



**STATEMENT OF**

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**

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**COMMITTEE ON ENERGY AND COMMERCE**

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## **INTRODUCTION**

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods, at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss our ongoing activities to implement our Food Protection Plan (FPP) to enhance food safety.

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the United States Department of Agriculture (USDA). FDA's responsibility extends to live food animals and animal feed. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more

quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies and to develop the Food Protection Plan.

## **ACTION PLAN FOR IMPORT SAFETY AND FOOD PROTECTION PLAN**

To address these challenges across the range of imported consumer products, last November, Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released the Food Protection Plan which provides a framework to identify and counter potential hazards with respect to both domestic and imported food. Achieving the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress.

On June 9, the Secretary announced that the Administration is increasing its Fiscal Year (FY) 2009 budget request for FDA by \$275 million. This increase brings the Administration's total proposed increase in FDA's budget for FY 2009 to \$404.7 million, a 17.8% increase over FY 2008. A large portion of this increase (\$125 million) will be used for food safety and will allow FDA to intensify actions to implement the Food Protection Plan. This is in addition to the \$42.2 million increase proposed for food protection in the budget announced in February 2008. \$100 million of these funds will be used to strengthen safety of drugs, biologics, and medical devices from product development and pre-approval testing, through approval, and post-approval safety

surveillance. Finally, \$50 million of the increase will be employed to strengthen FDA's initiatives in emerging science such as nanotechnology, cell and gene therapies, robotics, genomics, and advancing the critical path initiative. Across these program areas, \$65 million will be used to modernize FDA's information technology (IT) infrastructure.

We are moving forward to implement the Food Protection Plan and are working with all our partners to develop the science foundation and necessary tools to better understand the current risks in the food supply. We are developing new detection technologies and improved response systems to rapidly react to food safety threats.

The Plans build in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach encompasses three core elements: prevention, intervention, and response. The *prevention* element means working to encourage producers to build safety into their processes from the beginning for both domestic and imported foods and promoting increased corporate responsibility so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for better communication and increased speed and efficiency.

## **IMPLEMENTATION OF FOOD PROTECTION PLAN**

### **Key Themes**

Implementing the Food Protection Plan requires not only a major focus on many specific deliverables, but also a cross-cutting approach to a number of key areas that will support the implementation efforts. To this end, FDA has established a number of cross-cutting implementation teams within FDA to focus on key areas. These working groups include participants from FDA's Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine, the Office of Regulatory Affairs (ORA), the Office of Chief Counsel, the Office of Policy, the Office of International Programs, the Office of Crisis Management (OCM), the Office of the Chief Information Officer, the National Center for Toxicological Research, and other offices as needed to ensure full integration and participation across FDA. We are also working with our external food safety partners to gain valuable input and expertise from all our stakeholders. I would now like to describe five of the key, cross-cutting themes.

### **Risk-Based Approach**

FDA has been using a risk-based approach to setting priorities for many years. However, there are new models relating to risk assessments and new mechanisms that could improve our risk-based approach. FDA has developed an internal steering committee to address the various components of an Agency-wide risk-based approach to FDA-regulated food and feed products. The Agency needs to apply a risk-based approach to many activities such as research, determining where and what to inspect, and developing detection, prevention, and mitigation tools. FDA will work with the food industry, consumer groups, and

Federal, state, local, tribal, and international partners to generate the additional data needed to strengthen our risk-based approaches. A comprehensive, risk-based approach allows FDA to maximize the effectiveness of its resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

Working with the Centers for Disease Control and Prevention (CDC) and state and local officials, FDA will also build the capacity to better attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. FDA will also continue to work with the Department of Homeland Security (DHS) and other partners on identifying emerging food defense risks and developing rankings so that we can more effectively allocate our resources to manage these risks.

### **Outreach**

As part of implementing the FPP, FDA has undertaken a number of specific outreach activities. For example, FDA has met with representatives from many foreign governments. This has allowed FDA to gain insights into how other countries have addressed many of the same problems. Meetings with state and local partners, industry, and consumer groups have also contributed significantly to the implementation strategy. To provide a forum for local, state, and Federal partners to exchange information and ideas about implementing the plan and enhancing food safety, FDA will host a meeting on August 12-14, 2008, in St. Louis, Missouri, with regulatory, epidemiology, and laboratory officials from the departments of health and agriculture from all 50 States. We also recently established a docket and are soliciting comments from our stakeholders on the Food Protection Plan and on specific questions related to its implementation.

The comment period will remain open until July 31, 2008. We have numerous other outreach activities underway to engage our stakeholders in implementing elements of the Food Protection Plan.

### **Track and Trace**

The ability to trace products both forwards and backwards is critical for protecting consumers. FDA has formed an internal multi-Center group to meet with external entities (such as industry, consumers, and foreign governments) to better understand the universe of track and trace systems that are currently in use or are being developed. FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track and trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. FDA will use the information to develop the key attributes for a successful track and trace system. In addition, FDA plans to issue a Request for Applications to provide funding to six states to establish Rapid Response Teams to investigate multi-state outbreaks of foodborne illness.

