Agriculture and Food

Critical Infrastructure and Key Resources Sector-Specific Plan* as input to the National Infrastructure Protection Plan

May 2007

*Contains both the U.S. Department of Agriculture and the U.S. Department of Health and Human Services/Food and Drug Administration portions of the plan

Homeland Security

Department of Agriculture

FDA Food and Drug Administration

Food and Agriculture Sector Specific Plan
Government Coordinating Council
Letter of Agreement

The National Infrastructure Protection Plan (NIPP) provides the unifying structure for the integration of critical infrastructure and key resources (CI/KR) protection efforts into a single national program. The NIPP provides an overall framework for integrating CI/KR protection programs and activities that are underway in the various sectors. It includes 17 sector-specific plans (SSPs) that describe the application of the overall risk management framework for each of the sectors.

Each SSP describes a collaborative effort between the private sector; Federal, State, local, and Tribal governments; and nongovernmental organizations. This collaboration will result in the prioritization of protection initiatives and investments within and across sectors to ensure that resources can be applied where they contribute the most to risk mitigation by lowering vulnerabilities; deterring threats, and minimizing the consequences of attacks and other incidents. By signing this letter, the members of the Food and Agriculture Government Coordinating Council commit to:

- Support SSP concepts and processes; carry out assigned functional responsibilities including coordinating, implementing, and facilitating CI/KR protection activities; as described herein;
- Develop or modify existing plans concerning interagency and agency-specific CI/KR activities as appropriate, to facilitate compliance with the Food and Agriculture Sector SSP;
- Develop and maintain partnerships for CI/KR protection with appropriate State, regional, local, Tribal; the private sector; and nongovernmental organizations; and
- Encourage and facilitate appropriate CI/KR information sharing, consistent with agency-specific authorities and the process described herein.

Signatory departments and agencies follow.

Food and Agriculture Sector Specific Plan
Government Coordinating Council Signatories

Curt J. Mann
Co-chair, Food and Agriculture
Government Coordinating Committee
Department of Agriculture

David Acheson
Co-chair, Food and Agriculture
Government Coordinating Committee
Food and Drug Administration

R. James Caverly
Co-chair, Food and Agriculture
Government Coordinating Committee
Department of Homeland Security

December 28, 2006

Dr. Curt Mann
Deputy Under Secretary for Food Safety
US Department of Agriculture

Dr. David Acheson
Chief Medical Officer for Food Drug Administration
US Food and Drug Administration

On behalf of the National Association of State Departments of Agriculture (NASDA) and the National Assembly of State Animal Health Officials (NASAHO), we would like to thank you for the opportunity to participate in the Food and Agriculture Government Coordinating Council and, more specifically, to provide input into the development of the Food and Agriculture Sector Specific Plan (SSP) of the National Infrastructure Protection Plan. We recognize the importance of the mission to identify and protect the critical infrastructure and key resources in the food and agriculture sector, and we appreciate the recognition that this protection requires the cooperation and coordination between federal and state agencies.

As partners representing the interests of States, we are charged with providing written contributions for the SSP chapters that represent how state agencies are addressing the protection of animal health, agriculture, and food safety critical infrastructure and key resources. Unfortunately, the timeline for contributions did not allow for concerted input from state agriculture agencies, state animal health officials, and state public health officials. Time became a limiting step in this process especially in light of many competing priorities.

However, due to the magnitude of this charge and its potential ramifications on the food and agriculture sector, the NASDA and NASAHO are committed to provide thoughtful review and substantive comments to the SSP within the 2007 calendar year and recommend, respectfully, the following processes and timeline:

1. Limited comments will be provided on the existing documents, as appropriate, by the established deadline in December.
2. Beginning in January 2007, a more robust panel of reviewers and contributors representing our organizations' constituencies will be established in order to enrich and streamline the process.
3. A mechanism will be established within the U.S. Animal Health Association (Committee on Animal Emergency Management) and NASDA (the Homeland Security Committee) to enable contributors in providing valuable contributions to the SSP.
4. By November 30, 2007 our organizations will submit feedback as directed by the SSP guidelines.

We understand that the SSP is a work in progress and that it will be revised at least every three years. Following the incorporation of input from state partners into the SSP, we expect to efficiently and effectively participate in future established review cycles. We appreciate the spirit of collaboration from federal agencies and believe that the above strategy will provide meaningful contributions from state governments on how to best protect the food and agriculture sector.

Sincerely,

Douglas P. Gillespie
NASDA Representative to the Government Coordinating Council
Commissioner, Massachusetts Department of Agricultural Resources

Lee M. Myers, DVM

Lee M. Myers, DVM, MPH, Dipl. ACVPM
NASAHO Representative to the Government Coordinating Council
Georgia State Veterinarian

December 14, 2006

Dr. David Acheson
Director, Food Safety & Security
Department of Health and Human Services
Harvey W. Wiley Building, Room 3B003
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Acheson:

The National Infrastructure Protection Plan (NIPP) provides the unifying structure for the integration of critical infrastructures and key resources (CI/KR) protection efforts into a single national program. The NIPP provides an overall framework integrating programs and activities that are currently underway in the various sectors, as well as new and developing CI/KR protection efforts. The NIPP includes 17 sector-specific plans (SSPs) that detail the application of the overall risk management framework to each specific sector.

Each SSP describes a collaborative effort between the private sector, State, local and tribal governments, nongovernmental organizations, and the Federal Government. This collaboration will result in the prioritization of protection initiatives and investments within and across sectors. This prioritization helps ensure that government resources are applied where they offer the most benefit for mitigating risk by lowering vulnerabilities, deterring threats, and minimizing the consequences of attacks and other incidents, and encourages a similar risk-based allocation of resources within the private sector. By signing this letter, the subcouncils of the Food and Agriculture Sector Coordinating Council (FASCC) acknowledge that they:

- Support the overall SSP concepts and processes, and will continue to work with the Food and Drug Administration(FDA)/USDA and other security partners to further develop and implement the SSP;

- Have had the opportunity to provide insights and guidance on the unique needs, concerns, and perspectives of their organizations or members during the SSP drafting process;

- Will maintain partnerships for CI/KR protection with appropriate Federal, State, regional, local, tribal, and international entities; other private sector entities; and nongovernmental organizations; and

- Will work with DHS and the FDA/USDA to find effective and suitable mechanisms to share CI/KR protection-related information.

Sincerely,

Sub-Councils of the Food and Agriculture Sector Coordinating Council

- Agricultural Production Inputs and Services
- Plant-Producers Sub-Council
- Processors-Manufacturers Sub-Council
- Restaurant-Food Service Sub-Council
- Retail Sub-Council
- Warehousing-Logistics Sub-Council

Submitted by the

U.S. Department of Agriculture

Food (Meat, Poultry, and Egg Products) and Agriculture

Critical Infrastructure and Key Resources Sector-Specific Plan as input to the National Infrastructure Protection Plan

May 2007

Homeland Security

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Executive Summary

Protecting the Nation's agriculture and food critical infrastructure and key resources (CI/KR) is an important responsibility shared by Federal, State, local, and tribal governments and private industry. Because of the open nature of many portions of the Food and Agriculture Sector, attacks against the Nation by using food or agricultural infrastructure or resources as weapons could have a devastating impact on public health and the economy. Traditional physical security practices alone cannot protect the sector. A protection plan for food and agriculture infrastructure and resources must focus on planning and preparedness, as well as early awareness of an attack. Science-based surveillance measures are essential to recognizing a possible attack on the sector so that rapid response and recovery efforts can be implemented to mitigate the impact of an attack. A protection plan must also be coordinated closely with response and recovery plans.

The National Infrastructure Protection Plan (NIPP) provides the unifying structure for the integration of existing and future CI/KR protection efforts into a single national program. The cornerstone of the NIPP is its risk management framework. Risk, in the context of the NIPP, is defined as the potential for loss, damage, or disruption to the Nation's CI/KR resulting from destruction, incapacitation, or exploitation during some future manmade or naturally occurring event. The framework applies to the general threat environment, as well as to specific threats or incident situations.

1. Sector Profile and Goals

The U.S. Food and Agriculture Sector with its complex production, processing, and delivery systems has the capacity to feed people beyond the boundaries of the Nation. The sector comprises more than 2 million farms, approximately 900,000 firms, and 1.1 million facilities. Almost entirely under private ownership, it operates in highly competitive global markets, strives to operate in harmony with the environment, and provides economic opportunities and improved quality of life for rural and urban Americans. The sector accounts for roughly one-fifth of the Nation's economic activity when measured from inputs to tables of consumers at home and away from home.

The U.S. Department of Agriculture (USDA) has Sector-Specific Agency (SSA) responsibility for production agriculture and shares SSA responsibilities for food safety and defense with the Department of Health and Human Services (HHS) Food and Drug Administration (FDA). Specifically, FDA is responsible for the safety of 80 percent of all food consumed in the United States, including the entire domestic and imported food supply; however, meat; poultry; and frozen, dried, and liquid eggs are under the authority of USDA.

This Sector-Specific Plan (SSP) for CI/KR protection focuses on a portion of the U.S Food and Agriculture Sector as defined in the February 2003 *National Strategy for Physical Protection of Critical Infrastructures and Key Assets* (*the National Strategy*). The National Strategy defines the Food and Agriculture Sector as the supply chains for feed, animals, and animal products; crop production and the supply chains of seed, fertilizer, and other necessary related materials; and the post-harvesting components of the food

supply chain, from processing, production, and packaging through storage and distribution to retail sales, institutional food services, and restaurant or home consumption.[1] In general terms, the sector comprises our agricultural production and food systems from farm to table.

Sector Mission and Vision

The mission of the Food and Agriculture Sector is twofold: (1) to protect against any attack on the food supply, including production agriculture, that would pose a serious threat to public health, safety, welfare, or the national economy; and (2) to provide this steadily evolving sector with a central focus, emphasizing protection and strengthening of the Nation's capacity to supply safe, nutritious, and affordable food.

Securing the sector presents unique challenges because U.S. agriculture and food systems are extensive, open, interconnected, diverse, and complex structures providing attractive potential targets for terrorist attacks. Attacks on the sector, such as introducing animal or plant disease or food contamination, could result in severe animal, plant, or public health and economic consequences because food products rapidly move in commerce to consumers without leaving enough time to detect and identify a causative agent. The members of the government and industry public/private sector have established the following vision for the Food and Agriculture Sector:

Vision Statement for the Food and Agriculture Sector

Prevent the contamination of the food supply that would pose a serious threat to public health, safety, and welfare. 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, ensure that the industry has incorporated the concepts of HSPD–7 in their own critical asset protection plans, vulnerability/risk-reduction plans, and continuity of operations plans (COOP). The sector will provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management.

The Government Coordinating Council (GCC) and the Sector Coordinating Council (SCC) work collaboratively to accomplish the mission and to fulfill the vision. The sector councils are the primary method of coordination for the sector security partners. The GCC, with representation from Federal, State, local, and tribal governments, is the public sector portion of the Food and Agriculture public/private partnership, and the SCC is a self-governing body representing the food and agriculture industries. The GCC will work with the SCC to refine both the sector vision and mission statement for inclusion in the next iteration of the SSP.

2. Identify Assets, Systems, Networks, and Functions

Each sector must understand its critical components in order to meet the requirements of Homeland Security Presidential Directive 7 (HSPD-7) Critical Infrastructure Identification, Prioritization, and Protection and the NIPP for a strategic approach to infrastructure protection. Only after the sector is aware of each component may it consider threats, assess vulnerabilities, develop and implement protective measures or mitigation strategies, address research and development (R&D) needs, and measure success. A protection plan for this sector must begin with the farm and inputs, move through processing, and end

[1] Infrastructure protection activities related to agricultural systems but not included in the Sector description are addressed separately by the responsible Federal entity, the USDA, in collaboration with the relevant Federal, State, local, tribal, and private sector partners. Examples include forestry (timber), rural programs (utilities, housing), and resource conservation.

with the consumer. The protection plan must consider interdependent sectors, including cyber, chemicals, water, energy, communication, banking and finance, and transportation.

The Food and Agriculture Sector comprises systems of individual assets that are closely dependent upon each other. Because of its complexity, the sector has struggled to identify its most critical assets, systems, networks, and functions. While the sector understands its individual systems and basic interrelationships, the challenge has been to understand the complexities and interdependencies across the farm-to-table continuum on national and regional scales.

USDA and sector security partners have initiated the Agriculture and Food Criticality Project to identify the functions performed at an aggregate level by the Food and Agriculture Sector.[2] Information from this project will be used to define criteria for sector infrastructure, which will facilitate the identification and prioritization of critical assets, systems, networks, and functions within the sector. USDA will incorporate findings from the project regularly into this SSP and share that information with security partners to ensure that, upon the project's completion, the sector will be prepared to identify critical assets, systems, networks, and functions and determine the parameters of information to be collected for each.

3. Assess Risks (Consequences, Vulnerabilities, and Threats)

While many risk assessment tools are available for use by sector security partners, the GCC and SCC have selected the CARVER + Shock methodology to assess risk to specific commodities and processes within the Food and Agriculture Sector. This approach was selected, in part, because it offers a simplified and standardized means for conducting risk assessments that aid in the identification of attractive targets. This tool, selected by the sector as a whole, will be the focus for the SSP; other tools, which may be in use by individual sector partners, will not be addressed in this plan.

The CARVER + Shock approach provides a consistent means for evaluating the consequences, vulnerability, and threat faced by assets, systems, networks, and functions in the Food and Agriculture Sector. This methodology meets the baseline criteria for assessment methodologies (as required in the NIPP guidelines, appendix 5A) by being complete and consistent and by providing unbiased assessments across the wide range of assets and systems found in the sector; it also encourages careful examination of each point or node in the system. The CARVER + Shock approach is transparent and can be used independently or in concert by industry and government analysts to produce results that are defensible and reproducible.

CARVER is an acronym for the following six attributes used to evaluate the appeal of a target for attack:

- **C**riticality: Measure of public health and the economic impacts of an attack;
- **A**ccessibility: Ability to physically access and egress from target;
- **R**ecuperability: Ability of system to recover from an attack;
- **V**ulnerability: Ease of accomplishing attack;
- **E**ffect: Amount of direct loss from an attack as measured by loss in production; and
- **R**ecognizability: Ease of identifying target.

The seventh attribute, Shock, represents the combined health, economic, and psychological impacts of an attack. For a more detailed description of the CARVER + Shock components and additional information on the assessment process, see appendix 4.

[2] More detailed information on the project may be found in chapter 1, section 4, of this plan.

4. Prioritize Infrastructure

A prioritization of the sector's infrastructure requires a "systems" perspective because many individual pieces have interdependencies within and beyond the sector. The sector must determine what constitutes its assets, systems, networks, and functions and then establish criteria for differentiating between those in each category that are critical and those that are non-critical.

Traditionally, CI/KR protection efforts have focused on physical security for structures, (e.g., installations and equipment). These efforts tailored their approach to physical assets that have well-defined perimeters, such as chemical plants and nuclear power generation facilities. In contrast, the Food and Agriculture Sector has extensive, open, widely dispersed, diverse, and complex interdependent systems; therefore, the physical asset-based approach may not fit the Food and Agriculture Sector. To address the need for a tailored approach and a methodology to help determine what is critical in this sector, the GCC and SCC initiated the Agriculture and Food Criticality Project. The project brings together a multidisciplinary team of subject matter experts and analysts to develop, refine, and apply a methodology to objectively determine the criticality of assets, systems, networks, and functions in the Food and Agriculture Sector.

5. Develop and Implement Protective Programs

The protection and integrity of America's agricultural production and food supply systems are essential to the health and welfare of both the domestic and global community and the security of the national economy. Protective programs within the sector are based on the findings from risk or vulnerability assessments and on Intelligence Community and law enforcement-related information. The success of the variety of programs that address safeguarding plant and animal production agriculture and food defense depends upon the coordinated work of a broad range of Federal, State, local, tribal, and private sector security partners. USDA and its sector security partners collaborate to develop and implement protective programs that address the prevention, protection, response, and recovery elements of the protective spectrum.

Protecting the systems in this sector requires science-based approaches that enable the sector to rapidly identify when a threat agent is present and to swiftly respond to a threat agent. Science-based approaches should result in a shorter and more effective recovery, thus making the sector a less attractive terrorist target.

6. Measure Progress

Within USDA, the USDA Results Agenda and the President's Management Agenda provide the guidance used to evaluate program performance. In addition, the White House Office of Management and Budget (OMB) developed the Program Assessment Rating Tool (PART) to facilitate performance measurement and to assess and improve program performance across the Federal Government.

As part of the preparation for the next version of the SSP, the sector will work to develop sector-specific metrics. In the interim, the GCC and SCC will continue to consider and review security and defense programs, and USDA will rely on the guidance provided by PART. PART emphasizes the relationship between outcome, output, and efficiency measures; each kind of measure provides valuable information about program performance. Collectively, PART measures convey a comprehensive story about an agency's products and services, how effective they are, and their results.

7. CI/KR Protection Research and Development

Within the sector, Federal funds typically support high-level (sector-wide or industry-wide) R&D at the Federal or State level. The USDA Economic Research Service (ERS), USDA's primary in-house source of economic information and research, supports

sector efforts to protect critical assets, systems, networks, and functions. Private industry hosts R&D that is more focused or addresses a gap in protection that the government is not addressing; collaborative public and private efforts are common.

At the Federal level, the Agricultural Research Service (ARS) is the in-house scientific research arm of USDA that conducts research to meet the needs of its stakeholders within USDA, other Federal agencies, State and local governments, and industry. Most R&D activities are prioritized based on risk or similar assessment findings and all are subject to budgetary limitations. Also, the USDA Cooperative State Research, Education, and Extension Service (CSREES) supports extramural sector research. CSREES provides funding and leadership to land grant university-based cooperative extension services, State cooperative extension services, and State agricultural experiment stations, as well as to other research and outreach organizations for critical assets, systems, networks, and functions protection related to food and agriculture.

To track the many R&D activities within the sector and to prioritize R&D needs, the GCC and SCC have established the Food and Agriculture Sector Joint Committee on Research. The mission of this committee is to assess and advise the Food and Agriculture Sector (GCC and SCC) on homeland security researchable needs and goals. The committee will make use of existing vulnerability work, consider threat information, review current R&D projects, make discovery of operational needs in the sector, consult or involve the research community as needed, and refine or update recommendations periodically.

The committee will annually provide to the GCC and SCC a collective and coordinated list of researchable food and agriculture priority needs from both the perspective of those in operations and implementation (the private sector and the States), and the government agencies involved in maintaining homeland security coordination and oversight (the SSAs).

8. Manage and Coordinate SSA Responsibilities

The SSP reflects the sector's goals and priorities; therefore, it needs to be maintained and updated regularly. Updates to the SSP will undergo a thorough review that includes collaboration with the SCC, GCC, and other sector security partners on a triennial basis.[3] The USDA Homeland Security Office (HSO), responsible for version control of the document and the only entity authorized to revise it, will lead the SSP maintenance and triennial review. This process will be coordinated closely with FDA.

HSO will update the document, as warranted, on an ad hoc basis as a result of changes in the sector's security posture, goals, and priorities (developed on an annual basis by the sector). To ensure accuracy and to reinforce the partnership nature of this effort, any revised versions of the SSP will be coordinated with the SCC and GCC prior to release. This process will include reviewing the frequency of issuing updates.

USDA does not have authority over resources and budgets for the entire sector. As a result, USDA has limited information concerning how sector security partners allocate resources related to sector security and has minimal influence over how future resources are allocated. When reporting on budgetary and resource plans, USDA will continue to rely on the coordinated Food and Agriculture Defense Initiative, a collaborative budget process for setting funding levels for security and defense programs across the relevant USDA agencies and offices and across FDA.

[3] The Food and Agriculture Sector will probably issue an updated SSP in late 2007 or early 2008 to incorporate findings from the Agriculture and Food Criticality Project; updates will then follow on a triennial basis or more frequently as needed

Introduction

Protecting the critical infrastructure and key resources (CI/KR) of the United States is essential to the Nation's security, economic vitality, and way of life. According to Homeland Security Presidential Directive 7 (HSPD-7) and the National Infrastructure Protection Plan (NIPP), CI/KR includes the assets, systems, networks, and functions that provide vital services to the Nation. Terrorist attacks on CI/KR and other manmade and natural disasters could significantly disrupt the functioning of government and business alike and produce cascading effects beyond the affected sector and physical location of the incident.

Direct attacks on CI/KR could result in large-scale human casualties, property destruction, and economic damage and profoundly damage national prestige, morale, and confidence. Terrorist attacks using components of the Nation's CI/KR as weapons of mass destruction could have even more devastating physical, psychological, and economic consequences. The protection of the Nation's CI/KR is an essential part of the homeland security mission to make the United States safer, more secure, and more resilient from terrorist attacks and natural and manmade hazards. Protection includes actions to guard or shield assets, systems, networks, and their interconnecting links from exposure, injury, destruction, incapacitation, and exploitation.

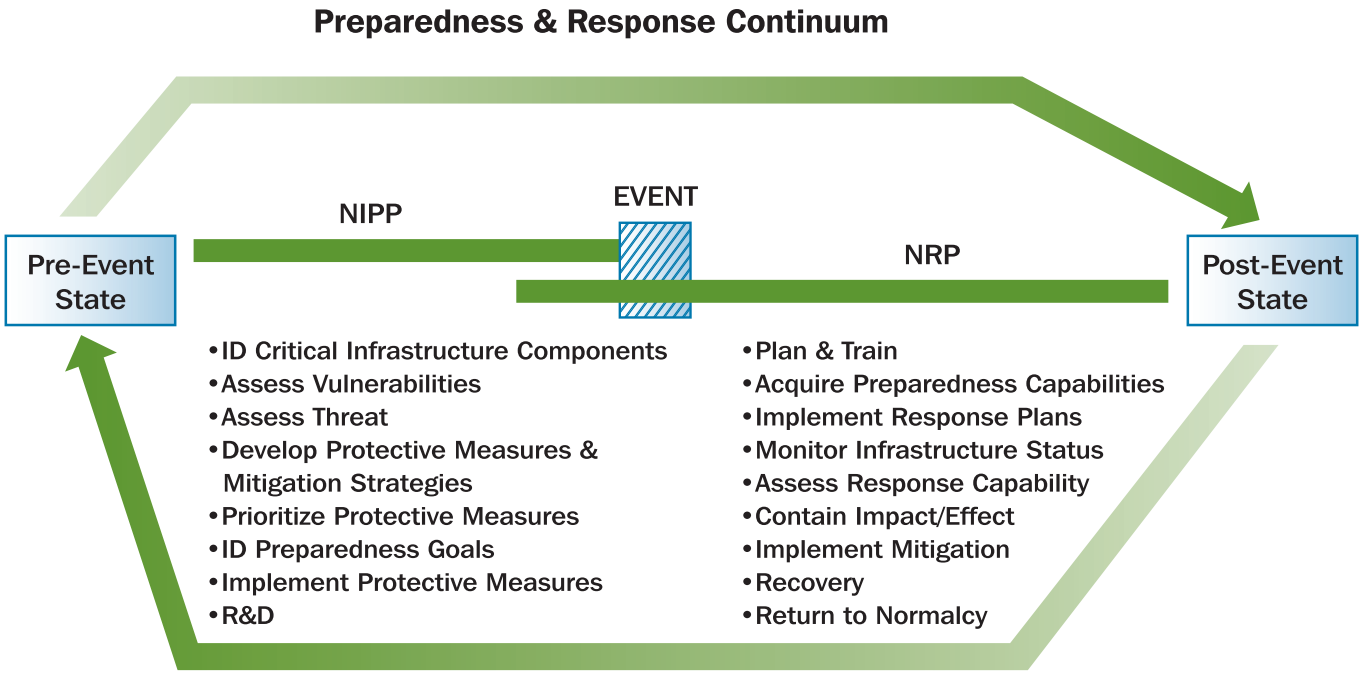
In the context of the NIPP, protection includes actions to deter, mitigate, or neutralize the threat, vulnerability, and consequences associated with a terrorist attack or other incident. Protection can include a wide range of activities, including hardening facilities, building resilience and redundancy, incorporating hazard resistance into initial facility design, initiating active or passive countermeasures, installing security systems, and implementing strict security measures.

Major components of the strategy to protect the Food and Agriculture Sector are countermeasures that include disease and pest surveillance, rapid identification, vaccine development, and disease-resistant crop development. By preventing or mitigating the effect of an attack, these countermeasures reduce the appeal of agriculture and food as a target and help make the sector safer.

A protection plan must be coordinated closely with response and recovery plans through a continuous feedback loop. Figure I-1 shows the preparedness and response continuum.

Sector protective program implementation will be facilitated using the Target Capabilities List (TCL). The TCL is a reference document that describes the capabilities and target levels for achieving national preparedness, including prevention and protection activities. Target capabilities are combinations of resources that provide the means to achieve a measurable outcome resulting from performance of one or more critical tasks under specified conditions and performance standards. The TCL is designed to assist jurisdictions and agencies in understanding and defining their respective roles in a major event and to identify the capabilities required to perform a specified set of tasks.

Figure I-1: Preparedness and Response Continuum

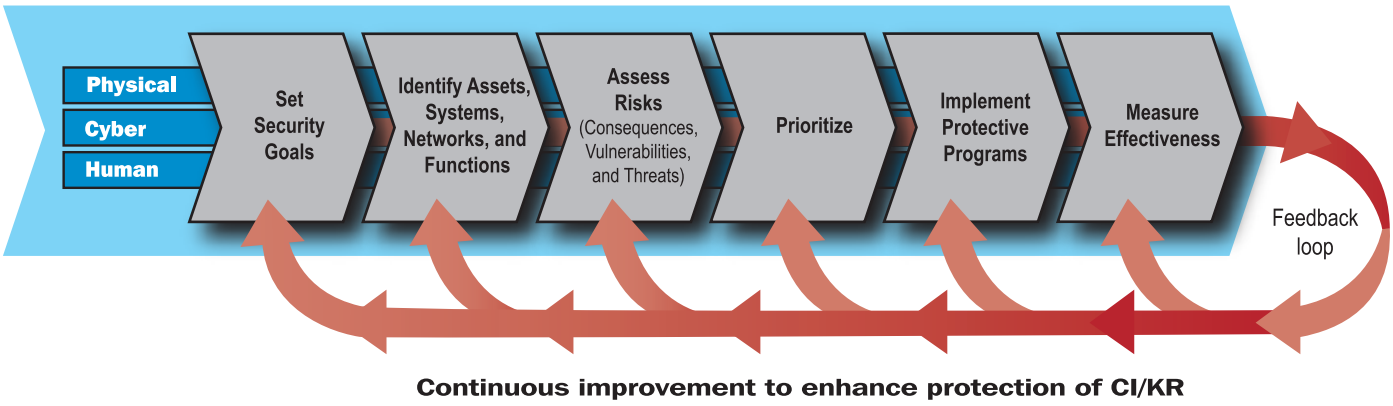


The NIPP and its complementary Sector-Specific Plans (SSPs) provide a consistent, unifying structure for integrating both existing and future CI/KR protection efforts. It also provides the core processes and mechanisms to enable government and private sector security partners to work together to implement CI/KR protection initiatives.

The Department of Homeland Security (DHS), the Sector-Specific Agencies (SSAs), and their security partners share the responsibility for overarching implementation of the risk management framework. SSAs are responsible for leading sector-specific risk-reduction programs and for ensuring that the sector-specific application of the risk management framework is addressed in their respective SSPs. DHS supports these efforts by providing guidance, tools, and analytical support to SSAs and other security partners. DHS is responsible for using the results obtained in sector-specific risk management efforts to conduct cross-sector risk analysis and management in collaboration with other security partners. This includes the assessment of dependencies, interdependencies, and cascading effects; identification of common vulnerabilities; development and sharing of common threat scenarios; development and sharing of cross-sector measures to reduce risk; and identification of specific research and development (R&D) needs.

The cornerstone of the NIPP is its risk management framework. Risk, in the context of the NIPP, is defined as the potential for loss, damage, or disruption to the Nation's CI/KR resulting from destruction, incapacitation, or exploitation during a future manmade or naturally occurring event. The NIPP risk management framework (see figure I-2) establishes the process for combining consequence, vulnerability, and threat information to produce a comprehensive, systematic, and rational assessment of national or sector-specific risk that drives CI/KR protection activities. The framework applies to the general threat environment and to specific threat or incident situations.

Figure I-2: NIPP Risk Management Framework



SSPs follow and support the NIPP risk management framework, which includes the following activities:

- **Set Security Goals:** Define specific outcomes, conditions, end points, or performance targets that collectively constitute an effective protective posture;
- **Identify Infrastructures:** Develop an inventory of the assets, systems, and networks and the critical functionality they provide, including infrastructure located outside the United States, that make up the Nation's CI/KR and collect information pertinent to risk management;
- **Assess Risks:** Determine risk by combining potential direct and indirect consequences of a terrorist attack or other hazards (including dependencies and interdependencies associated with each identified asset, system, or network), known vulnerabilities to various potential attack vectors, and general or specific threat information;
- **Prioritize:** Aggregate and analyze assessment results to determine assets, system, and network criticality, and present a comprehensive picture of national CI/KR risk in order to establish protection priorities and provide the basis for protection planning and the informed allocation of resources;
- **Implement Protective Programs:** Select appropriate protective actions or programs to reduce the risk identified and secure the resources needed to address priorities; and
- **Measure Effectiveness:** Use metrics and other evaluation procedures at the national and sector levels to measure progress and assess the effectiveness of the national CI/KR protection program.

DHS uses information from metrics and other evaluation tools to support a constant feedback loop. As shown in figure I-2, these activities are implemented based on a dynamic threat environment. The output is sector-specific strategies to protect assets. The ultimate objective of this SSP is to have the Federal, State, local, tribal, and private sectors work with the SSA and DHS to implement the plan in a way that is consistent, sustainable, effective, and measurable.

This document presents the SSP for the Food and Agriculture Sector and provides a detailed description of the specific processes that will be used to identify, assess, prioritize, and protect critical assets, systems, networks, and functions and measure the effectiveness of implementation plans. The plan was developed with contributions from Federal, State, local, and tribal government, and private sector security partners, and in coordination with the Food and Drug Administration (FDA), which is the other SSA for the sector. The first chapter of the SSP provides a sector-wide overview. The remaining chapters were developed to facilitate stakeholder use and are presented in chapters that provide specific information on the individual agriculture and food subsectors (production agriculture, processing, and distribution).

1: Food and Agriculture (Meat, Poultry, and Egg Products) Overview

1. Sector Profile and Goals

The Food and Agriculture Sector, composed of complex production, processing, and delivery systems, has the capacity to feed people beyond the boundaries of the Nation. These food and agriculture systems, which are almost entirely under private ownership, operate in highly competitive global markets, strive to operate in harmony with the environment, and provide economic opportunities and improved quality of life for rural and urban citizens of the United States and other peoples worldwide. When measured from inputs to tables at home and away from home, the sector accounts for roughly one-fifth of the Nation's economic activity.[4] The President's National Strategy for Homeland Security (July 2002) calls the Food and Agriculture Sector critical to the Nation's security because it provides "essential goods and services Americans need to survive."

The Food and Agriculture Sector operates in a global context, and the United States is a major player in international markets. The U.S. share of the global market for agricultural goods averages just under 20 percent.[5] Since U.S. farms produce far beyond domestic demand, maintaining a competitive agricultural system is essential to ensuring the economic vitality of U.S. agriculture. At the same time, U.S. agriculture is a diverse economic sector. Differences in commodity type, farm size, operator and household characteristics-even goals for farming- affect the competitiveness of individual operations and ultimately the sector as a whole. In recent years, changes in the rules of trade, shifts in domestic policy, and new developments in technology have altered the competitive landscape of global agriculture and the challenges facing American farmers. By providing food aid in disaster and poverty stricken areas around the world, these farmers also make a global humanitarian impact.

A relatively new challenge for the sector is addressing the threat of terrorism, both domestic and international. Robert Mueller, Director of the Federal Bureau of Investigation (FBI) said, "Most people do not equate terrorist attacks on people, planes, and

Defense of United States Agriculture and Food

"The United States agriculture and food systems are vulnerable to disease, pest, or poisonous agents that occur naturally, are unintentionally introduced, or are intentionally delivered by acts of terrorism. America's agriculture and food system is an extensive, open, interconnected, diverse, and complex structure providing potential targets for terrorist attacks. We should 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."

[4] National Agricultural Statistics Service, Agricultural Statistics Board, 2004.
[5] "Farm Attack–The Forgotten Terrorism," The Age, October 1, 2005.

buildings with attacks on plants and animals. But the threat is real, and the impact could be devastating."[5] The White House has acknowledged the importance of protecting the sector by issuing HSPD-9, Defense of United States Agriculture and Food. This plan is the strategic framework for the protection activities called for in HSPD-9.

1.1 Sector Profile

This infrastructure protection plan only focuses on the portions of the U.S. Food and Agriculture Sector that are considered part of the agriculture and food critical infrastructure, as defined by the *National Strategy for Physical Protection of Critical Infrastructures and Key Assets* (the National Strategy), published in February 2003. The National Strategy defines the Food and Agriculture Sector CI/KR as the supply chains for feed, animals, and animal products; crop production and the supply chains of seed, fertilizer, and other necessary related materials; and the post-harvesting components of the food supply chain, from processing, production, and packaging through storage and distribution to retail sales, institutional food services, and restaurant or home consumption.[6] In general terms, the Food and Agriculture Sector comprises the Nation's agricultural production and food systems from farm to table.

In order to function and produce food, the sector is dependent upon resources and services based in other sectors, including the Energy, Water, Transportation, Cyber, and Government Facilities sectors. The Food and Agriculture Sector relies on their resources and services (chemicals, electricity, water, delivery trucks, food inspectors, laboratories, etc.) and cannot operate without them. It is interdependent with many sectors because of the breadth of agricultural production and the responsibility of the sector to feed the Nation.

The complexity of the Food and Agriculture subsectors makes designing a critical infrastructure protection plan applicable across its entirety a challenge. The plan will divide the sector into discrete portions that are individually examined and then tied back to the overall sector goals. First, the plan will address infrastructure protection within the production agriculture subsector, which encompasses livestock and crop production at the farm level. Next, the plan will examine infrastructure protection within the food processing (meat, poultry, and egg products) subsector. All other food product infrastructure protection considerations will be addressed in the FDA SSP. USDA and FDA have collaborated to design the two plans so that together they would provide a complete picture of food-related infrastructure protection activities for the sector. Lastly, the plan will focus on infrastructure protection for food distribution activities.

Separating the plan into distinct subsectors will allow sector security partners to more easily follow the plan and thus implement it more effectively. A significant portion of SSP users will be Federal, State, local, or tribal government officials that have regulatory responsibility for the sector. They will look to the plan for guidance when developing their own infrastructure protection activities. These individuals may represent agriculture, food, public health, or law enforcement entities.

Private industry partners will also look to the plan for guidance. Creating a document that industry owners can easily use is important because almost all of the assets, systems, and networks are privately owned in this sector. Privately owned farms, ranches, groves, feedlots, slaughterhouses, food processing facilities, food assistance programs, and food distribution mechanisms (transportation and warehouses) make up most of this sector. Private industry has carefully organized itself through the SCC into seven subsectors that cover these systems from farm to table. Section 1.1.2 of this chapter describes the SCC more fully.

Federal, State, local, or tribal government partners also "own" a portion of the sector. The Federal Government is assigned the responsibility as an SSA to engage partners in sector security activities. The governmental portion of the sector includes the resources (personnel, equipment, facilities) related to regulating, assisting, and promoting the sector. For example, governmental sector assets or systems may include: personnel that provide regulatory oversight; personnel that provide technical assis-

[6] Infrastructure protection activities related to agricultural systems not included in the definition (e.g., forestry and timber or rural programs) are addressed separately by the lead Federal entity, USDA, in collaboration with the relevant Federal, State, local, tribal, and private sector partners.

tance; financial assistance mechanisms; scientific personnel, processes, and equipment used to conduct surveillance and related work; and the facilities that house these personnel and related research activities.

Although most of the sector is under private ownership, a significant portion of the sector is subject to Federal or State regulation or benefits from technical or financial assistance programs; therefore, strong partnerships between government and private industry are essential for successful sector protection programs. A description of the key authorities for the sector is available in appendix 3.

1.2 Security Partners

As noted previously, the sector comprises a set of private industries and government (Federal, State, local, and tribal) entities; therefore, security for the sector requires close collaboration between government and industry. In HSPD-7, USDA is assigned the task of SSA, with FDA, for the sector. USDA shares SSA responsibilities for food safety and defense with FDA. In that role, USDA and FDA have an obligation to provide leadership for sector infrastructure protection activities, including establishing information-sharing relationships and developing collaborative sector security plans with sector security partners.

USDA is responsible for the safety of 20 percent of all food consumed in the United States, including the entire domestic and imported meat; poultry; and frozen, dried, and liquid eggs food supply. FDA is responsible for all other domestic and imported foods. For a description of the FDA SSA responsibilities, see the FDA SSP.

This section describes the responsibility of USDA, as SSA, and the responsibilities of sector security partners (Federal, State, local, and tribal governments and private industry).

1.2.1 Sector-Specific Agency

At USDA, leadership for SSA responsibilities rests with the USDA Homeland Security Office (HSO), which coordinates with all USDA agencies and offices to meet SSA goals. Table 1.1-1 provides a list of USDA agencies by mission area.

Table 1.1-1: USDA Agencies by Mission Area

USDA Mission Area	Agency
Farm and Foreign Agriculture Services	• Farm Service Agency (FSA) • Foreign Agricultural Service (FAS) • Risk Management Agency (RMA)
Food, Nutrition, and Consumer Services	• Center for Nutrition Policy and Promotion (CNPP) • Food and Nutrition Service (FNS)
Food Safety	• Food Safety and Inspection Service (FSIS)
Natural Resources and Environment	• Forest Service (FS) • Natural Resources Conservation Service (NRCS)

USDA Mission Area	Agency
Research, Education, and Economics	• Agricultural Research Service (ARS) • Cooperative State Research, Education, and Extension Service (CSREES) • Economic Research Service (ERS) • National Agricultural Statistics Service (NASS)
Rural Development	• Rural Business Service (RBS) • Rural Housing Service (RHS) • Rural Utilities Service (RUS)
Marketing and Regulatory Programs	• Agricultural Marketing Service (AMS) • Animal and Plant Health Inspection Service (APHIS) • Grain Inspection, Packers, and Stockyards Administration (GIPSA)

USDA has statutory responsibilities to ensure plant and animal health and the safety of meat, poultry, and egg products. USDA is also a research leader in human nutrition, animal and plant health protection, and new crop technologies that allow producers to grow more food and fiber using less water and pesticides. USDA helps to ensure open markets for U.S. agricultural products and provides food aid to people in need domestically and overseas. USDA also provides a financial safety net to producers through market and disaster assistance programs and loans. Appendix 5 depicts USDA agencies and their jurisdiction in the farm-to-table continuum, along with their sector partners.

The nexus between these responsibilities and homeland security, specifically infrastructure protection, lies in the relationship between a safe and plentiful food supply and ensuring public health nationwide. The nexus is also demonstrated in the economic jobs dependent upon it.[7]

USDA has a long record of working with other governmental entities and private industry to support U.S. agriculture and food industries in ensuring the safety of our food supply.

Agencies and offices within USDA are very active in outreach activities to accomplish its mission. The agencies work to develop the productive and cooperative relationships of the large and diverse food and agriculture community through the creation of strategic alliances with stakeholders; however; these relationships have not typically included the appropriate security- or defense-related entities and have not included the entire range of stakeholder entities from farm-to-table.

1.2.2 Government Coordinating Council and Sector Coordinating Council[8]

USDA and FDA, in concert with DHS, recognized the need for a mechanism to facilitate interaction with sector security partners. A solution presented itself via HSPD-7, the White House directive that establishes national policy for Federal departments and agencies to identify and prioritize the CI/KR of the United States and to guard against efforts to undermine or exploit those sector assets. HSPD-7 directs Federal departments and agencies to identify, prioritize, and coordinate the protection of CI/KR in partnership with State, local, and tribal governments, and the private sector. The goal of establishing such a partnership

[7] Agricultural Statistics Board, National Agricultural Statistics Service, 2004. The sector accounts for approximately $1.24 trillion annually and is responsible for one in every six jobs.
[8] See the Federal Register, March 24, 2006 vol. 71 no. 57 pp. 14930-33 and Section 871 of the Homeland Security Act of 2002, 6 USC 451 for additional information on these partnerships.

is to leverage complementary resources within government and between government and industry to ensure a more robust, resilient, and secure sector.

Significant progress in the Food and Agriculture Sector on homeland security goals can only be accomplished through a partnership effort between all levels of government and those who own the critical infrastructure. The Food and Agriculture Sector's main coordination mechanisms for security partners are the Government Coordinating Council (GCC) and Sector Coordinating Council (SCC).

The GCC, with representation from Federal, State, local, and tribal governments, is the public sector portion of the public/private partnership framework. The objective of the GCC is to provide effective coordination of Food and Agriculture Sector defense strategies and activities, policy, and communication across government and between the government and the sector to support the Nation's homeland security mission. The GCC plays a coordination role to address the public health and clinical issues that would result from a terrorist act involving the food supply. It acts as the counterpart and partner to the private industry-led SCC to plan, implement, and execute sufficient and necessary sector-wide security programs for the Nation's Food and Agriculture Sector critical assets, systems, networks, and functions. The GCC works to accomplish this objective through the following activities:

- **Identifying Items That Need Public/Private Coordination and Communication of Issues.** The GCC will bring together diverse Federal, State, local, and tribal interests to identify and develop collaborative strategies that advance the protection of critical assets, systems, networks, and functions. While the focus is on CI/KR protection, the GCC will also function during events of national emergency or significance to coordinate and share information to augment existing emergency operation channels within Federal, State, local, and tribal government and with industry.
- **Identifying Needs/Gaps in Plans, Programs, Policies, Procedures, and Strategies.**
- **Acknowledging and Recognizing Successful Programs and Practices.** The GCC shall facilitate the sharing of experiences, ideas, best practices, and innovative approaches related to the protection of critical assets, systems, networks, and functions . The GCC shall acknowledge and recognize accomplishments that further the objective.
- **Leveraging Complementary Resources Within Government and Between Government and Industry.**

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 among their members or to communicate with the government through the GCC. The purpose of the SCC is to represent and communicate the interests of its subcouncils to the SCC leadership and to the GCC. SCC objectives include keeping subcouncil members apprised of key sector, inter-sector, and sector/government activities and bringing to bear their best judgment upon SCC decisions based on their understanding and experience within their subcouncil business area.

The GCC and SCC also work cooperatively. Both their leadership and the full membership interact regularly. Leadership discussions focus on identifying and solving policy issues. The GCC and SCC joint meetings acknowledge and recognize successful programs and practices and focus on assessing progress and accomplishments and on leveraging complementary resources within government and between government and industry. The two councils collaborate on joint initiatives such as identifying and prioritizing items that need public/private input, coordination, implementation, and communication; coordination and communication of issues to all members; and identification of needs/gaps in research and best practices and standards.

1.2.3 Sector Council Membership

The GCC and SCC documents describe membership requirements, which can be amended; the actual membership may fluctuate based on interest and participation.

The GCC membership comprises key representatives and influential leaders on food and agriculture safety, security, and defense issues from Federal, State, local, and tribal governments. GCC official members are director-level (or equivalent) representatives (and their alternates) from the following entities:

- Department of Homeland Security;
- Department of Agriculture;
- Department of Health and Human Services/Food and Drug Administration;
- Department of Defense;
- Environmental Protection Agency;
- Association of State and Territorial Health Officials;
- National Association of State Departments of Agriculture;
- National Association of County and City Health Officials;
- National Assembly of State Animal Health Officials; and
- Intertribal Agriculture Council.

The GCC reserves the right to invite ad hoc or ex officio membership to meet the expertise requirements necessary to fulfill its mission. Current ex officio members include the Association of Food and Drug Officials, the Department of Justice, the American Association of Veterinary Laboratory Diagnosticians, and the Association of Public Health Laboratories.

The GCC recognizes that each member represents a government entity or organization with inherent legal authorities and parameters within which they must operate. At times, these authorities may restrict a member's ability to provide agreement on a decision. These inherent legal authorities must be clearly articulated and understood by the council as the basis for dissent and the inability to enter into consensus.

The SCC membership consists of agriculture and food industry representatives from farm to table, including both individual owners and operators and trade association officials. Due to the great diversity in interests represented on the SCC, it is subdivided into seven subcouncils that can address issues relevant to the membership. These subcouncils include:

- Producers/Plant Subcouncil;
- Producers/Animals Subcouncil;
- Processors/Manufacturers Subcouncil;
- Restaurant/Food Service Subcouncil;
- Retail Subcouncil;
- Warehousing/Logistics Subcouncil; and
- Agricultural Production Inputs and Services Subcouncil.

1.2.4 Roles and Responsibilities

To function efficiently, the GCC and SCC have each selected leadership bodies to coordinate and collaborate on important issues. The leadership bodies report back to the full membership. In addition, the leadership ensures that the councils fulfill their roles and responsibilities as defined in their charters.

1.2.5 GCC Functions

Leadership of the GCC activities and meetings rests with the three main Federal agencies, USDA, HHS/FDA, and DHS and a State representative. Day-to-day leadership of meetings and activities rotates among the three Federal agencies through the GCC chairmanship. The chair collects from other members or initiates and then brings the initiatives or issues to the GCC for consideration and deliberation. The chair, working with other council members, monitors initiatives and issues and ensures that they are brought to closure.

The GCC Secretariat, appointed by DHS, provides meeting and organizational support, including coordination for agenda development, support for the chairman on monitoring and closure of issues and initiatives, administrative support, and logistics (travel, meeting rooms) support.

The GCC establishes work groups when substantial investigation, research, and other tasks are required that cannot be achieved at a regular GCC session. All products of the work group are intended to advise council members on important issues, direction, and processes.

1.2.6 SCC Functions

During the organizing process, private sector members stressed the importance and essential nature of building coordination from clearly identified subsector areas known as subcouncils.

Each Food and Agriculture Sector subcouncil will develop definitions on the focus and boundaries of its subsector areas so that members of the sector can clearly identify which subcouncil(s) may address their business and security interests. Each subcouncil will define its membership, priority issues, and areas of work and activity. Each subcouncil must have flexibility in prioritizing and identifying its needs and have been asked to examine the following general areas: communications and information sharing; R&D, including prevention and detection; incident management; vulnerability assessments; and recovery. As part of the process, the SCC sets clear goals for the establishment of subcouncils:

- Outreach, participation, and membership activities at the SSA subcouncil level are intended to be as inclusive as possible for relevant owners and operators and their associations.
- Subcouncils articulate their priorities and action items to the SCC, which then can communicate to the government through the GCC, other sectors, and other appropriate entities. Each subcouncil establishes a procedure for soliciting the views of subcouncil members on policies, programs, and activities, especially when conveying input to government-proposed or existing policies, plans, procedures, and activities.
- Each subcouncil will determine its own procedures for naming representatives to the SCC (two from each and one alternate), as well as replacing a member or alternate. In addition, each subcouncil will take responsibility for naming an ad hoc SCC representative for any one meeting when none of its named individuals (i.e., the two members and one alternate) can attend. Each subcouncil should establish and maintain subcouncil membership lists and contact information and establish communication procedures for sensitive and non-sensitive information. These should be conveyed to the SCC and updated on a regular basis.
- Each subcouncil should establish its own decisionmaking and operational procedures given the nature of standard business practices and relationships in that part of the food and agriculture subsector. Each subcouncil might consider the use of subject matter experts, subcouncil member work groups, and/or advisory work groups to assist in their activities.

1.2.7 GCC and SCC Principles of Participation

Both the GCC and SCC have adopted the following principles of participation:

- All members must be working toward the same goal and purpose of improving the security of the Nation's Food and Agriculture Sector systems;

- All members need to participate;
- Discussion and deliberations must recognize and take advantage of each member or organization's strengths, skills, and perspective;
- The result of discussion and deliberation must be a coherent report encompassing each member's contributions; and
- Each discussion must be honest and forthright.

1.2.8 Number and Frequency of Meetings

The GCC meets quarterly and has monthly conference calls. The SCC meets quarterly and individual subcouncils meet on an ad hoc basis. The GCC and SCC leadership host monthly conference calls. The full memberships of both councils meet in a joint session on a quarterly basis. Additionally, meetings or conference calls are coordinated as needed.

1.3 Sector Security Goals

During the sector organization process, GCC and SCC leadership coordinated the creation of a Food and Agriculture Sector Vision Statement and Sector Security Goals.

1.3.1 Sector Vision Statement

The mission of the Food and Agriculture Sector is twofold: (1) to protect against any attack on the food supply, including production agriculture, that would pose a serious threat to public health, safety, welfare, or the national economy; and (2) to provide the steadily evolving sector a central focus, emphasizing protection and strengthening of the Nation's capacity to supply safe, nutritious, and affordable food. To accomplish this mission, the GCC and SCC established a vision statement and long-term sector security goals.

Food and Agriculture Sector Vision Statement

Prevent the contamination of the food supply that would pose a serious threat to public health, safety, and welfare. 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, ensure that the industry has incorporated the concepts of HSPD-7 in their own critical asset protection plans, vulnerability or risk-reduction plans, and continuity of operations plans (COOP). The sector will provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management.

1.3.2 Sector Security Goal Development

Individual members from either the GCC or the SCC may propose security goals. The process begins within the individual councils, where members present suggested goals to their respective councils for feedback, modification, and support. The council will then decide if the goal will be a council goal or whether to take the proposed goal to the joint GCC/SCC session for discussion and deliberation. The decision to adopt the goal will be by consensus of the members of the individual councils for council goals or by both GCC and SCC members for joint council goals.

1.3.3 Sector Security Goals (Joint Goals)

The GCC and SCC established the following Joint Sector Security Goals that should be accomplished over the long term. These goals follow and are subject to modification as described above:

- **Improve Sector Analytical Methods to Enhance and Validate Detection of a Wide Spectrum of Threats.** Laboratory capabilities and capacities will be increased to address both traditional pathogens that contaminate foods and bioterrorist agents that could be used in an attack on food and agricultural products. This enhanced system will accommodate requirements that could result from a bioterrorist attack on the food supply.
- **Expand Laboratory Systems and Qualified Personnel.** The ability to effectively diagnose and treat animal disease outbreaks and crop contamination will be strengthened to prevent, respond to, and recover from an incident in the Food and Agriculture Sector.
- **Improve Sector Situational Awareness Through Enhanced Intelligence Communication and Information Sharing.** Industry stakeholders, law enforcement, and the Intelligence Community will provide more and better reporting of food and agriculture incidents and threats. Government-developed threat information will be expeditiously shared with the food and agriculture industry to facilitate threat-appropriate security measures.
- **Tailor Risk-Based, Performance-Based Protection Measures to the Sector's Physical and Cyber Assets, Personnel, and Customer 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.
- **Address Response and Recovery at the Sector Level, Not Just as Separate Enterprises.** Standards and planning for sector-wide continuity of operations will be developed. The sector will facilitate a close partnership with the public health community to enable rapid identification and treatment of bio-incidents in the Food and Agriculture Sector. The Food and Agriculture Sector will support the development of protocols and identification of resources to respond to and recover from an incident.
- **Enhance and Improve Two-Way Communications.** To facilitate information sharing within the law enforcement community, the Federal Government developed an information sharing tool known as the Joint Regional Information Exchange System, renamed the Homeland Security Information Network (HSIN) under DHS supervision. In light of the enthusiasm with which HSIN was received throughout the law enforcement community, DHS extended HSIN into the 17 CI/KR sectors identified in HSPD-7 through a parallel effort known as HSIN Critical Sectors (HSIN-CS). Under HSIN-CS, DHS is working with the GCCs and SCCs for each CI/KR sector to develop an online information-sharing tool specific to each sector for use by sector security partners. HSIN-CS is designed to enable communications within a given sector, between multiple sectors, and between sector and governmental entities. HSIN-CS offers four major components to network participants:
  - **Alerts/Broadcasting/Narrowcasting From DHS:** A secure medium for DHS and sector leaders to transmit actionable alerts and warnings to a specific audience about threats to critical infrastructure.
  - **HSIN-CS Portal:** The capability to store sensitive documents, including sophisticated imaging and maps. The portal enables real-time analysis of data and reporting tasks. It will provide a knowledge base that enables planning and coordination within the critical infrastructure sectors and eventually across these sectors.
  - **Collaboration Tools:** A peer-to-peer collaboration space for members to engage in real-time dialogue. Members can create their own private groups to discuss defined topics and collaborate on common documents.
  - **HSIN-CS Infrastructure:** The underlying technology platform and network, upon which additional infrastructure can be added.

Within HSIN-CS, a secure portal has been designed for the Food and Agriculture Sector. The HSIN-CS Food and Agriculture portal performs many of the functions previously done by the Information Sharing and Analysis Center or by other means, such as a secure Web portal, e-mail notifications, and incident reporting to DHS. Using the DHS Protected Critical Infrastructure Information (PCII) program and other available information protection mechanisms, sensitive business or security-related

information maintained on the HSIN-CS will be kept private to the maximum extent allowed by law. The GCC and SCC have agreed to use the HSIN-CS for two-way communications.

1.3.4 Sector Security Goals (GCC Goals)

The GCC has established the following security goals:

- **Work With State and Local Entities to Ensure That They Are Prepared to Respond to Incidents.** The 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 agriculture or food infrastructure.
- **Standardized CARVER + Shock Proposal.** The GCC will work with SCC members to produce a plan that will be used to develop a standardized CARVER + Shock methodology that States and industry can use to conduct vulnerability assessments.

1.3.5 Sector Security Goals (SCC Goals)

The SCC Producers/Animals Subcouncil has proposed the following security goal:

- **National Livestock Continuity of Business Plan Proposal:** The goal of the National Livestock Continuity of Business Plan (NL-COBP) project is to develop and implement a business continuity plan for the U.S. livestock and animal industry subsector using a Foot-and-Mouth Disease (FMD) outbreak as a model emergency.

Government emergency response and recovery efforts at all levels will be greatly enhanced by developing an NL-COBP that integrates and coordinates preparedness, response, and recovery capabilities with the various livestock and animal industry subsectors at the State, regional, and local levels. An NL-COBP will minimize the loss of business opportunity for U.S. livestock producers and affiliated industries. Using FMD as a model to create a severe animal health emergency scenario will enhance the ability of the sector to respond effectively to any natural or man-induced animal health emergency.

1.4 Value Proposition

U.S. food and agriculture industries annually generate more than $1 trillion in economic activity and, on a full-time-equivalent basis, employ more than 10 million people.[9] The Food and Agriculture Sector provides an abundant and safe food and fiber supply for families across the Nation and around the world through commercial trade and food aid. Protecting this sector and the well-being of all that depend upon it for food represents a difficult, yet critically important responsibility. The development of a comprehensive and strategic SSP for protecting the sector's critical assets, systems, networks, and functions will help meet this responsibility. The plan and the planning process will only succeed if they are fully supported by Federal, State, local, and tribal governments, and private industry.

The planning process is made more difficult by the sector's innate characteristics that are, in some cases, fragmented, dispersed, and resilient, and, in other cases, concentrated and interdependent. Understanding and communicating these complexities require the sustained commitment of both private and governmental security partners because the potential consequences to domestic and global human health, social, and economic well-being are enormous. The lessons learned in the development of the SSP will enable private and governmental interests to work together to better meet sector security goals. The lessons will enable all parties to make informed choices about where to allocate the scarce resources needed to improve the readiness and resilience of the sector.

[9] Bureau of Economic Analysis, Department of Commerce, "Gross Domestic Product by Industry Accounts," www.bea.gov/bea/pn/GDPbyInd_VA_NAICS.xls.

2. Identify Assets, Systems, Networks, and Functions

To meet its responsibilities under the Homeland Security Act and HSPD-7, DHS maintains a comprehensive national inventory of the information needed to identify those assets, systems, networks, and functions that make up the Nation's CI/KR. Currently, this inventory is maintained in the National Asset Database (NADB). DHS compiles the inventory in the NADB in a manner that enables it to be quickly scanned, searched, and analyzed. This allows DHS to rapidly identify those assets, systems, networks, and functions at greatest risk in different situations. This information is needed to help manage steady-state CI/KR protection and resiliency approaches and to inform and support the response to a wide array of incidents and emergencies. For example, the information may be used to quickly identify those assets, systems, networks, or functions that may be the subject of emergent terrorist statements or interest or that may be located in the area of greatest impact from natural disasters.

SSAs and DHS work together and in concert with State, local, and tribal governments, as well as private Food and Agriculture Sector security partners, to ensure that the NADB inventory data structure is accurate and current. The sector is currently developing criteria for determining the criticality of a sector asset, system, network, and function through the Food and Agriculture Criticality Project. Once complete, the SSA will share the criteria with its sector security partners so that they may apply it to their infrastructure. The SSA will ask each sector security partner to provide the relevant information for each item that is identified as critical to DHS for inclusion in the NADB. This effort will be a voluntary process.

2.1 Defining Information Parameters

To meet the requirements of the NIPP for a strategic approach to infrastructure protection, each sector must understand its critical components. Only after the sector is aware of each component, may it consider threats, assess vulnerabilities, develop and implement protective measures or mitigation strategies; address R&D needs; and measure success. A protection plan for this sector must begin with the farm and inputs, move through processing, and end with the consumer. The protection plan must consider interdependent sectors, including the Cyber, Chemicals, Water, Energy, Telecommunications, and Transportation sectors.

The Food and Agriculture Sector comprises systems of individual assets that are closely dependent upon each other. Because of its complexity, the sector has struggled to identify its most critical assets, systems, networks, and functions. While the sector understands its individual systems and basic interrelationships, the challenge has been in understanding the complexities and interdependencies across the farm-to-table continuum on national and regional scales.

USDA and sector security partners initiated the Agriculture and Food Criticality Project to identify the functions performed at an aggregate level by the Food and Agriculture Sector. Information from this project will be used to define criteria for sector infrastructure, which will facilitate the identification and prioritization of critical assets, systems, networks, and functions within the sector. USDA will incorporate findings from the project regularly into this SSP and share that information with security partners, so that upon completion of the project, the sector will be prepared to identify critical assets, systems, networks, and functions, and to determine the information parameters that will need to be collected for each. For more detailed information on the project, see Section 4 of this chapter.

2.2 Collecting Infrastructure Information

As stated in section 2.1, the diverse, complex nature of the sector poses a challenge to the task of determining which sector assets are critical. Once the criteria for criticality are available, the initial information collection effort must include an outreach component so that sector security partners within industry and the States understand the purpose of the criteria and what information is needed.

In some instances, a governmental entity may have access to relevant information via an ongoing program; however, challenges to using or sharing this information may emerge. For example, USDA, as a Federal regulator, has access to significant

information concerning the sector and its assets; however, legal hurdles often prevent sharing this information for non-regulatory purposes. Also, because of regulatory concerns, the private sector is often hesitant to voluntarily share non-required information with Federal and State officials.

Although the private sector would like to share sensitive business or security information with its Federal or State partners, it may hesitate to do so because of concerns about protecting the information from disclosure. The Food and Agriculture Sector is aware that the DHS PCII program offers a mechanism for industry to share sensitive business information.[10]

It is important that security partners work together to develop a process for collecting information that will minimize the burden of this activity on the SSA, the States, and industry. The sector councils will address this matter during the next SSP revision process.

2.3 Verifying Infrastructure Information

Information collected from USDA sources can be easily verified; however, to verify information from non-USDA sources, new resources for verification will be needed. It is important that security partners work together to develop a process for verifying information that will foster trust and minimize the burden of this activity on the SSA, the States, and industry. The sector councils will address this matter during the next SSP revision process.

2.4 Updating Infrastructure Information

Because the SSP is updated every 3 years or when intelligence or other information dictates, the States and industry will need to update their infrastructure information. Security partners must work together to develop a process for updating information that will minimize the burden of this activity on the SSA, the States, and industry. The sector councils will address this matter during the next SSP revision process.

3. Assess Risks

3.1 Use of Risk Assessments in the Sector

Risk assessments help to focus limited protection resources where they can have the greatest impact. They are especially useful for this large, diverse sector, which only receives limited resources for CI/KR protection. Within the Food and Agriculture Sector, risk assessments for homeland security purposes are not mandated by regulation and are voluntary in nature.[11] But because of the assistance they provide in focusing limited CI/KR protection resources, many security partners are actively engaged in conducting assessments; the GCC and SCC encourage members to conduct risk assessments regularly (as stated in HSPD-9).

At the Federal level, USDA has a history of risk assessment programs and innovations that were begun for safety purposes. These assessments have evolved to address security or defense purposes. For example, the USDA Food Safety and Inspection Service (FSIS) risk assessment programs have identified food products at risk for specific pathogens. This work has formed the backbone for programs to keep food safe and secure. Similarly, the USDA Animal and Plant Health Inspection Service (APHIS) has experience developing and using a variety of risk assessment tools to protect domestic plant and animal industries; these tools and assessments meet U.S. obligations to uphold international guidelines. USDA agencies have begun to address the HSPD-9 requirements for conducting assessments and will continue to strive to meet the requirements. Typically risk assessments

[10] Information submitted to satisfy the requirements of the Critical Infrastructure Information Act of 2002 is protected from public disclosure under the Freedom of Information Act, State and local disclosure laws, and use in civil litigation. More information about the PCII program is available at www.dhs.gov/pcii.
[11] HSPD-9, paragraph 11, directs USDA, HHS, and the DHS to expand and continue vulnerability assessments of the Food and Agriculture Sector and to update the assessments every 2 years.

conducted by the government are not site or company-specific; they focus on high-level operational or systems processes or a particular industry. These assessments are usually classified to protect the infrastructure information and analysis.

Several States have used risk assessments to identify food and agricultural-related vulnerabilities within their own jurisdictions. Some have partnered with the Federal Government and industry to do assessments jointly (see Strategic Partnership Program Agroterrorism in section 3.1.1 of this chapter). State assessments may be more narrowly focused on the industries within the State. The protection of this information varies by State law.

