



DEPARTMENT OF HEALTH & HUMAN SERVICES

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STATEMENT OF
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BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CIVIL SERVICE AND AGENCY ORGANIZATION
UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 30, 2004

FOR RELEASE ONLY UPON DELIVERY

Introduction

Good afternoon, Chairwoman Davis and Members of the Subcommittee. I am Robert E. Brackett, Ph.D., Director of the Center for Food Safety and Applied Nutrition (CFSAN) in the Food and Drug Administration (FDA or the Agency), which is part of the U.S. Department of Health and Human Services (HHS or the Department). Thank you for this opportunity to discuss the Federal food safety system and to provide testimony on behalf of HHS. Ensuring the safety of the food supply continues to be a top priority for HHS and the Administration. I am pleased to be here today with my colleague from the U.S. Department of Agriculture (USDA), Dr. Merle Pierson.

The Subcommittee has expressed interest in the potential benefits of a single food agency. Over the years, there has been much discussion about consolidating all food safety, inspection, and labeling functions into one agency with the intention of increasing the effectiveness of the food safety system. In 2002, the White House looked into food safety issues, including the single food agency issue, and concluded that the goals of the Administration are better advanced through enhanced interagency coordination rather than through the development of legislation to create a single food agency.

In my view, the important question is whether the various Federal agencies with food safety authorities are working together effectively. The answer to that question is yes. The existing system is working. The American food supply continues to be among the safest in the world. Food safety agencies are working more closely together than ever before.

Of course, we all face many challenges. We face the traditional challenge of reducing the incidence of foodborne illness from unintentional contamination. In addition, we now face a heightened challenge of protecting food from deliberate contamination. To address these challenges, HHS has been implementing the most fundamental enhancements in our food safety and food defense activities in many years. For example, the new authorities in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) provide significant new tools for protecting the nation's food supply. In addition, the President recently issued Homeland Security Presidential Directive 9 (HSPD-9) which establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. With the U.S. Department of Homeland Security (DHS) as the coordinating lead, HSPD-9 promotes interagency cooperation and leadership to protect critical infrastructure and key resources. HHS, USDA, the Environmental Protection Agency (EPA), and other appropriate agencies are working with DHS in this national effort.

In my testimony today, I will describe HHS' food safety and security responsibilities and our many cooperative activities with USDA and our other partners. I will also discuss FDA's ten-point plan for ensuring the safety and security of the nation's food supply.

HHS' Food Safety and Security Responsibilities and Collaborative Efforts

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. FDA is the Federal agency that regulates 80

percent of the nation's food supply—everything we eat except for meat, poultry, and certain egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. FDA is also 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. In addition, FDA is responsible for assuring that the health consequences of foods and medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

By way of background, while FDA has the lead responsibility within HHS for ensuring the safety of food products, the Centers for Disease Control and Prevention (CDC) within HHS has an important complementary and non-regulatory 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. In addition, these systems can be used to indicate new or changing patterns of foodborne illness. Because CDC also detects and investigates outbreaks of foodborne illness through its networks, CDC is able to alert FDA and USDA about implicated food products associated with foodborne illness and works closely with the agencies to take protective public health action. In keeping with its agency mission, CDC also identifies, evaluates, and offers expert scientific opinion on the effectiveness of foodborne disease prevention strategies.

FDA contributes to the Foodborne Diseases Active Surveillance Network (FoodNet), the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative activity of CDC, FDA, the Food Safety and Inspection Service (FSIS) of USDA, and ten EIP sites, (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee, and New Mexico). Through this active surveillance system, these sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. This surveillance system provides important information about changes over time in the burden of foodborne diseases. These data help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and develop future food safety activities. FDA provides monetary support and technical expertise to the program.

In addition, just as FDA works with state and local food safety counterparts, CDC works extensively with state and local health departments to build their epidemiology, laboratory, and environmental health expertise in foodborne disease surveillance and outbreak response. All of these collaborations draw on and apply the unique expertise within HHS to address significant and emerging challenges to our food supply.

FDA has a myriad of cooperative and collaborative activities with USDA that assist in ensuring public health and the safety of our nation's food supply. We have signed several Memoranda of Understanding (MOU) with FSIS that encompass dual jurisdiction establishments, food additive

petitions, and the detailing of Public Health Service Commissioned Corp Officers from HHS to FSIS - just to name a few examples. These MOU have been quite productive. For example, the sharing of information through the MOU regarding dual jurisdiction establishments has led to numerous recalls of both FDA- and USDA-regulated products.

