July 23, 2003

Progress Report to Secretary Tommy G. Thompson: Ensuring the Safety and Security of the Nation's Food Supply

MESSAGE FROM THE COMMISSIONER OF FOOD AND DRUGS

On July 23, 2003, the Food and Drug Administration (FDA) submitted to the Department of Health and Human Services Secretary Tommy G. Thompson this progress report entitled, "Ensuring the Safety and Security of the Nation's Food Supply," which summarizes the leadership demonstrated at FDA in combating the terrorist threat to foods.

FDA is responsible for ensuring the safety and security of 80% of the U.S. food supply. FDA's legislative mandate is to protect the public health by ensuring the safety of the production, processing, packaging, storage, and holding of domestic and imported food except those products (meat, poultry, and processed egg products) that are under the jurisdiction of the U.S. Department of Agriculture.

Although food safety and security are different aspects of food protection, they are inherently connected. FDA, at the direction of the Department of Health and Human Services (DHHS), has established a 10-Point Program for ensuring the safety and security of the food supply. Based on activities in FDA's 10-Point Program, the Agency is employing overall strategies to (1) develop increased awareness among federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge (Awareness); (2) develop capacity for identification of a specific threat or attack on the food supply (Prevention); (3) develop effective protection strategies to "shield" the food supply from terrorist threats (Protection); (4) develop capacity for a rapid, coordinated response to a foodborne terrorist attack (Response); and (5) develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack (Recovery).

Within the food safety and security strategies, FDA's program features 10 areas of focus, based on the following principles:

- Food security and safety are integrated goals. By building upon the Nation's core food safety/public health systems and expertise, while strengthening expertise and capabilities needed to address the terrorist threat, FDA is enhancing food security and is improving food safety in the process.

- The food safety and security system is comprehensive, addressing the full range of assessment, prevention, and response needs, throughout the food production and distribution chain. The system must be efficient and in the context of both safety and security, address the most significant threats first whenever possible.

- The food safety and security system is also built on a solid foundation of a national partnership with other entities involved in food safety and security 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 and will provide timely and relevant information about an attack if one occurs.

The events of September 11, 2001, heightened the nation's awareness and placed a renewed focus on ensuring the protection of the nation's critical infrastructures. A terrorist attack on the food supply could pose both severe public health and economic impacts, while damaging the public's confidence in the food we eat. Several food incidents since the fall of 2001 highlight the significance of FDA's food security activities. In the fall of 2002, a competitor of a restauranteur in China added a chemical compound to his competitor's food and killed dozens of people and sent hundreds more to hospitals. Also in the fall of 2002, three individuals were arrested in Jerusalem for allegedly planning to carry out a mass poisoning of patrons at a local café. One of the arrested individuals worked as a chef at the café. In January 2003, several individuals were arrested in Britain for plotting to add ricin to the food supply on a British military base Each of these incidents shows the potential for the nation's food supply to be used in an attack.

Even before September 11, HHS was taking steps to improve food security. As part of the initial response to these heightened concerns after September 11, Congress provided FDA with new statutory authorities and some additional resources for food inspection. As a result of new threats to the food supply and new opportunities, 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. The attached 10-Point Program reflects a risk-based strategy to achieve the greatest food security and safety improvements with the least additional costs or food restrictions for consumers. In these efforts, FDA will continue to work with the White House Homeland Security Council, the United States Department of Agriculture (USDA), and the Department of Homeland Security (DHS) to further enhance our ability to detect, deter, and respond to an attack on our food supply.

Mark B. McClellan, M.D., Ph.D.

> ***"Securing our food supply against terrorist threats is one of our most important public health priorities, especially at a time of heightened alert," said Tommy G. Thompson, Secretary of Health and Human Services.***

Food Safety and Security Progress: A 10-Point Program

FDA Food Security Strategy

In the months before and after Sept. 11, 2001, Secretary Thompson led the effort to encourage Congress to increase FDA funding to protect the nation's families from an attack on the food supply. In fiscal years 2002 and 2003, Congress enacted more than $195 million for food safety programs, allowing FDA to hire 655 new food personnel and conduct more than double the previous number of food import examinations. In President Bush's fiscal year 2004 budget, the Department of Health and Human Services (DHHS) is requesting $116.3 million, an increase of $20.5 million over FY 2003, to further protect the nation's food supply.