Private industry assessments, on the other hand, are typically focused on a particular company, site, or process within a company or site. Many private companies are choosing to assess themselves to determine how to best use their resources. These assessments, while not classified, are carefully guarded and rarely shared with government partners because they identify specific vulnerabilities within a company, site, or process point. However, a number of private firms, industries, their related trade organizations, and private voluntary organizations have demonstrated a general willingness to work with government partners to conduct risk assessments, as demonstrated during Strategic Partnership Program Agroterrorism (SPPA) exercises. Time constraints, concerns about exposing vulnerabilities, and assessment-related expenses limit the ability of some firms to participate in risk assessments.

Sector-Approved Risk Assessment Tool. While many risk assessment tools are available for use by sector security partners, the GCC and SCC have selected the CARVER + Shock methodology to assess risk to critical assets, systems, networks, and functions within the Food and Agriculture Sector. This approach was selected, in part, because it offers a simplified and standardized means for conducting risk assessments that aid in the identification of attractive targets. Because this is the tool selected by the sector as a whole, other tools, which may be used by individual sector partners, will not be addressed.

The CARVER + Shock method used by the sector is a modified version of a method designed by the Department of Defense (DOD) for offensive target prioritization. USDA and FDA refined the tool to make it appropriate for agriculture and food. Using a common assessment tool enables sector security partners to make decisions by comparing findings across commodities and subsectors.

The CARVER + Shock approach provides a consistent means for evaluating the consequences, vulnerability, and threat faced by assets, systems, networks, and functions in the Food and Agriculture Sector. This methodology meets the baseline criteria for assessment methodologies (as required in the NIPP guidelines, appendix 5A) by being complete and consistent and by providing unbiased assessments across the wide range of assets and systems found in the sector. The methodology also promotes careful examination of each point or node in the system. The CARVER + Shock approach is transparent and can be used independently or in concert by industry and government analysts to produce results that are defensible and reproducible.

CARVER is an acronym for the following six attributes used to evaluate the appeal of a target for attack:

- **C**riticality: Measure of public health and the economic impacts of an attack;
- **A**ccessibility: Ability to physically access and egress from target;
- **R**ecuperability: Ability of system to recover from an attack;
- **V**ulnerability: Ease of accomplishing attack;
- **E**ffect: Amount of direct loss from an attack as measured by loss in production; and
- **R**ecognizability: Ease of identifying target.

The seventh attribute, Shock, represents the combined health, economic, and psychological impacts of an attack. More detailed descriptions of the CARVER + Shock components and the assessment process are found in appendix 4.

The first factor to be considered in a risk assessment is the possible impact of an event. As outlined in HSPD-7, CARVER + Shock categorizes consequences in four categories: impacts on human life and physical well-being; direct and indirect economic impacts; effect on public confidence; and effect on the government's ability to maintain order, deliver minimum essential public services, ensure public health and safety, and carry out national security-related missions. The significance of possible impacts becomes a first filter through which assets, systems, networks, and functions are screened in CARVER + Shock assessments. More detailed descriptions of the CARVER + Shock components and the assessment process are found in appendix 4.

The SPPA initiative coordinates a majority of the Federal CARVER + Shock assessment activities for the sector.

3.1.1 Strategic Partnership Program Agroterrorism Initiative

To assist in protecting the Nation's food supply, four Federal partners, the FBI, USDA, FDA, and DHS developed the SPPA initiative, a joint assessment program using the CARVER + Shock tool. The purpose of this initiative is to conduct a series of assessments of the Food and Agriculture Sector in collaboration with industry and State volunteers.

SPPA assessments are conducted on a voluntary basis between one or more industry representatives for a particular product or commodity; their trade association(s); and Federal and State government agricultural, public health, and law enforcement officials. Together, they conduct an assessment of that industry's production process using the CARVER + Shock tool.

As a result of each assessment, participants collectively identify nodes or process points of highest concern, protective measures and mitigation steps that may reduce the vulnerability of these nodes, and research gaps and needs. At the conclusion of the SPPA initiative, the team will prepare a report describing risk within each of the Sector's seven subsectors (e.g. animal production, retail). Decision makers may use the report to compare risk across the subsectors.

3.1.2 Information Technology System Assessments

Information technology (IT) assessments are important to the Food and Agriculture Sector because of its reliance on IT systems and infrastructure. IT-related assessment policies vary across the sector. These systems are used daily by government and industry in the operation of processing plants and other agricultural and food-related businesses across the country and worldwide.

At the Federal level, USDA follows White House OMB Circular A-130, Appendix III guidance for performing assessments on IT systems. The appendix mandates that "adequate protection" be provided to Federal information systems. USDA also looks to the National Institute of Standards and Technology (NIST) for guidance on IT issues because NIST is the governing body for Federal standards as they relate to information technology. USDA and Federal partners follow guidance for computer risk assessments stated in NIST SP 800-30, Risk Management Guide for Information Technology Systems, and Federal Information

Processing Standards 199, Standards for Security Categorization of Federal Information and Information Systems. Federal computer security plans must comply with NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems. Federal certification and accreditation of IT systems must comply with NIST SP 800-37, Guide for the Security Certification and Accreditation of Federal Information Systems.

USDA regulations and guidance apply to IT security assessment activities within the department. For example, business impact analysis (BIA) and technical impact analysis (TIA) must be completed for each critical IT application. The BIA helps establish priorities for application recovery after a disaster and documents the business process, maximum allowable downtime, and liability and cost considerations. The BIA records the effect of downtime on customers and employees. The TIA identifies the technical requirements and estimated time to recover the system.

The Office of the Chief Information Officer (OCIO) coordinates with the United States Computer Emergency Response Team (US-CERT) daily through the reporting of security incidents that affect USDA agencies. In addition, OCIO works with US-CERT by ensuring that USDA agencies respond in a timely manner to recently identified vulnerabilities that could have a major impact on USDA operations. Finally, US-CERT provides the department with timely notification of security information that can be used to proactively combat security threats.

Requirements for State-level IT assessments vary by State; each industry or company determines its own IT assessment practices.

3.1.3 Department of Agriculture Facility Assessments

USDA owns and operates a portion of the sector's physical assets (e.g., laboratories). Of the USDA-owned assets, the department has identified mission-critical facilities and is continuing to perform assessments on these facilities.

3.1.4 Information Security: Classification Process

The results of an assessment may include sensitive information that could be harmful if released (e.g., the information may aid a terrorist in targeting the sector). The Federal Government uses classification as a process to determine whether information can potentially cause damage to U.S. national security and to protect such information. USDA has a Draft Information Security Program Manual to establish a uniform system for classifying, safeguarding, declassifying, and destroying classified national security information. When finalized, the manual will establish policy for all USDA mission areas, agencies, and offices and their contractors who possess, handle, distribute, process, transmit, transport, and/or store classified information. Individuals serving in an advisory or consultant capacity, who have been entrusted with USDA classified information, will be required to protect that information to standards equivalent to those discussed in the manual.

Sometimes unclassified information combined or associated with other unclassified information may warrant classification. This is referred to as classification by compilation or aggregation of information and will be done following the guidance provided in the Draft Information Security Program Manual.

Whenever possible, USDA will remove sensitive information from classified materials while maintaining the usefulness of the product, so that the materials may be shared with sector security partners. As private sector and State representatives obtain security clearances via their membership on the GCC and SCC, classified assessment information will be shared as appropriate.

3.2 Screening Infrastructure

As with other risk assessment approaches, application of the CARVER + Shock approach can be costly in terms of time and expenditures. Initial screening efforts that focus on public health and economic impact analyses are employed as a first-level screen to reduce the number of assets, systems, networks, and functions that might be considered for a complete risk assessment. This selection process weighs general assessments of possible economic and public health consequences, industry assessments of possible concerns, and awareness of possible interdependencies that might affect other sectors. This is not a formal

screening process. The sector will use the findings from the SPPA initiative (see section 3.1.1) to determine if a formal screening process is needed.

3.3 Assessing Consequences and Vulnerabilities

CARVER + Shock Risk Assessments

CARVER + Shock risk assessments incorporate consequence and vulnerability considerations as part of the same analysis. The consequences and vulnerabilities are treated separately within CARVER + Shock and are then combined in the overall ranking assessment. The attributes used to assess consequences and vulnerabilities are used by both FDA and USDA with the mindset that mass mortality and damaging the Nation's economy are goals of terrorist organizations. Any intentional food or agricultural incident could also have significant psychological impacts. Definitions for each component of the CARVER + Shock approach follow (for specific assessment and ranking criteria for each component, see appendix 4):

- **C**riticality: A target is critical when introduction of threat agents into this asset, system, or function would have significant health or economic impacts.
- **A**ccessibility: A target is accessible when an attacker can reach the target to conduct the attack and egress the target undetected. Accessibility is the openness of the target to the threat. This measure is independent of the probability of successful introduction of threat agents.
- **R**ecuperability: A target's recuperability is measured in the time it will take for the specific facility to recover productivity. The effect of a possible decrease in demand is considered in this criterion.
- **V**ulnerability: A measure of the ease with which threat agents can be introduced in quantities sufficient to achieve the attacker's purpose once the target has been reached. Vulnerability is determined both by the characteristics of the target (e.g., ease of introducing agents into a target) and the characteristics of the surrounding environment (e.g., ability to work unobserved, time available for introduction of agents). It is important to consider what interventions are already in place that might thwart an attack.
- **E**ffect: Effect is a measure of the percentage of system productivity damaged by an attack at a single facility.
- **R**ecognizability: A target's recognizability is the degree to which it can be identified by an attacker without confusion with other targets or components.
- **Shock:** Shock is the final attribute considered in the methodology. Shock is the combined measure of the health, psychological, and collateral national economic impacts of a successful attack on the target system. Shock is considered on a national level. If a large number of deaths occur, or the target has historical, cultural, religious, or other symbolic significance, the psychological impact will increase. Collateral economic damage includes such items as decreased national economic activity and increased unemployment in collateral industries. Psychological impact will also increase if victims are members of sensitive subpopulations such as children or the elderly.

The goal of a CARVER + Shock assessment is to identify the most vulnerable points or nodes within sector systems, networks, and functions (i.e., those that are the most likely targets for a terrorist attack). Identifying the critical nodes allows decision-makers, industry, and others potentially impacted by an attack to focus the development of countermeasures at those points that are most vulnerable within a given system. The identification of critical nodes aids in the identification of high-risk commodities and potential threat agents. In the CARVER + Shock method, each node is rated on a scale from 1 to 10 for each of the attributes. The sum of the scores for the seven attributes is calculated for each node. The nodes with the highest overall scores are considered to be the most vulnerable or at risk and should be the focus of countermeasures. Sample scoring sheets can be found in appendix 4, attachments 2B and 2C. The CARVER + Shock process incorporates sector interdependencies including chemical, transportation, water, and energy into the assessment scenarios.

Sector Interdependencies

The Food and Agriculture Sector has several very important interdependencies with other sectors. The most important of these interdependencies span the entire farm-to-table continuum and include the Chemical, Water, Transportation, and Energy sectors. The Food and Agriculture Sector also has interdependencies with the Public Health, Banking and Finance, Cyber, and Government Facilities sectors.

The Transportation Sector provides the means for delivering inputs such as seeds, seed stock, fertilizer, and feed required for agricultural production to the farm. The Transportation Sector is needed for the delivery of these agricultural products to processing facilities, then to distribution facilities and retailers, and finally to the consumer. The Energy Sector provides the fuel for farm machinery and transport vehicles and the power needed to run farm equipment and processing and storage facilities. The sector relies on the fertilizers and pesticides supplied by the Chemical Sector for the production of economical and plentiful agricultural products. The Food and Agriculture Sector is also dependent upon the veterinary pharmaceuticals and feed additives that are regulated by the FDA's Center for Veterinary Medicine, although this dependency is not specifically addressed in the sector.

The sector is interdependent on the Water Sector for water. The emphasis in the Water Sector is on water treatment and water delivery systems. Water is necessary for processing plants, livestock production, and crop irrigation at the farm level where water sources often include rivers, reservoirs, lakes, and groundwater.

The Food and Agriculture Sector has interdependencies with the Public Health Sector for managing zoonotic diseases impacting the workforce, the Banking and Finance Sector for financial transactions, the Cyber Sector for electronic transactions, and the Government Facilities Sector for SSA government facilities.

3.4 Assessing Threats

The Federal Government, under the NIPP, is responsible for providing threat information for each sector. Threat information is available from a variety of sources; however, DHS, law enforcement, and the Intelligence Community are the primary sources. USDA works in partnership with FDA and the DHS Homeland Infrastructure Threat and Risk Analysis Center (HITRAC), which is responsible for preparing sector-specific threat analysis products for sector security partners. USDA collaborates with HITRAC to ensure that the information provided is accurate and useful.

USDA has a relationship with law enforcement and the Intelligence Community. In both cases, USDA shares subject matter expertise and works closely to ensure that activities are coordinated. USDA receives regular briefings from the Intelligence Community and collaborates with law enforcement. USDA uses this threat information to select scenarios for vulnerability assessments that include that the appropriate threat agents and conditions.

States and private sector representatives work with local law enforcement to ensure that the threat information that they are aware of is shared with the appropriate Federal officials. The FBI's weapons of mass destruction coordinators play an important role in collaborating with the States and the private sector to maintain awareness of threats.

Risk and threat assessments aid in prioritizing resources to protect the sector's infrastructure.

4. Prioritize Infrastructure

Prioritization of the sector's infrastructure requires a systems approach because many individual pieces have interdependencies within and beyond the sector. It requires that the sector: (1) determine what constitutes the sector's assets, systems, networks, and functions, and (2) establish criteria for differentiating between critical and non-critical infrastructure.

Traditionally, CI/KR protection efforts have focused on physical security for structures (e.g., installations and equipment). These efforts tailored their approach to physical assets that have well-defined perimeters, such as chemical plants and nuclear power generation facilities. In contrast, the Food and Agriculture Sector has extensive, open, widely dispersed, diverse, and complex interdependent systems; therefore, the physical asset-based approach may not fit the Food and Agriculture Sector. To address this gap-the need for a methodology to determine what is critical in the sector-the sector initiated the Agriculture and Food Criticality Project.

Agriculture and Food Criticality Project

The Agriculture and Food Criticality Project brings together a multidisciplinary team of subject matter experts and analysts to develop, refine, and apply a methodology to objectively determine the criticality of systems or assets in the Food and Agriculture Sector. A steering committee comprising GCC and SCC membership manages the project. The Homeland Security Institute (HSI), a DHS Federally Funded Research and Development Center, began the research and analysis for this project. The steering committee has concluded the initial portion of the project with HSI. However, the project remains a priority for the Sector, so the steering committee will transition the remainder of the activity to another entity as soon as possible.

The following goals will drive the design of a novel Food and Agriculture Sector methodology:

- Provide a practical definition of criticality for Food and Agriculture Sector systems and assets;
- Permit ranking of systems and assets to prioritize protection investment decisions; and
- Enable cost-benefit calculations for critical asset, system, network, and function protection options by stakeholder groups.

The objectives of the project are to:

- Characterize the Food and Agriculture Sector, including the structures, roles, and functions within the sector, and the resources that enable those functions. Drawn primarily from existing work, this characterization will consist largely of the characterizations contained in the SSPs and modeling capabilities already developed by USDA, FDA, the Los Alamos and Sandia National Laboratories, and DHS, and modified for use in this project;
- Develop a methodology for determining the criticality of assets within the Food and Agriculture Sector;
- Define different levels of criticality at national and regional levels that are easily recognized and understood by Federal, State, local, and tribal authorities;
- Define and extend the understanding of first-, second-, and third-order events from the point of criticality; and
- Conduct a first-generation test run, applying the methodology to the Food and Agriculture Sector, to demonstrate the viability and practicability of the methodology and to refine it.

As progress is made, pieces will be incorporated into the sector's risk assessments and prioritization activities. Until then, the core factor in prioritizing systems and assets will be current risk assessment programs including the CARVER + Shock assessment tool and the SPPA (see appendix 4 and section 3.1.1 for more information on the assessment tool and the SPPA, respectively).

Prioritization of State critical assets, systems, networks, and functions will vary by State; however, prioritization should be influenced by homeland security guidance provided by DHS Office of Grants and Training.

5. Develop and Implement Protective Programs

5.1 Overview of Sector Protective Programs

The protection and integrity of America's agricultural production and food supply are essential to the health and welfare of both the domestic and global community. Protective programs are based on the findings from risk or vulnerability assessments and from intelligence and law enforcement-related information. With a variety of programs that address safeguarding plant and animal production agriculture and food defense, the success of these efforts depends upon the coordinated work of a broad range of Federal, State, local, tribal, and private sector security partners. USDA and its sector security partners collaborate to develop and implement protective programs that address the prevention, protection, response, and recovery elements of the protective spectrum. Figure 1.1 depicts the spectrum. The GCC and SCC provide the primary forum for collaboration with sector partners on joint initiatives.

As stated earlier, traditional protective security measures, namely physical security measures, are not very effective across the sector because production agriculture and portions of food processing are open systems (e.g., farms, ranches, agricultural and food transportation systems).[12] This openness makes it very difficult to prevent the introduction of a threat agent. In general, protecting these systems requires science-based approaches to rapidly identify when a threat agent is present and to swiftly respond to the agent, allowing for a shorter and more effective recovery.

5.1.1 Laboratory Networks

Diagnostic laboratories are an important component of the sector's critical infrastructure. The National Animal Health Laboratory Network (NAHLN), the Food Emergency Response Network (FERN), and the National Plant Diagnostic Network (NPDN) provide the diagnostic support needed to identify animal diseases, foodborne contaminants, and plant diseases, respectively. For additional information on these laboratory networks, see chapter 2, section 5.1; chapter 3, section 5.1.3; and the Food and Agriculture Sector Annual Report which is submitted to DHS.

USDA is a member of the national Integrated Consortium of Laboratory Networks (ICLN). The ICLN's purpose is to provide a coordinated and operational system of laboratory networks that produce timely, high-quality, and interpretable results for early detection and effective consequence management to acts of terrorism and other events requiring an integrated laboratory response. The ICLN cuts across all Federal agencies, including the departments of Defense, Agriculture, Energy, and Health and Human Services.

A list and description of key protective programs will be made available to DHS in the Food and Agriculture Sector Annual Report.

5.2 Determining Protective Program Needs

The determination of protective programs is a consensus-based process between the GCC and SCC, as described in section 1.3.2. For these cooperative initiatives, the consensus of the GCC and SCC membership is fundamental. The same procedure is used to decide how protective programs will be implemented and maintained.

At the Federal level, protective programs are developed based on the findings of the assessments conducted on sector critical assets, systems, networks, and functions, information collected by the government, sector-specific information provided by the intelligence and law enforcement communities, and DHS HITRAC. Information from these sources is analyzed and gaps in protective programs are identified. The information is shared with the relevant GCC and SCC members. For classified analyses, the information is shared with those sector representatives who have appropriate security clearances.

[12] This distinction (traditional physical security versus an interconnected science-based preparedness, response, and recovery program) has made it a challenge for the sector to obtain access to security-related preparedness grants.

The GCC and SCC provide a forum where a member may suggest ideas for protective programs (e.g., develop Incident Command System and National Incident Management System training for the sector partners). Specifically, the Food and Agriculture Sector Joint Committee on Research allows the GCC and SCC to collaborate on identifying sector protective needs. Chapter 1, section 7.2.2, provides additional information on the Food and Agriculture Sector Joint Committee on Research initiative. The process for determining needs at the State-level will vary by State. Similarly, each industry or company will have its own process.

It is a goal for the next version of the SSP to add information to this section concerning State or industry-specific protective programs.

5.3 Protective Program Implementation

Implementation of protective programs is determined through a consensus-based process between the GCC and SCC as described in section 1.3.2 of this chapter.

At the Federal level, USDA's implementation and maintenance of protective programs focus on protecting farm animals and crops from disease outbreaks and pest infestations; protecting the supply of meat, poultry, and egg products; enhancing agricultural and food safety research and laboratory facilities; and improving emergency preparedness and response. Within USDA, individual agencies determine who is responsible for implementing and maintaining their programs within budgetary constraints. The HSO coordinates budgets for all USDA food and agriculture security and defense programs.

5.4 Protective Program Performance

Because it is a strategic document, this plan does not contain specific programmatic information. The Food and Agriculture Sector NIPP Metrics Report and Food and Agriculture Sector Annual Report, which are provided to DHS, include detailed information concerning the performance of individual programs.

As detailed in section 6 of this chapter, a variety of means are used to measure performance within the sector. At this time, performance measurement mechanisms exist for public/private efforts. The sector's goal is to develop sector-specific metrics for inclusion in the next iteration of the SSP.

5.4.1 Public/Private Partnership Initiative and Program Performance

For joint public/private partner initiatives and programs, the GCC and SCC will provide oversight through regular updates and discussions so that areas of improvement may be identified and implemented. Section 6 describes how performance metrics for measuring program effectiveness will be developed. The GCC and SCC will evaluate the programs on an annual basis.

5.4.2 SSA Initiative and Program Performance

Within USDA, the USDA Results Agenda and the President's Management Agenda provide the guidance used to evaluate program performance. The White House OMB developed the Performance Assessment Rating Tool (PART) to facilitate performance measurement and to assess and improve program performance across the Federal government. A PART review helps identify a program's strengths and weaknesses to inform funding and management decisions aimed at making the program more effective. The PART looks at all factors that affect and reflect program performance, including program purpose and design; performance measurement, evaluation, and strategic planning; program management; and program results. Because the PART includes a consistent series of analytical questions, it allows programs to show improvement over time and comparisons between similar programs.

USDA will annually conduct PART analyses for CI/KR initiatives and programs. With each PART analysis conducted, USDA agencies learn about program strengths and weaknesses. PART information will be used to help revise goals, objectives, and performance measures for strategic planning; shape annual performance plans and budgets; and improve program operations

and procedures. PART analyses help create better, more effective programs by keeping the focus on strategic objectives and measurable performance.

6. Measure Progress

6.1 CI/KR Performance Measurement

The key to assessing program effectiveness is measuring the right things. Performance measures must reflect a program's mission and priorities, be few in number, and provide information to inform budget and management decisions.

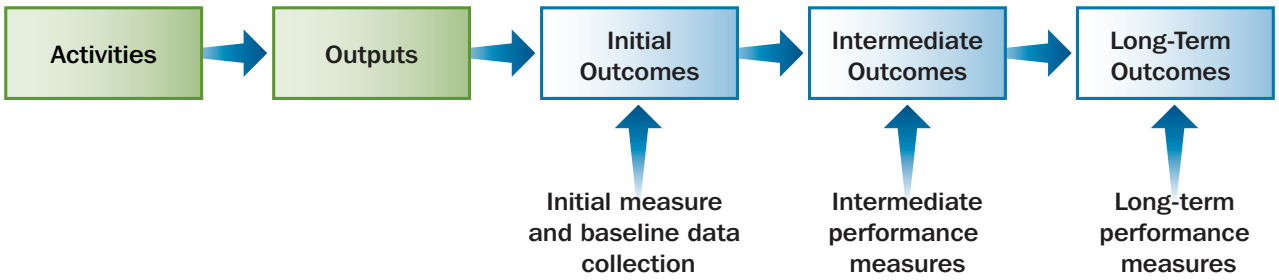
6.1.1 Developing Sector-Specific Metrics

As part of the preparation for the next version of the SSP, the GCC and SCC will work to develop sector-specific metrics. When working to develop the metrics, the GCC and SCC will consider the three types of metrics that should be tracked for CI/KR protection: output metrics, efficiency metrics, and outcome metrics. In general, the GCC and SCC will use the following steps to develop performance measures:

1. Determine which resources, activities, and goals are appropriate to measure;
2. Determine which resources, activities, and goals can be measured by output metrics, efficiency metrics, or outcome metrics;
3. For goals that are measured by outcome metrics, develop a logic model that tracks activities and outputs through initial, intermediate, and long-term outcomes of CI/KR protection;
4. Determine the appropriate stage for measuring and tracking progress;
5. Show the links from sector activity to final outcome;
6. Determine the appropriate stage for measuring and tracking progress;
7. Develop baseline data;
8. Implement programs; and
9. Track progress with intermediate and/or long-term performance measures.

Figure 1.6-1 depicts a logic model.

Figure 1.6-1: Logic Model



In figure 1.6-1, "activities" are defined as what the program actually does; "outputs" are the products produced by the activities; and "outcomes" are the changes that result. A logic model is the first, not the last, step in the evaluation. The model continually evolves as more information about outcomes and the effectiveness of activities becomes available.

In the interim, USDA will rely on the guidance provided in the PART. This useful mechanism demonstrates the relationship between outcome, output, and efficiency measures; each kind of measure provides valuable information about program performance. Collectively, these measures convey a comprehensive story on what products and services the agencies provide, how well they do, and the results derived from them. Within USDA, metrics are developed and performance measurements are done annually. They are based on guidance in the PART and in OMB Circular No. A-11, Preparing and Submitting the Performance Portion of the Performance and Accountability Report.

6.1.2 Information Collection and Verification

The Food and Agriculture Sector plans for collecting, using, protecting, and verifying information are addressed in sections 2.2 through 2.4 of this chapter.

6.2 Implementation Actions

Program performance measurement entails a comparison of actual performance with the projected (target) levels of performance as set out in the performance goals. At the Federal level, USDA develops plans to achieve unmet goals or recommends actions on unmet goals when it is impractical or not feasible to achieve the goals. The GCC and SCC provide the forum for addressing implementation issues regarding public/private collaborations.

Information concerning sector-specific protection programs will be made available to DHS in the Food and Agriculture Sector Annual Report and the Food and Agriculture Sector NIPP Metrics Report.

6.3 Challenges and Continuous Improvement

It may not be possible to have sector-wide consensus on any single issue because of the size and diversity of the Food and Agriculture Sector. The SSA must continue to engage the SCC at the subsector level and work with State organizations to obtain national, State-specific, and regional perspectives.

7. CI/KR Protection Research and Development

7.1 Overview of Sector R&D

The Agriculture and Food Sector depends upon science and technology for its daily activities and also for preparedness (including protection), response, and recovery programs. Because the greatest threats to the sector are biological or chemical agents, there is a reliance on science-based protection technologies. To ensure that the sector's R&D efforts are most efficiently using resources to meet needs, this plan will be coordinated with the National Plan for Research and Development in Support of Critical Infrastructure Protection and will be influenced by the sector councils' Joint Research Working Group (see below for more information on the group).

There are a variety of means, within the sector, to pursue protection R&D activities. Typically, Federal funds support high-level (sector-wide or industry-wide) R&D at the Federal or State level. And private industry typically hosts R&D that is more focused, or addresses a gap that the government is not addressing. Collaborative public and private efforts are also possible.

At the Federal level, the Agricultural Research Service (ARS) is the in-house scientific research arm of the USDA that conducts research to meet the needs of its stakeholders within the department, other Federal agencies, State and local governments, and

industry. Most R&D activities are prioritized based upon vulnerability or risk assessment findings and all are subject to budgetary limitations.

At USDA, ARS and its scientific expertise are available to help identify potential threats, assess vulnerabilities (including the basic data to be used for risk assessments), and develop effective countermeasures. The agency, through technology transfer activities, presents the results of its research activities to industry partners. However, because of the fundamental nature of much of the research in ARS, many of the research results are disseminated directly to the agricultural and food producers and commodity groups.

ARS research facilities range from standard laboratories to unique facilities that would be difficult to replicate elsewhere. Having a central position in the maintenance of germplasm resources, ARS, working with its partners, has the responsibility of maintaining and improving this important resource. In addition, ARS research scientists have unique and long-term research experience related to potential threats to plants, animals, and the food supply. They collaborate with DHS's Plum Island staff, and oversee the Ames, Iowa, research and quarantine facilities. These resources are important to the sector's protection activities.

The Cooperative State Research, Education, and Extension Service (CSREES) supports extramural sector research. CSREES provides funding and leadership to land grant universities' cooperative extension services, State cooperative extension services, State agricultural experiment stations, and other research organizations for food and agriculture CI/KR protection research and outreach. Research activities supported by CSREES address animal and plant diseases and pests, food processing, and food distribution systems. CSREES also works with agencies within USDA to help to identify research priorities.

The Economic Research Service (ERS) has economic modeling tools (information technology) and asset databases that aid decision makers on a variety of topics such as new policies or emergency response activities.

ERS research and development initiatives include database development efforts that can support a common information platform, and rapid assessments of the scope and context of emergencies. These efforts will require the guidance of and coordination across USDA agencies. The range of possible events across the sector and over time currently exceeds the analytical capability of single models or systems and hinders decision-making. As a result, a second research and development initiative is underway to combine epidemiological, GIS, and economic models into a more seamless expert system that manages information and provides appropriate tools for systematic analysis of risks and threats to the U.S. food system.

Also at the Federal level, the DHS Science and Technology (S&T) Directorate has a significant portfolio of R&D programs related to agricultural and food protection activities. DHS also hosts the University Centers of Excellence, two of which address sector-specific needs-the National Center for Foreign Animal and Zoonotic Diseases and the National Center for Food Protection and Defense. More information on the University Centers of Excellence can be found in section 7.3.2 of this chapter and will be made available to DHS in the Food and Agriculture Sector Annual Report.

State-level R&D activities vary by State. USDA and DHS maintain information only for those State R&D activities that are funded through their Federal programs.

Private industry hosts its own R&D activities where it sees a competitive advantage, where a gap must be addressed, or for other reasons. This work is typically conducted to benefit a particular company or industry and occurs independent of government activities.

In recent years, collaborative efforts between government and industry have grown more common. These activities often have a government leadership role and industry partners providing subject matter expertise and clarification on sector needs. The University Centers of Excellence exemplify such an activity-the centers were founded with significant government funding, and they approached private companies and industry associations seeking subject matter expertise and assistance in focusing their programs.

7.2 Sector R&D Requirements

The needs for sector R&D are determined by the SSA, GCC, SCC, and other agriculture and food security partners.

7.2.1 Federal R&D Requirements

To prioritize the problems to be addressed and to identify needs that are most critical, ARS is dependent upon input from other agencies in USDA (primarily APHIS and FSIS), other Federal departments (DHS, HHS, DOD, and EPA), State and local authorities, and commodity groups. Stakeholders provide ARS with input via a continuing dialogue concerning R&D needs. Frequent stakeholder meetings, some as often as every 3 months, facilitate this dialogue. The basic strategies are static in that research needs fall into the categories of detection, prevention, and inactivation. This is true for virtually all threats and all aspects of the sector. However, the particular objectives at any given time are a reflection of the stakeholders' needs. As stated above, while needs may be discussed at length, actual programs are limited by available resources.

CSREES also collaborates with stakeholders to determine needs and ways in which land grant universities may assist in addressing gaps.

7.2.2 Food and Agriculture Sector Joint Committee on Research

The mission of the Food and Agriculture Sector Joint Committee on Research is to assess homeland security-related researchable needs and goals and advise the GCC and SCC on them. The committee will make use of existing vulnerability work, consider threat information, discover the operational needs in the sector, consult or involve the research community as needed, and refine or update recommendations periodically.

The committee will annually provide to the two councils a collective and coordinated list of researchable food and agriculture priority needs from the combined perspectives of those involved in operations and implementation (the private sector), and of those government agencies involved in maintaining homeland security coordination and oversight (the SSAs and Federal and State partners). The committee will also develop a report providing an assessment and analysis strategy, consensus strategy, implementation and evaluation plan, and a dissemination plan. The GCC and SCC will receive these materials by April 1 each year to assist Federal R&D budget officials and decisionmakers as they prepare and prioritize program requests.

7.3 Sector R&D Plan

This SSP will provide the overview of the processes and procedures that the sector security partners will use to address R&D issues. It will not provide specific information on individual R&D activities. That information will be made available to DHS in the Food and Agriculture Sector Annual Report.

The sector will share the products of its Joint Committee on Research with decisionmakers and planners to help prioritize protective R&D programs. This information will also influence the National CI/KR Protection R&D Annual Report. A general overview of the Federal R&D protection goals follows. The sector is at an advantage because current safety activities, which receive more significant budgetary support, are often also applicable to security or defense needs. For example, activities related to the identification of emerging threats to plants and animals that might occur naturally provide the background knowledge that is applied to the study of intentionally introduced agents.

7.3.1 Intramural R&D

Within USDA, animal health research is centered on improved methods for detecting threat agents, including more sensitive and accurate diagnostic tests and their validation. Identification of the threats of greatest concern by APHIS largely determines the particular agents under study. ARS is also developing vaccines and antiviral treatment modalities to contain outbreaks of devastating animal diseases. Efforts for expansion in the animal health area include increasing the number of pathogens to be detected, improving the robustness of the diagnostic tests (including the development of tests that can identify multiple pathogens in a single sample), expanding the number of species that we can protect, controlling insect vectors of zoonotic diseases,

and producing multiple treatment options for containing disease outbreaks. ARS is working on these activities with appropriate Federal and State partners.

With regard to plant protection, ARS will continue to conduct research aimed at the identification of existing and emerging plant pathogens for crops of great economic importance. ARS research is aimed at quickly identifying an outbreak and then containing it. It is investigating treatment methods and developing methods of safely disposing of large amounts of potentially infectious material. Alternative germplasm is being screened to identify disease-resistant varieties. The host range is being determined for a number of plant pathogens and the persistence of the pathogens in the environment is also being studied. ARS obtains its list of priority pests and diseases and the crops of critical importance from agencies such as APHIS and DHS and is working with State agencies and diagnostic laboratories to carry out the research. ARS does not currently work with the private sector directly in this area. Frequent stakeholder meetings and workshops are held to solicit the needs of the stakeholders and priorities and research objectives are jointly developed. ARS has numerous cooperative agreements with universities and research organizations to help support its research mission.

With regard to food safety, ARS is working aggressively with the commodity groups and the food industry to develop and validate detection methods and tools for the identification of potential threat agents in foods. This includes the entire spectrum of food production from the farm to the table. Validation is a critical and often overlooked activity. While many detection techniques exist, their sensitivity and selectivity can be altered by the presence of other food components and the choice of processing techniques. The threat agents under study and the particular foods of interest are identified by the appropriate agency. In addition to detection, ARS is studying the growth and behavior of threat agents in a variety of foods. New and improved inactivation methods are being developed in collaboration with the food industry to inactivate pathogens and chemicals in foods, thereby reducing the vulnerability of the food supply. At many locations, ARS has partnered with land grant universities on these efforts.

7.3.2 DHS Centers of Excellence

DHS has established two Food and Agriculture Sector Centers of Excellence, the National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center) and the National Center for Food Protection and Defense (NCFPD), to protect the sector from terrorism.[13] These university-based partnerships develop centers of multidisciplinary research where important fields of inquiry can be analyzed and best practices developed, debated, and shared.

The FAZD Center has three main objectives: development of new diagnostics and vaccines; provision of new analytic methods for assessing the consequences of alternative strategies for preventing, responding to, and recovering from outbreaks; and an educational and outreach component.

The NCFPD addresses the vulnerability of the Nation's food system to attack through intentional contamination with biological or chemical agents. NCFPD's research and education program is aimed at reducing the potential for contamination at any point along the food supply chain and mitigating the potentially catastrophic public health and economic effects of such attacks.

Additional information on Centers of Excellence activities will be made available to DHS in the Food and Agriculture Sector Annual Report.

7.4 R&D Management Process

At the sector level, the co-chairs of the Food and Agriculture Sector Joint Committee on Research will lead the R&D management process with assistance from committee members (Federal, State, local, tribal, and industry). The committee will provide to the GCC and SCC a report containing recommendations for addressing sector R&D gaps. For information on the committee, see chapter 1, section 7.2.2.

[13] www.dhs.gov/xres/programs/editorial_0498.shtm.

At the Federal level, each department or independent agency manages its own R&D activities. However, this work is not done in a vacuum. There is constant feedback between the program managers and the sector stakeholders, including information from the Joint Committee on Research and from interagency forums addressing the sector's needs.

ARS has a rigorous process for managing research activity and research processes. The process is overseen by the ARS National Program Staff and the entire research portfolio is divided into 22 distinct national programs. Of these, three are involved with issues related to homeland security in support of the action agencies (APHIS and FSIS) and industry. These issues are food safety, animal protection, and plant protection. Although research plans are established for a 5-year period, there is an annual progress report, and modifications in the research program can be made at any time. New research needs may be addressed by a redirection of resources, typically in response to requests from action agencies and industry (or commodity) representatives.

Each national program develops an action plan at the beginning of the 5-year research cycle. This action plan forms the basis for the development of research objectives at the locations for ARS research. The process is initiated and overseen by a National Program Leader whose responsibility it is to identify research objectives based on the action plan. The Program Leader allocates fiscal resources and, in most instances, physical resources to the locations where the work is carried out to ensure that the research objectives are accomplished.

The DHS Centers of Excellence receive awards for 3 years and then must reapply for center status. USDA and others assist DHS in setting criteria for the centers and reviewing applications. Once a center has been selected, DHS provides oversight. Throughout the award period, USDA has regular interaction with a center's leadership. To ensure that the centers are aware of sector needs, the GCC and SCC host frequent briefings and discussions with center leadership and invite them to the sector councils' quarterly joint meetings and exercises.

State-level R&D management practices vary by State. It is a goal for the future to have a better understanding of how States prioritize and manage their agricultural and food protection R&D programs.

As explained earlier, private industry manages its own programs. Each company or entity will have its own business practices.

8. Managing and Coordinating SSA Responsibilities

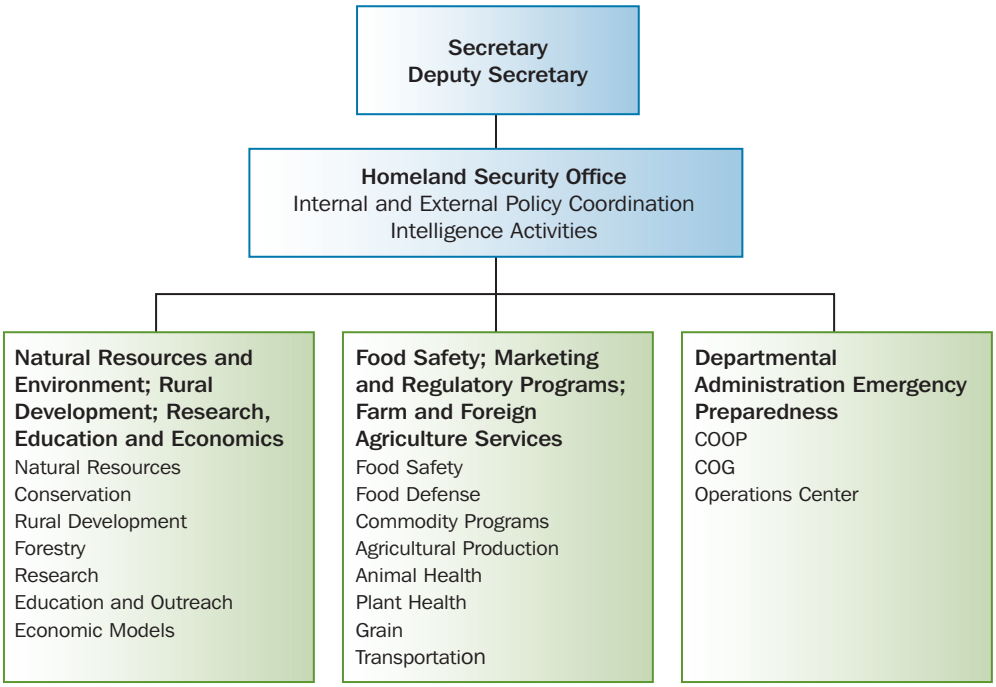
For many CI/KR sectors, including the Food and Agriculture Sector, developing and implementing a national plan that coordinates sector protective activities is a new challenge. This section describes many of the management and coordination activities that will be performed to meet this challenge.

This section will specifically address: (1) how USDA will manage its SSA responsibilities, (2) the processes for maintaining and updating the SSP, (3) how sector annual reporting requirements related to CI/KR protection will be satisfied, (4) the resources and budgets of sector security partners, (5) sector CI/KR protection training and education, (6) implementation of the sector partnership model, and (7) how information will be shared and protected.

8.1 Program Management Approach

Pursuant to HSPD-7, USDA is responsible for managing and coordinating Food (meat, poultry, and egg products) and Agriculture Sector security activities in partnership with FDA (all other food). A key SSA responsibility is to lead the development of an SSP for the sector. Within USDA, the SSA leadership responsibility, including responsibility for developing the SSP, has been delegated to HSO (see figure 1.8-1).

Figure 1.8-1: Homeland Security at USDA



In performing its responsibilities, HSO will work with sister USDA agencies and offices and FDA. Specific descriptions of the strategy and processes for CI/KR protection activities have been described previously in this SSP. Descriptions of specific protection activities will be made available to DHS in the Food and Agriculture Sector Annual Report.

As part of the DHS National Protection and Programs Directorate, Infrastructure Protection identifies and assesses current and future threats to the Nation's physical and informational infrastructure, issuing timely warnings to Food and Agriculture Sector security partners to prevent damage to the infrastructure that supports our community and economic life. The Infrastructure Partnerships Division (IPD) also has a key role in coordinating interagency, sector-wide, and cross-sector activities. Due to the importance of this division, the GCC and SCC have committed to selecting Federal, State, and private sector subject matter experts for assignment to IPD. These officials will assist DHS in understanding the sector and will enhance communications and connectivity with sector security partners.

8.2 Processes and Responsibilities

8.2.1 SSP Maintenance and Update

The SSP reflects the sector's goals and priorities. Therefore, it needs to be maintained and updated regularly. Updates to the SSP will be reviewed thoroughly in collaboration with the SCC, GCC, and other sector security partners on a triennial basis. The SSA, via HSO, is responsible for version control of the SSP and is the only entity currently authorized to revise it. The SSA will lead the SSP maintenance and triennial review. This process will be coordinated closely with FDA.

In addition to the formal triennial review, HSO will update the document on an ad hoc basis as warranted by changes in the sector's security posture, goals, or priorities (developed on an annual basis by the sector) or for any other reason agreed to by the GCC and SCC. To ensure accuracy and to reinforce the partnership nature of this effort, any revised versions of the SSP will be coordinated with the SCC and GCC prior to release. This process will include reviewing the frequency of updates.

8.2.2 Annual Reporting

HSPD-7, paragraph 35, requires that SSAs provide an annual report to DHS detailing the sector's efforts "to identify, prioritize, and coordinate the protection of critical infrastructure and key resources." DHS will use these Sector Annual Reports to inform the National CI/KR Protection Annual Report.

HSO will prepare the sector annual report based on the strategic framework provided in this SSP. Throughout the year, HSO will encourage USDA agencies and sector partners (via the GCC and SCC) to compile information for the annual report. HSO will collaborate with sector partners to prepare a draft report. Once completed, HSO will work with the GCC and SCC to verify the information in the document.

8.2.3 Resources and Budgets

Due to the breadth and depth of the Food and Agriculture Sector, a variety of Federal, State, local, tribal, and private sector security partners contribute resources to the protection of the sector. USDA, even in its role as the SSA, does not have authority over resources and budgets for the entire sector. Therefore, USDA has limited information concerning how sector security partners allocate their resources related to sector security, and minimal influence over how future resources are to be allocated.

To provide the best possible picture available of resources and budgets for sector security programs, USDA will continue to rely on the coordinated Food and Agriculture Defense Initiative, a collaborative budget process for setting funding levels for security programs across the relevant USDA agencies and offices and FDA. Some of the funds are provided to State institutions to support their programs. In addition, USDA will continue to seek information from DHS agencies and offices regarding their budgets for food and agriculture security and defense-related programs, especially the expenditures by the DHS S&T Directorate for R&D activities and the State grants provided by the DHS Office of Grants and Training for preparedness programs. USDA will also continue to offer subject matter experts to serve as technical reviewers for DHS grant programs related to food and agriculture, including the Centers of Excellence selection process and the review panels for State preparedness grants. In addition, USDA will continue to suggest that entities use the SCC and GCC as forums for obtaining input and consideration for agricultural security and food defense-related activities.

8.2.4 Training and Education

The successful implementation of the national risk management framework relies on building and maintaining individual and organizational CI/KR protection expertise. Training and education are key to achieving and sustaining such expertise. Food and Agriculture Sector security partners at the State and local levels and within industry could benefit from continued training and education.

In addition to individual training, organizational training and exercises are integral to improving the sector's overall security posture. For example, training all facility personnel to identify suspicious activity, to respond to an incident, or to shelter in place could dramatically reduce the likelihood of a successful terrorist incident or mitigate the consequences stemming from one. Various governmental and industry guidance materials are available on this topic.

Conducting red-teaming (intrusion testing) exercises at facilities can help asset owners and operators learn their facility's potential vulnerabilities and prepare staff to properly respond in the event of an actual incident. Tabletop exercises can provide similar results, not only for asset owners and operators, but also for State and local regulators, law enforcement officials, and Federal security partners, by sharing lessons learned from the exercises.

The Food and Agriculture Sector security partners currently support a variety of training and educational activities, including joint exercises; however, much more could be done. As part of the SSP implementation process, USDA will work with sector security partners to identify and encourage participation in additional training and educational opportunities. The GCC and SCC will use the HSIN-CS to advertise these opportunities to sector security partners.

8.3 Implementing the Sector Partnership Model

Section 1.2 of this chapter contains a description of the entities with primary roles in securing the Food and Agriculture Sector. The GCC and SCC are the overarching mechanisms for the sector partnership model. Section 1.2 describes in depth the GCC and SCC membership, leadership, goals, meeting frequency, and other key issues. The incorporation of State, local, and tribal government entities into the GCC membership is also described in the section. While the aforementioned section does not explicitly address international partnerships, their interests are represented through SCC members in the form of multinational firms and trade associations representing multinational firms.

8.4 Information Sharing and Protection

8.4.1 Information Sharing

As in most partnerships, effective communication is essential to success. The GCC and SCC have acknowledged that effective communication requires two-way, routine, information sharing and discussion, and they have set a goal to enhance sector communications.

NIPP Coordination Councils. To date, the SCC and GCC are the principal mechanisms for Federal, State, local, and tribal government representatives to coordinate with private sector representatives on homeland security issues concerning food and agriculture. Coordination involves regular conference calls and personal meetings. When analyzing how the sector security partners share information, it is important to be mindful of the expansive nature of the sector. The number of agricultural producers, food processors, and distribution and retail companies that comprise the sector presents a significant challenge to the SCC regarding communicating with all private sector members. To reach as many companies as possible, trade associations are encouraged to maintain membership in the SCC.

Homeland Security Information Network-Critical Sectors (HSIN-CS). As the GCC and SCC mature and are able to process and act on information, additional means of communication are necessary for ensuring real-time, robust information sharing. The councils are planning to use the HSIN-CS as the basis for communication and information sharing. For additional information on HSIN-CS Food and Agriculture, see chapter 1, section 3.3.

FBI's AgGard Program

The AgGard program is modeled after the InfraGard network, an FBI program that links Federal, State, tribal, and local government agencies; the private sector; and academia to build relationships that foster trusted communication and the exchange of information.

Through a secure AgGard Web portal, members of the agricultural community are sharing information with each other and with scientists, State and local law enforcement, and the FBI. Members can pose questions and alert the FBI to any suspicious or unusual activity.

Sharing Threat Information. Sector security partners rely mainly on DHS as the source for threat-related information. To educate sector security partners concerning potential threats, HITRAC[14] provides unclassified alerts, warnings, and information bulletins that are distributed via the GCC and SCC. Additionally, governmental sector partners participate in the Joint Terrorism Task Force program, where the FBI shares information with local law enforcement and other sector security partners concerning specific threat information and investigations involving terrorism (for which the FBI is the lead agency).

To further formalize the mechanism for the communication of threat information and to strengthen the FBI's relationship with the Food and Agriculture Sector, the FBI directed its field offices to establish formal agroterrorism working groups within their jurisdiction. These working groups will enhance the relationships between Federal partners by bringing together representatives from all entities involved in proactive prevention and awareness, intelligence, investigative response, and crisis management.

[14] See chapter 1, section 3.5, for additional information on HITRAC.

8.4.2 Information Protection

Often, the information used by sector security partners to effectively manage risk and secure the Nation's CI/KR will contain sensitive security information, sensitive business and proprietary information, or classified information. The latter is protected by Executive Order 12958, as amended under Executive Order 13292, and therefore the sector has minimal concerns about the security of that information. However, one challenge of classifying important sector security information is the inability to easily share it with key State and industry sector partners. While USDA, FDA, and DHS can take classified information and put it into an unclassified format for use by sector partners, it would benefit sector security if more State and industry officials had security clearances.

Information protection is a significant concern for those security partners who share sensitive business or proprietary information that cannot be classified for protection. The Federal leadership for the sector-USDA, DHS, and FDA-takes the need to protect this information seriously, and will do so to the maximum extent allowed by law.

Chief among the tools the sector uses to protect business sensitive or proprietary information is the DHS PCII Program. The program was developed pursuant to the Critical Infrastructure Information Act (CIIA) of 2002, which requires a Critical Infrastructure Information Program to be created under which sensitive and proprietary critical infrastructure information may be submitted to DHS, and if it satisfies the requirements of the CIIA, it will be protected from public disclosure to the maximum extent permitted by law.

The rules governing the PCII Program are located in Title 6, Part 29 of the Code of Federal Regulations (CFR). For general information on the PCII Program, including instructions on how to properly submit information in compliance with the program, see the DHS Web site at www.dhs.gov/pcii. Note that the final regulation also permits submissions to the Federal Sector-Specific Agency (USDA or FDA, in the case of the Food and Agriculture Sector).

In addition to the PCII Program, there are other regulations that may affect the privacy of data submitted to a Federal sector security partner. For instance, under the Freedom of Information Act (FOIA), the public may request access to information the government possesses. However, FOIA contains an exemption for trade secrets and confidential business information, and this exemption should cover information submitted regarding private facility security.

Despite the PCII Program and other such information protection initiatives, many private sector owners and operators are skeptical of the Federal Government's ability to keep sensitive proprietary business or security-related information secure from public disclosure. While some owners and operators have been willing to share information with the government, it will probably be difficult to convince all asset owners and operators to provide all of the information desired by the NIPP or this SSP.

Some States also face challenges in collecting critical infrastructure information because their laws do not protect such information from public release. This varies from State to State and may preclude sharing sensitive information with the States.

2: Production Agriculture

This chapter of the SSP will focus on production agriculture. For general information about the sector and sector processes, see Chapter 1, Agriculture and Food Overview.

1. Introduction

The focus of production agriculture is at the farm level.[15] There are more than 2 million farms covering more than 1 billion acres of land in the Nation. In addition to privately held farms, the USDA Forest Service has provisions allowing livestock grazing on portions of National Forest lands.

The Federal Government has both regulatory and marketing roles in this portion of the sector. Production agriculture can be divided primarily into crop and livestock industries and their affiliated associations. The crop industry includes diverse commodity groups such as grain, fruit, vegetable, and forage producers. It also includes individuals who produce or do research on biological control agents, genetically modified organisms, and exotic biological organisms (including micro-organisms). The livestock industry is composed of cattle, dairy, poultry, swine, goat, sheep, horse, other farmed animal producers (e.g., llama and ostrich); the manufacturers of veterinary biologics; and aquaculture.[16]

At the Federal level, USDA programs improve agricultural productivity and competitiveness and contribute to the national economy and to public health. Through cooperative programs, the USDA provides leadership in safeguarding the health of plants and animals. These programs include:

- Overseeing livestock and crop health monitoring and disease eradication;
- Issuing animal health and phytosanitary certificates for animals and plants and for animal and plant products, certifying that the requirements imposed by the importing countries have been met and thereby facilitating the trade of U.S. agricultural products;
- Facilitating the national and international marketing of livestock, poultry, cereals, oilseeds, and other agricultural products, and promoting fair and competitive trading practices for the overall benefit of consumers and American agriculture[17]; and
- Protecting and promoting U.S. agricultural health by ensuring the safe development and use of agricultural biotechnology products.

[15] Production agriculture encompasses livestock and crop production sites (e.g., ranches, groves, fields, etc.).
[16] Livestock is defined in the Animal Health Protection Act of 2002 as all farm-raised animals.
[17] FDA has the regulatory role for the safety of foods not regulated by USDA.

An intentional attack on crops or livestock could have a devastating impact on the U.S. economy. Securing this portion of the sector presents unique challenges due to the open nature of the farming industry. Protection efforts must focus on making production agriculture a less attractive target. This will require a collaborative approach by sector security partners.

2. Identify Assets, Systems, Networks, and Functions

For a broad overview of how assets, systems, networks, and functions are identified and defined, see chapter 1, section 2.

USDA and sector security partners initiated the Agriculture and Food Criticality Project to identify the functions performed at an aggregate level by the Food and Agriculture Sector. Information from this project will be used to define criteria for sector infrastructure, which will facilitate the identification and prioritization of critical assets, systems, networks, and functions within the sector. See Chapter 1, Section 4, for additional information about the project.

In the interim, USDA, as the SSA, will continue to rely on risk and vulnerability assessments when determining which assets, systems, networks, and functions are most critical. This determination will be regularly updated via a feedback process that includes assessments, sector stakeholder discussions, and GCC and SCC activities.

2.1 Defining Information Parameters

The production agriculture portion of the Food and Agriculture Sector is composed primarily of livestock and crop producers and supporting agricultural production industries and companies (e.g., fertilizer and vaccine manufacturers, agriculturalists, and veterinarians) that are owned and operated by the private sector. In addition, Federal and State government programs are also necessary for the functioning of the sector.

With regard to Federal assets, systems, networks, or functions, USDA has personnel, programs, and facilities that encompass the entire production phase of the farm-to-table continuum. For example, USDA personnel work to develop pest resistant crops, license veterinary vaccines, provide outreach to producers, and perform diagnostic testing. Two examples of important Federal assets and programs are the USDA Combined Services Plan for the National Centers for Animal Health (NCAH), and the planned modernization of the Ames, Iowa, facility. When completed, the new facility will enhance the prevention and control of animal diseases and the protection of the Nation's food supply. In addition to the NCAH, the USDA, National Wildlife Research Center in Fort Collins, CO, is adding additional research and diagnostic laboratory space that will improve the sector security posture by enhancing the capability to prepare for and react to foreign animal disease threats in wildlife.

More information on specific USDA assets, systems, networks, and functions will be made available to DHS in the Food and Agriculture Sector Annual Report.

State resources are similar to Federal resources—personnel, programs, and facilities—and are important to the daily activities of the sector. These resources will vary by State.

2.2 Collecting Infrastructure Information

For an explanation of how the sector plans to collect infrastructure information, see chapter 1, section 2.2. Every effort should be made to leverage existing information to reduce the burden of reporting and collecting information on sector security partners.

2.3 Verifying Infrastructure Information

As stated in chapter 1, the sector needs the criticality criteria from the Agriculture and Food Criticality Project before it can develop a process for identifying assets and for collecting, verifying, and updating information. At the Federal level, infrastructure information collected by USDA for regulatory or other mission-related purposes is verified by data quality control; implementing data validation through on-site meetings; and verification via producers and members of industry, other Federal Government agencies, and the States. This verification work is part of regulatory requirements.

There are currently no programs for verifying additional or new information for the purposes of this plan. The sector will develop a process for verifying information that will foster trust and minimize the burden on the SSA, the States, and industry.

2.4 Updating Infrastructure Information

State and industry security partners will receive the criteria developed from the Agriculture and Food Criticality Project and have an opportunity to apply it to identify their critical assets, systems, networks, and functions. These partners may voluntarily submit the findings to DHS. To obtain a complete picture of the sector, incentives will be required, especially the resources necessary to collect, share, validate, and update this information regularly.

3. Assess Risks

For an overview of how the sector assesses risk, see chapter 1, section 3. In addition, specific issues relevant to production agriculture are discussed below.

3.1 Use of Risk Assessment in the Sector

At the Federal level, as part of the SPPA Initiative, APHIS works in collaboration with the USDA, HSO, DHS, the FBI, and sector volunteers to conduct CARVER + Shock risk assessments on production agriculture systems. USDA shares the information from the assessments with State and local government partners to increase awareness and to aid in the identification of security countermeasures for agricultural vulnerabilities.[18]

In addition to the SPPA Initiative assessments, and as part of the mission to safeguard animal and plant health, APHIS conducts plant pest and animal disease risk assessments. These risk assessments support programs. In the area of plant protection, APHIS follows The Guidelines for Pathway-Initiated Pest Risk Assessments with the goal of harmonizing risk assessments with guidelines provided by the international Food and Agriculture Organization. In the area of animal health, APHIS follows the risk assessment framework of the World Animal Health Organization where appropriate.

3.2 Screening Infrastructure

It is a goal of the sector to develop screening tools useful for each subsector.

3.3 Assessing Consequences and Vulnerabilities

The production agriculture subsector utilizes the CARVER + Shock methodology, which addresses both consequences and vulnerabilities. For more details, see chapter 1, section 3.3.

3.4 Assessing Threats

For information on how the sector assesses threats, see chapter 1, section 3.4.

[18] Note that USDA works with industry participants to develop an unclassified product that will be useful for State, local, and tribal partners.

4. Prioritize Infrastructure

For an overview of how the sector prioritizes its infrastructure via the Agriculture and Food Criticality Project, see chapter 1, section 4. Information gleaned from the Criticality Project will provide the criteria needed to prioritize the sector's infrastructure.

5. Develop and Implement Protective Programs

For an overview of sector protective programs, see chapter 1, section 5. Specific information on individual protective programs will be made available to DHS in the Food and Agriculture Sector Annual Report. In addition, the production agriculture subsector has begun to address protective programs in coordination with Federal and State partners.

5.1 Overview of Sector Protective Programs

The primary focuses of protective programs for the production agriculture subsector are surveillance for early detection and the capability to respond quickly and aggressively to eliminate or mitigate the impact of a disease or pest. These programs include domestic and international surveillance activities, strong border controls, and flexibility to modify activities in response to emerging threats.

At the Federal level, USDA develops and implements programs to prevent the introduction of animal or plant pests and diseases and to mitigate the potential impact on American agriculture. Protective programs are an inherent part of the APHIS mission to safeguard American agriculture, and emergency management is one of the most important and critical issues facing animal and plant health in the world today. Disease introductions have the potential to impact the food security and economic stability of many countries. Preventing the introduction of foreign and emerging animal and plant pathogens, having an appropriate response system for control and eradication of the disease, and providing a system for recovery from an animal or plant health emergency are paramount to an effective protective strategy. Through leadership from USDA partnerships with other Federal and State agencies, teaching institutions, and national animal and plant industries, the sector is working toward these goals.

5.1.1 National Animal Health Laboratory Network

NAHLN is a Federal and State partnership that coordinates the efforts of veterinary diagnostic laboratories across the Nation. Members of NAHLN include USDA, individual State departments of agriculture, and the American Association of Veterinary Laboratory Diagnosticians.

NAHLN laboratories provide accessible, timely, accurate, and consistent animal disease laboratory services nationwide; provide laboratory data to meet epidemiological and disease reporting needs; respond to foreign animal disease outbreaks or other adverse animal health events (including bioterrorism events); and focus on animal (including exotic, zoonotic, and emerging) diseases. A goal for NAHLN is to enhance laboratory capabilities and surge capacity.

5.1.2 National Plant Diagnostic Network

NPDN is a functional national network of diagnostic laboratories in all States. Its purpose is to provide rapid and accurate detection and reporting of plant pests and diseases that have the potential for high consequence and/or to be introduced intentionally. NPDN provides geographically distributed diagnostic support by decreasing the time between the initial observation of an anomaly by first detectors and response, increasing the Nation's plant diagnostic capabilities through improved equipment and training, and providing diagnostic surge capacity in case of a concentrated or agroterrorist incident. An additional benefit of the NPDN is that training diagnostic personnel will increase the Nation's ability to detect incidents before they become widely distributed.

5.2 Determining Protective Program Needs

At the national or regional level, the need for protective programs is based on information from internal and collaborative risk assessments and threat intelligence from DHS, Federal law enforcement, and the Intelligence Community. These assessments typically focus on high-level industry-wide needs.

APHIS targets protective activities based on risk, including information on global pest and disease conditions. Specialists analyze the information in the form of risk assessments and make recommendations for quarantine, inspection, and detection actions. Emergency response guidelines are developed for pests that might invade the United States. When an introduction occurs, rapid response teams are deployed. If the pest or disease was not previously assessed, a working group is convened to assess the potential impact of the introduction and to make recommendations that consider thresholds for action. Cost-benefit analyses and economic impact assessments are tools used in the assessment.

APHIS also works with the DHS Customs and Border Patrol's (CBP's) National Targeting Center to analyze information based on scientific risk assessments and pathway analysis. This information aids in developing programs that identify import shipments for further inspection.

States and industry owners will use a more narrow focus to determine their individual needs.

5.3 Protective Program Implementation

Many national or regional protective programs must be cooperative efforts with sector security partners during both development and implementation. For emergency response and domestic programs, APHIS interfaces with State counterparts and uses memorandums of understanding and State emergency response plans to cooperate during animal and plant health emergencies.

When implementing protective programs to prevent introductions of animal diseases and plant pests into the United States, APHIS works closely with the CBP, sharing data and other information to better target quarantine and inspection activities at ports of entry.

States typically use Federal funding for their programs, which will vary by State. Each industry or company sets its own process for implementing protective programs.

5.4 Protective Program Performance

In general, the GCC and SCC will provide a forum for addressing sector protective programs.

Additionally, the Food and Agriculture Sector NIPP Metrics Report and Food and Agriculture Sector Annual Report, which are provided to DHS, include more detailed information concerning individual program performance.

6. Measure Progress

For an overview of how the sector measures the performance of protective programs, see chapter 1, section 6. Consult the Food and Agriculture Sector NIPP Metrics Report for additional information on sector CI/KR protection program performance measurement. Processes specific to production agriculture programs are described below.

6.1 CI/KR Performance Measurement

For Federal programs, APHIS provides continuous opportunities for input and feedback on program effectiveness. APHIS schedules and participates in frequent periodic meetings with the National Plant Board, the National Association of State Departments of Agriculture, and impacted industries to determine whether ongoing programs are effective and justified, and whether additional measures or activities are needed.

The success of protective programs for the production agriculture subsector may be measured by the exclusion of exotic or foreign diseases from the country and the dollar value or crops and livestock spared because of a rapid, effective response to an outbreak.

6.2 Implementation Actions

For an overview of how the sector will implement these actions, see chapter 1, section 6.2.

