Food Protection Plan
One-Year Progress Summary
December 2008

INTRODUCTION

All of us in the United States today enjoy unprecedented choice and convenience in filling the cupboard, but such progress brings new challenges to ensuring that our food is safe. This U.S. Food and Drug Administration (FDA) Food Protection Plan (FPP) One-Year Progress Summary documents initial implementation of FPP's strategies to build safety into every step of the food supply chain.

Core Elements of the Food Protection Plan

In November 2007, the FDA released the Food Protection Plan, containing integrated initiatives for protecting the nation's food supply. The FPP addresses both food safety and food defense for domestic and imported products. FDA is working collaboratively across the agency to implement the three core elements of protection: prevention, intervention, and response. Briefly, an explanation of the strategies is as follows:

Core Element #1: PREVENTION

Prevention is the first essential step for an effective, proactive food safety and defense plan that includes the full lifecycle of food—from production to consumption whether food is produced domestically or is imported. The prevention strategies are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are more susceptible to contamination than others, for example foods eaten raw versus cooked. The prevention elements of the FPP emphasize the importance for FDA and industry to work collaboratively to prevent food problems from occurring. This will be accomplished through a comprehensive review of food supply vulnerabilities. FDA will work with industry and other stakeholders to develop effective tools and science to prevent outbreaks of foodborne illness caused by unintentional and intentional factors.

Core Element #2: INTERVENTION

Because no plan can prevent 100 percent of food contamination, we must have targeted, risk-based interventions, particularly at the points of manufacture and during distribution, to provide a second layer of protection. These interventions must not only verify that the preventive measures called for are implemented correctly they must also identify contaminated food that either unintentionally or intentionally circumvents our prevention plan. Using robust risk-based analysis, FDA will conduct high-priority inspections that rely on statistical sampling and advanced risk-detection tools, and will verify industry business practices across the food chain to ensure that effective preventive measures are in place. Gathering and analyzing test results, adverse event reports, consumer complaints, and other information will help FDA track emerging food protection problems.

Core Element #3: RESPONSE

In the past year, FDA responded to a number of significant food safety problems. Whether contamination is unintentional or deliberate, there is a need to respond to it faster and communicate more effectively with consumers and other partners. FDA is committed to increasing its ability to quickly identify food safety problems, better coordinating a rapid emergency response among FDA, state and local government response teams as appropriate, and improving communications to the public, industry and other partners. These actions will better protect public health, help reduce the economic hardship of affected industries, and maintain consumer confidence in the U.S. food supply following an incident.

FDA remains committed to strengthening the nation's food protection system through implementation of the FDA Food Protection Plan. The Plan's strategic and partnered activities are driven by science and incorporate the use of 21st-century technologies.

OVERVIEW OF PROGRESS

Prevention Strategies

Several key prevention initiatives have been started since November 2007. These began with outreach to explain and involve others in FDA's Food Protection Plan. This outreach has involved multiple meetings with various foreign countries, state and local organizations, and industry and consumer groups. To further the interaction with federal, state and local partners, FDA held a meeting to share information and develop strategies and future activities between federal, state, and local partners. As a cross-cutting activity, FDA has formed an internal Risk-Based Steering Committee to ensure that a systematic, comprehensive risk-based approach is taken by the Agency with regard to food protection. A specific example of risk-based prevention activity is the work FDA is doing in collaboration with states, universities and industry on its Tomato Safety Initiative. On the international front, FDA has taken concrete steps to increase foreign capacity building and increase the Agency's presence beyond our borders. FDA will send the first staff to the Agency's new offices in China, India, Europe, and Latin America before the end of 2008.

