policy for Infectious Disease Dynamics
RFEM	radio-frequency environmental monitor
RFID	radio-frequency identification
RVF	Rift Valley fever
RVFV	Rift Valley fever vaccine
S&T Directorate	Directorate for Science and Technology (DHS)
SCC	Sector Coordinating Council
SIG	special interest group
SNP	single nucleotide polymorphism
SPPA	Strategic Partnership Program Agroterrorism
SSA	Sector-Specific Agency
SSP	Sector-Specific Plan
TAMU	Texas A&M University
TSE	transmissible spongiform encephalopathy
TSWG	Technical Support Working Group (DoD)
TVMDL	Texas Veterinary Medical Diagnostic Laboratory
UCD	University of California, Davis
UMN	University of Minnesota
USC	University of Southern California

USDA	U.S. Department of Agriculture
UTMB	University of Texas, Medical Board
VBIED	vehicle-borne improvised explosive device
WIFSS	Western Institute for Food Safety and Security
WMD	weapons of mass destruction
ZD	zoonotic disease

Attachment B: SPPA Assessments

Date	Sector-Specific Agency	Industry	State
11/2005	FDA	Yogurt	TN, MN
12/2005	FDA / USDA	Grain – export elevators	LA
01/2006	FDA	Bottled Water	NJ
02/2006	FDA	Baby Food – jarred applesauce	MI
02/2006	USDA	School Central Kitchens	NC
03/2006	USDA	Swine Production	IA
03/2006	FDA / USDA	Frozen Food – pizza	WI, FL
04/2006	FDA	Juice Industry – apple juice	NH
04/2006	USDA	Egg Products – liquid	PA
05/2006	FDA	Fresh-Cut Produce – bagged salads	CA
06/2006	FDA	Infant Formula	AZ
06/2006	USDA	Poultry Processing	AR
07/2006	FDA	Fluid Dairy – processing	NY
07/2006	USDA	Beef Cattle Feedlot	NE
08/2006	USDA	Ground Beef Processing	KS
08/2006	USDA	Cattle Auction Barn	MO, KS
09/2006	USDA	Dairy Farm	ID
10/2006	USDA	Corn Production	IA, IL
11/2006	USDA	Soybean Production	IL
01/2007	FDA	Retail Fluid Dairy Milk	TX
02/2007	FDA	Flour	OK
03/2007	FDA	Stadium Retail Food Service	KS
03/2007	USDA	Sausage Processing	WI
04/2007	USDA	Ground Beef Patty Formation	OH
06/2007	FDA	Commercial Feed Mill	IA
06/2007	USDA	Hot Dogs	PA
07/2007	USDA	Domestic Grain Cooperative	IA
07/2007	FDA	Breakfast Cereal Manufacturer	MN
08/2007	FDA	Grocery Store	PA
09/2007	USDA	USDA Commodity Warehouse	MO
09/2007	FDA	High Fructose Corn Syrup	AL
10/2007	USDA	Import Re-inspection Facility	MD
11/2007	FDA/USDA	Distribution	VA
12/2007	USDA	Poultry-Broiler Industry	GA
3/2008	USDA	Beet Sugar	MN
5/2008	USDA	Livestock Transportation	CO

This page intentionally blank

Attachment C: Risk Reduction Activity Questionnaires

Due to lack of resources, FDA was unable to complete the RRAQs for the protective programs listed in section 2 of this report.

This page intentionally blank

Attachment D: National Center for Foreign Animal and Zoonotic Disease Defense (FAZD) and the National Center for Food Protection and Defense Research and Development Activities

Table D-1: Evaluation of Mass-Scale Robotic ELISA Tests for Foot-and-Mouth Disease Using Sub-Genomic Replicons

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Evaluation of Mass-Scale Robotic ELISA Tests for Foot-and-Mouth Disease Using Sub-Genomic Replicons
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Apply the FMD ELISA test to a Beckman Biomek robotic liquid handling system using non-infectious sub-genomic replicons of FMD virus. Texas Veterinary Medical Diagnostic Laboratory (TVMDL), as a HUB laboratory, will also be involved in testing surveillance samples for FMD using RT-PCR techniques and we plan to compare these two methods for false positive rates; false negative rates cannot be established since the U.S. cattle herd is at this time negative.
Approach	Provide sub-genomic replicons of FMD virus grown in eukaryotic cells. The products are safe, killed, non-infectious antigens. Samples will lose all identity as to ownership of animal but will retain the information of the disease condition of the animal from where they originated as well as the condition of the sample itself (e.g., decomposition, hemolysis, etc.) An aliquot from the original sample will be labeled consecutively and the conditions recorded.

Table D-2: Development of New Targets for Antiviral Intervention and New Diagnostics to Detect Foot-and-Mouth Disease Virus Infection

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Development of New Targets for Antiviral Intervention and New Diagnostics to Detect Foot-and-Mouth Disease Virus Infection
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)

Table D-2 (Cont.)

Question	Detail
Goal	Develop new products and methods that will minimize the impact an outbreak of FMD will have on the livestock producers and food consumers; Produce a system to identify useful targets for developing antivirals for preventing FMDV infection and/or to develop FMDV-resistant livestock; Develop replicon-expressing eukaryotic cells as antigens for detecting the presence of antibodies to FMDV.
Current Status	Utilize a novel cell-based Functional Phenotype Filtering technology to identify drug targets for use in combating infectious agents. This technology will be applied to FMDV, ultimately producing candidate targets for drugs to treat infected animals. This technology will be combined with a subgenomic form of the FMDV genome that can be introduced into cells where it can accomplish a replication cycle similar to that of the live virus.

Table D-3: Innate Resistance as an Evolving Paradigm against Select Agents of Livestock Species

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Innate Resistance as an Evolving Paradigm against Select Agents of Livestock Species
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Identify the genetic basis for innate resistance to select agents. The objectives of this project are to map, sequence, and characterize allelic diversity in candidate genes for resistance to FMD, RVF, and BRU in cattle, beginning with the TLR and NOD gene families.
Approach	*RH Mapping*: All unmapped bovine candidate genes will be mapped on a subset of 90 clones from our original RH panel. *Gene Sequencing and SNP Analysis*: Each gene will likely require a different strategy for sequencing because of inconsistency in the resources available for individual cattle TLR and NOD genes at this time. *SNP Detection:* After development of appropriate primers, exons from each gene will be sequenced in all animals of the breed panel. All SNPs occurring in less than three individuals will be subcloned to verify correct scoring, and both alleles will be identified in subclones for such heterozygotes.

Table D-4: Development of a Rapid and Inexpensive Diagnostic Kit for Foot-and-Mouth Disease and Rift Valley Fever

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Development of a Rapid and Inexpensive Diagnostic Kit for Foot-and-Mouth Disease and Rift Valley Fever
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	The objective of this project is to provide a kit for rapid pen-side diagnosis of foot-and-mouth disease.
Approach	Seek to express RNA polymerase gene of foot-and-mouth disease (FMDV) (P3D) in a baculovirus expression vector. Vaccinated animals will only have an immune response to the P1 and P3C proteins, while infected animals will be positive to all the viral proteins, including P3D. The strategy includes the cloning of P3D gene of FMDV into a transfer plasmid vector, pVL1393, to generate pVL1393P3D. The recombinant baculovirus expressing the P3D gene of FMDV (bP3D) will be generated by standard homologous recombination between pVL1393P3D and wild type baculovirus DNA in Sf9 cells. The rapid kit is based upon reverse phase immuno-chromatography that is incorporated into an integrated device approximately the size of a match box. This rapid test utilizes the recombinant P3D-baculo protein of FMDV. The kit determines the presence of anti-P3D antibodies in a serum sample. To validate the rapid strip test, serum samples obtained from cattle which are either vaccinated with FMD VP1 protein or infected with FMDV will be tested at various dilutions.

Table D-5: Evaluation of Immunogenicity of Candidate Rift Valley Fever Vaccines in Sheep

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Evaluation of Immunogenicity of Candidate Rift Valley Fever Vaccines in Sheep
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop Rift Valley fever (RVF) vaccine candidates that are highly immunogenic in sheep within a few days post-vaccination and that will not compromise currently available and internationally accepted standardized diagnostic assays.

Table D-5 (Cont.)

Question	Detail
Approach	Apply strategies to develop vaccines rationally designed by computational algorithms and constructed through mutagenesis and/or antigen expression in alpha virus replicons and/or vacciniapox virus systems. The vaccines will be designed to avoid compromising currently available and internationally accepted standardized diagnostic assays. New candidate vaccines will be screened through in vitro target host cell culture systems, followed by evaluation for in vivo safety, immunogenicity and protection in laboratory animal models, and then finally tested for immunogenicity in the target livestock host, sheep, in small scale studies under appropriate containment conditions. Six non-vaccinated control sheep will be compared for immunogenicity to three groups of six sheep vaccinated under BSL3 at TAMU with 1) a recombinant vaccinia virus candidate vaccine for RVF with a deletion in the B8R and TK genes of VV (Wyeth strain) expressing glycoproteins of RVF virus and human IFN-g, 2) RVF candidate vaccine based on alphavirus replicons and recombinant viruses that lack the N protein (differentiating infected from vaccinated animals) and for some configurations which may carry a positive marker of vaccine exposure (positive test for previous vaccination) packaged into non-replicating viral particles expressing the protective glycoproteins (G1 and G2) of RVFV, or 3) modified attenuated live RVFV candidate vaccine based on multiple partial deletions of RVFV genes. All sheep will be pregnant ewes at the time of vaccination. Serum neutralization assays will be performed under BSL4 conditions at UTMB every second day for 14 days, then weekly through Day 56 postvaccination.

Table D-6: Candidate Rift Valley Fever Vaccines

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Candidate Rift Valley Fever Vaccines
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	The objective is to prepare Rift Valley fever (RVF) vaccines that are rapidly immunogenic and that can be produced rapidly.
Approach	Develop a live-attenuated RVFV vaccine suitable for use in sheep and cattle using MP-12 as a model. The other avenue of attack will utilize two related approaches: alphavirus replicons and recombinant viruses. Replicons with the genes of interest have been packaged into non-replicating viral particles that cannot revert to express RVFV and express some of the structural proteins of Sindbis, as well as the protective glycoproteins (G1 and G2) of RVFV.

Table D-6: Candidate Rift Valley Fever Vaccines

Question	Detail
	These vaccines will not be deployed in a vacuum, so diagnostics will also be developed. Use in press data on the sequence of RVFV strains to design PCR primers and test their utility in the diagnosis of several RVFV strains in vitro. Use sera and other samples developed in the process of mouse testing to verify their specificity and sensitivity. To follow disease transmission seroepidemiologically, produce and standardize recombinant ELISA antigens for future use.

Table D-7: Diagnosis of and Protection against Infectious Brucella Aerosols

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Diagnosis of and Protection against Infectious Brucella Aerosols
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop high throughput methods to identify Brucella infected hosts, and to provide enhanced protection against aerosol challenge; (1) Evaluate molecular approaches to rapidly identify infected animals. Focus on a comparison between PCR-based techniques to detect and amplify target DNA sequences versus genomic and proteomic approaches to identify biomarkers of infection; (2) Evaluate vaccine candidates that are safe and efficacious for use against aerosol challenge and identify correlates of protective immunity.
Approach	(1) Real-Time PCR-based detection: Evaluate Molecular approaches to rapidly identify infected animals; Bovine Genomic Arrays: For comparative gene expression analysis of infected and naïve cows, use the TAMU Bioinformatics Core to generate and analyze expression data using bovine microarrays; Protein Chips: Application of SELDI-TOF MS technology will be compared with genomic-based approaches in the development of biosignatures to identify animals infected with Brucella. (2) Evaluate vaccine candidates that are safe and efficacious for use against aerosol challenge and identify correlates of protective immunity. Candidate vaccines will be evaluated for protection against aerosol challenge in cattle.

Table D-8: Development of Highly Sensitive Immunoassays and Reagents for Detection of Avian Influenza

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Development of Highly Sensitive Immunoassays and Reagents for Detection of Avian Influenza

Table D-8 (Cont.)