6.3 Challenges and Continuous Improvement

Exercises provide an opportunity for the subsector to identify gaps in protective programs and to identify the measures that are most effective. In a feedback loop, security partners use exercises to test corrective actions that are based on lessons learned. They also use exercises to validate changes to policies or programs to identify the need for further improvements. The sector will continue to host exercises for these purposes.

7. CI/KR Protection Research and Development

7.1 Overview of Sector R&D

For an overview of how the sector determines what R&D is needed, see chapter 1, section 7. The Food and Agriculture Sector Annual Report, which is provided to DHS, includes information about specific sector R&D initiatives.

Within the production agriculture subsector, R&D is focused on surveillance. An important component of any disease surveillance and emergency response system is knowledge of disease organisms, their reservoirs, transmission cycles, and methods to block transmission. Research is therefore an important component of a surveillance system, and ideally knowledge provided by research will be available prior to an emergency.

7.2 Sector R&D Requirements

In addition to the recommendations from the Food and Agriculture Sector Joint Committee on Research, APHIS hosts working groups composed of USDA personnel, representatives of other agencies, and academicians with knowledge of the respective disease, reservoir species, or epidemiology that are responsible for identifying research issues. APHIS conveys recommendations from the working groups to ARS for incorporation into the USDA research portfolio.

7.3 Sector R&D Plan

For information about the sector's R&D Plan, see chapter 1, section 7.3.

7.4 R&D Management Process

For information about the sector's R&D management process, see chapter 1, section 7.4.

3: Food Processing (Meat, Poultry, and Egg Products)

This chapter of the SSP will focus on food processing (meat, poultry, and egg products) activities under the SSA's jurisdiction. For general information about the sector and sector processes for CI/KR protection, see Chapter 1, Agriculture and Food Overview. Also see the Food SSP prepared by FDA for information related to CI/KR protection for all other food products.

1. Introduction

With more than 26 billion pounds of beef, 22 billion pounds of pork, 40 billion pounds of poultry meat, and 73 billion eggs sold annually, the United States is the largest producer of meat, poultry, and egg products in the world. This portion of the sector is also almost entirely privately held. The processing facilities are privately owned; however, the government supplies the onsite Federal or State inspectors and owns the Federal and State laboratories that provide food safety and defense diagnostic services.[19] Imported meat, poultry, and egg products are also an important consideration in sector security because these products are distributed with domestic products. Protection for this part of the sector involves a combination of traditional physical security precautions (because the processing occurs in brick-and-mortar facilities) and non-traditional scientific measures (e.g., surveillance for contaminants and threat agents).

Regulatory oversight for this portion of the sector rests with the USDA's FSIS, which provides continuous inspection of all meat, poultry, and egg products prepared for distribution in commerce and re-inspects imported products to ensure that they meet U.S. food safety standards. FSIS also ensures that foreign partners have equivalent inspection and sampling programs. Several States also have State inspection programs that are supported in part by Federal funds.

To prevent, detect, and respond to food-related emergencies, each day, FSIS has more than 7,600 inspectors and veterinarians in approximately 6,000 Federal meat, poultry, and egg product plants, and at 147 import establishments. In 2002, FSIS established the Office of Food Defense and Emergency Response.[20] This office develops, maintains, and coordinates all FSIS activities to prevent, prepare for, respond to, and recover from emergencies resulting from non-intentional contamination or deliberate acts of terrorism affecting meat, poultry, and egg products. FSIS works closely with the FDA because of the similarities in regulatory authority, and with the DHS CBP for defense of imported products.

[19] Federal statutes require continuous inspection of meat, poultry, and egg products and facilities. See appendix 3 for a description of USDA authorities.
[20] Formerly known as the Office of Food Security and Emergency Preparedness.

2. Identify Assets, Systems, Networks, and Functions

2.1 Defining Information Parameters

For a broad overview of how the sector will identify assets, systems, networks, and functions, see chapter 1, section 2.

USDA and sector security partners initiated the Agriculture and Food Criticality Project to identify the functions performed at an aggregate level by the Food and Agriculture Sector. Information from this project will be used to define criteria for sector infrastructure, which will facilitate the identification and prioritization of critical assets, systems, networks, and functions within the Sector. For additional information about the project, see chapter 1, section 4.

The Food and Agriculture Sector is vast, with thousands of production and processing facilities located throughout the country. Because multiple facilities throughout the country produce and distribute the same or similar products, destruction of a single establishment, in many instances, will not have a substantial impact on the Nation's food supply.

Some food processing systems, however, utilize mass production systems and rapid national or international distribution systems, creating the potential for processing systems to be used as vehicles for the intentional delivery of threat agents. Such an act could result in large-scale public health and economic impacts, as well as widespread public fear and loss of confidence in the government. Therefore, when determining and assessing vulnerabilities, this subsector defines its critical infrastructure in terms of food processing systems as opposed to focusing on individual food processing facilities. By taking a systems-based approach to identifying critical assets, systems, networks, and functions, it is possible to identify the food types and processing systems most at risk for intentional contamination and to look within those systems to determine the most vulnerable points in the farm-to-table continuum.

Vulnerability and risk assessments form the basis for these determinations. States may look at criticality from a State-centric or regional geographic perspective, and private industry will include high-level industry-wide considerations, as well as individual company-level considerations.

2.2 Collecting Infrastructure Information

The sector has not yet established processes for collecting, verifying, and updating information on critical assets, systems, networks, and functions. Most of the relevant infrastructure information is held by private industry. Individual companies maintain records on data that are beneficial to company operations, such as production volume, ingredients used, product distribution, and personnel data. Only a portion of this information is available to Federal and State governments via regulatory programs.

The types of information to be collected will be based on the Agriculture and Food Criticality Project findings and will be updated to reflect new criteria as needed.

As part of food safety and food defense responsibilities, the Federal Government and the States must be able to identify and locate individual establishments. For response and recovery efforts, the subsector needs the ability to identify those facilities that might be affected by a terrorist attack, and to know the status of the regulated facilities following a natural disaster.

At the Federal level, FSIS maintains a number of databases on individual establishments to support its regulatory food inspection activities. The information in these databases includes street location and type of facility, which can be used to map facility locations using geographic information systems during emergencies. These FSIS databases have some limitations because they do not capture production volume, distribution information, and other proprietary information. In addition, the databases do not capture certain types of establishments, including egg processing facilities, retail facilities, and some exempted facilities, such as custom slaughter facilities. While not captured in the databases, FSIS has the regulatory authority to access company records during a food recall.

FSIS uses vulnerability assessments, as discussed in section 3.4, to better understand vulnerabilities within its regulated food systems. These assessments are conducted in conjunction with industry, State, and local representatives. They provide FSIS with specific vulnerability information about nodes in food processing systems not obtainable from data gathered under the FSIS regulatory activities.[21] Such information may be useful for protection, response, or recovery activities.

2.3 Verifying Infrastructure Information

The sector has not yet established a process for collecting, verifying, and updating information on critical assets, systems, networks, and functions. At the Federal level, FSIS' databases on individual facilities are updated regularly as part of regulatory activities. In addition, FSIS recognizes that industry partners often have the most readily available and accurate information on food processing and distribution. Therefore, FSIS will continue to rely on industry's cooperation with recalls in the event of a large-scale food emergency. State and local governments may have more complete information on the location of food processing facilities than FSIS, especially for non-FSIS-regulated facilities. Therefore, FSIS will look to those entities to identify such establishments during times of emergency. Other related information will be verified through updating and validating risk and vulnerability assessments.

At the industry level, verification processes vary greatly depending upon individual companies.

2.4 Updating Infrastructure Information

FSIS will continue to identify and update system information as new vulnerability assessments are conducted and as existing vulnerability or risk assessments are updated. FSIS plans for future assessments and updates are discussed in section 3.4.

3. Assess Risks

As stated in chapter 1, the SSA is required to regularly conduct and update assessments of the sector critical assets, systems, networks, and functions. Therefore, much of the available information on assessments is from the Federal perspective, and focuses on national-level or industry-wide assessments. While private industry is not required to do assessments, many choose to, but are hesitant to share their findings due to lack of trust in the government's ability to prevent public release of the information. For a general overview of assessing risks in the sector, including a description of the sector's assessment tool of choice, CARVER + Shock, see chapter 1, section 3, of this SSP. A description of risk assessment activities specific to this subsector follows.

3.1 Use of Risk Assessment in the Sector

When assessing risks to the food supply, it is important to look at potential vulnerabilities within food processing systems and to consider intelligence information that indicates potential threats to those systems. This section focuses on the assessment of vulnerabilities within food processing systems. Available intelligence information on potential threats is incorporated into those assessments. In addition, at the Federal level, USDA and FSIS have plans to enhance interactions with the Intelligence Community (see section 3.3 for a discussion of those plans).

3.2 Screening Infrastructure

Private industry conducts company- or facility-specific assessments. While specific findings are not relevant to the subsector, the fact that individual companies are conducting assessments and considering protective measures based on the findings is important to the overall sector security posture, because it demonstrates science- and risk-based approaches to infrastructure protection.

[21] This information is classified by USDA to protect critical infrastructure information.

The potential combinations of food products and threat agents are exhaustive. A screening mechanism is necessary to identify where full assessments are needed so that limited resources can be focused where they are most useful. The mechanism must consider national and regional issues and be scalable. The Agriculture and Food Criticality Project will inform efforts to design a sector screening mechanism. In the interim, USDA will continue to use threat and consequence information to inform the process for selecting assessment subjects, as well as economic and public health modeling to estimate the impact of a particular event.

Prior to the adoption of the CARVER + Shock tool, FSIS used a classical risk assessment approach to identify the characteristics of food processing systems that make them more vulnerable to attack. These assessments allowed FSIS to use a risk-based approach to focus its vulnerability assessments on those systems of greatest concern. The risk-based approach qualitatively evaluated the characteristics of threat agents and the characteristics of food processing to identify vulnerable points or nodes in food processing facilities or systems.

The initial FSIS risk assessments identified food processing systems with the following four characteristics as being a more attractive target for, and therefore at greater risk of, intentional contamination:

- Large batch size;
- Uniform ingredient mixing;
- Short shelf life of final product; and
- Ease of product accessibility during processing.

In addition, foods with large serving sizes that can mask a contaminant, lack tamper-evident packaging, are imported, are not further prepared by consumers (i.e., ready-to-eat products), and that have emotional aspects are more likely to be targeted for an attack.

Based on these initial screening assessments, FSIS has focused subsequent vulnerability assessments and food defense activities on food processing systems that meet the four key characteristics and attractive traits described above. Traits and characteristics have been validated by subsequent risk and vulnerability assessments and will be continually updated via a feedback loop (which includes findings from activities such as the SPPA initiative).

FSIS has shared this information with industry partners so that it may inform company or industry-level assessments.

3.3 Assessing Consequences and Vulnerabilities

At the Federal level, the FSIS approach to conducting risk and vulnerability assessments takes into account the potential consequences of a variety of means of intentional contamination of the food supply. Types of consequences that are assessed in the risk and vulnerability assessments include public health, economic impact, psychological impact, and the impact on the ability of the Federal Government to function.

The sector has selected the CARVER + Shock assessment tool as the main mechanism for assessing risks, consequences, and vulnerabilities. For more information on the sector's assessment goals or the tool, see chapter 1, section 1.3, and appendix 4.

For this subsector, USDA has assigned FSIS the responsibility of assessing meat, poultry, and egg products systems as required in HSPD-9. As determined by the sector, FSIS uses the CARVER + Shock method to assess critical infrastructure under its jurisdiction. That method is a modified version of a method designed by DOD for offensive target prioritization. USDA and FDA have refined this tool to make it appropriate for agriculture and food. Using a common assessment tool within USDA enables the department to make decisions by comparing findings across mission areas, commodities, and subsectors.

Within the subsector, completed assessments form the foundation for future evaluations. The focus of future assessments is on conducting, updating, or validating assessments of food processing systems identified as being at risk for intentional contamination. Within the subsector, FSIS will ensure that the updates occur every 2 years as called for in HSPD-9. Assessments will examine vulnerabilities in meat, poultry, and egg products that are processed domestically, imported, or enter the country illegally and will assess the feasibility of specific threat agents being used to contaminate the food supply. Vulnerability and risk assessments will be collaborative, involve industry members, and have the participation of State and local officials. Where appropriate, FSIS will protect the findings of the assessments by classifying them.

Some of the FSIS vulnerability assessments will be conducted as part of the SPPA and the Security and Prosperity Partnership of North America (SPP) initiatives. More information on the SPPA is available in chapter 1, section 1.4. The SPP initiative sets collaborative goals for Canada, the United States, and Mexico for hardening the food supply, and it includes plans for conducting joint vulnerability assessments.

As these assessments are conducted, especially those done in conjunction with industry and State partners through the SPPA initiative, information will be incorporated into future FSIS vulnerability assessments, inspection activities, training, and guidance materials, thereby providing a continual feedback loop.

3.4 Assessing Threats

As part of risk and vulnerability assessments of food processing systems, FSIS will identify food defense-related concerns using intelligence information about threats to the food supply. FSIS, through USDA HSO, utilizes intelligence information from the FBI, DHS, and the broader Intelligence Community to guide vulnerability assessments and improve threat information relevant to food security. Information from these sources aids in the production and review of sector-related intelligence and threat materials. Again, this is a continuous feedback process.

4. Prioritize Infrastructure

Assessing vulnerabilities and prioritizing assets for the vast Food and Agriculture Sector require a strong partnership between the government and industry, as well as a consistent but flexible approach. As discussed in more detail in section 3.1, government and industry have taken a systems-based approach to identifying and prioritizing CI\KR. The Agriculture and Food Criticality Project will facilitate this effort by providing criteria to rank assets, systems, networks, and functions within the sector. As this information becomes available, it will be incorporated into current activities. For additional information on the project, see chapter 1, section 4.

Government and industry have been using the CARVER + Shock tool for assessing vulnerabilities and consequences to food processing systems. These assessments, which include estimates of public health impact, economic impact, and the shock value of an attack on the food supply, are an important factor in prioritizing infrastructure.

At the Federal level, FSIS is conducting vulnerability assessments to identify the highest priority threat agents and the most vulnerable infrastructure points. The initial FSIS risk assessment prioritized FSIS-regulated domestic and imported products, analyzing potential threats and the consequences of a variety of modes of attack. Each risk assessment provides an objective assessment of the food processing systems most at risk for intentional contamination and the points in the individual systems that are most vulnerable. For more details regarding food processing system risk assessments, see section 3.

As required by HSPD-9, FSIS plans to produce up-to-date vulnerability assessments every 2 years for meat, poultry, and egg products processed domestically, imported, and entering the country illegally. The updates will be collaborative with input from industry and the States.

The private sector may also use assessments, in addition to other activities (e.g., cost-benefit analysis), to prioritize their infrastructure protection activities.

5. Develop and Implement Protective Programs

5.1 Overview of Sector Protective Programs

For a broad overview of sector protective programs, see chapter 1, section 5.1. A description of specific programs will be made available to DHS in the Food and Agriculture Sector Annual Report.

The sector continues to take a risk-based approach to developing protective programs and is using risk and vulnerability assessment findings to design and guide protective programs. Those programs-Outreach and Training, Countermeasure Development, Surveillance, Response, and Recovery-are discussed below.

5.1.1 Outreach and Training

Increasing awareness of the potential consequences of an intentional attack on the food supply and the resources and actions that can be taken to avoid or minimize the impact of an attack is crucial to protecting the food supply. The Federal Government has access to intelligence and other threat information not readily available to sector partners. Based on intelligence and other threat information, USDA provides guidance through outreach and training to sector partners to help them to focus limited protection resources. Industry associations have an important role in further distributing relevant information to their membership. In some instances, these associations may develop their own industry-specific training and outreach materials.

FSIS compiles lessons learned from vulnerability assessments and from food defense partners into guidance documents. Materials already developed and used by the sector security partners include guidance documents for individuals working at various points in food processing, a self-assessment checklist for industry, and model food defense plans. These and all guidance materials are updated following feedback from food defense partners. FSIS will continue to develop guidance materials and update or improve existing materials as new or changing threats or vulnerabilities are identified. FSIS strives to work closely with its food defense partners to learn how those vulnerabilities might have changed and to obtain feedback.

Domestically, FSIS focuses outreach and training efforts on USDA personnel, State and industry officials, and the Intelligence Community, working collaboratively with other agencies when appropriate. Outreach efforts are designed to increase awareness about the vulnerability of the food supply to intentional contamination; the roles of USDA, other government agencies, and industry members in preventing and responding to an attack; and information on available countermeasures to prevent or mitigate the effects of an attack. In addition, FSIS will continue to provide training to industry on vulnerability assessments and model food defense plans.

FSIS recognizes the value of organizations or associations that comprise portions of the sector, such as the National Association of State Departments of Agriculture (NASDA), the Association of Food and Drug Officials, and industry organizations. These organizations play an integral role in preventing, responding to, or recovering from an intentional attack on the food supply. Therefore, FSIS will also work to encourage and assist these organizations in the development of their food defense training and guidance materials. It is also important that consumers are aware of the importance of food defense activities. That information is available to consumers and consumer advocacy groups through the FSIS Web site and through meetings with consumer groups. FSIS also collaborates extensively with Federal partners (e.g., FDA) when developing these materials.

In today's global marketplace, the food supply extends beyond U.S. borders. Therefore, FSIS will continue to collaborate with other countries and international organizations to harden global food systems. International initiatives include work through the SPP with Canada and Mexico, and a Bioterrorism Expert Working Group composed of technical representatives from the Group of Eight (G8) countries. Additional activities are being developed with the Asian-Pacific Economic Council and other

international organizations. Those activities include providing training on vulnerability assessments and are coordinated in conjunction with the State Department. FSIS will also continue to work closely with DHS CBP, APHIS, and other agencies to monitor goods entering the country.

In addition to the FSIS meat, poultry, and egg products outreach activities, the Agriculture Marketing Service (AMS) has developed commodity-specific food defense requirements and is currently training its employees and licensed State partners in food defense awareness.

Outreach and training may also occur at the State and industry levels. This training should take the information learned from the Federal programs and share it with a broader audience to increase sector awareness.

5.1.2 Countermeasure Development

Countermeasures may be developed by any sector partner. However, successful application of countermeasures that are broadly applicable requires Federal collaboration with sector partners. FSIS will continue to develop countermeasures to prevent and mitigate the consequences of intentional contamination of meat, poultry, and egg products based on the results of vulnerability and risk assessments.

At the Federal level, one component of the preventive measures will be the continued incorporation of food defense monitoring into the daily activities of FSIS inspectors for all industries.[22] The specific monitoring activities are based on the vulnerabilities identified in risk-based assessments. The extent of food defense monitoring carried out by inspectors is dependent upon the DHS threat condition. The information collected through these activities will feed back into reviews of the activities conducted by the inspection force. This information will ensure that the focus of the monitoring is on the greatest vulnerabilities. The information will also be analyzed to further direct future guidance, outreach, and research activities.

A second component of the FSIS plans for preventive measures is to facilitate the identification and development of countermeasures to decrease the potential for intentional contamination of the food supply. These countermeasures will be based on the vulnerable points identified in FSIS assessments, FSIS inspection personnel activities, and industry concerns. Close collaboration between government and industry is necessary to establish trust so that industry will choose to share concerns and private sector countermeasure implementation information.

Information regarding current industry practices regarding implementation of countermeasures will be included in future assessments. In addition, any information learned in such activities will also be communicated to those industries and State partners through presentations, updated guidance, and other forms of outreach to allow those partners to incorporate the most up-to-date information into their own infrastructure protection plans.

States also have an important role in countermeasure development because many State personnel are conducting inspections in food processing facilities. States have information to share concerning potential vulnerabilities and a need to know about recommended countermeasures.

5.1.3 Surveillance

Early awareness of potential contamination is essential to reducing the impact of an event. Intelligence awareness also aids in potentially preventing an event. At the Federal level, in order to protect the food supply, FSIS must be aware of threat information and have the capability of monitoring and detecting events should they occur. FSIS works with HSO to ensure that relevant threat or intelligence information is available to those who need it. FSIS will further develop its surveillance capabilities to detect contaminated food products.

The Intelligence Community is increasing its awareness of the feasible threat and the consequences that a terrorist event can have on the Nation's food supply and public health. USDA is enhancing relationships with the Intelligence Community to

[22] Pursuant to FSIS Directive 5420.1, Homeland Security Threat Condition Response_Food Security Verification Procedures.

ensure that intelligence analyses consider potential threats to the Food and Agriculture Sector. Sector security partners will be made aware of relevant threat intelligence information through DHS HITRAC products.

FSIS field personnel are participating in information-sharing forums at the local level, such as the FBI-sponsored InfraGard/AgGard and Agriculture Security Working Groups. In addition, the Federal partners are addressing imports via the Area Maritime Security Committees at ports of entry.

FSIS will continue to increase its surveillance capacity to better detect and respond to intentional contamination events. Special attention will be paid to increasing the surveillance of the food systems identified as being vulnerable to intentional contamination. The FSIS surveillance capacity will be increased through the development of an automated analysis tool. Such a system will allow FSIS to proactively identify naturally occurring or intentionally introduced threats to FSIS-regulated food products that could have catastrophic health and economic effects.

FSIS is enhancing its existing surveillance systems, such as the Consumer Complaint Monitoring System. It is developing a centralized surveillance system that will integrate all of its data systems to provide capabilities to assess all data inputs and identify early indicators of potential attacks on the food supply. The improved systems will assist FSIS in detecting an intentional contamination incident. FSIS also plans to improve the linkages between its databases and those of other public health agencies through the National Biosurveillance Integration System. This integrated network will facilitate detecting and responding to food contamination incidents.

FSIS surveillance capacity will also be enhanced through increasing its own laboratory capabilities to detect threat agents through the Food Emergency Response Network (FERN), which FSIS co-directs with FDA. FERN brings together Federal and State laboratories, providing consistent methods for detection of threat agents and rapid sharing of test results. FERN not only monitors the food supply and shares data, it also assists in the handling of samples (surge capacity) in the event of an emergency. FERN will continue to be evaluated and upgraded as necessary. FSIS is also partnering with ARS and DHS to develop and validate detection methods for threat agents in food matrices.

States and private industry may also modify their surveillance activities at the State or industry level, based on relevant threat or other information. Federal partnerships facilitate this information sharing.

5.1.4 Response

Any response to a food-related emergency will require a coordinated effort by all subsector security partners. A rapid, coordinated response provides an opportunity to mitigate the impact of an event by reducing the amount of contaminated product that reaches consumers.

USDA coordinated with other Federal agencies to develop the Food and Agriculture Incident Annex to the National Response Plan (NRP). States play a key role in a response. To aid them, the annex outlines the food subsector's plan to respond to emergencies. FSIS has partnered with NASDA and FDA to develop a template to assist the States in developing their own response plans that meet the State's needs and are consistent with the NRP. That template has been tested by the States, and FSIS will continue to work with State partners to facilitate the creation, implementation, and testing of individual plans.

It is essential that infrastructure protection plans not only ensure that subsector security partners are prepared to respond to an emergency, but also that the responses are coordinated. To that end, the Federal Government must ensure that response plans use the Incident Command System (ICS) and are consistent with the National Incident Management System (NIMS) and the NRP. FSIS has done this. It is also vital that the State partners develop consistent plans because of the amount of interaction that occurs between Federal and State governments during a response situation.

FSIS will also continue to conduct exercises to practice responding to an intentional contamination incident in the food supply. As time and budget permit, these exercises will be systematically carried out at sites across the United States in conjunc-

tion with State and local government agencies and industry. The lessons learned from these response exercises will be used to develop and improve response plans and will be shared with subsector security partners.[23]

The FERN laboratory network is another important aspect of the subsector's response capabilities. Through that network, laboratories provide surge capacity that may be needed in responding to an intentional contamination event.

In terms of responding to an emergency, the ability of FSIS to fulfill its inspection mission is critical to the food and agriculture sector. FSIS has developed and tests, on a regular basis, standard operating procedures for emergency response and continuity of operations plans at its headquarters and all of its field locations.

It is important for private industry to understand the government response process because a majority of the response actions are performed by government entities. An education campaign to explain what to expect during a response would be helpful because it would provide the understanding needed to allow the industry to tailor its response activities so that they integrate seamlessly with those of government.

5.1.5 Recovery

FSIS will continue to develop materials, including plans, to assist in the recovery from an intentional food contamination incident. Planned activities will include expanding the disposal and decontamination guidelines[24] already developed, working to fill some of the gaps identified in the document, and working with the States on disposal-related issues.

5.2 Determining Protective Program Needs

For an overview of the sector's processes for determining protective program needs, see chapter 1, section 5.2.

5.3 Protective Program Implementation

For a broad overview of the sector's protective program implementation process, see chapter 1, section 5.3.

USDA and sector partners have worked diligently to support the mission of food defense for the meat, poultry, and egg processing portion of the Food and Agriculture Sector. Food defense programs focus on assessing vulnerabilities in food processing and using that information to develop protective programs. Collaboration with the States and the private sector is paramount to successful implementation of protective programs.

FSIS, in collaboration with subsector security partners, will continue to evaluate information collected from the implementation of protective programs. This information will be evaluated and used to improve the protective programs by minimizing the opportunity for an intentional attack and reducing the subsector's attractiveness as a target.

State-level program implementation processes will vary by State. However, one common issue is that the States rely on the DHS competitive grant programs for much of the funding to implement protective programs.

Within the private sector, each industry or company will have its own individual process.

5.4 Protective Program Performance

For a broad overview of the sector process for measuring protective program performance, see chapter 1, section 5.4.

Measurement of protective program performance may be limited because the food processing industry program focuses on preventive measures. It is a challenge to measure the success of something not happening (e.g., the lack of contaminated food

[23] Information will be posted to HSIN-CS, as well as other Federal Government-sponsored Web sites.
[24] FSIS, Guidelines for the Disposal of Intentionally Adulterated Food Products and the Decontamination of Food Processing Facilities, April 14, 2006.

due to protective measures). Therefore, the measures would be relative to the actual or perceived risks of an attack to the most vulnerable infrastructure points.

FSIS will continue to work with the States, industry, and the sector councils to monitor and evaluate protective programs focusing on food defense. Progress will be monitored based on attendance at workshops and exercises, the use of outreach materials, and inspection activities.

Activities at the State level will vary by State, and industry- and company-level activities will also vary.

6. Measure Progress

6.1 CI/KR Performance Measurement

For a broad overview of the sector process for CI/KR performance measurement, see chapter 1, section 6.1.

While a metric has not yet been established, the sector security partners will collaborate to identify and update critical systems as new risk and vulnerability assessments are conducted and as assessments are validated and updated. FSIS is working with security partners on developing and evaluating preventive measures based on information collected through food defense inspection activities and vulnerability and risk assessments.

6.2 Implementation Actions

The continued incorporation of food defense monitoring into the daily activities of FSIS inspectors will generate information that will contribute to evaluating and improving assessments. Additionally, outreach and training opportunities for Federal, State, local, and industry personnel will aid in increasing situational awareness and provide valuable information for improving protective programs.

6.3 Challenges and Continuous Improvement

While progress has been made toward securing meat, poultry, and egg processing, a number of challenges and opportunities remain. The sector is taking steps to meet these challenges at the national and local levels.

FSIS and subsector security partners have conscientiously been identifying, prioritizing, and coordinating infrastructure protection activities for the Nation's meat, poultry, and egg processing systems; working with Federal and State entities and industry to facilitate vulnerability assessments; encouraging the development of risk management strategies to protect against and mitigate the effects of potential attacks on critical assets, systems, networks, and functions; and developing mechanisms for information sharing and analysis.

In developing protective programs, some additional issues for ensuring that food processing systems are secure can be identified. Aggregated information on the vulnerabilities of various food processing sectors will be helpful in identifying further priorities for security improvements and research. However, two-way information sharing with sector security partners is a challenge due to private sector concerns about the possible public release of information and their lack of security clearances.

7. CI/KR Protection Research and Development

7.1 Overview of Sector R&D

For a broad overview of the sector's R&D processes and goals, see chapter 1, section 7.1.

The sector, via USDA, works with the White House Office of Science and Technology Policy and DHS to develop the National Plan for Research and Development in Support of Critical Infrastructure Protection. See the National Plan for details of the sector's food defense-related research agendas.

As with other food defense-related initiatives, the FSIS food defense research agenda is based on the findings of vulnerability and risk assessments and industry needs. FSIS works in partnership with other Federal agencies (e.g., ARS and the DHS National Biodefense Analysis and Countermeasure Center) and academic entities, such as the NCFDP, to ensure that research needs are met. In addition, the Food and Agriculture Sector Joint Committee on Research, composed of industry and food and agriculture regulatory agencies and coordinated by the SCC, is examining the sector's agricultural security or food defense research needs. For more information on the committee, see chapter 1, section 7.2.2.

7.2 Sector R&D Requirements

For a broad overview of the sector's R&D Management Process, see chapter 1, section 7.4.

The National Plan for Research and Development in Support of Critical Infrastructure Protection describes the research requirements that are driven by the risk and vulnerability assessments of food processing systems. Key requirements include research and technologies to better address the viability or survivability of threat agents in food matrices and validated laboratory methodologies. These requirements will be updated to include new risk and vulnerability assessment findings. They will also be updated to reflect recommendations from the Food and Agriculture Sector Joint Committee on Research.

7.3 Sector R&D Plan

For a broad overview of the sector's R&D Plan, see chapter 1, section 7.3.

Additional research is needed to support the food defense goals for outreach and training, countermeasures, surveillance, risk and vulnerability assessments, and management of food defense and food safety emergencies. Projects identified in the National Plan for Research and Development in Support of Critical Infrastructure Protection support these food defense goals and aid in the implementation of activities to protect the food processing subsector.

7.4 R&D Management Process

For a broad overview of the sector R&D management process, see chapter 1, section 7.4.

FSIS, in conjunction with other sector security partners, will continue to monitor and assess the impact of food defense measures by conducting regular risk and vulnerability assessments.

The research requirements discussed in the National Plan for Research and Development in Support of Critical Infrastructure Protection will be updated as new information is gathered by assessments or analysis of data collected from the Intelligence Community. A description of specific programs will be made available to DHS in the Food and Agriculture Sector Annual Report.

4: Food Distribution

This chapter of the SSP will focus on food distribution. For general information about the sector and sector processes, see Chapter 1, Agriculture and Food Overview. For additional information on distribution, see the Transportation SSP.

1. Introduction

Food distribution is an essential component of the farm-to-table continuum. It is a complex process that encompasses product transportation, storage, and logistics (including delivery to domestic nutrition assistance programs and international food aid programs). Approximately 21 million trucks transport products, including a majority of food and agricultural commodities, across the United States every day.[25] Rail transportation is also an important part of the domestic food distribution system.

In the food distribution subsector, Federal, State and industry partners work together to identify, build, and implement risk-based preventive measures. The roles and responsibilities of each partner in protecting food distribution networks and systems are clearly defined and, understood. All stakeholders work together to prevent or mitigate unintentional or intentional contamination of USDA commodity foods and to utilize a system to quickly identify problems and notify program operators and recipients.

USDA leads the Federal antihunger effort by administering domestic nutrition assistance programs and by providing funding or food to the States and food stamps to individuals. The national nutrition safety net administered by the USDA Food and Nutrition Service (FNS) includes 15 nutrition assistance programs. The cornerstone is the Food Stamp Program, which was created to make nutritious foods available for the people most in need. More than half of all food stamp participants are children. Other programs, including the Child Nutrition, Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and food distribution programs serve millions of children and low-income people in schools, daycare centers, clinics, food banks, food pantries, Indian reservations, and congregate feeding facilities across the Nation.

USDA nutrition assistance programs touch the lives of one in every five Americans. FNS works in partnership with the States in all its programs. States determine most of the administrative details regarding the distribution of food benefits and the eligibility of the participants, and FNS provides funding to cover a significant amount of the States' administrative costs.

In fiscal year 2005, more people were served in the major nutrition programs than in the previous fiscal year, including 25.6 million receiving food stamps each month, 29.6 million children receiving school lunches each day, and more than 8 million people participating in WIC.[26]

[25] USDA Food Safety and Inspection Service, FSIS Food Safety and Security for the Transportation and Distribution of Meat, Poultry, and Egg Products, revised 2005.
[26] USDA Food and Nutrition Service website (www.fns.usda.gov), updated March, 16, 2007.

Within USDA, AMS and the Farm Service Agency (FSA) work with FNS to purchase and deliver foods, often referred to as USDA commodities, for some of the domestic nutrition assistance programs. USDA also provides financial and technical assistance to State and local officials who purchase food for nutrition assistance programs.

In the event of a disaster declared by the President and as part of the NRP Emergency Support Function 11, AMS, FSA, and FNS collaborate with the private sector-including the commercial market, commercial distributors, and warehouse owners-as a part of the commodity procurement and distribution process to manage and coordinate the delivery of commodities to organizations such as the American Red Cross or the Salvation Army. These charitable and private voluntary organizations distribute the food to disaster victims.

The U.S. food aid infrastructure-which, unlike most food in the distribution chain, is owned by the U.S. Government-is important to the sector because food aid plays a critical role in establishing food security in many developing countries where food insecurity may create potential recruitment opportunities for terrorists.[27] Additionally, food aid that is destined for specific countries might be attacked by terrorists and destroyed, contaminated, or adulterated as a means of: (1) increasing deaths from famine, (2) harming the food aid recipient's health and safety, or (3) casting blame on the United States that serves to incite actions against U.S. interests.

The U.S. Agency for International Development (USAID) and USDA provide U.S. agricultural commodities to feed millions of hungry people in needy countries through direct donations and concessional programs.[28] The USDA Foreign Agricultural Service (FAS) administers food aid in conjunction with, through, and/or with assistance from USAID, FSA, the Commodity Credit Corporation (CCC), domestic private voluntary organizations, foreign governments, and the United Nations World Food Program, among others. FAS and FSA rely on the production of America's farmers and depend upon the U.S. agricultural commodity handling, processing, storage, and transportation systems to make food aid available to those in need.

During the response to a domestic or international disaster, the CCC may make its inventories available for commercial cash sales, for sale to other Federal Government agencies, foreign governments, and private entities. The CCC may also enter into barter exchanges for strategic and critical materials. The CCC may make its inventories available to relieve distress in any area of the United States declared by the President to be in need due to unemployment, other economic causes, or to sustain livestock in response to natural disasters.

The Bill Emerson Humanitarian Trust, a food reserve program administered by USDA, is another important resource ensuring that the U.S. Government can respond to emergency food aid needs. Under the program, commodities from the reserve can be tapped to respond to humanitarian food crises in developing countries, particularly crises that are unexpected.

Within USDA, FAS has the lead responsibility for the USDA-administered food aid programs, while FSA is responsible for procuring and supplying commodities for U.S. food aid donation programs. USDA agencies also coordinate shipments of food aid, ensure that commodity specifications are met, and provide quality control and cargo inspection services.

2. Identify Assets, Systems, Networks, and Functions

With regard to food distribution, most of the key assets, systems, networks, and functions are at the Federal level with FNS, or at the State level with the agencies that provide benefits directly to recipients. However, the Criticality Project (see chapter 1, section 4) will help the sector to more clearly define which items are more critical and may need to be the focus of an identification and information collection program.

[27] In the traditional sense, as used here, the term "food security" refers to the availability of food.
[28] Programs include the Agricultural Trade Development and Assistance Act (Public Law 480), and the McGovern-Dole International Food for Education and Child Nutrition Program.

FNS is responsible for ensuring the continuity of operations for the assets, systems, networks, and functions that ensure delivery of agency program benefits, namely funds and food. This includes relevant cyber and electronic assets. Critical FNS electronic assets include the systems that provide funds for payments (in the form of letters of credit) to State agencies, and the systems that provide food using the Electronic Commodity Ordering System (ECOS), the Processed Commodity Inventory System, and the Rapid Alert System component of ECOS.

Delivery of FNS program benefits is primarily dependent upon State and local program operators. Detailed information on program administration and program sites is maintained by State and local operators, who are responsible for identifying their assets, systems, networks, and functions. Delivery of program benefits also depends upon the availability of a steady stream of safe products from food processors and on a comprehensive transportation system. Additionally, a number of FNS programs (e.g., the Food Stamp Program and the WIC Program) depend on retail grocery operations and electronic benefit delivery systems.

For food aid, the bulk of the food is non-government owned. The domestic food chain is regulated by the U.S. Government to the point of distribution; however, for international food aid, the food is regulated by the U.S. Government only to the point of debarkation. From there, ownership is transferred to the responsible private voluntary or nongovernmental organizations and the recipient country.

2.1 Defining Information Parameters

The processes to collect information on USDA nutrition assistance programs are already in place, and the information parameters are defined because the data are required by FNS to administer the programs. As part of its programs, the FNS already collects the following information; contact information for State cooperators: program data such as funds allocation, participation numbers, meals served, pounds of USDA commodity foods purchased; and dollars spent on USDA commodity food purchases.

Parameters for other assistance programs may be more difficult to determine because they vary based on specific needs, such as those occurring during a disaster (e.g., after a tsunami or hurricane).

With respect to food aid, a number of resources for identifying sector assets currently exist. FSA has contacts with many private sector companies engaged in supplying and delivering food aid. Sector and commodity trade associations also maintain lists of members and assets. Identifying additional information regarding the size, capacity, or the frequency of use for particular assets, systems, or networks will be challenging, as will implementing the appropriate safeguards.

2.2 Collecting Infrastructure Information

For nutrition assistance programs, State and local operators are required to provide the nutrition assistance program data described in section 2.1 on a regular basis to FNS. In most cases, electronic data collection processes are used to gather and compile the data. Nutrition assistance program officials will probably not need to provide additional information to meet the requirements of the NIPP.

As stated in section 2.1, information concerning international or disaster food aid programs may be more difficult to obtain because of the circumstances during which the food is provided. However, if available, FAS and USAID will have information on their international programs and DHS Federal Emergency Management Agency (FEMA) will have information on food aid in response to domestic disasters. Other government agencies, such as the Department of Transportation, will also play a key role in identifying assets associated with food aid. Because of the unique aspects of food aid and the lack of direct U.S. Government oversight during portions of the transportation process, the approach taken to identify critical assets, systems, and networks must be based on risk. The CARVER + Shock methodology meets this requirement.

One of the key components for collecting infrastructure information is the ability to preserve the confidentiality of the information. In many instances, the data may contain proprietary company information provided voluntarily. Therefore, a level of trust that the information will be used for only the stated purposes and that it will be protected from public release is needed.

2.3 Verifying Infrastructure Information

There is a high level of confidence in the accuracy of the nutrition assistance information held by USDA because program participants must provide the information to receive benefits. In addition, each USDA nutrition assistance program data collection system includes internal verification processes to ensure the accuracy and validity of the data. FNS also hosts a program integrity effort that is a part of the agency's strategic plan and corporate priorities.

For a description of the challenges of collecting and verifying information related to certain international and domestic food aid efforts, see section 2.2 above.

2.4 Updating Infrastructure Information

USDA nutrition assistance program data are also updated regularly-the frequency depends on the specific program or report. Where appropriate, data are provided in the form of reports from program operators or are posted to the FNS Web site. As part of the agency's ongoing operations, FNS has processes in place to update State agency contact lists regularly.

For a description of the challenges of collecting, verifying, and updating information related to certain international and domestic food aid efforts, see sections 2.2 and 2.3 above.

3. Assess Risks

3.1 Use of Risk Assessments in the Sector

As discussed in section 2, the critical assets, systems, networks, and functions for food aid programs are currently broadly defined as the systems and networks for delivering funds and the systems and networks for procuring and distributing safe and wholesome USDA commodity foods to the USDA nutrition assistance programs.[29] Assessments of this subsector are included in the SPPA, which uses the CARVER + Shock assessment tool described in chapter 1, section 3.1.

The USDA also makes individual internal assessments of certain assistance programs. The vulnerabilities and consequences surrounding cyber elements, such as the provision of funds or the electronic systems involved in commodity food ordering and delivery, are assessed as a part of the FNS continuity of operations process. However, frequent assessments of the FAS cyber systems currently in use for international food aid programs are generally not needed because the systems are either stand-alone systems or systems that can easily and readily be duplicated manually. The long timeframe involved for procuring and distributing food aid, however, helps to mitigate the risk of distributing contaminated foods because it allows for the development of alternative solutions.

3.2 Screening Infrastructure

For a description of the sector's plans for developing infrastructure screening methods, see chapter 1, section 3.2.

[29] The findings from the Criticality Project may affect this description. See chapter 1, section 1.4, for information about the project.

3.3 Assessing Consequences and Vulnerabilities

For a description of the CARVER + Shock assessment tool used by the sector for assessing consequences and vulnerabilities, see chapter 1, section 3.3.

For nutrition assistance programs, FNS has considered vulnerabilities during assessments as part of the continuity of operations process and the SPPA, which uses the CARVER + Shock assessment tool as described in chapter 1, sections 3.3 and 3.4.

3.4 Assessing Threats

As described in chapter 1, section 3.5, HSO provides relevant threat and intelligence information to the Department's agencies so that they may carry out their agricultural security and food defense missions.

Additionally, FNS has a system to identify possible problems with USDA commodity food products. This system is an electronic commodity complaint system and a rapid alert and notification system for USDA commodity food hold and recall actions. The system connects USDA program officials with State authorities and program participants. In addition, FNS has regional offices in contact with State agencies that pass along any problems with USDA commodities, or other issues related to USDA nutrition assistance programs, to FNS headquarters. This close collaboration allows rapid communication in the event of a threat or incident.

4. Prioritize Infrastructure

For a description of the Criticality Project, a sector effort to determine criteria for assessing the criticality of agricultural and food systems, see chapter 1, section 4.

According to the NIPP, prioritization of infrastructure to help identify where risk reduction is most pressing, and to subsequently determine what protective actions should be taken, occurs after risk-related data have been collected, combined, and analyzed. At this time, FNS has only minimal information on risk, primarily from vulnerability assessments that have been conducted as part of the SPPA and related assessment programs. Therefore, comprehensive prioritization has not yet been done. However, after the conclusion of the Criticality Project, which will yield a methodology to identify and prioritize critical infrastructure, FNS can begin a comprehensive prioritization for nutrition assistance programs in collaboration with sector security partners.

In the interim, FNS will continue to collaborate with sector security partners to prioritize the nutrition assistance program infrastructure. Currently, priorities are set for key nutrition assistance programs based on the opinions of subject matter experts about the impact on program participants. Criteria for these priorities consider the number of program participants who would be affected by disruption or destruction of program assets, as well as the vulnerability of the target population. At this point, priorities are not listed according to assets, systems, or networks. There is no formal calendar for the frequency of prioritization efforts and updates.

5. Develop and Implement Protective Programs

5.1 Overview of Sector Protective Programs

Food distribution systems have an impact on a vulnerable population-nutrition assistance programs provide funds and food to groups such as school-age children, low-income families, pregnant women, and infants. The ultimate objective of protective programs for these systems is to ensure the delivery of accountable funds through USDA's electronic financial systems and to provide safe food through the department's commodity distribution networks. Because these systems are operated and maintained by USDA, the main protective programs are led at the Federal level. The desired outcome for FNS protective programs

is to detect and deter any disruptions to the assets or systems and to defend the assets or systems used to provide nutrition assistance benefits. Although the FNS focus is primarily on prevention and protection, measures for response and recovery exist as part of the FNS disaster preparedness activities. These activities are also closely coordinated with State partners.

For nutrition assistance programs, it is essential to protect the network and operations supporting State agencies' funding and commodity ordering. This includes setting policies and procedures to protect the underlying application systems and electronic networks. Continuity of operations plans are essential for each system, with emergency backup processing sites assigned for each.

The prevention of intentional contamination of USDA commodity foods that are procured and delivered to State participants for nutrition assistance or disaster relief involves an overall risk management approach. FNS leverages relationships and resources with its security partners to identify, develop, and implement individual protective measures for its commodity assets, networks, and systems. In conducting vulnerability assessments with Federal (AMS, FSIS, FDA, DHS, and FBI) and industry sector security partners, FNS has been able to take commercial practices into consideration as part of the assessment and evaluation process.

Where possible, USDA uses information from assessments as guidance for enhancing the safety and security of the products purchased for assistance programs. FNS provides extensive guidance to nutrition assistance program partners. The agency also works closely with program stakeholders in distributing funds and food to program operators and ultimately to program recipients. Part of the challenge of coordinating protective measures is due to the administrative chain that extends from the Federal through the State and local levels. This challenge can be addressed by increasing awareness and improving communication. Therefore, a key goal for this subsector has been to develop materials and to conduct training to raise security partners' awareness of the potential vulnerabilities in the commodity food procurement and distribution process.

Where possible, USDA has also applied information from assessments to update contractual requirements to enhance the safety and security of the products purchased for assistance programs. AMS has updated procurement contracts to include a requirement for security plans and audits. FSA has also required warehouse operators to certify that security plans are in place.

Rapid communications are another critical protective measure. It is essential to quickly communicate with partners about suspicious commodity products to ensure that contaminated products are not consumed. FNS has developed and implemented a rapid communication system to meet this need.

5.2 Determining Protective Program Needs

As stated in section 5.1, FNS has the main responsibility for protective programs for food distribution, specifically nutrition assistance programs. To date, FNS has uncovered vulnerabilities as part of vulnerability and risk assessments and has identified protective measures to address these vulnerabilities. FNS has also identified and implemented protective measures for cyber systems and networks as part of the continuity of operations process. FNS has program regulations requirements that support the implementation of protective programs.

5.3 Protective Program Implementation

For nutrition assistance programs, protective programs are implemented based on budget and in collaboration with relevant Federal and State partners. The implementation and maintenance of protective measures for nutrition assistance programs must be coordinated with the commodity food procurement agencies, AMS, and FSA. They interact with the food processing industry to procure, distribute, and coordinate with commercial vendors to implement protective measures for USDA commodity foods.

A key protective program focuses on rapid notification of a product hold and recall of suspect commodity food products. To ensure coordination for food recalls, FNS is conducting food defense awareness training with State and industry security partners. FNS will also continue to develop tabletop exercises to provide technical assistance and support for the development of State food defense plans and to test rapid communications capabilities.

From an international food aid perspective, the implementation of protective measures with private voluntary organizations and nongovernmental organizations may be slower than with other sector security partners who deal with the domestic food supply. Before the point of embarkation, international food aid normally travels through the same channels as the domestic food supply. Therefore, the safeguards that are used on the domestic food supply will be used to safeguard food aid at this stage. After the point of embarkation, title of the international food aid rests outside the U.S. Government, normally in areas controlled and regulated by foreign governments. Developing protective measures in this environment is a challenge for USDA.

5.4 Protective Program Performance

At the Federal level, all FNS electronic systems and networks undergo security certification and accreditation every 3 years as required by regulation. This process ensures the currency of all security-related documentation regarding the systems and provides for annual testing of the security controls in place.

For nutrition assistance programs, FNS continually monitors all elements of program administration and utilizes the information for future decisionmaking on program improvements, including the application of new technological developments as part of the management evaluation process.

There is a feedback loop in place to improve program performance for food distribution activities. Risk assessments have identified appropriate protective measures, and the successful implementation of these measures is tracked by monitoring policy changes. For example, assessments identified truck seals as an effective method for ensuring the safety of commodity products. As a result, AMS policy now requires seals on all segments of multidrop truck deliveries of commodities.

FNS is able to measure the impact of the Rapid Alert System by running reports within the system to evaluate who has received the notifications and to review the response data about the disposition of the suspect commodity products. FNS communicates information about protective programs through its food safety Web site, its training efforts, and technical assistance materials. These avenues will be used in the future to communicate to sector security partners about the success of and recommendations for protective programs.

6. Measure Progress

Specific program information, including partners and milestones, will be made available to DHS in the annual report.

6.1 CI/KR Performance Measurement

For a description of the sector's processes for measuring performance, see chapter 1, section 6.1.

FNS can provide descriptive metrics about the success of nutrition assistance programs, such as the number of program participants, the dollar value of benefits, and the pounds of commodity product procured and distributed. As described in section 2.2 of this chapter, there are existing requirements for the collection of information on USDA nutrition assistance programs. This information flows from the local operators to the State agencies to FNS. All parties involved in the administration of USDA nutrition assistance programs are responsible for collecting the data. There are internal processes in place to verify the accuracy of the data. A metric to measure enhanced security or protection has yet to be determined.

The responsibility for measuring the progress of some protective programs that impact FNS is shared among procurement agency partners such as AMS and FSA (e.g., requiring food defense plans in processing plants supplying commodity products and truck seals for multidrop truck shipments of commodity products). USDA will continue to work in collaboration with Federal, State, local, and tribal governments; private industry; and private voluntary and nongovernmental organizations to define sector-specific metrics for nutrition assistance programs.

6.2 Implementation Actions

For a description of the sector's processes for implementing protective programs, see chapter 1, section 6.2.

6.3 Challenges and Continuous Improvement

Measuring and validating progress toward SSP goals is different from measuring progress toward program administration goals because the focus is on infrastructure protection activities that are distinct from program activities. Measuring progress toward SSP goals may be more difficult because the sector has not addressed this issue. A challenge to measuring progress is commonly encountered when State and local partners must conduct data collection and reporting beyond existing requirements.

7. CI/KR Protection R&D

7.1 Overview of Sector R&D

For R&D concerning the security of USDA nutrition assistance programs, the primary focus is on detection, surveillance, analysis, and communication. Technology developments impact all of these goals. R&D to identify appropriate new technologies for application to USDA nutrition assistance programs is critical to protection efforts. For example, advancements in rapid detection methods, better surveillance technology, better product tracking technology, rapid communication systems, and better safeguards for cyber systems would all enhance protective measures.

7.2 Sector R&D Requirements

For a description of the sector's overall processes for addressing R&D requirements, specifically the Food and Agriculture Sector Joint Committee on Research, see chapter 1, section 7.2.

As part of the CI/KR protection R&D reporting process, all USDA agencies consider requirements that can be supported by technology development. Of the nine R&D areas identified in the National Plan for Research and Development in Support of Critical Infrastructure Protection, the areas of most importance to food distribution are detection and sensor systems, protection and prevention systems, entry and access portals, advanced infrastructure architectures, and human and social issues. For example, to lessen harm to program recipients, there is a need to develop methods for the rapid and early detection of contaminated food products.

FNS research needs are the same as those for the commercial food production and distribution system; therefore, they support the national common operating picture for the protection of critical assets, systems, networks, and functions. As an example, research is ongoing for radio-frequency tags. This research could be applied to cover radio-frequency identification systems for commodity food shipments.

7.3 Sector R&D Plan

For a description of the sector's overall processes for addressing R&D requirements and developing an R&D plan, see chapter 1, section 7.3. In the same section, also see the description of the Food and Agriculture Sector Joint Committee on Research.

7.4 R&D Management Processes

With regard to R&D for nutrition assistance programs, as new technologies are identified and tested, FNS will implement a management process to monitor progress and assess the impact on security goals. This process will consider FNS security partners and will connect with the larger R&D community to stay current with technology advances.

Appendix 1: List of Acronyms and Abbreviations

ACIO	Associate Chief Information Officer
AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
BIA	Business Impact Analysis
CARVER + Shock	Criticality, Accessibility, Recuperability, Vulnerability, Effect, Recognizability, + Shock
CBP	Customs and Border Protection
CCC	Commodity Credit Corporation
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CI/KR	Critical Infrastructure and Key Resources
CNPP	Center for Nutrition Policy and Promotion
COOP	Continuity of Operations Plan
CSREES	Cooperative State Research, Education, and Extension Service
DHS	Department of Homeland Security
DOD	Department of Defense
DOT	Department of Transportation
ECOS	Electronic Commodity Ordering System
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
ERS	Economic Research Service
FAS	Foreign Agricultural Service
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FGIS	Federal Grain Inspection Service
FISMA	Federal Information Security Management Act
FMD	Foot-and-Mouth Disease
FMIA	Federal Meat Inspection Act
FNS	Food and Nutrition Service
FS	Forest Service
FSA	Farm Service Agency
FSIS	Food Safety and Inspection Service
GCC	Government Coordinating Council
GIPSA	Grain Inspection, Packers, and Stockyards Administration
HHS	Department of Health and Human Services
HITRAC	Homeland Infrastructure Threat and Risk Analysis Center
HSIN	Homeland Security Information Network
HSIN-CS	Homeland Security Information Network-Critical Sectors
HSO	Homeland Security Office
HSPD	Homeland Security Presidential Directive
ICLN	Integrated Consortium of Laboratory Networks
IT	Information Technology
NADB	National Asset Database

NAHLN	National Animal Health Laboratory Network
NASDA	National Association of State Departments of Agriculture
NASS	National Agricultural Statistics Service
NIPP	National Infrastructure Protection Plan
NIST	National Institute of Standards and Technology
NL-COBP	National Livestock Continuity of Business Plan
NMFS	National Marine Fisheries Service
NPDN	National Plant Diagnostic Network
NRCS	Natural Resources Conservation Service
OCIO	Office of the Chief Information Officer
OMB	Office of Management and Budget
P&SP	Packers and Stockyards Programs
PART	Program Assessment Rating Tool
PCII	Protected Critical Infrastructure Information
PPIA	Poultry Products Inspection Act
PVO	Private Voluntary Organization
RBS	Rural Business Service
RD	Rural Development
RHS	Rural Housing Service
RMA	Risk Management Agency
RUS	Rural Utilities Service
S&T	Science and Technology
SCC	Sector Coordinating Council
SPP	Security and Prosperity Partnership of North America
SPPA	Strategic Partnership Program Agroterrorism
SSA	Sector-Specific Agency
SSP	Sector-Specific Plan
TCL	Target Capabilities List
TIA	Technical Impact Analysis
TSA	Transportation Security Administration
USAID	United States Agency for International Development
U.S.C.	United States Code
US-CERT	United States Computer Emergency Response Team
USDA	United States Department of Agriculture
WFP	World Food Program
WHO	World Health Organization
WIC	Special Supplemental Nutrition Program for Women, Infants and Children

Appendix 2: Glossary of Terms

Baseline. The starting point from which gains are measured and targets are set.

CARVER + Shock. An assessment methodology that provides a consistent means for evaluating the consequences, vulnerability, and threat faced by assets, systems, networks, and functions in the Food and Agriculture Sector. CARVER is an acronym for the following six attributes used to evaluate the appeal 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, Shock, represents the combined health, economic, and psychological impacts of an attack.

Critical Infrastructure and Key Resources. The assets, systems, networks, and functions that provide vital services to the Nation.

Criticality. A description of the importance of a particular sector asset, system, network, or function in relation to national or regional security issues. Includes a consideration of public health and economic impacts.

Farm-to-Table. Refers to the broad spectrum of industries responsible for all facets of food production, from where it is grown on the farm until it reaches the consumer's table.

Food and Agriculture Defense Initiative. The U.S. Department of Agriculture and the Food and Drug Administration collaborate to prepare the Initiative a cross-agency breakdown of homeland security-related activities.

Food and Agriculture Sector. The *National Strategy for Physical Protection of Critical Infrastructures and Key Assets* defines the sector as the supply chains for feed, animals, and animal products; crop production and the supply chains of seed, fertilizer, and other necessary related materials; and the post-harvesting components of the food supply chain, from processing, production, and packaging through storage and distribution to retail sales, institutional food services, and restaurant or home consumption. In general terms, the sector is composed of the agricultural production and food systems from the farm to the table.

Food and Agriculture Sector Annual Report. The Sector-Specific Agency prepares a report each year describing accomplishments in meeting Sector-Specific Plan goals. The report includes details about specific programs related to critical infrastructure and key resources protection. The SSA submits the report to the Department of Homeland Security for incorporation into the National CI/KR Annual Report.

Outcome Efficiency Measure. The best efficiency measure captures improvements in program outcomes for a given level of resource use. Outcome efficiency measures are generally considered the best type of efficiency measure for assessing the program overall.

Outcome Measure. Describes the intended result of carrying out a program or activity. It defines an event or condition that is external to the program or activity and that is of direct importance to the intended beneficiaries and/or the general public.

Output Efficiency Measure. It may be difficult to express an efficiency measure in terms of an outcome. In such cases, an acceptable efficiency measure could focus on how to produce a given output level with fewer resources.

Output Measure. Describes the level of activity that will be provided over a period of time, including a description of

the characteristics (e.g., timeliness) established as standards for the activity. Output refers to the internal activities of a program (i.e., the products and services delivered).

Performance Goal. Sets a target level of performance over time, expressed as a tangible, measurable objective, against which actual achievement can be compared, including a goal expressed as a quantitative standard, value, or rate. A performance goal is composed of a performance measure with a target and timeframes.

Performance Measure. Indicator, statistic, or metric used to gauge program performance.

Sector Security Partner. Federal, State, local, and tribal governments and private industry representatives from the Food and Agriculture Sector that partner together to enhance security for food and agricultural systems.

Strategic Goal or Strategic Objective. A statement of aim or purpose included in a strategic plan (required under the Government Performance and Results Act of 1993). In a performance budget/performance plan, strategic goals group multiple program outcome goals. Each program outcome goal should relate to and in the aggregate be sufficient to influence the strategic goals or objectives and their performance measures.

Targets (performance). Refers to improved levels of performance needed to achieve the stated goals.

USDA Commodity Foods. Foods purchased by the Department of Agriculture for distribution to child nutrition programs such as the National School Lunch Program, as well as the Emergency Food Assistance Program, Commodity Supplemental Food Program, and Food Distribution Program on Indian Reservations. USDA commodity foods serve the dual purpose of supporting U.S. agriculture and providing nutritious foods to children and needy families in accordance with the authorizing legislation for each of the programs cited above.

Appendix 3: Authorities

The U.S. Department of Agriculture (USDA) has a number of mission areas comprised of agencies and a variety of departmental offices each with extensive legal authorities. The following are highlights of the key authorities concerning USDA's activities for agricultural and food safety and security.

Animal and Plant Health. The Animal and Plant Health Inspection Service (APHIS) is responsible for protecting and promoting U.S. agricultural health, administering the Animal Welfare Act, and carrying out wildlife damage management activities. APHIS's mission is an integral part of USDA's efforts to provide the Nation with safe and affordable food. The Plant Protection Act, Animal Health Protection Act, Virus Serum Toxin Act, Agricultural Bioterrorism Protection Act of 2002, and the Animal Welfare Act are the primary statutory authorities employed to achieve the agency's mission. These acts give APHIS the ability to restrict the importation, exportation, and interstate movement of plants, animals, plant and animal products, and plant and animal pathogens. Additionally, APHIS ensures that veterinary biologics are pure, safe, potent, and effective, and that the standards governing humane handling, care, and treatment of animals are met.

The Grain Inspection, Packers, and Stockyards Administration (GIPSA) works to ensure a productive and competitive global marketplace for U.S. agricultural products. One of GIPSA's programs, the Packers and Stockyards Programs (P&SP), promotes fair and competitive markets for livestock, meat, and poultry by enforcing the Packers and Stockyards Act of 1921. P&SP provides financial protection to livestock producers and poultry growers, and promotes fair and competitive markets within its regulatory framework. The Federal Grain Inspection Service (FGIS) provides the U.S. grain market with Federal quality standards and a uniform system for applying them. GIPSA's statutory authorities for these services are provided by the Agricultural Marketing Act of 1946 and the U.S. Grain Standards Act. FGIS has both service and regulatory roles, and was founded to provide impartial, accurate quality and quantity measurements to create an environment that promotes fairness and efficiency.

Cyber Security. The Federal Information Security Management Act (FISMA) is the most recent legal requirement mandating that Federal agencies develop a comprehensive IT security program. Laws such as the Computer Security Act of 1987, as well as requirements in Office of Management and Budget (OMB) Circular A-130, also mandate that security must be developed at both the programmatic and systemic levels. The USDA Office of the Chief Information Officer's (OCIO) Cyber Security Program directs and administers the USDA Information Security Program in accordance with these Federal regulations and laws, and USDA agency and staff office requirements.

The Associate Chief Information Officer (ACIO) for Cyber Security acts as USDA's senior agency information security officer, a position required by FISMA. In this capacity, the ACIO for Cyber Security directs the OCIO Cyber Security Program. In particular, the Cyber Security Program provides oversight of USDA agency and staff office information security programs, develops cyber security policy and guidance, provides assistance to agency chief information officers and information system security program managers, is responsible for security incident handling, reviews and approves information system capital expenditures to ensure compliance with security policy and architecture, and develops risk management methodologies and tools to ensure

compliance with related Federal Government and USDA regulations. In addition, OCIO's Cyber Security Program is responsible for administering programs designed to address specific security issues such as contingency planning, security awareness training, certification and accreditation, and privacy policy.

The department and its agencies are all subject to a number of Federal statutes and administrative guidance concerning cyber security. Additionally, where applicable, the department has issued regulations to clarify cyber security responsibilities. Relevant references include the Computer Security Act of 1987 (Public Law 100-235), and OMB Circular A-130, Appendix III, Security of Federal Automated Information Resources, which requires all Federal agencies to plan for the security of all sensitive information systems throughout their life cycles. OMB Circular A-130, Appendix III, establishes a minimum set of controls to be included in Federal automated information systems security problems, and assigns Federal agencies the responsibilities for security of automation information. It also links agency automated information system security programs and agency management control systems established in accordance with OMB Circular A-123, Management Accountability and Control. Also important is Departmental Regulation (DR) 3140-001, USDA Information Systems Security Policy, which establishes policies to ensure that comprehensive protections are in place to safeguard all IT resources. It requires that USDA managers ensure that measures are in place to protect against accidental or deliberate, unauthorized alteration, destruction, delay, theft, access, use, or damage to systems, data, applications, equipment, and telecommunications.

Domestic Nutrition Assistance. The Food and Nutrition Service (FNS) is the Federal agency responsible for managing the domestic nutrition assistance programs of the USDA. Authorities for the administration of FNS nutrition assistance programs are found in several places_the Child Nutrition Act of 1966, as amended; the Richard B. Russell National School Lunch Act, as amended; the Food Stamp Act of 1977, as amended; the Agriculture and Consumer Protection Act of 1973, as amended; and, the Emergency Food Assistance Act of 1983, as amended. Some food is purchased by USDA agencies for the nutrition assistance programs. Authorities to conduct purchase activities are provided for by five statutes: Section 32 of Public Law 74-320, Section 410(b) of the Disaster Relief Act of 1974; the Richard B. Russell National School Lunch Act, as amended; the Agriculture and Consumer Act of 1973; and the Older Americans Act of 1964.