The Agency is employing overall strategies to (1) develop increased awareness among federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge **(Awareness)**; (2) develop capacity for identification of a specific threat or attack on the food supply **(Prevention)**; (3) develop effective protection strategies to "shield" the food supply from terrorist threats **(Preparedness)**; (4) develop capacity for rapid, coordinated response to a foodborne terrorist attack **(Response)**; and (5) develop capacity for rapid, coordinated recovery from a foodborne terrorist attack **(Recovery)**.

Within the food safety and security strategies, FDA's program provides 10 areas of focus. The table below illustrates FDA's 10-Point Program and how each program area fits within the overall food safety and security strategies.

FDA has worked and continues to work closely with the states and other food safety, law enforcement, and intelligence agencies to collaborate on research, emergency response, and information exchange, all of which significantly strengthen the Nation's food safety and security system.

Strategies

FDA 10-Point Program	Awareness	Prevention	Preparedness	Response	Recovery
Stronger FDA-New Staff	X	X	X	X	X
Imports - Strategic Approach		X	X		
Bioterrorism Act Regulations		X	X	X	

Industry Guidance and Preventive Measures	X	X	X		
Vulnerability and Threat Assessments	X	X	X		
Operations Liberty Shield	X	X	X		
Emergency Preparedness and Response	X			X	X
Laboratory Enhancements		X	X	X	X
Research		X	X	X	X
Interagency and International Communication and Collaboration	X	X	X	X	X

Progress and Next Steps

1. **Stronger FDA - New Staff**

   In the wake of September 11, 2001, HHS, working with bipartisan Congressional support and action, obtained funding for the FDA. FDA moved expeditiously and quickly to establish this additional investigative and scientific team by rapidly hiring and training 655 additional field personnel. Of the 655, 97% are allocated to food safety field activities: 300 support the conduct of consumer safety investigations at 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.

   The Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) was enacted in June 2002 and by the end of the year, FDA had started to place additional, trained investigators and analysts at targeted locations. Training of these new personnel has been paramount. Utilizing the platform provided by the Office of Regulatory Affairs' University (ORA U), FDA has retooled its existing "new hire" curriculum for investigators and its "new hire" curriculum for analysts so that new investigators and new analysts are prepared to do basic work within three months of employment. This basic investigatory work includes recall audits, sample collections, complaint follow-up investigations, and import exams. The basic analytical work includes basic lab operations and sample preparation. The curricula continue through the first 12 months of employment, culminating in an on-the-job audit of performance where the new employee demonstrates job competency to an auditor using standardized criteria.

   U.S. borders are flooded with FDA-regulated imports from all over the world, and the continuous threat of terrorism requires FDA to remain vigilant in its effort to retain a competent, trained

workforce if we are to maintain a high level of readiness. With FDA's limited resources to meet the challenge of assuring the food safety and security for more than 6 million entries per year, FDA must strategically develop hiring, targeting resources and succession planning to be prepared in the event of a terrorist attack.

FDA not only mobilized new staff but redirected, trained current investigators and scientists to integrate and strengthen its food safety and security mission and ensured that the agency has the necessary scientific and logistical 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, preventive technologies and acquired substantial knowledge of these agents to help support domestic and import activities. FDA's Office of Regulatory Affairs (ORA) has developed a succession plan to ensure that the agency will continue to have highly trained and competent scientists, investigators, analysts, and managers to accomplish the agency's overall mission of consumer protection. FDA realizes that recruitment and retention of our highly skilled and sometimes very specialized workforce requires thoughtful planning so that we will be ready to effectively and efficiently meet the future challenges FDA faces.

2. **Imports - Strategic Approach**

FDA continues to adjust its import program via the development of an Import Strategic Plan (ISP) to reflect the changing nature of risks and trade associated with imported goods. This approach encompasses and addresses the full "life-cycle" of imported products. As part of the ISP, FDA is assessing information derived from foreign and domestic inspectional operations, adverse events, consumer complaints, recall activities, and information technology. The goal of the ISP is to better protect the public health and safety by decreasing the risk that unsafe, ineffective, or violative products will enter U.S. commerce through our borders, ports, and other import hubs. Moreover, when implemented, the ISP will provide FDA with the critical flexibility it needs to shift resources as import trends alter the risks and change priorities for public health and safety protection.