Intervention Strategies

FDA is working to improve the targeting of risk-based inspections and sampling to focus resources where they will have the greatest impact. FDA has completed a three-year plan to increase state inspections and will hire an additional 130 employees to conduct food field exams, inspections, and sample collections. FDA issued a Federal Register notice to solicit input on third-party certification programs, issued draft guidance on voluntary third-party certification, and is piloting the use of voluntary third-party programs. FDA is working to develop better tools to identify food safety threats at the border, including the development of an advanced screening system. This system, known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), was piloted on a small scale in recent months and the assessment of the pilot is currently under agency review. FDA has established a research coordinating committee to develop a collaborative research agenda that supports activities under prevention, intervention and response, such as mitigation strategies and rapid detection systems.

Response Strategies

In order to improve the response to a threat to food safety, FDA scheduled public meetings in October and November to engage with stakeholders on identifying product tracing best practices so that contaminated product can be identified and removed from commerce more quickly. FDA is also working with states to improve response through Incident Command System training. Additionally, the Agency has awarded grants to six states to establish Rapid Response Teams to enable rapid, localized response to incidents. In an effort to improve communication with the public, FDA reviewed and worked to improve its recall communication processes and presented new recall templates to FDA's Risk

Communication Advisory Board for input in March 2008.

Building a Sustainable Food Protection Program

FDA continues to work with Congress to ensure the Agency has adequate resources to protect the safety of the U.S. food supply. On June 9, 2008, the Administration announced an FY 2009 budget amendment with an increase of $275 million over the original budget request. The increased request includes $125 million for food protection. On June 30, 2008, the President signed the FY 2008 Supplemental Appropriation into law, providing $150 million for FDA, including $72 million for Food Protection.

Legislative Authorities Requested in the Food Protection Plan

FDA believes that, while it has the statutory and regulatory authority needed to carry out its commitment to food protection, its ability to ensure food safety would be strengthened significantly by the additional legislative authorities that were requested in the Food Protection Plan and are listed below. These authorities are critical to future food protection implementation efforts and will be built into actionable deliverables when Agency authorities are granted by Congress. In the meantime, the Agency will continue to look for opportunities to work productively with Congress to ensure understanding of the design of and need for these authorities.

- 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 current food product categories for purposes of registration
- 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
- Give FDA enhanced access to food records during emergencies

ONE-YEAR ACCOMPLISHMENTS

Food Protection Plan
Core Element #1: PREVENTION

FPP Goal 1.1: Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses - *FDA will work with all stakeholders to ensure food protection is built into the full food product life cycle from production to consumption.*

FDA's current and planned actions will enable FDA to:

- Enhance communication with stakeholders on preventive approaches to protect the food supply;
- Build-in food safety upfront through the identification and implementation of best practices and standards;
- Increase foreign capacity and technical assistance; and

- Establish an FDA presence beyond our borders.

Accomplishments:

Enhance Communication with Stakeholders on Preventive Approaches to Protect the Food Supply

FDA undertook several activities to engage with stakeholders on the implementation of the FPP and preventive approaches to ensure food protection.

- FDA held a 50 state meeting, "Gateway to Food Protection" August 12-14, 2008, in St. Louis, Missouri. The meeting brought together over 200 Federal, State, Local, Tribal, and Territorial partners to address challenges and opportunities to ensure the safety of the food supply Americans enjoy and demand.
- FDA issued a Federal Register Notice announcing a docket for stakeholder comment on the implementation of the FPP as part of a broad outreach plan. Docket number FDA-2008-N-0188, Food Protection Plan; Outreach Activities; Opportunity for Public Comment, can be found at www.regulations.gov. FDA has reviewed stakeholder comments and taken comments into consideration when planning for the implementation of activities under the Food Protection Plan.
- FDA held a public meeting on May 13, 2008, in Rockville, MD to solicit input on the requirements of Sections 1002, 1003, and 1005 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) concerning pet food labeling, standards for ingredients and processing for all animal feed, early warning surveillance, and effective communication during pet food recalls. Stakeholder presentations included representatives from the American Veterinary Medical Association, the Association of American Feed Control Officials, Defend Our Pets, pet owners, and consulting veterinarians. The discussion topics included substantiated label claims, emergency preparedness, country of origin labeling, and increased consumer awareness. The meeting transcript can be viewed at http://www.fda.gov/cvm/Transcripts051308.htm.
- FDA held a public meeting on May 13, 2008, in Rockville, MD to present changes to the Animal Feed Safety System (AFSS) project and the ranking of feed hazards according to the risk they pose to animal and public health. The objective of the meeting was to present (1) Changes to the AFSS Project and (2) The Ranking of Feed Hazards According to the Risks They Pose to Animal and Public Health; Part 3: Swine Feed Example. The meeting transcript can be viewed at http:/www.fda.gov/cvm/AFSS051408Transcripts.htm.