FNS is also responsible for disaster feeding in the event of a presidentially declared disaster, using USDA commodity foods and food stamps (if retail outlets are available). The statutory authority to purchase and/or use and distribute food to victims of a presidentially declared disaster includes Section 410(b) of the Disaster Relief Act of 1974 (42 U.S.C. 5180(b)), normal Federal Acquisition Regulation (FAR) procedures, plus Section 412 and 413 (b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act); Section 5(h) of the Food Stamp Act of 1977, as amended; Section 416 of the Agricultural Act of 1949; Section 4(a) of the Agriculture and Consumer Protection Act of 1973; 7 CFR 250.43 and 250.44; and 7 CFR 280.1, 7 CFR 274.6, and 7 CFR 272.3.

Food Processing (Meat, Poultry, and Egg Products). Food processors under USDA's jurisdiction are subject to the four key legal and statutory authorities under which FSIS operates. The Federal Inspection Acts that are most important to the Food Safety Inspection Service (FSIS) are the Federal Meat Inspection Act (FMIA, 21 United States Code (U.S.C.) 601 et seq.), the Poultry Products Inspection Act (PPIA, 21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA, 21 U.S.C. 1031 et seq.). Under the authority of these acts, FSIS provides continuous inspection of all meat, poultry, and egg products prepared for distribution in commerce, and re-inspects imported products, to ensure that they meet U.S. food safety standards. FSIS tests for and conducts enforcement activities to address situations of microbiological, chemical, and other types of contamination, and conducts epidemiological investigations in cooperation with the Centers for Disease Control and Prevention based on reports of foodborne health hazards and disease outbreaks. FSIS also carries out provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). FSIS food security initiatives are undertaken pursuant to the act. Additionally, the 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Act direct FSIS to assess whether State inspection programs that regulate meat and poultry products are at least equal to the Federal program, in accordance with the 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Act. Furthermore, the 1967 Wholesome Meat Act extended FSIS

jurisdiction over meat and meat products, granting authority to regulate transporters, renderers, cold storage warehouses, and animal food manufacturers.

International Food Assistance. The U.S. Government has historically been involved with international food aid to help in disaster situations or where there is a need due to natural circumstances. Through various agencies, including FAS, international food aid is distributed to the needy in a variety of methods. Direct food aid, food aid through a distribution channel by way of private voluntary organizations or nongovernmental organizations, food aid to school children, and concessional loans are some of the methods by which a number of U.S. laws governing food aid are administered.

Through the Commodity Credit Corporation (CCC), the U.S. Agency for International Development (USAID) and USDA provide U.S. agricultural commodities to feed millions of hungry people in needy countries through direct donations and concessional programs. Food aid may be provided through four program authorities: (1) Public Law 480, also known as Food for Peace; (2) Food for Progress; (3) Section 416(b); and (4) the McGovern-Dole International Food for Education and Child Nutrition Program.

See table A1-1 for distinctions between USDA/FSIS and HHS/FDA jurisdictions over food, and see table A1-2 for a more comprehensive list of key security and emergency response-related authorities.

Marketing. The Agricultural Marketing Service (AMS) carries out a wide range of program activities that facilitate the marketing of U.S. agricultural production under the authorization of the Agricultural Marketing Act of 1946, the Perishable Agricultural Commodities Act, and more than 50 other statutes. These programs improve the efficiency of the national and international marketing of U.S. agricultural products by providing a language of trade and a network of marketing services that enhance returns to producers, lower prices to consumers, and help to ensure fair trading in the marketplace. Two-thirds of the funds needed to finance AMS activities are derived from voluntary user fees charged for quality grading services. AMS provides these services to private industry, as well as Federal and State agencies.

Table A1-1: USDA/FSIS and HHS/FDA Jurisdictional Overlap for Commercial Food Products*

Product	HHS/FDA	USDA/FSIS
Red meat products	Nonspecified red meats (e.g., bison, rabbit, game animals, zoo animals, elk, wapiti, moose)	Cattle, sheep, swine, goats, horses, mules, other equine
Poultry	Nonspecified birds: wild turkeys, wild ducks, wild geese	Domesticated birds: chicken, turkey, ducks, geese, guineas, ratites
Other meat products	Products containing < 3% red meat (wet) and closed-faced meat sandwiches	Products containing 3% or more red meat (wet) and open-faced meat sandwiches
Other poultry products	Products containing < 2% poultry (wet)	Products containing 2% or more poultry (wet)
Eggs	Shell eggs, products containing egg products and other egg processing not covered by USDA (e.g., restaurants, cake mix plants, bakeries); Enforcement of shell egg labels/labeling	Pasteurized processed egg products, egg processing plants (washing, sorting, breaking, and pasteurizing)

Product	HHS/FDA	USDA/FSIS
Soup	All soup not covered by USDA	Soup containing 3% or more red meat or 2% or more poultry (e.g., chicken noodle)
Other products	Cheese, onion, mushroom pizza; spaghetti sauces (less than 3% red meat), spaghetti sauce with mushrooms and 2% meat, pork and beans, sliced egg sandwich (closed-faced), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets	Pepperoni pizza, meat lovers stuffed-crust pizza, meat sauces (3% or more red meat), spaghetti sauce with meatballs, open-faced roast beef sandwich, hot dogs, beef/vegetable pot pie, chicken sandwich (open-faced)
Exceptions to the above	All foods involved in an outbreak aboard an interstate vessel, plane, train, bus	

* USDA/APHIS also regulates commercial foods imported into the United States that contain meat, milk, poultry, or eggs, or meat, milk, poultry, or egg products.

Table A1-2: Key Security and Emergency Response-Related Authorities

Authority	Summary
16 U.S.C. 551	Provides for protection against destruction by fire and depredation upon the public forests and National Forests.
16 U.S.C. 551a	Authorizes the Secretary of Agriculture to cooperate with and provide reimbursement to any State or political subdivision for enforcement of their laws on the National Forest System.
16 U.S.C. 553	Provides that Forest Service officials shall aid States with regard to forest fires.
16 U.S.C. 559	Authorizes Forest Service employees to make arrests for violation of the laws and regulations of the National Forest.
36 CFR Part 261	Relates specifically to acts that are prohibited on the National Forest System.
50 U.S.C. 82	Authorizes the procurement of ships and material during war.
50 U.S.C. App. 468	The act delegates authorities vested in the President, with respect to placing orders for prompt delivery of articles or materials, to the Secretary of Agriculture over all matters with respect to food resources.

Authority	Summary
7 CFR 250, Section 43 (disasters); 7 CFR 250, Section 44 (situations of distress)	Contain the regulations implementing food donations, and statutory authorities that authorize the Secretary of Agriculture to make donated food available to victims of disasters and situations of distress, respectively.
7 CFR 272, Section 3	Contains regulations implementing food stamp statutory authorities that authorize the Secretary of Agriculture to make coupons available to disaster/emergency victims; specifically, contains requirements outlining operating guidelines for participating State agencies.
7 CFR 274, Section 6	Contains regulations implementing food stamp statutory authorities that authorize the Secretary of Agriculture to make coupons available to disaster/emergency victims; specifically, contains requirements outlining non-discrimination guidelines for participating State agencies.
7 CFR 280, Section 1	Contains regulations implementing food stamp statutory authorities that authorize the Secretary of Agriculture to make coupons available to disaster/emergency victims, specifically, contains interim disaster procedures allowing the Secretary to establish temporary emergency standards of eligibility for the duration of the emergency for households that are victims of a disaster that disrupts commercial channels of food distribution.
Agricultural Act of 1949, Section 416(b), 7 U.S.C. 1431	Section 416(b) of the Agricultural Act of 1949, as amended, provides for overseas donations of surplus commodities acquired by the Commodity Credit Corporation (CCC). Section 416 also authorizes the Secretary of Agriculture to donate surplus commodities to disaster victims, subject to certain requirements.
Agricultural Bioterrorism Protection Act of 2002, Title II, Subtitle B, Sections 211-213 of the Public Health Security and Bioterrorism Preparedness and Response Act, Public Law 107-188	Requires that entities, such as Federal, State, and private research laboratories, universities, vaccine companies, and individuals that possess, use, or transfer select biological agents or toxins identified as a severe threat to public health or animal and plant health register with USDA APHIS or with the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), depending on the agent they possess.
Agricultural Marketing Act of 1946, 7 U.S.C. 1621-1627, Section 203(h)	Authorizes the Secretary of Agriculture to inspect, certify and identify the class, quality, quantity, and condition of agricultural products when shipped or received in interstate commerce.
Agricultural Marketing Act of 1946, 7 U.S.C. 74	GIPSA administers and enforces certain inspection and standardization activities related to rice, pulses, lentils, and processed grain products such as flour and corn meal, as well as other agricultural commodities.

Authority	Summary
Agricultural Marketing Act of 1946, Section 203(j), 7 U.S.C. 1621	Authorizes the Secretary of Agriculture to assist in improving transportation services and facilities, and in obtaining equitable and reasonable transportation rates and services and adequate transportation facilities for agricultural products and farm supplies. AMS may conduct, assist, and foster research, investigation, and experimentation to determine the best methods of transporting agricultural products; and foster and assist in the development of new or expanded markets (domestic and foreign) for moving larger quantities of agricultural products through the private marketing system to consumers in the United States and abroad.
Agricultural Marketing Act of 1946, Section 203(k), 7 U.S.C. 1621	Authorizes the Secretary of Agriculture to collect, tabulate, and disseminate statistics on marketing agricultural products, including, but not restricted to, statistics on market supplies, storage stocks, quantity, quality, and condition of such products in various positions in the marketing channel, utilization of such products, and shipments and unloads thereof.
Agricultural Reform and Improvement Act of 1996, 7 U.S.C. 950aaa	To encourage and improve telemedicine services and distance learning services in rural areas through the use of telecommunications, computer networks, and related advanced technologies by students, teachers, medical professionals, and rural residents.
Agricultural Research Act of 1935, 7 U.S.C. 427	Authorizes the Secretary of Agriculture to ensure agriculture a position in research equal to that of industry, which will aid in maintaining an equitable balance between agriculture and other sections of our economy.
Agricultural Research and Marketing Act of 1946, 7 U.S.C. 1621-1627, 1624 specifically	Authorizes the Secretary of Agriculture to cooperate with other entities, including branches of the Federal Government, State agencies, and private research organizations in producing, transporting, storing, processing, marketing, and distributing agricultural products whether operating in one or more jurisdictions.
Agricultural Trade Development and Assistance Act of 1954, Title I, 7 U.S.C. 1701 et seq.	The CCC finances the sale and exportation of agricultural commodities to developing countries on concessional credit terms. Developing countries are countries that have a shortage of foreign exchange and difficulty meeting all of their food needs through commercial channels. In addition to meeting immediate food needs, the local currency resources generated by the sale of the commodities in the recipient country may be used to improve food availability and agricultural development, alleviate poverty, and promote broad-based, equitable, and sustainable agriculture and broad-based economic growth. CCC closely coordinates activities with the U.S. Agency for International Development (USAID) to identify needs and avoid duplication of efforts.
Agriculture and Consumer Protection Act of 1973, 7 U.S.C. 612c	Appropriation to encourage exportation and domestic consumption of agricultural products. Section 4(a) authorizes the Secretary of Agriculture to donate surplus commodities to disaster victims, subject to certain requirements.
Agriculture Marketing Act of 1946, 7 U.S.C. 1621-1627	Congress resolved that the prosperity of the Nation depends on an efficient, private system for distributing and marketing agricultural products. To achieve this goal, the Agriculture Marketing Act of 1946 was passed to provide for continuous research to improve agriculture marketing, cooperation between Federal and State agencies, and to integrate the administration of laws enacted by Congress to aid the distribution of agricultural products.

Authority	Summary
Animal Health Protection Act, 7 U.S.C. 8301	Authorizes the Secretary of Agriculture to prohibit or restrict the importation, exportation, and interstate movement of animals or other articles as necessary to prevent pests or diseases of livestock (any farm-raised animals, including fish) from being introduced into, or disseminated within, the United States.
Animal Welfare Act, 7 U.S.C. 2146	Authorizes the Secretary of Agriculture to promulgate regulations and standards governing the humane handling, care, treatment, and transportation of animals, as defined in the act, by dealers, exhibitors, and other regulated persons.
Bill Emerson Humanitarian Trust	A resource to ensure that the U.S. Government can respond to emergency food aid needs. The Emerson Trust is not a food aid program, but a food reserve administered under the authority of the Secretary of Agriculture. U.S. commodities from this reserve can be tapped to respond to humanitarian food crises in developing countries, particularly when a crisis emerges unexpectedly. Up to 4 million metric tons of U.S. wheat, corn, sorghum, and rice can be kept in the reserve. The Secretary is authorized to release commodities from the Emerson Trust to provide food aid for unanticipated emergency needs that cannot otherwise be met through Public Law 83-480. The reserve was originally authorized by the Agricultural Trade Act of 1980 as the Food Security Wheat Reserve. Subsequent legislation broadened the number of commodities that can be held in the reserve and, in 1998, it was renamed the Bill Emerson Humanitarian Trust. Most recently, the Farm Security and Rural Investment Act of 2002 reauthorized the Emerson Trust through 2007.
Child Nutrition Act of 1966, as amended	Authorizes the Child Nutrition Programs (National School Lunch Program, School Breakfast Program, Child and Adult Care Food Program, and the Summer Food Service Program) and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The programs provide States with cash, commodity, and other assistance, including nutrition services and food packages in the WIC program. FNS administers these programs at the Federal level.
Consolidated Farm and Rural Development Act, Section. 321(a) Emergency Loan Program, 7 U.S.C. 1961 et seq.	Authorizes direct and guaranteed loans to farms and ranchers who are U.S. citizens who operate family farms that have been substantially affected by a quarantine imposed by the Secretary of Agriculture under the Plant Protection Act or the animal quarantine laws, a natural disaster, or by a major disaster or emergency designated by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.).
Consolidated Farm and Rural Development Act, 7 U.S.C. 1921 et seq., Public Law 87-128	Revises and consolidates the authorization of the Secretary of Agriculture to make and insure loans to farmers and ranchers in order to provide for more effective credit services to farmers; authorizes Farm Service Agency to provide emergency loans to help producers recover from production and physical losses due to drought, flooding, other natural disaster, or quarantine.
Defense Production Act, 50 U.S.C. 2071	Authorizes the Secretary of Agriculture to place priority ratings on contracts or orders with respect to food resources, food resource facilities, and the domestic distribution of farm equipment and commercial fertilizer.

Authority	Summary
Defense Production Act, 50 U.S.C. App. 2061 et seq.	Authorizes the President to establish priorities under contracts, which the President deems necessary or appropriate to promote the national defense and to allocate materials, services, and facilities in such manner, upon such conditions, and to such extent, as he shall deem necessary or appropriate to promote the national defense.
Department of Agriculture Reorganization Act of 1994, 7 U.S.C. 6941 et seq.	Establishes conditions associated with financial assistance in the maintenance of the Department of Rural Utilities Service within the Office of Rural Development, to the service such functions, as the Secretary of Agriculture considers appropriate.
Disaster Relief Act of 1974, 42 U.S.C. 5180(b)	The Secretary of Agriculture shall utilize funds appropriated under Section 612c of Title 7 to purchase food commodities necessary to provide adequate supplies for use in any area of the United States in the event of a major disaster or emergency in such area. FSA and AMS are the purchasing agencies for commodity programs, and FNS is the administering agency.
Disaster Relief Act of 1974, Section 32 of Public Law 74-320, Section 410(b)	Authorities to conduct purchase activities, appropriations equal to 30 percent of gross customs receipts collected during each preceding calendar year, and unused balances up to $500 million are available for encouraging the domestic consumption or exportation of agricultural commodities; pursuant to Section 32, AMS purchases non-price-supported commodities such as meats and fish, fruits and vegetables, and poultry and egg products to stabilize market conditions.
Egg Products Inspection Act (EPIA), 21 U.S.C. 1031 et seq.	FSIS provides continuous inspection of all egg products prepared for distribution in commerce and re-inspects imported products to ensure that they meet U.S. food safety standards. FSIS tests for and conducts enforcement activities to address microbiological, chemical, and other types of contamination and conducts epidemiological investigations in cooperation CDC based on reports of foodborne health hazards and disease outbreaks.
Emergency Conservation Program (ECP) of the Agricultural Credit Act of 1978, Public Law 95-334	Authorizes the ECP, which provides emergency funding and technical assistance to farmers and ranchers for rehabilitating farmland damaged by natural disasters and for carrying out emergency water conservation measures in periods of severe drought.
Emergency Food Assistance Act of 1983, as amended	USDA purchases and provides commodities to State agencies to assist low-income households and needy persons at food pantries and soup kitchens and other “emergency feeding organizations.” Such organizations may also include disaster relief programs.
Executive Order 12742	With respect to the placing of orders for prompt delivery of articles or materials, the President delegates to the Secretary of Agriculture authority with respect to all food resources.
Executive Order 12919	Delegates authorities and addresses national defense industrial resource policies and programs.

Authority	Summary
Farm Security and Rural Investment Act of 2002, Public Law 107-171, Title X, Subtitle E	Consolidates a number of pre-existing animal health-related statutes into a single comprehensive law; among other items, authorizes the Secretary of Agriculture to prohibit or restrict the importation, exportation, and interstate movement of animals or other articles as necessary to prevent pests or diseases of livestock from being introduced into, or disseminated within, the United States; and authorizes the Secretary to issue any regulations or orders that the Secretary considers necessary to carry out the Animal Health Protection Act. Also reauthorized the Emerson Trust through 2007. (See Bill Emerson Humanitarian Trust in this table).
Federal Crop Insurance Act, 7 U.S.C. 1502	The Federal Crop Insurance Corporation and Risk Management Agency are enabled under the Federal Crop Insurance Act to provide risk management programs. There is no provision in the Federal Crop Insurance Act to provide coverage against acts of terrorism.
Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, Public Law 103-354	Authorizes the Noninsured Crop Disaster Assistance Program (NAP), which provides financial assistance and risk management tools to eligible producers affected by natural disasters; covers noninsurable crop losses and planting prevented by disasters.
Federal Meat Inspection Act (FMIA), 21 U.S.C. 601 et seq.	FSIS provides continuous inspection of all meat products prepared for distribution in commerce and re-inspects imported products, to ensure that they meet U.S. food safety standards. FSIS tests for and conducts enforcement activities to address microbiological, chemical, and other types of contamination and conducts epidemiological investigations in cooperation with the CDC based on reports of foodborne health hazards and disease outbreaks.
Food for Progress Act of 1985, 7 U.S.C. 1736o	The CCC may donate, or sell on credit terms, agricultural commodities in support of developing countries and emerging democracies that have made commitments to introduce free enterprise elements in their agricultural economies. The CCC may donate agricultural commodities to foreign governments, private voluntary relief organizations or intergovernmental organizations, and other private entities. The CCC may purchase commodities for donation abroad under this authority. Commodities may be used for direct humanitarian relief or sold and the sales proceeds used for economic development purposes. In addition to the commodities, up to $10 million may be made available each fiscal year to provide assistance in the administration and monitoring of food assistance programs and to provide technical assistance to strengthen private sector agriculture in recipient countries. The CCC closely coordinates donation activities with the US Agency for International Development to identify needs and avoid duplication of efforts.
Food Quality Protection Act 1996, Public Law 104-170	Authorizes the Pesticide Data Program to develop and communicate comprehensive, statistically reliable information on pesticide residues in food to improve government dietary risk assessment procedures.
Food Stamp Act of 1977, Section 5(h), as amended	Provides the Secretary of Agriculture the authority to: establish temporary emergency standards of eligibility during any disaster where commercial channels of food distribution have been disrupted and again restored; provide emergency allotments to replace the value of food destroyed up to a limited amount; and adjust reporting and other requirements to be consistent with what is practicable under actual conditions.

Authority	Summary
Food, Agriculture, Conservation, and Trade Act of 1990, 7 U.S.C. 950aaa	Encourages and improves telemedicine services and distance learning services in rural areas through telecommunications, computer networks, and related technologies.
Launching Our Communities Access to Local Television Act of 2000, 47 U.S.C. 1101	Facilitates access to signals of local television stations for households in nonserved and underserved areas.
Livestock Assistance Programs (Food Security and Rural Investment Act of 2002, Section 10104, 7 U.S.C. 1472)	The Secretary of Agriculture is authorized to provide assistance to dairy and livestock producers to cover economic losses incurred by producers in the form of: (1) indemnity payments for livestock mortality losses; (2) livestock feed assistance for producers affected by shortages of feed; (3) compensation for sudden increases in production costs; and (4) such other assistance, and for such other economic losses, as the Secretary determines appropriate. Triggered by the Secretary determining that economic losses to livestock producers have occurred. Appropriation of funds is needed before program may be implemented.
McGovern-Dole International Food for Education and Child Nutrition Program, Public Law 107-171, Section 3107	Helps support education, child development, and food security for some of the world's poorest children. It provides for donations of U.S. agricultural products, as well as financial and technical assistance, for school feeding and maternal and child nutrition projects in low-income, food-deficient countries that are committed to universal education. The commodities are made available for donation through agreements with private voluntary organizations, cooperatives, intergovernmental organizations, and foreign governments. This authority was established under the Farm Security and Rural Investment Act of 2002.
National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended, 7 U.S.C. 3121-3122	The enactment of subsequent laws modified, extended, or added new research authorities for ARS.
Organic Act of 1862, 7 U.S.C. 2201	The act is the main authority for the establishment of the USDA and ARS.
Public Law 83-480, Title I, Trade and Development Assistance	Provides for government-to-government sales of U.S. agricultural commodities to developing countries on credit terms or for local currencies.
Public Law 83-480, Title II, Emergency and Private Assistance	Provides for the donation of U.S. agricultural commodities to meet emergency and non-emergency food needs in other countries, including support for food security and availability goals.
Public Law 83-480, Title III, Food for Development	Provides for government-to-government grants to support long-term growth in the least developed countries.

Authority	Summary
Packers and Stockyards Act of 1921, 7 U.S.C. 181	Prohibits unfair, deceptive, and fraudulent practices by market agencies, dealers, packers, swine contractors, and live poultry dealers in the livestock, poultry, and meatpacking industries.
Plant Protection Act (PPA) (Title IV of the Agricultural Risk Protection Act of 2000, Public Law 106-224)	Consolidates pre-existing pest quarantine and exclusion statutes into a single comprehensive law; authorizes the Secretary of Agriculture to prohibit or restrict the importation, exportation, and interstate movement of plants, plant products, biological control organisms, noxious weeds, plant pests, or other articles as necessary to prevent plant pests or noxious weeds from being introduced into, or disseminated within, the United States; authorizes the Secretary to issue any regulations or orders that the Secretary considers necessary to carry out the PPA.
Poultry Products Inspection Act (PPIA), 21 U.S.C. 451 et seq.	FSIS provides continuous inspection of all poultry products prepared for distribution in commerce and re-inspects imported products to ensure that they meet U.S. food safety standards. FSIS tests for and conducts enforcement activities to address microbiological, chemical, and other types of contamination and conducts epidemiological investigations in cooperation with CDC based on reports of foodborne health hazards and disease outbreaks.
Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188	FSIS food defense initiatives are undertaken pursuant to the act.
Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), Section 412	Authorizes the President, at his discretion, to issue food benefits to low-income households that are unable to purchase adequate amounts of nutritious food due to a major disaster or emergency. This authority was delegated to the Secretary of Agriculture and re-delegated to the FNS Administrator .
Rural Electrification Act (RE Act) of 1936, 7 U.S.C. 901	Established Rural Electrification Administration (the predecessor of Rural Utilities Service) as a lending agency with the responsibility for developing a program for electrification.
Stafford Act, Sections 412 and 413(b)	Authorizes the Secretary of Agriculture to distribute surplus commodities and to purchase food commodities necessary to provide adequate supplies for use in any area of the United States in the event of a disaster. Both commodity assistance and food stamp assistance activities may be used to supply food. FNS provides USDA-donated food assistance through State food distribution agencies. All States have stocks of USDA food on hand; these stocks can be released immediately for use in a declared disaster under the Stafford Act.

Authority	Summary
United States Warehouse Act, 7 U.S.C. 241 et seq., amended by Public Law 106-472	The act authorizes the Secretary of Agriculture to license public warehouse operators in the business of storing agricultural products, to examine such federally licensed warehouses, and to license qualified persons to sample, inspect, weigh, and grade agricultural products. The Secretary is also authorized to issue regulations that govern the establishment and maintenance of electronic systems under which electronic documents, including title documents related to the shipment, payment, and financing, may be issued or transferred for any agricultural product. Operations carried out under the act are user fee funded, with funds being collected from the federally licensed warehouse community. Under the authority provided by the act, FSA provides depositors reliable protection of their deposits from loss; establishes a uniform regulatory system for the storage of agricultural products; establishes the warehouse receipt as a negotiable document of title; and provides for electronic warehouse receipts and other electronic documents for all agricultural products.
U.S. Grain Standards Act of 1916, 7 U.S.C. 79	Congress established the Federal grain inspection entity in 1976 to manage the national grain inspection system and to institute a national grain-weighing program.
Virus-Serum-Toxin Act of 1913, 21 U.S.C. 151-159	Authorizes the Secretary of Agriculture to regulate veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin) to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective.
Wholesome Meat Act 1967, 21 U.S.C. 601	FSIS is also responsible for assessing whether State inspection programs that regulate meat are at least equal to the Federal program; the act extended FSIS jurisdiction over meat and meat products granting authority to regulate transporters, renderers, cold storage warehouses, and animal-food manufacturers.

Appendix 4: CARVER + Shock Primer

CARVER + Shock Method for Food and Agriculture Sector Vulnerability Assessments

Overview

The CARVER + Shock method is a proactive targeting prioritization tool that has been adapted for use in the Food and Agriculture Sector. This tool can be used to assess the vulnerabilities within a system or infrastructure to an attack. It allows the user to think like an attacker by identifying the most attractive targets. Conducting a vulnerability assessment and determining the most vulnerable points in the infrastructure permits the user to focus resources on protecting those points that are most vulnerable.

CARVER is an acronym for the following six attributes (discussed in further detail later) used to evaluate the attractiveness of a target for attack:

- **C**riticality: Measure of public health and economic impacts of an attack;
- **A**ccessibility: Ability to physically access and egress from target;
- **R**ecuperability: Ability of system to recover from an attack;
- **V**ulnerability: Ease of accomplishing attack;
- **E**ffect: Amount of direct loss from an attack as measured by loss in production; and
- **R**ecognizability: Ease of identifying target.

In addition, the modified CARVER tool evaluates a seventh attribute, the combined health, economic, and psychological impacts of an attack, or the Shock attributes of a target.

The attractiveness of a target can be ranked from 1 to 10 on scales developed for each of the seven attributes. Conditions associated with lower attractiveness (or lower vulnerability) are assigned lower values (e.g., 1 or 2), whereas conditions associated with higher attractiveness as a target (or higher vulnerability) are assigned higher values (e.g., 9 or 10). Evaluating or scoring the various elements of the food sector infrastructure of interest for each of the CARVER + Shock attributes can help identify where within that infrastructure an attack is most likely to occur. Federal agencies, such as the Animal and Plant Health Inspection Service (APHIS), Food Safety and Inspection Service (FSIS), and the Food and Drug Administration (FDA), 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.

Steps for Conducting a CARVER + Shock Analysis

Step 1: Establishing Parameters

Before any scoring can begin, the scenarios and assumptions to be used in the analysis must be established in order to guide all further steps. Users need to determine what is to be protected and from what it is to be protected. These parameters include the following:

- What agricultural production or food supply chain is to be assessed (e.g., hot dog production versus deli meat production versus chicken nugget production; overall assessment based on generic process from farm to table versus post-slaughter processing in a specific facility)?
- What is the endpoint of concern (e.g., foodborne illness and death versus economic impacts)?
- What type of attacker and attack is the user trying to protect against? Attackers could range from disgruntled employees to international terrorist organizations. Different attackers have different capabilities and different goals. For example, a major assumption by FSIS and FDA in their vulnerability assessments for food is that one of the goals of terrorist organizations is to cause mass mortality by adding acutely toxic agents to food products. With regard to agricultural production, APHIS has made the assumption that the terrorist goal is to impact the U.S. economy by introducing a plant or animal disease. These assumptions have a major effect on the scoring of the various parts of the supply chain, and the scales for the attributes (see below) have been developed with that in mind.
- What agent(s) might be used? The agent used in the scenario will affect the outcome of the assessment. Potential agents include biological, chemical, or radiological agents. Different agents have different properties-potency, heat stability, pH stability, half-life-that will determine the impact of an intentional contamination incident.

Step 2: Assembling Experts

A team of subject matter experts should conduct the assessment. The team should consist of, at a minimum, experts in agricultural or food production (specifically for the food process being evaluated), food science, toxicology, epidemiology, microbiology, medicine (human and veterinarian), radiology, and risk assessment. The team will apply the CARVER + Shock method to each element of food system infrastructure and come to a consensus on a value from 1 to 10 for each attribute, using the scenario and assumptions established in step 1.

Step 3: Detailing Food Supply Chain

The analysis begins by developing a description of the system under evaluation. A graphical representation (flowchart) of the system and its subsystem, complexes, components, and nodes (its smaller structural parts) should be developed to facilitate this process. For example, if evaluating hot dog production, the food system is hot-dog production, which can be broken down into subsystems (production of live animals subsystem, slaughter/processing subsystem, distribution subsystem). The subsystems can be further broken down into complexes (e.g., slaughterhouse facility and processing facility). Complexes can be broken down into components and would include the raw materials receiving area, processing area, storage area, shipping area, and to the smallest possible nodes (e.g., individual pieces of equipment).

Step 4: Assigning Scores

Once the infrastructure has been broken down into its smallest parts (i.e., components and nodes), these can be ranked or scored for each of the seven CARVER + Shock attributes to calculate an overall score for that node. The nodes with the higher overall scores are those that are potentially the most vulnerable nodes because they would be the most attractive targets for an attacker. The rationale for a particular consensus score should be captured.

Step 5: Applying What Has Been Learned

Once the critical nodes of the system have been identified, a plan should be developed to put countermeasures in place that minimize the attractiveness of the nodes as targets. Countermeasures might include enhancements to physical security, personnel security, and operational security that help to minimize aggressor access to the product or process. In addition, countermeasures may address means for rapid identification and response to a threat agent such as enhanced surveillance technology and activities, deployment of rapid field identification kits, and implementing response, recovery, and continuity of business plans.

Description of Attributes and Scales

The following section defines the attributes used by FDA and USDA to conduct vulnerability assessments and provides the scales used by the agencies for scoring each attribute. These scales were developed on the assumption that mass mortality is a goal of terrorist organizations. It is important to remember, however, that any intentional food contamination could also have major psychological and economic impacts on the affected industry. Tables to assist in calculating the public health impacts and the overall CARVER + Shock scores can be found in attachments 2.A and 2.B later in this appendix, respectively.

Criticality. A target is critical when introduction of threat agents at its location would have significant health or economic impact. Example metrics are as follows:

Criticality Criteria	Scale
Loss of more than 10,000 lives or loss of more than $100 billion	9–10
Loss of life is between 1,000 - 10,000 OR loss between $10 billion and $100 billion	7–8
Loss of life between 100 and 1,000 OR loss between $1 billion and $10 billion	5–6
Loss of life less than 100 OR loss less than $1 billion	3–4
No loss of life OR loss less than $100 million	1–2

Accessibility. A target is accessible when an attacker can reach the target to conduct the attack and egress the target undetected. Accessibility is the openness of the target to the threat. This measure is independent of the probability of successful introduction of threat agents. Example metrics are as follows:

Accessibility Criteria	Scale
Easily Accessible (e.g., target is outside building and no perimeter fence). Limited physical or human barriers or observation. Attacker has relatively unlimited access to the target. Attack can be carried out using medium or large volumes of contaminant without undue concern of detection. Multiple sources of information concerning the facility and the target are easily available.	9–10
Accessible (e.g., target is inside building, but in unsecured part of facility). Human observation and physical barriers limited. Attacker has access to the target for an hour or less. Attack can be carried out with moderate to large volumes of contaminant, but requires the use of stealth. Only limited specific information is available on the facility and the target.	7–8
Partially Accessible (e.g. inside building, but in a relatively unsecured, but busy, part of facility). Under constant possible human observation. Some physical barriers may be present. Contaminant must be disguised, and time limitations are significant. Only general, nonspecific information is available on the facility and the target.	5–6
Hardly Accessible (e.g., inside building in a secured part of facility). Human observation and physical barriers with an established means of detection. Access generally restricted to operators or authorized persons. Contaminant must be disguised and time limitations are extreme. Limited general information available on the facility and the target.	3–4
Not Accessible. Physical barriers, alarms, and human observation. Defined means of intervention in place. Attacker can access target for less than 5 minutes with all equipment carried in pockets. No useful publicly available information concerning the target.	1–2

Recuperability. A target's recuperability is measured in the time it will take for the specific facility to recover productivity. Example metrics are as follows:

Recuperability Criteria	Scale
Recovery > 1 year	9–10
Recovery 6 months to 1 year	7–8
Recovery 3 to 6 months	5–6
Recovery 1 to 3 months	3–4
Recovery < 1 month	1–2

Vulnerability. A measure of the ease with which threat agents can be introduced in quantities sufficient to achieve the attacker's purpose once the target has been reached. Vulnerability is determined both by the characteristics of the target (e.g., ease of introducing agents, ability to uniformly mix agents into target, ability to rapidly spread from animal to animal or plant to plant) and the characteristics of the surrounding environment (ability to work unobserved, time available for introduction of agents). It is also important to consider what interventions are already in place that might thwart an attack. Example metrics are as follows:

Vulnerability Criteria	Scale
Target characteristics allow for easy introduction of sufficient agents to achieve aim.	9–10
Target characteristics almost always allow for introduction of sufficient agents to achieve aim.	7–8
Target characteristics allow 30 percent to 60 percent probability that sufficient agents can be added to achieve aim.	5–6
Target characteristics allow moderate probability (10 percent to 30 percent) that sufficient agents can be added to achieve aim.	3–4
Target characteristics allow low probability (less than 10 percent) sufficient agents can be added to achieve aim.	1–2

Effect. Effect is a measure of the percentage of system productivity damaged by an attack at a single facility or site. Thus, effect is inversely related to the total number of facilities producing the same product. Example metrics are as follows:

Effect Criteria	Scale
Greater than 50 percent of the system's production impacted.	9–10
25 percent to 50 percent of the system's production impacted.	7–8
10 percent to 25 percent of the system's production impacted.	5–6
1 percent to 10 percent of the system's production impacted.	3–4
Less than 1 percent of system's production impacted.	1–2

Recognizability. A target's recognizability is the degree to which it can be identified by an attacker without confusion with other targets or components. Example metrics are as follows:

Recognizability Criteria	Scale
The target is clearly recognizable and requires little or no training for recognition.	9–10
The target is easily recognizable and requires only a small amount of training for recognition.	7–8
The target is difficult to recognize or might be confused with other targets or target components and requires some training for recognition.	5–6
The target is difficult to recognize. It is easily confused with other targets or components and requires extensive training for recognition.	3–4
The target cannot be recognized under any conditions, except by experts.	1–2

Shock. Shock is the final attribute considered in the methodology. Shock is the combined measure of the health, psychological, and collateral national economic impacts of a successful attack on the target system. Shock is considered on a national level. The psychological impact will be increased if there are a large number of deaths or the target has historical, cultural, religious, or other symbolic significance. Mass casualties are not required to achieve widespread economic loss or psychological damage. Collateral economic damage includes such items as decreased national economic activity, increased unemployment in collateral industries, etc. Psychological impact will be increased if victims are members of sensitive subpopulations such as children or the elderly. The metrics for this criterion are as follows:

Shock Criteria	Scale
Target has major historical, cultural, religious, or other symbolic importance. Loss of more than 10,000 lives. Major impact on sensitive subpopulations (e.g., children or elderly). National economic impact more than $100 billion.	9–10
Target has high historical, cultural, religious, or other symbolic importance. Loss of between 1,000 and 10,000 lives. Significant impact on sensitive subpopulations (e.g., children or elderly). National economic impact between $10 billion and $100 billion.	7–8
Target has moderate historical, cultural, religious, or other symbolic importance. Loss of life between 100 and 1,000. Moderate impact on sensitive subpopulations (e.g., children or elderly). National economic impact between $1 billion and $10 billion.	5–6
Target has little historical, cultural, religious, or other symbolic importance. Loss of life less than 100. Small impact on sensitive subpopulations (e.g., children or elderly). National economic impact between $100 million and $1 billion.	3–4
Target has no historical, cultural, religious, or other symbolic importance. Loss of life less than 10. No impact on sensitive subpopulations (e.g., children or elderly). National economic impact less than $100 million.	1–2

By definition, terrorists attempt to achieve strong emotional responses from their target audience. Aspects of targets that terrorists view as increasing a target's shock value are symbolism (e.g., the Pentagon), large number of casualties, sensitive nature of facilities (e.g., nuclear facilities), and the ability to strike at core values and primal emotions.

Calculation of Final Values and Interpretation

Once the ranking on each of the attribute scales has been calculated for a given node within the food supply system, the ranking on all of the scales can then be totaled to give an overall value for that node. This should be repeated for each node within an agricultural production or food supply system. The overall values for all the nodes can then be compared to rank the vulnerability of the different nodes relative to each other. The summary table provided in attachment 2.B can assist in summarizing the rankings. The nodes with the highest total rating have the highest potential vulnerability and should be the focus of countermeasure efforts.

CARVER + Shock Primer

Attachment 2.A

This attachment provides the following worksheet that can be used to calculate the potential number of deaths and illnesses resulting from addition of a particular adulterant at a particular point in a given food production process. Details of the batch size to which the adulterant is added, the number of servings that will be sold and eaten from that batch, and the characteristics of the adulterant (including its lethality) must be known to use this worksheet. The numbers generated in this worksheet will help determine where on the criticality scale a given attack will fall.

Note: This worksheet may not be applicable for calculating criticality for agricultural production.

CARVER + Shock Primer

Table 2.A: Worksheet for Calculating Criticality

Product:								
Entry Point	Agent	A Batch Size	B Serving Size	C Servings per Batch A/B	D Dose Required per Serving	E Total Amount Required per Batch C x D	F Distribution Unit	G Units Produced A/F
H % of Units Sold Before Warning	I Units for Potential Consumption H/100 x G	J Consumers per Distribution Unit	K Number of Potential Exposures I x J	L % of Units Consumed Before Warning	M Number of Exposures K x L/100	N Morbidity/ Mortality Rate	O Number of Illnesses/ Deaths M x N	

Attachment 2.B

Attachment 2.B provides a summary sheet that can be used to total the scores across the CARVER + Shock attributes for each node. The totals can then be compared across the various nodes to determine which nodes are critical. The nodes with the highest scored are the critical nodes and should be the focus for beginning to implement countermeasures.

CARVER + Shock Primer

Following is the summary sheet for totaling scores for notes across CARVER + Shock attributes.

	Overall Score									
	Shock									
	Recognizability									
	Effect									
	Vulnerability									
	Recuperability									
	Accessibility									
	Criticality									
Product:	Target (Nodes)									

CARVER + Shock Primer

Attachment 2.C

Attachment 2.C provides a summary sheet that can be used to summarize the CARVER + Shock score on each attribute for a given node. The table includes a place for a brief narrative of the rationale or justification for giving a node a particular score, allowing the thoughts that went into the scoring to be captured.

The following is a summary sheet for analysis of individual nodes, including the justification for the score given.

CARVER + Shock Primer

Attachment 2.C

Product:		
Target Complex:		
Target Node:		
Factor	Score	Justification
Criticality		
Accessibility		
Recuperability		
Vulnerability		
Effect		
Recognizability		
Shock		
Overall		
Rank		

Appendix 5: Farm-to-Table Continuum

Point in the Continuum*	USDA Agency	Governmental Security Partners
Production Agriculture		
Loans, grants to farmers for production	FSA	None
Loans, grants to rural communities	RD	None
Conservation assistance (technical assistance with pesticide use, plant/crop/animal health destined for food purposes, farm-grown animal feeds, water, animal feed lots/sale barns/auction houses, and also financial assistance for their construction)	FSA, NRCS	None
Risk management tools (insurance)	RMA	None
Outreach education	CSREES	State officials (EDEN), State Cooperative Extension Services
Research (intramural and extramural)	ARS, CSREES	State and local officials
Disaster assistance/market recovery	FSA	Numerous DHS organizations
Pesticide use	APHIS, AMS (Pesticide Data Program, monitors pesticide residue on a variety of products)	EPA (regulates pesticides) and State and local officials

Point in the Continuum*	USDA Agency	Governmental Security Partners
Plant/crop health (plants or crops destined for food purposes or possible vectors for disease)	APHIS, CSREES	State and local officials
Quality of seed/germination rate	AMS	State officials
Plant/crop health (destined for seed purposes)	APHIS	None
Animal health (animals destined for food purposes or as possible vectors for disease)	APHIS	DHS CBP and State and local officials
Veterinary biologics (includes animal vaccines) and diagnostics	APHIS, CSREES, ARS	DHS S&T (Plum Island) and State and local officials
Animal feed and medicine	APHIS (if product contains animal byproducts)	FDA (regulates feed and medicine for animals)
Livestock auction markets	GIPSA	State and local officials
Water (crop/plants and animal uses)	None	EPA
Transport of plants, crops, and animals after harvest or from the farm to the next point in the continuum	APHIS (can detain or hold product), AMS (advocate for lower rates)	DOT, DHS Transportation Security Administration (TSA), and State and local officials
Food Processing and Distribution		
Inspection of processed fruits and vegetables/dairy	None	FDA
Inspection of processed grain	GIPSA	State inspection programs
Inspection of livestock/poultry at slaughter and processing	FSIS	State inspection programs

Point in the Continuum*	USDA Agency	Governmental Security Partners
Slaughter and processing for "custom" use (use of the owner of the animal and his family/guests; not for commercial sale)	FSIS (for sanitation only)	State inspection programs
Shell egg processing (for liquid egg products, etc.)	FSIS, AMS	None
Shell eggs for human consumption	AMS (for grading purposes)	FDA and State inspection programs (for safety)
Non-meat, poultry, or egg products food processing	None	FDA and State inspection programs
Seafood	None	FDA, National Marine Fisheries Service (NMFS)
Grading FSIS- and FDA-regulated products (voluntary fee-for-service activity)	AMS	FDA, AMS-trained State officials
Imported food products	FSIS (meat, poultry, and egg products only), FAS, APHIS (fruits and vegetables)	FDA, DHS Customs and Border Protection (CBP)
Transportation of food products	FSIS (regulates meat, poultry, and egg products in commerce, not the mode of transport; can seize and detain suspected contaminated product), AMS (studies transportation and is an advocate for lower freight rates)	FDA, DOT, DHS TSA, DHS Office of Infrastructure Protection, State and local officials (FDA regulates non-meat, poultry, and egg products)
Cold storage facilities and warehouses	FSIS (meat, poultry, and egg products), FSA and FNS (warehouses holding food in USDA commodity programs), FNS (for oversight of transport to storage by recipient agencies)	FDA, State and local officials, and State distributing agencies (SDAs)
Treatment facilities	APHIS (cold treatment and fumigation)	DHS CBP
Hotels, restaurants, institutions, and grocery stores (minimal processing, per FSIS regulations do not require FSIS inspection)	FSIS (regulates the product not the site; can seize and detain suspected contaminated product)	State and local officials and FDA

Point in the Continuum*	USDA Agency	Governmental Security Partners
Nutrition assistance programs using USDA commodity foods (National School Lunch Program, Emergency Food Program, and other commodity programs) and International Food Aid	FNS, AMS, FSA (after product has been inspected by FSIS or FDA)	FDA, State and local public health and education officials, FEMA (for disaster relief)
Emergency response to plant and animal disease outbreaks	APHIS	HHS (zoonotic), State and local public health and education officials, FEMA (for disaster relief)
International Food Assistance Programs	FAS, FSA	USAID, FDA, World Food Program (WFP), World Health Organization (WHO)

* Note that Federal- and State-owned infrastructure is woven throughout the continuum (i.e., inspection personnel, laboratory facilities and sampling programs, and personnel to ensure that programs operate, such as the emergency feeding programs, etc.).

Appendix 6: SSP Working Group Proposed Initiatives

Emergency Response Coordination Training

The NRP lays out the national strategy to prevent, prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies. An effective response to these incidents of national significance requires public and private sector collaboration. To facilitate coordination of the public and private sectors during a response, all must become familiar with the National Incident Management System (NIMS) and the Incident Command System (ICS). NIMS provides the doctrine, concepts, principles, terminology, and organizational processes needed for effective, efficient, and collaborative incident management at all levels. ICS is a standardized on-scene emergency management concept specifically designed to allow its users to adopt an integrated organizational structure equal to the complexity and demands of single or multiple incidents without being hindered by jurisdictional boundaries.

The Government Coordinating Council will work with the Sector Coordinating Council to develop and implement a training plan that will include the NIMS and ICS that will be used to facilitate public/private coordination during the response to an incident that impacts the sector.

Submitted by the

U.S. Food and Drug Administration

Food

Critical Infrastructure and Key Resources Sector-Specific Plan as input to the National Infrastructure Protection Plan

May 2007

Homeland Security

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Executive Summary

Protecting the Nation's food and agricultural critical infrastructure and key resources (CI/KR) is an important responsibility shared by Federal, State, local, and tribal governments and private industry. Attacks against the Nation, using food or agricultural infrastructure or resources as weapons of mass destruction (WMD), for example, could have a devastating impact to public health and the economy. A protection plan for food and agriculture infrastructure and resources must focus on early awareness of an attack, via surveillance, and must be coordinated closely with response and recovery plans.

1. Sector Profile and Goals

The Food and Drug Administration (FDA) regulates 80 percent of all food consumed in the United States-the entire domestic and imported food supply except meat, poultry, and frozen, dried, and liquid eggs, which are under the authority of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA), which establishes tolerances for pesticide residues in foods and ensures the safety of drinking water (EPA has jurisdiction for municipal water and FDA has jurisdiction for bottled water). FDA shares its food safety responsibility and mission with its sister agencies from USDA, including FSIS, the Agricultural Marketing Service (AMS), the Food and Nutrition Service (FNS) and the Animal and Plant Health Inspection Service (APHIS) to regulate the entire food industry.

While FDA's mission is to protect and promote public health, that responsibility is shared with others; Federal, State, and local agencies; regulated industry; academia; health providers; and consumers all have a role to play.

FDA regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and $59 billion worth of cosmetics sold across State lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale, with numerous food establishments (including food manufacturers, processors, and warehouses) and cosmetic firms. In addition, roughly 600,000 restaurants and institutional food service establishments and an estimated 235,000 supermarkets, grocery stores, and other food outlets are regulated by State and local authorities that receive guidance, model codes, and other technical assistance from FDA. FDA enhances its programs by supporting State and local authorities with training and guidance to ensure uniform coverage of food establishments and retailers.

Sector Mission and Vision

The mission of the Food and Agriculture Sector is to protect against an attack on the food supply, including production agriculture, that would pose a serious threat to public health, safety, welfare, or to 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.

Securing this sector presents unique challenges because U.S. agriculture and food systems are extensive, open, interconnected, diverse, and complex structures providing attractive potential targets for terrorist attacks. Due to the rapidity by which food products move in commerce to consumers and the time required for detection and identification of a causative agent, attacks on the food and agriculture sector-such as animal or plant disease introduction or food contamination-could result in severe animal, plant, or public health and economic consequences. The government and industry members have set the following vision for the sector:

Agriculture and Food Sector Vision Statement:

Prevent the contamination of the food supply that would pose a serious threat to public health, safety, and welfare. 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, ensure that the industry has incorporated the concepts of HSPD-7 in their own critical asset protection plans, vulnerability/risk reduction plans, and continuity of operations plans (COOP). The sector will provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management.

The Government Coordinating Council (GCC) and the Sector Coordinating Council (SCC) work collaboratively to accomplish the mission and to fulfill the vision and are the primary method of coordination for the sector security partners. The GCC, with representation from Federal, State, local, and tribal governments, is the public sector portion of the food and agriculture public-private partnership; the SCC is a self-governing body representing the food and agriculture industry.

2. Identify Assets, Systems, Networks, and Functions

In order to meet the requirements of the National Infrastructure Protection Plan (NIPP) for a strategic approach to infrastructure protection, each sector must understand its critical components. Only once the sector is aware of each component, may it consider threats, assess vulnerabilities, develop and implement protective measures or mitigation strategies, address research and development (R&D) needs, and measure success. A protection plan for this sector must include a farm-to-table approach, as well as the consideration of interdependent sectors, including, but not limited to, Cyber, Chemicals, Water, Energy, and Transportation.

FDA and sector security partners initiated the Agriculture and Food Criticality Project to identify the functions performed at an aggregate level by the Food and Agriculture Sector. Information from this project will be used to define criteria for sector infrastructure, which will facilitate the identification and prioritization of CI/KR within the sector. In early 2007, we began transitioning the project to a new institution for continuation of the project.

3. Assess Risks

The Food and Agriculture Sector has chosen the CARVER + Shock methodology to assess risk to CI/KR. CARVER + Shock is an offensive targeting tool that analyzes the economic and psychological (i.e., shock) consequences, in addition to the public health consequences, of an attack. Additionally, these analyses more thoroughly integrate threat information, especially the capabilities and intent of the threat, into the analysis.

4. Prioritize Infrastructure

The CARVER + Shock analyses identified a number of considerations that affect the risk that a food, at a particular point in its production, could become the target of intentional contamination. These analyses have been used to prioritize the food and agriculture infrastructure. The following four characteristics were common to each of the food products identified as being at a higher risk:

- Large batch size, resulting in large number of servings;
- Short shelf life or rapid turnaround at retail and rapid consumption;
- Uniform mixing of contaminant into food; and
- High accessibility to the critical node of production, processing, or distribution.

The "higher risk" foods are receiving priority attention by FDA for the identification and implementation of preventive measures. Also, the results from the Agriculture and Food Criticality Project will be used to define criteria for sector infrastructure, which will facilitate the identification and prioritization of CI/KR within the sector.

5. Develop and Implement Protective Programs

Protective programs within the sector are based on congressional mandates, the findings from vulnerability assessments, previous food contamination incidents, suggestions from State health or agriculture departments, and sector-specific information provided by the intelligence and law enforcement communities and the Department of Homeland Security's (DHS's) Homeland Infrastructure Threat and Risk Analysis Center (HITRAC). FDA issues regulations in accordance with congressional mandates and issues guidance documents to the private sector that contain suggested food defense practices in accordance with applicable government regulations. The private sector voluntarily implements those security countermeasures that are applicable for each food establishment as appropriate.

6. Measure Progress

As part of the preparation for the next version of the Sector-Specific Plan (SSP), the sector will work to develop sector-specific metrics. In the interim, the GCC and SCC will continue to consider and review security and defense programs. Collectively, these measures convey a comprehensive story regarding what products and services agencies provide, how well they do so, and with what result.

7. CI/KR Protection Research and Development

Federal Critical Infrastructure Protection (CIP) R&D planning is based on the NIPP and Homeland Security Presidential Directive 7 (HSPD-7). In addition to the NIPP, HSPD-7 establishes an annual requirement for the National Critical Infrastructure Protection Research and Development Plan (NCIP R&D Plan). As the primary R&D arm of DHS, the Science and Technology Directorate supports the Secretary of Homeland Security by preparing the annual NCIP R&D Plan in partnership with the Executive Office of the President's Office of Science and Technology Policy.

FDA's food safety and defense research approach is threefold, involving an intramural program; an extramural program; and consortia with industry, other government agencies, and/or academia. FDA conducts research that ensures food safety, promotes sound nutrition, enhances the safety of cosmetic products, and defends the food supply from being a vehicle for terrorist attacks against the United States. This FDA mission-critical research ensures the health and well-being of the American public through enhanced technologies for identifying, preventing, eliminating, and responding to both unintentional and intentional

foodborne threats. Just as important, the research provides the scientific basis for regulating the food producing industries to ensure a safe and nutritious food supply from farm to table.

The GCC and SCC have established the Food and Agriculture Sector Joint Committee on Research. The mission of this committee is to assess and advise the Food and Agriculture Sector (GCC and SCC) on homeland security researchable needs and goals. The committee will make use of existing vulnerability work, consider threat information, make discovery of operational needs in the sector, consult or involve the research community as needed, and refine or update recommendations periodically.

The committee will annually provide to the councils a collective and coordinated list of researchable food and agriculture priority needs from both the perspective of those involved in operations and implementation-the States and the private sector, and those government agencies involved in maintaining homeland security coordination and oversight-the Sector-Specific Agencies (SSAs).

8. Managing and Coordinating SSA Responsibilities

This SSP reflects the sector's goals and priorities. Therefore, it needs to be maintained and updated regularly. Updates to the SSP will undergo a thorough review that includes collaboration with the SCC, GCC, and other sector security partners on a triannual basis. Revisions to this SSP will be coordinated closely with USDA.

Introduction

Protecting the critical infrastructure and key resources (CI/KR) of the United States is essential to the Nation's security, economic vitality, and way of life. CI/KR includes the assets, systems, networks, and functions that provide vital services to the Nation. Terrorist attacks on CI/KR and other manmade and natural disasters could significantly disrupt the functioning of government and business alike, and produce cascading effects far beyond the affected CI/KR sector and physical location of the incident. Direct attacks could result in large-scale human casualties, property destruction, and economic damage, and also profoundly damage national prestige, morale, and confidence. Terrorist attacks using components of the Nation's CI/KR as weapons of mass destruction (WMD) could have even more devastating physical, psychological, and economic consequences.

The protection of the Nation's CI/KR, therefore, is an essential part of the homeland security mission of making America safer, more secure, and more resilient from terrorist attacks and other natural and manmade hazards. Protection includes actions to guard or shield CI/KR assets, systems, networks, or their interconnecting links from exposure, injury, destruction, incapacitation, or exploitation. In the context of the National Infrastructure Protection Plan (NIPP), this includes actions to deter, mitigate, or neutralize the threat, vulnerability, or consequences associated with a terrorist attack or other incident. Protection can include a wide range of activities including hardening facilities, building resiliency and redundancy, incorporating hazard resistance into initial facility design, initiating active or passive countermeasures, installing security systems, and implementing cyber security measures. The NIPP provides the framework for the unprecedented cooperation that is needed to develop, implement, and maintain a coordinated national effort that brings together government at all levels, the private sector, and international organizations and allies.

The NIPP and its complementary Sector-Specific Plans (SSPs) provide a consistent, unifying structure for integrating both existing and future CI/KR protection efforts. It also provides the core processes and mechanisms to enable government and private sector security partners to work together to implement CI/KR protection initiatives.

The Department of Homeland Security (DHS), the Sector-Specific Agencies (SSAs), and their security partners share the responsibility for overarching implementation of the risk management framework. The SSAs are responsible for leading sector-specific risk-reduction programs and for ensuring that the sector-specific application of the risk management framework is addressed in their respective SSPs. The DHS supports these efforts by providing guidance, tools, and analytical support to SSAs and other security partners. The DHS is responsible for using the results obtained in sector-specific risk management efforts to conduct cross-sector risk analysis and management in collaboration with other security partners. This includes the assessment of dependencies, interdependencies, and cascading effects; identification of common vulnerabilities; development and sharing of common threat scenarios; development and sharing of cross-sector measures to reduce risk; and identification of specific research and development (R&D) needs.

The cornerstone of the NIPP is its risk management framework. Risk, in the context of the NIPP, is defined as the potential for loss, damage, or disruption to the Nation's CI/KR resulting from destruction, incapacitation, or exploitation during some future

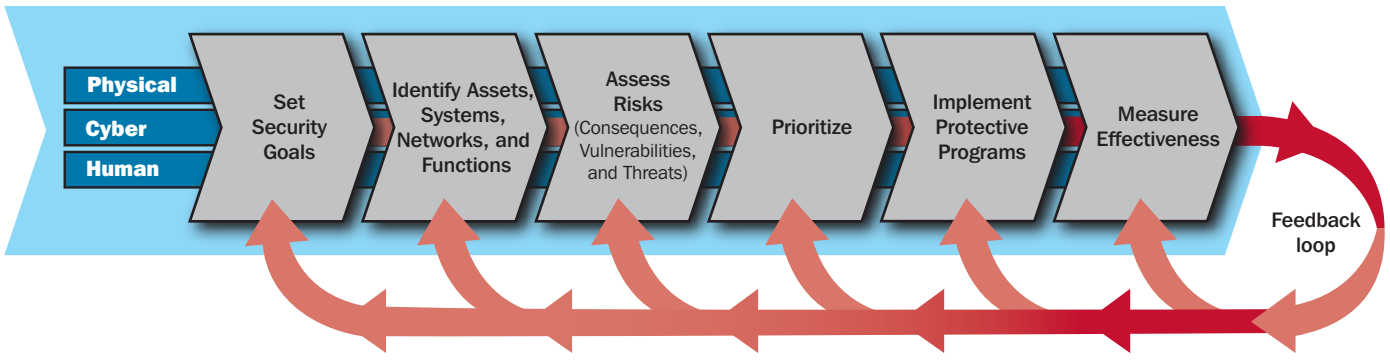
manmade or naturally occurring event. The NIPP risk management framework (see figure below) establishes the process for combining consequence, vulnerability, and threat information to produce a comprehensive, systematic, and rational assessment of national or sector-specific risk that drives CI/KR protection activities. The framework applies to the general threat environment, as well as to specific threats or incident situations.

The SSPs follow and support the NIPP risk management framework, which includes the following activities:

- **Set Security Goals:** Define specific outcomes, conditions, end points, or performance targets that collectively constitute an effective protective posture.
- **Identify Infrastructures:** Develop an inventory of the assets, systems, and networks, and the critical functionality they provide, including infrastructure located outside the United States, that make up the Nation's CI/KR, and collect information pertinent to risk management.
- **Assess Risks:** Determine risk by combining potential direct and indirect consequences of a terrorist attack or other hazards (including dependencies and interdependencies associated with each identified asset, system, or network), known vulnerabilities to various potential attack vectors, and general or specific threat information.
- **Prioritize:** Aggregate and analyze assessment results to determine assets, system, and network criticality, and present a comprehensive picture of national CI/KR risk in order to establish protection priorities and provide the basis for protection planning and the informed allocation of resources.
- **Implement Protective Programs:** Select appropriate protective actions or programs to reduce the risk identified and secure the resources needed to address priorities.
- **Measure Effectiveness:** Use metrics and other evaluation procedures at the national and sector levels to measure progress and assess the effectiveness of the national CI/KR protection program.

The DHS uses information from metrics and other evaluation tools to support a constant feedback loop. As shown in the figure below, these activities are implemented based on a dynamic threat environment. The resulting output is sector-specific strategies to protect assets. The ultimate objective of this SSP is to have Federal, State, local, and tribal governments and the private sector work with the SSA and the DHS to implement the plan in a way that is consistent, sustainable, effective, and measurable.

Figure I-1: NIPP Risk Management Framework



This document presents the FDA SSP for the Agriculture and Food Sector and provides a detailed description of the specific processes that will be used to identify, assess, prioritize, protect CI/KR and measure the effectiveness of implementation plans. The plan was developed with contributions from Federal, State, local, tribal, and private sector security partners, and in coordination with the U.S. Department of Agriculture (USDA), the other SSA for the Agriculture and Food Sector.

1. Sector Profile and Goals

The Food and Drug Administration (FDA) regulates 80 percent of all food consumed in the United States-the entire domestic and imported food supply except meat, poultry, and frozen, dried, and liquid eggs, which are under the authority of the Food Safety and Inspection Service (FSIS) of the USDA and the Environmental Protection Agency (EPA), which establishes tolerances for pesticide residues in foods and ensures the safety of drinking water (EPA has jurisdiction for municipal water and FDA has jurisdiction for bottled water). FDA shares its food safety responsibility and mission with its sister agencies from USDA, including FSIS, the Agricultural Marketing Service (AMS), the Food and Nutrition Service (FNS), and the Animal and Plant Health Inspection Service (APHIS) to regulate the entire food industry.

While FDA's mission is to protect and promote public health, that responsibility is shared with others; Federal, State, and local agencies; regulated industry; academia; health providers; and consumers all have a role to play.

1.1 Sector Profile

1.1.1 FDA Activities

FDA regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and $59 billion worth of cosmetics sold across State lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale, with numerous food establishments (including food manufacturers, processors, and warehouses) and cosmetic firms. In addition, roughly 600,000 restaurants and institutional food service establishments and an estimated 235,000 supermarkets, grocery stores, and other food outlets are regulated by State and local authorities that receive guidance, model codes, and other technical assistance from FDA. FDA enhances its programs by supporting State and local authorities with training and guidance to ensure uniform coverage of food establishments and retailers.