Historically, the volume of U.S. imports of FDA-regulated products was relatively small and consisted of raw ingredients and bulk materials intended for further processing or incorporation into finished products. Therefore, FDA could rely more heavily on physical examination and domestic inspections to ensure that imported raw ingredients and bulk materials were properly handled, received, quarantined, released and processed according to good manufacturing practices and sanitation principles.

Even with the recent increases of personnel for counter terrorism efforts, border inspections cannot manage the changes in the nature of risks and trade. FDA is taking steps to implement a risk-based approach towards covering the importation of FDA-regulated goods. These proactive steps will assist FDA in identifying patterns of transportation while goods are in international streams of commerce; increase our ability to conduct effective, efficient foreign inspections; and will aid FDA in making admissibility decisions before goods enter domestic commerce. Moreover, the risk-based approaches we are contemplating include exploring the feasibility of

forming regulatory partnerships to provide better information to FDA - and, ultimately, better protection to U.S. consumers.

FDA is supporting this enhanced import strategic plan by providing a greater import presence at our nation's borders. FDA is enhancing our capacity and capability to perform normal import operations such as sample collection and analysis, field examinations, and inspections across all our programs. In 2001, FDA provided coverage at about 40 ports of entry. By 2002, FDA had more than doubled its presence to 90 ports of entry.

In addition, since 2001, FDA more than quintupled the number of food import examinations. In 2001, FDA conducted 12,000 food exams. FDA has conducted over 62,000 food exams already this fiscal year and has surpassed its 2003 year-end goal of 48,000 food exams. This increased coverage was due to redirecting resources dedicated to assure increased import coverage during Operation Liberty Shield when the Nation was at a heightened security alert.

FDA is working to increase import filer evaluations to ensure integrity of importers and import entry data and to increase collections 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.

3. **Bioterrorism Act Regulations**

FDA is on schedule to publish four major new regulations in accordance with provisions of the Bioterrorism Act. The agency intends to publish two final rules in October of this year and two additional final rules by the end of this year. 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

On February 3, 2003, FDA and the Department of Treasury jointly published in the *Federal Register* a proposed regulation implementing the provisions in the Bioterrorism Act that would require owners, operators, or agents of a foreign or domestic facility where food is manufactured/processed, packed, or held to submit a registration to the FDA that includes basic information about the facility, emergency contact information, and the categories of food the facility handles.

On February 3, 2003, FDA and the Department of Treasury also jointly published in the *Federal Register* a proposed regulation implementing the provisions in the Bioterrorism Act that would require FDA to receive prior notice before imported food arrives at the U.S. port of arrival.

On May 9, 2003, FDA published in the *Federal Register* a proposed regulation implementing the provisions in the Bioterrorism Act that would require manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers of food to keep records identifying the

immediate previous source from which they receive food, as well as the immediate subsequent recipient, to whom they sent food.

On May 9, 2003, FDA also published in the *Federal Register* a proposed regulation implementing the provisions in the Bioterrorism Act related to FDA's new authority to detain any article of food for which there is credible evidence or information that the article poses a threat of serious adverse health consequences or death to human or animals. The administrative detention authority granted to FDA under the Bioterrorism Act is self-executing and currently in effect.

FDA published each of the regulations with a 60-day comment period. We received many comments on each rule that suggested ways the rules could be improved to minimize the impact on commerce, while accomplishing the statutory objective. FDA is considering these comments and will make appropriate changes to the rules before issuing them in final form. These rules primarily are designed to give FDA additional information about food intended for consumption in the United States and the facilities that handle that food. As such, these statutory provisions do not raise the "science issues" as many of our rulemakings do (nor did the Agency receive comment in that area), or as other provisions in the Bioterrorism Act do.