Question	Detail
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop immmunoreagents and specific immunoassays for detection of avian influenza (AI); (1) Establish baculovirus expression of avian influenza proteins (2) Develop multiplexing microsphere-based immunoassays for detection and subtyping of AI virus and anti-AI antibodies (3) Develop an Oligonucleotide-based Lateral Flow Immunoassay (OLFIA) that detects AI nucleoprotein as well as H5 and H7 proteins.
Approach	(1) Express AI specific nucleocapsid (NP), hemaglutinine (H5, H6, H7) and neuraminidase (N1, N2, N3, N7) proteins. Use Bac-to-Bac® Baculovirus Expression System that facilitates rapid and efficient generation of recombinant baculoviruses (Invitrogen). (2) Coat microspheres with different fluorescent properties with baculovirus expressed NP, H5, H6, H7, N1, N2, N3 and N7 AI proteins (see Objective 1). React beads with serum samples from experimentally AI infected chickens and examined for the presence of antibodies specific for the different HA and N subtypes and NP protein. (3) The conjugation of antibodies with colloidal gold will provide an indicator of positive or negative samples and test completion, while the conjugated oligonucleotides will increase the specificity and number of samples to be assayed on a single OLFIA strip.

Table D-9: Analysis and Utilization of CpG-Motif Oligonucleotides as Potential Poultry Immunostimulatory Agents against Avian Influenza Challenge

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Analysis and Utilization of CpG-Motif Oligonucleotides as Potential Poultry Immunostimulatory Agents against Avian Influenza Challenge
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Evaluate and analyze the safety, efficacy, and the potential of CpGmotif oligonucleotides (ODN) as immunostimulatory agents against an avian influenza challenge.
Approach	Compare and evaluate an elicited immune response following set repetitive vaccination schedules with an inactivated AI and non-AI vaccine with and without CpG-motif ODN.

Table D-10: Characterization of Avian Influenza Viruses in Live Bird Market Settings

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Characterization of Avian Influenza Viruses in Live Bird Market Settings
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop a reagent, validate the diagnostic tests, and characterize avian influenza (AI) viruses in the live bird market setting; (1) Reagent Development: Develop reagents for which there are gaps, for example, a polyclonal H6N2 avian influenza antibody and a polyclonal H6 antibody (2) Validation of Diagnostic Tests: Validate the diagnostic tests used for three species: humans, swine, and birds; (3) Characterization of Avian Influenza Viruses in the Live Bird Market Setting: The birds in the live bird market setting will be sampled in two ways: a) Every other day for two weeks, birds will be choanally and cloacally swabbed. The location in the market of each bird swabbed will be recorded and mapped; b) the movements of poultry in the markets, and the isolation of AI viruses will be mapped for each market. These interactions will serve as input for an AI transmission model and the basis for a public health risk assessment.
Approach	The majority of all commercial poultry AI outbreaks in the United States can be traced back to live bird markets, as can the outbreaks of human AI in Hong Kong. Live bird markets in the United States are similar to those in Asia in character, and are often closely associated with the same communities in which newly smuggled birds are sold.

Table D-11: Role of Natural Killer Cells in FMDV in Cattle-Characterization and Identification of Modulation Strategies

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Role of Natural Killer Cells in FMDV in cattle-characterization and identification of modulation strategies
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)

Table D-11 (Cont.)

Question	Detail
Goal	Characterize the anti-viral potential of bovine NK cells. The objectives that will determine the importance of natural killer cells in the immune response to FMDV are (1) Determine the potential for NK cell mediated lysis of FMDV infected cells, and effect of cytotoxicity on reduction of infectious virus and (2) determine if natural killer cells with enhanced cytotoxic/effector potential increase in peripheral blood and traffic to sites of infection following FMDV infection.
Approach	Develop an in vitro assay for measuring general NK cell lysis of virally infected bovine targets and reduction of viral replication. Expression of cytotoxic and effector proteins (perforin, granulysin, FasL, IFNγ) by NK cells will be assessed by real time PCR, flow cytometry, and/or western blot, following culture of NK cells with virally infected macrophages. The ability of NK cells to reduce viral replication in infected macrophages and lyse infected targets will also be determined. The killing activity of bovine NK cells against virally infected targets will be assessed in the absence of exogenous cytokines and following activation with cytokines known to enhance cytotoxicity and effector function in NK cells in other species. In addition, the expression of cytokines by macrophages that activate NK cell proliferation and cytotoxicity will be assessed by real time PCR before and after viral infection. The in vitro system described above for analysis of NK cell activation by virally infected targets will be repeated using FMDV infected targets.

Table D-12: Spatial Epidemiologic Modeling of Foot-and-Mouth Disease in the United States

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Spatial Epidemiologic Modeling of Foot-and-Mouth Disease in the United States
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	(1) Model Development: To continue development, verification, and validation of the UCD foot-and-mouth disease (FMD) model. We anticipate that economic and environmental analyses will periodically need to be supported with data derived from the spatial-temporal epidemiologic simulation model to service the array of strategic analyses that will need to be pursed in the Center.

Table D-12 (Cont.)

Question	Detail
	(2) Model Geographic Expansion: To increase the model scope to permit the evaluation of FMD spread and its control throughout the U.S. The model being modified in Objective 1 will be extended to permit evaluation of statewide, regional and national-level epidemiologics. To permit this, we will incorporate information obtained through Objective 1 as well as identify and modify existing transmission algorithms, or develop new ones as needed.
Approach	(1) Collect and analyze direct and indirect contact data. Examine simulating interstate animal movements from an infected to susceptible state or region, using available state-level movement data. The intent is to make the model sufficiently functional to simulate a large-scale spatial-temporal disease simulation, such as that expected with FMD. (2) Obtain available data from governmental (state and national) agencies regarding animal location and intra- and inter-state movements.

Table D-13: Rift Valley Fever Modeling and Vulnerability Analysis

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Rift Valley Fever Modeling and Vulnerability Analysis
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	(1) Develop and refine geospatial models of Rift Valley fever (RVF) transmission and spread. (2) Apply these models to a vulnerability analysis for RVF.
Approach	(1) Develop a mathematical model of RVFV transmission between the relevant natural, livestock, and human populations susceptible in the United States, based on RVF disease ecology In this modeling approach, the number of individuals in the SEIR compartments changes with time according to key species-specific epidemiologic parameters such as incubation periods, population densities, periods of infectiousness, and birth and death rates. Validation will take place by confronting the model with trends from historical outbreaks recorded in Africa and the Middle East. At the end of this phase we will have developed a spatial model that will enable us to evaluate, for a unifocal outbreak, RVF dynamics and the likelihood of epizootic and epidemiologic versus enzootic and endemic spread. (2) Apply the models developed in Objective 1 to analyze geospatial RVF vulnerability. Simulation modules will emerge that address issues of scale, geospatial reasoning and agent behavior of disease spread. A state-level vulnerability assessment will be conducted in Texas once the geocoding of the relevant variables is completed.

Table D-13 (Cont.)

Question	Detail
	Given the geocoded database and the models from Objective 1, three major tasks are anticipated: • Analyze the risk of RVF spread as a function of livestock transportation networks. • Analyze risk of RVF spread as a function of herd distribution and size. • Analyze risk of RVF spread as a function of geospatial vector density. Other analyses, e.g., examining specific introduction scenarios to identify potential Achilles' heels in the domestic livestock handling system, may suggest themselves as research develops over the first two years of the project.

Table D-14: Middleware and Adapt Biophysical Models for Integration in the Foreign Animal and Zoonotic Disease Decision Support System

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Middleware and Adapt Biophysical Models for Integration in the Foreign Animal and Zoonotic Disease Decision Support System
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	(1) Analyze the system structure of critical biophysical models. (2) Develop a mechanism for easing integration and develop data coupling.
Approach	(1) Adapt Models: There are four important biophysical models for use in integrated impact assessment for policy and technology: SWAT, EPIC, PHYGROW, and NUTBAL. The focus of this project involves the following: a) PHYGROW – add a diet quality component to the plant growth model so that it can feed the intake function of the NUTBAL to all prediction of the interaction between forage supply and animal performance; b) NUTBAL – adapt the computation engine to an integrated modeling environment with multiple time steps and add a module for predicting reproductive performance based on body condition scores: c) SWAT – improve the structure of the data tables to ease integration with other plant growth and crop models. Review the computation needs of carcass disposal model and integrate new algorithms to accommodate the issue of various strategies to support the environmental analysis; 4) EPIC – adapt the new version of EPIC to the integrated environment to allow improved data flow between the models. (2) Develop Middleware: Perform a systems design analysis will be conducted to determine the desired degree of coupling necessary to service integrated analyses within FAD-ZD defense.

Table D-15: Collaborative Grid Computing System

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Collaborative Grid Computing System
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop a grid computing system network that supports multi-location computation in FAD-ZD defense.
Approach	The computation capacity of FAD-ZD defense core members is currently insufficient to support the expanded analysis and data needed to support the Center's activities. To address this issue and provide each institution with flexible computational capacity, a collaborative grid computing system will be put in place. This proposal only covers the component at TAMU, as another system will be linked from UCD with the existing system at USC-ISI.

Table D-16: Animal Population Estimators and Geocoded Databases for Direct and Indirect Disease Transmission

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Animal Population Estimators and Geocoded Databases for Direct and Indirect Disease Transmission
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	(1) Develop an ecologically based methodology for virtual, spatially explicit representation of livestock and wildlife populations. (2) Develop a comprehensive geocoded database of direct and indirect contact points for Texas and California to support epidemiologic modeling.
Approach	(1) Using the United States Geological Survey (USGS) 30-m resolution LANDSAT 5 based land use/land cover data set for the U.S. as the basis for habitat classification; use a "relative capacity" methodology for disaggregating county level data on cattle, sheep, and goats. Determine if other point sampling methods can be used to develop regional correction factors for redistribution of the animals. For wildlife species, we will focus on white-tailed deer and feral hogs. The resulting gridded livestock and wildlife population density data will be used in both the epidemiologic modeling and in the vulnerability analysis outline in the other work plans.

Table D-16 (Cont.)

Question	Detail
	(2) Implement a major data collection and geo-spatial designation of that data to support the epidemiologic modeling efforts as well as the vulnerability analyses that are planned in the other work plans. This study serves as the initial entry point for testing protocols and tools. Lessons learned will then serve as a template for testing in California and eventually move out to the rest of the U.S. after the first three years of this project. The primary criteria for geocoding the critical direct and indirect contact points within the Texas Pilot. This study will support variables for the foot-and-mouth disease (FMD) epidemiologic model being developed and deployed by UCD researchers. Once the Texas Pilot Study data is completed, we will transfer the lessons learned to California and complete that same data acquisition and geocoding process in that state as well.

Table D-17: Improving the Epidemilogic Engine of Current Foot-and-Mouth Disease Models

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Improving the Epidemilogic Engine of Current Foot-and-Mouth Disease Models
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Our overall objective is to define a “livestock premises” in intensive and extensive livestock operations as it pertains to both strategic and incident planning for accidental or deliberate introduction of foreign animal and zoonotic diseases. (1) The first objective is to assist in improving the “epidemiologic engine” of the current foot-and-mouth disease models developed at UCD to apply to larger geographical areas and models that can be used as platforms to develop methods to apply to the model at varying levels of scale from farm to national. (2) The second objective is to assist in developing an epidemiologic simulation environment capable of accommodating FAD-ZD beyond foot-and-mouth disease models.
Approach	(1) Use the geocoding results which use county censuses on cattle inventories and spatially available ecologic data to determine where range livestock will be most likely to aggregate and compare those results to physical inventories in the extensive modeling site in Uvalde where the UCD-FMD model will be applied.

Table D-17 (Cont.)

Question	Detail
	(2) Provide estimates livestock and wildlife spatial distributions and densities in a geographically well-defined pilot area for application in the UCD-FMD model. Test some long-standing hypotheses concerning the relative impact of intra-herd and inter-herd mixing as it is impacted by scale in the context of epidemiologic behavior of diseases such as FMD.

