



**Testimony  
Before the Subcommittee on Emerging Threats,  
Cybersecurity, and Science and Technology**

**Committee on Homeland Security**

**United States House of Representatives**

**“Federal Efforts to Mitigate Vulnerabilities in the Food  
Supply Chain”**

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**Statement of  
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## **INTRODUCTION**

Good afternoon, Chairman Langevin and Members of the Subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the Food and Drug Administration (FDA or the Agency) which is part of the Department of Health and Human Services (HHS or the Department). I am pleased to be here today with my colleagues from the Department of Homeland Security (DHS) and the Department of Agriculture (USDA). FDA appreciates the opportunity to discuss our food defense activities.

A great deal has been done in the past few years to enhance the safety and defense of the food supply in the United States. FDA has worked with other Federal, state, local, and tribal food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry to significantly strengthen the nation's food safety and defense system across the entire distribution chain, from farm to table, to better protect our food supply against deliberate and accidental threats. This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. The Office of Management and Budget and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in the Government Accountability Office's designation of Federal oversight of food safety as a high-risk item in February 2007.

Food safety and food defense continue to be top priorities for this Administration. A terrorist attack on the food supply could have both severe public health and economic consequences, while damaging the public's confidence in the food we eat. The changes in food defense that we have been implementing in the last few years are fundamental enhancements.

The Commissioner of Food and Drugs, Dr. Andrew von Eschenbach, recently appointed me to the new position of Assistant Commissioner for Food Protection. My first priority in this position is to develop a new strategy for the integration of food safety and food defense that will address changes in the global food safety and food defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the risks posed by the types of foods we regulate and that focuses on prevention, ensures compliance with preventive controls, and rapidly responds when contaminated food or feed is detected, or when there is possible risk to humans or animals.

In my testimony today, I will first briefly describe HHS' role in counterterrorism activities. Then, I will discuss our collaborative activities with our food safety and defense partners. I will also describe some of FDA's food defense activities to enhance protection of the food supply.

## **HHS' ROLE IN FOOD-RELATED COUNTERTERRORISM ACTIVITIES**

Under the President's National Response Plan, HHS leads Federal public health activities to ensure an integrated and focused national effort to anticipate and respond to biological weapons, emerging diseases, and other threats. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the State and local medical and public health response to mass casualty events.

FDA is the Federal agency that regulates all of the food we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA also is responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as veterinary drugs are safe and effective and that cosmetics are safe.

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. While performing our mission, we play a central and a leadership role in the nation's defense against terrorism. First, terrorists could use an FDA-regulated product, such as food, as a vehicle to introduce biological, chemical, or radiological agents into the U.S. stream of commerce. Second, FDA-regulated products, such as human drugs, vaccines, tissues, blood, blood products, and medical devices, as well as veterinary drugs, will play a central role in preventing or responding to human and/or animal health concerns created by an act of

terrorism. It is HHS's goal, with FDA working closely with other HHS agencies and other Federal agencies, and with State, local, and tribal governments, industry, and the public, to reduce the likelihood that an FDA-regulated product could be used to poison or otherwise harm Americans. We also help ensure that the nation's public health system is prepared to deter a potential threat and is ready to respond to an act of terrorism.

By way of background, although FDA has the lead responsibility within HHS for ensuring the safety of food products, the Centers for Disease Control and Prevention (CDC) has an important complementary public health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the U.S. attributable to the entire food supply. The disease surveillance systems coordinated by CDC provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness.

## **COLLABORATION WITH FOOD SAFETY AND FOOD DEFENSE PARTNERS**

In its food safety and defense efforts, FDA has many partners – Federal, State, local, and tribal agencies, academia, and industry. FDA is working closely with our Federal partners such as USDA, DHS, the Homeland Security Council at the White House, the Department of State, the Central Intelligence Agency (CIA), and the Federal Bureau of Investigation (FBI) to have the best information possible and to be prepared to act as needed. I also want to emphasize FDA's close working relationships with its sister public health agency, CDC, with Customs and Border Protection (CBP) in DHS, and with USDA's Food Safety and Inspection Service (FSIS). Some of our many Federal partners

include USDA's Animal and Plant Health Inspection Service (APHIS), USDA's Foreign Agriculture Service, USDA's Agricultural Research Service, USDA's Food and Nutrition Service, Department of the Army Veterinary Services Activity, the Environmental Protection Agency (EPA), and the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau.