FDA held two major satellite downlinks to explain the proposed regulations to affected parties around the world. The first was held on January 29, 2003 and discussed food facility registration and prior notice proposed requirements. The second was held on May 7, 2003 and discussed the proposed administrative detention procedures and the proposed requirements governing the establishment and maintenance of records. The broadcasts were made available in English, Spanish and French and were viewed at over 20 FDA sites, in Canada, Mexico, and South America. Viewers included importers, brokers, manufacturers and processors of foods and feeds, transporters, state officials, foreign embassy officials, foreign governments, and representatives of trade associations. In addition, the agency has conducted outreach regarding these regulations in other forums.

FDA has trained a cadre of speakers and has participated in over 80 meetings in many venues such as the Alliance for Food Safety and Security in Washington, DC, the World Trade Organization in Geneva, Switzerland, and at a meeting hosted by the government of Japan in Tokyo, Japan, giving presentations and talks on the proposed rules. FDA senior officials involved in developing the rules also attended meetings with government officials and industry representatives in Canada, Mexico, and the European Union.

FDA is intent on reviewing the many comments concerning the proposed regulations and is taking steps to implement these regulations with recognizing current business practices and emphasizing efficiency to implement and meet the intent of the Act.

FDA also developed and conducted demonstrations of the rapid, easy-to-use on-line registration system that companies can use to register starting in mid-October 2003.

FDA is working with the Bureau of Customs and Border Protection (CBP), to streamline the implementation of the prior notice requirements of the Bioterrorism Act. This will allow food

importers to provide required information on food imports to both agencies using a single IT process.

FDA is working to finalize these regulations. We are currently considering all the timely comments that were submitted, and where appropriate, making appropriate changes to the regulations for food facility registration, prior notice, establishment and maintenance of records, and administrative detention before issuing them in final form. FDA is planning to host satellite downlinks and regional meetings to assist stakeholders in understanding and complying with the final rules. FDA is also developing "user-friendly" materials to serve as aids and to assist stakeholders.

4. **Industry Guidance and Preventive Measures**

On January 9, 2002, FDA published in the *Federal Register* and made available on its Website two draft guidance documents related to food security. The first, "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance," is designed to aid operators of food establishments. The second, "Importers and Filers: Food Security Preventive Measures Guidance," is designed to help food importers. Each document recommends the types of preventive measures that companies can consider to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions. Following public comment, FDA issued final versions of the guidance documents on March 21, 2003, in conjunction with FDA's efforts during Operation Liberty Shield. We discuss Operation Liberty Shield in more detail later in the document.

On March 21, 2003, FDA published in the *Federal Register* and made available on its Website two additional draft guidance documents related to food and cosmetic security. The first, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance," is designed to aid operators of food retail food stores and food service establishments. The second, "Cosmetic Processors and Transporters: Cosmetic Security Preventive Measures Guidance," is designed to help operators of cosmetic establishments. Each document recommends the types of preventive measures that companies can consider to minimize the risk that food or cosmetics under their control will be subject to tampering or criminal or terrorist actions.

FDA developed and made available on July 11, 2003, an additional guidance document related to food security preventive measures for milk, "Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors; Food Security Preventive Measures Guidance."

FDA, in collaboration with the Technical Support Working Group (TSWG) of the Department of Defense, is working with the John A. Volpe National Transportation Systems Center in Cambridge, Massachusetts on a project related to the security of domestic and overseas transport of food.

TSWG and FDA are also working with St. Joseph's University, Philadelphia, Pennsylvania, to

develop an accredited modular food security and protection training curriculum for both academics and professionals that is capable of being delivered in a traditional classroom setting as well as via CD-ROM and though web-based delivery formats. Industry representatives at the first user's group meeting in June 2003 confirmed the value of the training.

TWSG and FDA are working with Sensor Research and Development, a small company in Orono, Maine, to develop a prototype of a food pathogen detector (MIPSTRIP).

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.

5. **Vulnerability and Threat Assessments**

Using the methodology called Operational Risk Management (ORM), FDA developed a vulnerability assessment for foods. The assessment evaluates the public health consequences of a range of product-agent scenarios associated with potential tampering, criminal, malicious, or terrorist activity. This relative risk ranking is designed to facilitate decision-making about the assignment of limited federal, state, and local public health resources to minimize such risks. It is also designed to assist the food industry in identifying areas where enhancements in preventive measures could increase the security of the food supply. This internal assessment identified a number of food/agent combinations that FDA is focusing on to implement shields for protecting those commodities. These shields will be implemented in partnership with our regulatory counterparts and industry.