Table D-18: A Simulation Supported Exercise Environment to Support Foreign Animal and Zoonotic Disease Defense Strategic Planning and Training Needs

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	A Simulation Supported Exercise Environment to Support Foreign Animal and Zoonotic Disease Defense Strategic Planning and Training Needs
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop a simulation support exercise environment capable of supporting strategic planning needs for animal biosecurity and incident management training.
Approach	Study the elements and needs of strategic planning and incident management for a simulation-supported exercise. Use these elements to develop fundamental design of the system and involve requirement analysis and higher order architecture analysis. We intend to use a blended system of modeling involving agent-based modeling of decisions of livestock movements within regions and through market chains linked to probability networks. The incident entry point will reflect the disease diffusion process that results in transmission of the disease and in the early stages of development will use a blend of modeling tools from epidemiologic modeling with emphasis on foot-and-mouth disease (FMD). We anticipate that a mid-term activity will be a less sophisticated disease spread model will emerge that fills the gap between purely rule-based disease transmissions to high intensive epidemiologic models.

Table D-19: Vulnerability Assessment of Foot-and-Mouth Disease and Rift Valley Fever

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Vulnerability Assessment of Foot-and-Mouth Disease and Rift Valley Fever
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	The objective of this project is to provide a spatial assessment of vulnerability of cattle, sheep, and goat populations in Texas and California to foot-and-mouth disease (FMD) and to Rift Valley fever (RVF).
Approach	A team of collaborators will be assembled to create a first order "indexing" method for assigning severity of rate of disease spread for key direct and indirect contact points as part of the Texas Pilot Study. The resulting index map will then be exposed to an independent group of experts that have experience in disease spread and its management to react to the analysis. Based on the expert's reactions, the indexes will then be refined to allow creation of a second-order version of the vulnerability index to FMD and RVF in Texas. The resulting technique will then be applied in California and compared to the intensive modeling efforts of the FMD group based on their prior work there.

Table D-20: Gap Analysis to Support Animal Biodefense Strategic Planning

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Gap Analysis to Support Animal Biodefense Strategic Planning
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	The objective of this project is to identify the critical missing components of overall animal biosecurity strategies.
Approach	Gap analysis will focus on identifying the critical missing components of the overall animal biosecurity strategy. Such aspects as organizational roles, key decision makers, information gaps, technology gaps and resource gaps will be the focus of this analysis. The Center will also work closely with the National Biodefense Analysis and Countermeasures Center to support their analysis once a collaborative relationship is established and key components for analysis identified.

Table D-21: Economic and Environmental Consequences of Carcass Disposal

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Economic and Environmental Consequences of Carcass Disposal
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	(1) Develop spatial data and methodology to support decision making on environmental impact of carcass disposal. (2) Evaluate alternative carcass disposal methods and examine economic consequences of alternatives and regulatory compliance. (3) Determine environmental consequences of a series of economic scenarios targeting carcass disposal.
Approach	(1) To support the carcass disposal analysis, spatial data will be collected and methodology to support decision making on environmental impacts will be outlined. (2) This study will evaluate the integrated impact of the most promising alternatives to large volume carcass disposal. This study will also focus on an economic analysis of the cost of recommended disposal methods including those not allowed, and preparation of an integrated discussion of the alternatives, their cost, their environmental cost, and needed regulatory reforms to allow them. (3) Several spatial techniques will be explored to answer specific questions that can emerge during outbreaks. Environmental analysis using both the spatial data and the SWAT basin scale model will be used to explore impacts on issues of water quality and microorganism loading for the alternative carcass disposal methods identified in the economic analysis.

Table D-22: Developing a Scalable and Generic Epidemiologic Model

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Developing a Scalable and Generic Epidemiologic Model
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	The objective of this project is to develop a design structure for addressing epidemiologic modeling at multiple scales that can meet the needs of different types of diseases.

Table D-22 (Cont.)

Question	Detail
Approach	The idea of a scalable generic epidemiologic model has been discussed for many years among animal epidemiologists. The short-comings of all models and emerging ideas have all been noted. However, most of the debate has taken place in a limited decision environment and not subjected to serious planning where outcomes are expected of the design process. The Center is in a unique position to address this issue given the critical mass of epidemiologic modelers working with the Center. There is concurrence among key players that this activity should be pursued as a feasibility study. There will be three phases to this process. One is the initial "think tank" or brainstorming approach where the team meets with the goal of discussing what the key design issues of such a system are. We will then conduct a design analysis and prepare a document describing the system and how it should be built and used. The next phase in the out years would focus on development of a first-order working prototype that would serve as the foundation for exploring the concept further.

Table D-23: Economic Studies Regarding Comprehensive Decision Making for Agricultural Biosecurity

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Economic Studies Regarding Comprehensive Decision Making for Agricultural Biosecurity
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	(1) Contribute to a framework that unifies economic sector and regional analyses, biological science studies, information systems for the analysis of alternatives and options related to the intentional introduction of FAD-ZD. This project component will concentrate on providing the economic components of the framework. (2) Develop risk-based analysis capability on potential disease protocols affect the cost of disease management and outbreak control system. (3) Conduct analyses of strategic and operational options for scenarios using economic and other modeling capability to evaluate strategies and allocate resources. (4) Participate in the study of alternative carcass disposal methods examining economic consequences of alternatives and regulatory compliance. (5) Examine the effects of outbreaks and released information on the meat and milk demand and on the dynamic recovery of demand.

Table D-23 (Cont.)

Question	Detail
Approach	(1) Contribute Economic Component to Center DSS: Extend existing models and develop new ones to provide economic components involving the following: Regional Livestock Model: For Texas and California, develop models portraying stochastic outbreaks, initially for a foot-and-mouth disease; Sector-Wide Agricultural Model: modify the national Agricultural Sector Model (ASM), to include disease outbreak stochastic events. (2) Risk Analysis: Address how the incorporation of potential foreign animal and zoonotic disease protocols lowers the cost. (3) Analysis of Selected Disease Cases: Conduct analyses of strategic and operational options for a set of selected disease case scenarios by pursuing analysis of strategic and operational options (4) Outbreaks, Meat and Milk Demand, Information, and Recovery: Review the literature and do statistical investigations on how such outbreaks have altered demand in historical settings and how information management altered the rate of recovery.

Table D-24: Economic Analysis of Foreign Animal and Zoonotic Disease Policies

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Economic Analysis of Foreign Animal and Zoonotic Disease Policies
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	1) Develop a framework unifying economic sector and regional analyses; 2) Conduct risk-based analysis on how the incorporation of potential alternative protocols affects the cost of the total disease management; 3) Conduct analyses of strategic and operational options for scenarios using economic modeling capability to evaluate alternatives at the strategic and management levels; 4) Analyze the consequences of an outbreak of foot-and-mouth disease (FMD).
Approach	(1) Develop a Regional Economic Analysis Model: Extend existing models with economic components and provide the capability to interchange data. (e.g., California Regional Livestock Model: Develop a model to interact with a FMD epidemiologic model that includes the economic impacts of stochastic outbreaks) (2) Risk Analysis: The interaction of the epidemiology and regional economic models will enable a formal economic risk analysis of potential alternative FAD-ZD protocols. (3) Disease Case Analyses: Conduct analyses of strategic and operational options for disease cases scenarios. (4) Analysis of the Trade Consequences of FMD: Evaluate the effects of trade barriers and product quality certifications on international trade, inter-regional trade and on consumer demand.

Table D-25: Risk Assessment and Analysis for Improved Planning for Foreign Animal & Zoonotic Disease Defense

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Risk Assessment and Analysis for Improved Planning for Foreign Animal & Zoonotic Disease Defense
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Develop a risk-based understanding of how the incorporation of potential alternative foreign animal and zoonotic disease protocols can lower costs.
Approach	Using lessons learned from participating in a CARVER+shock process with a feedlot in the Panhandle of Texas, we will review the process and investigate improved protocols for conducting risk analysis that integrates the new data and analysis technologies developed by others in the FAZD Center. Ultimately, risk and cost consequences trade off analysis will employ a more holistic approach toward developing the risk and cost minimizing protocol involving a risk-based analysis methodology.

Table D-26: Systems Design Requirements for an Integrated Modeling Environment

Question	Detail
Program	National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
Project Name	Systems Design Requirements for an Integrated Modeling Environment
Name of Principal Investigator or Performer	Texas A&M University (TAMU) and collaborating partners – University of California, Davis (UCD), University of Texas, Medical Branch (UTMB), University of Southern California (USC)
Period of Performance	July 31st 2004 – December 31st 2007 (may include no cost extension)
Goal	Provide guidance on design of computational environments being developed to integrate an array of analytical tools used for data acquisition/access and modeling of risk/vulnerability, epidemiologic response, livestock transportation systems and economic consequences of threats/intervention scenarios.
Approach	Design of an integrated modeling environment for large scale, integrated modeling of epidemiologic response and economic consequences of intentional introduction of foreign animal and zoonotic diseases.

Table D-27: Food Biological Agent Detection System (FBADS)

Question	Detail
Program	Surveillance and Detection R&D
Project Name	Food Biological Agent Detection System (FBADS)
Name of Principal Investigator or Performer	Lead: Edward Rhyne, DHS-Science & Technology
Period of Performance	FY 2007 – FY 2008
Goal	Develop new detectors and concepts of operation for the protection of the Nation's critical food infrastructure which are compatible with the existing food processing operations
Approach	Specifications for the detection system were worked out in partnership with FDA and industry representatives, a BAA issued (see hsarpabaa.com), and performers selected. Phase 1 will prototype detection of a representative agent in milk. Phase will extend this technology to detection of multiple agents in a variety of liquid food products.
Current Status	Food Biological Agent Detection System (FBADS) Phase 1 prototype has been developed and will enter testbed at the start of FY08, working with one of the NCFPD's industrial partners. Phase 2 funding is currently lacking, delaying the extension of this system to multiple agents in a variety of liquid food products.

Table D-28: Threat Agent Survivability in Food Matrices

Question	Detail
Program	Threat Awareness and Characterization
Project Name	Threat Agent Survivability in Food Matrices
Name of Principal Investigator or Performer	National Biodefense Analysis and Countermeasure Center (NBACC)/Biological Threat Characterization Center (BTCC)
Period of Performance	FY 2006 – FY 2008
Goal	Evaluate the stability of agents of concern in selected food matrices to provide improved characterization of the risk posed by these agents and to guide needed protective actions
Approach	This program consists of a number of experiments each focused on a different agent-food matrix combination, with individual performers selected for the expertise and facilities for conducting these studies. In general, each experiment consists of two phases with the first phase involving the development of an assay for the agent that is compatible with the food matrix. The second phase of the project analyzes the stability of the agent in the food matrix and, in some cases, the infective dose in the animal model.
Current Status	Several experiments have been completed and a number of others are still undergoing review and awaiting approval.

Table D-29: Bioterrorism Risk Assessment (BTRA)—Food & Agricultural Aspects

Question	Detail
Program	Threat Awareness and Characterization—Biological Threat Characterization Center (BTCC)
Project Name	Bioterrorism Risk Assessment (BTRA)—Food & Agricultural Aspects
Name of Principal Investigator or Performer	National Biodefense Analysis and Countermeasure Center (NBACC)
Period of Performance	FY 2006 – FY 2008
Goal	The Bioterrorism Risk Assessment (BTRA) provides critical assessments to allow for risk-informed investments in national strategic biodefense planning. The BTRA identifies key knowledge gaps and defines critical vulnerabilities. The Lab Experiments and Studies portion of the program is used to address key knowledge gaps on technical feasibility and vulnerability for biothreats with major operational impact. Subsequent iterations of the BTRA are informed by previous assessments and continue to expand with the evolving nature of the threat.
Approach	The BTRA accomplishes its goal via a thorough analysis of the likelihood and consequence of a biological attack – from the acquisition and production of an agent, to its dissemination in a broad range of scenarios, to the human health and economic impacts of those attacks. The resulting information is used to prioritize the risks posed by various agents, to identify vulnerabilities, and to identify associated major scientific knowledge gaps. The BTRA takes advantage of the Probabilistic Risk Assessment (PRA) approach. Using a prioritized list of potential bioterrorism and animal disease agents determined by the interagency, the BTRA aggregates the risk based on estimations of consequences and probabilities through millions of enumerated scenarios.
Current Status	Several experiments have been completed and a number of others are still undergoing review and awaiting approval.

