

Implementing FDA's Food Protection Plan

On November 6, 2007, FDA issued the Food Protection Plan, An Integrated Strategy for Protecting the Nation's Food Supply (FPP). This document is a comprehensive FDA initiative to protect food and feed.

The FPP advances an integrated strategy based on three core elements: prevention, intervention, and response. The foundation of the FPP is to identify potential food defense and food safety threats and counteract them before they can harm consumers.

On December 26, 2007, the President signed the Consolidated Appropriations Act into law, which provides appropriations for FDA for FY 2008. The Congressional statement to accompany the conference agreement for this appropriations act advised FDA to articulate a plan for organizational, managerial, statutory, and regulatory changes to protect the food supply that FDA regulates.

This exhibit responds to the request for FDA to articulate the implementation plan requested in the statement to accompany the conference agreement. This exhibit refers to three components: the FPP, the FPP organizational plan, and the FPP operations plan. These three components are part of the FDA response to the statement in the conference agreement.

The full text of FDA's Food Protection Plan, which also is a component of this exhibit, appears at: <http://www.fda.gov/oc/initiatives/advance/food/plan.html>. Finally, the business case paper, "Protecting America's Food Supply: An Investment in the FDA Food Protection Plan" also is a component of this exhibit. This business case paper is printed in the Executive Summary of the FY 2009 Congressional Justification.

The statement to accompany the conference agreement requests that FDA provide a plan to improve food defense and food safety. The November 6, 2007, Food Protection Plan responds to the request in the conference agreement. The FPP Operations Plan, which is a component of this exhibit, also responds to the request in the conference agreement.

The FPP Operations Plan charts FDA's strategic actions, components, and outputs to achieve the food defense and food safety goals in FDA's Food Protection Plan. As the statement to accompany the conference agreement requests, the detail in the FPP Operations Plan reflects benchmarks and goals to improve the safety of domestic and imported foods over a multiyear period. The information in the FPP Operations Plan contains the detail that responds to the request in the conference agreement. The FPP Operations Plan also supplements and expands on the goals that FDA articulated in the Food Protection plan.

The FPP Operations Plan is a multiyear implementation plan. FDA will use FY 2008 and requested FY 2009 resources to initiate the actions identified in the Food Protection Operations Plan and achieve the food defense and food safety priorities in the Food Protection Plan.

The statement to accompany the conference agreement also requests that FDA describe organizational, managerial, statutory, and regulatory changes necessary to achieve the goals of

the Food Protection Plan. The two section headings that appear below (FPP Organization and Management Structure; FPP Proposed Legislative and Regulatory Changes) contain FDA's response to this request.

Finally, the statement to accompany the conference agreement requested that FDA include statutory language for legislative proposals that strengthen food defense and food safety. FDA identified and described ten proposed statutory changes in the text of the Food Protection Plan. The Administration intends to provide technical assistance to Congress to enact the ten legislative proposals in the Food Protection Plan.

Background on the FPP

The FPP details FDA's food safety and food defense goals. The FPP is a comprehensive approach to food safety and defense, covering both domestic and imported food. The FPP includes actions tied to risk-based preventive controls (HAACP-like systems) and a process for reviewing the food safety systems in countries that export food to the United States. Finally, the FPP contains other important prevention, intervention, and response actions.

The FPP operates through a set of integrated strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems

FDA's Integrated Strategy Provides Three Elements of Protection.

Prevent Foodborne Contamination:

- Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

Intervene at Critical Points in the Food Supply Chain:

- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System "Signals" that Indicate Contamination

Respond Rapidly to Minimize Harm

- Improve Immediate Response
- Improve Risk Communications to the Public, Industry and Other Stakeholders

FPP Organization and Management Structure

Due to the overlapping nature of the FPP and the related Import Safety Action Plan (ISAP), FDA established a structure to ensure that each FDA component has a clear lead(s) and that the implementation of these plans is fully coordinated. As shown in the organizational chart in this exhibit, Dr. David Acheson, in his role as Associate Commissioner for Foods within the Office

of the Commissioner, has the overall management lead for implementing the Food Protection Plan. Assistant Commissioner for Policy Jeff Shuren and Associate Commissioner for Regulatory Affairs Margaret Glavin have overall responsibility for implementing the IASP.

Cross-cutting Implementation Teams supports the implementation of the FPP and IASP. These teams have representation from the following organizations within FDA:

- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Veterinary Medicine (CVM)
- National Center for Toxicological Research (NCTR)
- Office of the Commissioner (OC)
- Office of External Relations (OER)
- Office of Crisis Management (OCM)
- Office of General Counsel (OGC)
- Office of Information Technology (IT)
- Office of International Programs (OIP)
- Office of Management (OM)
- Office of Policy and Planning (OPPL)
- Office of Regulatory Affairs (ORA)

An Internal Steering Committee, which has oversight of the implementation and integration of the FPP with the Import Safety Action Plan, coordinates the FPP and the ISAP. Dr. Acheson reports on implementation efforts to the Commissioner and to the FDA Management Council, which is comprised of FDA Center Directors and other FDA leadership staff.

FPP Operations Plan

The FPP Operations Plan appears at the end of this exhibit. The Operations Plan contains the goals of the FDA Food Protection Plan, divided into specific multiyear activities. The FDA Food Protection Operations Plan provides measurable benchmarks for achieving the FDA goals set forth in the FDA Food Protection Plan.

FPP Proposed Legislative and Regulatory Changes

The Food Protection Plan proposes ten proposals for legislative authority to safeguard Americans from food defense and food safety threats. The details of the 10 legislative authorities appear on pages 15, 18, 19, 20, and 22 of the FPP. Where necessary, FDA will implement the legislative changes through regulations or guidance to industry.

FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply. The FPP identifies the administrative and regulatory actions FDA is proposing to take within the Agency. This Plan also recommends legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illnesses.

Additional Protections that Involve Legislative Changes to FDA's Authority:

Prevent Foodborne Contamination

- allow FDA to require preventive controls to prevent intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain
- authorize FDA to issue additional preventive controls for high-risk foods
- require food facilities to renew their FDA registrations every two years, and allow FDA to modify the registration categories

Intervene at Critical Points in the Food Supply Chain

- authorize FDA to accredit highly qualified third parties for voluntary food inspections
- require new reinspection fee from facilities that fail to meet current good manufacturing practices
- authorize FDA to require electronic import certificates for shipments of designated high-risk products
- require new food and animal feed export certification fee to improve the ability of U.S. firms to export their products
- provide parity between domestic and imported foods if FDA inspection access is delayed, limited, or denied

Respond Rapidly to Minimize Harm

- empower FDA to issue a mandatory recall of food products when voluntary recalls are not effective
- give FDA enhanced access to food records during emergencies

Following the release of the FPP, FDA immediately began to implement many of the FPP elements. FDA will implement the remaining elements of the FPP over time as noted in the FPP Operations Plan.