FDA initiated and awarded a task order to the Institute of Food Technologists (IFT) to conduct an in-depth review of ORM and provide a critique on its application to Food Security. As part of this review, IFT was asked to apply ORM to food and to evaluate the relative public health consequences of a range of product-agent scenarios. This review validated FDA's vulnerability assessment process and provided additional information on the public health consequences of a range of product, agent, and process scenarios. This assessment affirmed the food/agent combinations identified in the FDA ORM assessment and identified additional commodities to consider for shield implementation.

As an additional step, on June 4, 2003, FDA awarded an additional task order to IFT, requesting that IFT conduct an in-depth review of preventive measures that food processors may take to reduce the risk of an intentional act of terrorism or contamination. The review will assess ways to prevent or reduce the risk of contamination of processed food and will provide information on various research needs related to elimination or reduction of the risks. IFT will provide information on various processing technologies that might be used for eliminating or reducing the risk of an intentional act of terrorism or contamination for several commodity, agent, and processing combinations.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment". The assessment affirmed the findings of the FDA/CFSAN Operational Risk Management Assessment, provided an additional decision-making tool for performing risk assessments, incorporating a Hazard Analysis Critical Control Points (HACCP) type approach, and made a number of recommendations about 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 provides regular updates to Congress about threat assessments and vulnerabilities related to the safety and security of the U.S. food supply. FDA will be providing to Congress the threat assessments conducted by FDA, IFT and the Battelle Memorial Institute.

FDA is conducting additional assessments of the vulnerability of FDA-regulated foods to intentional contamination with biological, chemical and radiological agents. These assessments use processes adapted from techniques developed by the U.S. Department of Defense for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of the assessments will be used to develop countermeasures, identify research needs, and provide guidance to the private sector

6. **Operation Liberty Shield: FDA Food Security Enhancements in Times of Heightened Alert**

In March 2003, the United States government launched Operation Liberty Shield to increase security and readiness in the United States at a time of elevated risk for a terrorist attack. Operation Liberty Shield, a comprehensive national plan of action to protect many of America's critical infrastructures, was a unified operation coordinated by the Department of Homeland Security that integrated selected national protective measures with the involvement and support of federal, state, local, and private responders and authorities from around the country. Operation Liberty Shield was designed to provide increased protection 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 has established protocols, trained staff and deployed supplies and equipment for future and similar elevated threat level actions. A key component of Operation Liberty Shield was increasing and targeting surveillance of both domestic and imported food. The Agency initiated the following activities:

- FDA issued new industry guidance documents on security measures and encouraged industry to voluntarily assess their security measures in response to an increased threat level. These guidance documents were discussed earlier in the document.

- FDA held a series of conference calls to brief state regulatory agencies, industry trade associations, consumer groups, and their federal counterparts, on Operation Liberty Shield and to request their assistance in distributing the food security guidance documents to domestic facilities and the portion of the import community that handles food products.

- FDA increased its surveillance of the domestic food industry, during Operation Liberty Shield, by conducting 844 inspections of domestic firms based on risk/threat assessments with a focus on enhancing awareness of food security at these facilities by providing copies of appropriate food security guidance documents. These investigations targeted examinations of specific commodities based on risk/threat assessments and sampled specific commodities based on risk/threat.

- FDA increased its monitoring of imported foods, during Operation Liberty Shield, by conducting increased examinations of specific imported commodities based on FDA's risk/threat assessments; enhancing the import communities' awareness of food security at ports by providing copies of FDA's food security guidance documents and sampling imported foods based on risk/threat assessments. FDA collected and analyzed 387 import samples for chemical and microbiological contaminants.

- FDA conducted domestic and import reconciliation exams to confirm that regulated commodities were what they purported to be, exposed unexplained differences between associated documentation and the product, and uncovered signs of tampering or counterfeiting.

- FDA increased joint activities with federal, state, and local partners to help ensure a safe and secure food supply, including working with the Centers for Disease Control and Prevention to ensure that outbreaks or unusual patterns of illness or injury are quickly investigated.