Table D-30: Supply Chain Security Best Practices—Suppliers and Manufacturers

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Supply Chain Security Best Practices—Suppliers and Manufacturers
Name of Principal Investigator or Performer	Lead: Davis Closs, Michigan State University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Development security assessment and benchmarking tool that will help companies (1) understand and organize their supply chain security practices, particularly the often overlooked areas of communications, management support, and interaction with suppliers, customers, and carriers, (2) identify practices that have the greatest impact on efforts to enhance supply chain security, and (3) provide a low-risk tool to educate supply chain partners regarding the importance of implementing security practices.

Table D-30 (Cont.)

Question	Detail
Approach	The framework for documenting and characterizing security initiatives developed in this project is based on a review of the literature and on interviews with supply chain and security executives, followed by surveys of food companies. The results will be used to foster continuous improvements in supply chain security. The primary focus of this project is an assessment and benchmarking spreadsheet tool for companies to compare the security practices and processes of their corporate operations, divisions, suppliers, and customers.

Table D-31: Supply Chain Productivity and Resiliency—Logistics and Transportation

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Supply Chain Productivity and Resiliency—Logistics and Transportation
Name of Principal Investigator or Performer	Lead: Alan Erera and Chip White, Georgia Tech
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	To develop a supply chain resiliency model that supports inventory planning in single-source supply chains to reduce costs associated with random disruptions at a single chokepoint.
Approach	Collaborators at Georgia Tech are analyzing security practices among logistics and transportation carriers serving the food industry.

Table D-32: Supply Chain Benchmarking—Wholesale, Retail, and Food Service

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Supply Chain Benchmarking—Wholesale, Retail, and Food Service
Name of Principal Investigator or Performer	Lead: Jean Kinsey, University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Conduct a survey to benchmark current supply chain management practices and use the results to provide (1) confidential assessments for each participating company on their current level of preparedness for prevention, detection, response, and recovery, along with specific recommendations for improving their preparedness; (2) a benchmarking software tool for industry use; (3) a set of best practices for enhancing food defense at wholesale and retail food companies, and (4) overall recommendations on improving food security practices, protecting employees and consumers, reducing vulnerabilities, and enhancing consumer confidence in the safety of the food supply.

Table D-32 (Cont.)

Question	Detail
Approach	Data are obtained through interviews and comprehensive surveys with company executives. The results will be used to provide benchmark reports on preparedness to participating companies and to develop recommendations on improving security, protecting employees and consumers, reducing vulnerabilities, and enhancing consumer confidence in the safety of the food supply.

Table D-33: Supply Chain Standards

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Supply Chain Standards
Name of Principal Investigator or Performer	Lead: Omar Helferich and John Griggs, GSC Mobile Solutions
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop a comprehensive, dynamic, strategic process by which various stakeholders and end users can customize, implement, and monitor best practice initiatives to enhance food defense.
Approach	Review existing and emerging food defense standards, metrics, best practices, and guidelines; review industry feedback on gaps and priorities; develop a pilot strategic process to achieve a best practices corporate program; report on expansion of guidelines to cover the extended supply chain; report results of a survey of environmental health agencies to assess needs for linkage between the food industry and environmental health specialists for improved response capabilities at the local level.

Table D-34: Incident Management Infrastructure

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Incident Management Infrastructure
Name of Principal Investigator or Performer	Lead: John Griggs and Omar Helferich, GSC Mobile Solutions
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop an integrative software program for communications and information management, consistent with the National Incident Management System (as required by HSPD-5), to support secure, two-way communication for supply chain monitoring and response in the event of a catastrophic food-related incident.
Approach	Develop a software prototype, incorporating industry standard protocols, in-field data collection connectivity, and mapping features; and report on the cost-effectiveness of the system in supporting incident management.

Table D-35: Consequence Management System (CMS)

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Consequence Management System (CMS)
Name of Principal Investigator or Performer	Lead: Jeff Sholl, BT Safety LLC
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Realistic models for food system events and public health response capabilities to enable improved interventions/countermeasures.
Approach	Develop a Consequence Management System (CMS) modeling tool; model the public health system response; evaluate timelines for botulism outbreaks; and analyze and model comprehensive public health investigations of multi-state food-borne disease outbreaks.

Table D-36: Modeling the Public Health System Response to a Terrorist Event

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD
Project Name	Modeling the Public Health System Response to a Terrorist Event
Name of Principal Investigator or Performer	Lead: Don Schaffner, Rutgers University, and Craig Hedberg, University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop a computer simulation of the public health system's response to a deliberate attack on the food system that allows the estimation of the speed with which various types of attacks propagate through the system. Use the results to identify potential weak points and bottlenecks in the system where allocation of additional resources may have the greatest benefit.
Approach	Three specific sets of simulations are being developed: (1) the speed and effectiveness of public health responses based on the size, scope, and characteristics of the outbreak, (2) the potential for consumer-based food borne illness complaint systems to lead to the identification of contaminated food products, and (3) the process of decontaminating food facilities after an event and reconditioning them for the safe resumption of food production (in conjunction with NCFPD Disposal and Decontamination teams). The simulation will provide a unique opportunity to evaluate variability and uncertainty in public health responses to events, either intentional or unintentional.

Table D-37: Evaluation of Timelines for Botulism Outbreaks

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Evaluation of Timelines for Botulism Outbreaks
Name of Principal Investigator or Performer	Lead: Craig Hedberg, University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)

Table D-37 (Cont.)

Question	Detail
Goal	Analyze how botulism outbreaks are currently handled and use the results to inform recommendations for enhanced preparedness and support the development of public health response models with NCPFD's Consequence Management System.
Approach	This study examines how botulism cases are detected and successfully investigated, yielding recommendations for enhancing preparedness and coordinating surveillance; this includes areas such as more consistent practices within hospitals and emergency rooms, improved education for health care providers regarding recognition of botulism cases, enhanced coordination among local, state, and federal public health authorities to identify related cases and outbreaks, use of public health laboratories for advanced etiologic studies, and immediate interview of cases and use of detailed food exposure questionnaires.

Table D-38: Public Health Investigation of Multistate Foodborne Outbreaks

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Public Health Investigation of Multistate Foodborne Outbreaks
Name of Principal Investigator or Performer	Lead: Craig Hedberg, University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	This study evaluates how surveillance processes and decision-making structures affected the initiation and outcome of multi-state outbreak investigations reported to CDC from 1998 to 2003, with specific reference to how decision-making structures affect the timelines of these investigations.
Approach	Data on all reported multistate outbreaks of foodborne diseases during the past decade are obtained from CDC and state health departments and are analyzed to understand the response timelines and the factors that drive them.

Table D-39: Economic Impact Analysis

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Economic Impact Analysis
Name of Principal Investigator or Performer	Lead: Tom Stinson, State of Minnesota and University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Provide estimates of potential indirect and direct economic impacts of a terrorist attack on the food system using a large-scale econometric model of the U.S. economy to simulate the changes in GDP caused by a major terrorist attack on any sector.

Table D-39 (Cont.)

Question	Detail
Approach	Model and scenario creation using historical data
Current Status	Currently addressing two additional areas: (1) development of a model to estimate the time before the food sector recovers from an attack; (2) sensitivity analysis of the national economic results.

Table D-40: Consumer/Citizen Survey

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Consumer/Citizen Survey
Name of Principal Investigator or Performer	Lead: Jean Kinsey and Tom Stinson, University of Minnesota and State of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Conduct a survey to better characterize public attitudes towards ant-terrorism activities to better inform preparedness, response and risk communication strategies.
Approach	Design, pilot test, and conduct a national survey on public attitudes toward anti-terrorist activities; analyze the data to determine common themes across demographic groups such as regions, age, income, and ethnicity; apply various data-mining techniques (e.g., testing for statistically significant differences in various attitudes and values by types of consumers); prepare papers and presentations.

Table D-41: Reduction of Economic Impact

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Reduction of Economic Impact
Name of Principal Investigator or Performer	Lead: William Nganje, North Dakota State University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Identify benefits in efficiency and productivity to the food system from the adoption of cost-effective new security measures
Approach	This project will develop economic “real option” models (using the tomato garden matrix[t] and the stochastic optimization model) to determine private sector costs and value of risk reduction (risk premium) of security measures such as RFID (radio frequency identification) and RFEM (radio frequency environmental monitors) for alternative mitigation strategies.

[t] The tomato garden matrix (as proposed by Timothy Luehrman in an article in the Harvard Business Review, 1998) is a framework for identifying and prioritizing a set of nested options, a series of strategies explicitly designed to affect each other, to analyze their cost-effectiveness. The matrix is used here to analyze public investment strategies for all sectors of the grain supply chain to help determine cost-effective strategies for surveillance and mitigation of agroterrorist threats to the grain production and logistics system.

Table D-42: Statistical Risk Metrics (using Extreme Value Theory)

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Statistical Risk Metrics (using Extreme Value Theory)
Name of Principal Investigator or Performer	Lead: Hamid Mohtadi, University of Wisconsin-Milwaukee and University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Use extreme value theory to estimate the probability of terrorist attacks and to serve as a risk management tool for the food industry, the insurance industry, and government.
Approach	A statistical methodology known as "extreme value theory" is used to measure, calculate, and forecast the risk of rare but catastrophic events, such as an attack on the food system. To construct the risk metric analysis, this project developed a new dataset of instances of chemical, biological, and radionuclear (CBRN) attacks and combined it with data compiled from an existing dataset through the National Memorial Institute for the Prevention of Terrorism (MIPT). The model also allows the calculation of expected recurrence period for a catastrophic event.

Table D-43: Determining Optimum Investments in Security Measures and Assessing Vulnerability in Information Flow

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Determining Optimum Investments in Security Measures and Assessing Vulnerability in Information Flow
Name of Principal Investigator or Performer	Lead: Hamid Mohtadi, University of Wisconsin-Milwaukee and University of Minnesota
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Identify optimum levels of investments needed to improve information exchange and communication among supply chain partners and to compare those best practices with actual current practices in the food industry
Approach	The analysis is based on the use of an analytical/statistical model incorporating data on the probability of catastrophic events derived from the Statistical Risk Metrics project, as well as data on actual industry practices derived from NCFPD's supply chain benchmarking surveys.

Table D-44: Models of Interdependent Security in Food Supply Chains

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Models of Interdependent Security in Food Supply Chains
Name of Principal Investigator or Performer	Lead: Vicki Bier, University of Wisconsin–Madison, and William Nganje, North Dakota State University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)

Table D-44 (Cont.)

Question	Detail
Goal	Develop models for the dairy industry (single and multiple dairies) and for the wheat industry including cost and risk premium data and use the model to analyze the effects of deliberate introduction of contaminated ingredients.
Approach	This project will use the tools of engineering risk analysis and game theory. The analysis focuses on the wheat and dairy industries to demonstrate the effects of introducing deliberately contaminated ingredients early in the farm-to-table food chain.
Current Status	(Year 3 project; began in 2006)

Table D-45: Electrochemical Biosensors for *B. anthracis*

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Electrochemical Biosensors for B. anthracis
Name of Principal Investigator or Performer	Lead: Vangie Alociljia, Michigan State University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop electrochemical biosensor technology for rapid, sensitive, and specific detection of select bioterrorism agents in food products.
Approach	Basic laboratory research, development, testing and evaluation.
Current Status	Late stages of development: system refinement and improvement.

Table D-46: Rapid Testing for Botulinum Toxin using Egg Yolk Antibodies

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Rapid Testing for Botulinum Toxin using Egg Yolk Antibodies
Name of Principal Investigator or Performer	Lead: Mark Cook, University of Wisconsin–Madison
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	The capability of laying hens to produce high levels of antibodies in egg yolk offers the potential for large-scale antibody production—a key step in meeting a sudden demand for sufficient quantities of antibody testing reagents during a major contamination event. This project also focuses on the development of effective neutralizing antibodies as a treatment for the ingestion of food contaminated with botulinum toxin.
Approach	Basic laboratory research and development.