Build-In Food Safety Upfront through the Identification and Implementation of Best Practices and Standards

FDA is working with industry and stakeholders to identify and ensure the use of best practices for early prevention of food safety threats.

- FDA issued a Federal Register Notice soliciting stakeholder comments, scientific data, and information to improve the guidance to industry set forth in the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" issued in 1998 (i.e., the Good Agricultural Practices Guidance). Docket number FDA-2008-N-0455 can be viewed at www.regulations.gov.
- FDA released the CARVER self-assessment tool for industry to minimize the risk of intentional contamination of food and conducted a series of Webinars to train industry stakeholders on the use of the tool to evaluate food facilities vulnerabilities to a deliberate attack.
- FDA translated ALERT materials into French and Portuguese and distributed materials to Federal, State, and Local regulatory authorities and food industry managers. In addition, FDA translated the ALERT web-based training tool into Spanish and posted it on the FDA website. ALERT is an initiative intended to raise the awareness of state and local government agency and industry representatives regarding food defense issues and preparedness. More information on ALERT is available at:

http://www.cfsan.fda.gov/~dms/alert.html

- FDA awarded cooperative agreements for the Ruminant Feed Ban Support Program to further enhance the infrastructure of state, territorial, and tribal animal feed safety and bovine spongiform encephalopathy (BSE) prevention programs.
- FDA awarded Innovative Food Defense grants that will generate novel solutions and outreach to address gaps in or provide enhancement to, food defense nationwide.
- FDA, in collaboration with the U.S. Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture (USDA), launched its food defense awareness training kit for First-Line Employees in the food and agriculture industry from farm to table. Employees FIRST is a food defense awareness initiative for employees that food industry management can include in its ongoing food defense training programs. This is the second in a line of Food Defense Awareness Materials, following on the ALERT initiative.
- FDA is 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. As part of the initiative, FDA has led assessments of grower practices focusing on the factors believed to be associated with contamination of tomatoes with *Salmonella*. FDA has conducted assessments in Virginia and completed two sets of assessments in Southern and Central Florida and is planning a third assessment in Northern Florida. FDA is analyzing the information in order to prepare a report on the assessments that can be shared with industry and other stakeholders.
- FDA has gathered input on animal feed best practices for preventive controls from industry groups including the National Grain and Feed Association, the American Feed Industry Association, the Pet Food Institute, and the Association of American Feed Control Officials (an organization of state feed control officials).
- FDA issued a draft Compliance Policy Guide (CPG) on *Listeria monocytogenes*. The CPG, when finalized, will provide guidance for FDA staff on the agency's enforcement policy for *Listeria monocytogenes* in ready-to-eat food. FDA issued a Federal Register Notice to solicit comment and held a public meeting on the draft. Docket number FDA-2008-D-0058-0001, Draft Compliance Policy Guide Sec.555.320 *Listeria monocytogenes*, can be found at www.regulations.gov. FDA also issued draft guidance on controls that processors can use to minimize contamination of food with *Listeria monocytogenes.* Docket number FDA-2008-D-0096, Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat-Foods, is available at www.regulations.gov.
- FDA issued a final rule entitled, "Substances Prohibited from Use in Animal Food or Feed." This rule enhances the current Bovine Spongiform Encephalopathy (BSE) rule by prohibiting certain specified risk materials in all animal feed in addition to all of the original requirements. Docket number 2002-N-0031 can be found at www.regulations.gov.