FDA's activities in a public health emergency are coordinated through the HHS Secretary's Operations Center. This relationship facilitates communication among all HHS Operating Divisions, the Department, and other Federal agencies and departments, including DHS. FDA also has worked closely with the Interagency Food Working Group of the White House Homeland Security Council on three initiatives – development of a national network of food laboratories, identification of vulnerabilities and subsequent mitigations for commodities of concern, and the development of a national incident management system. Further, FDA worked in partnership with EPA, USDA, DHS, and the Department of Defense (DoD) to describe general Federal roles and responsibilities for decontamination and disposal in response to animals, crop, and food incidents.

In addition, FDA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies as well as the intelligence community so that it can receive and act on any information regarding the intentional contamination of FDA-regulated products. OCI has a specialized counterterrorism staff with the clearances, capabilities, and backgrounds to analyze information from law enforcement and intelligence community agencies and to assist

those agencies in conducting terrorism-related threat assessments involving FDA-regulated products. OCI has agents assigned to selected FBI Terrorism Task Forces throughout the United States.

FDA is working closely with DHS and other Federal agencies to implement the President's Homeland Security Presidential Directives (HSPDs). The Secretary of DHS is responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the nation, including food and agriculture defense. The President has issued HSPD-7,-8, and-9, which identify critical infrastructures, improve response planning, and establish a national policy to defend the agriculture and food systems against terrorist attacks, major disasters, and other emergencies. Among other things, HSPD-9 calls for the development of a National Veterinary Stockpile (NVS). FDA and CDC participate in NVS Steering Committee activities.

The HHS and USDA Secretaries or their designees exercise key responsibilities as food sector-specific agencies. DHS serves as the coordinator of the Food and Agriculture Sector within the Government Coordination Council (GCC). The GCC is charged with coordinating agriculture and food defense strategies, activities, and communication across government and between the government and the private sector partners.

Within the GCC, HHS and USDA serve as co-leads for the food sector, and USDA serves as the lead for the agriculture sector. The Food and Agriculture Sector is a public-

private partnership that combines expertise from several Federal agencies (FDA, USDA, EPA, DoD, Department of Commerce, Department of the Interior, and the Department of Justice) as well as that of state, local, and tribal officials (representing agriculture, public health, and veterinary services), and the private sector (more than 100 trade associations and individual firms participate). As part of the HSPD-7 National Infrastructure Protection Plan (NIPP) development, FDA and USDA developed sector-specific plans with input from states and the private sector. DHS recently released the sector specific plans. With the close working relationship of FDA and USDA and the other government and industry collaborators, the Food and Agriculture Sector activities to protect critical infrastructure have set the organizational and operational standard for other critical infrastructure sectors. DHS has applauded the Food and Agriculture Sector's organizational structure, consensus building, and the steps it has taken to improve food defense.

FDA also is working closely with our state partners to enhance food defense. For example, earlier this year, FDA conducted a Food Defense Surveillance Assignment for FDA and USDA personnel and participating state and local authorities to conduct food defense-related inspections and reconciliation examinations (to verify the accuracy of declarations in the shipping documents by comparing them with the actual products) and to collect and analyze samples of food products that may have an elevated risk for intentional contamination. The activities in this exercise were planned in cooperation and collaboration with USDA and a number of organizations representing state and local interests including the Association of American Feed Control Officials, Association of

Food and Drug Officials, Association of Public Health Laboratories, Association of State and Territorial Health Officials, National Association of County and City Health Officials, National Association of Local Boards of Health, National Association of State Departments of Agriculture, National Environmental Health Association, and United States Animal Health Association. The purpose of this assignment was to deter intentional contamination of food through heightened and targeted preventive activities at various points in the food supply and to test the system for responding to an increased risk from food so that gaps in the system can be identified and addressed. This assignment enhanced multiple Federal, state, and local government agencies' preparedness for a future threat involving an FDA-regulated product. Since that time, FDA has issued a Protein Surveillance Assignment (PSA) to increase food defense awareness and assess the safety of the human food and animal feed supply following the finding of contaminated vegetable protein concentrate coming into the country from China. FDA continues to further integrate our food defense activities into our food safety work.