Table D-47: Botulinum Neurotoxin Sensing Technologies

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Botulinum Neurotoxin Sensing Technologies
Name of Principal Investigator or Performer	Lead: Eric Johnson, University of Wisconsin–Madison
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	This study focuses on the development of a sensitive and specific micro-scale detection system for BoNT that can be used to detect BoNT in intentionally contaminated foods, with results communicated using wireless technology for remote monitoring. It will also facilitate timely and appropriate communication about locations and specific targets of intentional contamination.
Approach	Laboratory research, development, testing and evaluation.

Table D-48: FASTMAN Integrated Device for Detection of Select Agents

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	FASTMAN Integrated Device for Detection of Select Agents
Name of Principal Investigator or Performer	Lead: Vivek Kapur, University of Minnesota/ANDX
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop and validate analytic methods for the quantitative assessment of B. anthracis as a model for pathogens that could be involved in intentional contamination incidents.
Approach	Laboratory research, development, testing and evaluation.
Current Status	Currently developing an Internal Amplification Control, an essential reagent control needed (and previously unavailable) to quantitatively estimate the burden of the target pathogen in a sample in a range of existing platforms and assays.

Table D-49: Biosensors for Detection of Chemical Toxins

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Biosensors for Detection of Chemical Toxins
Name of Principal Investigator or Performer	Lead: Paul Takhistov, Rutgers University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop an immunosensor that can be integrated into existing food safety and biosecurity systems for routine, on-site detection of foodborne toxins in the food production, packaging, and distribution chain.
Approach	Laboratory research, development, testing and evaluation.

Table D-50: Bioluminescent Bacteria as Biological Sensors for Toxic Agents in Food

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Bioluminescent Bacteria as Biological Sensors for Toxic Agents in Food
Name of Principal Investigator or Performer	Lead: Evangelyn Alocilja, Michigan State University; Undergraduate Student: Trevor McLean, MIT & Michigan State University
Period of Performance	August 2006 - ?
Goal	Evaluate the effectiveness of using luminescent bacteria for rapid, non-specific detection of toxic contaminants in food products.
Approach	Develop a method of maintaining luminescent bacterial growth in various food matrices; evaluate the effect of toxic substances on the bioluminescent properties of the bacteria under pure bacterial cultures; and develop a method of measuring bacterial bioluminescence in artificially contaminated food samples.

Table D-51: Bioluminescent Imaging for High-Throughput Screening for Bacterial Pathogens and Toxins

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Bioluminescent Imaging for High-Throughput Screening for Bacterial Pathogens and Toxins
Name of Principal Investigator or Performer	Lead: Mansel Griffiths, University of Guelph; Investigator: Lubov Brovko, University of Guelph
Period of Performance	August 2006 - TBD
Goal	Develop cell-based biosensors for rapid, high throughput screening for the presence of potential bacterial pathogens and toxins.
Approach	Develop cell-based sensors that monitoring the level of bioluminescence to detect and quantify the presence of biological agents; test the hypothesis that the number of bacterial cells or toxin molecules attached to the surface of a mammalian cell monolayer, and the changes in concentration of certain metabolites (such as calcium ions and ATP) in mammalian cells after infection, will correlate with bacterial pathogenicity and potential toxic effects.

Table D-52: A Systematic Approach toward the Detection of Bioterrorism Agents in Complex Sample Matrices

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	A Systematic Approach toward the Detection of Bioterrorism Agents in Complex Sample Matrices
Name of Principal Investigator or Performer	Lead: Lee-Ann Jaykus, North Carolina State University; Investigators: Ruben Carbonell, Orlando Rojas, North Carolina State University; Srinand Sreevatsan, University of Minnesota
Period of Performance	August 2006 - TBD

Table D-52 (Cont.)

Question	Detail
Goal	Develop sample preparation techniques to facilitate the detection of selected agents in complex food matrices.
Approach	Develop engineered, selective ligands to facilitate pre-analytical processing and subsequent detection of priority pathogens and bioagents (*B. anthracis* spores and ricin) in foods, based on the development of new robust surface chemistries that can be applied to the ligands (short peptides and nucleic acid aptamers) for pathogen binding.

Table D-53: Extraction, Concentration, and Detection of Toxins in Solid Food Systems using Molecular Imprinted Polymer Films

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Extraction, Concentration, and Detection of Toxins in Solid Food Systems using Molecular Imprinted Polymer Films
Name of Principal Investigator or Performer	Lead: Keith Warriner, University of Guelph; Investigators: Subrayal Reddy, University of Surrey (UK)
Period of Performance	August 2006 - TBD
Goal	Develop novel sample extraction and concentration methods to enable detection of nanogram quantities of toxins from solid food matrices.
Approach	To develop methods for (1) extracting toxins from food homogenates using ultra-filtration; (2) concentrating toxins using solid phase extraction based on molecular imprinted polymers formed from hydrogels; (3) detecting concentrated toxins using reagentless impedimetric immunosensors fabricated by immobilizing antibodies onto the surface of conducting polymer electrodes; and (4) integrating these extraction, concentration, and detection steps into an automated unit to enable detection of nanogram quantities of biological and chemical toxins; in Year 1 this project will focus on proof-of-concept for extraction and concentration (parts 1 and 2).

Table D-54: Stability of Ricin and Abrin to Conventional Food Processing Operations and Investigations of Food Contact Surface Decontamination Methods

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Stability of Ricin and Abrin to Conventional Food Processing Operations and Investigations of Food Contact Surface Decontamination Methods
Name of Principal Investigator or Performer	Lead: Peter Varelis, National Center for Food Safety and Technology–Illinois Institute of Technology (NCFST-IIT); Investigators: Martin Cole, NCFST-IIT; Lauren Jackson, FDA
Period of Performance	August 2006 - TBD
Goal	Provide data on the stability of ricin and abrin in foods under various food processing conditions.

Table D-54 (Cont.)

Question	Detail
Approach	Evaluate the chemical stability and cytotoxicity of abrin under some common food processing conditions in milk, orange and apple juices; develop information on the decontamination of processing plant equipment following intentional contamination with ricin or abrin; establish a state-of-the-art analytical capability for performing activity-based assays for ribosome-inhibiting proteins such as ricin and abrin in order to measure the potency of such proteins after various treatments such as high-pressure processing and both UV and high-temperature pasteurization.

Table D-55: Fate of Toxins in At-Risk Foods

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Fate of Toxins in At-Risk Foods
Name of Principal Investigator or Performer	Lead: F. Omar Holguin, New Mexico State University; Investigators: Ramona Parra, Andrew Barber, Myles Culbertson, New Mexico State University; Graduate Students: Veronica Vasquez, Chelsie Rollins, New Mexico State University
Period of Performance	August 2006 - TBD
Goal	Provide data on the stability of a broad range of toxins in high risk foods.
Approach	Evaluate the chemical stability of potential plant, fungal, marine, and algae toxins (e.g., nicotine, solanine, aflatoxin, tetrodotoxin, anatoxin-A, aconitine, and T-2 toxin) in high-risk foods and the degradation of certain chemical classes by characterizing thermal toxin breakdown products; identify markers indicating the presence of a toxin that may have been neutralized during processing.

Table D-56: Use of Commercial Household Sanitizers to Inactivate Spores

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Use of Commercial Household Sanitizers to Inactivate Spores
Name of Principal Investigator or Performer	Lead: Katie Swanson and Bruce Cords, Ecolab Inc
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Evaluate several types of household disinfectant-sanitizers that have potential for use by consumers to decontaminate foods or surfaces in the home, thereby enabling consumer control.
Approach	Laboratory research, development, testing and evaluation.

Table D-57: Containment and Remediation System

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Containment and Remediation System
Name of Principal Investigator or Performer	Lead: Susan Harlander, BT Safety LLC
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop a functional containment and remediation software system for planning, managing, and tracking a variety of activities critical to minimizing the impact of an intentional food contamination incident and managing the recovery process—disposal of contaminated products, decontamination of sites, certification of readiness for resumption of business, and communication strategies.
Approach	Incorporation of validated agent- and food-specific remediation protocols and recommendations on the use of personal protection equipment.

Table D-58: Plasma Technology to Decontaminate Surfaces

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Plasma Technology to Decontaminate Surfaces
Name of Principal Investigator or Performer	Lead: Amy Wong and Ferencz Denes, University of Wisconsin–Madison
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Apply atmospheric pressure plasma-aided technologies to the development of methods to disinfect surfaces and air in food processing environments contaminated with B. cereus spores, a surrogate agent for B. anthracis.
Approach	Apply atmospheric pressure plasma-aided technologies to the development of methods to disinfect surfaces and air.

Table D-59: Evaluation of Methods for Decontamination of Food Processing Equipment and Facilities Deliberately Contaminated with *Bacillus* Spores

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Evaluation of Methods for Decontamination of Food Processing Equipment and Facilities Deliberately Contaminated with *Bacillus* Spores
Name of Principal Investigator or Performer	Lead: Martin Cole and Peter Slade, National Center for Food Safety and Technology–Illinois Institute of Technology
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Develop more moderate and less destructive options for decontamination within a food-processing environment, using aqueous and gaseous technologies.
Approach	Laboratory research, development, testing and evaluation.

Table D-60: Toxin/Pathogen Inactivation and Disposal of Intentionally Contaminated Foods

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Toxin/Pathogen Inactivation and Disposal of Intentionally Contaminated Foods
Name of Principal Investigator or Performer	Lead: Craig Benson, University of Wisconsin–Madison
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Summarize and document the state of knowledge concerning microorganisms and toxins regarding their susceptibility to various physical and chemical decontamination processes (including heat, acid ozone, UV light, radiation, and chlorine) and their likely fate during disposal into landfills or treatment in sewage treatment facilities.
Approach	(1) A comprehensive literature review on microorganisms and toxins with regard to decontamination and likely fate during disposal into landfills and during sewage treatment, (2) two focus meetings with key experts to identify issues for research, and (3) a first level risk analysis of treatment and disposal options in the event of a contamination incident.
Current Status	Pilot project that began in 2006.

Table D-61: Risk Communication Training

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Risk Communication Training
Name of Principal Investigator or Performer	Lead: Will Hueston, University of Minnesota, and Tim Sellnow, North Dakota State University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	(1) Development of best practices, key messages, and strategies for active engagement of diverse audiences and stakeholders in effective risk communication prior to, during and after potentially catastrophic food system incidents; (2) development of culturally-specific risk communications messages and delivery strategies for minority and under-represented populations; (3) development of online training modules and instructional resources; (4) collection of visuals that support accurate and informative media coverage of food system events; (5) delivery of communications training for subject matter experts to enhance their effectiveness as spokespersons; and (6) identification of a rapid response team to support NCFPD and its external partners and stakeholders with risk and crisis communications during a food system event.
Approach	A team of experts assembled for this effort to bridge a wide range of disciplines: agriculture, food science, veterinary medicine, communication, psychology, journalism, and public health.
Current Status	Currently collaborating with the International Food Information Council (IFIC) in the development of an online trainer's resource repository.

Table D-62: Educational Programs

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Educational Programs
Name of Principal Investigator or Performer	Lead: Ed Mather, Michigan State University
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	This project focuses on expanding the availability of educational opportunities and developing expertise in all aspects of food protection and defense. Its goals include: (1) collecting and disseminating educational resources, including curricula, pertaining to food protection and defense, drawing from a wide range of disciplines including education, security, food production, biological sciences and public health; (2) identifying educational needs within the food system and evaluating them by supply chain component, discipline, and scientific depth; (3) establishing protocols for the integration of education and training materials, (4) creating a comprehensive clearinghouse of educational resources and content materials for course development; (5) assessing and evaluating educational delivery methods to allow continual enhancement; and (6) identifying and creating opportunities for students to study in food protection and defense fields.
Approach	Multidisciplinary group of subject matter experts available for input and; analysis and assessment of educational needs in food defense; identification and compilation of existing educational resources; development of new courses and programs in food defense to fill gaps identified by the needs assessment; evaluation of delivery methods and technology usage for food defense education.