Increase Foreign Capacity and Technical Assistance

FDA is building foreign capacity by engaging with foreign partners on the implementation of the FPP and by providing technical assistance to foreign countries to ensure the safety of imported food.

- FDA established an International Notification Coordinator position to manage overall enhanced information exchange between FDA and foreign counterpart regulatory authorities.
- On May 5-9, 2008, a small assessment team of FDA experts from the U.S. visited Lima, Peru to meet with Peru's Asia-Pacific Economic Cooperation (APEC) officials, and key stakeholders from the public and private sectors to raise awareness of the APEC Food Defense Proposal, ascertain which food sectors are most receptive to the technical support being offered by this initiative, and to plan regional food defense workshops.
- On September 15-20, 2008, FDA held a series of three regional workshops on raising food defense awareness in Peru. They were held in succession in Ica, Lima, and Trujillo, Peru. The workshops were the second phase of a pilot project approved by APEC and focused on engendering food defense awareness and encouraging close communication and collaboration on food defense issues among stakeholders, as well as developing

food defense plans for individual companies with the assistance of both private and public sector expertise. The workshops were part of an ongoing collaborative effort of FDA, USDA/Foreign Agriculture Service (FAS) (Washington and Lima), State Department, USDA/Food Safety Inspection Service (FSIS), APEC, U.S. Trade Representative (USTR), Universidad Nacional Agraria La Molina, and U.S. private sector consultants.

- A delegation from FDA attended the Food Safety Quadrilateral meeting with Canada, New Zealand, and Australia in April 2008 to advance the FPP. One of the proposals under consideration is the establishment of a rapid alert system to share information from any of the countries regarding potential significant public health problems found in food or feed.
- In response to finding unapproved drugs in Chinese aquaculture products, FDA conducted a review of aquaculture drug residue control procedures at thirteen Chinese firms that have been certified by the Chinese government as in compliance with the requirements of the import alert on Chinese aquaculture products.
- FDA was part of a U.S. Department of Health and Human Services delegation to Vietnam to discuss establishing a cooperative arrangement with the Ministry of Health covering food, feed, and medical products. An agreement with Vietnam was recently signed.
- FDA provided a briefing to Washington, DC based foreign embassy personnel on FDA actions under the FPP.
- FDA was part of a U.S. Department of Health and Human Services delegation to China to conduct workshops with Chinese government officials on the recent outbreak of foodborne illness in the U.S. related to fresh produce as well as the melamine contamination of dairy products in China.

Establish FDA Presence Beyond our Borders

FDA is expanding our presence beyond our borders by establishing offices in five regions of the world.

- FDA is establishing office in five locations around the world: China, Latin America, India, Europe, and the Middle East. The FDA has already hired staff for its offices in China and India.
- Implementation of a Memorandum of Agreement (MOA) with China has begun. FDA has met its first set of deadlines by providing registration materials to the Chinese government, identifying points of contact for the MOA, and drafting the first 12-month work plan.
- The first bilateral meeting with China was held in March 2008 in Beijing. The meeting focused on the relationship with the General Administration of Quality, Supervision, Inspection, and Quarantine (AQSIQ). There was verbal agreement to limit the present efforts in fulfilling the MOA to aquaculture (five species plus tilapia) and ingredients (wheat gluten, corn gluten, and rice protein).

FPP Goal 1.2: Identify Food Vulnerabilities and Assess Risks – *FDA will conduct risk-based prevention to better protect American's food supply. FDA and industry will better understand food safety and food defense vulnerabilities and work to define the optimum preventive controls to reduce the greatest risks.*

FDA's current and planned actions will enable FDA to:

- Increase identification and understanding of food vulnerabilities; and
- Target risk reduction through implementation of risk-based processes.

Accomplishments:

Increase Identification and Understanding of Food Vulnerabilities

Research has been conducted in a number of areas related to both food safety and food defense. FDA has worked with the food industry, consumer groups, and Federal, State, Local, and International partners to strengthen the understanding of food safety and food defense risks.
A better understanding of the stability of contaminants in food leads to a better understanding of potential threats to food safety.

