FOOD DEFENSE – COUNTERTERRORISM -- $30.074 Million

Desired Outcome

Safeguard the public by defending the food system against terrorist attacks, major disasters, or other emergencies.

Program Objectives

U.S. agriculture and food systems are vulnerable to disease, pest, or poisonous agents that occur naturally, are unintentionally introduced, or that are intentionally delivered by acts of terrorism. This system is extensive, open, and interconnected. FDA strives to provide the best protection possible against an attack on the food system, which could have catastrophic health and economic effects.

FDA, USDA's Food Safety & Inspection Service (FSIS), and the White House Homeland Security Council are implementing Homeland Security Presidential Directive-9 (HSPD-9), which established a national policy to defend the food supply from terrorist attacks. In this budget, the Administration requests $30,074,000 for FDA to implement this homeland security initiative.

The request, which continues food defense and counter-terrorism activities previously funded in FY 2005, supports the following HSPD-9 goals:

- Developing awareness and early warning capabilities to recognize threats;
- Mitigating vulnerabilities at critical production and processing nodes;
- Enhancing response and recovery procedures; and,
- Enhancing screening procedures for domestic and imported products.

Based on the Administration's priorities, this request is focused primarily on five major cross-cutting initiatives:

- Establishing a national network known as the Food Emergency Response Network (FERN) to increase analytic surge capacity in the event of terrorist attack by developing adequate laboratory testing capacity for biological, chemical and radiological threats;
- Targeted food defense research efforts, including prevention technologies, methods development, determination of infectious dose for certain agents when ingested with food, and agent characteristics within specified foods;
- More effective targeted risk-based inspections using data from FDA's Prior-Notice system as authorized in the 2002 BT Act;
- Improved coordination and integration of existing food surveillance capabilities with the Department of Homeland Security's (DHS) integration and analysis function, as part of the government-wide Bio-Surveillance Initiative; and,
- Upgrading Crisis/Incident Management capabilities.

Requested Increases for FY 2006
(Dollars in $000)

Program	Center	Field	Total
CFSAN	4,822		4,822
Field/ORA		22,752	22,752
Other Activities	1,500		1,500
NCTR	1,000		1,000
Total	7,322	22,752	30,074

Lab Preparedness

FERN--$20.0 million
FERN, which is managed by ORA, is a multiyear effort to establish a comprehensive network of Federal and state laboratories across the U.S. that will enable FDA to test thousands of food samples within a matter of days in the event of an act of terrorism or other emergency.

The requested increase, in conjunction with base funding, will provide an additional 19 FDA-funded state laboratories, adding to the six that were funded in 2005 and to the 10 FDA laboratories that are already up and running. Currently, 93 labs in 42 states and Puerto Rico have satisfactorily completed the FERN Laboratory Qualification Checklist, which provides vital information to determine if a lab meets the criteria for participation in FERN and is eligible for Federal funding (see map at the conclusion of this section).

These funds will also permit FERN's National Program Office to manage the laboratory response in the event of a food related emergency and coordinate the FERN support programs which provide validated food testing methods, proficiency testing for laboratories, electronic communications, and training programs for laboratory personnel.

FERN, developed in accordance with HSPD-9, integrates the nation's laboratory infrastructure to detect and identify biological, chemical or radiological threat agents in food at the local, state, and Federal levels. Its primary objectives include prevention (Federal and state surveillance sampling programs); preparedness (strengthen laboratory capacity and capabilities); response (surge capacity to handle terrorist attacks or a national emergency involving the food supply); and, recovery (support recalls, seizures, and disposal of contaminated food to restore confidence in the food supply). FERN resources are leveraged by collaborating and coordinating with other lab networks including the Laboratory Response Network (LRN) and the National Animal Health Laboratory Network.

Food Defense Research--$5.574 million

This applied and targeted research initiative addresses the significant need for research funding to ensure our ability to detect or inactivate a broad range of agents that could pose serious threats to the food supply. These funds will:

- expand and accelerate the food defense research plan by identifying additional agent/commodity combinations which will effect the relevant food defense research thrusts of methods development, agent characteristics, prevention technologies, and dose-response relationships;

- provide the required base support from FDA for the microbial forensics program that the Interagency Agreement with the DHS/National Biodefense Analysis and Countermeasures Center specifies; and,

- help to maintain the foods defense research enterprise infrastructure (equipment maintenance and repair, BSL-3 labs, select agent inspections, animal care inspections, and LRN labs).