- Likewise, USDA undertook similar food security measures and activities for its regulated industries including meat, poultry and processed egg products. Thus, in combination, FDA and USDA comprehensively covered the U.S. food supply.

7. **Emergency Preparedness and Response**

FDA has established an Office of Crisis Management (OCM) to coordinate 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 FDA Emergency Operations Center serves as the chief communications node and point of contact within FDA.

Over the past two years, FDA has participated in and conducted multiple emergency response exercises. Frequently, these exercises are coordinated with other federal and state agencies. In both exercises and everyday issues, FDA's OCM works closely with the Department of Health and Human Services/Office of Public Health Emergency Preparedness (OPHEP) and the Secretary's Command Center (SCC). This relationship facilitates communication between all HHS Operating Divisions, the Department, and other federal agencies and Departments, including the Department of Homeland Security. 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 2003, FDA participated in the TOPOFF 2 terrorism exercise, a national, full scale, fully functional exercise intended to simulate two separate terrorist acts that had implications for food products (e.g., the possibility of food contamination by radiation), as well as the ensuing response by federal, state, and local governments.

FDA has also signed an Inter Agency Agreement (IAG) with the U.S. Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to provide timely and efficient analyses of samples being offered for import into the U.S. and/or in the event of terrorist activity. The mobile laboratories are expected to be ready for deployment in 2004.

Within current resources, FDA is assessing its ability to respond to high-risk product-agent scenarios and for what sustained period. 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.

8. **Laboratory Enhancements**

Methods Development

FDA has redirected laboratory staff to develop laboratory methods for priority biological and chemical agents in food. Methods have been developed for the highest priority select agents.

FDA has reviewed and modified current regulatory analytical methods for their applicability to terrorism related samples. Methods have been 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 toxin screening method for application as a surveillance tool.

FDA has established an 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 the Department of Defense to develop and validate methods to detect agents most likely to be used in a terrorist attack on the food supply, and engaged in interagency agreements that would allow the Department of Defense 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.

Network Development

FDA has worked with CDC, USDA, EPA, DOE and the States to initiate development of a nationwide Food Emergency Response Network (FERN). FERN is a network of state and federal laboratories that is committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist event in this country. As of June 2003, there were 63 laboratories participating in the FERN network, representing 27 states and 5 federal agencies. Following the events of September 11, 2001, FDA took aggressive action to develop this network building on then-existing laboratory capabilities. FDA is working to add additional food laboratories to the FERN. Furthermore, FDA will work with CDC and the states to improve laboratory capacity to enhance response capability for food security concerns. With CDC grant funds, states are initiating additional activities to increase lab capacity for food-related emergencies.

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 on a password protected website.

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

Ninety five laboratories representing 48 states are participating in the Electronic Laboratory Exchange Network (eLEXNET), the nation's first seamless, integrated, web-based data exchange system for food testing information. eLEXNET allows health officials at multiple government agencies engaged in food safety activities to compare, share, and coordinate laboratory analysis findings on food products. At its inception in 2000, eLEXNET included a mere 8 labs from 7 states and was capable of tracking a sole analyte. Whereas FERN laboratories are involved in the actual analysis of food samples, eLEXNET provides a forum for the exchange of laboratory data. FDA is continuing efforts to expand eLEXNET to provide better nationwide data on food product analyses by regulatory agencies.

Staff Development and Training

FDA has trained its staff as well as staff from USDA, state food laboratories and the CDC Laboratory Response Network public health laboratories in the analysis of foods for several microorganisms.

9. **Research**

HHS Secretary Tommy Thompson and FDA Commissioner Dr. Mark McClellan announced the

commitment of $5M in supplemental funding from the Office of Management and Budget (OMB) to support FDA's food security research initiative. The FDA plans to focus this new food security research thrust on three broad areas: (1) development of prevention and mitigation technologies/strategies, (2) the elucidation of agent characteristics needed to develop these prevention technologies, and (3) the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. This integrated program will draw upon all three components of FDA's research infrastructure: its intramural research capabilities, its 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 extramural research programs that provides competitive research contracts and grants. Specific projects will 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 security/safety system; the development of methods for decontaminating food processing facilities, retail establishment s , 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 PC-based Analytical Modeling Tool to facilitate rapid response to food security and safety emergencies.