- FDA conducted a food defense research symposium of agency sponsored research, participated, as part of the Middle East Partnership Initiative, in the Middle East Workshop "Protecting the Middle East Food Supply from Intentional Contamination."
- FDA and CDC entered into a Memorandum of Understanding to provide two Oak Ridge Institute of Science and Education epidemiologists to the OutbreakNet unit at CDC.
- FDA assessed and published data on the microbiological load of bagged, ready-to-eat produce. These findings suggest that in bagged, ready-to-eat lettuce, the microbial load may be relatively higher than expected. FDA published these findings in February 2008 in the *Journal of Applied Environmental Microbiology*. FDA is planning a follow-up study.
- FDA completed an Inter-Agency Agreement with the USDA and the Department of Homeland Security (DHS) to determine the survivability of *Bacillus anthracis* (anthrax) in processed liquid egg products, which include whole eggs, egg yolks, and egg whites. Further studies are being conducted to determine the role of lyzozyme 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.

Target Risk Reduction through Implementation of Risk-Based Processes

FDA established a Risk-Based Steering Committee to ensure that a systematic comprehensive risk-based approach is taken with regard to food protection.

- FDA developed and is currently piloting the use of a Standard Operating Procedure for applying cross-Agency risk-based approaches to activities under the FPP.
- FDA's Office of Regulatory Affairs (ORA), Center for Food Science and Nutrition (CFSAN), and the Food Field Committee collaborated to develop and use a risk-based high priority list to create a FY 2008 work plan for the ORA field force.
- FDA applied a risk-based approach for all of the feed Compliance programs and has developed program specific priority lists for use by the Office of Regulatory Affairs (ORA) field force when conducting inspections. FDA has established a team to enhanced modeling capability for relative risk-ranking across programs. The team will use the information gathered during the FY 2008 risk-based inspections to assess the risk-ranking models and to determine which models need fine tuning and which additional models may need to be developed. As a result, ranking the relative risk posed by feed hazard will enable FDA to better direct its surveillance and inspectional resources to areas presenting the greatest risk and thereby improve feed and food safety as well as maximizing the use of resources.

FPP Goal 1.3: Expand the Understanding and Use of Effective Mitigation Measures – *FDA will develop and validate rapid detection tools to detect and mitigate potential problems.*

FDA's current and planned actions will enable FDA to:

- Expand FDA research, development, and evaluation of detection and mitigation strategies.

Accomplishments:

Expand FDA Research, Development and Evaluation of Detection and Mitigation

Strategies

FDA has worked to identify and implement tools for use in the application of effective detection and mitigations strategies.

- FDA approved the use of irradiation of iceberg lettuce and spinach for the control of pathogens, such as *Escherichia. coli*, in or on those foods.
- FDA established an internal research coordinating committee and held an internal roundtable discussion on rapid detection technologies and applications for microbial pathogens.
- FDA developed methods to detect melamine and cyanuric acid in feed and feed ingredients, antibiotics in fermentation products of distiller's grains used for animal feed, and prohibited proteins in animal feeds.
- FDA developed a method to detect multi-drug resistant *Salmonella* in imported seafood.
- FDA published a paper on the effects of cleaning on the removal of allergens titled "Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-Contact in Food Processing Operations" *J. Food Prot.* 71:445-458.
- FDA posted a food package database on the web to provide information on package defect classification and identification.
- FDA published a paper on the antimicrobial susceptibility profiles of *Salmonella* in imported seafood (*Food Microbiol.* 25: 29-35).
- FDA approved the use of cetylpyridinium chloride (CPC) as an antimicrobial agent applied in solution to raw poultry carcasses to prevent contamination with *Salmonella* or *E. coli*.
- FDA is using genetic analysis to identify hundreds of *Salmonella* strains from seafood imports. The analysis provides information that can be used to trace *Salmonella* outbreaks and implement surveillance programs to ensure food safety.