In the food defense area, mission-critical knowledge gaps are addressed through an integrated portfolio of intramural, extramural, and consortia-based programs, which address the need to anticipate, prevent, detect, respond, and recover from a terrorist attack on the food supply. This requires research activities in:

- knowledge of the behavior and susceptibility of the population to microbiological, chemical, radiological, and biologically-derived toxic agents in priority vulnerable foods during the stages of production, distribution, marketing, and preparation;

- identification and/or development of new techniques for "shielding" priority vulnerable foods through the development of new prevention and/or security technologies;

- development of enhanced sampling and detection methods for priority agents in vulnerable foods including field deployable and in-line sensor-based screening, analytical, and investigational (forensic) technologies;

- development of effective methods for ensuring that critical food production and manufacturing infrastructure can be rapidly and effectively decontaminated if a terrorism event were to occur;

- assessments of vulnerabilities of foods and identifying areas where enhancements in preventive measures could increase the security of the food supply, and,

- knowledge of consumer behaviors and the critical role consumers play in preventing illness associated with an attack on the food supply, to ensure timely and relevant information about threats and/or an attack is understood by consumers.

The mission critical needs require that the research not stop at the generation of new knowledge and technologies, but also include the validation of those approaches under realistic conditions that reflect the diversity of the food industry, and the transfer of that technology to the appropriate sectors of the food industry.

<u>Crisis Management: Emergency Operations Network Project and Incident Management System--$1.5 million</u>

The request also supports the Emergency Operations Network/Incident Management System Project to provide

a comprehensive system for managing emergencies and related incidents in FDA's centers and field offices. The development of this system conforms to HSPD-5, "Management of Domestic Incidents", and the establishment of a National Incident Management System.

The Emergency Operations Network Incident Management System (EON IMS), managed by the FDA Office of Crisis Management, is the central hub for exchanging and relaying all emergency-related information into, within, and outside of FDA. One of its overarching objectives is to integrate multiple data streams from other electronic systems – such as the FERN, eLEXNET, Epidemic Information Exchange (EPI-X), and from FDA laboratories/investigators and external agencies -- into a coherent fashion during critical decision points. This improved information management will create a safety net that significantly reduces the probability that terrorists will achieve their aims and minimize the impact of these threats if they occur. The EON IMS is important in all emergencies and exercises requiring efficient receipt and dissemination of large volumes of information to our stakeholders, including the public and other federal and state agencies. This system will provide a web-based connection for all FDA offices and our partners, through which accurate real-time information about various incidents can be shared and discussed.

The EON IMS, which is critical for the agency to manage, plan for, and respond to emergency situations, has three components: incident tracking and contact management, a collaboration and knowledge management tool for meetings and document management, and a Geographic Information System (GIS) for mapping and impact assessment.

By developing and incorporating agency-wide guidance in the EON IMS, FDA will ensure that its emergency response is uniform, consistent, and coordinated. Participants coordinating an emergency will be able to provide input and access real-time data regarding a specific emergency, Agency operating plans and procedures, contact databases, and analysis tools which will enhance the agency's capability of responding in the most efficient way possible.

For example, during a hurricane, EON IMS would provide a central location for FDA to disseminate real-time information about the storm. Using the GIS module, we will be able to view the locations of FDA regulated firms that have been severely impacted by the storm's path. That data can then be used by FDA to implement a targeted assessment and response of those industries that would have been the most severely impacted by the storm. Forecast advisories, health-related statistics, and other facts would be posted in the incident records for all users to view. Emergency contact information would be available for FDA representatives throughout the agency, including temporary information for those individuals deployed as part of an on-site response. These contacts would be sorted by their respective office or program area, and allow coordinators to track down experts as needed.

The EON IMS also provides a system for incident management to strenghthen preparedness capabilities of FDA. The

system will also be used during emergency preparedness and response exercises, establishing vital links with federal, state and local partners in accordance with HSPD-8, "National Preparedness."

In 2004, several outbreaks of Salmonellosis associated with Roma tomatoes affected approximately 400 people in over 15 states. FDA traceback and farm investigations with CDC and the respective state and local public health and agriculture agencies were coordinated by the FDA using a pilot version of EON. It was used to manage and create tools for the investigation, including a map of locations for the onsite investigations, a contact list of investigation participants, and a log of significant investigation activities. As demonstrated during this outbreak, the EON will be used to manage the large volume of incident related information and disseminate that information to interested stakeholders in an efficient manner.

Biosurveillance/NBIS--$3.0 million

The DHS is leading the development of the National Biosurveillance Integration System (NBIS), which is intended to integrate systems that monitor health, environment, and intelligence information in order to provide early detection of threats, guided responses to events, and information sharing among agencies. eLEXNET and FERN data capture system, have been identified as a food sector specific surveillance and detection system that is a candidate system to participate in NBIS. FDA's ORA will contribute to the Administration's Bio-Surveillance Initiative by developing nationally recognized standards for data messaging and communication in the health area and by establishing the appropriate connectivity with the NBIS.