Table D-63: Assessment of Industry Use of Best Practices for Food Security

Question	Detail
Program	National Center for Food Protection and Defense (NCFPD)
Project Name	Assessment of Industry Use of Best Practices for Food Security
Name of Principal Investigator or Performer	Lead: Fred Shank, Institute of Food Technologists
Period of Performance	July 1st 2004 – November 30th 2007 (may include no cost extension)
Goal	Produce take-home messages and appropriate checklists, outlining the steps to consider when developing effective food defense procedures and practices.
Approach	Development of a survey instrument for food defense plan assessment, conduct the assessment, and use the results to formulate take-home messages and to develop food defense checklists.
Current Status	Developed the primary version of the best practices assessment tool; numerous food industry safety/security personnel have reviewed the tool; in March-May 2006, presentations to food industry audiences in Wisconsin, California, Arizona, and Washington.

Table D-64: Criticality Study

Question	Detail
Program	University Programs-Centers of Excellence
Project Name	Criticality Study
Name of Principal Investigator or Performer	Lead: Shaun Kennedy, UMN; Gary LaFree, START; Detlof ConWinterfelt, CREATE; Neville Clark & Mike Orocz, FAZD; John Ambrosiano, Kevin J. Saeger, Mac Brown, LANL; Frank Busta, John Hoffman, Jeff Sholl, Sue Harlander, Craig Hedberg, Don Schaffner, NCFPD; Paul Kaplan, Sandia
Period of Performance	March 01, 2007 – November 01, 2007
Goal	Develop a suite of scalable, risk-based tools for States to identify and rank their at-risk food and agriculture systems, critical components and assets
Approach	Three phase project: Phase 1 develops an approach for identifying critical components and assets; Phase 2 will deliver the preliminary guidelines for States to identify critical food and agriculture sector (FAS) assets requiring protection. Phase 3 will see the delivery of a 2008 FAS Guidance to States in a format that will provide instructions and procedure to allow the states to undertake the preliminary assessment and deliver to the FAS steering committee.
Current Status	Phase I

* In addition to all aforementioned studies, there are seven additional studies that have been approved to initiate in year 3 (as of August 2006).

* The initial lead academic collaborators in NCFPD's research consortium include the University of Minnesota (UMN), Michigan State University (MSU), University of Wisconsin – Madison (UW), North Dakota State University (NDSU), Georgia Institute of Technology, University of Tennessee – Knoxville (UTK), and individual collaborators from 17 other universities. Additional research collaborators are drawn from private sector research organizations, federal and state health and agricultural agencies, and professional organizations.

This page intentionally blank

Attachment E: Capability Gap Statements

Item	Response
Tracking Number	2008-001-FDA (Food and Agriculture Sector)
Date	June 20, 2008
Proposed Title of Capability Gap	Biological and chemical agent detector for use with a multitude of food matrices
Goal/Objective/Driver to which Capability Gap Responds	HSPD-9 states that the Secretaries of DHS, USDA, and HHS will conduct countermeasure research and development that will include new methods of detection, for high consequence agents in the food supply.
Gap in Existing Capabilities	The intentional introduction of biological or chemical agents into the U.S. food supply could have devastating public health, economic, and psychological consequences. For many of the agents that could be intentionally introduced, there are either limited or no methods available for their detection. Also, the FDA does not conduct routine sampling of food products for the detection of agents of concern. The food industry will typically perform quality control testing for agents that pose a food safety concern, e.g. *Salmonella* spp., *Listeria* spp., etc. Also, the methods that are currently available utilize a variety of technologies and will typically only detect one agent. There is a great need for a single platform that will allow for the detection of several biological and chemical agents at the same time and within a short amount of time.
Description of Required Operational Capability	*Summarize the high-level mission need and capability requirement (this should not be system specific).* The federal government and the food industry have an immediate need for a single platform detector that will detect biological and chemical agents of food safety and food defense concern. The technology must be easy to use and of a reasonable size. *Define high-level critical task elements and performance requirements:* ▪ *Describe the specific desired outcome not presently achievable:* – A bench-top single platform detector that will detect chemical and biological agents in a variety of food matrices. ▪ *Identify the operational performance parameters (capabilities and characteristics) required for the proposed capability:* – Threat agents detected. Threshold: Must detect but not be limited to *Bacillus anthracis*, *Burkholderia mallei, Burkholderia psuedomallei, Clostridium botulinum* toxin A and B, *Francisella tularensis*, *Escherichia coli* O157:H7, *Listeria monocytogenes, Salmonella* spp *Yersinia* spp., abrin, aconitine, amanitin, cyanide, and fluoroacetic acid. – Weight: Threshold: Goal: bench-top model – Specificity: Threshold: Goal: needs to be discussed – Time to Detection: Threshold: 30 min. Goal: 15 min. – Detection Probability: Threshold: 95%; Goal: 99% – Operation: Easy to use; minimal sample preparation

Item	Response
	▪ *Provide examples of who might use this capability - where, when and how, and -under what conditions:* – Used by food industry and federal government in a laboratory environment – Must connect to standard power sources. ▪ *Describe interfaces with other systems/components:* – Unknown at this time
Identification of Existing Related Capabilities or Technology	*If known, provide information on existing systems and/or technologies that may provide leverage and assist in the development of this capability:* It is requested that S&T explore what systems may exist that can be leveraged.
Key Point of Contact	Dr. LeeAnne Jackson, LeeAnne.Jackson@fda.hhs.gov, 301-436-1593

Item	Response
Tracking Number	2008-002-FDA (Food and Agriculture Sector)
Date	July 15, 2008
Proposed Title of Capability Gap	Mitigation of biological threat agent contamination of high risk foods.
Goal/Objective/Driver to which Capability Gap Responds	HSPD-9 states that the Secretaries of DHS, USDA, HHS, the Administrator of EPA and other appropriate Federal departments and agencies shall prioritize, develop, and implement, as appropriate, mitigation strategies to protect vulnerable critical nodes of production or processing from the introduction of diseases, pests, or poisonous agents.
Gap in Existing Capabilities	The intentional introduction of biological agents into the U.S. food supply could have devastating public health, economic, and psychological consequences. Some biological threat agents and/or their toxins are relatively heat resistant. Currently, the only real countermeasure identified to mitigate biological contamination of high risk foods is thermal inactivation. The application of heat can change the organoleptic and physical properties of the food. Foods may also be contaminated after the heat lethality step has been applied. Other foods, such as produce, are often consumed partially processed or raw.
Description of Required Operational Capability	*Summarize the high-level mission need and capability requirement (this should not be system specific).* The food industry has an immediate need for alternative processing technologies besides thermal treatment to mitigate biological agents or their associated toxins. *Define high-level critical task elements and performance requirements:* ▪ *Describe the specific desired outcome not presently achievable:* – Identified technology must be applicable to a wide array of food commodities and eliminate or inactivate biological agents of concern.

Item	Response
	▪ *Identify the operational performance parameters (capabilities and characteristics) required for the proposed capability:* – Alternate and innovative intervention strategies are needed that will mitigate the effects of biological threat agent contamination of high risk food products with heat resistant agents or for foods that are contaminated after the heat lethality step. Intervention strategies are also needed for high risk foods that will be consumed either raw or after partial processing. – Edible biofilms and generally recognized as safe (GRAS) antimicrobials are needed that will either inactivate biothreat agents or will significantly inhibit growth of biological threat agents when applied to high risk foods or their packaging materials. – The inactivating material must be non-toxic, and not interfere with the organoleptic properties of the food product to include taste testing. – Other non-thermal processing alternatives should be explored as well. – Examples of threat agents to consider: *Bacillus anthracis*, *Burkholderia mallei, Burkholderia psuedomallei, Clostridium botulinum* toxin A and B, *Francisella tularensis*, *Escherichia coli* O157:H7, *Listeria monocytogenes, Salmonella* spp *Yersinia* spp., abrin, aconitine, amanitin, cyanide, and fluoroacetic acid. ▪ *Provide examples of who might use this capability - where, when and how, and -under what conditions:* – Used by food industry during the manufacture/processing of food products ▪ *Describe interfaces with other systems/components:* – Unknown at this time
Identification of Existing Related Capabilities or Technology	*If known, provide information on existing systems and/or technologies that may provide leverage and assist in the development of this capability:* Antimicrobials compounds have been developed that can be sprayed in a fine mist into hotdog and sausage packaging that inhibits the growth of *Listeria monocytogenes.* Potassium lactate and sodium diacetate are effective in controlling *L. monocytogenes* in ready to eat meats. Acidifiers, such as sodium chlorite are effective for controlling pathogens on beef. Other acidifiers, notably acidic calcium sulfate, are effective in reducing the levels and controlling the outgrowth of *L. monocytogenes* on the surface of frankfurters during prolonged refrigerated storage. In a new technology patented by ARS, the vacuum produced by the packaging system distributes the antimicrobial across the surface of the product and kills the targeted pathogen and /or spoilage microbe upon contact. In recent work conducted for DHS, National Biodefense Analysis and Countermeasures Center (NBACC), Food Safety Inspection Service (FSIS) and FDA researchers discovered that egg white contains compounds that kill the spores of *B. anthracis.* In addition, in studies that FSIS conducted for DHS/NBACC, it was determined that certain hams contained ingredients that increased the time for lag phase growth of *B. anthracis*. USDA-ARS is evaluating the antimicrobial activities of a large number of naturally-occurring, plant-derived, food-compatible antimicrobial compounds dissolved or suspended into apple puree and

Item	Response
	tomato puree slurries. The bactericidal activities of these slurries are being evaluated against foodborne pathogenic bacteria including *Escherichia coli* O157:H7*, Salmonella enterica, Listeria monocytogenes*, and *Bacillus cereus.* The physicochemical and sensory properties of films made from these apple and tomato puree slurries and applications of the antimicrobial films to different food categories including fruits, vegetables, meat, poultry, and rice products are being explored. These compounds could be tested as mitigation compounds against threat agent bacteria in addition to the traditional food borne pathogens.
Key Point of Contact	Dr. LeeAnne Jackson, LeeAnne.Jackson@fda.hhs.gov, 301-436-1593

Attachment F: DHS Grants Awarded for Food and Agriculture Defense

Information regarding DHS grants awarded for Food and Agriculture Sector defense is For Official Use Only (FOUO). The information is available upon request from DHS.

This page intentionally blank

Attachment G: Food and Agriculture Sector Joint Committee on Research 2008 Annual Report and Recommendations

April 29, 2008

Mr. Richard Ryan, Committee Chair
Assistant Deputy Director, Corporate Security
Archer Daniels Midland Critical Infrastructure Partnership Council
Food and Agriculture Sector

Executive Summary

In July 2006, the Food and Agriculture Sector ("the Sector"), mandated by HSPD-7 to coordinate critical infrastructure protection (CIP) activities across the spectrum of systems and activities that move agricultural and food products from "farm-to-fork," established an owner-operator led Critical Infrastructure Partnership Advisory Council (CIPAC) working group known as the Joint Committee on Research (JCR). Reflective of the entire Sector, the JCR includes representatives from Federal, State, and local government, and the private sector.

Created to establish priorities and commonalities in Sector security shortcomings and to identify applicable recent or ongoing research initiatives, the Sector charged the JCR with collecting information to identify and study potential gaps in agricultural security and food defense ("security/defense") research and development (R&D) efforts.

As reported in the 2007 Annual Report, the JCR proposed a number of recommendations to address both short-term and long-term deliverables regarding R&D for the Sector. In addition to these R&D recommendations, the JCR also recommended improving its own efficiency and productivity. Specifically, JCR members felt the lack the fiscal and personnel resources necessary to collect, review, and categorize relevant information in a timely, thorough manner. To that end, the JCR recommended expanding support for the JCR, to include staff and software-supported data collection.

During 2007, the JCR determined that this recommendation to seek support for the JCR is of utmost importance in order to achieve any further success with its R&D goals. Data management challenges have proven prohibitive to JCR progress without investment in functional methods to review and quantify incoming information. Additionally, the JCR has neither the internal resources, such as dedicated staff or analytical tools, nor monetary wherewithal to fund the support needed to move forward. Moreover, the JCR is reluctant to engage in soliciting industry for their identified research gaps until the capacity exists to do something useful with the collected information.

The JCR's first year revealed both the complexities of its mission as well as JCR's inability to successfully complete mission given operational support levels and the Sector's R&D integration with the overall DHS priorities at the time. This situation resulted in a second year marked by

relative inactivity of the JCR as a group while JCR leadership attempted to follow up on first year recommendations and consider a redirection of effort to allow for more progress towards the accomplishment of the critical mission originally envisioned for the Committee.