FDA works very closely with USDA on common research activities. FDA meets quarterly with the National Program Leaders from USDA's Agricultural Research Service (ARS) to discuss FDA's food safety research needs that ARS has the expertise and/or program time to undertake. FDA also meets regularly with the National Program Leaders of USDA's Cooperative State Research Education and Extension Service (CSREES) to identify the Agency's research needs for consideration in their various granting programs.

FDA, CDC, and USDA also work together on Healthy People 2010 – the prevention agenda for the nation. Healthy People 2010 is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats. FDA and FSIS co-lead the Healthy People 2010 Food Safety Focus Area, which includes goals and objectives for improving food safety, as measured by decreasing foodborne illness and allergic reactions to foods, improving food preparation practices in retail establishments and by consumers, and preventing an increase in antimicrobial resistance in foodborne pathogens.

FDA, CDC, and FSIS also work jointly on the Food Code to provide a model ordinance to local, state, and Federal governmental bodies and tribal nations to ensure that the food provided by retail food establishments and institutions, such as nursing homes and child care centers, is not a vector of communicable diseases. The Food Code is updated every two years and provides practical, science-based guidance to assist in mitigating risk factors known to cause foodborne illness.

Another example of our cooperative food safety efforts is the Partnership for Food Safety Education, a public-private partnership established to educate the public about safe food handling to help reduce foodborne illness. FDA and FSIS were founding members along with CDC, USDA's CSREES, consumer groups and industry. This cooperative effort yielded the Fight BAC![®] campaign that was launched in 1998 and to date has reached millions of consumers. The four key food safety messages within the Fight BAC![®] campaign are: Clean, Separate, Cook, and Chill. Thousands of teachers, dietitians, public health officials, and extension agents across the U.S. use Fight BAC![®] materials every year.

From an international perspective, the Codex Alimentarius Commission (Codex) is a further example of our collaborative efforts. Codex was created in 1962 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. Codex is the major international mechanism for encouraging fair international trade in food while promoting the health and economic interests of consumers. In the U.S., Codex activities are coordinated by officials from USDA, FDA, and the Environmental Protection Agency

(EPA). FDA exercises leadership in Codex committees to promote development of science-based international food safety and labeling standards that provide a level of consumer protection and label information consistent with that provided by corresponding U.S. regulations and laws.

FDA has long been actively involved nationally and internationally in efforts to understand and prevent the spread of Bovine Spongiform Encephalopathy (BSE). To address these concerns, FDA collaborates extensively with USDA's Animal and Plant Health Inspection Service (APHIS) and FSIS, Customs and Border Protection (CBP), EPA, the U.S. Department of State (DOS), our HHS colleagues at CDC and the National Institutes of Health (NIH), other Federal agencies, state and local jurisdictions, with affected industries and consumer groups, and the World Trade Organization. Specific examples of the cooperative efforts FDA has undertaken with CBP and USDA to restrict the spread of BSE include:

- Instituting a multi-tiered approach by FDA, CBP, and APHIS to ensure that BSE infected material is not introduced into the domestic human or veterinary food supply. At each stage in the import process (manifest, entry, and release) the appropriate agency reviews the data submitted and cross checks results with the other agencies.
- Establishing a seamless coordinated system for import review to safeguard against BSE. CBP agricultural inspection officers review vessel and truck manifests to determine if ruminant material is present and, if so, whether the appropriate USDA permits have been obtained. Non-permitted material is denied entry. When the importer files the customs entry, CBP's Automated Commercial System (ACS) screens the entry against the

Harmonized Tariff Schedule (HTS) classifications selected by APHIS which may contain products of ruminant origin or which may contain ruminant materials and which originate from a BSE country. CBP refers any such entries to USDA for further review and possible denial of entry. CBP's ACS electronically transmits data for FDA-regulated products to the Agency's Operational and Administrative System for Import Support (OASIS) for entry admissibility review. As part of this review, OASIS electronically screens the FDA product code supplied by the entry filer against lists of products known to contain ruminant material and BSE countries. Suspect products are referred to USDA for further action. If the product has already been released by CBP, USDA may request that CBP order the redelivery of the product to CBP custody for return to the port and storage in a bonded warehouse.