Intramural Program

Although modern technology has considerable potential to improve our ability to keep the nation's food supply secure, research on food security is a relatively new concept. To take advantage of the opportunities for making foods safer and more secure through research and development of new technologies, FDA, HHS, and the Administration are taking unprecedented steps to develop this new area of research. In particular, FDA has already redirected existing research staff to ensure that appropriate resources are focused on key priority food safety and security issues. FDA has over 25 intramural research projects ongoing related to food security.

Steps Toward Establishment of Extramural Food Security Research Program

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/gram of food without pre-growth or selective enrichment; (2) development of PCR-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.

New Research Collaborations

FDA is collaborating with the National Institutes of Health (NIH) on a joint project to fund critical research on the thermal stability of key select agent(s) in high risk food(s).

FDA has initiated cooperative research programs with the National Center for Food Safety and Technology (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.

FDA participates in the Technical Support Working Group (TSWG), the U.S. national forum that identifies, prioritizes and coordinates interagency and international research and development requirements for combating terrorism

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a public-private partnership established between FDA and the University of Maryland in 1996, in collaboration with the US-Israel Binational Agricultural Research and Development (BARD) Fund held a food security conference, "Science and Technology Based Countermeasures to Foodborne Terrorism," on June 29 - July 2, 2003. The conference provided a forum to discuss the current state of knowledge about foodborne terrorism, including threat assessment methods, methods of detection, tracking, tracing, authenticating and anti-tampering technologies and hazard mitigation.

Establishing Broader Research Agenda

FDA is developing a broader research agenda to address critical research needs to aggressively meet food security challenges. The research would focus on three broad areas: (1) development of prevention and mitigation technologies/strategies, (2) the elucidation of agent characteristics needed to develop prevention technologies, and (3) the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. These research needs are being prioritized into short, medium, and longer-term phases: (1) technological assessment 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 research and development projects lasting 12-24 months, and (3) research and development that will require elucidation of new technologies or substantial extension of existing scientific knowledge (24 - 60 months). Such research is being planned as an integrated program that will draw upon all three components of FDA research infrastructure: its intramural capabilities, its collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, and National Center for Natural Products Research), and extramural research program that provides competitive research contracts. FDA will also actively collaborate with other federal government research organizations, including NIH, USDA, and DoD.

10. **Interagency and International Communication and Collaboration**

Food security, like other aspects of protecting our Nation's critical infrastructures, requires 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 Department of Health and Human Services (DHHS) Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, the Department, and other federal agencies and Departments, including Homeland Security. Some of these security steps facilitated by this coordination are outlined below.

FDA holds regularly scheduled interagency conference calls with representatives from USDA ¬Animal and Plant Health Inspection Service (APHIS) and FSIS|, CDC, Environmental Protection Agency (EPA), DoD, Department of Commerce, Tax and Trade Bureau, and the Bureau of Customs and Border Protection (CBP). FDA also regularly consults with its interagency partners.

On February 4, 2003, FDA, in conjunction with the National Association of State Departments of Agriculture (NASDA), 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 the State Departments of Health titled "Homeland Security - Protecting Agriculture, the Food Supply and Public Health - The Role of the States."

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 States and FDA.

FDA is also represented on the White House Homeland Security Council's Interagency Food Working Group (IFWG). The IFWG includes representation from DHHS/FDA, USDA/FSIS, Department of Defense, Environmental Protection Agency, Department of Transportation, Central Intelligence Agency, Federal Bureau of Investigation, Department of Treasury, Federal Emergency Management Agency, and a variety of White House representatives. FDA is developing plans for improved laboratory preparedness, and product security, and is drafting a National Interagency Food Response Plan in coordination with states, industry, and food trade associations. FDA is represented on three IFWG subgroups: Laboratory Subgroup, Shields Subgroup, and Incident Command Subgroup.