Food Protection Plan
Core Element #2: INTERVENTION

FPP Goal 2.1: Focus Inspections and Sampling Based on Risk – *FDA will increase field and state capacity to perform sampling based on risk (e.g. risk assessment, risk ranking, risk analysis, attribution data, etc.).*

FDA's current and planned actions will enable FDA to:

- Expand field capacity for domestic and imported foods utilizing risk-based inspections and sampling;
- Advance screening technology at the border; and
- Increase imported food safety through voluntary third-party certification programs.

Accomplishments:

Expand Field Capacity for Domestic and Imported Food Utilizing Risk-Based Inspection and Sampling

FDA is conducting risk-based inspections to focus resources where they will have the greatest impact.

- FDA completed 5,930 high-risk domestic food establishment inspections during FY 2008.
- FDA piloted the high-risk firm inspection and sampling program in Denver and Minneapolis during the Democratic National Convention and the Republican National Convention.
- A targeted risk-based inspection of a canning facility in 2008 identified cans with viable *Clostridium botulinum* spores and a recall was initiated. FDA initiated this inspection, along with inspections of other Low Acid Canned Food (LACF) manufacturers, following

four cases of botulism in consumers in 2007. FDA increased inspection efforts to ensure that manufacturers of all types of LACF products are adhering to applicable FDA requirements. These actions illustrate the need for companies to operate under adequate preventive control systems.
- ORA has completed a 3-year plan for increasing state inspections.

Advance Screening Technology at the Border

FDA is working to develop better tools to identify food safety threats at the border. Under contract to FDA, New Mexico State University is developing a prototype system for improving electronic screening, using open-source intelligence, of imported products offered for entry into the U.S.

- The evaluation of the prototype system, PREDICT, has been completed and the final pilot evaluation document is currently under review.
- FDA established a steering committee to transition the PREDICT from the pilot phase to an FDA-wide tool.
- FDA is testing new technological approaches to improve the efficiency of field examinations and sample collections.
- FDA and U.S. Customs and Border Protection jointly issued the Prior Notice of Imported Food under the Public Health and Biosecurity Preparedness and Response Act final rule and accompanying Compliance Policy Guide (CPG).

Increase Imported Food Safety through Voluntary Third-Party Certification Programs

FDA is exploring the use of Voluntary Third-Party Certification Programs to ensure the safety of imported food.

- FDA issued "Draft Guidance for Industry on Voluntary Third-Party Certification Programs for Food and Feed." Docket FDA-2008-D-0381 can be viewed at www.regulations.gov.
- FDA issued Federal Register notice, "Voluntary Third-Party Certification Programs for Imported Aquacultured Shrimp; Notice of Pilot Program" and received substantive application for participation in Phase I of the pilot. FDA is currently reviewing applications as part of Phase I of the pilot program. Federal Register Notice FDA-2008-N-0382 can be viewed at www.regulations.gov.
- FDA issued a Federal Register Notice for Food and Feed Third-Party Certification Programs. The notice seeks public comment on the existence and use of third-party certification programs to better understand how they can be used to help ensure that food products are safe, secure, and meet FDA requirements. Docket Number FDA-2008-N-0183-001, Third-Party Certification Programs for Foods and Feeds, can be viewed at www.regulations.gov.

FPP Goal 2.2: Enhance Risk-Based Surveillance through Increased Laboratory Capacity – *FDA will utilize up-to-date technologies and assays and build laboratory infrastructure for faster testing.*

FDA's current and planned actions will enable FDA to:

- Enhance surveillance through increased laboratory capacity.

Accomplishments:

Enhance Surveillance through Increased Laboratory Capacity

FDA is working to further enhance its laboratory capacity in order to conduct greater surveillance and achieve faster response efforts.