Collaborative activities such as these enabled implementation of a multi-layered system of firewalls to reduce the U.S. consumer's risk of exposure to the BSE infectious agent, including development and testing of Agency contingency response plans that were initiated immediately upon discovery of the first case of a BSE-positive cow within the U.S. This collaboration also has enabled the Agency to further strengthen safeguards for FDA-regulated products.

FDA and FSIS are also working on a joint proposed rule to develop general principles for reviewing and revising food standards regulations. FDA also collaborates with USDA on a variety of food security issues that will be discussed in the remaining portion of this testimony.

Ten-Point Plan for Ensuring the Safety and Security of the Nation's Food Supply

On July 23, 2003, former FDA Commissioner Mark B. McClellan issued a report to HHS Secretary Tommy G. Thompson entitled, "Ensuring the Safety and Security of the Nation's Food Supply." The report outlines a comprehensive ten-point program for safety and security, now referred to as defense, of our food supply. The ten-point program is based on four overall principles:

- Food defense and food safety are integrated goals. By building upon the Nation's core food safety/public health systems and expertise, FDA is enhancing food defense and improving food safety in the process.
- The food safety and defense system is comprehensive, addressing the full range of assessment, prevention, and response needs throughout the food production and distribution chain.
- The food safety and defense system is built on a solid foundation of a national partnership with other entities involved in food safety and food defense that fully integrates the assets of state, local and tribal governments, other Federal agencies, and the private sector.
- Americans must have confidence that the government is taking all reasonable steps to protect the food supply and is providing Americans with timely and relevant information about threats.

Consistent with these principles, the Agency is employing the following overall strategies:

- Awareness: develop increased awareness among Federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge;
- Prevention: develop capacity to identify a specific threat or attack on the food supply;
- Preparedness: develop effective protection strategies to “shield” the food supply from terrorist threats;
- Response: develop capacity for a rapid, coordinated response to a foodborne terrorist attack; and
- Recovery: develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack.

In these efforts, FDA has many partners – Federal and state agencies, academia, and industry. We are working closely with our Federal partners such as USDA, DHS, the Homeland Security Council (HSC) at the White House, DOS, and the U.S. Trade Representative, as well as with law enforcement and intelligence-gathering agencies. I also want to emphasize our close working relationships with our sister public health agencies, CDC and NIH, and FSIS, our counterpart agency responsible for meat, poultry, and certain egg products, and with CBP, our partner at the border. Some of our other Federal partners include APHIS, USDA’s Foreign Agriculture Service, USDA’s Agricultural Research Service, USDA’s Food and Nutrition Service, Department of the Army Veterinary Services Activity, U.S. Air Force, Department of Commerce’s (DOC) National Oceanic and Atmospheric Administration, the Environmental

Protection Agency (EPA), the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), the Federal Bureau of Investigation, and the Central Intelligence Agency (CIA).

Now, I would like to describe the program areas in the ten-point plan.

1. Stronger FDA

Thanks to bipartisan Congressional support, a Fiscal Year 2002 supplemental appropriation included counterterrorism funds for FDA. This enabled FDA to hire over 800 employees, 655 of whom were hired by FDA's Office of Regulatory Affairs (ORA) as additional field personnel. Of the 655 field personnel, 635 were hired principally to address food safety and food defense issues, primarily at the border. These staff have all been hired, trained, and deployed. Three hundred support consumer safety investigations at 90 U.S. ports of entry, 100 support laboratory analyses on imported products, 33 are for criminal investigations of import activities, and the remaining personnel support domestic efforts.

As I mentioned earlier, in addition to ensuring the safety and security of the food supply, FDA is responsible for the safety of cosmetics and the safety and efficacy of human and veterinary drugs, human biologicals, medical devices and radiological products. FDA's field staff is responsible for conducting operations in these multiple product areas in both the domestic and import arenas, and their time is not completely obligated in only one specific product area. While the 635 field staff primarily conducts food work, they also conduct work in these other important product areas when needed. Should a single food agency be created, there may be a

request to reallocate these 635 field personnel to the newly formed agency. Such a reallocation would measurably diminish FDA's ability and efficiency to potentially address issues involving the safety and efficacy of the other FDA-regulated commodities. This could potentially increase the vulnerability of the population to the exposure of unsafe or ineffective products.