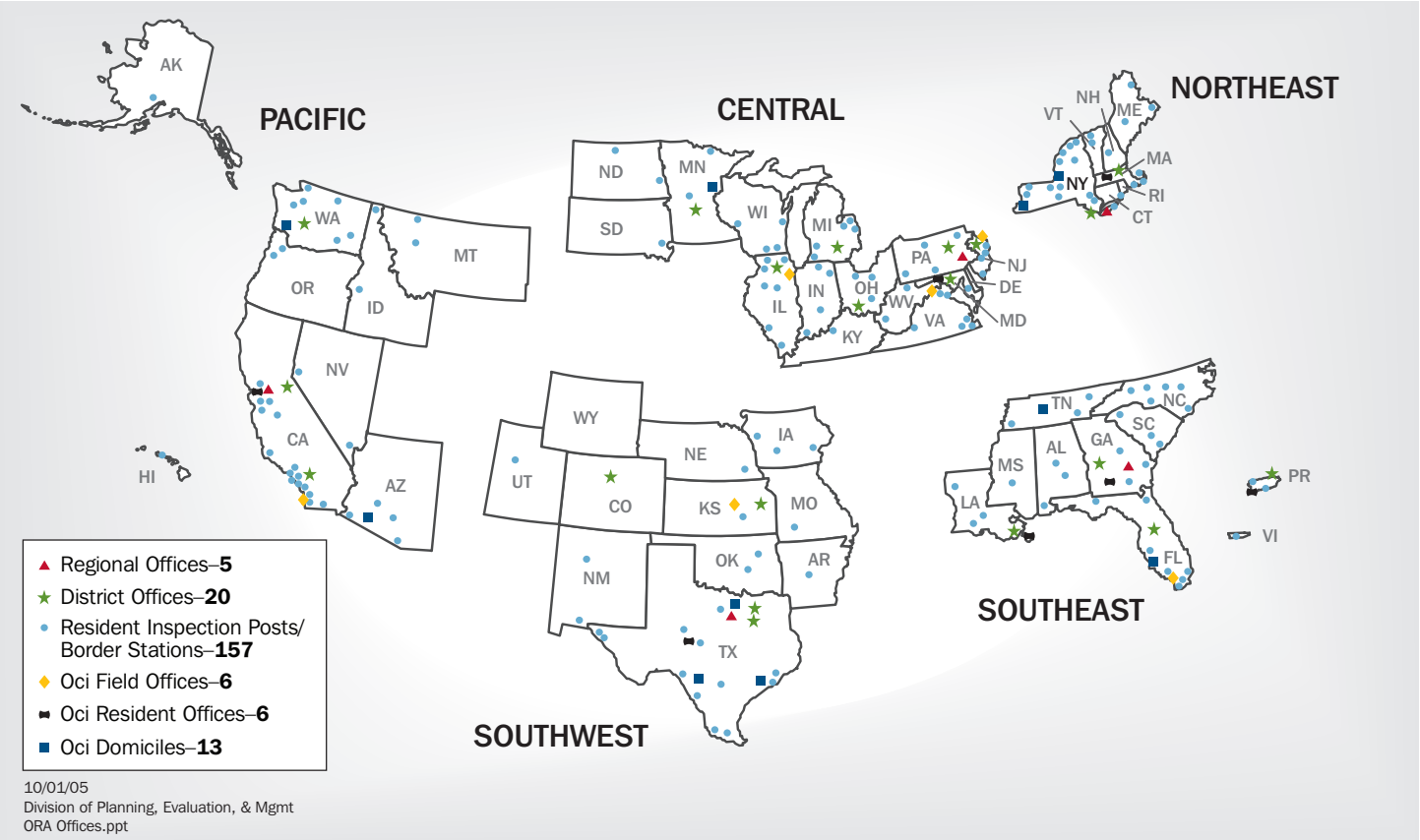
The Office of Regulatory Affairs (ORA) is the lead office for all FDA field activities. Each of FDA's five major program areas (human drugs, devices, biologics, food and cosmetics, and animal drugs and feeds) has a complementary field component responsible for supporting the centers that ensure compliance with FDA regulations. ORA accomplishes this by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, maintaining import data entry systems, and advising key officials on regulations and compliance-oriented matters that impact policy development and execution, and long-range program goals.

Table 1-1: FDA Program Activity: Fiscal Year (FY) 2005 Parameters

	Foods	Cosmetics	Drugs	Biologics	Animal Drugs and Feeds	Devices
Inspections	19,744	138	2,594	2,077	9,036	9,283
Field Exams	88,525	1,983	4,288	143	4,298	7,845
Samples	40,939	241	2,491	_	2,594	1,533
Import Line Entry Decisions	8.672 M	1.146 M	0.265 M	0.0399 M	0.212 M	4.484 M

In FY 2007, staffing is comprised of approximately 3,300 people in the field and 170 people in the Office of Shared Services, more than 85 percent of whom work in 5 Regional Offices, 20 District Offices, 13 laboratories, and 150 Resident Posts and Border Stations. This includes the Office of Criminal Investigation (OCI), whose staff is located throughout the field organization in Field Offices, Resident Offices, and Domiciles, which are located in 25 cities throughout the United States. FDA maintains offices and staff in all States except Wyoming. The FDA also maintains staff in the District of Columbia, the U.S. Virgin Islands, and Puerto Rico.

Figure 1-1: Office of Regulatory Affairs - 207 Offices in FY 2006



FDA also regulates animal feed through its Center for Veterinary Medicine (CVM). A safe animal feed supply helps to ensure the health of animals and people. To that end, CVM monitors and establishes standards for feed contaminants, approves safe feed additives, and manages the FDA's medicated feed and pet food programs.

Cyber information technology (IT) systems within FDA fall under one of three investment categories: post-market, pre-market, or general support. These systems facilitate release of information to industry and the public, act as conduits for industry to submit compliance data, or are used to process data internal to the agency.

1.1.2 U.S. Food Industry

The economic importance of the American food industry is enormous. It contributes about 20 percent of the U.S. gross national product, employs about 14 million individuals, and provides an additional 4 million jobs in related industries.

Although the U.S. food supply is among the world's safest, the increase in variety of foods, the exponential increase in food imported into the United States, the global nature of food commodities, and the convenience items available has brought with it public health concerns. The complexity of the food industry, and of the technologies used in food production and packaging, is increasing. Because a growing proportion of the American food supply is imported, FDA also works with international organizations (e.g., the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and the Codex Alimentarius Commission (Codex)) and occasionally works directly with foreign governments to ensure their understanding of U.S. requirements and to harmonize international food standards. The following table provides the number of foreign and domestic food establishments by type in the Registrations database.

Table 1-2: Total Registrations by Establishment Type*

Type	Domestic	Foreign
Warehouses / Holding Facilities	77,165	66,988
Acidified / Low-Acid Food Producer	2,189	7,091
Interstate Conveyance Caterer / Catering Point	1,202	2,852
Molluscan Shellfish Establishment	1,611	3,321
Commissary	1,383	3,340
Contract Sterilizer	281	2,661
Labeler / Re-labeler	11,025	34,840
Manufacturer / Processor	27,989	87,736
Re-Packer / Packer	19,567	55,378
Salvage Operator (Re-conditioner)	512	2,115
Animal Food Manufacturer / Processor / Holder	10,330	7,272
Total	153,254	273,594

* Data are current as of November 20, 2006.

1.1.3 U.S. Animal Feed Industry

The U.S. animal feed industry is large, diverse, and dynamic, and manufactures approximately 160 million tons of feed per year. Manufactured poultry feeds make up about one-third of the total, followed by manufactured feeds for swine, dairy, beef, sheep, catfish, horses, and pets. Many on farm operations supply their own grain to the smaller mills. Therefore, the actual tonnage processed may be greater than reported. An estimated additional 2,500 plants mill grain while many other plants provide other ingredients, such as enzymes, vitamins, fermentation products, and minerals. Livestock producers may also mix a quantity of feed on their own premises. The U.S. feed industry manufactures feed based on the least cost formulations concept, which means that feedmill nutritionists purchase feedstuffs, other nutritional ingredients, and additives based on nutritional value and cost. This results in a reliance on a wide range of feed components.

For the purpose of this document, animal feed refers to mixed feed and individual ingredients intended for all animals. Animal feed is viewed as a nutrition delivery system primarily and as a medication delivery system secondarily, when drugs are added to the feed. Ingredients used in animal feed are from diverse sources. Many are byproducts of human food processing; examples of these byproducts include such items as soybean oil meal, various wheat products left after wheat grain is processed for flour and other purposes, and rendered animal proteins and fats. Other ingredients are grown, produced, or manufactured strictly for animal feed, such as field corn and certain enzymes.

A feed ingredient is a component part or constituent or any combination/mixture added to and comprising the feed. Feed ingredients might include grains, milling byproducts, added vitamins, minerals (e.g., mined products such as phosphates), fats/oils, proteins, and other nutritional and energy sources. Animal feeds provide a practical outlet for plant and animal byproducts not suitable for human consumption. The *Official Publication of the Association of American Feed Control Officials* (AAFCO) contains a list of feed ingredients with their definitions. Many of these ingredients are not approved food additives and may not meet the criteria needed to be recognized as "generally recognized as safe" (GRAS) for human consumption (21 Code of Federal Regulations (CFR) 570.30). Nevertheless, FDA has not objected to the listing of certain ingredients (e.g., those used as sources of nutrients, aroma, or taste) in the AAFCO *Official Publication* or their marketing in interstate commerce, provided there are no apparent safety concerns about the use or composition of the ingredient.

The FDA regulates pet foods similarly to other animal feeds. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that pet foods, like human foods, be pure and wholesome, safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. In addition, canned pet foods must be processed in conformance with FDA's low-acid canned food regulations (21 CFR 113) to ensure that the pet food is free of viable microorganisms.

1.2 Security Partners

1.2.1 Federal Partners

FDA has interagency agreements with many other Federal and State agencies to delineate respective responsibilities pertaining to food and feed safety. These agreements provide the basic foundation for mapping the relationships and delineating responsibilities between and among these Federal partners.

FDA maintains close communications with other Federal agencies, including USDA, the Department of Commerce's National Marine Fisheries Service (NMFS), the Centers for Disease Control and Prevention (CDC), DHS Customs and Border Protection (CBP), the Federal Trade Commission (FTC), the Department of Transportation (DOT), the Consumer Product Safety Commission (CPSC), and the Department of Justice (DOJ). The FDA also receives information from other governmental security agencies and guidance from the Office of Management and Budget (OMB). Incidents related to cyber security and/or terrorism are reported through the FDA's Information Systems Security Officer (ISSO).

FDA primarily regulates food products sold in interstate commerce, whereas products made and sold entirely within a State are regulated by that State. In addition, formal agreements with the States for conducting inspections enhance the FDA's ability to meet its public health mission. FDA personnel work with State agriculture and health departments to resolve food safety concerns and economic fraud cases. In addition, formal agreements with the States for conducting inspections enhance the FDA's ability to meet its public health mission.

Other government and allied organizations that FDA works with include:

- Association of American Feed Control Officials (AAFCO);
- Association of Food and Drug Officials (AFDO);
- Association of Public Health Laboratories (APHL);
- Association of State and Territorial Health Officials (ASTHO);
- American Veterinary Medical Association (AVMA);
- Council of State and Territorial Epidemiologists (CSTE);
- National Association of County and City Health Officials (NACCHO);
- National Association of Local Boards of Health (NALBOH);
- National Association of State Departments of Agriculture (NASDA);
- National Environmental Health Association (NEHA);
- Office of Science and Technology Policy (OSTP);
- U.S. Animal Health Association (USAHA); and
- U.S. Trade Representative (USTR).

1.2.2 National Food Safety Laboratory System

Reliable laboratory analyses of foods and food contaminants are fundamental to science-based food safety regulation and enforcement. FDA has co-chaired, with FSIS, the development of the Food Emergency Response Network (FERN) to integrate the Nation's laboratory infrastructure for the detection of threat agents in food at the Federal, State, and local levels. In September 2003, the FERN Steering Committee (Federal and State representation) was established. The FERN Steering Committee serves as an advisory and policy-recommending body for FERN. The FERN Steering Committee is comprised of representatives from FDA, USDA, CDC's Laboratory Response Network (LRN), National Animal Health Network, State Public Health Laboratory, State Agriculture Laboratory, Department of Defense (DOD), EPA, and the DHS. Participation is open to Federal, State, and local government laboratories that are capable of conducting food testing and forensic analysis for a wide variety of chemical, biological, or radiological agents. FERN will provide critical laboratory surge capacity in the event of national emergencies, including terrorist threats that may affect the food supply. FDA is also part of the Electronic Laboratory Exchange Network (eLEXNET), which is described under Identifying Sector Assets.

1.2.3 Food and Agriculture Sector State Partners

The Division of Federal-State Relations (DFSR) is one of four work units within the Office of Regional Operations that is part of ORA. The division participates in cooperative and educational efforts designed to inform industry, health professionals, and the public about FDA's functions and its commitment to safeguard the public health. DFSR interacts with and serves as the focal point for State and local food and drug officials, and associations of these State officials to promote cohesive and uniform poli-

cies and activities in food- and drug-related matters. FDA has numerous interactions with State partners through cooperative programs such as the National Conference on Interstate Milk Shipments, the Conference for Food Protection, and many other programs. For example, DFSR manages various contract programs with the States. These contract programs benefit States with technical training, familiarity with Federal requirements, and more uniform enforcement of consumer laws through cooperation and coordination with FDA. The contract programs allow FDA to enlarge coverage of the Official Establishment Inventory (OEI) and also to redirect resources to other priorities. These contract programs include: Food (under this program, inspections are performed in selected food manufacturers/processors to determine compliance with the FFDCA, State law, or both) and Feed (under this program, inspections of feed establishments are performed to determine compliance with the FFDCA and State feed laws (if the contractor's feed law has the provisions of the current AAFCO Uniform State Feed Bill)). Inspections will include ensuring compliance with 21CFR 589.2000, Substance Prohibited From Use in Animal Food or Feed and Animal Proteins Prohibited in Ruminant Feed, commonly known as the Bovine Spongiform Encephalopathy (BSE) Rule.

State food regulatory officials are organized primarily through AFDO. FDA, in conjunction with NASDA, ASTHO, USDA, and CDC, sponsored a 1-day executive-level meeting with the secretaries of State departments of agriculture and the State departments of health, entitled "Homeland Security-Protecting Agriculture, the Food Supply, and Public Health: The Role of the States", to discuss the important roles and responsibilities the States play in ensuring food security and safety.

FDA is also actively promoting the commissioning by FDA of State secretaries of agriculture and health so they can receive and review food safety and security documents from FDA. This helps promote information sharing between the States and FDA.

Animal feed regulatory officials from the States and other municipalities are organized through the American Association of Control Officials and its various subsidiary bodies, including the AAFCO. Every year, FDA participates in multiple meetings with State regulatory and industry representatives through these organizations. AAFCO is comprised of Federal, State, and international regulatory officials who are responsible for the enforcement of State laws regulating the safe production and labeling of animal feed, including pet food. FDA and AAFCO work together in the area of feed regulation, particularly in the establishment of definitions to describe new feed ingredients. Each year, AAFCO publishes the *Official Publication of the Association of American Feed Control Officials*, which includes a model feed bill for States to adopt in regulating feed products and a list of accepted feed ingredients. Most States have adopted all or part of the model feed bill and allow feed ingredients listed in the publication to be used in their respective territories.

FDA contracts with the States to perform feed mill inspections under FDA guidance (e.g., BSE, medicated feeds). Under these contracts, AAFCO members run various inspectional programs, sample and testing feed and feed materials for drugs and contaminants and act in conjunction with FDA as first-line investigators in the detection and investigation of feed contamination incidents. AAFCO has addressed feed safety issues for more than 37 years. Currently, AAFCO's Feed Safety Committee is helping to draft FDA's Good Manufacturing Practices Regulations, which will be designed to help feed manufacturers prevent incidents that might cause animal and human harm.

Two major feed industry organizations, American Feed Industry Association (AFIA) and the National Grain and Feed Association (NGFA), play a major role in communicating and developing voluntary programs with the feed industry. Additionally, there are other organizations, such as the American Farm Bureau and species-oriented producer groups that offer other avenues of communication with the on-farm feed mixers. FDA's Animal Feed Safety initiative is intended to promote communication with all of these involved groups.

1.2.4 Industry Partners

FDA ensures that food safety standards, which the FDA develops and enforces, are consistent with current science and the law, and are in the best interest of the health of the public. FDA managers seek to gain industry input into the agency's standard-setting activities by holding public meetings to learn firsthand industry's views on state-of-the-art science.

FDA has issued four food security guidance documents addressing certain segments of the U.S. food industry: producers, processors, and transporters; importers/filers; retail food stores and food service establishments; and dairy farms, bulk milk transporters, bulk milk transfer stations and fluid milk processors. In the event of a food defense-related emergency, FDA will provide fast, accurate, and useful information to the affected industry members and stakeholders. FDA maintains an emergency contact list for industry trade groups and a database to quickly notify field personnel regarding threats to the food supply. The Center for Food Safety and Applied Nutrition (CFSAN) Web site has a Food Defense and Terrorism page (www.cfsan.fda.gov/~dms/defterr.html) that links to a wide range of FDA's homeland security information, including progress on the bioterrorism regulations, consumer information on tampering, and food security guidance to industry. The Web page makes guidance materials and background information more widely available and easily accessible for consumers, industry, and government employees.

The DHS Information Bulletin, entitled *Measures for Reducing the Vulnerability of the Food Supply to Chemical/Biological Agents*, developed in collaboration with FDA and USDA and issued on March 18, 2004, is another tool to alert industry about food security threats or incidents.

1.3 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 homeland security 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 system against "terrorist attacks, major disasters, and other emergencies." HSPD-7 focuses on issues concerning protection of all national CI/KR, the majority of which are owned and operated by the private sector. HSPD-5 ensures that all levels of government responding to an incident of national significance have the capability to work efficiently and effectively together using a common national domestic incident management approach, and HSPD-8 provides guidance on how to prepare for such a response, including prevention activities.

Homeland security is not the responsibility of one department or agency within government-it is a partnership effort. Significant progress in the Food and Agriculture Sector, one of the identified critical infrastructures, on homeland security goals can only be accomplished through a partnership effort between all levels of government and those who own the critical infrastructure. 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 among themselves 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 component 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 government and between the government and the sector to support the Nation's homeland security mission.

The mission of the Food and Agriculture Sector is to prevent an attack on the food supply, including agricultural production, that would pose a serious threat to public health, safety, or welfare, or to 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 their own asset protection plans, vulnerability/risk reduction plans, and continuity-of-operations plans (COOP). The sector will provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management.

To accomplish this mission, the GCC and SCC established long-term sector security goals. When accomplished, the Food and Agriculture Sector will have achieved its desired security posture.

1.3.1 Elements and Characteristics of Sector Security Goals

Long-Term Security Goals:

1. **Work with State and local entities to ensure that they are prepared to respond to incidents:** The 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 agriculture or food infrastructure.

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 terrorist 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.

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 stakeholders, law enforcement, and the intelligence communities. Government-developed threat information will be expeditiously shared with the food and agriculture industry to facilitate threat-appropriate security measures.

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.

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 Food and Agriculture Sector.

6. **Expand laboratory systems and qualified personnel:** The ability to effectively diagnose and treat animal disease outbreaks and crop contamination will be strengthened to prevent, respond, 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.

The sector acknowledges that these goals will require time to accomplish. As a first step towards achieving the sector security posture they describe, the GCC and SCC jointly established the following goals for calendar year 2006. The sector sees these goals as the foundation for enhanced security.

Calendar Year 2006 Goals:

1. **Enhance and improve two-way communications:** Communication is the cornerstone to build on. The SCC and GCC members acknowledge a need for improved two-way communications. To facilitate this, there is a need to establish a structure to compile, share, and receive information that supports, utilizes and leverages SCC subcouncils. The sector has selected the Homeland Security Information Network (HSIN) as the structure it will use. The current HSIN has the capabilities to function well; however, it lacks the personnel resources necessary to make it a proactive mechanism that sector stakeholders will regularly use to share information. The sector has identified the following as key components of a proactive HSIN site for food and agriculture:

   – Identify and incorporate Information Sharing and Analysis Center (ISAC) functions, including the timely distribution of alerts, news, and other relevant information; and

   – Create a forum to capture, analyze, and share lessons learned and best practices/successes.

2. **Improve preparedness:** Since the sector is extremely large, not all aspects can be equally protected. Preparedness requires that the sector understand what is at risk or vulnerable and is able to prepare those assets to withstand a possible attack. The sector supports the continuation of the Strategic Partnership Program Agroterrorism (SPPA) initiative, which is a partnership among Federal, State, local, tribal, and industry partners to conduct vulnerability assessments nationwide from farm to table. Preparedness also requires conducting exercises. The sector called for two tabletop exercises of SPPA-evaluated commodities to be held within the year. Preparedness must also continue at the individual level, thus, the SCC is promoting continuity-of-business-operations plans.

3. **Conduct research to define Food and Agriculture critical assets:** Establishing a better understanding of the critical systems within the Food and Agriculture Sector will enhance the council's ability to coordinate preparedness activities occurring at all levels of government and industry. In particular, this project will identify systems, assets, and interdependencies in the Food and Agriculture Sector. It will also provide a mechanism to prioritize identified systems, assets, and interdependencies. The findings will be used to develop SSPs for protecting food and agriculture critical infrastructure.

4. **Implement OK 4-72 Program:** Citizens often have a 72-hour period of self-reliance before Federal and State resources are fully activated following a major disaster. The OK 4-72 Program, an SCC-led project, will work to educate the citizenry of some steps they can take to be better prepared to take care of themselves for 72 hours in the wake of a major incident.

5. **Review Pandemic/Avian Flu Preparedness Plan:** The SCC has acknowledged that avian flu has the potential to impact the sector in multiple ways. First, because avian flu could dramatically affect the poultry industry, it is imperative for the sector to consider how an outbreak in the United States would impact the poultry industry and what response an outbreak would necessitate. Second, if a flu pandemic impacted the general population within the United States, production capacity could be severely limited due to an unavailable workforce. Therefore, the SCC has initiated an industry examination of existing plans and planning recommendations.

6. **Establish key contacts for industry during emergency response:** Due to the breadth and depth of the sector, the SCC has requested the establishment of protocols for obtaining and using points of contact information for Federal and State government agencies. The SCC will use this information to: (a) prepare for an incident that affects its industries; (b) offer assistance for response to an incident; and (c) alert government of an incident occurring at a sector industry.

7. **Conduct sector review of Stafford Act and National Response Plan:** The 2005 hurricane season raised questions within the SCC concerning gaps within the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act) and the National Response Plan related to the Food and Agriculture Sector. The Stafford Act and the National Response Plan are the basis for response and recovery operations in response to an incident. The SCC has initiated a review of these documents. Ensuring that these documents properly recognize and account for the needs of the Food and Agriculture Sector will limit situations where the needs of a sector owner, operator, or industry are not addressed.

8. **Promote participation of industry in State Emergency Operations Centers (EOC):** State GCC members recommended that industry representatives be included in State EOC activities during incident response. Their inclusion will increase the public-private coordination and enable the private sector to more swiftly respond to incidents and to needs of their local communities.

1.4 Value Proposition

The Food and Agriculture Sector's main mechanisms for engaging and coordinating security partners are the GCC and the SCC.

1.4.1 Authority for the GCC and SCC

HSPD-7 establishes national policy for Federal departments and agencies to identify and prioritize the U.S. CI/KR and to guard against efforts to undermine or exploit those sector assets. HSPD-7 directs Federal departments and agencies to identify, prioritize, and coordinate the protection of CI/KR in partnership with State, local, and tribal governments, and the private sector. The goal of establishing such a partnership is to leverage complementary resources within government and between government and industry to ensure a more robust, resilient, and secure sector. In accordance with guidance provided by the Secretary of Homeland Security, under HSPD-7, the SSAs (USDA and FDA) will collaborate with all relevant partners to prevent, deter, and mitigate deliberate efforts to destroy, incapacitate, or exploit the sector.

1.4.2 GCC Objective

The objective of the GCC is to provide effective coordination of Food and Agriculture Sector defense strategies and activities, policy, and communication across government and between the government and the sector to support the Nation's homeland security mission. In addition, the council plays a coordination role with the public health and clinical issues that would result from a terrorist act involving the food supply. It acts as the counterpart and partner to the private industry-led SCC to plan, implement, and execute sufficient and necessary sector-wide security programs for the Nation's food and agriculture critical infrastructure. The GCC will accomplish this objective through the following essential activities:

1. **Identify items that need public-private coordination and communication of issues.** The GCC shall bring together diverse Federal, State, local, and tribal interests to identify and develop collaborative strategies that advance critical infrastructure protection (CIP). While the focus is on CIP, the GCC will also function during events of national emergency or significance to coordinate and share information to augment existing emergency operation channels within Federal, State, local, and tribal governments and with industry.
2. **Identify needs/gaps in plans, programs, policies, procedures, and strategies.**
3. **Acknowledge and recognize successful programs and practices.** The GCC will facilitate the sharing of experiences, ideas, best practices, and innovative approaches related to CIP. The GCC will acknowledge and recognize accomplishments that further the objective.
4. **Leverage complementary resources within government and between government and industry.** The SCC is established to represent and communicate the interests of their subcouncils to the GCC and the government in sector matters. Its objectives also include: keeping subcouncil members apprised of key sector, inter-sector, and sector-government activities; and bringing to bear their best judgment on SCC decisions based on their understanding and experience within their subcouncil business area.

1.4.3 Joint GCC-SCC Objectives

The GCC and SCC meet quarterly at Joint Industry-Government Coordination Council meetings that provide a public/private forum for effective coordination of agriculture and food security strategies and activities, policy, and communication across the entire sector to support the Nation's homeland security mission. It provides a venue to mutually plan, implement, and execute sector-wide security programs, procedures, and processes; exchange information; and assess accomplishments and progress for defending the Nation's food and agriculture critical infrastructure. It is a central forum for introducing new initiatives for mutual engagement, evaluation and implementation, resolution of issues, and mutual education.

Specific joint initiatives include identifying and prioritizing items that need public-private input, coordination, implementation, and communication; coordination and communication of issues to all members; and identification of needs/gaps in research, best practices/standards, and communications. The councils' joint meetings also acknowledge and recognize successful pro-

grams and practices, and focus on assessing progress and accomplishments and on leveraging complementary resources within government and between government and industry.

1.4.4 Sector Councils' Membership

Membership requirements for the GCC and SCC are described in their respective charters. While the requirements are static, unless amended, the actual membership may fluctuate based on interest and participation.

GCC Membership

The council's membership is comprised of key representatives and influential leaders on food and agriculture safety, security, and defense issues from Federal, State, local, and tribal governments. GCC official members are director-level, or equivalent, representatives (and an alternate) from:

- Department of Homeland Security;
- Department of Agriculture;
- Department of Health and Human Services Food and Drug Administration;
- Department of Defense;
- Environmental Protection Agency;
- Association of State and Territorial Health Officials;
- National Association of State Departments of Agriculture;
- National Association of County and City Health Officials;
- National Assembly of State Chief Livestock Health Officials; and
- Intertribal Agriculture Council.

The GCC reserves the right to invite ad hoc or ex officio membership to meet expertise requirements necessary to fulfill its mission. Current ex officio members include AFDO and DOJ.

SCC Membership

The SCC includes agriculture and food industry representatives from farm to table, including both individual owners or operators and trade associations. Due to the great diversity in interests represented on the SCC, seven subcouncils that can address issues relevant to the membership were established. These subcouncils are:

- Producers/Plant Subcouncil (45 members);
- Producers/Animals Subcouncil (53 members);
- Processors/Manufacturers Subcouncil (49 members);
- Restaurants/Food Service Subcouncil (11 members);
- Retail Subcouncil (3 members);
- Warehousing/Logistics Subcouncil (2 members); and
- Agricultural Production Inputs and Services Subcouncil (18 members).

Both the GCC and SCC recognize that each member represents a government entity or organization with inherent legal authorities and parameters within which they must operate. At times, these authorities may restrict a member's ability to provide agreement on a decision. These inherent legal authorities must be clearly articulated and understood by the council as the basis for dissent and the inability to enter into consensus.

1.4.5 Roles and Responsibilities

In order to function efficiently, the GCC and SCC have each selected leadership bodies to coordinate and collaborate on important issues. The leadership bodies report back to the full membership. In addition, the leadership ensures that the councils fulfill their roles and responsibilities as defined in their charters.

GCC Functions

Leadership of the activities and meetings rests with the three main Federal agencies (USDA, FDA, and the DHS) and a State representative. Day-to-day leadership of meetings and activities rotates among the three Federal agencies via the GCC chairmanship. The lead collects from other members and initiates or brings issues to the GCC for consideration and deliberation. The chairperson, working with other council members, monitors and ensures that initiatives or issues are brought to closure.

There are 13 decision-making members of the GCC. There is one member for five Federal agencies, two members each from State organizations, one member from the State veterinarians, and one tribal representative.

An alternate is assigned to represent the council member during his/her absence. The alternate will have decision-making authority as designated by the member as the member deems appropriate for the issues to be presented at a meeting. Each member has the flexibility to have other representation at meetings other than the official alternates, but must clearly designate the representative's decision-making authority prior to the meeting.

The GCC Secretariat, provided by the DHS, provides meeting and organizational support, including coordination for agenda development, support for agency lead on monitoring and closure of issues and initiatives, administrative support, and logistics (travel, meeting room facility).

GCC ex-officio members are defined as non-voting participants whose criteria and qualifications for participating will be based on the ongoing needs for expertise and decisions by the GCC leadership. The purpose of their membership is for the GCC to gain relevant organizational and institutional representation and expertise. Ex-officio members may attend all meetings and conference calls. Ex-officio membership will be withdrawn, by the determination of the council, if the need for ongoing expertise is no longer required.

Subject matter experts are non-voting participants drawn from any organization from which the council needs expertise on an ad hoc basis.

Work groups are established when substantial investigation, research, or other tasks are required that cannot be achieved at a regular GCC session. All products of the work group are meant to advise council members on various issues, directions, and processes.

SCC Functions

During the organizing process, sector members stressed the importance and essential nature of building coordination from clearly identified subsector areas known as subcouncils.

Each Food and Agriculture Sector subcouncil will develop definitions regarding the focus and boundaries of its subsector areas so that members of the sector can clearly identify which subcouncil(s) may involve their business and security interests.

Each subcouncil will define its membership, priority issues, and areas of work and activity. Each subcouncil will need flexibility in prioritizing and identifying its needs, but should examine the general areas of communications and information sharing; research and development, including prevention and detection; incident management; vulnerability assessments; and recovery.

Within the SCC, outreach, participation, and membership at the subcouncil level are intended to be as inclusive as possible of relevant owners and operators and their associations.

Subcouncils will articulate their priorities and action items to the SCC so that they can then be communicated to government, other sectors, and other appropriate entities.

Each subcouncil will determine its own procedures for naming representatives to the SCC (two from each with one alternate), as well as replacing a member or alternate. In addition, each subcouncil will take responsibility for naming an ad hoc SCC representative for any one meeting when none of its named individuals (i.e., the two members and one alternate) can attend.

Each subcouncil should establish its own decisionmaking and operational procedures given the nature of the standard business practices and relationships in that part of the food and agriculture subsector.

Each subcouncil might consider the use of subject matter experts, subcouncil member work groups, and/or advisory work groups to assist in their activities.

Each subcouncil should establish a procedure for soliciting subcouncil members' views on policies, programs, and activities, especially when conveying input to government on proposed or existing policies, plans, procedures, and activities.

Each subcouncil should establish and maintain subcouncil membership lists and contact information, as well as establish communication procedures for sensitive and non-sensitive information. These should be conveyed to the SCC Leadership and updated on a regular basis.

GCC and SCC Principles of Participation

Both the GCC and SCC have adopted the following as their principles of participation:

- All members must be working toward the same goal and purpose of improving the security of the Nation's food and agriculture system;
- All members need to participate;
- Discussions and deliberations must recognize and take advantage of each member/organization's strengths, skills, and perspective;
- Results of discussions and deliberations must be a coherent voice made up of each member's contributions; and
- Each discussion will be honest and forthright.

1.4.6 Number and Frequency of Meetings

The GCC meets quarterly in the Washington, DC, area, with additional meetings and/or conference calls as needed. The SCC meets quarterly and individual subcouncils meet on an ad hoc basis. The GCC and SCC leadership hold monthly conference calls and their full memberships meet in joint session quarterly. Additional meetings may be held on an ad hoc basis.

Decisions will be made at the joint GCC-SCC meetings through a consultative process, encouraging the exchange of information and points of view. Decisions will be made on a consensus basis, meaning that all voting GCC members and each of the seven SCC subcouncils can accept the decision. If one or more of the voting GCC members or subcouncils cannot accept the decision proposed, they are obliged to clarify the reasons underlying their disagreement and to propose an alternative solution that can satisfy their interests, as well as those of the other voting members. Members will strive to understand and to close

any gaps creating disagreements. When there is dissension, the councils will make every effort to find solutions that all members can accept and that enable members to fulfill their obligations. The councils will strive to meet timelines and deliverables.

The councils recognize that each member represents a government entity or organization with inherent legal authorities and program parameters within which they must operate. At times, these legal obligations or authorities may cause a member to abstain from a decision or restrict a member's ability to provide agreement on a decision. These inherent barriers must be clearly articulated by the member and understood by the councils when this presents a challenge to reaching a consensus decision.

2. Identifying Assets, Systems, Networks, and Functions

2.1 Defining Information Parameters

2.1.1 Inspection Assets

The Office of Regulatory Affairs (ORA) is the primary office for the investigative assets of the FDA. ORA conducts pre-market inspections for new human and animal drugs, biological products, and medical devices. In addition, foreign and domestic inspections of establishments can include bio-research monitoring of clinical research, pre-approval inspections and laboratory method validations needed for pre-market application decisions, and inspections of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in the application.

To complement these pre-market activities, the largest portion of ORA's work involves conducting domestic and foreign post-market inspections of foods, human drugs, biologics, animal drugs and feed, and medical device manufacturers to assess their compliance with Good Manufacturing Practices (GMPs). ORA also monitors and samples imports to ensure the safety of imported foods and medical products.

In addition to overseeing regulated products on a surveillance or "for cause" basis when a problem is encountered, ORA staff also responds to emergencies and investigates incidents of product tampering and terrorist events or natural disasters that may impact FDA-regulated goods.

To complement the regular field force, the Office of Criminal Investigations (OCI) investigates instances of suspected criminal activity in FDA-regulated industries.

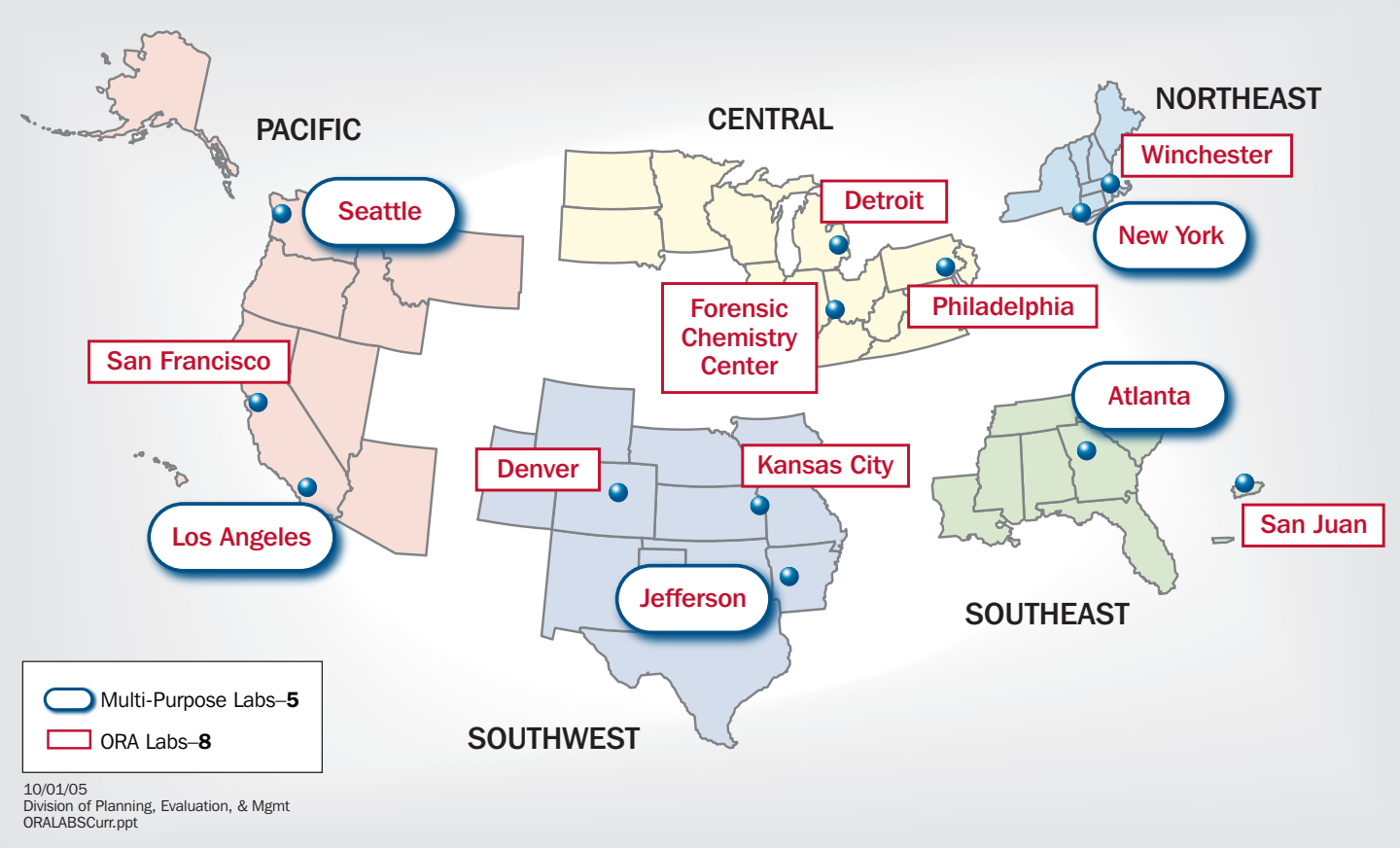
2.1.2 Laboratory Assets

In addition, ORA's laboratory capability consists of 13 laboratories (5 regional laboratories, 4 district laboratories, and 4 specialty laboratories). The regional and district laboratories are general servicing laboratories that conduct a wide variety of analytical work. Specialty laboratories are located in Philadelphia, Pennsylvania, and San Juan, Puerto Rico, for pharmaceutical analyses; the Winchester Engineering and Analytical Center in Winchester, Massachusetts, for medical device and radionuclides; and the Forensic Chemistry Center in Cincinnati, Ohio, for criminal analytical support. Specialized analyses within general servicing laboratories include seafood products research in Seattle, Washington; metal analysis in San Francisco, California; animal drug research and analysis in Denver, Colorado; nutritional analysis in Atlanta, Georgia; total diet program in Kansas City, Missouri; and dioxin analysis in Jefferson, Arkansas.

Analytical staff at FDA laboratories includes chemists, microbiologists, entomologists, biologists, engineers, physicists, and research scientists. Food analyses include chemistry analysis for pesticide residues, metals, mycotoxins, seafood toxins, nutrients, radionuclides, antibiotics, feed additives, and color additives. Food microbiological analyses include a wide variety of

bacterial pathogens, as well as can seam analysis, organoleptic analysis, and sanitation work. Pharmaceutical analyses involve testing for identity, potency, impurities, release rates, sterility, particulates, and endotoxins. Veterinary product testing is for medicated feeds and feed microscopy. Medical devices tested include condoms and gloves, x-ray devices, microwave ovens, and in vitro diagnostics to name a few. Counterterrorism analytical work includes both chemical and microbiological agents.

Figure 2-1: Office of Regulatory Affairs Field Laboratories



2.1.3 Process for Identifying Sector Assets

Identification of industry sector assets begins by reviewing FDA's databases; adding information compiled from agency collaboration with other Federal, State, and local food agencies; and using non-sensitive information in databases maintained by other Federal, State, and local authorities. The following list can be used as a starting point to determine the specific information needed in a model to determine critical national assets:

- **Field Accomplishments and Compliance Tracking System (FACTS):** Automated FDA system for tracking FDA operations such as domestic field and compliance activities, foreign inspections, and domestic and import sample analyses.
- **Operational and Administrative System for Import Support (OASIS):** Automated FDA system for processing and making admissibility determinations for shipments of FDA-regulated products of foreign origin seeking to enter domestic commerce.

- **Food Facility Registration Module (FFRM):** FDA system that requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption to register their facility under section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act (the Bioterrorism Act) of 2002.

  Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about these facilities. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In the future, such information may enable FDA to quickly notify the facilities that might be affected by the outbreak.

- **Prior Notice System Interface (PNSI) and the Automated Broker Interface of the Automated Commercial System (ABI/ACS):** Import shipment information is submitted to FDA that allows FDA to review information pertaining to FDA-regulated shipments of food for humans and animals before the food is imported into the United States (unless the food is excluded from the Prior Notice requirements of Section 307 of the Bioterrorism Act).

  Prior Notice information is required for FDA-regulated food for human and animal consumption that is imported or offered for import into the United States. This includes food that is imported for export, food trans-shipped through the United States to another country, and food for use in a Foreign Trade Zone. For food shipments arriving in the United States through international mail, notification of the import must be sent through the PNSI before the article is mailed.

  Prior Notice information is not required for the following products: food that is imported then exported from the port of arrival without leaving the port; meat, poultry, or egg products that are under the exclusive jurisdiction of USDA; food carried by or otherwise accompanying an individual when entering the United States for personal use; food contact substances (including food packaging), pesticide chemicals, or pesticide chemical residues.

  Prior Notice information must provide the identity of the food, the manufacturer, the shipper, the grower (if known), the FDA Country of Production, the country from which the food is shipped, and the anticipated port of arrival. In addition, the notification must provide the identity of the person who submits and transmits the Prior Notice; the importer; the owner; the consignee; the carrier; the CBP entry identifier; anticipated time and date of arrival; anticipated shipment information; and, if the food has been refused admission and is required to be held, the location where it is held.

  Prior Notice requires that the persons responsible for food imported or offered for import into the United States to notify FDA of their intent to import articles of food through an importer, customs broker, purchaser, or other agent. Submission of Prior Notice information must be electronic. Any change in Prior Notice information requires resubmission of corrected or new information. The minimum Prior Notice time is 2 hours for articles of food arriving in the United States by vehicle, 4 hours for articles of food arriving by train and by air, and 8 hours for articles of food arriving by vessel.

  FDA has been receiving approximately 169,000 Prior Notice submissions each week since February 2004. Approximately 88 percent (2.1 of 2.4 million) were submitted as additional information on transactions through CBP's Automated Commercial System (ACS) and approximately 11 percent came through PNSI. Less than 1 percent are transactions in a new form that CBP and FDA provided for submitting information through ACS on food shipments that do not require ACS submission at the time of arrival in the United States (e.g., Transportation and Exportation, Immediate Transportation, and Foreign Trade Zones).

- The **Electronic Laboratory Exchange Network (eLEXNET)** is a seamless, integrated, secure system that allows multiple government agencies engaged in food safety activities to compare, communicate, and coordinate laboratory analysis findings. eLEXNET provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends. eLEXNET is funded by the FDA.

  The original goal of eLEXNET was to demonstrate how an Internet-based system could be used by the eight participating labs in the *Escherichia coli* O157:H7 pilot to exchange data. In 2001, FDA provided funding to Federal, State, and local laboratories to expand the system to include data for *Salmonella, Listeria monocytogenes*, and *Campylobacter jejuni*.

Through technology, data standardization, a secure network, and a well-designed infrastructure, eLEXNET serves as the Nation's first integrated food safety system for laboratory food samples and test results data. Currently, the system is capable of accepting information on antibiotics, color additives, food additives, pesticides, mycotoxins, microbiology, naturally occurring toxins, radionuclides, toxic elements, and parasites in foods.

- The **Food Emergency Response Network (FERN)** 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. The FERN Steering Committee serves as an advisory and policy-recommending body for FERN. The FERN Steering Committee is comprised of representatives from FDA, USDA, CDC's Laboratory Response Network, the National Animal Health Network, State public health laboratories, State agriculture laboratories, DOD, EPA, and the DHS.
- The **Laboratory Report Network (LRN)** is a network of Federal, State, and local public health laboratories developed to provide surge capacity for samples in the event of a public health emergency caused by a select agent. FERN biological laboratory network members that perform select agent analysis will also have to become members of the LRN.

Applications for membership in FERN will be reviewed based on the following criteria:

- Laboratory facility (operational area, facility upgrade, laboratory security);
- Personnel qualifications;
- Laboratory management practices (laboratory personnel: security, quality management system, staffing management, workload management);
- Sample analysis capacity and commitment;
- Applicability to enhance food safety and security; and
- Overall technical merit.

The Center for Veterinary Medicine's (CVM's) primary method for identifying sector assets has been the FACTS database. CVM has also relied on associations, industry, State regulatory agencies, and academic institutions. The method used to identify sector assets has been broken into the following components:

- Raw materials (micro-ingredients, macro-ingredients):
  - Unprocessed (forage, etc.); and
  - Processed (grain, etc.);
- Renderers:
  - Slaughter house;
- Transportation (bulk feeds);
- Storage;
- Processing:
  - Batching, mixing, extruding, pelleting; and
  - Mobile mixers;
- Distribution (bulk and prepackaged); and
- Imports.

CVM also identifies assets through information exchange with industry associations such as the American Feed Industry Association (AFIA), State departments of agriculture, Federal regulatory agencies, and larger companies.

2.1.4 Defining Asset Data Parameters

The FDA can initially classify similar food assets in the databases by whether the asset is domestic (FDA jurisdiction or State) or foreign. Once this initial classification has been completed, then each asset in the database can be further classified by type of establishment (e.g., manufacturer/processor, packer, or holder of food for human or animal consumption). These categories can be further subdivided into groups based on the type of product produced or handled. Once the groups have been defined, specific bits of information (data fields) can be used for comparative and other analyses.

In the Prior Notice interim final rule, FDA required that certain food distributors and importers have access to sufficient cyber assets to transmit required notifications to the agency's OASIS system or CBP's notification system. This, coupled with the registration requirement, provides FDA with the ability to monitor, but not control, the cyber assets within the food distribution chain. FDA does recommend that all systems follow National Institute of Standards and Technology (NIST) guidance for securing their cyber assets at all times.

The following lists contain the information normally collected by FDA from the sources identified in section 2.1.3.

General information to be gathered for each asset (where applicable):

- Asset name, address, city, State, province, country of origin*;
- FDA jurisdiction*;
- Establishment type*;
- General product category associated with the identified establishment type (i.e., industry code)*;
- Identification of inspected product associated with the asset*;
- FDA Establishment Identifier number*;
- FDA District association*;
- Registration number;
- Owner/operator and address;
- Emergency contact information; and
- Importer/Broker/Consignee relationship.*

Other information for each asset (as available):

- Inspection findings*;
- Sampling findings*; and
- Prior Notice.*

* Information already captured by the FDA during the normal course of domestic and import activities and stored within various data tables of FACTS and OASIS. Other information will be available as part of the registration database.

2.2 Collecting Infrastructure Information

A shared application between the FACTS and OASIS systems contains a "firm/company" table and database that includes information for both domestic and foreign firms. Due to the implementation of the FFRM due to the Bioterrorism Act, coordination and synchronization of the information for certain data elements were transferred to the "firm/company" database. Registration information being collected in the FFRM is a one-time submission to the agency, with updates by the submitter of the information as necessary.

As of November 20, 2006, 426,848 facilities that manufacture/process, pack, or hold food for human or animal consumption have registered with FDA (153,254 domestic and 273,594 foreign facilities).

All data being captured within the FFRM are considered exempt from disclosure under the Freedom of Information Act. If information in the "firm/company" database is matched with information already in the FFRM database, the matching information would not fall under this exemption. However, the information derived solely from the registration, such as the registration number (transferred) and the owner/operator address and emergency contact information (not transferred) are all considered non-disclosable. No information derived from a facility registration is disclosable if the firm/company database does not have any previous asset information on the facility (approximately 113,000 registrants are new facilities in the sense that they are not in the firm/company database).

The facilities captured by the registration database represent only part of the entire food distribution system. The database does not contain data on retail establishments, such as restaurants and grocery stores, or the food transportation system. If the FDA databases captured all participants in food distribution, the number of facilities covered would be more than 2 million. Section 306 of the Bioterrorism Act gives the FDA access to the records of most of these facilities in the event of a threat of serious adverse health consequences or death. However, in a non-emergency situation, these records and other information on facilities not recorded elsewhere are not available to the agency during the normal course of business.

The analytical information entered into eLEXNET is voluntary for FDA, State, and local laboratories. The additional analytical information obtained from eLEXNET is not to be used in any publication without the consent of the participating laboratories. However, the information can be used for laboratory analysis by each participant as long as it is not disclosed. Sensitive data, such as the asset's name and address, are not available in eLEXNET. eLEXNET has an internal committee set up to ensure data quality. At this time, 107 laboratories are actively submitting data to eLEXNET.

With respect to animal feed, CVM is in close contact with other Federal regulatory agencies, State regulatory agencies, and the regulated industry. Specific sources used to gather asset data include academia, private consultants, and industry publications such as the Redbook and Feed Management. Other sources include professional meetings, workshops, personal communication, FDA and State field assignments, the Internet, industry complaints, and anonymous sources. An example of a site where data were collected can be found at www.fda.gov/cvm/index/bse/bsetoc.html.

2.3 Verifying Infrastructure Information

FDA is currently investigating duplicate and erroneous registrations. When these entries are identified, FDA will issue letters to the affected facilities, requesting them to delete the duplicate registrations or re-submit the corrected information. Facilities will have 60 days from receipt of the letter to correct their information before FDA proceeds with possible regulatory action.

FDA will verify basic information submitted in domestic registrations during normally scheduled inspections and as resources permit. Facility registration to comply with the Bioterrorism Act is required prior to operation in any new food facility. Verification of information for new facilities will take place as FDA resources permit or through State counterparts, if feasible. Information provided for new facilities poses a unique problem because new facilities do not enter "optional" information. Without the optional information, we can make no clear link between a facility and the product it manufactures or processes.

FDA and CBP will verify registration of foreign facilities through the Prior Notice mechanism. If a foreign facility has not registered with FDA, then the product to be imported may be held pending the submission of the appropriate information.

CVM verification activities include in-house inquiries (querying State departments of agriculture/AAFCO, field inspections, and laboratory analysis) and searching the Internet for illegal products. Experts review contamination, health hazard evaluations (HHEs), and other reports. Feed firms must notify FDA when the drug content in feeds is outside of specifications (official assay limit, GMPs, and Records and Reports regulations).

2.3.1 Assessing Potential Consequences

The data on regulated assets will increase the ability of FDA to rapidly identify, locate, and notify the pertinent domestic facilities either before or during the occurrence of a food-related concern. The following list constitutes an initial assessment of the potential consequences of compromised data:

- Inability to identify where problem products may be located, leading to an inability to investigate and detain those products, if necessary;
- Inability to seize problem products and prevent movement into interstate commerce;
- Losses to the economy due to loss of product if data gaps make FDA unable to separate products of concern from products posing no risk;
- Undermining the public's confidence in the safety and security of the food supply, with potential economic losses associated with unnecessary preventive behavior undertaken by consumers and manufacturers; and
- Potential harm to public health, including potential loss of life.

In addition, technology will play a critical role in FDA's future counter terrorism efforts in analyzing potential threats. The newly created CFSAN Adverse Event Reporting System (CAERS) is providing a single system for tracking and evaluating adverse events and consumer complaints received by FDA concerning food, dietary supplements, and cosmetics. Previously, CFSAN had several systems for monitoring adverse events: the Adverse Reaction Monitoring System (ARMS) system for food and color additives; the Cosmetic Adverse Reaction Monitoring Database for cosmetic products; and the Special Nutritional Adverse Event Monitoring System (SN/AEMS) for dietary supplements, infant formulas, and medical foods. This combining of systems was made possible in part by funds provided by Congress in the FY 2002 appropriations and beyond.

In June 2003, after 2 years of development, these systems were combined into the new CAERS database, which records events concerning CFSAN-regulated products. Currently, congressional funding has allowed for the development of a basic system for report collection, which includes a document management system that permits scanned reports to be seen at users' computer stations, data entry, and some report redaction.

CAERS is receiving, on average, approximately 3,000 consumer complaints and adverse reports from FDA district offices and MedWatch each year.

Also in 2003, a database search tool, Business Objects, was launched into CAERS. Using this tool, CFSAN can now improve its search capability for adverse event data and unusual adverse event patterns. Additionally, Business Objects helps staff to respond to a large variety of inquiries from Congress and others, and is capable of generating yearly reports that describe the 3,000 voluntary received reports. Thus, CAERS can become a critical tool for identifying new and emerging food and cosmetic public health problems and threats.

CAERS started operation on June 16, 2003, and provides clinical review of these reports and also sends to manufacturers notification of received adverse event reports. If feasible and appropriate, CAERS information indicating a potential food security incident may be shared with affected industry sectors and the Food and Agriculture Sector through HSIN. Collection of food

post-market reports about CFSAN-regulated products will significantly improve the agency's ability to identify and analyze food product-related risks in real time.

With respect to animal feed, the potential human health consequences of asset compromise may not be catastrophic. However, there could be severe effects on animal health and a potentially great economic impact. Loss of a domestic source of animal protein for human consumption could, under some circumstances, have negative public health consequences. Due to the limited rendering capacity in the United States, some issues associated with mass animal casualties could have negative social and environmental consequences (e.g., how to properly dispose of many dead animals). Potential consequences of asset compromise are assessed by data analysis.

Every FDA cyber system has been assessed for potential risks and threats and a mitigation action defined. In addition, CFSAN maintains an up-to-date security and contingency plan that details the steps to be taken in the event that the system is compromised. Backup systems, alternative sites, and an overall center COOP support the system and the surrounding infrastructure.

2.4 Updating Infrastructure Information

FDA (CFSAN/CVM/ORA) will continually update the asset data with information acquired during normally scheduled inspections and operations, as resources permit. FDA will use historical import information from archived databases to monitor new information provided by Prior Notice and during actual entry of products into the United States to ensure that this out-of-date information is not being used by firms in order to move their products into U.S. commerce. FDA will retain domestic information to ensure that facilities that are affected by mergers or changes in operational status (e.g., out of business) update their registration information with FDA. It is not anticipated that this information will be classified in nature.

FDA will review new data that are entered into the registration database and will adjust criteria for review, as necessary. As resources are available, FDA intends to enhance the current system and develop a seamless link between all of the agency's systems and associated databases.

Data will be updated periodically by CVM using similar processes to those used initially to establish asset status. The investigational and inspectional processes will be periodically performed using vulnerability assessment and risk analysis processes (delineated in the Animal Feed Safety System (AFSS) and others). Many of the sources from which data are obtained are not classified. Security status of the data will be provided upon request.

FDA maintains a complete inventory of all of its physical cyber assets. This is maintained by system administrators, operators, and managers, and is integrated into the overall master inventory. Physical examination of all physical cyber assets is performed annually.

2.5 Anticipated Activities

FDA identified specific activities that may be necessary to collect the proper CI/KR information with regard to facility registration.

- Prepare official letters to facilities requesting that they update their registration information.
- Verify information obtained from new domestic facilities and determine whether Federal or State jurisdiction applies.
- Enhance the quality of information in the "firm/company" database by eliminating duplicate registration information and merging information from ABI/ACS.
- Fill in gaps that may exist in some of the data sets. TheFDA intends for the databases to cover the critical parts of the food distribution system. Because the system is large, varied, and ever-changing, we cannot create and use a comprehensive database. The challenge is to fill in gaps where failure to do so would leave out a critical part of the food distribution system.

- Integrate the main asset data with existing operational data to prepare asset profiles. The information from these profiles could speed the data analyses needed to more effectively rank categories and allocate resources for coverage.
- Conduct more outreach programs for State and local laboratories for participation in eLEXNET and FERN.
- Enhance the quality of data in systems through quality assurance activities.
- Upgrade FACTS and OASIS data systems by developing a new Mission Accomplishment Regulatory Compliance System (MARCS).
- Enhance the tracking and traceback ability of FDA with regards to food and feed products.

In addition, FDA has access to medicated feed mills because they must be licensed with FDA before they can receive a specific category 2, type A medicated article. However, it will be difficult to identify unlicensed feed mills should they choose not to register under the new registration rule under the Bioterrorism Act.

3. Assess Risk

3.1 Use of Risk Assessment in the Sector

Prior to the tragic events of September 11, 2001, FDA began conducting vulnerability (risk) assessments of the food and cosmetics supply. However, shortly after the events of 9/11, FDA quickly expedited the process of assessing the vulnerabilities and prioritizing the assets of the food and cosmetics industries regulated by the FDA. FDA held meetings with the major food and cosmetics trade associations to solicit industry perceptions of vulnerabilities in the U.S. food and cosmetics production, processing, and distribution system. Feedback from these meetings, coupled with input from agency experts led to the development of a list of foods that warranted a formal evaluation of risk.

FDA developed a list of Priority Terrorism Agents With Potential for Dissemination via Food (now classified as Secret) by first consulting the CDC lists of bioterrorism agents and chemical agents. These lists were adjusted to form the FDA list by taking into account such factors as the stability of the agent in a food matrix; odor, flavor, and color characteristics of the agent that may alert the consumer to its presence; severity of public health outcomes; oral infective/toxic dose; availability of the agent; and threat intelligence about the potential for use of the agent as an intentional contaminant in food. This document is classified as Secret.

The FDA's first vulnerability assessment efforts involved the application of Operational Risk Management (ORM). This relative risk ranking was designed to facilitate decision-making about the assignment of limited Federal, State, and local public health resources to minimize the risk of intentional contamination of the food supply, especially by terrorist organizations. It was also designed to assist the food industry in identifying areas where enhancements in preventive measures could result in an increase in the security of the food supply.

The ORM analysis evaluated the public health consequences (i.e., morbidity and mortality) of a range of product-agent scenarios. While non-public health consequences, such as economic losses to the industry, interruption of the food stream, and loss of public confidence in the food supply, were not considered in this analysis, it was recognized that these latter consequences could be enormous, perhaps overshadowing the actual public health consequences, even with a single death or a small number of serious illnesses. Evaluating the public health consequences of tampering or criminal, malicious, or terrorist activity was the analysis for which the agency was best equipped and which was most closely aligned with its public health mission. For those reasons, it was chosen as the starting place for an assessment. Additionally, it was expected that solid assessments of the morbidity and mortality risk of tampering or criminal, malicious, or terrorist activity posed by specific food groups would probably be useful in mitigating the loss of consumer confidence that may follow any tampering event or criminal, malicious, or terrorist activity against the food supply. They also would be useful to mitigate interruption of the food stream and economic losses to the industry.

The ORM analysis facilitated the separation of food/agent/activity (i.e., point in the farm-to-table continuum) combinations into lower, medium, and higher risk categories, allowing the agency to focus its food security efforts in those areas where the risks of attack were the greatest. The ORM analysis has since been classified as Secret.

After completion of the first set of 31 products to be analyzed using the ORM process, FDA contracted with the Institute of Food Technologists (IFT) to validate its analyses. The IFT task group was provided with the FDA methodology and a list of agents and foods subjected to the FDA analysis. IFT's results were generally consistent with FDA's findings, but included some insights not considered in the FDA analyses.

In 2004, at the urging of the White House Homeland Security Council's Interagency Food Working Group, FDA began the application of another assessment tool, CARVER + Shock, to those food products identified by the ORM analysis as having a higher risk of intentional contamination (i.e., "higher risk" foods). CARVER + Shock is an offensive targeting tool, as opposed to ORM, which is more accurately described as a defensive vulnerability assessment tool. The CARVER + Shock analyses consider the economic and psychological (i.e., shock) consequences, in addition to the public health consequences, of an attack. Additionally, these analyses more thoroughly integrate threat information, especially the capabilities and intent of the threat, into the analysis, than was possible using the ORM tool. Finally, these analyses more completely examined the food processes, procedures, raw ingredients, and packaging, as well as the type of transport and physical equipment information than could be completed using the ORM method.

Notwithstanding the differences in the analytical methods, the CARVER + Shock results are generally consistent with the initial ORM results, but again provide additional insights.

The CVM has been working on vulnerability assessments in conjunction with the risk analysis portions of the animal feed safety system. Regulations being developed regarding BSE have served as a model for ways of introducing a particular agent throughout the food chain from animal feed to animals and humans (see 62 Federal Register (FR) 30976, June 5, 1997). Health Hazard Evaluations (an assessment of risk) provide information on drugs and toxic food contaminants and how they are mishandled. An important goal of AFSS is to assess the vulnerability of the assets to intentional and unintentional contamination and prevent hazards from entering the feed supply. The CARVER analysis is useful for evaluating the risk of intentional and deliberate contamination. The larger plan under AFSS is contemplated to be a risk-based system that would detect hazards before a feed is distributed, thus minimizing detrimental animal and human health effects from hazards in the feed supply.

CVM experts in consultation with other Federal and State experts (including intelligence experts) will assess and prioritize vulnerabilities according to a number of factors (including the potential impact of compromise). CVM experts assembled for these activities include veterinarians, chemists, toxicologists, and other area experts. Through FDA-structured mechanisms, CVM will communicate with industry our findings with regard to weaknesses and vulnerabilities.

In July 2005, the DHS, USDA, FDA, and the Federal Bureau of Investigation (FBI) announced a new collaboration with private industry and the States in a joint effort, the Strategic Partnership Program Agroterrorism (SPPA) initiative. The SPPA initiative is a true partnership program, where an industry member, trade association, or State may volunteer to participate in this vulnerability assessment program utilizing the CARVER + Shock method (described in detail later in this section). To volunteer, the industry or State member must submit a completed response form. Information about the SPPA initiative can be accessed at www.cfsan.fda.gov/~dms/defprog.html.

3.1.1 Program Objectives

The Federal Government members, in partnership with industry and State volunteers, have been and will continue to:

1. Validate or identify sector-wide vulnerabilities by conducting CI/KR assessments in order to:

   a. Identify gaps;

b. Inform Centers of Excellence and SSAs of identified research needs; and

c. Catalog lessons-learned.

2. Identify indicators and warnings that could signify planning for an attack.

3. Develop mitigation strategies to reduce the threat/prevent an attack. Strategies may include actions that either industry or government may take to reduce vulnerabilities.

4. Validate assessments conducted by the U.S. Government for food and agriculture sectors.

5. Gather information to enhance existing tools that both the U.S. Government and industry employ.

6. Provide the U.S. Government and industry with comprehensive reports, including warnings and indicators, key vulnerabilities, and potential mitigation strategies.

7. Provide subsector reports for the U.S. Government that combines assessment results to determine national critical infrastructure vulnerabilities to support the NIPP and national preparedness goals.

8. Establish and/or strengthen relationships between Federal, State, and local law enforcement and the food and agriculture industry, along with the critical food and agriculture sites visited.

3.1.2 Implementation

To facilitate this work, a series of site visits are conducted at multiple food and agriculture and production facilities. Every Food and Agriculture Sector subsector will be studied (i.e., production, processing, retail, warehousing, and transportation) in order to assess the farm-to-table continuum. The primary purpose of the visit is to work with industry to validate or identify vulnerabilities at the specific site and the sector as a whole. These visits will build on the work done by the SSAs in order to assist in developing the NIPP, Federal SSPs, and State SSPs. All of the visits will be conducted on a volunteer basis.

Teams comprised of knowledgeable personnel from the SSA, the FBI, the DHS, State and local officials, and industry will be formed to conduct the surveys.