Import Field Exams and New Prior-Notice Security Review Performance Goals – Redirection of Base Resources to Risk-based Prior-Notice Security Reviews

FDA is taking advantage of the capabilities developed by the Prior-Notice Center (PNC) that was established under the BT Act of 2002. The PNC will additively complement existing efforts applied to import exams. The risk based model developed by this center is being used to identify high-risk food imports based on available intelligence and information gained from Prior-Notice requirements that collectively will enable FDA to identify and interdict suspect products.

The events of September 11th heightened the nation's awareness of security and placed a renewed emphasis on ensuring the safety of the food supply. Import food field exams, along with laboratory analyses, were FDA's major tool to physically monitor imports prior to the BT Act. Under this approach, FDA steadily increased the number of import field exams from 12,000 in FY 2001 to a target of 60,000 per year in 2004.

FDA has become aware that import field exams are not singularly the most effective approach to ensure import safety. The BT Act, which established Prior-Notice requirements, provided FDA with an additional tool to assess the risks of imported food and improve the focus of import food risk assessment. These new Prior-Notice Import Security

Reviews are just one example of the expanded targeting and follow through on potentially high risk import entries that FDA is developing to complement the import field exam.

The PNC receives and evaluates notices of imported foods prior to their arrival at our borders. These notices describe what each shipment contains and provides additional information, such as country of origin, so that FDA is better situated to know what products are entering, whether they are of concern and if so, to direct inspectors to conduct an examination at the port. The PNC operates side-by-side with the intelligence arm of the Customs and Border Protection to integrate and supplement this information.

Once an item is targeted, a security review is conducted. The PNC will receive feedback from import field exams and filer evaluations and begin targeting those firms that continuously violate the law. In addition, broader surveillance of products imported from countries considered to be at a higher risk for terrorist activities can be incorporated into targeting goals. Strategies used to ensure effective targeting will include:

- Intelligence regarding countries, commodities, and information specific to shipment or shipping entities;
- Information gleaned from Foreign and Domestic Establishment Inspection Reports that identify security breaches**;**
- Sample collection and analysis for counterterrorism; and,
- Prior-Notice discrepancies reported during import field exams.

By prioritizing some resources from field import exams to Prior-Notice Security reviews in FY 2006, FDA will implement a better tool to protect the food supply. As shown below, even with this redirection, the number of imported food entry reviews would remain roughly the same as our previous FY 2006 target. FDA believes this new system, which complements the field food exams, provides for risk based targeting and follow through on potentially high risk import entries. We believe this system places FDA in a better position to keep up with rising import volume.

Performance goal	**FY 05 target under previous system**	**FY 05 Target in New Risk-Based System**	**FY 06 Target in New Risk-Based System**
Import Field Exams	97,000	60,000	60,000
Prior-Notice Security Reviews	--	38,000	38,000

Why is FDA's Contribution so Important?

The Administration has designated the food supply as part of the nation's critical infrastructure. An attack on the food supply could pose severe public health and economic impacts, while damaging the public's confidence in the food we eat. FDA is making progress on many fronts, such as working with industry as well as state and local

food we eat. FDA is making progress on many fronts, such as working with industry as well as state and local governments, to provide sound guidance on food defense and conducting its own threat assessments.

Consequences of Not Achieving the Objective

The events of September 11th heightened the nation's awareness and placed a renewed focus on ensuring the protection of the nation's critical infrastructures. Several food incidents since the Fall 2001 highlight the significance of FDA's food security activities.

On February 27, 2004, the Office of Criminal Investigations was advised by FDA Emergency Operations of a tampering and extortion complaint received in Cincinnati, Ohio. A British citizen was convicted of trying to extort $180,000 from a Supermarket chain by threatening to place contaminated baby food on store shelves.

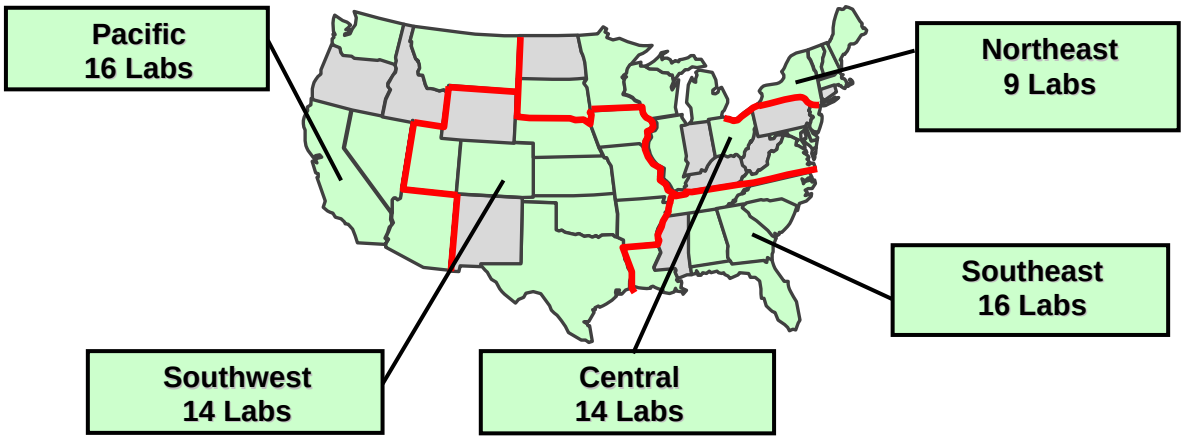
PNC collaborated with CBP in FY 2004 to direct field personnel to hold and examine 20 suspect shipments of imported food. In addition, the PNC responded to 20,430 inquiries and conducted 33,111 intensive reviews of prior notice submissions in order to intercept contaminated products before entering the domestic food supply.