- FDA is currently utilizing the high throughput laboratory in Denver, Colorado to increase laboratory capacity for food testing and enhancing data quality.
- FDA awarded cooperative agreements for food safety and security monitoring to provide funding to Food Emergency Response Network (FERN) chemistry laboratories. The grants may be used for facility upgrades, training in current food testing methodologies, and increased laboratory sample analysis capacity.

FPP Goal 2.3: Improve the Detection of Food System "Signals" that Indicate Contamination – *FDA will deploy state-of-the-art technology to improve the integration and analysis of incoming signals and achieve faster mitigation and response.*

FDA's current and planned actions will enable FDA to:

- Improve capability for early detection of contaminated foods; and
- Improve adverse event reporting.

Accomplishments:

Improve Capability for Early Detection of Contaminated Food

FDA is developing methods to more rapidly and accurately identify contaminants in food and to interpret signals that indicate potential food safety threats.

- FDA has developed a rapid detection method using flow cytometry to identify *E. 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 received training at CDC's *Salmonella* Reference Laboratory on a new molecular method for rapidly and accurately identifying *Salmonella* serovars. The instruments needed to rapidly and accurately identify *Salmonella* serovars have been purchased by both CFSAN and ORA laboratories.
- FDA has developed a method for detecting mycotoxins in fermentation products distiller's grains used for animal feed.

Improve Adverse Event Reporting

FDA is working to improve adverse event reporting as well as the Agency's ability to analyze such data in order to maximize the utility of the data to initiate appropriate FDA responses.

- FDA awarded the development contract for the establishment of the reportable food registry required by FDAAA. This system will permit FDA to establish an electronic portal through which instances of reportable food may be reported to the agency and will be easy to use, for both those submitting the reports to the agency and FDA.
- FDA is expanding its adverse drug event database to include adverse feed events. FDA has increased the emergency response and recall team to include scientists and regulators that specialize in responding to feed adverse events and recalls. These capabilities will increase FDA's capacity to quickly and appropriately respond to animal feedborne outbreaks, contamination episodes, and/or product defects.
- FDA is continuing to develop infrastructure to support the implementation of the mandatory reportable food registration system and the MedWatch Plus adverse events reporting system.
- FDA has enhanced data mining for the current adverse events reporting system leading to long term trending capability.
- FDA is developing epidemiological tools for investigating adverse events associated with animal feeds.

Food Protection Plan
Core Element #3: RESPONSE

FPP Goal 3.1: Improve Immediate Response – *Working with partners, FDA will rapidly detect and respond to foodborne outbreaks.*

FDA's current and planned actions will enable FDA to:

- Improve speed and collaboration on response efforts; and
- Enhance traceability capabilities for more rapid and precise product tracing.

Accomplishments:

Improve Speed and Collaboration on Response Efforts

FDA is enhancing the Agency's ability to coordinate a comprehensive Agency response to foodborne illness events.

- FDA has enhanced mapping capabilities by establishing a dedicated Geospatial Analyst position and expanding the capabilities of its Geographic Information System with the purchase of enhanced authoring tools used to track emergency response resources and other locations of interest.
- FDA hired two emergency/complaint response coordinators to improve its response to animal feed emergencies, including pet food emergencies.

FDA is working in conjunction with States to improve response to food safety threats.

- FDA awarded Rapid Response Team cooperative agreements to develop, implement, exercise, and integrate an all-hazards food and food-borne illness response capability to more rapidly react to potential threats to our food supply. The Rapid Response Teams are designed to operate in conjunction with other food and feed agencies within state program, other Rapid Response Teams, FDA district offices, and state emergency operations centers to enhance response capabilities. The funded states were North Carolina, Massachusettes, California, Michigan, Florida, and Minnesota.
- FDA has conducted 10 Incident Command System Trainings.
- FDA has developed an additional Farm Investigation Course for federal, state, and international investigators. Training was held in February 2008.
- A targeted high-risk inspection led FDA investigators to a canning facility in Michigan and the discovery of viable *Clostridium botulinum* spores. Consequently, the firm recalled product that may have been under-processed.
- FDA completed an Inter-Agency Agreement with the USDA and DHS to determine the survivability of *Bacillus anthracis* (anthrax) in processed liquid egg products, which include whole eggs, egg yolks, and egg whites. Further studies are being conducted to determine the role of lyzozyme in *Bacillus anthracis* inactivation.
- After reports from China of melamine-contaminated infant formula, FDA worked with its State and local counterparts to quickly canvas over 2,100 Asian markets to remove any infant formula from China that might be available and to sample milk-derived products to check for melamine contamination.