3.1.3 Results

The desired results of the SPPA initiative are:

1. Reports that detail identified vulnerabilities, possible mitigation strategies, and warnings and indicators for each site. The reports will be distributed to all site participants.

2. Reports that outline sector-wide vulnerabilities and lessons learned to effectively and appropriately prioritize national assets and resources. The reports will be distributed to the DHS, USDA, FDA, and the FBI.

3. Each industry subsector will apply the CARVER assessment tool, and adapt, if necessary, to its unique production, processing, retrial, warehousing, and transportation system. Data sets will be set by GCC. Those data sets will be collected during the site visits and will be compiled by subsector (i.e., slaughterhouse, processing plant, etc.). This data will be translated so outputs can be compared with other critical infrastructure sectors.

4. CARVER + Shock templates.

5. Lessons learned.

6. Assessment templates for each system by subsector that can be exported to other sites to identify vulnerabilities that incorporate existing tools.

7. Sector-specific investigative templates and field guides for those within the intelligence community that focus on food and agriculture issues.
8. Provide data to the NIPP working groups for further development of the NIPP and national preparedness plans.
9. Increase awareness within industry and government regarding resource requirements and capabilities, current threats, and recognition of attack indicators.
10. Identify and validate R&D initiatives related to the Food and Agriculture Sector. Ensure that industry concerns and issues are carried forward to further R&D efforts.

3.1.4 Example Timeline for Site Visit

After receiving an application from an industry or State volunteer, the SSA will work through the Food and Agriculture Sector Coordinating Councils to establish contact initially. After the site selection and initial contact has been made by the SSA, the following serves as an example of how to approach the visit:

- **4 weeks prior to the visit:** The contractor will contact the participant to set up administrative and logistical arrangements.
- **1 week prior to the visit:** The contractor will confirm all arrangements for the site visit and send a read-ahead packet to the industry participants. The contents will probably include objectives and an agenda for the visit and any supporting or relevant documents.
- **Site visit:** The total visit will take 2 to 5 days to complete, depending on complexity.

Proposed Agenda:

- Introductions (all agencies represented and industry);
- Threat brief and/or case studies;
- CARVER + Shock review by lead SSA;
- Design flow diagram of subject food, animal, or plant production/process;
- Documents/references:
  - Template;
  - Agents; and
  - Technical information;
- Conduct assessment of vulnerabilities;
- Review results (including implications of an attack, investigative leads);
- Identify mitigation strategies;
- Identify gaps to serve as research questions; and
- Close.

The SPPA is intended to provide representative, factual information about identifiable product types, commodities, and activities across the Food and Agriculture Sector. It is not the intent of the SPPA to assess the specific vulnerabilities of an individual company or facility. To achieve the representative information needed for the SPPA, the strong preference is to secure participation in the CARVER + Shock from multiple companies and the representative trade association(s) from the sector or subsector

being assessed. However, where this is not feasible, expertise from a single company may be used to determine more generalized, representative processes and operations.

Each participant in an SPPA CARVER + Shock assessment is required to sign a sensitive information non-disclosure agreement. The final report of each assessment includes the detailed data and information used in the assessment. This report is prepared by a U.S. Government contractor as a classified document that is protected under national security authorities. An appropriate security clearance will be necessary for accessing the classified information and the report. The U.S. Government will provide periodic classified briefings for Federal, State, and industry partners, with necessary security clearances on a scheduled basis, such as semi-annually. Participants in each CARVER + Shock assessment will receive documentation, which will be identified as working notes. The working notes will be prepared by the U.S. Government contractor and agreed to by participants before the closure of the assessment, and will include only non-sensitive information.

The assessments conducted or scheduled under the SPPA initiative are provided in Table 3-1.

Table 3-1: SPPA Assessments Conducted or Scheduled (September 2005 - November 2006)

Status	Date	Sector- Specific Agency	Industry	State
Completed	11/2005	FDA	Yogurt	TN, MN
Completed	12/2005	FDA/USDA	Grain - Export elevators	LA
Completed	01/2006	FDA	Bottled Water	NJ
Completed	02/2006	FDA	Baby Food - Jarred applesauce	MI
Completed	02/2006	USDA	School Central Kitchens	NC
Completed	03/2006	USDA	Swine Production	IA
Completed	03/2006	FDA/USDA	Frozen Food - Pizza	WI, FL
Completed	04/2006	FDA	Juice Industry - Apple juice	NH
Completed	04/2006	USDA	Egg Products - Liquid	PA
Completed	05/2006	FDA	Fresh-Cut Produce - Bagged salads	CA
Completed	06/2006	FDA	Infant Formula	AZ
Completed	06/2006	USDA	Poultry Processing	AR
Completed	07/2006	FDA	Fluid Dairy - Processing	NY
Completed	07/2006	USDA	Beef Cattle Feedlot	NE
Completed	08/2006	USDA	Ground Beef Processing	KS

Status	Date	Sector- Specific Agency	Industry	State
Completed	08/2006	USDA	Cattle Auction Barn	MO, KS
Completed	09/2006	USDA	Dairy Farm	ID
Completed	10/2006	USDA	Soybean Farm	IL
Completed	11/2006	USDA	Corn Farm	IA, IL

The first year status report of the SPPA initiative can be found at www.cfsan.fda.gov/~dms/agroter5.html.

3.1.5 CARVER + Shock Software Tool for the Food and Agriculture Sector

During the fall of 2005, FDA contracted with the Institute of Food Technologists (IFT) and Sandia National Laboratories (SNL) to develop a software tool that implements its security methodology in food production. The tool will be developed with the assistance of an advisory team consisting of seven respected experts in the food safety or security field. The project will initially refine and optimize the CARVER security methodology. A beta version of the software will be tested and evaluated and refined version 1.0 will be released in early 2007. The second year will include maintenance of the software and a limited upgrade of the software performance.

The purpose of this project is to develop the CARVER + Shock methodology into a set of detailed inquiries that can then be inserted into an existing software screening tool for evaluating potential threats of chemical, biological, or radiological contamination within the food industry from deliberate acts.

The tool will be based on the CARVER + Shock methodology being implemented by CFSAN, risk assessment methods (such as CARVER expertise; water and building risk assessments) developed at SNL and the synergistic outcome of blending the multidisciplinary project team with the expert advisory panel. The software tool is expected to be used by State and local food security agencies, industrial providers, and any other interested parties in food safety and/or security. The software must be user-friendly and as accurate and useful as possible. The tool will be designed to address as many food groups as practical and its efficacy will be tested on the list of 31 high-priority food groups provided at the project's outset. All food groups will be kept in mind, however, throughout the method development. This will ensure expansion potential, versatility, and overall usefulness.

It is proposed that the initial CARVER software tool consist of three principal modules:

- Flow Diagram Generation;
- CARVER + Shock Analysis; and
- Results.

3.2 Screening Infrastructure

In November 2001, FDA released a document entitled, *Food Safety and Security: Operational Risk Management Systems Approach*. At the time, the U.S. Air Force, Office of the Surgeon General was developing guidelines for food safety and security for military personnel. Due to their support for national food safety and security and homeland defense, they allowed FDA to use their document as a model. Their document reported:

"First and foremost, concern is centered on protecting the public, our most important asset, by providing them with safe food and water sources. Food and water systems can be very complex and literally stretch around the world. For the purpose of this handbook, we want to identify our national assets.

U.S. Agriculture is a $200 billion business with over $55 billion in exports each year (agriculture has a $1 trillion value and provides 22% of all jobs). The United States is the largest producer of food and agriculture products in the world, and agriculture and food production is the Nation's largest business. The United States has over 500,000 farms, and over 6,000 meat, poultry, and egg product and production establishments.

There are in excess of 57,000 food processors in the United States that provide processed foods to our citizens and exports to the world. These processors include canners, dairy product producers, wineries, and other food and beverage manufacturers and distributors. The United States produces over 50% of the world's processed tomato products, and the majority of the canned peaches, fruit cocktail, and black ripe olives. It also processes millions of tons of garlic, prunes, and strawberries. Retail food facilities (restaurants, grocery stores, and other operations serving/selling foods direct to the consumer) number in excess of 1.2 million."

Shortly before 9/11 and expedited after the events of 9/11, FDA began to assess the vulnerabilities and prioritize the assets of the food and cosmetics industries regulated by the FDA. FDA held meetings with the major trade associations representing the industries described above to solicit industry perceptions of vulnerabilities in the U.S. food and cosmetics production, processing, and distribution system. Feedback from these meetings, coupled with input from FDA experts, led to the development of a list of foods that warranted a formal evaluation of risk.

CVM risks were selected by a working group of individuals representing various stakeholders. The AFSS is dedicated to the control of all feeds, medicated and non-medicated, so they can be manufactured with the minimal risk of feed contamination. CVM regularly works with States and takes into consideration work that the States are already doing with regard to feed safety.

CVM will maintain a list of feed hazards. For each hazard, CVM will address exposure, risk, and the significance of the potential health consequences. The risks to humans and animals will be ranked independently and a current regulatory control will be described for each hazard.

CVM is also participating in FDA activities, as appropriate, including an analysis of the feed industry in the CARVER + Shock tool.

Based on information obtained from within FDA and from industry trade associations, as previously described, FDA compiled a list of products that were perceived to represent a heightened potential for intentional contamination. From this list, the following products have been assessed using the ORM approach:

- Baby food, jars
- Breaded food, frozen, raw
- Canned food, low-acid
- Cereal, whole grain, not heat-treated
- Deli salads
- Dietary supplement, botanicals, tablets
- Entrées, fully cooked
- Flour
- Fruit juice, refrigerated, not from concentrate
- Fruit juice, shelf-stable, from concentrate
- Gum arabic (ingredient)
- High-fructose corn syrup (ingredient)
- Honey
- Ice cream
- Infant formula, liquid
- Infant formula, powdered
- Milk, fluid
- Peanut butter
- Produce, cut, modified atmosphere packaged
- Produce, fresh
- Seafood, cooked, refrigerated, ready-to-eat
- Soft drink, carbonated
- Spices, untreated
- Spices, irradiated
- Spices, ethylene oxide-treated
- Vitamins, capsules
- Water, bottled, spring
- Water, bottled, mineral
- Water, bottled, municipal source
- Yogurt, live culture

Additional products may be assessed as they are identified. In the conduct of the ORM analyses, extensive reliance was placed on elicitation of expert opinions in conjunction with consensus conferences to rank the risk of the various product-agent scenarios. Consensus conferences were comprised of the following experts:

- Food technologist;
- Food microbiologist;
- Food chemist;
- Epidemiologist;
- Tampering/counterfeiting expert;
- Risk assessor;
- Toxicologist; and
- Medical doctor.

Potential agents listed in FDA's Priority Terrorism Agents With Potential for Dissemination via Food (classified as Secret) were divided into the following categories:

Biological Agents:

- Spore-forming bacteria (SFB) (e.g., *Bacillus anthracis*);
- Vegetative bacteria, protozoa, and viruses (VBPV) (e.g., *Salmonella*);
- Heat-stable bacterial toxins (HSBT) (e.g., *Staphylococcus aureus* toxin); and
- Heat-labile bacterial toxins (HLBT) (e.g., *Clostridium botulinum* neurotoxin).

Chemical Agents:

- Water-soluble, heat-stable chemicals (WSHSC) (e.g., cyanide);
- Lipid-soluble, heat-stable chemicals (LSHSC) (e.g., digoxin); and
- Lipid-soluble, heat-labile chemicals (LSHLC) (e.g., ricin).

The analysis of risk for each food was preceded by the development of a flow diagram for each product, from farm to table, for example:

1. Farm;
2. Bulk transportation;
3. Processing;
4. Finished product transportation;
5. Warehousing; and
6. Retail/food service.

As previously mentioned, ORM is an integration of separate judgments on severity and probability. For the purposes of the analyses, severity refers to the potential public health impact of the hazard if introduced as a consequence of a control weakness. It includes consideration of the criticality of the illness and the exposure of the population (i.e., the number of people

affected). Where the criticality of the illness is high (i.e., death or life-threatening illness or injury), as is generally the case for the agents under consideration, exposure tends to predominate in the calculation of severity. A scale of severity was designed with definitions for low, medium, high, and very high. They are not provided here because of their sensitivity. Chronic effects were not considered in the assessment.

Probability refers to the likelihood that the control weakness will occur to the extent necessary to result in the identified severity. The following ranges of severity apply:

- **Very low** = Probability is minimal and the control weakness is unlikely to result in an event of the identified severity.
- **Low** = Probability is slight and it is expected that the control weakness would seldom expose the population to the risk of an event of the identified severity.
- **Medium** = Probability is significant and it is expected that the control weakness would occasionally or sporadically expose the population to the risk of an event of the identified severity.
- **High** = Probability is great and it is expected that the control weakness would likely or regularly expose the population to the risk of an event of the identified severity.
- **Very high** = Probability is extraordinary and it is expected that the control weakness would frequently or continuously expose the population to the risk of an event of the identified severity.

Risk—the integration of the probability and severity ratings—is determined from the following table:

Table 3-2: Operational Risk Management Matrix

		PROBABILITY				
		Very High	High	Medium	Low	Very Low
SEVERITY	Very High	Higher Risk	Higher Risk	Higher Risk	Higher Risk	Lower Risk
	High	Higher Risk	Higher Risk	Higher Risk	Lower Risk	Lower Risk
	Medium	Higher Risk	Lower Risk	Lower Risk	Lower Risk	Lower Risk
	Low	Lower Risk	Lower Risk	Lower Risk	Lower Risk	Lower Risk
		RISK LEVELS				

A separate risk calculation was performed for each combination of food, activity, and agent (i.e., agent category). Those foods for which at least one risk calculation fell into the "higher risk" category have been identified for analysis using the CARVER + Shock tool. The CARVER + Shock analyses for two food products are now classified as Secret and analyses for seven additional products will soon enter classification review. CARVER + Shock analysis for the remaining "higher risk" products will follow.

3.2.1 Cyber-Security Risk Assessment

The FDA Division of Information Resources Management (DIRM) performs and continues to perform computer and database system risk assessments that report on the following information:

- Date of most recent identified threat or risk;
- Area of threat or risk;
- Possible source of threat or risk;
- Probability of occurrence;
- Mitigation strategy; and
- Current remediation status.

3.3 Assessing Consequences

It is important to note that in applying the ORM methodology, risk is independently determined for each combination of food, activity, and agent, and that the risk for a particular food routinely varies for different activities or agents. Nonetheless, risk, as defined by the ORM process, is comprised of two components—severity and probability.

The ORM analysis evaluated the public health consequences (i.e., morbidity and mortality) of a range of product-agent scenarios. While non-public health consequences, such as economic losses to the industry, interruption of the food stream, and loss of public confidence in the food supply, were not considered in this analysis, it was recognized that these consequences could be enormous, perhaps overshadowing the actual public health consequences, even with a single death or a small number of serious illnesses. Evaluating the public health consequences of tampering or criminal, malicious, or terrorist activity was the analysis for which the agency was best equipped and which was most closely aligned with its public health mission. For those reasons, it was chosen as the starting place for an assessment. Additionally, it was expected that solid assessments of the morbidity and mortality risk of tampering or criminal, malicious, or terrorist activity posed by specific food groups would probably be useful in mitigating the loss of consumer confidence that may follow any tampering event or criminal, malicious, or terrorist activity against the food supply. They also would be useful to mitigate interruption of the food stream and economic losses to the industry.

As previously discussed, those foods identified as "higher risk" by the ORM process are being subjected to further evaluation using the CARVER + Shock tool. The CARVER + Shock analyses consider economic and psychological (i.e., shock) consequences, in addition to the public health consequences, of an attack. This tool is described in detail in section 3.4.

The consequences of concern identified for CVM and the animal feed industry thus far for the vulnerability of the assets are addressed, in part, by our compliance policy programs:

- Drug Process and New Animal Drug Inspections;
- Illegal Sales of Veterinary Prescription Drugs;
- Feed Contaminants Program (includes pesticide residue in feed data, mycotoxins in feed, salmonella in feed, dioxin in feed, and heavy metals in feed);
- Feed Manufacturing Compliance Program;
- Type A Medicated Articles;

- Illegal Drug Residues in Meat and Poultry Program (includes the Residue Violation Information System (RVIS) and the Tissue Residue Management Systems (TRMS));
- Imported Bulk New Animal Drugs;
- National Drug Residue Milk Monitoring; and
- BSE/Ruminant Feed Ban Inspection.

3.4 Assessing Vulnerabilities

The Food and Agriculture Sector utilizes the CARVER + Shock vulnerability assessment method to determine the vulnerabilities in the sector using a systems approach.

The CARVER + Shock method is an offensive targeting prioritization tool that has been adapted for use in the food sector. This tool can be used to assess the vulnerabilities within a system or infrastructure to an attack. It allows the user to think like an attacker by identifying the most attractive targets for attack. By conducting such a vulnerability assessment and determining the most vulnerable points in the user's infrastructure, the user can then focus their resources on protecting their most vulnerable points.

CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:

- **C**riticality: Measure of public health and economic impacts of an attack;
- **A**ccessibility: Ability to physically access and egress from target;
- **R**ecuperability: Ability of system to recover from an attack;
- **V**ulnerability: Ease of accomplishing attack;
- **E**ffect: Amount of direct loss from an attack as measured by loss in production; and
- **R**ecognizability: Ease of identifying target.

In addition, the CARVER tool evaluates a seventh attribute, the combined health, economic, and psychological impacts of an attack—the **Shock** attributes of a target.

The attractiveness of a target can then be ranked on a scale from 1 to 10 on the basis of scales that have been developed for each of the seven attributes. Conditions that are associated with lower attractiveness (or lower vulnerability) are assigned lower values (e.g., 1 or 2), whereas, conditions associated with higher attractiveness as a target (or higher vulnerability) are assigned higher values (e.g., 9 or 10). Evaluating or scoring the various elements of the food sector infrastructure of interest for each of the CARVER + Shock attributes can help identify where, within that infrastructure, an attack is most likely to occur. Federal agencies, such as FSIS and FDA, 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.

A complete discussion of the CARVER + Shock method can be found in appendix 5.

3.5 Assessing Threats

FDA will work with our intelligence partners and the Homeland Infrastructure Threat and Risk Analysis Center (HITRAC) to obtain threat information. The following types of threat products will be utilized:

- **Common Threat Scenarios:** Common threat scenarios present terrorist methods that could be employed in attacks against the U.S. infrastructure. The DHS developed these scenarios from the analysis of terrorist intentions and capabilities and plans to update them as required.
- **General Threat Environment:** These assessments are sector-specific threat products that include known terrorist threat information. General threat environment assessments also include longer term strategic assessments and trend analyses of the evolving threat to the sector's critical infrastructure.
- **Specific Threat Information:** This threat information is critical infrastructure-specific information that is based on real-time intelligence streams. This product will drive short-term protective measures to mitigate risk. It will also contribute to the general threat environment and common threat scenario products produced by the DHS.

The FDA Office of Criminal Investigation (OCI) has primary responsibility for coordination of intelligence with our Federal intelligence partners and will play a primary role in the HITRAC coordination.

4. Prioritize Infrastructure

The ORM and CARVER + Shock analyses identified a number of considerations that affect the risk that a food, at a particular point in its production, could become the target of intentional contamination. These analyses have been used to prioritize the food and agriculture infrastructure. The following four characteristics were common to each of the food products identified as being at a higher risk:

- Large batch size, resulting in a large number of servings;
- Short shelf life or rapid turnaround at retail and rapid consumption;
- Uniform mixing of contaminant into food; and
- High accessibility to the critical node of production, processing, or distribution.

The following additional considerations also affected the risk classifications:

- Severity of the illness or injury caused by the agent;
- Consumption by children or elderly (i.e., dose response);
- Incubation period of the agent;
- Effect of heat treatment, chlorination, decolorization, washing, removal of outer layers, dilution, etc., at that step or at subsequent steps on the agent;
- Consumer handling practices for the food;
- Quantity consumed in a serving;
- Stability of the agent in the food (e.g., effect of desiccation or acidity);
- Ability of sufficient quantity of agent to be incorporated in or on the food;
- Ability of the food to disguise the agent;
- Efficiency of the method of delivery;
- Technical difficulty of the method of delivery;
- Difficulty of the product to be tampered with or counterfeited;
- Availability of the agent;

- Desirability of the product as a target (e.g., association with children or with American culture);
- Countries in which the product or an ingredient of the product (e.g., pomegranate juice concentrate from Iran, gum Arabic from Senegal) is produced;
- Patterns of past incidents of terrorist activity/tampering/counterfeiting; and
- Quality control procedures commonly employed at the step or subsequent steps.

FDA began distributing an unclassified (For Official Use Only (FOUO)) version of the results of the agency's ORM analyses to State public health and food regulatory agencies and industry trade associations in April 2004. This document lists 19 "higher risk" foods. They were so identified based on the ORM scoring system, which integrates judgments about: (1) the probability of an intentional contamination event occurring against a particular food, at a particular point in its production, using a particular agent, with (2) the public health consequences (i.e., severity) of such an attack. Each of the factors listed above affect either the probability or severity judgments, or both.

The "higher risk" foods are receiving priority attention by FDA for the identification and implementation of preventive measures; through the SPPA process described in section 3. Within this list, FDA has further prioritized its attention based on the scores contained in the classified version of the document. Where a "higher risk" food has special critical infrastructure implications (e.g., the food is critical to the diet of the general population of a subpopulation, there is no replacement food available, and the food is available from limited sources), these implications were considered in addition to the ORM scores in the prioritization process.

Having prioritized "higher risk" foods, it is important to note that "lower risk" does not mean *no risk*. Consequently, the FDA continues to work to upgrade the security of all food production, processing, and distribution systems.

4.1 Food and Agriculture Sector Criticality Project

In 2006, FDA, USDA, and the DHS initiated the Agriculture and Food Criticality Project to develop a methodology for defining infrastructure criticality within the Agriculture and Food Sector. In early 2007, we began transitioning the project to a new institution for continuation of the project.

4.2 Cyber Security and Infrastructure

FDA IT systems have been identified as priority assets based on the impact of loss on the FDA mission. Protection of these systems is provided through the use of alternative backup systems, a COOP, and system contingency plans. All data and systems are backed up continually.

5. Develop and Implement Protective Programs

5.1 Overview of Sector Protective Programs

5.1.1 ALERT Initiative

In 2006, FDA in cooperation with CDC, USDA, and State and local organizations representing food, public health, and agriculture interests announced a new food defense awareness initiative—ALERT. ALERT is an acronym that stands for Assure, Look, Employees, Reports, and Threat. It is linked to five questions designed to heighten awareness within the food sector on key food defense issues, such as product security and reporting of suspicious behavior. The ALERT initiative is designed to provide a uniform and consistent approach to food defense awareness and is generic enough for use at any point in the food supply chain, from farm to retail establishment.

The questions associated with the ALERT acronym are as follows:

A How do you **ASSURE** that the supplies and ingredients you use are from safe and secure sources?

L How do you **LOOK** after the security of the products and ingredients in your facility?

E What do you know about your **EMPLOYEES** and people coming in and out of your facility?

R Could you provide **REPORTS** about the security of your products while under your control?

T What do you do and whom do you notify if you have a **THREAT** or issue at your facility, including suspicious behavior?

ALERT initiative materials are being distributed through Federal, State, and local inspectors and other food industry liaisons. Additional information regarding the ALERT initiative is available on the CFSAN website at www.cfsan.fda.gov/alert.

The content for the ALERT initiative was developed through a Federal-State partnership in consultation with a consortium of stakeholders. Federal representatives from FDA, CDC, USDA, and State and local representatives from NEHA, NALBOH, NACCHO, ASTHO, APHL, AAFCO, and NASDA assisted with the development of this food defense awareness initiative.

Industry Guidance

CFSAN has published the following four industry guidance documents on food security. These documents identify the kinds of preventive measures that may be taken to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. The implementation of any of the measures included in each of these documents is entirely voluntary on the part of the industry. Notwithstanding, FDA's field personnel, as part of routine inspections, distribute and discuss these guidance documents with firms that have not previously received them.

• FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, www.cfsan.fda.gov/~dms/secguid6.html.

• FDA Importers and Filers: Food Security Preventive Measures Guidance, www.cfsan.fda.gov/~dms/secguid7.html.

• FDA Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance, www.cfsan.fda.gov/~dms/secgui11.html.

• FDA Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors: Food Security Preventive Measures Guidance, www.cfsan.fda.gov/~dms/secguid8.html.

Consumer Education on Tampering

Consumers play a critical role in preventing illness due to food tampering. FDA encourages consumers when shopping to carefully examine all food product packaging, check any anti-tampering devices on the packaging; not to purchase products if the packaging is open, torn, or damaged; not to buy products that are damaged or that look unusual; and to check the "sell by" dates. Consumers are also encouraged to carefully inspect products at home when opening the container and to never eat food from products that are damaged or that look unusual. FDA has created a fact sheet for consumer to assist them in identifying product tampering. The fact sheet, entitled "Food Tampering: An Extra Ounce of Caution," is posted on FDA's Web site at www.cfsan.fda.gov/~dms/fstamper.html.

Increased Food Security Awareness Training

FDA and USDA cooperatively developed a Web-based food security awareness training program. This training is targeted toward other Federal agencies responsible for food security, State and local food manufacturing and retail inspection staff, and the food industry.

The goals of the training are to:

• Raise awareness of food security in the target audiences;

• Provide a rudimentary understanding of the food security efforts undertaken to date by FDA, particularly in the area of vulnerability assessments;

• Provide a set of rudimentary tools to the target audiences to help them identify high-risk conditions and preventive measures that can reduce the risk; and

• Introduce references that provide further assistance and provide contacts for follow-up.

The training can be accessed at www.fda.gov/ora/training/orau/FoodSecurity/default.htm.

Increased Inspections of Imports

In addition, since 2001, FDA has more than quintupled the number of food import examinations. In 2001, FDA conducted 12,000 food exams. In 2003, FDA surpassed its goal of 48,000 import examinations, conducting 78,569 food import examinations. This significant increase was due, in large part, to increased surveillance of imported food products during Operation Liberty Shield when the Nation was at a heightened security alert status. For this reason, the increased coverage does not necessarily reflect the level of import surveillance during normal operations; however, it does illustrate the agency's ability to increase the number of inspections when needed.

FDA is working to increase import filer evaluations to ensure the integrity of importers and import entry data and to increase the collection of samples for laboratory analysis.

FDA is working on additional enhancements to the Operational and Administrative System for Import Support (OASIS) to include real-time screening with multi-agency import databases to help target inspection resources.

Implementation of Bioterrorism Act

FDA (CFSAN) published four major new regulations in accordance with provisions of the Bioterrorism Act. These rules implement new authority that FDA received in the Bioterrorism Act and are one of the most significant enhancements of FDA's statutory authority to keep food imports secure. The four new regulations are:

- Establishment and Maintenance of Records;
- Prior Notice of Imported Food Shipments;
- Administrative Detention; and
- Registration of Food Facilities.

Food Security Enhancements in Times of Heightened Alert

In 2004, FDA initiated a series of assignments associated with special security events (i.e., the Group of Eight (G8) Summit and the Democratic and Republican National Conventions) that focused on ensuring the safety and security of the Nation's food supply. These special event assignments were regional and limited in scope. Based on heightened security during the national election in November 2004, FDA decided to issue a broader nationwide food defense assignment. This FDA Security Surveillance Assignment (FSSA) was designed to be national in scope; integrate food safety and defense activities; and involve Federal, State, local, and industry partners.

The FSSA commenced on October 12, 2004 and continued for 6 weeks. The primary goals of the FSSA were to deter intentional contamination of the food supply through heightened and targeted preventive activities at various points in the food distribution chain and to exercise the systems and networks for responding to a food-related emergency during a period of increased food security risk. These systems included communications and logistics among FDA, and State and industry partners, prioritizing examination of food commodities, identification of firms handling FDA-regulated products, laboratory response capabilities, import and domestic traceability of products and interfacing data, and sharing information with the intelligence community.

The activities in the assignment were conducted in cooperation and collaboration with all FDA District Offices, 44 States, and the Commonwealth of Puerto Rico. Five different food commodities were selected for the assignment based on the highest potential for intentional contamination, as determined by vulnerability assessments previously undertaken by FDA. A total of 1,737 inspections were conducted of FDA-regulated firms, 49 of which were not formerly in FDA's Official Establishment Inventory (OEI). In addition, 276 samples were collected during the inspections and analyzed for multiple microbiological and chemical agents using FERN laboratories, including FDA, USDA, and State facilities. All sample results were negative.

The food safety component of the assignment resulted in classification of 93 percent of the inspections as "no regulatory action indicated," 6 percent as "voluntary actions indicated," and less than 1 percent of firms had official action taken by FDA. No criteria applicable under the Bioterrorism Act, particularly the threat of a serious adverse health consequence, were found. During the inspections, FDA and State inspectors engaged each firm's management in a discussion aimed at increasing food defense awareness specific to their operations, as well as provided appropriate FDA food security guidance documents. Upon being asked, approximately 90 percent of the inspected establishments were willing and able to provide investigators with distribution records (i.e., one up and one down) of their suppliers or consignees.

During the assignment, FDA's Prior Notice Center, which interfaces with CBP personnel and databases and other agencies (e.g., the FBI, USDA, and the U.S. Coast Guard), examined 9,058 import entries, including 14,794 entries determined to be related to the 5 food commodities. Screening criteria was based on commodity type, previous regulatory history, intelligence, and geographic areas of concern. Thirty-eight entries were identified as high risk, resulting in directed inspection assignments by 12 different FDA District Offices across the country.

The system for responding to an increased risk of intentional contamination of the food supply was exercised through the planning and implementation of the FSSA. While it is difficult to measure the level of deterrence that this assignment afforded, there was clearly a significant increase in food defense coverage, awareness, and preparedness achieved by the preventive activities of FDA and State inspectors at multiple and targeted points in the food distribution system and through communication with the industry. Many of the gaps identified in this assignment have already been resolved by FDA, providing for a more prepared national network capable of responding to an intentional contamination.

Following the FSSA in 2004, FDA began incorporating food defense aspects into each food safety assignment that was issued to their field staff. This involved discussing the provisions in FDA's regulations issued in accordance with the Bioterrorism Act, as well as providing facility management with copies of FDA's food security guidance documents.

Emergency Preparedness and Response

FDA, through the Office of Crisis Management (OCM) and the Emergency Operations Center (EOC), works closely with the Department of Health and Human Services' (HHS) Office of Public Health Emergency Preparedness (OPHEP) and the Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, and from Operating Divisions to HHS, and other Federal agencies and departments, including DHS. In particular, FDA has focused on strengthening its working relationship with USDA by joint testing of several response plans in an exercise environment. In May 2005, FDA participated in the TOPOFF 3 terrorism exercise, a national, full-scale, fully functional exercise intended to simulate two separate terrorist acts, as well as the ensuing response by Federal, State, and local governments. In addition to exercises, FDA has leveraged with FEMA to receive training and incorporate the Incident Command structure in FDA's emergency response.

FDA has developed and exercised FDA response plans for chemical, biological, and radiological emergencies and BSE incidents, and commented on national emergency preparedness and response documents (e.g., the National Response Plan (NRP), the National Incident Management System (NIMS)). FDA continues to exercise these three plans and public versions of the plans are posted on the FDA Web site. During FY 2004, FDA revised the FDA Bovine Spongiform Encephalopathy Emergency Response Plan, version 5.0, December 24, 2003. In addition, in response to a case of BSE in the United States in December 2003, the FDA activated their EOC and coordinated the agency's response for working with internal offices, as well as other external agencies (e.g., USDA, DHS).

On October 7, 2003, FDA hosted the first trilateral food terrorism tabletop exercise via videoconference with Mexico and Canada. The exercise was conducted from FDA's OCM/EOC. Participants included FDA's CFSAN, ORA, the Office of International Programs, the Southwest Import District, the New York District, Mexico's Federal Commission for the Protection Against Sanitary Risk, Health Canada, and the Canadian Food Inspection Agency. The objectives of the exercise were 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 to an international terrorism event. At the Trilateral Meeting on October 29, 2003, in Baltimore, Maryland, a discussion was held on the lessons learned, including the challenges related to notification; sharing of data, including classified information; and the sharing of intelligence information within and among the three countries. Another trilateral exercise will be conducted in 2004.

OCM coordinates the preparedness and emergency response activities of the five FDA Centers, ORA, and their offices working with their Federal, State, and local counterparts that may be engaged in a variety of different emergencies involving FDA-regulated products and/or the need to provide medical countermeasures. Within OCM, the EOC serves as the chief communications node and point of contact within FDA.

FDA's OCM/EOC will coordinate FDA participation in other interagency exercises. FDA has coordinated and participated in several terrorism and emergency exercises and special events, including TOPOFF 3, international Trilateral Exercises, meetings such as the G8 Summit, and State and local government and industry emergency exercises. FDA continues to develop the

agency's COOP, as well as coordinate FDA emergency response to more than 150 incidents annually, including BSE (Canada and the United States), multi-State foodborne outbreaks, etc. OCM is currently developing the agency's Crisis Management Plan.

FDA will continue to work with other Federal partners. FDA and USDA have also closely coordinated BSE efforts both prior to and following the identification of the BSE-positive cow in Washington State. During late 2001 and 2002, FDA in conjunction with USDA, conducted a series of three exercises to test BSE response plans. These exercises served us well in establishing the lines of communication and coordination needed to respond to the finding of the BSE-positive cow in December 2003. Once notified of the finding, FDA and USDA were in close communication at multiple levels. At a headquarters staff level, USDA hosted daily interagency calls with APHIS, FSIS, FDA, DOD, and CDC to share information. FDA personnel were sent to the APHIS emergency operations center to assist that operation. Local communication occurred in Washington State between the FDA district office in Seattle and the local USDA incident command center. Many of the inspections of facilities in Washington State were conducted as joint inspections with FDA, USDA, and State inspectors participating. FDA worked closely with USDA on the disposal of rendered product produced from the index cow. Numerous other policy-level meetings and teleconferences occurred between FDA and USDA senior officials.

FDA developed a prototype for the FDA Emergency Operations Network Incident Management System (EON IMS), in accordance with HSPD-5 and the establishment of NIMS. When fully functional, the Emergency Operations Network (EON) will provide a system to fully support the enterprise for the full range of FDA emergencies. A cross-agency systematic and proactive approach to the emergency organization, resourcing, and processes will be implemented by the functional infrastructure improvements. The system will provide seamless, integrated access for EON users to incident management, surveillance, and alert information, coupled with collaboration tools and robust Geographic Information System (GIS) capability. EON IMS is a critical initiative to support the agency's ability to more effectively and efficiently manage, plan for, and respond to emergency situations, including foodborne outbreaks, product contamination, and possible food safety threats involving FDA products that would have an adverse effect on public health. EON IMS will provide a Web-based connection for all FDA offices through which accurate, real-time information about various incidents can be shared and discussed.

Within current resources, FDA is assessing its ability to respond to high-risk product-agent scenarios and for what period we can sustain our response. This includes a review of our current scientific capabilities that may be available for extramural sources (academia, DOD, etc.) and efforts to enhance the Nation's food laboratory capacity at Federal, State, and local facilities to conduct rapid, accurate tests to determine quickly the precise extent of food contamination in the event of an actual or suspected terrorist attack.

Laboratory Enhancements

Methods Development

- FDA has redirected laboratory staff to develop laboratory methods for priority biological and chemical agents in food. Methods continue to be developed for the highest priority select agents.

- FDA has reviewed and is modifying current regulatory analytical methods for their applicability to terrorism-related samples. Methods continue to be modified to provide more rapid analysis while maintaining practical sensitivity.

- FDA is enhancing its capacity to develop methods that can be used for rapid analysis of suspect foods for select agents or toxins, including the development of rapid methods that can be deployed and used in a field setting.

- FDA is working to adapt an FDA chemical toxin screening method for application as a surveillance tool.

- FDA has established an Interagency Agreement (IAG) with Edgewood Arsenal and a task order contract with Midwest Research Institute for the validation of methods for the detection of microbiological agents in foods.

• FDA has partnered with DOD to develop and validate methods to detect agents most likely to be used in a terrorist attack on the food supply, and is engaged in IAGs that would allow DOD to provide laboratory support in the event of an attack.

• Under contract to FDA, the New Mexico State University (NMSU) Physical Science Laboratory (PSL) is evaluating rapid test methods for microbiological analyses of produce samples. NMSU's evaluation includes the assessment of rapid test methods for a particular analyte(s) or food commodity, which is required prior to the agency adoption of any kit for use in the regulatory arena.

Surge Capacity and Network Development

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate foodborne 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. One of the major components of FERN is response (surge capacity). FDA is working closely with Federal and State food testing laboratories to build FERN to include a substantial number of laboratories capable of analyzing foods for agents of concern. FERN is a joint initiative with FSIS.

FDA is seeking to expand laboratory capacity through agreements with other Federal and State laboratories. As of May 2004, 70 laboratories representing 35 States have submitted laboratory qualification checklists for membership in FERN. Once completed, FERN will encompass a nationwide network of Federal and State laboratories capable of testing the safety of thousands of food samples, thereby enhancing the Nation's ability to swiftly respond to a terrorist attack.

FDA has made available methods for the isolation and detection of high-priority microorganisms and chemical agents not usually found in food that can be utilized by Laboratory Response Network (LRN) and FERN laboratories. These methods have also been submitted for use in the LRN. In addition to methods dissemination, FDA has used emergency funding to purchase rapid-method test kits for chemical and microbiological agents and has distributed the materials to laboratories within FERN.

FDA is also expanding Federal, State, and local involvement in eLEXNET by increasing the number of laboratories around the country that participate in this electronic data system as described earlier. FDA is continuing efforts to expand eLEXNET to provide better nationwide data on food product analyses by regulatory agencies.

Moreover, during the U.S./Canada/Mexico Trilateral Cooperation Meeting held in October 2003, the three governments agreed to establish a pilot to use eLEXNET to share food sample data among the three countries' laboratories. FDA and the Office of the Assistant Secretary for Public Health and Emergency Preparedness in HHS have begun working with Mexico and Canada to establish an integrated secure network between U.S., Mexican, and Canadian food testing laboratories. One of the major goals of the project is to create an early warning notification system to identify potentially hazardous foods and more quickly contain their distribution to prevent consumption.

FDA will continue to train its staff, as well as FERN laboratory participants, including Federal; State public health, agriculture, and veterinary diagnostic; and local laboratories in the analysis of foods for several priority agents.

FDA Cyber Security Protective Programs

CFSAN maintains an information technology COOP. The objective of this IT Contingency Plan is to allow CFSAN to recover business functions after unplanned events that curtail normal operations. This plan will allow FDA to assess damages/outages and initiate recovery actions. In addition, FDA works with the department to ensure the security of all computer networks utilized by FDA.

Also, FDA subscribes to e-mail notifications from the United States Computer Emergency Readiness Team (US-CERT). US-CERT is the operational arm of the National Cyber Security Division (NCSD) at the DHS. It is a public-private partnership.

Industry-Initiated Protective Programs

Private Sector Guidance and Other Activities

Some trade associations have developed food security guidance that is appropriately focused for that specific industry. For example, several food trade associations, including the International Dairy Food Association (IDFA) and the Food Products Association have developed food security guidance documents and manuals as an aid to the industry. FDA encourages other trade associations to evaluate the preventive measures and adapt them to their specific products and operations and to supplement FDA's guidance with additional preventive measures when appropriate. As an example, a coalition representing 16 food or food transportation associations, together with several food company representatives, worked with FDA and USDA to create the Bulk Over-the-Road Food Tanker Transport Safety and Security Guidelines, which are available either from the cooperating associations or the FDA Web site at www.cfsan.fda.gov/~acrobat/transafe.pdf. FDA welcomes dialogue on the content of sector-specific guidance with appropriate trade associations.

The International Bottled Water Association has provided members with a detailed security checklist that includes information and resources covering the entire bottled water production process, the bottled water plant and surrounding grounds, warehouses and storage facilities, sources, employees, and suppliers. Also included are crisis preparedness and response, and emergency contact information.

5.1.2 Other Activities

Many trade associations, their members companies, and countless third-party entities have initiated programs that address private sector communications improvements, security audits, background checks, vulnerability assessments, and emergency operations. Whereas prior to 9/11, most trade associations and companies did not have points of contact for food/agriculture defense issues, now most do. For example, with FDA assistance, the following food trade associations, with the participation of invited member companies, conducted a CARVER + Shock analysis of their respective industries: the Bottled Water Association/Bottled Water, Food Products Association and Juice Products Association/Juice and Juice Products joint analysis, IDFA/Milk and Milk Products, Pork Processors/Pork Production, etc. In addition, food industry and food trade association representative have participated in numerous joint CARVER + Shock analysis sessions with the DHS, FDA, USDA, FBI, State and local food officials for specific food segments (water, juice, milk and milk products, baby food, infant formula, etc.). Additional information on this effort may be found in section 3.

Food industry laboratories having expertise in dealing with certain select agents have registered with CDC/APHIS and may be in a position to provide backup support to government laboratories should concerns arise with the specific agent(s) in their area of expertise.

State/Local Activities

Countless State and local initiatives and activities have taken place in the past few years, which include, but are not limited to, the development of numerous documents and Web sites to assist the public and industry. The following are some examples:

- Industry Vulnerability Assessment for Food Security (available in PDF) (Department of Health Services, Arizona);
- Public Health Emergency Preparedness (Department of Health, New York, New York);
- Bioterrorism Preparedness and Response (Department of Human Services, Oregon);
- Bioterrorism (Department of Health, South Dakota);
- Bioterrorism (Department of State Health Services, Texas); and
- Bioterrorism (Department of Health, Kentucky).

AFDO created the Food Protection and Defense Committee, which holds bimonthly conference calls to address food defense issues at the State and local levels, and has presented food defense topics and held tabletop exercises on food defense at its national meeting, as well as at its regional affiliates meetings. Many members of the food and agriculture community participate in AFDO activities and have played a role in and supported AFDO's Food Protection and Defense Committee and FoodSHIELD, a Web-based platform supporting food and agriculture protection and defense.

5.2 Determining Protective Programs Needs

FDA determines which protective programs to pursue based on congressional mandate, the findings from vulnerability assessments, previous food contamination incidents, suggestions from State health or agriculture departments, and sector-specific information provided by the intelligence and law enforcement communities and HITRAC. Information from these sources is analyzed and gaps in protective programs are identified. The information is also shared with the relevant GCC and SCC members. For classified analyses, the information is shared with those sector representatives who have appropriate security clearances.

5.3 Protective Program Implementation

FDA issues regulations in accordance with congressional mandates and issues guidance documents to the private sector that contain suggested food defense practices in accordance with applicable government regulations. The private sector voluntarily implements those security countermeasures that are applicable for each food establishment, as appropriate.

5.4 Protective Program Performance

The FDA Food and Agriculture Sector NIPP Metrics Report and the FDA Food and Agriculture Sector CI/KR Protection Annual Report, both provided to the DHS, include more detailed information concerning individual programs performance.

6. Measure Progress

6.1 CI/KR Performance Measurement

This section describes measures for evaluating whether FDA's planned and implemented activities accomplish the goals for protecting the food supply. These measures will provide a basis for describing the current status of activities in the program, document where performance meets planned expectations, and help determine where gaps in protection occur or where there is a need to alter activities and partnerships to protect the critical infrastructure.

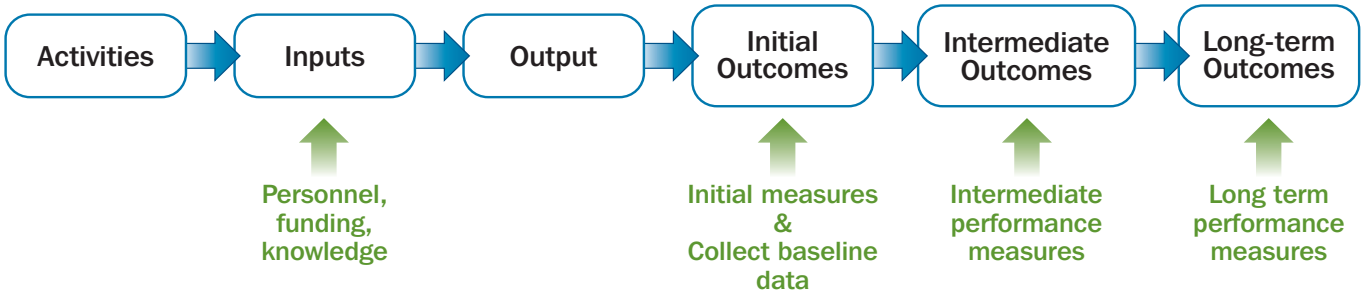
Three types of metrics will be tracked for the CIP program: descriptive metrics, process metrics, and outcome metrics. Descriptive metrics are necessary to understand sector resources and activity, but do not reflect CIP performance; process metrics measure whether specific activities that are important to the execution of a program were performed as planned, track the progression of a task, or report on the output of a process; and outcome metrics track progress toward a strategic goal in terms of results rather than level of activity.

FDA's steps for developing performance measures are:

1. Determine which resources, activities, and goals are appropriate to measure.
2. Determine which resources, activities, or goals can be measured by descriptive metrics, process metrics, and/or outcome metrics.
3. For goals that are measured by outcome metrics, develop a logic model that tracks FDA activities and outputs through initial, intermediate, and long-term outcomes of CIP.
4. Determine the appropriate stage and database for measuring and tracking progress.
5. Show the links from FDA activity to final outcome. Determine which of these outcomes are directly influenced by FDA or directly influenced by others, such as industry, with FDA contributing to the outcome.
6. Develop baseline data.
7. Implement programs.
8. Track progress with intermediate and/or long-term performance measures.

A simple graphical depiction of a logic model is shown in Figure 6-1.

Figure 6-1: Depiction of a Logic Model



For the above simple model, activities are defined as what the program actually does, outputs are the products produced by the activities, and outcomes are the changes that result. A logic model is the first, not the last, step in evaluation. The model continually evolves as more information about outcomes and the effectiveness of activities becomes available.

Before further defining how to measure progress on implementing the SSP, it is important to consider the overarching goals of the CIP program:

- **Awareness**: Identify and assess the vulnerability of the Nation's food supply. Develop increased awareness among Federal, State, local, and tribal governments and the private sector for ensuring the safety and security of the Nation's food supply by collecting, analyzing, and disseminating information and knowledge.
- **Protection**: Develop the capacity to identify a specific threat or attack on the food supply and develop effective protection strategies to shield the food supply from terrorist threats.
- **Partnership**: Establish a collaborative environment across all levels of government and the private sector to better protect the Nation's food supply.
- **Coordination**: Coordinate and integrate, as appropriate, with other Federal emergency management and preparedness activities, including the NRP.

The Food Supply Sector's critical infrastructure protection activities will support the achievement of these goals. Resources will be directed toward those activities that best support accomplishment of the goals. Activities that are not advancing goals will be re-designed or eliminated over time. It is important, then, to measure the progress of the sector's activities.

Figure 6-2: FDA Food Defense Performance Activity Categories and Associated Outputs

Outputs (Examples)

1. Vulnerability Assessment: Conduct assessments
2. Bioterrorism Act: FDA has published four rules.
3. Strategic Approach to Imports: Increased number of food import exams and Import Strategic Plan to be implemented in the future.
4. Industry Guidance: Published four industry guideline documents on food security.
5. Enhance Laboratories: FDA established the FERN Methods Development of biological and chemical methods, FERN Proficiency Testing, FERN training and expansion of eLEXNET. FDA staff redirected to develop laboratory methods for priority biological and chemical agents in food, and provide support for cooperative expansion of eLEXNET and FERN.
6. Emergency Preparedness and Response: FDA establishes Office of Crisis Management.
7. Increase Awareness: Food defense awareness Web-based training and the ALERT initiative.

Performance Measures for Outputs (Examples):

At this level, primarily descriptive metrics will be used:

- **Descriptive metrics: Some of these measures will include describing the resources available, such as the increase in the number (and percentage) of personnel added to field operations, food import exams, domestic inspections, and researchers re-directed to develop laboratory methods for priority biological/chemical agents in foods, etc., and the number of databases in place. Describe if guidance documents were disseminated to industry as planned.**

Need to collect baseline data for outcome metrics (examples): Adverse event reports in CAERS, recalls, inspection information; sampling data. CDC and USDA collect other data that may provide baseline data.

Figure 6-3: FDA Food Defense Initial Outcomes

Initial Outcomes (Examples)

1. Vulnerability Assessment: Number of assessments conducted with industry.
2. Bioterrorism Act: Initial outcomes following publication of final regulations:
   – Food facilities have started registering;
   – Prior Notice of imported food shipments is occurring; and
   – FDA will begin to administratively hold and detain products.
3. Strategic Approach to Imports: Increased import filer examinations.
4. Industry Guidance: Published four industry guidance documents on food security.
5. Enhance Laboratories: Laboratory methods for priority chemical and biological agents in food are being developed.
6. Emergency Preparedness/Response: FDA response plans in place for chemical, biological, and radiological emergencies.
7. Increase Awareness: Development of food defense awareness Web-based training, development of ALERT materials.

Performance Measures for Initial Outcome (Examples):

At this level, primarily descriptive and process metrics will be used:

- **Descriptive metrics:** Some of these measures will include describing the increase in number (and percentage) of recall audits, complaint follow-up investigations, and filer evaluations since the Bioterrorism Act was enacted; describing FDA response plan dissemination.
- **Process metrics:** Some of these measures will include evaluation of training for new personnel; evaluation of the type/number of improved or new laboratory methods; tracking progress with entering registration data into the FFRM, entering Prior Notice data into the PNSI, and demonstrating output from these databases; tracking increased examinations of specific imported commodities based on FDA's risk/threat assessments; tracking new laboratory methods developed for biological/chemical agents in food.

Figure 6-4: FDA Food Defense Intermediate Outcomes

Intermediate Outcomes (Examples)

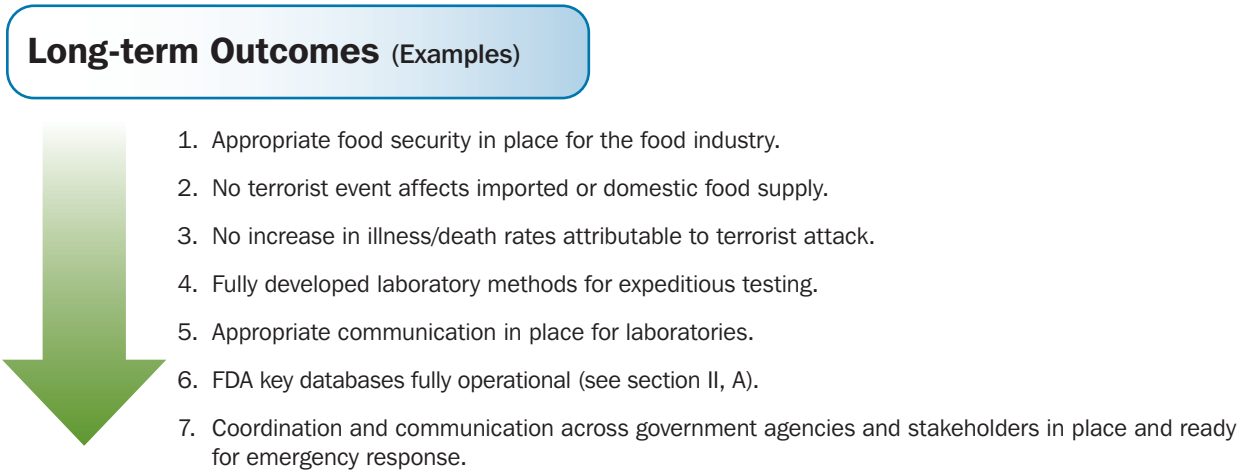
1. Vulnerability Assessment: Based on the conducting of assessments with industry, FDA expects that affected industries will improve food security measures and practices.
2. Bioterrorism Act: For two final regulations:
   – FFRM is operational and is being populated with data; and
   – Prior Notice System Interface and AMI..... are operational and are being populated with data.
3. Strategic Approach to Imports: Additional enhancements to OASIS to help target inspection resources.
4. Industry Guidance: Industry approves food security measures and practices.
5. Enhance Laboratories: Additional or improved laboratory methods for priority chemical and biological agents in food.
6. Emergency Preparedness/Response: Engage in tabletop and emergency response exercises, improve coordination and communication for emergency preparedness with other governmental agencies, and continue to cooperatively expand FERN for laboratories.
7. Increase Awareness: Federal, state and local officials, as well as industry representatives complete the food defense awareness Web-based training; distribution of ALERT materials to Federal, State, and local officials, as well as industry representatives.

Performance Measures for Intermediate Outcomes (Examples):

At this level, descriptive, process, and outcome metrics will be used:

- **Descriptive metrics:** Some of these measures include describing dissemination of the food security awareness training program, and describing enhancements to OASIS and other databases, such as eLEXNET.
- **Process metrics:** Some of these measures include tracking feedback from industry trade associations and commodity groups in the "highest" category about food security protection based on industry response to the agency's analysis of the most vulnerable foods and tracking changes in technology that may affect this analysis; compare information from inspections with data in FFRM to determine if there are gaps in information; also measure gaps in registration from foreign facilities through the Prior Notice mechanism (FDA collaborates with CBP).
- **Outcome metrics:** A qualitative outcome metric would use simulation exercises (tabletop and emergency response exercises) to determine gaps in communication and coordination with other governmental agencies for emergency preparedness. After further progress on communication and coordination, determine with repeat exercises if these gaps have been repaired. (Note: FDA's usual work with Federal, State, and local partners to ensure that foodborne disease outbreaks or unusual patterns of illness or injury are quickly investigated provides an additional area for developing communication and coordination.)

Figure 6-5: FDA Food Defense Long-Term Outcomes (Examples)



Performance Measures for Long-Term Outcomes (Examples):

At this level, emphasis will be placed on outcome metrics.

- **Outcome metrics: Demonstrate that no illnesses or deaths have resulted from a terrorist attack on the food supply. (Note: We cannot show this outcome by simply demonstrating an absence of unusual clusters of illness and death because there is an ongoing background of foodborne illness and outbreaks due to food safety problems that are not related to terrorism.) Some data that may help with inferring that no terrorism-related event has occurred:**
  - **Adverse events reported to FDA: Demonstrate that there is no change over time of a sudden upsurge of a large number of illnesses or deaths reportedly due to one category of product that is unexplained by usual food safety problems.**
  - **Information from selected States on syndromic surveillance.**

6.1.1 Information Collection and Verification

Industry Implementation of Countermeasures

FDA does not have the authority to collect information from the private sector with regard to the implementation of food defense countermeasures since the implementation of those measures is entirely voluntary of by the industry. Nonetheless, during routine food safety inspections, FDA discusses and provides a copy of the food security guidance to firms that have not previously received the guidance.

Food Facilities Registration

FDA established a Food Facilities Registration Database in response to section 305 of the Bioterrorism Act, as implemented by the Registration of Food Facilities Final Rule co-issued by the Secretaries of HHS and the DHS on October 10, 2003 (21 CFR Part 1, Subpart H). Section 305 of the Bioterrorism Act requires, in part, that the Secretary of HHS compile and maintain an up-to-date list of facilities that are registered under this section; the Secretary has delegated this responsibility to FDA. Registration provides FDA with information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify more quickly the facilities that might be affected by the outbreak.

The Bioterrorism Act and sections 1.225 and 1.230 of the final rule specifically require owners, operators, or agents in charge of domestic (U.S.) and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA by December 12, 2003, unless the facility begins operations after that date. In those instances, the final rule requires registration with FDA before the facility begins operations. (Note: All section citations to the final rule are found in 21 CFR Part 1, Subpart H.) As of November 20, 2006, 153,2545 domestic food facilities and 273,594 foreign food facilities have registered with FDA. A breakdown of the number of domestic facilities in each State within the United States, as well as the number of foreign facilities registered by country as of September 1, 2006, is available on FDA's Web site.

As stated in 21 CFR 1.232(e), the registration for domestic facilities must include an emergency contact telephone number that is accessible at all times. In addition, domestic facilities may choose also to provide, as stated in section 1.233(d), the emergency contact's name, title, and e-mail address.

Section 1.232(d) of the final rule requires the registration for foreign facilities to include the name, address, telephone number, and emergency contact telephone number of the facility's U.S. agent (if there is no other emergency contact listed under section 1.233(e)). Under section 1.227(b)(13) of the final rule, a U.S. agent must be a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 United States Code (U.S.C.) 321(e))) who resides or maintains a place of business in the United States whom a foreign facility designates as its agent for purposes of this final rule. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present. FDA further states in the final rule that the U.S. agent must act as a communications link between FDA and the foreign facility for both emergency and routine communications and will be the person FDA contacts if an emergency occurs, unless the registration specifies under section 1.233(e) another emergency contact. FDA further states that we will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility (21 CFR 1.227(b)(13)). Foreign facilities also may choose to provide the title, fax number, and e-mail address of their U.S. agent, as provided in section 1.233(f).

Section 1.234 of the final rule requires owners, operators, or agents in charge of domestic and foreign facilities to update any of the information that is required in an initial registration within 60 calendar days of any change to the information submitted to FDA. The rule also requires owners, operators, or agents in charge of a registered facility to cancel a registration when ownership changes or a facility ceases operation within 60 days of the change; new owners are required to re-register with a facility that will continue operations.

From July 10, 2006, through August 2, 2006, FDA conducted an initial test to verify the accuracy of the emergency contact information contained in our Food Facility Registration Database. FDA's objective in conducting the test was to verify the accuracy of the emergency contact information in the registration database, and assess whether FDA can use this information to quickly notify facilities that may be affected by an actual or potential threat to the U.S. food supply as intended. Specifically, the test was intended to allow us to estimate with 95 percent confidence the answers to two questions:

1. The accuracy of the primary mode of transmission (i.e., whether an emergency alert that FDA sends to domestic and/or foreign facilities in our Food Facilities Registration Database by primary e-mail, fax, or telephone would actually reach its intended recipient); and

2. The accuracy of the identity of the emergency contact/U.S. agent information in the Food Facility Registration Database (i.e., whether the intended recipient of FDA's alert is actually the emergency contact and/or U.S. agent for the facility).

The specific data FDA reviewed for accuracy during this test were limited to the data provided to FDA by the registrants pursuant to sections 1.232 and 1.233 of the final rule (i.e., the facility emergency contact information and/or the U.S. agent information). To conduct the test, FDA randomly selected a statistically representative sample of 800 facilities (400 domestic facilities and 400 foreign facilities) from the Food Facilities Registration Database to be the subject of this test.

The report from this test may be accessed at www.cfsan.fda.gov/~furls/ffregacc.html.

6.1.2 Reporting

FDA submitted their Food and Agriculture CI/KR Annual Report by July 1, 2006, as requested by the DHS.

6.2 Implementation Actions

6.2.1 Industry Implementation of Countermeasures

FDA does not have the authority to collect information from the private sector with regard to the implementation of food defense countermeasures since the implementation of those measures is entirely voluntary by the industry. Nonetheless, during routine food safety inspections, FDA discusses and provides a copy of the food security guidance to firms that have not previously received the guidance.

6.2.2 Outreach and Training Activities

Continued food defense awareness training of Federal, State, and local regulators and the private sector will aid in increasing situational awareness and provide valuable information that can be used to improve protective programs. This training is provided through Web-based and in-person programs.

6.3 Challenges and Continuous Improvements

The most significant challenge is monitoring progress by the private sector due to the voluntary nature of the adoption of security measures.

7. CI/KR Protection Research and Development

7.1 Overview of Sector Research and Development (R&D)

Federal CIP R&D planning is based on the NIPP and HSPD-7:

"In coordination with the Director of the Office of Science and Technology Policy, the Secretary shall prepare, on an annual basis, a Federal Research and Development Plan in support of this directive."

Homeland Security Presidential Directive 7

In addition to the NIPP, HSPD-7 establishes an annual requirement for the NCIP R&D Plan. As the primary R&D arm of the DHS, the Science and Technology Directorate supports the Secretary of Homeland Security by preparing the annual NCIP R&D Plan in partnership with the Executive Office of the President's Office of Science and Technology Policy (OSTP). The long-term vision of the NCIP R&D Plan is set out in three strategic goals:

- A national common operating picture for critical infrastructures;
- A next-generation Internet architecture with security "designed-in" and inherent in all elements rather than added after the fact; and
- Resilient, self-diagnosing, and self-healing physical and cyber infrastructure systems.

HSPD-7 also instructs OSTP and the DHS to coordinate interagency R&D to enhance the protection of CI/KR. Planning needs to be collaborative so that cross-sector priorities can be identified and R&D solutions developed to meet the needs of a specific infrastructure sector can be made available to all sectors. To assist the agencies and sector industries in coordinating their R&D, the Science and Technology Directorate and OSTP have organized the NCIP R&D Plan into nine research theme areas:

- Detection and Sensor Systems;
- Protection;
- Entry Portals;
- Insider Threats;

- Analysis and Decision Support Methods;
- Response, Recovery, and Reconstitution;
- New and Emerging Threats and Vulnerabilities;
- Advanced Infrastructure Architectures and System Designs; and
- Human/Social Issues.

Each theme area includes both physical and cyber R&D, and each theme area supports the three NCIP R&D strategic goals.

CFSAN's food safety and defense research approach is threefold, involving an intramural program, an extramural program, and consortia with industry, other government agencies, and/or academia. FDA conducts research that ensures food safety, promotes sound nutrition, enhances the safety of cosmetic products, and defends the food supply from being a vehicle for terrorist attacks against the United States. This FDA mission-critical research ensures the health and well-being of the American public through enhanced technologies for identifying, preventing, eliminating, and responding to both unintentional and intentional foodborne threats. Just as important, research provides the scientific basis for regulating the food producing industries to ensure a safe and nutritious food supply from farm to table.

CVM is the primary Federal agency responsible for ensuring the safety of animal feed. Animal feeds and feed commodities are potential high-value targets of intentional contamination with disease-causing microorganisms or chemical toxins. Either of these hazards could have a devastating effect on the American food supply and, consequently, consumer confidence in the food supply. CVM addresses many issues through its feed contaminants programs and other surveillance systems for chemical and microbial hazards and adverse events. Presently, CVM oversees a program of sampling and analyzing feeds for contaminants that pose a threat to animal and human health (Feed Contaminants Program). This program is an important bridge that connects the United States' ability to manage risks associated with agroterrorism to foodborne threats to humans.