Introduction

To complete its mission towards R&D, the JCR identified the following basic task-sequence of activities that would lead to the eventual end-goal of identifying research gaps in Sector security/defense R&D:

1. Identify and assess existing, on-going research throughout the Sector;
2. Screen identified research for relevance and categorize into a useable database;
3. Identify current industry security/defense research needs;
4. Match on-going research with identified needs, as appropriate;
5. Conduct gap analysis to identify security/defense research needs that on-going research does not address;
6. Make formal recommendations for agricultural security and security/defense research funding to DHS via the Sector.

Since its inception, under the leadership of JCR Chair, Mr. Rich Ryan, Assistant Deputy Director, Corporate Security, Archer Daniels Midland Company (ADM), the JCR has addressed Task 1 to the best of its ability. As part of this effort, the JCR solicited and obtained a large amount data from the White House Office of Science and Technology Policy (OSTP) listing all known government-funded research with potential application for security/defense programs. The FDA and USDA initially screened the data for relevant projects funded through their organizations. Through the initial screening process, the JCR discovered that the data provided by OSTP covers a patchwork of federally funded research projects, including many which are not relevant to security/defense in the Sector. Additionally, the JCR found that the data exists in a variety of formats with significant variations in both the accuracy and focus of specific research project data. Finally, the JCR determined that by only focusing on government funded research initiatives, the collected data from year one also misses relevant international and private research that may otherwise be available for consideration.

The JCR's work in the last year has reinforced the concept of the Food-Agriculture Sector as an amalgam of critical systems that constitute the Sector as a whole. It is clear that traditional security measures (i.e., the "gates, guns, and guards" approach) cannot provide an acceptable level of security/defense in the food supply system. Through its initial research, the JCR has further revealed that within these systems, the currently used risk analysis methods for security/defense are inadequate for reliable understanding as to the true nature of the Sector's intentional food/feed contamination risk.

While the work on Task 1 is a promising step forward and has provided insight into the research and development needs of the sector, the JCR reached an impasse with the tasking-sequence due to a lack of funding and resources with which to complete its goals and objectives, as stated in the introduction. To remedy the lack of money and resources, the JCR is seeking funding from the Department of Homeland Security to support the transition of data management and analysis to the National Center for Food Protection and Defense, a National Center of Excellence (See attachment G.1: Data Analysis White Paper).

While this effort to secure funding is on-going, JCR leadership has continued to work on first year JCR recommendations and plan a path forward for the future. The purpose of the 2008 Annual Report, therefore, is to provide an update as to the progress of the 2007 Annual Report recommendations and detail what measures the JCR will take next towards accomplishing its mission and goals.

2007 JCR Annual Report Recommendation Status

1. Provide for staff and software supported research identification, evaluation and classification capabilities.

The JCR was not successful during its second year in its effort to obtain the foundational support necessary to move forward towards the accomplishment of its stated mission. As a result, a second white paper has been prepared for submission to DHS to specifically request the transfer of the data management function to the National Center for Food Protection and Defense. This shift in operational responsibility will allow the JCR to focus its effort towards the identification of practical industry food defense research needs, the relative prioritization of those needs from the industry perspective, and the coordination of effort to ensure that research toward practical solutions for identified real-world security/defense issues are recommended (see attachment G.1).

2. Develop a food-contamination-agent matrix containing agent characteristics sufficient to allow for agent modeling through an industrial or agricultural process to determine agent-specific threat.

In order for industry to conduct the agent modeling necessary to identify security/defense research needs, it is necessary that private companies have access to a comprehensive list of known and anticipated agents of concern as well as agent characteristics relevant to the modeling process. Much of that information currently exists, but is classified. The JCR has initiated numerous requests for classified level discussions between industry representatives with security clearances and government Sector-Specific agencies to discuss potential over-classification and to work towards an equitable solution to this issue. No such meetings were arranged during the report year. The request is still active.

3. Develop an evaluation tool to allow for equitable comparison for the Sector when compared with other Critical Infrastructure and Key Resource (CI/KR) Sectors for risk-based DHS funding.

The criticality tool developed during the year by the National Center for Food Protection and Defense is designed to support State level criticality assessments, but does not directly address the relative cross-sector risk comparison envisioned in Recommendation 3. Two risk consequence categories common to all sectors that may allow for true cross-sector risk comparison are potential losses or costs associated with economic impact and human health impact. In order to obtain accurate data to allow for those comparisons, however, risk evaluations must be based on end-to-end systems analysis (see 2007 recommendation 4).

4. Develop systems risk analysis projects to determine cascading impacts of a contamination event at various points throughout the "food system" and to identify the most efficient points within the "food system" to integrate detection or mitigation/control technologies.

A systems approach to risk analysis not only provides the potential for cross-sector relative risk comparison, but also allows for the identification of true "critical nodes" within the system so that countermeasure development research is surgically applied on a priority basis to address the most serious system vulnerabilities first. JCR worked with the National Center for Food Protection and Defense and Argonne National Labs to develop a white paper proposal to encourage the development of a methodology for security/defense systems risk analysis (see attachment G.2, Food Protection and Defense Systems Risk Assessment).

5. Identify the "human health impact dose" for potential agents.

Current data available for modeling many critical threat agents, particularly chemical agents, use LD50 as the basis for human health impact evaluation. From the industry perspective, LD50 is inadequate for a variety of reasons, including that any level of negative health impact can result in catastrophic impact on business, with resultant cascading economic impact on interdependent systems. Additionally, useful detection technology cannot be developed without data to support acceptable sensitivity for the screen. JCR is not aware of projects to address this critical issue.

JCR Next Steps: Moving Forward in 2008

If the JCR's current data management concerns are successfully addressed, the JCR has three critical tasks to work toward during the next year in addition to continued work towards the 2007 JCR Recommendations.

1. Develop a methodology to ensure that research and development recommendations to DHS from JCR are based on a sound industry developed R & D priorities.

JCR leadership determined during 2007 that the Sector Coordinating Council will decide upon and approve recommendations to the Department of Homeland Security. To facilitate the evaluation by SCC if identified research needs, a methodology must be developed to evaluate considered research needs according to criteria independent of individual company concerns and consistent with Sector and National impact concerns.

2. Identify industry food defense research needs.

A methodology and reporting protocol should be developed to assist interested companies in their effort to identify food defense research gaps necessary for their security/defense process to attain the level of food defense necessary for business viability as well as to protect the public from harm and the food system from adverse impact resulting from an intentional contamination event. In addition, much work is necessary to motivate industry and companies throughout the Sector to participate actively within the DHS structure.

3. Revitalize the JCR membership.

JCR membership must be expanded to include representation across the Food and Agriculture Sector. If the JCR situation evolves such that meaningful progress can be made toward the accomplishment of the original JCR mission, and in doing so be able to demonstrate tangible benefits for participating companies, JCR and SCC leadership must actively reach out to sub-sector representatives to encourage participation.

Conclusion

The Food and Agriculture Sector is highly complex, vast in international scope, highly dynamic and essential to the welfare of society. As a network of critical systems, it is evident that the traditional approach to security, focusing on physical protection of assets, does not provide adequate security and defense measures for the Food and Agriculture Sector. Moreover, within these systems, the currently used risk analysis methods for security/defense are inadequate for reliable understanding as to the true nature of the Sector's intentional food and feed contamination risk.

The mission of the JCR to identify and study potential gaps in agricultural security and food defense research and development efforts is critical to the advancement of safety and security of the Food and Agriculture Sector. The JCR has confidence that, with the support of DHS and the private sector, it can accomplish that mission and, in doing so, contribute to the assurance that this essential critical sector is adequately protected.

This page intentionally blank

Attachment G.1: Data Analysis White Paper

Food and Agriculture Sector
Joint Committee on Research
Data Analysis White Paper
For Assistant Secretary for Infrastructure Protection, DHS

Purpose

To request funding of the Food and Agriculture Sector's Joint Committee on Research to further the Sector's research and development goals regarding agricultural security and food defense.

Background

In July 2006, the Food and Agriculture Sector ("the Sector"), mandated by HSPD-7 to coordinate critical infrastructure protection (CIP) activities across the spectrum of systems and activities that move agricultural and food products from "farm-to-fork," established an owner-operator led Critical Infrastructure Partnership Advisory Council (CIPAC) working group known as the Joint Committee on Research (JCR).1 Created to establish priorities and commonalities in Sector security shortcomings and to identify applicable recent or ongoing research initiatives, the Sector charged the JCR with collecting information to identify and study potential gaps in agricultural security and food defense ("security/defense") research and development (R&D) efforts.

To complete its mission, the JCR identified the following basic task-sequence of activities that would lead to the eventual end-goal of identifying research gaps in Sector security/defense R&D:

1) Identify and assess existing, on-going research throughout the Sector;

2) Screen identified research for relevance and categorize into a useable database;

3) Identify current industry security/defense research needs;

4) Match on-going research with identified needs, as appropriate;

5) Conduct gap analysis to identify security/defense research needs that on-going research does not address;

6) Make formal recommendations for agricultural security and security/defense research funding to DHS via the Sector.

Since its inception, under the leadership of JCR Chair, Mr. Rich Ryan, Assistant Deputy Director, Corporate Security, Archer Daniels Midland Company (ADM), the JCR has addressed Task 1 to the best of its ability. As part of this effort, the JCR solicited and obtained an enormous amount data from the White House Office of Science and Technology Policy (OSTP) listing all known government-funded research with potential application for security/defense programs.

The FDA and USDA initially screened the data for relevant projects funded through their organizations. Through the initial screening process, the JCR discovered that the data provided by OSTP covers a patchwork of federally funded research projects, including many which are not relevant to security/defense in the Sector. Additionally, the JCR found that the data exists in a variety of formats with significant variations in both the accuracy and focus of specific research project data. Finally, the JCR determined that by only focusing on government funded research initiatives, the collected data from year one also misses relevant international and private research that may otherwise be available for consideration.

JCR Members include: Archer Daniels Midland, The National Pork Board, Food Products Association, Cargill, Indiana State Department of Health, North Carolina Department of Health and Human Services USDA, FDA, and DHS.

The Problem:

The JCR's work in the last year has reinforced the concept of the Food-Agriculture Sector as an amalgam of critical systems that constitute the Sector as a whole. It is clear that traditional security measures (i.e., the "gates, guns, and guards" approach) cannot provide an acceptable level of security/defense in the food supply system. Through its initial research, the JCR has further revealed that within these systems, the currently used risk analysis methods for security/defense are inadequate for reliable understanding as to the true nature of the Sector's intentional food/feed contamination risk.

The work on Task 1 is a promising step forward and has provided insight into the research and development needs of the sector, which the JCR seeks to address. Yet, the JCR has reached an impasse with the tasking-sequence. Data management challenges are proving prohibitive to JCR progress without investment in functional methods to review and quantify incoming information. Additionally, the JCR has neither the internal resources, such as dedicated staff or analytical tools, nor monetary wherewithal to fund the support needed to move forward with Tasks 2, 4 and 5.

Moreover, while the JCR has explored the possibility of continuing with Task 3 (soliciting industry for their identified research gaps) prior to the completion of Tasks 1 & 2, industry participants have expressed their hesitation to invest in such a data-call without the mechanisms already in place to analyze the results. The JCR, too, is reluctant to engage in such an activity until the capacity exists to do something useful with the collected information.

Suggested Resolution:

To address the above issues and ensure the continuance of the JCR's intended activities, the JCR proposes a dual-faceted approach:

First, the JCR recommends immediately transferring the first two tasks to the National Center for Food Protection and Defense (NCFPD), at the University of Minnesota, for completion. NCFPD,

a Homeland Security Center of Excellence, has a proven history of success with the Sector based on industry relationships and its recent work with the Sector in its Criticality Study Project, and is a natural choice to partner with the JCR. In order to facilitate Task 1 and 2, the JCR further recommends that NCFPD obtain, or have access to, enhanced data-mining capability to facilitate real-time data collection and initial screening, such as the analytic software offered by the technology firm, RiverGlass, or similar software-solution company. As the JCR is unable to provide funding for NCFPD on its own, the JCR will request funding through the Department of Homeland Security's Science and Technology Directorate.