The continuous threat of terrorism requires FDA to remain persistent in its effort to recruit and retain a competent, trained workforce if we are to maintain a high level of readiness. A key component of FDA's strategic plan is to assure a high-quality professional workforce. Capable personnel with the appropriate expertise are critical for the success of FDA and for the Agency's ability to maintain a high level of public trust in its activities. FDA's responsibilities require a very special workforce, one that can keep up with rapid changes in the industries that it regulates and one that is capable of developing and implementing effective and innovative public health measures. Our workforce includes a solid cadre of experienced physicians, toxicologists, chemists, microbiologists, statisticians, mathematicians, biologists, pharmacologists, veterinarians, and other highly qualified and dedicated professionals.

FDA continues to find innovative ways to educate and train our staff and further develop the necessary scientific, technical, and investigational skills to integrate food safety and food defense activities. FDA has not only mobilized the new staff but also has redirected and trained current investigators and scientists to ensure that the Agency has the necessary expertise to respond to an event that could threaten the safety and security of the food supply. FDA has hired or re-trained scientific experts in biological, chemical, and radiological agent research, detection

methodology, and preventive technologies. It has also acquired substantial knowledge of biological, chemical, and radiological agents.

2. Imports

The volume of imported food shipments has been rising steadily in recent years, and this trend is likely to continue. In Fiscal Year 2003, FDA had the challenge of assuring the safety and security of approximately 6 million line entries of imported food. We anticipate 7.1 million line entries of imported food this fiscal year. To manage this ever-increasing volume, we are using risk management strategies to achieve the greatest food protection with our limited resources. We are working to increase the information gathered throughout the life cycle of imported products – from raw materials to foreign processing to shipping to the U.S. consumer – to create a risk profile of imported products that will allow us to focus our resources on products that present the greatest risk.

While we cannot physically inspect every shipment, it is important to note that every shipment that contains FDA-regulated products that is entered for consumption or warehouse storage through CBP's ACS is electronically reviewed by FDA's OASIS 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 concentrate its limited inspection resources on high-risk shipments while allowing low-risk shipments to proceed into commerce.

With the new prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the United States. This not only allows the electronic system to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the United States, but it will also allow for FDA staff review of prior notices for those products flagged by the systems as presenting the most significant risk. FDA worked very closely with CBP in developing this screening system.

In addition, FDA has been actively working with the analysts at CBP's National Targeting Center to utilize their Automated Targeting System as an additional tool to enhance the Agency's ability to focus attention on those imported foods that may pose a serious threat to public health. We anticipate that the use of FDA's and CBP's screening systems will enable both agencies to effectively target shipments posing the greatest risk in order to further focus our border inspection efforts. FDA worked very closely with CBP in developing this screening system.

We have also increased surveillance. With the additional field employees that we mentioned earlier, we have expanded FDA's presence at ports of entry, increased surveillance of imported foods, increased domestic inspections, and enhanced our laboratory analysis capacity. More specifically, within the last two years, we have more than doubled the number of ports that have an FDA presence from 40 to 90 ports. We have increased by more than six-fold the number of food examinations at the border. This past fiscal year, we surpassed our

goal of 48,000 import examinations, conducting 78,569 food import examinations compared to 12,000 just two years ago. This increase was so significant 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. The President's FY 2005 budget proposal requests \$7 million for increased FDA inspections of domestic and imported food to reduce the risk of contaminated products entering the U.S. market.

3. Implementation of the Bioterrorism Act

Title III of the Bioterrorism Act provided the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these food safety and food defense provisions. This landmark legislation represents the most fundamental enhancement to our food safety and food defense authorities in many years. These new authorities will help improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies.

The Agency has been working hard to implement this law effectively and efficiently. On October 10, 2003, we published two interim final regulations to implement Section 305, Registration of Food Facilities, and Section 307, Prior Notice of Imported Food Shipments. In accordance with the Bioterrorism Act, these two regulations became effective on December 12, 2003. We have also published proposed regulations to implement Section 303, Administrative Detention, and Section 306, Maintenance and Inspection of Records for Foods. We intend to

finalize the regulations on these two provisions in the near future. Section 303 gives FDA new authority to detain any article of food for which there is credible evidence that it poses a threat of serious adverse health consequences or death. When finalized, the recordkeeping regulation will help FDA track and contain foods that pose a threat of serious adverse health consequences or death from accidental or deliberate contamination of food.