As a result of new threats to the food supply, FDA has made fundamental changes in how we implement our mission of protecting our food supply, so that all Americans can have confidence that their foods are not only safe but also secure. In these efforts, the FDA and the USDA's FSIS will continue to work with the White House Homeland Security Council, DHS, and other federal agencies to further enhance our ability to detect, deter, and respond to an attack on our food supply.

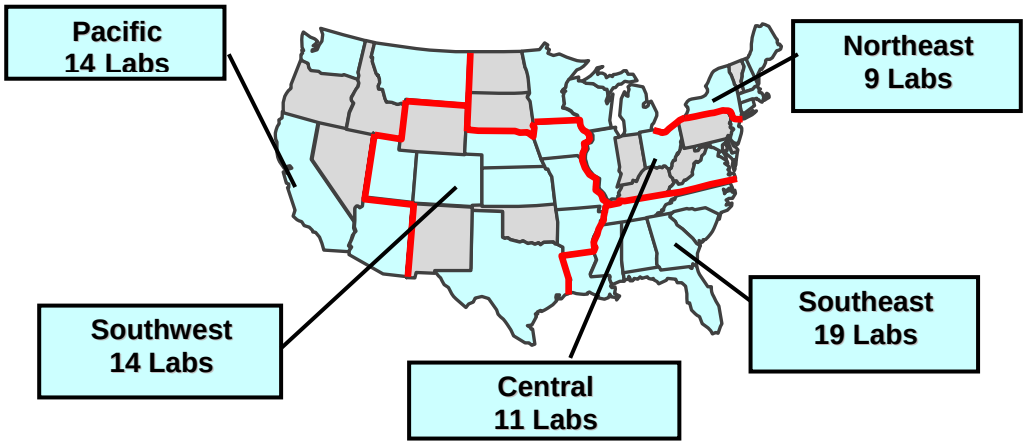
In FY 2006, FDA expects to expend $180,026,000 on Food Defense.

Food Emergency Response Network (FERN)

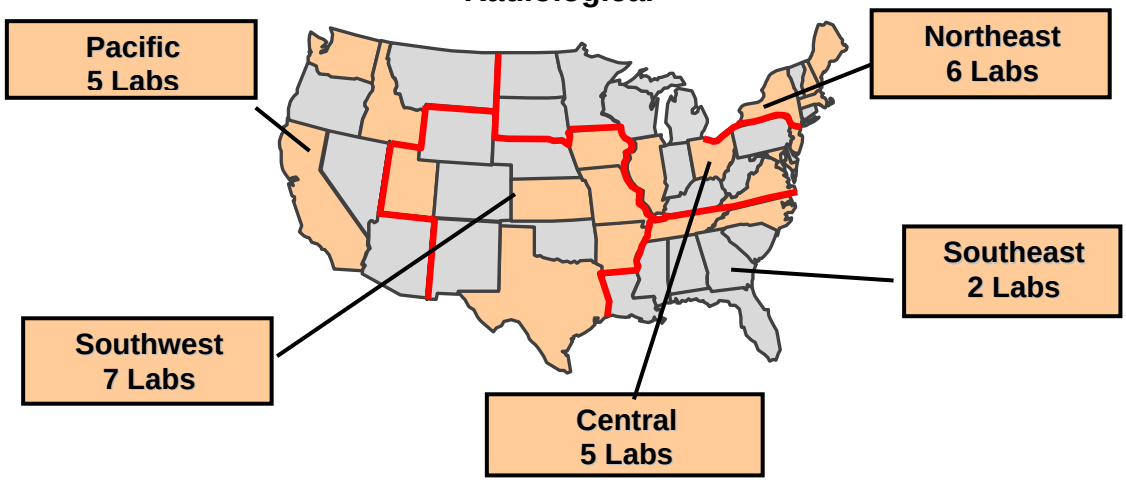
Microbiological



Chemical



Radiological



NOTE: Total lab numbers reflect laboratory capabilities for microbiological, chemical, and radiological analysis rather than actual laboratory locations because some laboratories will have capability to analyze samples for several types of agents at one location.