Enhance Traceability Capabilities for More Rapid and Precise Product Tracing

FDA is working to enhance product tracing capabilities because the ability to quickly identify where a contaminated product came from and where it has been distributed is essential for a rapid response to a foodborne illness outbreak.

- FDA is currently engaging in dialogue with industry and other stakeholders on current track and trace models and standards to identify best practices for product tracing.
- FDA announced two public meetings in the fall of 2008 in Maryland and California regarding tracking and tracing of fresh produce. Docket FDA-2008-N-0513 can be viewed at www.regulations.gov.

- FDA awarded a task order to the Institute of Food Technologists (IFT) to review industry best practices regarding tracking and tracing and provide a report back to FDA on IFT's findings and current best practices employed with many different commodities of the FDA- regulated food sector.

FPP Goal 3.2: Improve Risk Communications to the Public, Industry, and Other Stakeholders – *So that consumers can protect themselves and their families from foodborne illness by responding promptly to FDA alerts.*

FDA's current and planned actions will enable FDA to:

- Communicate more effectively with consumers during food-related events; and
- Provide more rapid alerts to all stakeholders during food-related events.

Accomplishments:

Communicate More Effectively With Consumers During Food Related Events

FDA is working to develop more effective food protection risk communication messages and strategies for use during a food related event.

- FDA held regular briefing conference calls for consumer organizations during the *Salmonella* Saintpaul outbreak in the summer of 2008 and regularly updated a web page that provided information on the outbreak investigation and how consumers could protect themselves and their families.
- FDA is currently analyzing data from consumer interviews focused on consumer preparedness for a food terrorism event. The Agency will use this information to inform the development of social marketing strategies to communicate with consumers more effectively in the event of a food related event
- The FDA has developed information for the public, which is available on its website, on the safe handling of pet food and treats, pet food labeling, and implementation of the feed ban enhancement. Information on pet food labeling enables consumers to better understand the nutritional profile on a product and, in conjunction with their veterinarian, make informed and better choice of diets for their animals. FDA also has developed consumer information pieces on the safe handling of pet food, the safe handling of baby turtles, and a video for the transportation industry on implementing the BSE regulation in the trucking industry. This information will improve the ability of consumers and industry to handle food safely.

Provide More Rapid Alerts to All Stakeholders During Food-Related Events

FDA is working on providing more rapid alerts to all stakeholders, including retailers, industry, public health officials, and consumers during food-related events.

- FDA is engaged in developing and implementing provisions of section 1002 of FDAAA designed to enhance the speed of communications of human and pet food recalls to the public through development of a searchable recalls database and to enhance FDA's ability to acquire data from companies and professional associations during a recall.
- Fellows from FDA & FSIS, as part of the Annenberg Leadership Institute, developed recommendations for improving recall-related interagency communication. The fellows researched the recall process in both agencies and examined best practices in analogous situations both internal and external to the agencies to develop recommendations.
- FDA developed templates for recall communications and presented them to the FDA Risk Communications Advisory Committee for input in March 2008.

SUMMARY

The FPP One-Year Progress Summary identifies FDA's current food safety goals as well as recent accomplishments toward realizing the complete vision and strategies outlined in the FPP. The FPP program will continue to evolve based on the Agency's understanding of effective prevention practices, successful intervention methods at key points in the food production system, and enhanced emergency capabilities so that the Agency working with its partners can respondimmediately when problems are identified. The FDA is committed to sustaining and growing a food protection framework that keeps the American food supply safe.

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