7.2 Sector R&D Requirements

7.2.1 CFSAN Food Defense Priority Research Needs

When faced with new challenges related to defending the Nation's food supply from potential intentional contamination, FDA identified vulnerabilities associated with our ability to address the complex issues related to defending human food and animal feed that could be most effectively addressed through a targeted R&D program. The gaps identified, which are summarized briefly below, were the basis for a priority multi-year research program. The progress toward achieving the goals of that initiative is summarized in the next section. FDA's progress has been substantial in relation to the available resources. In addition to traditional research activities, this initiative has also required the development of computer software, and the education and training of key scientific and laboratory personnel who would be relied upon in the event of a food defense emergency.

The CFSAN's foods 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 non-traditional 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.

Threat assessments have indicated that pertinent priority agents include both exotic and traditional microorganisms/toxins. Furthermore, there is a wide range of foods that could serve as potential vehicles. The timely realization of these research goals will require the implementation of an integrated program of intramural, collaborative, and extramural research.

New Methods

Effective methods for the preliminary detection of foods, purposefully contaminated with chemical and microbiological agents, are critical components of 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 abortis*. Priority chemical agents include abrin, aminitin, *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. abortis*, and *Shigella dysentariae*. 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 non-destructive 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.

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. abortis, 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.

• **Characteristics of microbiological and chemical agents in food:** Additional assessments of the abilities of non-traditional 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 foodborne 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; and
- Establishing partition coefficient values needed to develop solvent extraction methods for the separation of various biologically derived toxins and toxic chemicals from foods.

• **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.

7.2.2 The DHS National Center for Food Protection and Defense Research Program

The National Center for Food Protection and Defense (NCFPD) research program is organized thematically into three primary areas: (1) *systems* (supply chain, public health response, economic analysis, and security), (2) *agents* (detection, inactivation, and decontamination), and (3) *training* (risk communication and education). Preparedness is a major component of the training theme, with an emphasis on pre-crisis communication planning; message development; communication with under-represented populations; media relations; and risk communicator training for a variety of audiences, including subject matter experts, government officials, food industry representatives, and extension educators.

Each theme represents two or more research teams. Leaders of the research teams oversee their group of projects and serve as points of contact for coordination of research within NCFPD, as well as between NCFPD and other Centers of Excellence, national laboratories, and Federal regulatory agencies. Four NCFPD core groups (Public Health, Laboratory, Risk Communication, and Education) are designed to work closely with the research teams to disseminate new tools and information developed by the research teams. Additional information about NCFPD's research efforts can be found in their 2005 Annual Report at www.fpd.umn.edu/files/annual_report_2005.pdf.

7.2.3 Additional Needs in Support of Foods Defense R&D

Training

Training is a critical element in technology transfer—the translation of R&D into useful tools for counter-proliferation efforts. Moving from FY 2004 into FY 2006 (Q1-Q3), FDA has built on the laboratory bio-safety, chemical safety, and radiation safety training conducted in FY 2003, institutionalizing core training in an annual training plan. FDA has also expanded the early

combined classroom/laboratory training sessions in detection methods for non-traditional agents in food, increasing the numbers of trained scientists in FDA field laboratories and State laboratories approximately four-fold over that of FY 2003. This training has been critical in expanding FERN. In FY 2004 and FY 2005, FDA also made a concerted effort to cross-train additional headquarters scientists and support personnel for expanded surge capacity, bringing the headquarters laboratories to a potential 24/7 operational level and further enhancing FERN. Last, but not least, as technology has advanced and new methods have emerged as the deliverables from earlier research, FDA has developed and sponsored training to transfer the technology to the field laboratories. The training program in Reverse Transcriptase-Polymerase Chain Reaction for identification and confirmation of certain non-traditional agents, initiated in FY 2004, and now coupled in FY 2006 with training in a new instrument and methodology for isolation of target organisms from food, is now bringing a highly selective, specific, high-throughput technique to the laboratory front line of counter-proliferation efforts. FDA expects to provide training in new techniques and methodology as they emerge from the R&D pipeline, and to continue to provide required annual training in specialized laboratory safety requirements.

CFSAN Research Infrastructure

CFSAN's ability to conduct its intramural and extramural food defense research is dependent upon the ability to maintain and enhance its research infrastructure. This research infrastructure, along with FDA's scientific personnel, is an important asset that FDA brings to the table when leveraging critical efforts through its Centers of Excellence and/or collaborations with other Federal agencies (e.g., the DHS, DOD, National Institutes of Health (NIH), USDA, EPA).

CFSAN's research facilities include:

Muirkirk Research Campus (MRC), Laurel, Maryland: The MRC facility is unique due to its capabilities, certifications/licenses, location, staff, training, and its growing pool of Federal and academic collaborative partners. As summarized below, each facet of the infrastructure complements all other facets, together creating this unique FDA asset.

MRC is certified by the Association for the Assessment and Accreditation of Laboratory Animal Care International. The MRC houses laboratory animals, primarily rodents, for its research and regulatory programs in an environmentally controlled animal facility that utilizes a clean/dirty corridor system. Entrance into the animal facility is through controlled locker rooms. MRC's capability to perform animal studies on site provides it with a capability unmatched by most FDA laboratory facilities.

MRC is one of CFSAN's sites designated to handle select agents; MRC is registered, as per the Bioterrorism Act, with CDC for these activities. Scientists at MRC are engaged in research that utilizes a number of different radionuclides; indeed, most of the investigative work involving radioactivity listed under CFSAN's Nuclear Regulatory Commission (NRC) license is conducted at MRC. The consistent quality and readiness of the facility, the expertise of its personnel, and its tailored procedures are evidenced by the many successfully completed inspections of the facility conducted by the varied organizations that provide oversight of laboratories. MRC has been successful in each of its efforts regardless of the perspective of a particular agency or inspection team because of its comprehensive and layered approach to security, safety, and procedures that emphasize a team approach to emerging issues.

CFSAN's Office of Applied Research and Safety Assessment (OARSA) is housed in MRC's MOD1 facility, located at 8301 Muirkirk Road, Laurel, Maryland. MOD1 was dedicated in August 1990 and is comprised of approximately 235,000 gross square feet. This facility was originally designed to house approximately 300 personnel. MOD1's net usable area is 100,000 square feet, of which approximately 50,000 square feet is dedicated to small animal research. The third floor of MOD1 has recently undergone a complete renovation and has yielded approximately 10,000 square feet of modern, state-of-the-art microbiology and molecular biology laboratories. These renovated laboratories complement the other approximate 24,000 square feet of non-animal laboratories in the four-floor facility. The remaining 16,000 square feet are used for administrative functions and storage.

OARSA provides research and regulatory program support in the areas of toxicology, microbiology, and molecular biology. The mission of OARSA is to establish and conduct a cohesive mission-relevant research program in the areas of toxicology, microbiology, and molecular biology that will ensure the safety of the U.S. food supply and the establishment of sound food defense measures. To accomplish its mission, OARSA has an agency-approved Strategic Research Plan and supports several counterterrorism initiatives. OARSA's research is focused in the following eight program areas:

- Reproductive Toxicology;
- Neuro/Behavorial Toxicology;
- Immunotoxicology;
- In Vitro Toxicology, with special emphasis on Hepatotoxicity;
- Virulence Assessment;
- Immunobiology;
- Microbial Genetics; and
- Molecular Virology.

MRC's location and history of performance resulted in it being designated part of the LRN and FERN. MRC houses OARSA's research program in pathogen evolution and molecular forensics. OARSA has been recently named as a Center of Excellence for Enteric Pathogens by the DHS. OARSA scientists at MRC will be working closely with the DHS and the FBI in setting standards for microbial forensics. MRC will develop and house the Nation's repository of select enteric microbial strains. MRC scientists also collaborate and leverage with Johns Hopkins, the University of Maryland, and other academic institutions.

In addition to OARSA, CFSAN has two other elements at the Muirkirk Road Campus. Parts of the Office of Cosmetics and Colors (OCAC) and the Office of Seafood are located in the Beltsville Research Facility at 8501 Muirkirk Road, Laurel, Maryland. The Beltsville Research Facility laboratories were initially opened in 1964. However, the antiquated laboratories were completely renovated in 2003-2004 to state-of-the-art research facilities with a total of approximately 42,000 square feet. And, MRC is the site of a sister center, FDA's Center for Veterinary Medicine (CVM), which houses laboratories for work with larger animals.

The combination of a certified animal facility, registry with both NRC and CDC, plus MRC's location near the University of Maryland and USDA laboratories, presents a unique environment for research and training that is not easily found or duplicated. Other attributes of the site include:

- FDA's first Biological Safety Level (BSL) 3 laboratory to be brought on line (expect certification in mid-2007);
- 24/7 operational and security procedures, with an on-site Operations and Maintenance Contractor; and
- Emergency power operators, allowing for operations under emergency conditions for a limited period of time.

National Center for Food Safety and Technology, Bedford Park, Illinois: CFSAN's Office of Plant and Dairy Foods, Division of Food Processing and Packaging (DFPP) occupies approximately 15,000 square feet of laboratory and office space at the National Center for Food Safety and Technology (NCFST) in Bedford Park, Illinois. NCFST, a food safety research consortium, was created to establish a mechanism through which government, academia, and industry could join together to exchange technical information and conduct cooperative research to determine the impact of processing and packaging technologies, particularly new, novel, or innovative technologies, on the safety and quality of foods. As CFSAN's only division focused on food processing and packaging, DFPP conducts laboratory and pilot plant research in collaboration with academic and industrial partners at NCFST to address emerging food-processing- and packaging-related safety issues. This provides a sound scientific base of knowledge for CFSAN's food policy decisions.

The NCFST pilot plant is a 40,000-square-foot facility containing food-processing and packaging equipment that includes a muti-mode water/steam-air/water spray retort; a small still steam retort; a continuous rotary simulator retort; a large-scale batch high-pressure processing unit; a semi-continuous high-pressure processing unit; a 300-gallon-per-hour, high-temperature short-time (HTST) pasteurization system; tray and rotary sprouters; and a complete aseptic particulate processing line consisting of contherm scrape-surface heat exchangers, tubular coolers, and a Scholle bag filler. A RiboPrinter(tm) system allows fully automated characterization of microbes to the strain level. The ribotyping device can identify eight isolates in 8 hours and is available for collaborative research or independent use by industry members of the NCFST. DFPP also assists the NCFST in its outreach activities, which include teaching, training, and participation in scientific symposia and seminars. Facilities are being constructed to add the capability of conducting food-related counterterrorism food-processing research in a BSL-3 laboratory and pilot plant.

DFPP performs validation studies involving new technologies, including high-pressure processing, and conducts research to study the safety of shelf-stable and extended shelf-life foods with a focus on canned foods (low-acid canned foods (LACFs)). Personnel on site are experts concerning *C. botulinum* and aseptic processing of foods with particulates. Studies with *C. botulinum* are conducted in CDC-approved select agent laboratories. A multidisciplinary research program determines the effect of food processing on safety, which may involve non-thermal or innovative technologies. This research includes studying intervention strategies to inactivate pathogenic microorganisms and to reduce the level of unwanted minor constituents, including chemical reaction products and contaminants in processed foods. Other research focuses on the detection, enumeration, and characterization of foodborne pathogens, assessing the safety of bioengineered foods, and allergen safety issues in processed foods and food plants. DFPP staff members include internationally recognized food technologists, chemists, microbiologists, and engineers.

Gulf Coast Seafood Laboratory, Dauphin Island, Alabama: The Gulf Coast Seafood Laboratory (GCSL) is a CFSAN field facility. CFSAN carries out regulatory research and educational activities that cover a wide range of seafood-related issues. These include public health hazards and economic deception. The mission of the GCSL is to conduct research to understand the nature and severity of hazards in seafood and to develop options to control those hazards. More technically phrased, the GCSL conducts research in hazards analysis, risk assessment, and risk management.

Ensuring the safety of seafood presents special challenges to both the seafood industry and the governmental agencies charged with protecting public health. The importance of seafood has grown tremendously in the past 10 years, both in its role in the diet and in its contribution to the gross national product. Consumer concerns with health and nutrition have led to inclusion of greater amounts of seafood in our diets than ever before. Fish are subject to a wide range of hazards. They are exposed to bacteria and viruses that occur naturally in their environment, as well as to those that result from pollution. Fish can also accumulate chemical pollutants and natural toxins; they also may harbor parasites.

The National Academy of Sciences, in a 1991 report entitled *Seafood Safety* concluded, and FDA concurs, that most hazards presented by seafood originate in the harvest waters. According to the report, "Most seafood available to the U.S. public is wholesome and unlikely to cause illness in the consumer." Nevertheless, it pointed out "... there are areas of risk."

The seafood safety research program at GCSL has unique expertise and infrastructure that has been important for research on viruses, *Vibrio* spp., and seafood toxins (e.g., brevitoxins, ciguatoxins, saxitoxin, tetrodotoxin) in relation to both food safety and defense. This facility also has extensive emergency preparedness experience, most recently facilitating the recovery and response efforts after hurricanes Katrina and Rita in 2005.

GCSL is located on Dauphin Island, Alabama, a barrier island on the northern coast of the Gulf of Mexico. The site provides a unique setting for studying contaminants of seafood. The Gulf of Mexico is a leading producer of seafood and GCSL has easy access to the gulf, its bays and tributaries, and its fisheries. Fish, oyster, shrimp, and crab processing plants are numerous in the area and are accessible for the study of the effect of processing on the safety of seafood. Louisiana, Mississippi, and Alabama are the largest aquaculture producing States in the United States. Culture ponds and processing facilities are within a few hours'

drive of the laboratory and provide opportunities for the study of seafood safety problems caused by the natural pond processes or culture practices. The facility is on 4.2 acres of waterfront property on Mobile Bay and Mississippi Sound. There are several buildings; the main building houses laboratory modules, offices, and wet laboratories using static or flow-through freshwater and saltwater systems. Total usable area is approximately 15,000 square feet. Several smaller buildings include a boat house and docks, library, shop, emergency power generator and pump houses, solvent and waste storage buildings, and a warehouse. The laboratory has three boats used in field investigations.

There are two research units at the GCSL: the Chemical Hazards Research Unit (CHRU), and the Microbial Hazards Research Unit (MHRU). Research emphases in the CHRU include marine toxins, aquaculture drugs, and petrochemical hazards. Research emphases in the MHRU include pathogenic microbial and viral ecology. Both units focus on hazards analysis and risk assessment for the development of risk management strategies, and development and evaluation of analytical methods for monitoring and management programs. All studies provide sound, up-to-date data and information to the seafood industry and consumers, and for the development of regulations, criteria, and guidelines.

College Park Campus, College Park, Maryland: The Harvey W. Wiley Federal Building occupies a 12-acre site at the intersection of Paint Branch Parkway, River Road, and 51st Avenue in College Park, Maryland. The site is across from the College Park Metro Station and one-half mile from the University of Maryland campus. The building rises four stories to a height of 84 feet and has one level below ground. It provides state-of-the-art laboratory, office space, and support facilities, serving as the headquarters for CFSAN.

The Wiley Building has five floors of state-of-the-art chemistry and microbiology laboratories, as well as several specialized laboratories such as a trace mineral laboratory, a pathology laboratory, an insectory, and a herbarium. There are 20 laboratory modules per floor for a total of 100 modules that occupy about 100,000 gross square feet. The laboratories have been designed utilizing a uniform module that includes zones for a closed, adjacent office; laboratory bench work; large laboratory equipment; and centralized facilities for common use equipment. The original design of certain laboratories has been modified to allow for some of the laboratories to work with high-hazard agents. This includes several high-security laboratories that are approved for work with certain select agents. All laboratories are capable of operating at the BSL-2 level. Each laboratory is designed with fume hood connections, point exhaust connections, and gas manifold towers at the bench.

The laboratories at the Wiley Building include three floors of chemistry laboratories that offer unique capabilities that directly support the FDA research program in food defense. The facility houses laboratories that have capabilities in all major forms of mass spectrometry, a key technology for analyzing foods for literally thousands of different toxic chemicals and biologically derived toxins. This facility is considered one the leading laboratories for the detection of proteinaceous toxins using mass spectrometry. The chemistry facilities also house several laboratories devoted to the development of immunologically based rapid methods for the detection of biologically derived toxins, microbiological toxins, and mycotoxins. These facilities include capabilities in both purification and preparation of the toxins for the development of immune sera and the development of prototype kits. These laboratories are supported by a variety of additional chemistry analytical suites with extensive capabilities in the detection and analysis by various instrumental platforms of toxic elements, various toxin compounds, pesticides, mycotoxins, and a variety of plant- and animal-derived toxins (e.g., ricin, abrin, amanitin, arsenic, organophosphates).

The Wiley Building also houses 2 floors (20 laboratory bays) of BSL-2 level microbiology laboratories that are capable of working with a wide range of foodborne pathogens and other microorganisms that have been considered as potential WMD that could be disseminated in foods. Characterization of agents is enhanced by specialized equipment for the enumeration of cultures and the determination of resistance characteristics, such at thermal resistance, acid tolerance, and dehydration stress responses. This includes extensive facilities for evaluating the characteristic of these pathogens in food systems and for the development methods for sampling, pre-enrichment, enrichment, isolation, identification, and confirmation systems for a wide array of microorganisms in a wider variety of foods. This facility includes extensive facilities for working with *C. botulinum* and

its neurotoxins, including a BSL-2+ laboratory for enhanced containment. This laboratory is actively sought out by other agencies (e.g., the DHS) for their expertise in the evaluation of systems for the detection of the neurotoxins.

University Station, College Park, Maryland: University Station is leased research and office space. The building was occupied by CFSAN in October 2004. The site is located next to the Wiley Building parking lot at 4300 River Road, College Park, Maryland. The CFSAN Office of Food Additive Safety and the Office of Cosmetics and Colors (OCAC) management and laboratory functions are housed in this space (with the exception of the OCAC Skin Penetration and Metabolism Team currently located at the Beltsville Research Facility at 8501 Muirkirk Road, Laurel, Maryland, and the OCAC Cosmetics Technology Team and the Cosmetics Toxicology Branch both of which are located in the Harvey W. Wiley Federal Building). CFSAN occupies more than 50,000 square feet of consolidated office and laboratory space within University Station, with another 13,000 square feet available for a tenant not yet identified. Laboratory activities at University Station involve OCAC's Color Certification Program. This program derives its budget entirely from the industry it regulates and is responsible for the certification of all color additives used in foods, drugs, cosmetics, and medical devices and sold domestically or imported. Color certification is a continuous operation and the Division of Color Certification and Technology maintains a 5-day period for analyzing a color sample for certification.

Bio-Containment Facilities

CFSAN is developing and/or expanding BSL-3 laboratories at MRC in Laurel, Maryland, and with its academic/industry consortium at NCFST in Bedford Park, Illinois, to address methods and characteristics/prevention (shields) research, respectively, with select agents in foods. Since MRC is a CDC LRN-accepted and key FERN laboratory, the BSL-3 status will be a significant laboratory enhancement for the national laboratory networks. A completed BSL-3 laboratory as part of the pilot processing plant will be a nationally unique and significant laboratory enhancement for CFSAN's Prevention and Intervention Program at NCFST. FDA's Office of Regulatory Affairs (ORA) is also in the process of establishing four BSL-3 laboratories.

7.3 Sector R&D Plan

Current R&D Initiatives

CFSAN's current food defense research thrust includes: the development of prevention and mitigation technologies/strategies; the elucidation of agent characteristics needed to develop these prevention technologies; the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents; and some initial efforts to establish the dose response relationships of threat agents in very select foods. This integrated program draws on all three components of FDA's research infrastructure: (1) intramural research capabilities, (2) collaborative Centers of Excellence (e.g., NCFST, Joint Institute for Food Safety and Applied Nutrition (JIFSAN), National Center for Natural Products Research (NCNPR)), and (3) extramural research programs that provide competitive research contracts and grants.

Specific projects involve: determining the stability of select chemical threat agents in foods and the impact of processing operations; the development of enrichment techniques for the isolation of select microbial agents from high-priority foods; the development of prevention/mitigation strategies for intentional contamination of animal feed used for food-producing animals; the development of risk assessment tools for assessing critical control points within a food defense/safety system; the development of methods for decontaminating food-processing facilities, retail establishments, and transportation equipment that have been exposed to microbiological, chemical, or radiological agents as a result of a terrorism incident involving foods; the acceleration of the development of rapid, field deployable analytical methods for detecting select agents in foods; and the development of a personal computer-based Analytical Modeling Tool to facilitate rapid response to food defense and safety emergencies.

FDA reports each year to Congress on the status of its counterterrorism research efforts, in accordance with the Bioterrorism Act. The latest report may be viewed at www.fda.gov/oc/bioterrorism/report_adulteration.html.

Intramural Program. Although modern technology has considerable potential to improve our ability to defend the Nation's food supply, research on food defense is a relatively new concept. To take advantage of opportunities for making foods safer and more secure through the development of new technologies, FDA, HHS, and the administration are taking unprecedented steps toward develop this new area of research. In particular, CFSAN has already redirected existing research staff to ensure that appropriate resources are focused on key priority food safety and defense issues. CFSAN currently has several intramural research projects ongoing or recently completed related to food defense (see appendix 6).

The research plan includes biological select agents and typical foodborne pathogens. The research thrusts include the development of analytical detection methods and the characterization (growth, stability, inactivation, and fingerprinting) of agents in FDA-regulated foods. For many agents of concern, there are few methods for which performance has been verified in a variety of food matrices. Therefore, the methods development work includes in-house validation and performance testing of existing rapid screening test kits for priority agents on high-priority foods, with the ultimate goal of having field-deployable technologies that meet performance/validation standards.

Methods work also includes the development of methods for the isolation and detection of select agents in food, such as the evaluation and validation of confirmatory tests and the development of fingerprinting approaches. CFSAN's MRC, Wiley Building/College Park Laboratory, and NCFST laboratory are certified as part of CDC's LRN, and are important laboratories in the new FERN. Relative to fingerprinting, CFSAN is also supporting its intramural microbial forensics research program (in collaboration with the DHS, FBI, and Central Intelligence Agency (CIA)), an activity that is key to the criminal investigation to determine if the presence of an agent is related to an act of terrorism or is accidental in nature. An MOU between the DHS, FDA, and FBI has been established, and the DHS has designated the MRC as a National Center of Excellence for Microbial Forensics of Enteric Pathogens.

Additionally, characteristics research involves the assessment of the abilities of non-traditional bacterial pathogens to survive and grow in FDA-regulated foods during processing. CFSAN's Prevention and Intervention Program at NCFST is using this characteristics information in conjunction with assessing the efficacy of several intervention technologies (prevention or shields) used in food processing.

CFSAN is developing and/or expanding BSL-3 laboratories at MRC and NCFST to address methods, and characteristics and intervention technologies research, respectively.

The research plan also includes chemical select agents and typical foodborne chemical contaminants of concern. The research thrusts include the development of analytical detection methods and the characterization (stability, inactivation) of chemical agents in FDA-regulated foods. For many agents of concern, there are few methods for which performance has been verified in a variety of food matrices. Therefore, the methods development work includes in-house validation and performance testing of existing rapid screening test kits for priority agents on high-priority foods, with the ultimate goal of having field-deployable technologies that meet performance/validation standards.

Methods work also includes the development of methods for the isolation and detection of select agents in food, such as the evaluation and validation of confirmatory tests. Characteristics research involves the determination of the stability and activity of chemical agents while present in food and the potential for their inactivation (prevention or shields) during food processing. These studies on the characteristics of microbiological and chemical hazards are already having an impact in relationship to identifying intervention technologies that can be successfully implemented by different segments of the food sector.

Finally, the research plan includes radionuclide agents. The principal effort involves the development of a transportable system for radionuclide analysis in FDA-regulated foods. Specific activities include setup, calibration, testing, and the writing of supporting documentation for a transportable radionuclide analysis system for quantitative analysis of gamma emitters and qualitative analysis of alpha and beta emitters. The system will be used to augment CFSAN's and ORA's existing radio-analytical capabilities, for training, for evaluation of FDA's radiological emergency response plans, and for radiological monitoring.

CFSAN Food Defense Outreach to Industry and the Research Needs Generated. Following the conduct of vulnerability assessments with industry in FY 2004-2005 on a variety of foods regulated by the FDA, a number of research questions were generated. The commodities evaluated were dairy products, fruit juices, bottled water, water used for food processing, and infant formula. The research questions fell into the following general categories:

- Partitioning of chemical compounds into the water or lipid fractions of a food;
- Thermal stability of chemical and microbiological agents;
- Stability of chemical and microbiological agents to acidic and alkaline pH;
- Changes in food conductivity upon exposure to chemical agents;
- Ultraviolet inactivation of biological agents;
- Effectiveness of disinfection agents against chemical and biological agents;
- Oral toxicity of chemical agents; and
- Filtration to eliminate or reduce chemical and biological agents

A summary of the main research results and specific details on each project may be found at www.cfsan.fda.gov/~dms/defres05.html. This program is continuing in FY 2006 in response to additional research needs identified by different segments of the food industry.

Establishment of an Extramural Food Defense Research Program. CFSAN uses extramural grants, cooperative agreements, and contracts to further its mission-relevant research agenda. In granting these awards, CFSAN has sought projects of high scientific quality and promise that can complement the agency's existing intramural research program. By providing the talent, capabilities, and resources that the agency does not immediately possess, these projects enhance the agency's overall research effort and thus enable it to acquire the scientific knowledge and tools needed for FDA to plan and execute its regulatory efforts on a sound scientific basis.

On June 25, 2003, FDA published in the Federal Register a Request for Applications (RFA) entitled "Food Safety, Nutrition, Bioterrorism, Agricultural Research, Medical, Analytical Methods and Risk Assessment." The RFA requested applications to support collaborative research efforts and to complement and accelerate ongoing research in four project areas: (1) development and rapid analytical screening methods for the detection of pathogens that are not usually associated with food and foodborne illness at a contamination level of 100 to 10,000 microbial pathogens per gram of food without pre-growth or selective enrichment; (2) development of Polymerase Chain Reaction-based methods for rapid confirmatory identification of pathogens that are not usually associated food and foodborne illness; (3) development of rapid screening methods capable of detecting a broad range of non-traditional chemical and toxin adulterants; and (4) development of improved equipment, software, procedures, and/or methods for determining radionuclide contamination in foods. In September 2003, FDA awarded cooperative agreement research funds to augment its food safety and food defense research program. Five new grants totaling $2,828,759 were funded from the June 2003 RFA. The grants cover the full cost of the awards, which are typically for 3 years (i.e., the efforts are continuing through FY 2006).

New Research Collaboration:

- CFSAN is collaborating with NIH on a joint project to fund critical research on the thermal stability of key select agent(s) in high-risk food(s).
- CFSAN has initiated cooperative research programs with NCFST on the impact of food processing on the stability of microbiological and chemical agents in foods under conditions that would occur in commercial operations.

• CFSAN participates in the Technical Support Working Group, the U.S. national forum that identifies, prioritizes, and coordinates interagency and international research and development requirements for combating terrorism

CVM Animal Feed R&D Activities

• CVM addresses many issues through its Feed Contaminants Program and other surveillance systems for chemical and microbial hazards and adverse events.

• CVM is the sole government repository for adverse drug reactions caused by drugs and medicated feeds given to food animals and other species. A system currently exists for electronically reporting clinical signs and symptoms to a database.

• The Center has drafted a preliminary assessment of vulnerabilities in the feed industry and is integrating the results of that system into the Animal Feed Safety System.

• Compounding, illegal manufacturing, and counterfeiting of animal drugs are at an all-time high. Many of these drug ingredients come from questionable sources and enter the country identified for use as human drug products. The purity and quality of these ingredients are not tested by the pharmacies. There exists the possibility that these unapproved active pharmaceutical ingredients contain unknown toxic impurities that are deliberately or accidentally introduced.

• Real-time Polymerase Chain Reaction analysis for the detection of ruminant animal protein (BSE rule) is being developed.

• CVM's Office of Research routinely identifies bacterial isolates through molecular methods. Antibiograms are determined and genetic relatedness assessed via pulse field gel electrophoresis.

• BSE: Development of methods to detect prohibited proteins from prohibited species in animal feed (to help enforce FDA's feed ban).

• NARMS: National Antimicrobial Resistance Monitoring System (establish baseline levels).

• PulseNet: Deoxyribonucleic acid (DNA) fingerprinting of foodborne pathogens.

• Microbial Source Tracking: Identification of the animal origin of foodborne pathogens.

• Rapid Test Methods (microbiological and, possibly, chemical).

7.3.1 Planned R&D Initiatives

CFSAN Food Defense Research Initiative

During the past several years, CFSAN has mobilized and redirected a substantial portion of its research program to support the development and implementation of its food defense initiatives. However, the enormity of the scientific needs associated with implementation of an integrated national food defense program has far outstripped the FDA's limited intramural and extramural research resources. The agency has tried to address some of this shortfall by enlisting the help of its research partners, such as NIH, the USDA Cooperative State Research Education and Extension Service, and the USDA Agricultural Research Service. These agencies have been highly supportive within the context of their missions and established priorities. However, for the same reasons that FDA has always had its own research capabilities, our research collaborators are not able to meet all of FDA's research priority needs, many of which are unique to the specific mission of the agency.

Research needs in food defense fall into four broad areas, including: (1) detection methodologies; (2) prevention and mitigation technologies/strategies; (3) agent characterization in food systems; and (4) assessment of oral dose response relationships for oral transmission of chemical and microbiological agents. These categories, in turn, can be subdivided into subcategories that reflect different application foci. For example, detection methodology research can be subdivided into development of field-based screening methods, laboratory-based screening methods, laboratory-based confirmatory methods, forensic methods for criminal investigations, continuous detection technologies, and data for methods validation.

With the country's heightened concern about the potential use of foods as a vehicle for the dissemination of chemical, microbiological, and radiological agents, there has been a concerted effort during the past several years to: (1) enhance the detection capabilities of laboratories, including the development and validation of methods suitable for use with foods; and (2) ensure the availability of adequate medical countermeasures. These endeavors have been and will continue to be priority areas for the vast majority of the FDA's limited intramural and extramural research programs. However, the Nation's food defense programs are now moving into the next phase, wherein the ability to respond rapidly is being integrated with the development of strategies for preventing or deterring the use of foods as a vehicle for terrorism. There is a critical need for proactive steps, wherein validated technologies that can actively reduce food defense risks are integrated into the manufacture, distribution, and marketing of foods. Likewise, the Nation needs to be prepared with technologies that can verifiably assist the food industry in recovery if a terrorism event involving foods were to occur. For example, there is a need for validated methods for decontaminating food-processing facilities and, possibly, the remediation or disposal of large quantities of food products.

Successful implementation of this component of an integrated food defense program is dependent upon the availability of key scientific information and its application via technologies that can be applied practically both to the domestic and imported food industries.

The focus of the proposed Food Defense Research Initiative is the acquisition of scientific information and technological advances that are needed to develop effective shields to attacks on the security of the Nation's food supply. As such, the research will focus on the following areas: development of prevention and mitigation technologies/strategies; the elucidation of agent characteristics needed to develop these prevention technologies; and the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. The proposed Food Defense Research Initiative is to be conducted in three phases that represent: (1) technological assessments and critical data deficiencies that can be addressed in the short term (12 months), (2) critical knowledge deficiencies or technology applications that can be addressed with targeted R&D projects lasting 12 to 24 months, and (3) research and development that will required the elucidation of new technologies or substantial extensions of existing scientific knowledge (24 to 60 months).

The FDA Food Defense Research Initiative is planned as an integrated program that will draw on all three components of FDA research infrastructure: intramural research capabilities, collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, National Center for Natural Products Research), and an extramural research program that provides competitive research grants and contracts.

Specific examples of the priority research needs/projects are provided below.

7.3.2 Research Needs To Be Addressed Through Short-Term Research

The following items represent priority research areas that have been identified as critical to food defense programs that are already being planned for immediate implementation:

Identification of preventive controls and associated research needed by the food industry to minimize/reduce the risk of an intentional act of terrorism or contamination. The FDA, working with the Institute of Food Technologists (IFT), have identified and evaluated the relative public health consequences of a range of product-agent scenarios associated with potential tampering and terrorist activity. Currently, FDA and IFT are working together to identify preventive controls that industry could currently implement to reduce the risk for an intentional act of terrorism or contamination. While this analysis will be highly useful in the short run, the resulting report would be even more effective if it could additionally evaluate other promising technologies from an industrial standpoint. This knowledge could then be used as the basis for recommending future directions in R&D, both for the current FDA Food Defense Research Initiative and for potential initiatives proposed by the food industry. It is critical that the next generation of safeguards that will further decrease terrorism risks are identified and timely investment in these technologies be undertaken.

Food defense risk communication materials. It is universally agreed that in the event of a terrorism incident involving foods, a critical component is the ability of the Federal agencies to effectively communicate with the public, both nationally and internationally. However, the risk communication strategies currently being considered are either based on the techniques that are employed either in communicating food safety information or non-food-related incidents of terrorism, such as the contamination of mail with B. *anthracis*. Waiting until an actual incident occurs to determine which approach (if either) is effective is not an option. There is a critical need to conduct short-term communications research to determine how a threat to the food supply could be presented to the country in order to maximize transfer of the critical information needed to safeguard the public without causing panic.

Stability of ricin in foods and the impact of processing operations. Ricin is a potent protein toxin derived from the beans of the castor plant (*Ricinus communis*) that is universally recognized as a potential agent for the intentional contamination of foods. Castor beans are ubiquitous worldwide, and the toxin is fairly easily produced. As a protein, it may be possible to greatly reduce the risk associated with this toxin through the use of food-processing techniques that are known to denature proteins. However, information on the biological stability of ricin in foods is severely limited either before or after processing. Several studies suggest that ricin can be detoxified by thermal treatment; however, the information is in a form that provides little useful information to the food industry in terms of developing heating protocols to eliminate the toxin while minimizing the deleterious effects on the nutrient content. Likewise, little information is available on other potential approaches for denaturing the toxin, such as use of proteolytic enzyme treatments or alkali treatment. Acquisition of the information needed will require a two-phase approach consisting of determining an effective, but simple, measure of biological potency, and the treatment of contaminated foods under conditions that mimic possible conditions that would actually exist during the processing of key foods.

Enrichment techniques for the isolation of *Brucella* spp., *Francisella tularensis*, and *Yersinia pestis* from high-priority foods. A number of the microorganisms not traditionally associated with foodborne disease that could be used as an agent for the intentional contamination of foods have in common the ability to cause disease at very low doses. This reality, in turn, requires that our laboratories have an effective means for enriching food samples to facilitate the growth of the organism to sufficient levels, wherein rapid methods such as real-time Polymerase Chain Reaction can be employed with some degree of assurance. The challenges to the development of an effective enrichment medium are considerable, such as the inability of these microorganisms to compete effectively against the other microorganisms that are likely to be present in food samples. However, the criticality of this research to our ability to analyze high-priority foods in a timely manner cannot be overemphasized.

Development of prevention/mitigation strategies for intentional contamination of animal feed used for food-producing animals. FDA is interested in protecting/monitoring animal feed from possible terrorist threats, thereby protecting food animal health and, most importantly, public health. CVM has an animal feed mixing facility. This capability could be employed to examine potential prevention/mitigation strategies for intentional contamination of animal feed used for food-producing animals.

7.3.3 Research Needs To Be Addressed Through Intermediate-Term Research

The following research needs/programs have been identified as either promising areas in relationship to prevention/mitigation technologies or are knowledge deficiencies that have been identified as barriers to implementation of planned food defense programs.

Development of Prevention and Mitigation Technologies/Strategies

Use of shear-producing food processes to inactivate protein toxins. Fluid food products (milk, juice, and water) are typically produced and consumed with limited thermal processing. The capability of the processes used to manufacture any of these products to detoxify *C. botulinum* neurotoxin contamination may be limited. This project would investigate the effect of both hydrostatic and ultra-high shear pressure (e.g., in a homogenizer or extruder) on *C. botulinum* neurotoxin. Temperature, flow rate, and backpressure would be tested for the ultra-high shear conditions. Temperature and pressure would be tested for

the hydrostatic tests. The commercial application would be to incorporate an ultra-high shear condition in conjunction with pasteurization temperatures to inactivate *C. botulinum* neurotoxin.

Mitigation of protein toxins in foods using proteases. Decontamination of *C. botulinum* neurotoxin from surfaces such as in a plant is typically conducted using either sodium hydroxide or sodium hypochlorite solutions. Neither of these solutions can be added to a food product at the levels necessary to decontaminate the food product and still allow the food product to be usable. Protease and/or bacteria containing protease will be used to biodegrade *C. botulinum* toxin within (or on the surface of) food products. A number of proteases will be measured for their detoxification capability. In addition, different bacteria that secrete proteases will be investigated. The effect of product composition, pH, water activity, and temperature will be tested. Tests will be conducted adding the protease/bacteria both before and after traditional processing procedures. This project will identify a biodegradable alternative to traditional detoxifying practices. This approach could also be used on food contact surfaces without the issue of residuals and may have additional applications in the inactivation of infectious prions, such as those which cause BSE.

Elucidation of Agent Characteristics

Thermal resistance of microbiological agents associated with bioterrorism. The most widely used and inexpensive technology for the destruction of pathogenic microorganisms in foods is the use of thermal processing. However, successful application of the various forms of thermal processing of foods is dependent upon the availability of accurate information on the thermal resistance characteristics of the pathogens, including how food parameters such as pH and water activity influence this microbial characteristic. Likewise, biological factors, such as inducible thermal resistance systems or cross-protection resulting from the induction of other stress response mechanisms, can substantially influence the thermal resistance of a microbial species. Finally, there can be substantial variability in the thermal resistance of strains within a single species. However, there is relatively little information available about the thermal resistance of pathogenic microorganisms that have not traditionally been associated with foodborne transmission, including *B. anthracis, F. tularensis, Y. pestis, Brucella spp., B. mallei,* and *B. pseudomallei*. There is even less information available on the thermal stability of viruses that could be transmitted via foods.

Development of risk assessment tools for assessing critical control points within a food defense/safety system. The systems for the production, processing, distribution, and marketing of foods are highly complex. Determining the efficacy of different food defense programs when used in combination is highly complex and requires the integration of a variety of factors, many of which are not consistent over time (e.g., food composition, raw ingredient sources). Initial studies indicate that risk assessment modeling techniques can be highly informative if applied to food defense issues. However, an adequate assessment of the various modeling tools requires a systematic evaluation of selected examples for representative high-priority food products. Such an evaluation will significantly enhance the targeting of key food defense activities. The ultimate goal would be the development of user-friendly computer simulation tools that could be used by the food industry to evaluate the likely degree of increased security that could be achieved by different combinations of food defense strategies.

Development of a Means for Continuously Assessing Foods

Rapid assay of food samples for Americium 241 (Am-241) via gamma ray spectrometry. Am-241, an alpha-emitting radionuclide, is highly toxic when ingested, and its presence in the food supply would pose a serious public health risk. Am-241 is available in large quantities, as it is used in the manufacture of household smoke detectors and other devices, and, as such, is one of the radionuclides that is of concern in relationship to the deliberate contamination of food. Conventional techniques to determine alpha-emitting radionuclides require chemical separation of the radionuclides from the food matrix to enable direct detection of alpha particles, and, as such, are not amenable for real-time, continuous screening of foods. However, Am-241 also emits low-energy gamma rays detectable with minimal or no processing of the food sample, using a germanium diode low-energy gamma ray well detector system. This well detector system may be adaptable to in-line detectors that screen large numbers of samples for Am-241, and may be amenable to in-line applications. This technology may also be adaptable to other low-energy gamma ray-emitting radionuclides.

7.3.4 Research Needs To Be Addressed Through Longer Term Research

Development of Prevention and Mitigation Technologies/Strategies

• Use of gaseous phase antimicrobials (chlorine dioxide, acetic acid, ozone) for the treatment of shipments of fresh produce to eliminate potential intentional contamination with vegetative cells of pathogenic microorganisms.

• Use of solvent partition technologies for the removal of toxic chemicals from selected foods.

• Development of new technologies for the inactivation of vegetative cells and spores of microbial agents in dry foods and cosmetics.

• Development of methods for decontaminating food-processing facilities, retail establishments, and transportation equipment that have been exposed to microbiological, chemical, or radiological agents as a result of a terrorism incident involving foods.

• Mitigation of infectious and toxigenic microorganisms in food and food environments using bacteriocins.

• Use of intense pulsed light for the decontamination of food contact surfaces exposed to microbiological agents.

• Identification of motivating factors that influence the continued vigilance of food workers in the implementation of food defense and food safety programs.

Elucidation of Agent Characteristics

• 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 food terrorism agents.

• 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.

• Growth and survival characteristics of *B. mallei* and *B. pseudomallei* in foods.

• Characterization of the radiation resistance of *B. anthracis* spores in selected foods.

• Determination of the effects of food composition parameters on the radiation doses needed to inactivate vegetative cells of microorganisms that have potential as food terrorism agents.

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

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

• Comparison of the relative infectivity of *B. anthracis* spores versus vegetative cells for the induction of gastrointestinal anthrax.

Development of a Means for Continuously Assessing Foods

• Development of techniques for overcoming the interferences and fouling of immunologically based biosensors that occur when used in conjunction with foods containing significant levels of protein and lipids.

• Use of on-line infrared spectroscopy for the detection of minor variations in the chemical composition of foods indicative of intentional contamination.

• Use of vapor phase gas chromatography to detect the presence of volatile toxic chemicals in containers of foods at the border and during in-plant operations.

• Determination of plutonium and americium radioactivity in food samples by inductively coupled plasma mass spectrometry and alpha spectrometry.

• Development of a continuous liquid scintillation counting method for determination of gross alpha and beta radioactivity in food and its packaging on a continuous, real-time basis.

• Evaluation of continuous particle detection sensors for the detection of microscopic particles in product streams of liquid foods.

• Evaluation of potential use of automated elemental analysis and other technologies for the continuous monitoring of food product streams for the presence of toxic elements.

CVM Food Defense Research Initiative

In addition to the above, CVM has outlined the following planned R&D initiatives:

• FDA will contribute to the development of integrated databases between the DHS, HHS, and State veterinary diagnostic laboratories that will enable the quick identification of qualified laboratories that have the capability of analyzing animal tissues and/or feed for the presence of a chemical or biological agent; contact information for national experts on the disease or toxicant to obtain help in diagnosis and appropriate followup; and information on how to take, preserve, and ship an appropriate feed or animal sample to the laboratory for analysis.

• Urgent need for development of rapid test kits with validation procedures for feed contaminants.

• Enhancement of feed surveillance on imported and domestic hazards that pose the greatest risk to animal and human health by developing a risk-based system that would detect hazards before feed products are distributed.

• Enhancement of a drug-resistance surveillance system to rapidly associate illnesses that are sensitive to approved antibiotics as they relate to clusters of human diseases.

• Fostering an increase in the national capacity to manufacture animal drug products, especially in times of a national emergency, by providing alternative sources of drugs beyond the pioneer manufacturer. Enhancing the generic animal drug approval process provides multiple sources of each type of drug needed, thus ensuring an adequate supply in times of emergency.

• Increasing the number of inspections of the production of possible illegal counterfeit veterinary drugs, followup inspections of drug residue violations, and high-risk firms.

• Creating a novel academic-Federal linkage that will provide graduate-level training in public health and epidemiology for FDA employees to increase the capacity for the protection of animal and public health.

• CVM will continue close communication with stakeholders through periodic meetings, working groups, and telecommunications.

7.4 R&D Management Processes

7.4.1 R&D Management Processes and Considerations

CFSAN is developing a R&D management process called the "meeting of the minds" approach (Figure 7-1). In this approach, the CFSAN Management Council provides general direction and defines the broad needs of program offices. The program offices identify and prioritize more narrow research needs by obtaining pertinent input from all scientific personnel within their divisions and incorporating input from the support offices. At this point, the bench scientists develop options for providing solutions to the identified needs. The effort is coordinated by the Office of Science.

Figure 7-1: Research and Development Management Process

There is a need to define several important terms related to a research program when discussing business processes. For the purposes of this section, the following terms will be used:

- **Program**: Broad areas are based on current office/division organizational structure (e.g., Food Defense, Dietary Supplements, Chemical Contaminants, Microbiological Studies, etc.).
- **Project:** Broad areas more narrowly defined (e.g., Methods Development for Chemical and Botanical Identification or In Vitro Methods Development for Safety Assessment).
- **Proposals**: A general description of a proposed project, including mission relevance, objectives, the scientific approach, and budget.
- **Protocols**: A detailed description of specific experiments to achieve goals within a proposal.
- **Milestones**: Discrete points in timelines.
- **Deliverables**: Specific outcomes (e.g., technology transfer to field laboratories).

A flexible framework is needed in which to conduct research. The principal clients for CFSAN research are the program offices. The needs and concerns of other customers/stakeholders (Congress, consumers, industry, other agencies, etc.) are filtered through the offices. The current organizational structure of CFSAN can be characterized as a composite organization where line management (e.g., program and support offices) interacts with cross-cutting groups (e.g., Office of Science, Office of Food Safety, and the security staff). In such a matrix, a project manager may be a staff member within one program/support office who coordinates a project with staff from other program/support offices. The recommendations below are based on maintaining the current organizational framework.

Identifying, Prioritizing, and Approving Research

The meeting-of-the-minds approach in research management continues to be refined.

Within this framework, two sets of funds would be incorporated: a base budget for maintaining research support of current regulatory needs and a center emerging issues budget for initiating new projects. The current budget set-aside by the center for emergency issues would remain. These issues are generally short term and, by necessity, cannot undergo the extensive development, review, and initiation process that is being recommended in this document.

The base budget would be under the purview of the office directors, while the center emerging issues budget would be administered through the Office of Science. When a base budget project ends, the program office can reallocate base budget funds to support other research priorities within the office. When a center emerging issues project ends, the Office of Science can reallocate emerging issues funds on a competitive award basis.

The center emerging issues budget should be a fixed line item within the center budget and should not be dependent upon unspent (e.g., underburned full time equivalents (FTEs)) funds. The rationale for the emerging issues program is the need to anticipate what the center's regulatory needs will be 2 to 3 years in the future.

Under this scenario, there are essentially four types of research proposals:

- Proposals supported within the base resource allocation;
- Proposals supported within the base resource allocation that would have significant added value if additional resources could be provided from the emerging issues budget;
- Proposals supported within the emerging issues budget; and
- Proposals involving outside collaborations.

All proposals require pre-approval. The proposed process includes:

- A yearly update (e.g., the FY 2006 needs would be identified in the fall of FY 2004) by the program offices of the Regulatory Research Needs document. The program offices are strongly encouraged to begin early and develop a dialog with their bench scientists. Additionally, the program offices should develop a dialog with the support offices.
- The Regulatory Research Needs document serves as the basis for all research proposals submitted.
- Proposals include a description of the project, mission relevance, objectives, general scientific approach (not specific protocols), with defined milestones and deliverables and a lifetime budget. They should:
  - Have a finite time period (e.g., 3 years);
  - Include a life-time budget estimate;
  - Be submitted through line management;
  - Have cross-office collaborations that would be developed jointly, with each office identifying the resources they will provide. A lead office for administering the collaboration should be determined; and
  - Have outside collaborations submitted, with the office identifying the resources they will provide and the resources provided by the collaborator.
- The Office of Science, in conjunction with the program offices, reviews the proposals:
  - Proposals supported within an office (or offices) base allocation are subject to an external office review for the scientific merit of the proposed approach.
  - Proposals requesting support from the center emerging issues budget are subject to an external office review for final concurrence based on regulatory need (current and anticipated); assessment of its scientific approach, including identification of the necessary collaborations; and assessment of the requested resources.
- Proposals are approved in the prior fiscal year.
- Offices need to be cognizant of planning and committing to multi-year funding, where applicable.

Tracking Progress of Research and Resources

The development of an integrated, computerized system to track both resource allocation (FTEs and dollars) and research progress should be a high priority. An automated system would permit the amendment of initial resource projections in the approved proposals to actual resource allocation, permitting costs to be tracked from estimation to final expenditure.

This system must serve three functions: (1) track and report progress on research projects; (2) provide HHS with inventories (e.g., counterterrorism research portfolio, microbial food safety, biotechnology, etc.); and (3) provide stakeholders/customers with information on resource utilization and CFSAN's improvements in regulatory science. Any integrated system chosen or developed in-house should at least include fields for:

- Title of the project;
- Short description of the project (include mission relevance, objectives, and scientific approach);
- Short description of the resources allocated to the project, including identifying multi-year funding commitments; and
- List of milestones. As milestones are accomplished, a short description of how the milestone was achieved (e.g., published manuscript or report) and the amount of resources expended.

Ideally, detailed information on the resources expended will be derived from sub-components of the reporting system that is only available behind the scenes, with viewing and access-input by appropriately cleared individuals. A completely integrated system needs to be developed by a qualified contractor. FDA uses the CFSAN Automated Research Tracking System (CARTS) to track and report on research projects (see section 7.3).

The system will need to include a mechanism to account for those resources diverted from an approved research project because of an emergency. Milestones and deliverables associated with the previously approved project will also have to be adjusted.

Reviewing Merit and Progress of Research

There are two points at which a research activity is reviewed: the first review occurs before the initiation of an activity (see above) and the second review(s) occurs during the assessment of progress. CFSAN is continuing with the current line management's continual informal review of an approved activity (personnel and progress). At the same time, there is a need for an annual review of projects (not necessarily individual protocols within the projects) external to the office where the research activity is occurring. This review would be conducted through the submission of 6-month and annual reports prepared by the division or offices using the CARTS reporting function. The annual reports would be submitted to the Office of Science who will, in turn, assemble a review panel of lead scientists.

A third type of review would involve a periodic review of the CFSAN's research programs. This activity requires reviewers from outside FDA and occurs in a 5-year cycle with no more than one program per year (e.g., Food Defense, Dietary Supplements, Microbial Hazards, Chemical Hazards, Cosmetics and Colors, etc.), with each program having a set schedule. CFSAN's Food Defense Research Program was reviewed in FY 2004 by the FDA Science Council and received highly complimentary remarks.

Terminating Research Activity

A research protocol within a given research project should be terminated in one of two ways: (1) upon completion of research goals, or (2) upon the discretion of the scientist and first line management when they determine that the approach is unsuccessful.

By establishing a life-cycle approach for research projects, a revised project proposal needs to be submitted periodically (e.g., every 3 years). While the project area may be the same, this method provides an opportunity to change emphasis on specific aspects and revise milestones and deliverables.

7.4.2 Coordination of R&D With HHS and FDA Strategic Planning

FDA is represented on the HHS Research Coordination Council (RCC), which reviews and determines needs for Research, Demonstration, and Evaluation (RD&E) activities across HHS for Bioterrorism and Food Safety and other HHS priority research areas. The goal of the RCC is to define RD&E goals and approaches at each HHS agency, ensure that they match the President's and the Secretary's priorities, determine unplanned redundancies, and foster appropriate collaborations within HHS (and the broader Federal sector, where appropriate) to inform the HHS RCC and, in turn, the FY budget development process. The ultimate goal of the RCC is to direct HHS resources to where they are needed and to complete the associated activity in a timely, cost-effective, and informative manner. The process has helped inform the FY 2003-2007 HHS RD&E budget. These efforts also feed into the activities of senior FDA officials who represent FDA on the parent RCC committee. Priority activities are, in turn, represented in FDA's 2003 Strategic Plan (see www.fda.gov/oc/mcclellan/strategic.html).

The President's and the Secretary's RD&E priorities for food safety and food defense are represented under the HHS Research Coordination Council's Priority VIII: Ensuring Our Homeland is Prepared to Respond to Health Emergencies.

Theme A under this overarching priority is Research on Bioterrorism and Chemical Terrorism, which includes the Priority Research Area (sub-theme) 3—Develop scientific knowledge and technology to rapidly identify, assess, and control intentionally released biological or chemical agents in the food supply or in the environment. CFSAN has redirected about 30 percent of its research intramural program to address this RCC priority since FY 2002.

Theme B under this overarching priority is Food Safety Research, which includes 10 Priority Research Areas (sub-themes). These 10 sub-themes involve typical applied research functions (research, education, outreach) that CFSAN has traditionally been active in, such as analytical methods development, assessment and control (prevention) of hazards, risk assessment and communication, immunopathogenesis of foodborne pathogens (especially in specified circumstances or segments of the public), human behavior and its impact on food safety, the identification of the adverse health effects of environmental toxicants, the improvement of knowledge of food-associated allergens, and the development of approaches to apply and translate scientific knowledge to food safety practices.

FDA's ongoing and planned activities clearly match the themes and sub-themes of RCC Priority VIII. From the RCC activity, it is apparent that food safety and food defense activities are highly collaborative within HHS (most notably with CDC (e.g., PULSENET and FOODNET surveillance) and NIH (e.g., basic research on foodborne contaminants, especially microbial pathogens, to assist in risk assessment)) and also across the Federal sector.

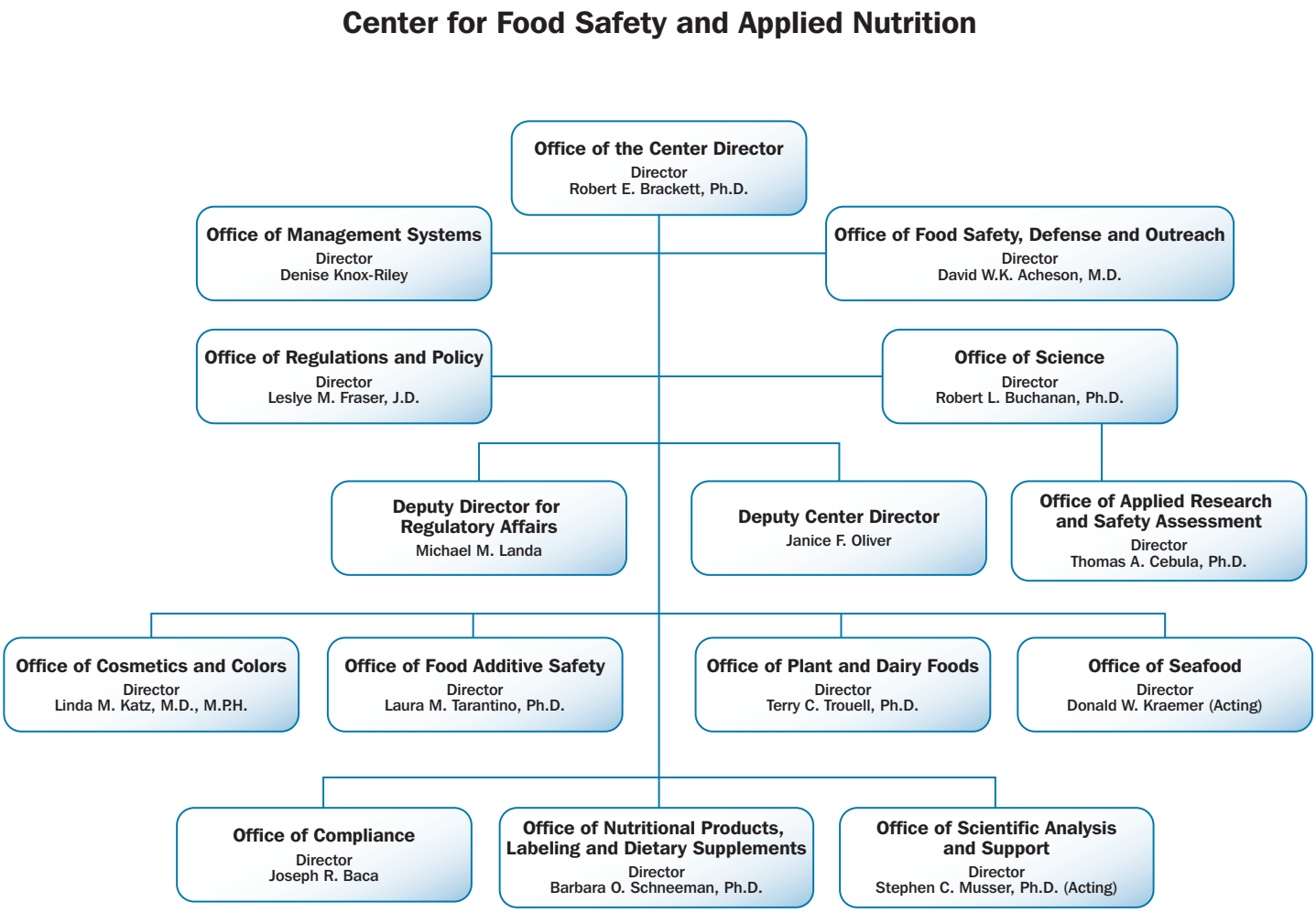
8. Managing and Coordinating SSA Responsibilities

For many CI/KR sectors, including the Food and Agriculture Sector, developing and implementing a national plan that coordinates sector protective activities is a new challenge. This section of the SSP describes many of the management and coordination activities that will be performed in order for the sector to meet this challenge. Specifically, this section will address: (1) how FDA will manage its SSA responsibilities, (2) the processes for maintaining and updating the SSP, (3) how sector annual reporting requirements related to CI/KR protection will be satisfied, (4) resources and budgets of sector security partners, (5) sector CI/KR protection training and education, (6) implementation of the sector partnership model, and (7) how information will be shared and protected.

8.1 Program Management Approach

Pursuant to HSPD-7, FDA is responsible for managing and coordinating Food (all foods with the exception of meat, poultry, and egg products) and Agriculture Sector security activities in partnership with USDA (meat, poultry, and egg products), including leading the development of an SSP for the sector. Within FDA, the SSA leadership responsibility, including developing the SSP, has been delegated to the Office of Food Safety, Defense, and Outreach (OFSDO) within CFSAN (see figure 8-1).

Figure 8-1: Office of Food Safety, Defense, and Outreach at CFSAN



In performing its responsibilities, OFSDO will work with other components within CFSAN and FDA, as well as the USDA, to reduce the possibility of an event within the Food and Agriculture Sector. Specific descriptions of many of the CI/KR protection activities have been described previously in this SSP and will be further described in the Food and Agriculture Sector Annual Report provided to the DHS.

8.2 Processes and Responsibilities

8.2.1 SSP Maintenance and Update

The SSP reflects the sector's goals and priorities. Therefore, it needs to be maintained and updated regularly. Updates to the SSP will undergo a thorough review that includes collaboration with the SCC, GCC, and other sector security partners on a triannual basis. OFSDO, which is responsible for version control of the document and is the only entity currently authorized to revise the document, will lead the SSP maintenance and triannual review. This process will be coordinated closely with USDA.

In addition to the formal biannual review, OFSDO will update the document on an as-needed basis as warranted by changes in the sector's security posture, goals, and priorities (developed on an annual basis by the sector). To ensure accuracy and to

reinforce the partnership nature of this effort, any revised versions of the SSP will be coordinated with the SCC and GCC prior to release. This process will include reviewing the frequency of updates.

8.2.2 Annual Reporting

HSPD-7, paragraph 35, requires that SSAs provide an annual report to the DHS detailing the sector's efforts "to identify, prioritize, and coordinate the protection of critical infrastructure and key resources." These sector annual reports will be used by the DHS to modify and update the National CI/KR Protection Annual Report.

OFSDO will prepare the sector annual report based on guidance provided by the DHS. Once completed, OFSDO will work with the GCC and SCC to verify the information in the document.

8.2.3 Resources and Budgets

The Food and Agriculture Sector is a diverse and complicated system. A variety of Federal, State, local, and tribal government, and private sector security partners contribute resources to the protection of the sector. No one entity has authority over resources and budgets for the entire Food and Agriculture Sector. As a result, FDA has limited information concerning how sector security partners allocate resources related to sector security, and minimal influence over how future resources should be allocated.

According to HSPD-9, FDA will continue to work with the Secretaries of Agriculture and Homeland Security, through Health and Human Services, to submit to the Director of the Office of Management and Budget, an integrated budget plan for defense of the United States food system. In addition, FDA will continue to seek information from the DHS agencies and offices regarding their budgets for food and agriculture security and defense-related programs, especially the expenditures by the DHS Science and Technology Directorate for R&D and the grants provided by the DHS Office of Grants and Training to States for preparedness programs. FDA will also continue to offer subject matter experts to serve as technical reviewers for the DHS grants related to food and agriculture, including the Centers of Excellence selection process and the review panels for State preparedness grants. In addition, FDA will continue to suggest that entities use the SCC and GCC as a forum for obtaining input and consideration for agriculture- and food-related activities.

8.2.4 Training and Education

The successful implementation of the national risk management framework relies on building and maintaining individual and organization CI/KR protection expertise. Training and education are key to achieving and sustaining such expertise. All Food and Agriculture Sector security partners at the Federal, State, tribal, and local level, as well as law enforcement and the private industry, could benefit from continued training and education.

FDA and USDA jointly developed a Web-based food defense awareness training program. This training is targeted toward other Federal agencies responsible for food defense, State and local food manufacturing and retail inspection staff, and the food industry.

In 2006, FDA in cooperation with the CDC; USDA; and State and local organizations representing food, public health, and agriculture interests announced a new food defense awareness initiative—ALERT. ALERT is an acronym that stands for Assure, Look, Employees, Reports, and Threat. It is linked to five questions designed to heighten awareness within the food sector on key food defense issues such as product security and reporting of suspicious behavior. The ALERT initiative is designed to provide a uniform and consistent approach to food defense awareness and is generic enough for use at any point in the food supply chain from farm to retail establishment. Additional information about the ALERT initiative can be found in section 5.1 and on CFSAN's Web site at www.cfsan.fda.gov/alert.

FDA has also been working with our State partners, law enforcement, and the private sector to conduct vulnerability assessments under the SPPA initiative. This initiative allows private industry to determine where the vulnerabilities are within their food system and to determine how they can address these vulnerabilities.

FDA has had the CARVER + Shock vulnerability assessment tool for several years. In order to aid the industry in conducting vulnerability assessments, FDA is developing a software-based version of CARVER + Shock that should be available for distribution in mid-2007.

FDA also has information for consumers on food tampering available on our Web site. More information on our training and education efforts can be found in sections 3 and 5 of this document.

All members of the Food and Agriculture Sector can benefit from emergency response exercises. FDA conducts internal exercises and also participates in departmental exercises, as well as intergovernmental exercises. The Food and Agriculture Sector has also hosted two tabletop exercises. These exercises have proven to be very valuable for all participants.

The Food and Agriculture Sector security partners currently support a variety of training and educational activities, including joint exercises; however, much more could be done. As part of the SSP implementation process, FDA will work with sector security partners to identify and encourage participation in additional training and educational opportunities.