As part of the Department-wide collaboration and effort to improve nationwide capacity, the Centers for Disease Control and Prevention (CDC) has initiated a cooperative agreement program and has made funds available to upgrade state and local jurisdictions' public health preparedness for and in response to bioterrorism, other outbreaks of infectious disease, and other public health threats and emergencies. CDC is making available $870 million this fiscal year. Awards will be made to address needs in seven focus areas: (1) Preparedness Planning and Readiness Assessment, (2) Surveillance and Epidemiology Capacity, (3) Laboratory Capacity - Biologic Agents, (4) Laboratory Capacity - Chemical Agents, (5) Health Alert Network/Communications and Information Technology, (6) Communicating Health Risks and Health Information

Dissemination, and (7) Education and Training. Improving laboratory capacity, including for food analysis, is an integral part of this effort.

FDA is working very closely with the Department of Homeland Security and the White House Homeland Security Council on a variety of issues. We are consulting with DHS and HSC on research initiatives, shield implementation, and seeking security clearances for appropriate individuals within the food industry in order to share classified information.

FDA has conducted numerous emergency response exercises with our federal counterparts to strengthen the federal response to a food incident. The Department of Health and Human Services has participated in several Deputy Secretary level exercises with USDA, DoD, EPA, CIA, and FBI to test our emergency response capabilities. TOPOFF 2 was an excellent example of interagency cooperation by USDA/FSIS sending representatives to the DHHS/Command Center and the FDA Emergency Operations Center.

Despite the comprehensive work that FDA has accomplished to date, there are additional steps that are being contemplated. These future projects are discussed below.

FDA is working with the Department of Homeland Security and USDA, to establish a Food Sector and a Food Information Sharing and Analysis Center (ISAC) to facilitate the overall protection of the food sector's critical infrastructure and to share information about vulnerabilities, threats, and incidents.

FDA is working closely with Canada and Mexico in an effort to assess and strengthen our public health and food security systems and infrastructure at our mutual borders. FDA and USDA are working with our Canadian and Mexican counterparts through bilateral workgroups to enhance existing partnerships, e.g. Global Health Security Action Group, forge new and improved food and agriculture security measures and systems covering prevention and preparedness; response to and recovery from potential threats.

FDA is collaborating with the Department of Homeland Security and USDA (Food Safety and Inspection Service) and has proposed projects for the prevention of and response to an intentional threat to the food supply.

SUMMARY

FDA thorough it's aggressive program, has made significant progress in strengthening the safety and security of the Nation's food supply.

Nearly 20% of all imports into the U.S. are food and food products. FDA anticipates that we will receive over 8 million food shipments from over 200,000 foreign manufacturers this year--a huge volume that continues to grow rapidly. To meet this challenge, FDA is providing a greater import presence. FDA has placed an additional 300 field personnel at U.S. ports of entry. FDA now has a presence at 90 ports of entry and quintupled the number of food import examinations it performed this year compared to 2001--FDA has exceeded its year-end goal of 48,000 by 14,000 food import examinations.

FDA is using risk-based strategies to provide better information and in its collaborative efforts with other entities. This includes working with foreign authorities and manufacturers to improve production and shipping practices abroad as an alternative to detailed inspections at the boarder. FDA is using better information on imports to focus border checks on products that present significant potential risks and is working with producers to improve checks on the integrity of ingredients and to implement common-sense steps to reduce security risks.

FDA is on schedule to publish four major new regulations in accordance with provisions of the Bioterrorism Act that provide the agency with most significant enhancements to FDA's statutory authority to keep food imports secure. The agency intends to publish two final rules in October of this year and two additional final rules by the end of this year.

FDA has taken unprecedented steps to develop food security research. FDA has received $5 million in supplemental funding from OMB to support FDA's food security research initiative. FDA is using this supplemental funding to focus on three broad areas: development of prevention and mitigation technologies and strategies, elucidation of agent characteristics, and development of means for continuously assessing foods for contamination. FDA has redirected existing research staff to focus on key priority issues and has over 25 intramural research projects ongoing related to food security. FDA is developing a broader research agenda to address critical research needs to aggressively meet food security challenges including development of prevention and mitigation technologies/strategies, elucidation of agent characteristics needed to develop prevention technologies, and development of means for continuously assessing foods for contamination.

FDA remains dedicated to ensuring the safety and security of the nation's food supply. Americans depend on FDA to keep food safe and secure, and FDA will keep doing all we can to fulfill this critical mission.

Ensuring the Safety and Security of the Nation's Food Supply

National Food Safety Programs

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