### **FDA Beyond Our Borders**

#### ***Agreement with China***

Consistent with the goals of the Action Plan and the FPP, on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of the People's Republic of China signed an Agreement to enhance the safety of food and animal feed products exported from China to the United States. The Agreement establishes a bilateral mechanism to provide greater information to ensure products exported from China to the United

States meet U.S. safety standards. The key terms of the Agreement include enhanced registration and certification requirements, greater information-sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress.

The first formal bilateral meeting under the Agreement between FDA and Chinese regulators was held the week of March 17, 2008, in Beijing. Initially, the focus is on six species of aquacultured fish and three specific ingredients that could be used in foods for humans or animals (wheat gluten, corn gluten, and rice protein).

FDA's Beyond Our Borders Initiative includes increased collaboration with foreign regulators to expand FDA's capacity for the regulation of food and other FDA-regulated products. As part of this initiative, FDA has also made a commitment to station Agency representatives in China to increase our ability to carry out foreign inspections and to assist the Chinese government officials in their regulatory work associated with FDA-regulated products that are to be exported to the U.S. FDA is considering similar endeavors in other countries. For example, we have had discussions with government officials in India regarding an FDA presence there. FDA is also exploring the possibility of expanding FDA's presence in the Middle East, Europe, and Central and South America.

### **Voluntary Third Party Certification Programs**

On April 2, 2008, FDA published a notice in the *Federal Register* to solicit public comments on the use of voluntary third-party certification programs for foods and feeds, including pet foods. Third-party certification could provide FDA with additional assurances of safety and with

valuable compliance information that would allow FDA to allocate inspection resources more effectively. FDA would not be bound by the information from these third-party organizations in determining compliance with FDA requirements. The public comments will assist FDA in the design and development of third-party certification programs.

### **Additional Implementation Activities**

Implementing the FPP is a long-term, multi-year process. Using the funding increases provided by Congressional appropriations in FY 2008, FDA will be hiring additional staff to assist in addressing the highest priority action items. FDA will hire 161 new full-time equivalents (FTEs) in FY 2008. Of these, ORA will hire 130 new FTEs to conduct food field examinations, inspections, and sample collections. CFSAN will hire 29 new FTEs to assist with research, the development of guidance and regulations, and other food safety-related work. OCM will hire two new FTEs to assist in rapidly responding to and mitigating food safety threats.

The President's FY 2009 Budget requests \$167.2 million to implement the FPP. These funds, which include the \$42.2 million requested by the President in February 2008 and the \$125 million added to that request this week, will allow FDA to advance important food defense and food safety priorities. FY 2009 prevention activities include performing essential food research, determining the greatest threats of intentional and unintentional contamination to the food supply, and expanding food protection activities beyond our borders. Our intervention activities include conducting more risk-based inspections and surveillance and deploying new food defense and food safety screening tools. FY 2009 response activities include establishing more

rapid response teams, strengthening emergency response, and improving our ability to conduct food tracebacks.

To achieve these objectives and safeguard American consumers, FDA will also improve its IT systems that support our research, risk assessment, inspection, and surveillance activities.

Finally, FDA's FY 2009 food protection initiative includes \$12 million for the cost-of-living pay increase for FDA's food safety and food defense programs. These funds allow FDA to retain its professional workforce. With the funding requested in the President's amended FY 2009 budget, we will hire an additional 353 FTEs to accelerate our food protection plan implementation activities.

I have described above some of the actions we have taken to implement the FPP. I would now like to provide a few more specific examples of our ongoing implementation activities. Under the *Prevention* category, recent accomplishments include:

- FDA held a public meeting to solicit input on ingredient, processing, and updated labeling standards for pet food. We also asked for input on ingredient and processing standards for animal feed generally.
- FDA held a public meeting regarding a modernized risk-based Animal Feed Safety System (AFSS) and the ranking of feed hazards according to the risk they pose to animal and public health. AFSS describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals.

- FDA has been working in collaboration with the State Health and Agriculture departments in Virginia and Florida, several universities, and the produce industry on a multi-year Tomato Safety Initiative.
- FDA released self-assessment tools for industry to minimize the risk of intentional contamination of food and cosmetics.
- FDA issued a draft Compliance Policy Guide to provide guidance for FDA staff on the Agency's enforcement policy for *Listeria monocytogenes* in ready-to-eat food. FDA also issued draft guidance on controls that processors can use to minimize contamination of food with *Listeria monocytogenes*.
- FDA completed an Inter-Agency Agreement with USDA and DHS to determine the survivability of *Bacillus anthracis* (anthrax) in processed liquid egg products which includes whole eggs, egg yolks, and egg whites. Further studies are being conducted to determine the role of lysozyme in *Bacillus anthracis* inactivation.
- FDA developed an assay to assess the stability of two bioterrorism agents in high-risk foods. This assay can be used to assess other chemicals that may be used by terrorists to contaminate the food supply.
- FDA has established a research coordinating committee to provide a collaborative and integrated FPP research agenda.