The interim final rule on registration requires domestic and foreign facilities that manufacture or process, pack, or hold food for human or animal consumption in the U.S. to register with FDA. FDA will have, for the first time, a roster of foreign and domestic food facilities. In the event of a potential or actual terrorist incident or an outbreak of foodborne illness, the registration information will help FDA to quickly identify and locate the facilities that may be affected. FDA expects up to 420,000 facilities to register under this requirement.

FDA's electronic registration system became operational on October 16, 2003. The system is available 24 hours a day, seven days a week, to anyone with access to the Internet. We are also providing technical assistance to persons who need help with the registration process. Facilities are strongly encouraged to use the electronic system to register. As of March 24, 2004, 194,889 facilities have registered. This includes 94,716 domestic and 100,173 foreign facilities.

The interim final regulation on prior notice requires the submission to FDA of prior notice of food, including animal feed that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target inspections at

the border to ensure the safety of imported foods before they move into the U.S. CBP represents the Administration's attempt to build a single lead border authority, which was part of the rationale for establishing DHS. FDA has been receiving about 25,000 notifications about incoming shipments each day since the regulation became effective on December 12, 2003. The timeframes for submitting prior notice are the least amount of time that FDA needs to meet our statutory responsibility to receive, review, and respond to the prior notice submission. They take into account different modes of transportation. The regulations allow two hours for arrival by land by road, four hours for arrival by air or land by rail, and eight hours for arrival by water. The staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with shorter transport times and to defer review of shipments with longer transport times.

HHS and DHS co-signed the regulations. FDA and CBP worked collaboratively to ensure the new regulations promote a coordinated strategy for border protection. Thanks to this collaboration, prior notice may be submitted by using CBP's ACS or by using FDA's Prior Notice System Interface. FDA and CBP are committed to the joint implementation of a plan for increasing integration and assessing the coordination of the prior notice timeframes that will: (1) achieve the goal of a uniform, integrated system; (2) build on current operational procedures; and (3) implement the law with minimal disruption to current entry practices. Although the interim final rules became effective December 12, 2003, FDA and CBP intend to generally exercise enforcement discretion for several months following implementation. During this time, FDA and CBP intend to focus on educating our stakeholders about the requirements of the rules.

Pursuant to the commissioning authority provided in Section 314 of the Bioterrorism Act, FDA and CBP have signed an MOU to commission CBP employees to conduct investigations and examinations on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff in the enforcement of FDA's prior notice requirements. In accordance with this new authority, FDA has already commissioned over 7,500 CBP employees. The Agency will continue to explore use of this authority with other agencies as a tool to further improve efficiencies.

4. Industry Guidance and Preventive Measures

FDA has 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. We have issued such guidance, "Security Preventive Measures Guidance Documents," for food producers, processors, and transporters; for importers and filers; for retail food stores and food service establishments; and for cosmetic processors and transporters. In addition, we have issued specific security guidance for the milk industry. During domestic inspections and import examinations, FDA's field personnel continue to distribute and discuss these guidance documents with firms that have not previously received them.

5. Vulnerability and Threat Assessments

As part of our efforts to anticipate threats to the food supply, we have 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. This framework was provided to us by the U.S. Air Force. 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.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment." The assessment also affirmed the findings of FDA's ORM assessment. In addition, it provided another decision-making tool for performing risk assessments. Further, the Battelle assessment made a number of recommendations that addressed research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between Federal, state, and local governments to ensure food security. FDA is addressing each of these recommendations.

FDA is continuing to update and refine these assessments regarding the vulnerability of FDA-regulated foods to intentional contamination from biological, chemical, and radiological agents. These refinements use processes adapted from techniques developed by the U.S. Department of Defense (DOD) for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments will be used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector. Through an HSC interagency working group, FDA, FSIS, APHIS, and the Food and Nutrition Service worked together on their assessment efforts, utilizing DOD assessment techniques, to ensure that each agency was using the same approach to assess its vulnerabilities.