Second, while NCFPD works on Tasks 1 & 2, the JCR will begin the process of focusing on the identification of industry needs, Task 3, a process that can be run concurrently with the completion of Tasks 1 & 2.

Following the completion of Tasks 1 – 3, the JCR will collaborate with NCFPD for completion of the final Tasks, including matching identified research needs with current research, running gap analyses on existing research vs. identified needs, and identifying research gaps for further funding.

The end product of this effort by the JCR, and similarly the investment in the project by DHS, will be:

- The ability of the Sector to meet its annual reporting requirement to identify research and development capability gaps;
- A better understanding of R&D needs and capabilities between the private sector and Federal and state governments;
- The opportunity for more effective funding through systemized analysis that enumerates research gaps and limits the chance of duplicate research efforts by different organizations;
- Streamlined connection between need and capability and between the people who need a product and the people who can perform the R&D;
- A connection between the work of critical system identification and tangible products to better protect the "farm to fork" pathway.

Cost Estimate:
REDACTED

This page intentionally blank

Attachment G.2: Food Protection and Defense Systems Risk Assessment

Background

The needs for a system-based risk assessment are based in the Presidential Directives related to Critical Infrastructure Identification, Prioritization, and Protection (HSPD-7) and Defense of United States Agriculture and Food (HSPD-9). HSPD-7 directs agencies to undertake strategic improvements in security to "make it more difficult for attacks to succeed and can lessen the impact of attacks that may occur." Infrastructure sectors are to implement "strategic security enhancements, tactical security improvements" to deter, mitigate, or neutralize potential attacks. To identify and implement these improvements HSPD-7 calls for lead agencies to:

1. collaborate with all relevant Federal departments and agencies, State and local governments, and the private sector, including with key persons and entities in their infrastructure sector;

2. conduct or facilitate vulnerability assessments of the sector; and

3. encourage risk management strategies to protect against and mitigate the effects of attacks against critical infrastructure and key resources

HSPD-9 recognizes America's agriculture and food system as "an extensive, open, interconnected, diverse, and complex structure providing potential targets for terrorist attacks." The agriculture and food sector is charged to "provide the best protection possible against a successful attack on the United States agriculture and food system, which could have catastrophic health and economic effects." To achieve the protection level, several steps are identified in HSPD-7 including:

1. identifying and prioritizing sector-critical infrastructure and key resources for establishing protection requirements;

2. developing awareness and early warning capabilities to recognize threats;

3. mitigating vulnerabilities at critical production and processing nodes;

4. enhancing screening procedures for domestic and imported products; and

5. enhancing response and recovery procedures.

Under HSPD-9, the Secretaries of Agriculture, Health and Human Services, and Homeland Security are charged to "expand and continue vulnerability assessments of the agriculture and food sectors." As appropriate, the vulnerability assessments are to identify requirements of the National Infrastructure Protection Plan developed by the Secretary of Homeland Security. The

vulnerability assessments will allow agencies to "prioritize, develop, and implement mitigation strategies to protect vulnerable critical nodes of production or processing from the introduction of diseases, pests, or poisonous agents."

Current Risk Assessment Approaches

One of the most commonly used tools in assessing threats and their impacts to individual processes and subsectors of the food production system is CARVER +Shock. CARVER + Shock was derived from a military usage for prioritizing targets for offensive targeting. The system has been adapted from the military version for use in the food industry. The system may be used to evaluate vulnerabilities within a subsector, subsystem, or infrastructure to a terrorist attack. Because of its origin, the tool puts the user in an attacking mode, seeking to identify targets with high impact from a number of perspectives. When CARVER + Shock is used to assess an attack on a food production facility or process, the most vulnerable points in the system are identified leading the user to focus protective resources on the most susceptible points in their subsystem.

Six attributes are used in CARVER to evaluate the attractiveness of a target for attack:

- Criticality - measure of public health and economic impacts of an attack
- Accessibility - ability to physically access and egress from target
- Recuperability - ability of system to recover from an attack
- Vulnerability - ease of accomplishing attack
- Effect - amount of direct loss from an attack as measured by loss in production
- Recognizability - ease of identifying target

The seventh attribute of shock was added to assess the combined health, economic and psychological impacts of an attack within the food industry.

Each of the seven attributes is qualitatively ranked to constitute an overall attractiveness of a subsector or subsystem to a terrorist attack. Federal agencies, such as FDA and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), have used this method to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities. The method can also be used to assess the potential vulnerabilities of individual facilities or processes. Other risk tools are used in the food production system to assess vulnerabilities and risk to specific pathogens or actions on defined subsectors, subsystems, facilities or processes.

Agencies and Industry Needs

The Biennial National Center for Food Protection and Defense held in the Minneapolis area in 2007 highlighted some of the agency needs in risk assessment both at the food system and

subsector level. Among the needs identified by a range of Federal agencies including DHS, FDA, and USDA were:

- End to end quantitative assessment of bioterrorism;
- End to end assessment of food contamination;
- Food distribution models;
- Input data to risk assessment models;
- Risk-based assessments of agriculture and food systems vulnerabilities;
- Targeted interventions based on risk assessments;
- Decision support tools for use during agriculture and food system events;
- Accurate risk assessments including pathogen behavior and event modeling;
- Event modeling for consequence, risk, and vulnerability assessment.

All of these elements address specific parts of the total food system and may provide insight into the best approaches to take in developing a methodology for performing a complete food system level risk assessment. Numerous industry representatives participated in the Biennial NCFPD meeting across the range of elements being researched. The industry wants to be able to apply their resources to reducing the risk at critical points within the food and agriculture system. In order to meet this goal, an understanding of the risk and vulnerabilities on a systems basis is needed.

The 2007 FDA Food Protection Plan is designed to operate on integrated strategies that focus on risk over a product's life cycle, target resources to maximum risk reduction, and use science and modern technology systems. The life cycle risk approach represents a recent shift in FDA's approach. The need for a comprehensive risk-based approach is recognized by FDA along with the need to consider the wide range of variables used to define risk. The plan also identifies the need to use science to determine the optimal interventions to reduce the likelihood of contamination. The Food Protection Plan includes numerous risk-based elements in the three elements of protection for food protection such as:

- Identification of food vulnerabilities and assessment of risks;
- Enhancing risk-based surveillance;
- Focusing inspections and sampling based on risk.

The Food Protection Plan goes on to advocate legislative changes that allow intervention at critical points in the food supply chain. The operations plan associated with the plan includes elements to enhance modeling capabilities for relative risk ranking, to evaluate and prioritize risks of food and feed agents, and to increase software capability to assist the industry with identifying areas of food safety risk. While the focus in this plan is on food protection, the expansion of the risk assessment to all of the subsectors and the total food and agriculture system can build on these elements.

Summary

The Food and Agriculture Infrastructure is a complex system comprised of diverse, interactive, and dynamic subsectors. The system is both national and global with significant interdependencies with a number of other infrastructures including finance, transportation and energy. Recent events regarding Chinese imports have highlighted how an apparently isolated event can cascade through the entire system leaving a broad wake of impacts on the food and agriculture sectors and processes. While a number of risk assessment activities have been undertaken for components of the system, a methodology for an integrated system risk assessment has yet to be developed and deployed. The drive by the full range of involved Federal agencies to include risk at all levels of the system warrants the development of a system risk assessment to guide the investment of both Federal research and implementation funding and the expenditures by the major industry leaders in securing the food and agriculture system while maintaining an economical and accessible food supply for the nation. With the drivers in place from both the government side and the industry side, the timing is right to develop and implement a system wide risk assessment methodology to guide future research and investment in the security of the food and agriculture system.

Objective

The objectives of the System Risk Assessment program are:

- To perform a systems wide risk assessment of the sector components to identify common vulnerabilities, the cascading impacts associated with the interruption of various subsectors of the system and potential countermeasure to prevent or minimize the risks.

- To use the results of the systems risk assessment to prioritize actions and research to improve the defense of the nation's food system

Approach

System Definition

The first step in developing a risk assessment is the definition of the system. The food and agriculture system is complex with multiple layers and interlocking functions ranging from production to processing to distribution to sales. The approach is to develop an understanding of the relationships among the various subsystems and the critical interfaces that may result in vulnerabilities in the system as a whole. The program will define the nature of the linkages and the interdependent aspects of those linkages.

System Sectors

The individual subsectors of the food and agricultural system have unique characteristics that relate them to their linked subsystems. The program will develop a characterization of each subsector to include general capacity, global and national geographic distribution, key vulnerabilities, common traits and vulnerabilities with other subsectors, key linkages to other subsectors, and dependencies on other major infrastructure sectors.

Cascading Impacts

Based on the systems definition and the understanding of the nature of the interfaces between the systems subsectors, the program will develop and quantity the upstream and downstream impacts of a range of disruptions to a particular subsector on related subsectors. These cascading impacts will be traced both forward and backward in the food and agriculture system due to the sensitivity both upstream and downstream of a system impact.

Interdependent Infrastructures

The food and agriculture system is dependent on many of the other major infrastructure sectors including finance, transportation, and energy. Impacts in these sectors can have major impacts on the food and agriculture system. The program will identify for each subsector its interdependency with other major infrastructure sectors. The program will develop and quantity the impacts of a range of disruptions to a particular subsector on related infrastructure sectors and the impact of a range of disruptions to interdependent infrastructures on food and agriculture subsectors.

Integrated System Risk/Vulnerability Assessment

Using the collected knowledge regarding the nature of the system, the linkages between subsectors and the reliance on other infrastructure sectors, the program will develop a methodology to integrate the individual subsector risks and vulnerabilities, the cascading impacts, and the infrastructure independencies into a system risk assessment. The systems assessment will incorporate tools developed from ongoing risk assessment actions and research, NCPFD research and development (CMS, Supply Chain Resiliency), Argonne National Laboratory research and development and applications for infrastructure assurance (CIPS-DSS, Inland Waterways Study, Synchmatrix, E-List, CVPIPM) and ADM's systems knowledge and experience in all phases and sectors of the industry. The program will pilot the Systems Risk Assessment methodology against a limited but diverse set of "farm to fork" threads to refine the methodology. Selection of these threads will be performed in consultation with the sponsor and the key industry members involved in the food and agriculture subsystems.

Prioritizing Protection and Research

The application of the System Risk Assessment methodology will allow the program to identify linkages or subsystems that need additional definition or those that are critical unmitigated vulnerabilities. The program will apply the refined methodology to a wide spectrum of food and agricultural lines and threads to identify and prioritize these key and common vulnerabilities and knowledge gaps. By using the system risk assessment methodology, the program can evaluate the best currently available technologies and methodologies for high priority key and common vulnerabilities to guide development of new protection methods or systems options to decrease the vulnerabilities. The System Risk Assessment may also provide insight regarding basic research needs that can address future needs in the food and agriculture system.

Participants and Roles

The Food and Agriculture System Risk Assessment program team integrates academia, industry and a national laboratory to bring the diverse resources to bear on a complex problem. The combination of NCFPD led by the University of Minnesota, Archers Daniel Midlands Company, and Argonne National Laboratory brings expertise in the research into food system subsector, practical experience and expertise and infrastructure assurance and systems risk assessment expertise together to pursue development of a system risk assessment methodology. The roles of each organization in the program are briefly described in the following paragraphs.

National Center for Food Protection and Defense: Manage the research and development program, integrate tools developed and under development within NCFPD to the systems assessment, identify and provide subject matter experts in the subsectors and related elements of the food and agriculture system, and provide outreach to the academic components of NCFPD

Archer Daniels Midland Company: Provide subject matter expertise for food and agriculture subsectors, provide industry perspective on the practicalities of implementing systems risk assessments, identify and qualify interdependent infrastructures, and provide guidance in piloting the systems assessment

Argonne National Laboratory: Develop the risk and vulnerability assessment methodology and associated tools, integrate currently available tools from a range of programs to the integrated systems assessment, integrate NCFPD developed tools, integrate and improve current cascading impact and infrastructure interdependency tools, and develop a methodology for identifying, measuring, and prioritizing key and common vulnerabilities and countermeasures.