In addition, FDA and CDC have collaborated with the Council of Association Presidents to develop a nationwide food defense awareness training program. This Council, which consists of ten of the major state and local public health and regulatory professional associations, has an outreach capability to reach virtually all state and local public health officials. The training program, which began in March 2006 with a satellite downlink nationwide broadcast, has helped to raise food defense awareness at the local, state, and

Federal levels. This program is now available for streaming download on the website of FDA's Center for Food Safety and Applied Nutrition.

Now, I would like to describe some of FDA's other food defense activities.

## **INDUSTRY GUIDANCE AND PREVENTIVE MEASURES**

This year, FDA, in cooperation with CDC, USDA, and state and local organizations representing food, public health, and agriculture interests, initiated the ALERT awareness program. It provides a uniform and consistent approach to food defense awareness at any point in the supply chain, from farm to retail establishment.

ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility: They are:

- **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 who do you notify if you have a THREAT or issue at your facility, including suspicious behavior?

We have prepared ALERT materials in several languages and offer training on the ALERT system on our website that is suitable for state, local, and industry stakeholders.

In 2003, FDA issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. FDA issued a general guidance entitled “Food Producers, Processors, and Transporters: Food Security Preventive Measures.” The guidance is designed as an aid to firms that produce, process, store, re-pack, re-label, distribute or transport food or food ingredients. In addition, we have issued specific security guidance for the milk industry, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. During domestic inspections and import examinations, FDA’s field personnel, as well as our state counterparts, continue to hand out and discuss these guidance documents.

To help reduce the risk of an attack on the food supply, FDA and our partners at USDA developed a web-based food security awareness training program entitled, “Protecting the Food Supply from Intentional Adulteration: An Introductory Training Session to Raise Awareness.” The training is directed at individuals who play an important role in defending our nation’s food from attack: Federal, state, local, and tribal food-industry regulators; school food authorities; and nutrition assistance program operators and administrators. Representatives from the food industry and individuals essential in responding to a food emergency due to an intentional attack – such as law enforcement,

public health, and homeland security officials – also are encouraged to participate in the training program. The program is available to any interested individuals free of charge.

## **VULNERABILITY AND THREAT ASSESSMENTS**

FDA's risk-based approach to food defense helps the Agency determine where to focus its resources. As part of its efforts to anticipate threats to the food supply, FDA has conducted extensive scientific vulnerability assessments of different categories of food, determining the most serious risks of intentional contamination with different biological or chemical agents during various stages of food production and distribution. FDA's initial assessment utilized an analytical framework called Operational Risk Management (ORM) that considers both the severity of the public health impact and the likelihood of such an event taking place. As part of this process, FDA has incorporated threat information received from the intelligence community.

To validate our findings, FDA contracted with the Institute of Food Technologists to conduct an in-depth review of ORM and provide a critique of its application to food security. This review validated FDA's vulnerability assessment and provided additional information on the public health consequences of a range of scenarios involving various products, agents, and processes.

The ORM approach provided a high-level view of foods and agents that were of greatest concern. Since the completion of the ORM, FDA has undertaken more in-depth vulnerability assessments of specific food commodities using a method called

CARVER+Shock. This method uses processes adapted from techniques developed by DoD for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments are being used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector.