6. Operation Liberty Shield

In March 2003, the Federal government launched Operation Liberty Shield to increase security and readiness at a time of elevated risk for terrorist attack. Operation Liberty Shield was a comprehensive national plan to increase protections for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of life. FDA's efforts during Operation Liberty Shield were targeted towards increasing the Agency's surveillance activities in the food and cosmetic areas in an effort to enhance defense of these products. This targeted approach was based on the vulnerability assessments described above and included domestic inspections and import examinations, sample collections of targeted commodities, and import reconciliation examinations. Domestic and import reconciliation examinations were conducted to ensure that: 1) the targeted food/cosmetic was what it purported to be; 2) there were no unexplained

differences in the quantity of products ordered and what was subsequently received; 3) there were no visible signs of tampering or counterfeiting; and 4) sampled products were not adulterated with contaminants of concern. During each and every domestic inspection or import examination, FDA personnel handed out and discussed FDA's "Security Preventive Measures Guidance Documents."

7. Emergency Preparedness and Response

FDA has established an Office of Crisis Management (OCM) to coordinate the preparedness and emergency response activities within FDA and with our Federal, state, and local counterparts. Over the past three years, FDA has participated in and conducted multiple emergency response activities including exercises coordinated with other Federal and state agencies. For example, FDA and USDA's FSIS have focused on strengthening our working relationships through joint testing of several response plans in an exercise environment. FDA has also reviewed food security and rapid response and recovery procedures with industry groups and trade associations.

In May 2003, FDA participated in the government-wide TOPOFF2 counterterrorism exercise led by the DHS and the Department of Justice. This was a national, full-scale, fully functional exercise intended to simulate two separate terrorist attacks -- detonation of a "dirty bomb" in Seattle and aerosol release of plague in Chicago -- that had implications for food products (e.g., the possibility of food contamination by radiation). The ensuing response involved participation from 17 Federal departments and agencies, the state governments of Washington and Illinois, the

local governments of the affected cities, and the Canadian Government. FDA's response was coordinated from our Emergency Operations Center (EOC) on an around-the-clock basis throughout the exercise, working together with all of FDA's Centers.

From September 8 – 10, 2003, FDA participated in Exercise Global Mercury. Global Mercury involved the G-7 countries plus Mexico and was designed to test international communications during a public health emergency in the international community. Coordination of HHS participation was done through the Secretary's Command Center. Other U.S. players in the exercise were CDC and DOS.

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, Office of International Programs, Southwest Import District, New York District, Mexico's Federal Commission for Health Risk Protection (COFEPRIS), 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, and to use videoconferencing to practice international response communications. The players were pleased with the opportunity to participate in the exercise and found it to be a valuable learning experience. 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 sharing of intelligence information between and among the three countries. Another trilateral exercise will be conducted this year.

FDA and USDA have also closely coordinated our 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 our 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 USDA/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 were conducted as joint inspections with FDA, USDA, and state inspectors all 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.

Finally, FDA's OCM/EOC will coordinate FDA participation in other interagency exercises planned for this year and will conduct two additional exercises to test updated response plans for chemical/biological and radiological emergencies.

The President's FY 2005 budget proposal requests an additional \$3 million to upgrade the agency's crisis management capacity for a rapid and coordinated response to a threat to the food supply.

8. Laboratory Enhancements

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with CDC and USDA/FSIS to augment the Laboratory Response Network by establishing 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. As of last week, 30 laboratories representing 23 states have submitted laboratory qualification checklists for membership in FERN. The President's FY 2005 budget proposal requests \$35 million for FDA to enhance FERN. The President's budget proposal also requests funding for USDA to enhance 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.

We also are expanding Federal, state, and local involvement in our Electronic Laboratory Exchange Network (eLEXNET) by increasing the number of laboratories around the country that

participate in this electronic data system. eLEXNET is a seamless, integrated, web-based data exchange system for food testing information that allows multiple agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET is funded by FDA and supported by USDA and DOD. It enables health officials to assess risks and analyze trends, and it provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. At present, there are 108 laboratories representing 49 states that are part of the eLEXNET system with 62 laboratories actively submitting data. We are continuing to increase the number of participating laboratories.

Moreover, during the U.S./Canada/Mexico Trilateral Cooperation Meeting held in Baltimore, Maryland, at the end of October, 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.

In addition, FDA's ORA has signed an Interagency Agreement with the U.S. Department of the Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to enhance our ability to provide timely and efficient analyses of imported food. The mobile laboratories are expected to be ready for deployment this year.