- FDA is using genetic analysis to identify hundreds of *Salmonella enterica* strains from seafood imports. The analysis provides information that can be used to trace outbreaks of *Salmonella enterica* and implement surveillance programs to ensure the safety of imported seafood.
- FDA has initiated a collaborative multi-institutional study to reduce the risk of *Escherichia coli* O157:H7, funded by USDA under the National Integrated Food Safety Initiative. The work will examine pathogen risk mitigation strategies for leafy greens from field to table.
- FDA assessed and published data on the microbiological load of bagged, ready-to-eat produce. FDA is planning a follow-up study.
- FDA recently announced the availability of approximately one million dollars in research funds and issued a Request for Applications. The funds will be used to support research efforts to advance the safe transportation and preparation of produce to improve the safety of fresh-cut produce.
- FDA established a Memorandum of Understanding with DHS and the Department of Justice (DOJ) to develop forensic tools to allow the identification and differentiation of individual strains of foodborne bacteria. This will assist in rapid identification of the source of contamination.

- FDA has initiated research on the susceptibility of pathogens found in raw and processed meats and imported seafood to antimicrobial agents and mechanisms by which these pathogens develop a resistance to antimicrobial agents.

Looking ahead:

- FDA plans to issue a *Federal Register* notice this year announcing the availability for comment of draft modified industry guidance documents for leafy greens and melons.
- FDA plans to issue a *Federal Register* notice this year to solicit comment on updating the 1998 Good Agricultural Practices (GAPs) guidance document.
- FDA expects to publish a Final Rule this year on requirements to prevent *Salmonella enteritidis* contamination of shell eggs during egg production.
- FDA plans to release this year the 4<sup>th</sup> Edition of Fish and Fishery Products Hazards and Controls Guidance with updates to the previous editions to incorporate the current scientific and technical information regarding hazards associated with the harvest, processing, and storage of fish and fishery products.

Some examples of activities to implement the *Intervention* components of the FPP include:

- FDA has completed a pilot test of the prototype system, PREDICT (Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting), for seafood imported through the ports of Los Angeles. PREDICT is a tool to better target food safety threats at the border. It has been developed under contract with New Mexico State University. We are working to develop the necessary technical requirements to expand the application of this system.
- FDA has developed a rapid detection method using flow cytometry to identify *Escherichia coli* and *Salmonella* in food. This system is being used in poultry processing facilities to detect and prevent bacterial contamination during food processing.
- FDA microbiologists attended training at CDC's Salmonella Reference Laboratory and learned a new molecular method for rapidly and accurately identifying *Salmonella* serovars. The instruments have been purchased by both CFSAN and ORA laboratories.

Additional examples of actions to implement the *Response* components include:

- FDA has completed four Incident Command System training courses that have included state representatives.

- FDA has developed additional Farm Investigation Courses for Federal, state, and international investigators.

## **LEGISLATIVE AUTHORITIES**

Finally, I would like to just mention the legislative authorities identified as necessary for achieving full implementation of the FPP. These authorities would:

- Allow FDA to require preventive controls against intentional adulteration at points of high vulnerability in the food chain;
- Authorize FDA to issue additional preventive controls for certain high-risk foods;
- Require food facilities to renew their FDA registrations at least every two years and allow FDA to modify the registration categories;
- Authorize FDA to accredit highly-qualified third parties for voluntary food inspections;
- Require a new reinspection fee from facilities that fail to meet Current Good Manufacturing Practice (cGMPS) requirements;
- Empower FDA to require electronic import certificates for shipments of designated high-risk products from countries with which FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet FDA standards;
- Allow FDA to charge export certification fees for food and animal feed to improve the ability of U.S. firms to export their products;
- Authorize FDA to refuse admission of imported food if FDA inspection access is delayed, limited or denied;

- Empower FDA to issue a mandatory recall of food products if voluntary recalls are not effective; and
- Give FDA enhanced access to food records during emergencies.

We appreciate the work of this Committee in drafting legislation intended to help provide these authorities. We look forward to working with you to develop this important legislation.

## **CONCLUSION**

Together, the Food Protection Plan and the Action Plan for Import Safety provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. The approach involves some fundamental changes and, as such, requires a comprehensive implementation strategy. This implementation will be built on a sound risk-based foundation and will not be a rapid endeavor. The degree of progress and the overall success are dependent on both resources and new legislation.

FDA remains committed to working closely with all of its partners to implement the Plans' measures to protect the nation's food supply. We commend this Committee for its efforts and look forward to working with Congress to develop and obtain passage of the necessary legislative authorities identified in the Food Protection Plan and the Action Plan for Import Safety. Thank you for the opportunity to discuss FDA's activities to implement the Food Protection Plan to enhance food safety. I would be happy to answer any questions.