8.3 Implementing the Sector Partnership Model

In section 1 of this document, there is a description of the entities that have a primary role in securing the Food and Agriculture Sector. The GCC and SCC are the overarching mechanisms for the sector partnership model. An indepth description of the GCC and SCC membership, leadership, goals, meeting frequency, and other key issues may be found in section 1.4. The incorporation of State, local, and tribal government entities into the GCC membership is also described in the section. While the aforementioned section does not explicitly address international partnerships, their interests are represented via the SCC membership in the form of multi-national firms and trade associations representing multi-national firms.

8.4 Information Sharing and Protection

8.4.1 Information Sharing

As in most partnerships, effective communication is essential to success. The GCC and SCC have acknowledged that effective communication requires two-way, routine information sharing and discussion, and they have the goal of enhancing sector communications.

To date, the SCC and GCC are the principal mechanisms for Federal, State, local, and tribal government representatives to coordinate with private sector representatives. This coordination is done via regular conference calls and in-person meetings. When analyzing how the sector security partners share information, it is important to be mindful of the expansive nature of the sector. The number of agricultural producers, food processors, and distribution and retail companies that comprise the sector presents a significant challenge to the SCC regarding communicating with all private sector businesses. To reach as many companies as possible, trade associations are encouraged to maintain membership in the SCC.

Homeland Security Information Network

As the GCC and SCC mature and are able to process and act on information, additional means of communication are necessary for ensuring real-time, robust information sharing. The GCCs and the SCCs are planning to use HSIN as the basis for communications and information sharing.

The HSIN Food and Agriculture Portal is a communications portal for use by approved private sector entities and individuals, as well as Federal, State, and local government employees. The HSIN Food and Agriculture Portal is comprised of a number of different areas or subportals that have various restrictions with respect to who can and cannot access them.

When a bona fide HSIN Food and Agriculture (HSIN-FA) user logs into HSIN-FA, they will be taken to the main or common area page. Depending upon their predetermined access rights and interests, they may obtain access to additional areas within the portal. Beyond the main page, HSIN-FA will be divided into two major areas—an SCC area and a GCC area.

The SCC area (including any subportals) shall be for the exclusive use and benefit of the private sector users. Control of the SCC area shall reside exclusively with the private sector. Any and all materials posted in or otherwise conveyed through the SCC areas will and shall remain the property of the private sector and shall under no circumstances constitute or be considered to be government information. The SCC area shall be further broken down into subportals, which shall be under the complete and exclusive jurisdiction and control of each of the respective subcouncils of the FASCC. For example, the Processor Manufacturer Subcouncil shall have control over the HSIN-FA Processor Manufacturer area(s) of the portal. Information shared and posted in the HSIN-FA Processor Manufacturer area shall remain within that portal and for users with access to that portal. The Processor Manufacturer Subcouncil may grant or restrict access from other non-processor manufacturer users as it solely and exclusively deems appropriate.

The Federal, State, and local government agencies and their affiliated users/employees shall control and maintain the GCC portion(s) of HSIN-FA. They may grant, or refuse to grant, private sector access in the sole discretion of the GCC. The GCC will create and eliminate subportals under the main GCC areas and post information to those areas as it deems appropriate.

FoodSHIELD

Food SHIELD is a highly sophisticated Web-based platform that facilitates communication, coordination, education, and training among the diverse communities that comprise the Food and Agriculture Sector. FoodSHIELD is sponsored by the National Center for Food Protection and Defense in partnership with AFDO. FoodSHIELD is comprised of two comprehensive databases designed to identify and profile the farm-to-table infrastructure responsible for protecting and defending the food supply: the Laboratory Directory of Integrated Resources (LabDIR) and the Food and Agriculture Directory of Integrated Resources (Food&AgDir). FoodSHIELD is also a primary portal to a wealth of materials on food and agriculture defense. Additional information on FoodSHIELD may be accessed at www.FoodSHIELD.org.

FBI's AgGard Program

The AgGard program is modeled after the InfraGard network (an FBI program that links citizens within the private sector; academia; and Federal, State, and local government agencies to build relationships that foster trusted communications and the exchange of information). Through a secure Web portal, members of the agricultural community are sharing information with each other and with scientists, State and local law enforcement, and the FBI. Members can pose questions and alert the FBI to any suspicious or unusual activity.

Sharing of Threat Information

Sector security partners mainly rely on the intelligence or law enforcement community as the source for threat-related information. To educate sector security partners concerning potential threats, HITRAC provides unclassified alerts, warnings, and information bulletins that are distributed via the GCC and SCC to State Homeland Security Advisors. Additionally, governmental sector partners participate in the Joint Terrorism Task Force program, where the FBI shares information with local law enforcement and other sector security partners concerning specific threat information and investigations involving terrorism (for which the FBI is the lead agency).

To further formalize the mechanism for communication of threat information and to strengthen the FBI's relationship with the Food and Agriculture Sector, FBI directed its field offices to establish formal Agroterrorism Working Groups within their

jurisdiction. These working groups will enhance the relationships between Federal partners by bringing together representatives from all entities involved in the areas of proactive prevention and awareness, intelligence, investigative response, and crisis management.

8.4.2 Information Protection

Often, the information used by FDA and sector security partners to effectively manage risk and secure the Nation's CI/KR will contain sensitive security information, sensitive business and proprietary information, or classified information. The latter is protected via Executive Order 12958 as amended under Executive Order 13292. One challenge with classifying important sector security information is the inability to share it with key sector partners at the State and private sector. While FDA, USDA, and the DHS have successfully taken classified information and put it into an unclassified format for use by sector partners, it would benefit sector security if more State and industry officials had security clearances.

Information protection is a significant concern for those security partners who share sensitive business or proprietary information that cannot be classified for protection. The Federal leadership for the sector (FDA, USDA, and the DHS) takes the need to protect this information seriously, and will do so to the maximum extent allowed by law.

Chief among the tools used by the sector to protect business sensitive or proprietary information is the DHS Protected Critical Infrastructure Information (PCII) Program. This program, known as the PCII Program, is being managed by the DHS PCII Program Office. The program was developed pursuant to the Critical Infrastructure Information Act (CIIA) of 2002, which requires a critical infrastructure information program to be created under which sensitive and proprietary critical infrastructure information submitted to the DHS—if it satisfies the requirements of the CIIA—will be protected from public disclosure to the maximum extent permitted by law.

The rules governing the PCII Program are located in 6 CFR Part 29. General information on the PCII Program, including instructions on how to properly submit information in compliance with the program, can be found on the DHS Web site at www.dhs.gov/pcii. Note that the final rule also permits submissions to the Federal SSA (in the case of the Food and Agriculture Sector, USDA or FDA).

In addition to the PCII Program, there are other regulations that may affect the privacy of data submitted to a Federal sector partner. For instance, under the Freedom of Information Act (FOIA), the public may request access to information possessed by the Federal Government. However, FOIA contains an exemption for confidential business information, and this exemption would cover much of the information submitted regarding private facility security.

Despite the PCII Program and other such information protection initiatives, many owner/operators are skeptical of the Federal Government's ability to keep sensitive proprietary business or security-related information confidential. Consequently, while some owner/operators have been willing to share information with the Federal Government, it will probably be difficult to convince all asset owner/operators to provide the desired information.

Appendix 1: List of Acronyms and Abbreviations

AAFCO	Association of American Feed Control Officials
ABI	Automated Broker Interface
ACS	Automated Commercial System
AFDO	Association of Food and Drug Officials
AFIA	American Feed Industry Association
AFSS	Animal Feed Safety System
AHI	Animal Health Institute
APHIS	Animal and Plant Health Inspection Service
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
AVMA	American Veterinary Medical Association
BARD	U.S.-Israel Binational Agricultural Research and Development
BSE	Bovine Spongiform Encephalopathy
BSL	Biological Safety Level
BT Act	Bioterrorism Act of 2002
CAERS	CFSAN Adverse Event Reporting System
CARTS	CFSAN Automated Research Tracking System
CARVER	Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability
CBP	Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CIA	Central Intelligence Agency
CIIA	Critical Infrastructure Information Act
CI/KR	Critical Infrastructure and Key Resources
CIP	Critical Infrastructure Protection
Codex	Codex Alimentarius Commission
COOP	Continuity-of-Operations Plan
CPSC	Consumer Product Safety Commission
CVM	Center for Veterinary Medicine
DFPP	Division of Food Processing and Packaging
DFSR	Division of Federal-State Relations
DHS	Department of Homeland Security
DIRM	Division of Information Resources Management
DOD	Department of Defense
DOJ	Department of Justice
DOT	Department of Transportation
EIP	Emerging Infections Program
eLEXNET	Electronic Laboratory Exchange Network
EOC	Emergency Operations Center
EON	Emergency Operations Network
EPA	Environmental Protection Agency
FACTS	Field Accomplishments and Compliance Tracking System
FAO	Food and Agriculture Organization
FAS	Foreign Agricultural Service
FBI	Federal Bureau of Investigation

FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug, and Cosmetic Act
FFRM	Food Facility Registration Module
FGIS	Federal Grain Inspection Service
FNS	Food and Nutrition Service
FOIA	Freedom of Information Act
FOUO	For Official Use Only
FR	Federal Register
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
FTE	Full Time Equivalent
GCC	Government Coordinating Council
GCSL	Gulf Coast Seafood Laboratory
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
HACCP	Hazard Analysis Critical Control Points
HHE	Health Hazard Evaluation
HHS	Department of Health and Human Services
HITRAC	Homeland Infrastructure Threat and Risk Analysis Center
HLBT	Heat-Labile Bacterial Toxins
HSBT	Heat-Stable Bacterial Toxins
HSC	Homeland Security Council
HSIN	Homeland Security Information Network
HSIN-FA	HSIN Food and Agriculture
HSPD	Homeland Security Presidential Directive
IAG	Interagency Agreement
IFT	Institute of Food Technologists
IFWG	Interagency Food Working Group
IMS	Incident Management System
ISAC	Information Sharing and Analysis Center
ISO	International Organization for Standardization
ISP	Import Strategic Plan
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
LRN	Laboratory Response Network
LSHLC	Lipid-Soluble, Heat-Labile Chemicals
LSHSC	Lipid-Soluble, Heat-Stable Chemicals
MARCS	Mission Accomplishment Regulatory Compliance System
MHRU	Microbial Hazards Research Unit
MOU	Memorandum of Understanding
NACCHO	National Association of County and City Health Officials
NALBOH	National Association of Local Boards of Health
NARMS	National Antimicrobial Resistance Monitoring System
NASAHO	National Association of State Animal Health Officials
NASDA	National Association of State Departments of Agriculture
NCFPD	National Center for Food Protection and Defense
NCFST	National Center for Food Safety and Technology
NEHA	National Environmental Health Association
NFPA	National Food Processors Association
NGFA	National Grain and Feed Association
NIH	National Institutes of Health
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NIST	National Institute of Standards and Technology
OASIS	Operational and Administrative System for Import Support
OCAC	Office of Cosmetics and Colors
OCI	Office of Criminal Investigation
OCM	Office of Crisis Management
OFSDO	Office of Food Safety, Defense, and Outreach
OPHEP	Office of Public Health Emergency Preparedness
ORA	Office of Regulatory Affairs

ORM	Operational Risk Management
OSTP	Office of Science and Technology Policy
PCII	Protected Critical Infrastructure Information
PCR	Polymerase Chain Reaction
PNSI	Prior Notice System Interface
PSL	Physical Science Laboratory
RCC	Research Coordination Council
R&D	Research and Development
RD&E	Research, Demonstration, and Evaluation
RFA	Request for Applications
RVIS	Residue Violation Information System
SCC	Sector Coordinating Council
SNL	Sandia National Laboratories
SPPA	Strategic Partnership Program Agroterrorism
SSA	Sector-Specific Agency
SSP	Sector-Specific Plan
TOPOFF	Top Officials
TRMS	Tissue Residue Monitoring System
TSWG	Technical Support Working Group
U.S.C.	United States Code
US-CERT	United States Computer Emergency Readiness Team
USDA	U.S. Department of Agriculture
VBPV	Vegetative Bacteria, Protozoa, and Viruses
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WSHSC	Water-Soluble, Heat-Stable Chemicals

Appendix 2: Authorities

FDA performs its public health duties pursuant to some of the statutory authorities listed below. This list is not exhaustive but merely illustrative of the broad authority that the agency possesses.

- Federal Import Milk Act (1927);
- Federal Food, Drug, and Cosmetic Act of 1938, as amended;
- Public Health Service Act (1944);
- Fair Packaging and Labeling Act (1966);
- Infant Formula Act of 1980, as amended;
- Nutrition Labeling and Education Act of 1990;
- Dietary Supplement Health and Education Act of 1994;
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act); and
- Other related statutes.

FDA also performs its activities under numerous directives such as Homeland Security Presidential Directives and Office of Management and Budget Directives such as OMB A-130.

FDA has many tools at its disposal for ensuring food safety and security. Among these are:

- Inspection of establishments;
- Collection and analysis of samples;
- Investigations of foodborne disease outbreaks and consumer complaints;
- Monitoring of imports;
- Traceback procedures;
- Recalls;
- Liaisons with law enforcement and intelligence agencies;
- Participation on FBI Joint Terrorism Task Forces;
- Detention without physical examination;

- Seizure of violative product;
- Targeted analysis of anticipated imports through FDA's/CBP's Prior Notice Center;
- Criminal investigative tools, including search and seizure warrants, arrest capability, prosecution, etc.;
- Pre-market review (e.g., food and color additives);
- Notification programs (e.g., food contact substances, infant formula);
- Regulations/guidance;
- Interagency and cooperative agreements (e.g., memoranda of understanding);
- Consumer studies, focus groups;
- Laboratory research to:
  - Develop/improve methods for detecting pathogens and chemical contaminants in food;
  - Determine the health effects of food contaminants;
  - Determine the effects of processing on food composition;
  - Determine the health effects of dietary factors; and
  - Investigate the factors that contribute to the virulence of biological contaminants;
- Pilot plant for food processing and packaging and biotechnology studies;
- Cooperative activities/technical assistance;
- Data collection and trend analysis;
- Stakeholder awareness through education and public meetings;
- Information and outreach activities;
- Education of consumers on food safety; and
- Emergency response and preparedness training to contain a food contamination event.

The FDA mission is mandated by the Federal Food, Drug, and Cosmetic Act (FFDCA) and includes promoting human and animal health by ensuring that human food and animal feed are safe. The FFDCA defines food to include animal feed; however, for the purposes of this document, food refers to human food and food for animals is referred to as feed. Under HSPD-7, HHS, along with USDA, is assigned oversight of the food and animal feed sector.

Other guidance and policy documents explaining FDA's authority and enforcement policies include Federal Register statements of policy and FDA Compliance Policy Guides.

Federal regulations require animal feed ingredients to be listed on the product label by their common or usual name in descending order of predominance according to weight (21 CFR 501.4). A common or usual name is one that accurately identifies or describes the basic nature of the ingredient (21 CFR 502.5). FDA has recognized the definitions as they appear in the *Official Publication of the Association of American Feed Control Officials* as the common or usual name for animal feed ingredients, including pet food (www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg665-100.html). There is only one exception to the requirement to list animal feed ingredients by their common or usual names on the label-when an ingredient is part of a collective name. Regulation 21 CFR 501.110 describes the permissible use of collective names. The following are acceptable collec-

tive names: animal protein products, forage products, grain products, plant protein products, processed grain byproducts, and roughage products. These collective names may be used in the ingredient list for livestock and poultry feeds, but not pet foods.

Authority From the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Section 303 of the Bioterrorism Act, Administrative Detention and Temporary Hold, authorizes FDA to order the administrative detention of food if an officer or qualified FDA employee finds during an inspection, examination, or investigation, credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals. This authority took effect upon enactment of the Bioterrorism Act in June 2002. FDA issued final regulations implementing the procedures for exercising this authority in May 2004. Section 303 also authorizes temporary holds at ports of entry for a period not to exceed 24 hours when FDA has credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals and FDA needs more time to inspect, examine, or investigate.

Section 304 of the Bioterrorism Act, Debarment for Repeated or Serious Food Import Violations, authorizes debarment of persons convicted of a felony for conduct related to the importation of any food or of persons who have engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

Section 305 of the Bioterrorism Act, Registration of Food Facilities, requires the owner, operator, or agent in charge of a domestic or foreign facility that manufactures, processes, packs, or holds food for consumption in the United States by humans or animals to register with FDA pursuant to this provision. The registration must contain the information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business; the general food category as identified under 21 CFR 170.3; and for foreign facilities, the name and contact information of its U.S. agent. On October 10, 2003, FDA published an interim final rule to implement these provisions, which took effect on December 12, 2003 (68 FR 58894).

Section 306 of the Bioterrorism Act, Maintenance and Inspection of Records for Foods, provides that when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food must provide access to records related to the food that are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. This section also authorizes FDA to develop regulations that require the establishment and maintenance of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. Such records are to allow for the identification of the immediate previous sources and immediate subsequent recipients of food in order to address credible threats of serious adverse health consequences or death to humans or animals. FDA issued the final regulation implementing this section on December 6, 2004.

Section 307 of the Bioterrorism Act, Prior Notice of Imported Food Shipments, requires that FDA receive Prior Notice of food imported or offered for import into the United States before the food arrives, which must include the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. On October 10, 2003, FDA published an interim final rule to implement these provisions, which took effect on December 12, 2003 (68 FR 58974). The purpose of Prior Notice is to better target efforts to monitor and inspect imported foods.

Section 308 of the Bioterrorism Act, Authority to Mark Articles Refused Admission Into the United States, authorizes FDA to require the marking of refused food (other than food required to be destroyed). Marking is to be done at owner's expense. This provision also makes food misbranded if it fails to bear the required label when FDA has found that the food presents a threat of serious adverse health consequences or death to humans and animals and FDA has notified the owner or consignee that the label is required and that the food presents such a threat.

Section 309 of the Bioterrorism Act, Prohibition Against Port Shopping, deems food adulterated if a food is offered for import that has been previously refused admission unless the person reoffering the food establishes that the article is in compliance.

Section 310 of the Bioterrorism Act, Notices to States Regarding Imported Food, requires FDA to notify States when there is credible evidence or information indicating that a shipment, or portions of a shipment, of imported food presents a threat of serious adverse health consequences or death to humans or animals. If known, the Secretary must provide notice to the States in which the food is held or will be held and to the States in which the manufacturer, packer, or distributor of the food is located. The Secretary is directed to request the State to take appropriate action to protect the public health.

Section 314 of the Bioterrorism Act, Authority to Commission Other Federal Officials to Conduct Inspections, authorizes another Federal department or agency's officers and employees to conduct examinations and investigations on FDA's behalf, pursuant to the signing of a memorandum of understanding (MOU) between FDA and the head of the other Federal agency. Under this authority, FDA and CBP entered into an MOU on December 3, 2003, which provided that CBP commissioned officers will assist FDA with examinations and investigations pursuant to the Prior Notice statutory requirements and implementing regulations at ports and other facilities/locations subject to CBP jurisdiction.

Animal Feed Regulation. FDA has focused its animal feed regulation on areas that, to date, have been recognized as playing an important role in human health. For example, medicated feed good manufacturing practice (GMP) regulations help prevent potentially unsafe drug residues in edible animal tissue, like beef and poultry, which is consumed by people. Likewise, the animal protein feed ban helps prevent the spread of BSE and the potential for variant Creutzfeldt-Jakob Disease in humans.

However, there is no comprehensive Federal regulatory program in place for ensuring that all animal feed products are safe for their intended use. While the emphasis on fostering safety has been on end-product sampling and enforcement, we are now exploring risk-based, preventive measures designed to help prevent feed-related hazards from occurring and to detect problems in feed products before they are distributed and sold.

It is important to note that each State also has its own law(s) governing animal feed. Nearly all State feed laws are based on the Association of American Feed Control Officials (AAFCO) Model Bill, which AAFCO intended for State and local authorities to adopt as their law for governing many aspects of animal feed, including safety. FDA works in harmony with the States to carry out our joint responsibilities for animal feed safety when our authority overlaps the States' authority.

FDA has regulatory authority for all feed articles that are in or intended for interstate commerce. FDA is required to inspect all medicated feed manufacturers. By regulation, FDA exempts from routine inspection firms that are manufacturing feeds not reasonably thought to pose a risk of residues that may be harmful to animals or humans.

Appendix 3: FDA/USDA Jurisdictional Overlap for Commercial Food Products

Table A3-1: FDA/USDA Jurisdictional Overlap for Commercial Food Products

Product	FDA	USDA
Red meat products	Non-specified red meats (e.g., bison, rabbit, game animals, zoo animals, elk, wapiti, moose)	Cattle, sheep, swine, goats, horses, mules, other equine
Poultry	Non-specified birds (wild turkeys, wild ducks, wild geese, emus, ratites)	Domesticated birds (chicken, turkey, ducks, geese, guineas)
Other meat products	Products containing < 3% red meat (wet) and closed-faced meat sandwiches	Products containing ≥ 3% red meat (wet) and open-faced meat sandwiches
Other poultry products	Products containing < 2% poultry (wet)	Products containing ≥ 2% poultry (wet)
Eggs	Shell eggs, products containing egg products, and other egg processing not covered by USDA (e.g., restaurants, cake mix plants, bakeries). Enforcement of shell egg labels/labeling	Pasteurized processed egg products, egg processing plants (washing, sorting, breaking, and pasteurizing)
Soup	All soup not covered by USDA	Soup containing ≥ 3% red meat or ≥ 2% poultry (e.g., chicken noodle)
Other products	Cheese, onion, mushroom, pizza, spaghetti sauces (< 3% red meat), spaghetti sauce with mushrooms and 2% meat, pork and beans, sliced egg sandwich (closed-faced), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets	Pepperoni pizza, meat lovers stuffed-crust pizza, meat sauces (≥ 3% red meat), spaghetti sauce with meatballs, open-faced roast beef sandwich, hot dogs, beef/vegetable pot pie, chicken sandwich (open-faced)
Exceptions to the above	All foods involved in an outbreak aboard an interstate vessel, plane, train, bus	

Appendix 4: Food and Agriculture Sector GCC Charter

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1. Official Designation
The official designation of this Council is the "Food and Agriculture Sector Government Coordinating Council," herein after referred to as the "GCC."

2. Authority
Homeland Security Presidential Directive-7 (HSPD-7) establishes national policy for Federal departments and agencies to identify and prioritize the United States' critical infrastructure and key resources and to guard against efforts to undermine or exploit those sector assets. Federal departments and agencies will identify, prioritize, and coordinate the protection of critical infrastructure and key resources. Federal departments will work with State, tribal, and local governments to develop a partnership with the private sector to leverage complementary resources within government and between government and industry to ensure a more robust, resilient and secure sector. These identified critical infrastructures and key resources provide the essential services for American society, disruption could cause catastrophic health effects, mass causalities, negative impacts on economic well-being, or profoundly affect our national prestige and morale. The designated Sector Specific Agencies for agriculture and food are the Department of Agriculture and the Department of Health and Human Services. In accordance with guidance provided by the Secretary of Homeland Security these agencies shall collaborate with all relevant partners to prevent, deter, and mitigate deliberate efforts to destroy, incapacitate, or exploit the sector.

3. Objective
The objective of the GCC is to provide effective coordination of agriculture and food defense strategies and activities, policy, and communication across government and between the government and the sector to support the nation's homeland security mission. In addition, the Council plays a coordination role with the public health and clinical issues resulting from a terrorist act involving the food supply. It acts as the counterpart and partner to the private industry-led Food and Agriculture Sector Coordinating Council (SCC) to plan, implement and execute sufficient and necessary sector-wide security programs for the nation's Food and Agriculture Critical Infrastructure.

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4. Scope of Activity

The GCC will accomplish this objective through the following essential activities:

- **Identifying items that need public-private coordination, and communication, coordination and communication of issues.** The GCC shall bring together diverse federal, state, local and tribal interests to identify and develop collaborative strategies that advance critical infrastructure protection (IP). While the focus is on IP, the GCC will also function during events of national emergency or significance to coordinate and share information to augment existing emergency operation channels within federal, state, local and tribal government and with industry.
- **Identifying needs/gaps in plans, programs, policies, procedures and strategies.**
- **Acknowledging and recognizing successful programs and practices.** The GCC shall facilitate the sharing of experiences, ideas, best practices, and innovative approaches related to critical infrastructure protection. The GCC shall acknowledge and recognize accomplishments that further the objective.
- **Leveraging complementary resources within government and between government and industry.**

5. Membership

The membership will be composed of key representatives and influential leaders on food and agriculture safety/defense issues from federal, state, local and tribal governments. Official members named to the Council are director-level, or equivalent, representatives from:

- Department of Homeland Security
- Department of Agriculture
- Department of Health and Human Services/Food and Drug Administration
- Department of Defense
- Environmental Protection Agency
- Association of State and Territorial Health Officials – two representatives
- National Association of State Departments of Agriculture – two representatives
- National Association of County and City Health Officials – two representatives
- National Assembly of State Chief Livestock Health Officials
- Intertribal Agriculture Council

The Council reserves the right to invite ad hoc or ex officio membership to meet expertise requirements necessary to fulfill its mission.

The Council recognizes that each member represents a government entity or organization with inherent legal authorities and parameters within which they must operate. At times, these authorities may restrict a member's ability to provide agreement on a decision. These inherent legal authorities must be clearly articulated and understood by the Council as the basis for dissent and the inability to enter into consensus.

6. Roles and Responsibilities

Leadership of the activities and meetings rests with the three main federal agencies: USDA, FDA and DHS. Day-to-day leadership of meetings and activities would rotate among these three, with detail and procedures to be developed. The lead would collect from other members and initiate or bring issues to the GCC for consideration and deliberation. They will monitor and assure initiatives or issues are brought to closure, working with other council members.

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There are 13 decision-making members of the GCC. There is one member for five federal agencies (USDA, FDA, DHS, DoD, EPA), two members each from state organizations (ASTHO, NACCHO, NASDA), one member from the state veterinarians and one tribal representative.

An alternate is assigned by each member to represent the council member during his/her absence. The alternate will have decision-making authority as designated by the member as the member deems appropriate for the issues to be presented at a meeting. Each member has the flexibility to have other representation at meetings other than the official alternates, but must clearly designate the representative's decision-making authority prior to the meeting.

The Secretariat, provided by DHS, will provide meeting and organizational support to include: coordination for agenda development, support for agency lead on monitoring and closure of issues and initiatives, administrative support, logistics (travel, meeting room facility), and will establish a communication mechanism for the GCC and with the SCC.

Ex officio members are defined as non-voting participants whose criteria and qualifications for participating will be based upon the ongoing needs for expertise and decisions by the GCC leadership. The purpose of their membership is for the GCC to gain relevant organizational and institutional representation and expertise. Ex officio members may attend all meetings and conference calls. Ex officio membership will be withdrawn, by determination of the Council, as need for ongoing expertise is no longer required.

Subject matter experts are non-voting participants drawn from any organization from which the council needs expertise on an ad hoc basis.

7. Workgroups

Workgroups are established when substantial investigation, research or other tasks are required which cannot be achieved at a regular GCC session. All products of the workgroup are meant to advise council members on various issues, directions and processes.

8. Principles of Participation

- All members must be working towards the same goal and purpose of improving the nation's agriculture and food system security.
- All members need to participate.
- Discussion and deliberations must recognize and take advantage of each members/organization's strengths, skills, and perspective.
- Result of GCC discussion and deliberations must be a coherent voice made up of each member's contributions.
- Each discussion shall be honest and forthright.

9. Number and Frequency of Meetings

The Council will meet quarterly in Washington, DC area, with additionally scheduled meetings and/or conference calls as needed.

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David Acheson, M.D.
Chief Medical Officer and Director
Office of Food Safety, Defense, and Outreach
Center for Food Safety and Applied Nutrition
Department of Health and Human Services/Food and Drug Administration

R. James Caverly
Director
Infrastructure Partnerships Division
Preparedness Directorate
Department of Homeland Security

Dr. Curt Mann
Deputy Under Secretary of Food Safety
Department of Agriculture

Robert Blake
Environmental Health Director
State of Georgia
National Association of County and City Health Officials

Robin Chapell
Health ~~Agent~~ Director
Walpole Health Department
National Association of County and City Health Officials

Ellen Embrey
Deputy Assistant Secretary of Defense
Force Health Protection/Readiness
Department of Defense

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Leah Devlin
State Health Director
North Carolina Department of Health and Human Services
Association of State and Territorial Health Officials

Jay Ellenberger
Deputy Division Director
Office of Pesticides Programs
Environmental Protection Agency

Patty Judge
Secretary
Iowa Department of Agriculture and Land Stewardship
National Association of State Departments of Agriculture

Dianne Mandernach
Health Commissioner
State of Minnesota
Association of State and Territorial Health Officials

Dr. Lee Myers
State Veterinarian
State of Georgia
National Assembly of State ~~Chief Livestock~~ Animal Health Officials

Ross Racine
Executive Director
Intertribal Agriculture Council
National Assembly of State Chief Livestock Health Officials

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ANNEX A

Meeting Management
Standard Operating Procedures

Decision Making

Quorum
A quorum for decision-making is defined as consisting of at least one representative from each of the three lead federal agencies and three state organizations: USDA, FDA, DHS, ASTHO, NACCHO, NASDA.

Process
Council members will make decisions through a consultative process, encouraging the exchange of information and points of view, and will strive for consensus. Although any member may disagree with a decision, other members will strive to understand and strive to close the gaps creating the disagreement. Dissension will be recognized and reasons clearly understood by all other members when a member absolutely cannot agree. When there is dissension, the Council may move forward and take action, nevertheless to fulfill obligations of members of the Council GCC leaders/members will strive to meet timelines and deliverables even when less than full agreement.

The Council recognizes that each member represents a government entity or organization with inherent legal authorities and parameters within which they must operate. At times, these authorities may restrict a member's ability to provide agreement on a decision. These inherent legal authorities must be clearly articulated and understood by the Council as the basis for dissent and the inability to enter into consensus.

Meeting Support
The Secretariat will:

1) Consult with designated lead agency to provide support for developing agenda, maintaining calendar for GCC and joint council meetings.
2) Provide to all members a clear and set agenda with documents and preparatory materials before the meeting, no later than one week before the meeting.
3) Compile the minutes of each meeting and send to GCC members with the leader concurrence within a week of the meeting for review and concurrence by all the members.
4) Develop processes to identify and develop issues to support Council and its leadership.
5) Maintain and follow up on catalogue of GCC topic/issues and work products and their status.
6) Develop and implement logistics of meetings, either in person or teleconference.
7) Provide other support as needed.

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Day to Day Communications
The Secretariat will maintain a list serve of Council members, which any member may use as deemed appropriate.

Meeting Governance
Discussion and deliberations must recognize and take advantage of each member's organization's strengths, skills, and perspective.

1) The lead, through the Secretariat, will canvass GCC members prior to the scheduled meeting for priorities and agenda topics.
2) The GCC will hold its discussion for set amount of time or upon agreement/closure, bringing in Subject Matter Experts as needed.
3) The lead member will ask for GCC agreement for continuation/completion/reconsideration for each agenda topic.
4) If substantial work effort is required through workgroups, the lead member will appoint a GCC member to lead the workgroup
5) A minimum of three (3) GCC members must offer subject matter experts to the workgroup.

Leadership
The GCC leadership will be held for a one-year period, on a rotating basis, starting January 1, 2006. USDA will host the leadership in 2006, followed by FDA in 2007, DHS in 2008, and will continue on same yearly rotation.

Establishing Work Groups
The Council establishes work groups:

To conduct substantial investigation, research and or development when required, which cannot be achieved by a regular session of the Council;
Which consist of representation to be determined by the scope of the topic;
By identifying a GCC member to lead to maintain continuity and consistency;
With specific and clear charge, time limit, and deliverable as part of initiating the work group;
Supported by the Secretariat as desired.

Information Sharing
The GCC is a coordination council that guides policy across Government agencies. Decisions and information discussed and shared in GCC discussions should not be distributed outside of the GCC as it may have policy implications. GCC information should not be divulged until it has been formally released.

Ex Officio Membership
The GCC agreed on July 21, 2004 to include the departments of Commerce, Interior and Justice, and the Association of Food and Drug Officials (AFDO) as ex officio members. Their membership is based on the current needs of the Council and may be withdrawn at any time at the determination of the Council.

Appendix 5: CARVER + Shock Primer

An Overview of The Carver + Shock Method For Food Sector Vulnerability Assessments[1]

Overview

The CARVER plus Shock method is an offensive targeting prioritization tool that has been adapted for use in the food sector. This tool can be used to assess the vulnerabilities within a system or infrastructure to an attack. It allows you to think like an attacker by identifying the most attractive targets for attack. By conducting such a vulnerability assessment and determining the most vulnerable points in your infrastructure, you can then focus your resources on protecting your most vulnerable points.

CARVER is an acronym for the following six attributes (discussed in further detail later) used to evaluate the attractiveness of a target for attack:

- **C**riticality - measure of public health and economic impacts of an attack
- **A**ccessibility - ability to physically access and egress from target
- **R**ecuperability - ability of system to recover from an attack
- **V**ulnerability - ease of accomplishing attack
- **E**ffect - amount of direct loss from an attack as measured by loss in production
- **R**ecognizability - ease of identifying target

In addition, the modified CARVER tool evaluates a seventh attribute, the combined health, economic, and psychological impacts of an attack, or the **SHOCK** attributes of a target.

The attractiveness of a target can then be ranked on a scale from one to ten on the basis of scales that have been developed for each of the seven attributes. Conditions that are associated with lower attractiveness (or lower vulnerability) are assigned lower values (e.g., 1 or 2), whereas, conditions associated with higher attractiveness as a target (or higher vulnerability) are assigned higher values (e.g., 9 or 10). Evaluating or scoring the various elements of the food sector infrastructure of interest for each of the CARVER-Shock attributes can help identify where within that infrastructure an attack is most likely to occur. Federal agencies, such as the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA), have used this

[1] For additional information, contact Michelle Catlin, Ph.D., FSIS/USDA, via email at michelle.catlin@fsis.usda.gov or Donald A. Kautter, Jr., CFSAN, via email at donald.kautter@fda.hhs.gov.

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.

Steps for Conducting a CARVER + Shock Analysis

Step 1 – Establishing Parameters

Before any scoring can begin, the scenarios and assumptions you wish to use in the analysis must be established in order to guide all further steps. That is, you need to answer the question of what you are trying to protect and what you are trying to protect it from. Those parameters include:

- What food supply chain you are going to assess (e.g., hot dog production versus deli meat production versus chicken nugget production, overall assessment based on generic process from farm to table versus post-slaughter processing in a specific facility, etc.);
- What is the endpoint of concern (e.g., foodborne illness and death versus economic impacts, etc.);
- What type of attacker and attack you are trying to protect against. Attackers could range from disgruntled employees to international terrorist organizations. Those different attackers have different capabilities and different goals. For example, a major assumption used by FSIS and FDA in their vulnerability assessments is that one of the goals of terrorist organizations is to cause mass mortality by adding acutely toxic agents to food products. That assumption has a major impact on the scoring of the various parts of the supply chain and the scales for the attributes (see below) have been developed with that in mind;
- What agent(s) might be used. The agent used in your scenario will impact the outcome of the assessment. Potential agents include biological, chemical or radiological agents. Different agents have different properties-potency, heat stability, pH stability, half-life, etc.-that will determine the impact of an intentional contamination incident.

Step 2 – Assembling Experts

A team of subject matter experts should be compiled to conduct the assessment. The team should consist, at a minimum, of experts in food production (specifically for the food process being evaluated), food science, toxicology, epidemiology, microbiology, medicine (human and veterinarian), radiology, and risk assessment. The team will apply the CARVER-Shock method to each element of food system infrastructure and come to a consensus on the value from 1 to 10 for each attribute, using the scenario and assumptions established in Step 1.

Step 3 – Detailing Food Supply Chain

The analysis begins by developing a description of the system under evaluation.

A graphical representation (flow chart) of the system and its subsystem, complexes, components and nodes (its smaller structural parts) should be developed to facilitate this process. For example, if you are evaluating hot dog production, the food system is hot-dog production, which can be broken down into subsystems (production of live animals subsystem, slaughter/processing subsystem, distribution subsystem). Those subsystems can be further broken down into complexes (e.g., slaughterhouse facility and processing facility) Those can be broken down into components and would include the raw materials receiving area, processing area, storage area, shipping area, etc.), and to the smallest possible nodes (e.g., individual pieces of equipment).

Step 4 – Assigning Scores

Once the infrastructure has been broken down into its smallest parts (i.e., components and nodes), these can be ranked or scored for each of the seven CARVER-Shock attributes to calculate an overall score for that node. The nodes with the higher

overall scores are those that are potentially the most vulnerable nodes (i.e., most attractive targets for an attacker). The rationale for a particular consensus score should be captured.

Step 5 – Applying What Has Been Learned

Once the critical nodes of the system have been identified, a plan should be developed to put countermeasures in place that minimize the attractiveness of the nodes as targets. Countermeasures might include enhancements to physical security, personnel security, and operational security that help to minimize aggressor access to the product or process.

Description of Attributes and Scales

The following section defines the attributes used by FDA and USDA to conduct their vulnerability assessments and provides the scales used by the agencies for scoring each attribute. These scales were developed with the mindset that mass mortality is a goal of terrorist organizations. It is important to remember, however, that any intentional food contamination could also have major psychological and economic impacts on the affected industry. Tables to assist in calculating the public health impacts and the overall CARVER + Shock scores can be found in Appendix A and B, respectively.

Criticality: A target is critical when introduction of threat agents into food at this location would have significant health or economic impact. Example metrics are:

Criticality Criteria	Scale
Loss of more than 10,000 lives OR loss of more than $100 billion	9–10
Loss of life is between 1,000 - 10,000 OR loss between $10 billion and $100 billion	7–8
Loss of life between 100 and 1000 OR loss between $1 and $10 billion	5–6
Loss of life less than 100 OR loss less than $1 billion	3–4
No loss of life OR loss less than $100 million	1–2

Accessibility: A target is accessible when an attacker can reach the target to conduct the attack and egress the target undetected. Accessibility is the openness of the target to the threat. This measure is independent of the probability of successful introduction of threat agents. Example metrics are:

Accessibility Criteria	Scale
Easily Accessible (e.g., target is outside building and no perimeter fence). Limited physical or human barriers or observation. Attacker has relatively unlimited access to the target. Attack can be carried out using medium or large volumes of contaminant without undue concern of detection. Multiple sources of information concerning the facility and the target are easily available.	9–10
Accessible (e.g., target is inside building, but in unsecured part of facility). Human observation and physical barriers limited. Attacker has access to the target for an hour or less. Attack can be carried out with moderate to large volumes of contaminant, but requires the use of stealth. Only limited specific information is available on the facility and the target.	7–8
Partially Accessible (e.g. inside building, but in a relatively unsecured, but busy, part of facility). Under constant possible human observation. Some physical barriers may be present. Contaminant must be disguised, and time limitations are significant. Only general, non-specific information is available on the facility and the target.	5–6
Hardly Accessible (e.g., inside building in a secured part of facility). Human observation and physical barriers with an established means of detection. Access generally restricted to operators or authorized persons. Contaminant must be disguised and time limitations are extreme. Limited general information available on the facility and the target.	3–4
Not Accessible. Physical barriers, alarms, and human observation. Defined means of intervention in place. Attacker can access target for less than 5 minutes with all equipment carried in pockets. No useful publicly available information concerning the target.	1–2

Recuperability: A target's recuperability is measured in the time it will take for a food system to recover productivity. The effect of a possible decrease in demand is considered in this criterion. Example metrics are:

Recuperability Criteria	Scale
> 1 year	9–10
6 months to 1 year	7–8
3–6 months	5–6
1–3 months	3–4
< 1 month	1–2

Vulnerability: A measure of the ease with which threat agents can be introduced in quantities sufficient to achieve the attacker's purpose once the target has been reached. Vulnerability is determined both by the characteristics of the target (e.g., ease of introducing agents, ability to uniformly mix agents into target) and the characteristics of the surrounding environment (ability to work unobserved, time available for introduction of agents). It is also important to consider what interventions are already in place that might thwart an attack. Example metrics are:

Vulnerability Criteria	Scale
Target characteristics allow for easy introduction of sufficient agents to achieve aim.	9–10
Target characteristics almost always allow for introduction of sufficient agents to achieve aim.	7–8
Target characteristics allow 30 to 60% probability that sufficient agents can be added to achieve aim.	5–6
Target characteristics allow moderate probability (10 to 30%) that sufficient agents can be added to achieve aim.	3–4
Target characteristics allow low probability (less than 10%) sufficient agents can be added to achieve aim.	1–2

Effect: Effect is a measure of the percentage of system productivity damaged by an attack at a single facility. Thus, effect is inversely related to the total number of facilities producing the same product. Example metrics are:

Effect Criteria	Scale
Greater than 50% of the system's production impacted	9–10
25–50% of the system's production impacted	7–8
10–25% of the system's production impacted	5–6
1–10% of the system's production impacted	3–4
Less than 1% of system's production impacted	1–2

Recognizability: A target's recognizability is the degree to which it can be identified by an attacker without confusion with other targets or components. Example metrics are:

Recognizability Criteria	Scale
The target is clearly recognizable and requires little or no training for recognition.	9–10
The target is easily recognizable and requires only a small amount of training for recognition.	7–8
The target is difficult to recognize or might be confused with other targets or target components and requires some training for recognition.	5–6
The target is difficult to recognize. It is easily confused with other targets or components and requires extensive training for recognition.	3–4
The target cannot be recognized under any conditions, except by experts.	1–2

Shock: Shock is the final attribute considered in the methodology. Shock is the combined measure of the health, psychological, and collateral national economic impacts of a successful attack on the target system. Shock is considered on a national level. The psychological impact will be increased if there are a large number of deaths or the target has historical, cultural, religious or other symbolic significance. Mass casualties are not required to achieve widespread economic loss or psychological damage. Collateral economic damage includes such items as decreased national economic activity, increased unemployment in collateral industries, etc. Psychological impact will be increased if victims are members of sensitive subpopulations such as children or the elderly.

The metrics for this criterion are:

Shock	Scale
Target has major historical, cultural, religious, or other symbolic importance. Loss of more than 10,000 lives. Major impact on sensitive subpopulations, e.g., children or elderly. National economic impact more than $100 billion.	9–10
Target has high historical, cultural, religious, or other symbolic importance. Loss of between 1,000 and 10,000 lives. Significant impact on sensitive subpopulations, e.g., children or elderly. National economic impact between $10 and $100 billion.	7–8
Target has moderate historical, cultural, religious, or other symbolic importance. Loss of life between 100 and 1,000. Moderate impact on sensitive subpopulations, e.g., children or elderly. National economic impact between $1 and $10 billion.	5–6
Target has little historical, cultural, religious, or other symbolic importance. Loss of life less than 100. Small impact on sensitive subpopulations, e.g., children or elderly. National economic impact between $100 million and $1 billion.	3–4
Target has no historical, cultural, religious, or other symbolic importance. Loss of life less than 10. No impact on sensitive subpopulations, e.g., children or elderly. National economic impact less than $100 million.	1–2

By definition, terrorists attempt to achieve strong emotional responses from their target audience. Aspects of targets that terrorists view as increasing a target's shock value are symbolism (e.g., the Pentagon), large number of casualties, sensitive nature of facilities (e.g., nuclear facilities), and the ability to strike at core values and primal emotions (e.g., targeting children).

Calculation of Final Values and Interpretation

Once the ranking on each of the attribute scales has been calculated for a given node within the food supply system, the ranking on all of the scales can then be totaled to give an overall value for that node. This should be repeated for each node within a food supply system. The overall values for all the nodes can then be compared to rank the vulnerability of the different nodes relative to each other. The summary table provided in appendix B can assist in summarizing the rankings. The nodes with the highest total rating have the highest potential vulnerability and should be the focus of countermeasure efforts.

APPENDIX A

This appendix provides a table that can be used to calculate the potential number of deaths and illnesses resulting from addition of a particular adulterant at a particular point in a given food production process. Details of the batch size to which the adulterant is added, the number of servings that will be sold and eaten from that batch, and the characteristics of the adulterant (including its lethality) must be known to use this worksheet. The numbers generated in this worksheet will help determine where on the criticality scale a given attack will fall.

CARVER + Shock Primer

Table A-1: Worksheet for Calculating Criticality

Product:								
Entry Point	Agent	A Batch Size	B Serving Size	C Servings per Batch A/B	D Dose Required per Serving	E Total Amount Required per Batch C x D	F Distribution Unit	G Units Produced A/F
H % of Units Sold Before Warning	I Units for Potential Consumption H/100 x G	J Consumers per Distribution Unit	K Number of Potential Exposures I x J	L % of Units Consumed Before Warning	M Number of Exposures K x L/100	N Morbidity/ Mortality Rate	O Number of Illnesses/ Deaths M x N	

APPENDIX B

Table B-1: Summary Sheet for totaling Scores Across CARVER + Shock Attributes

Table B-1 provides a summary sheet that can be used to total the scores across the CARVER + Shock attributes for each node. The totals can then be compared across the various nodes to determine which nodes are critical. The nodes with the highest scored are the critical nodes and should be the focus for beginning to implement countermeasures.

CARVER + Shock Primer

Table B-1: Summary Sheet for totaling Scores Across CARVER + Shock Attributes

	Overall Score									
	Shock									
	Recognizability									
	Effect									
	Vulnerability									
	Recuperability									
	Accessibility									
	Criticality									
Product:	Target (Nodes)									

APPENDIX C

Table C-1: Summary Sheet for Analysis of Individual Nodes, Including the Justification for the Score Given.

This appendix provides a table that can be used to summarize the CARVER + Shock score on each attributes for given node. The table includes a place for a brief narrative of the rational or justification for giving a node a particular score, allowing the thoughts that went into the scoring to be captured.

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Table C-1: Summary Sheet for Analysis of Individual Nodes, Including the Justification for the Score Given.

Product:		
Target Complex:		
Target Node:		
Factor	Score	Justification
Criticality		
Accessibility		
Recuperability		
Vulnerability		
Effect		
Recognizability		
Shock		
Overall		
Rank		

Appendix 6: CFSAN's Automated Research Tracking System (CARTS) List of Intramural Foods Defense Research Projects

CARTS - Search Results Screen

CARTS Home | Project List | Adv. Search | Profile Search |

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0002	The Detection and Confirmation of Protein Toxins in Foods using Mass Spectrometry	Foods Defense+	Office of Scientific Analysis and Support	01-JUL-2003	30-JUN-2006
0005	Neurotoxic Shellfish Poisoning	Foods Defense+	Office of Seafood	01-JUL-2003	30-JUN-2006
0010	Use of real-time PCR for human pathogen detection, identification, and quantification in seafoods	Foods Defense+	Office of Seafood	01-JAN-2004	30-SEP-2006
0013	Inactivation of Viral Pathogens in Molluscan Shellfish by Post Harvest Treatment Technologies Including Thermal and High Hydrostatic Pressure	Foods Defense+	Office of Seafood	01-JAN-2004	31-DEC-2006
0016	Molecular Evolution and Phylogeny of Enteric Pathogens	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2004	30-JUN-2007
0019	Isolation and Identification of Biothreat Agents in Food	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2004	30-JUN-2007
0022	Infrared (IR) microspectroscopic and pattern recognition strategies for the rapid screening of microarrayed whole-cell bacteria and bacterial genes	Foods Defense+	Office of Scientific Analysis and Support	01-OCT-2003	30-SEP-2006

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0024	Study of nisin and sublancin in a strategy for protection of the United States food supply from pathogenic bacterial spores introduced through bioterrorism	Foods Defense+	Office of Food Additive Safety	01-OCT-2003	30-JUN-2005
0034	Identification and Classification of Foodborne Bacteria and Spores by GC-FID and GC-MS	Foods Defense+	Office of Nutritional Products, Labeling and Dietary Supplements	01-JUL-2004	30-JUN-2007
0035	Sampling for Pathogens on foods: Bacterial identification using DNA Microarray analysis and infrared spectroscopy	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2007
0039	Molecular Characterization of Atypical Strains of Enterohemorrhagic Escherichia coli (EHEC)	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-SEP-2006
0045	Evaluation of Indicator Microorganisms for Indexing Viruses in Shellfish and Harvest Waters	Foods Defense+	Office of Seafood	01-JAN-2004	31-DEC-2006
0046	Detection of the presence of Bacillus anthracis and determination of its characteristics in foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2007
0047	Quantitative methodology for Listeria monocytogenes in seafood products	Foods Defense+	Office of Seafood	01-OCT-2004	30-SEP-2005
0048	Assessment of Food-related Neurotoxic Hazards: Neuro/Behavioral Toxicity	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2004	30-JUN-2007
0050	Developing methods to detect the presence of Francisella tularensis and determining its characteristics in foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2007
0051	Survival and growth of non-traditional pathogens in foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-SEP-2005
0053	Developing methods to detect the presence of Clostridium botulinum toxin in foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2007
0056	Identification and Characterization of Virulence Determinants for Vibrio Species	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2004	30-JUN-2007
0063	Rapid Detection Methods for Food- and Waterborne Pathogenic Protozoan Parasites: Strategies for Development and Application	Foods Defense+	Office of Applied Research and Safety Assessment	01-OCT-2003	30-SEP-2006
0071	Development of LCMS Negative Ion screen for the detection of counter terrorism agents	Foods Defense+	Office of Food Additive Safety	01-JUL-2004	30-SEP-2006

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0072	Thermal resistance of Yersinia sp under different environmental and physiological conditions	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-SEP-2005
0077	Application of FTA and PCR Technology for the Detection of Microbial Pathogens in Foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2004	30-SEP-2006
0081	On-Line Clostridium botulinum Bibliographic Database	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2004	30-SEP-2007
0084	Effect of variety of stress factors on the immune systems of poultry and subsequent infection of shell eggs by Salmonella enteritidis	Foods Defense+	Office of Applied Research and Safety Assessment	01-OCT-2004	30-SEP-2007
0094	Detection Methods for Paralytic Shellfish Poisoning Toxins	Foods Defense+	Office of Seafood	01-OCT-2004	30-SEP-2006
0095	Emerging Vectors for Paralytic Shellfish Poisoning	Foods Defense+	Office of Seafood	01-OCT-2004	30-SEP-2006
0100	Validation of aflatoxin M1 commercially available rapid kits in milk	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2006
0101	The Inactivation Kinetics of Clostridium botulinum Toxin in Various Liquid Foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2004	30-SEP-2005
0102	Evaluation of Two Commercially Available ELISA Kits for Detection of T-2 Toxin in Foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2006
0103	Detection of Clostridium botulinum toxin in foods using a DIG-ELISA method and enumerating C. botulinum spore levels in raw foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2004	30-SEP-2005
0109	Adaptation and Validation of Elisa Test Kits for the detection of Amanitin in Food Matrices	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2004	30-JUN-2006
0112	Detection and Identification of Foodborne Gastrointestinal Viruses	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2004	30-JUN-2007
0119	Structure and Function of the Chromosome of Enteric Pathogens	Foods Defense+	Office of Applied Research and Safety Assessment	01-OCT-2004	30-SEP-2007
0121	Assay of Abrins A, B, C, and D by gel electrophoresis and HPLC	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2004	31-DEC-2005
0127	Development of an LC/MS method for the confirmation, identification, and decomposition of tetrodotoxin and saxitoxin in food matrices	Foods Defense+	Office of Scientific Analysis and Support	01-APR-2005	31-MAR-2008

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0129	Development and Evaluation of Antibody Based Technologies for the Detection of Abrin in Food and Multiplex, Multianalyte Detection of Proteinaceous Toxins and Biomarkers	Foods Defense+	Office of Plant and Dairy Foods	01-APR-2005	30-SEP-2007
0132	Development of a method for the detection of Salmonella Typhi in foods	Foods Defense+	Office of Plant and Dairy Foods	01-APR-2005	31-MAR-2008
0133	Rapid PCR and biosensor identification methods for microbial pathogens in foods	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2005	31-DEC-2007
0134	Detection of Toxic Elements in Foods With X-Ray Tube Hand-held Analyzers	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	30-SEP-2006
0136	The Detection of Ricin in Food Matrices Using Rapid Immunology Based Assay Devices	Foods Defense+	Office of Plant and Dairy Foods	01-APR-2005	31-MAR-2008
0137	Stability of Shiga toxins 1 and 2 to acidic and alkaline pH	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2005	31-DEC-2005
0138	Deionization and filtration to eliminate or reduce biological and chemical agents in bottled water and water used for processing	Foods Defense+	Office of Scientific Analysis and Support	01-JUL-2005	31-DEC-2005
0145	Stability of saxitoxin and tetrodotoxin to acidic and alkaline pHs	Foods Defense+	Office of Seafood	01-JUL-2005	31-DEC-2005
0146	Thermal stability of saxitoxin and tetrodotoxin: parameters for inactivation	Foods Defense+	Office of Seafood	01-JUL-2005	31-DEC-2005
0148	Evaluation of a Commercial Portable Vapor Analysis System for the Rapid Determination of Volatile Chemicals That May Contaminate Foods or Food Packaging	Foods Defense+	Office of Food Additive Safety	01-APR-2005	31-DEC-2006
0150	Stability of Chemical Agents to Acidic and Alkaline Conditions	Foods Defense+	Office of Food Additive Safety	01-JUL-2005	31-DEC-2005
0155	Filtration to eliminate or reduce biological agents in bottled water and water used for processing	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0156	Effect of Toxic Chemicals on the Conductivity of Liquid Foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0158	Effect of Common Disinfection Agents on Protein/ Peptide Toxins in Water and on Surfaces	Foods Defense+	Office of Scientific Analysis and Support	01-JUL-2005	31-DEC-2005

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0159	Stability of Protein/Peptide Toxins to Acidic and Alkaline pHs	Foods Defense+	Office of Scientific Analysis and Support	01-JUL-2005	31-DEC-2005
0162	Efficacies of disinfectants on BT agents/surrogates attached to equipment and food surfaces	Foods Defense+	Office of Seafood	01-JUL-2005	31-DEC-2005
0163	Thermal Inactivation of Francisella tularensis in food matrices	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0164	Partion coefficients of amanitin, ricin and T-2 toxin in multiphase foods	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-MAR-2006
0165	Thermal Stability of Picrotoxin in Apple juice (single strength)	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0168	Evaluation of Solid Phase Microextraction (SPME)-GC-MS as a tool for the detection of volatile and semi-volatile chemicals relevant to food defense and food safety	Foods Defense+	Office of Food Additive Safety	01-JUL-2005	30-JUN-2007
0169	Thermal Stability of Ricin in a Model Food System	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0170	Partition coefficients for agents in multiple phase foods using a separator and raw milk	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0171	Thermal resistance of Yersinia pestis in orange and apple juice	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0173	Partition coefficients for staphylococcal entero-toxin in selected multiple phase foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2005	31-MAR-2006
0175	Effect of environmental factors on survival of Francisella tularensis in media and foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2005	30-SEP-2006
0177	Thermal resistance of Yersinia species related to solids levels, water activity, and fat level in foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2005	30-SEP-2007
0182	UV inactivation to eliminate or reduce Yersinia pseudotuberculosis in water and apple juice	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0183	Estimating Clostridium botulinum spore levels in raw foods	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2005	30-SEP-2006
0185	Standardization of sample preparation methods for use with the Digoxigenin-labeled Enzyme Linked Immunosorbent Assay (DIG-ELISA) for Clostridium botulinum toxin detection	Foods Defense+	Office of Plant and Dairy Foods	01-OCT-2005	30-SEP-2006

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0187	Thermal stability of Bacillus anthracis spores in juices	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0188	Chemical and Thermal Inactivation of Ricin in Food and on Food-Contact Surfaces	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2006	30-SEP-2006
0189	Potential toxicity of oral colchicine in young adult male and female rats: interactions of vehicle matrix and co-exposure to the foodborne toxin, lipopolysaccharide	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2005	31-DEC-2005
0198	Thermal Characterization of Botulinum Neurotoxin using Scanning Differential Calorimetry	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2006	30-SEP-2006
0204	Counter Terrorism Methods for Proteinaceous Toxins — Abrin	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2006	31-DEC-2008
0206	Counter Terrorism Methods for Mushroom Toxins — Amanitin	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2006	31-DEC-2008
0207	Effect of common disinfection agents on biological and chemical agents attached to equipment and foods surfaces or in water	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2005	31-DEC-2005
0208	Application of commercially available test methods to the detection of food contaminants.	Foods Defense+	Office of Food Additive Safety	01-APR-2006	30-SEP-2008
0210	Microbiological and Molecular Identification of Foodborne Bioagents	Foods Defense+	Office of Applied Research and Safety Assessment	01-APR-2006	31-MAR-2008
0214	Counter Terrorism for Proteinaceous Toxins: Ricin, C. Bot., and SEB	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2006	31-DEC-2008
0215	Counter Terrorism Methods for Fungal and Plant Toxins: T2 Toxin, Diacetoxiscirpenol (DAS), Picrotoxin, Aconitine	Foods Defense+	Office of Plant and Dairy Foods	01-JAN-2006	31-DEC-2008
0218	Multiplex PCR Assay for the identification of human pathogenic EHEC serotypes	Foods Defense+	Office of Plant and Dairy Foods	01-APR-2006	31-DEC-2006
0219	Infrared Detection of Label-Free DNA Hybridization on a Microarray Platform. Identification of Virulence Genes in Foodborne Microorganisms	Foods Defense+	Office of Scientific Analysis and Support	01-APR-2006	31-MAR-2009
0222	Detection of Staphylococcal Enterotoxin in Food Matrices Using Rapid Antigen-Capture Technology	Foods Defense+	Office of Applied Research and Safety Assessment	01-APR-2006	31-MAR-2007

Project Number	Project Title	Profile Matches	Lead Office	Start Date	Complete Date
0225	Effect of Staphylococcus Enterotoxin B on Primary Yogurt Production	Foods Defense+	Office of Applied Research and Safety Assessment	01-JUL-2006	31-MAR-2007
0227	Effect of high-pressure processing on infectious agents and protein-based toxin	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2006	31-MAR-2007
0228	Effect of dehydrated storage on the survival of Y. pseudotuberculosis, S. enterica, and E. coli	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2006	30-JUN-2007
0229	Effect of hot-fill pasteurization treatment times and temperatures used for pasteurization of juices on Clostridium botulinum neurotoxins	Foods Defense+	Office of Plant and Dairy Foods	01-JUL-2006	31-DEC-2006
0230	Development and Evaluation of Detection Methods for Tetrodotoxin	Foods Defense+	Office of Seafood	01-JUL-2006	30-JUN-2008
0231	Development and validation of improved micro-chip surface chemistries and detection techniques for more sensitive SPR detection of small (toxins) and large (bacteria/viruses) analytes	Foods Defense+	Office of Seafood	01-JUL-2006	30-JUN-2007

Appendix 7: CFSAN's CARTS List of Ongoing or Recently Completed Extramural Foods Defense Research Projects

CARTS - Search Results Screen

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Project Number	Project Title	Profile Matches	Sponsoring Office	Funding Mechanism	Award Date
0005	Development and Implementation of a Risk-Ranking Framework to Evaluate Potential High Threat Microbiological Agents, Toxins and Chemicals in Food	Foods Defense+	Office of Science	Grant / Cooperative Agreement	30-SEP-2002
0009	Heat Treatment of Bacterial Spores in Dairy Products	Foods Defense+	Office of Science	Grant / Cooperative Agreement	30-SEP-2002
0010	Protein Markers for Verifying Inactivation of TSE Agents	Foods Defense+	Office of Science	Grant / Cooperative Agreement	26-SEP-2002
0011	Development of PCR Device for Pathogen Detection	Foods Defense+	Office of Science	Grant / Cooperative Agreement	23-SEP-2003
0012	Development of Waveguide Immunoassay for Yersinia pestis	Foods Defense+	Office of Science	Grant / Cooperative Agreement	23-SEP-2003
0013	Rapid Immunoassay Silver Amplification Test System	Foods Defense+	Office of Science	Grant / Cooperative Agreement	23-SEP-2003

Project Number	Project Title	Profile Matches	Sponsoring Office	Funding Mechanism	Award Date
0014	Rapid Screening of Foods for Toxins by TLC-Bioluminescence	Foods Defense+	Office of Science	Grant / Cooperative Agreement	14-OCT-2003
0015	Rapid Food Screening for Biological Toxins on a Microchip	Foods Defense+	Office of Science	Grant / Cooperative Agreement	23-SEP-2003
0017	Development of Cell and Nanoparticle Based Sensors for BSE	Foods Defense+	Office of Science	Grant / Cooperative Agreement	30-SEP-2001
0018	Development of Viral Extraction Processing and Detection Methods for Food Commodities	Foods Defense+	Office of Science	Grant / Cooperative Agreement	01-JAN-2001
0019	Multi-Analyte Array Sensor for Food-Borne Contaminants	Foods Defense+	Office of Science	Grant / Cooperative Agreement	30-SEP-2002
0027	Optical Biosensor Technology for Food Safety	Foods Defense+	Office of the Center Director	Grant / Cooperative Agreement	30-SEP-2002
0033	Evaluation of Detection Methods for Specific Microbial Contaminants in High Priority Foods/Midwest Research Institute - Security Sensitive	Foods Defense+	Office of Applied Research and Safety Assessment	Contract	23-SEP-2002
0036	Centers for Disease Control and Prevention-Support for National Prion Disease Pathology Surveillance Center at Case Western Reserve University	Foods Defense+	Office of Science	Inter Agency Agreement (IAG)	02-SEP-2002
0044	Food Source Identification and Tracking System (FSITS)	Foods Defense+	Office of Science	Contract	30-SEP-2004
0061	Evaluation of ZeptoMark PPS system for the analysis of toxins in foods	Foods Defense+	Office of Scientific Analysis and Support	Contract	27-AUG-2004
0070	Use of NIST Reactor for Neutron Activation Analysis	Foods Defense+	Office of Plant and Dairy Foods	Inter Agency Agreement (IAG)	01-OCT-2005
0072	National Center for Food Safety and Technology	Foods Defense+	Office of Plant and Dairy Foods	Consortia Collaboration	29-SEP-2004

Homeland Security

Department of Agriculture

FDA

Food and Drug Administration