9. Research

To prioritize research needs and avoid duplication, FDA coordinates with its sister agencies within HHS, such as CDC and NIH, and with other Federal partners such as USDA, DHS, DOD, and the Department of Energy. Within FDA, we have embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. To enhance food defense, FDA has significantly redirected existing research staff to ensure that appropriate resources are focused on priority food safety and defense issues. For example, research sponsored by FDA's CFSAN is aimed at developing the tools essential for testing a broad array of food products for a multiple number of biological and chemical agents. We are actively working with our partners in government, industry, and academia to develop such methods. In addition, research conducted at FDA's National Center for Toxicological Research is providing rapid detection techniques and risk assessment models for biological pathogens. FDA's work with AOAC International, an association of analytical chemists, on validating analytical methods for the detection of biological, chemical, and radiological agents in foods is considered the "gold standard" against which other validations programs are judged. Likewise, FDA's research on microbial genomics and analytical chemistry is widely recognized for its importance to other Federal agencies charged with forensic investigations of terrorism events.

In compliance with Section 302 of the Bioterrorism Act, on October 16, 2003, we submitted a report to Congress, "Testing for Rapid Detection of Adulteration of Food," about the research that is underway. FDA has commenced more than 90 different research projects to develop tests and sampling methodologies to increase the detection of adulteration of food. A number of the

research projects are designed specifically to develop tests suitable for inspections of foods at ports of entry. For example, commercially available test kits are currently being analyzed for a variety of food matrices to evaluate their suitability for use in the field at ports of entry.

The President's FY 2005 budget proposal requests \$15 million to fund additional research on prevention technologies, methods development and determination of the infectious dose for potential terrorism agents when ingested with food, and identification of agent characteristics within specified foods. Developing these strategies will shield the food supply from potential attacks and enable rapid response if needed.

10. Interagency and International Communication and Collaboration

Food safety and food defense require effective and enhanced coordination across many government agencies at the Federal, state, and local level. FDA's activities in public health security are coordinated through the HHS Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, the Department, and other Federal agencies and departments, including DHS. FDA has also worked closely with the Interagency Food Working Group of the White House HSC on three initiatives – development of a national network of food laboratories, identification of vulnerabilities and subsequent mitigation tactics for commodities of concern, and the development of a national incident management system. Additional Federal agencies participating in these efforts are USDA, CDC, DOD, EPA, and CIA.

FDA conducts regularly scheduled interagency conference calls with representatives from USDA's APHIS and FSIS, CDC, EPA, DOD, DOC, TTB, and CBP. On February 4, 2003, FDA, in conjunction with the National Association of State Departments of Agriculture, the Association of State and Territorial Health Officials, USDA, and CDC, sponsored a one-day executive level meeting with the Secretaries of State departments of agriculture and State departments of health titled "Homeland Security – Protecting Agriculture, the Food Supply and Public Health – the Role of the States." FDA is also working closely with Canada and Mexico in an effort to assess and strengthen our public health and food security systems and infrastructures at our mutual borders.

In addition, ORA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies to receive and act on any information regarding product tampering. OCI is FDA's liaison with the intelligence community (CIA, National Security Agency, and others). OCI agents serve on several interagency committees including the FBI's Joint Terrorism Task Forces, the U.S. Attorney's Office Anti-Terrorism Task Forces, and DHS' Bureau of Immigration and Customs Enforcement Task Forces around the country. OCI has a specialized staff with the capability and background to analyze information from law enforcement and intelligence community sources to assist in terrorism-related threat assessments pertaining to FDA-regulated products.

Many of the activities described above will help achieve the goals established in HSPD-9, which I mentioned earlier. HSPD-9 has five major objectives:

- Identifying and prioritizing sector-critical infrastructure and key resources for establishing protection requirements;
- Developing awareness and early warning capabilities to recognize threats;
- Mitigating vulnerabilities at critical production and processing nodes;
- Enhancing screening procedures for domestic and imported products; and
- Enhancing response and recovery procedures.

HHS, USDA, EPA, and other appropriate agencies are working with DHS to achieve these objectives.

Conclusion

In conclusion, FDA is making tremendous progress in our ability to ensure the safety and defense of the nation's food supply. Due to the enhancements being made by FDA and other agencies and due to the close coordination between the Federal food safety, public health, law enforcement, and intelligence-gathering agencies, the U.S.'s food safety and defense system is stronger than ever before.

Thank you for this opportunity to discuss HHS' food safety and defense activities. I would be pleased to respond to any questions.