In 2003, FDA began using the CARVER+Shock analytical tool to perform vulnerability assessments to identify what an individual or group, intent on doing damage to the food and agriculture sector, could potentially do based on the person's or group's capability, intent, and past history. The CARVER+Shock methodology was modified under Homeland Security Council leadership for use in the food and agriculture sector by FDA, USDA, and DoD with coordination by DHS, CIA, and FBI. FDA's approach has been to seek voluntary, mutually beneficial partnerships with various segments of the food industry. We have completed such cooperative assessments with segments of the regulated industry that involve bottled water, fluid dairy products, juice products, and infant formula. FDA also has collaborated with USDA to provide assistance to the USDA Food and Nutrition Service on the use of this analytical tool on specific commodities in the school lunch program.

Since 2005, FDA has been part of a joint Federal initiative along with USDA, DHS, and the FBI called the Strategic Partnership Program on Agroterrorism (SPPA). The SPPA initiative is again using the CARVER+Shock tool and, through industry and state volunteers, is taking the tool to local venues. Local industry, FBI, DHS, FDA, USDA, State Departments of Health, and State Departments of Agriculture participate in these

assessments. These assessments not only identify vulnerabilities in other food commodities but also build local infrastructure around food defense issues. The SPPA program will run for approximately two years and has a goal of completing 40-50 assessments during this period. The results from these assessments will be used to identify mitigation strategies and to focus food defense research questions. These assessments included yogurt, export grain, baby food - applesauce, frozen entrees/pizza, bottled water, fresh cut produce, apple juice, fluid milk processing, milk at retail, infant formula, flour, stadium retail food service, and animal feed.

Just last month, FDA released a new CARVER + Shock software tool to help processors, manufacturers, warehouseers, and transporters in the food industry utilize the CARVER+Shock method to determine the vulnerability of individual food facilities to biological, chemical, or radiological attack. The software tool is available free of charge on FDA's website.

## **LABORATORY ENHANCEMENTS**

An additional step in enhancing our response capability is to improve our laboratory capacity. An important component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of food samples that could potentially be contaminated for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with USDA's FSIS to establish the Food Emergency Response Network (FERN) to include a

substantial number of laboratories capable of analyzing foods for agents of concern. We are seeking to expand our capacity through agreements with other Federal and state laboratories. At present, the network includes 134 laboratories representing all 50 states and Puerto Rico. Participation continues to grow. Once it is operating at full capacity, FERN will encompass a nationwide network of Federal, state, and local laboratories working together to build the capacity to test the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

Last fall, the FERN network proved to be a critical asset in the *E. coli* O157:H7 outbreak associated with fresh spinach. FERN expanded our laboratory capacity to handle the large number of food samples being tested. In addition, FERN analysts worked closely with CDC's Laboratory Response Network personnel to harmonize and approve a modified FERN method for detecting *E. coli* O157:H7 in spinach. This method allowed for substantially improved testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels. The FERN program also supplied the necessary reagents to the laboratories performing the testing.

More recently, on April 30, 2007, FDA issued a domestic vegetable PSA, in conjunction with our state and local regulatory partners, to test a variety of protein concentrates commonly found in the U.S. food and animal feed supply for the presence of melamine. Eight State FERN laboratories are involved in the analysis of the samples being collected.

## **IMPORTS**

To manage the ever-increasing volume of imported food shipments, FDA utilizes risk-management strategies in the review of foods that are being imported or offered for import into the United States. Currently, working with information submitted either through CBP's electronic systems used for import entries or through FDA's Internet-based Prior Notice System Interface, FDA screens shipments electronically before they arrive in the U.S. to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. This electronic screening allows FDA to better determine how to deploy its limited physical inspection resources at the border on what appear to be higher-risk food shipments while allowing lower-risk shipments to be processed in accordance with traditional import procedures after the electronic screening. FDA is working to enhance its targeting ability by utilizing data from a much wider range of sources to inform our entry decisions.

These are just a few of the many activities we have underway to enhance protection of the food supply.

## **CONCLUSION**

In conclusion, due to the enhancements being made by FDA and other agencies and due to the close coordination between the Federal and state food safety, public health, law enforcement, and intelligence-gathering agencies, the United States' food defense system is stronger than ever before. Although we have made progress, we are continuously working to improve our ability to prevent, detect, and respond to terrorist threats.

Thank you for this opportunity to discuss our food defense activities. I would be pleased to respond to any questions.