

**Protecting America's Food Supply:
An Investment in the FDA Food Protection Plan
+\$42,232,000 / 94 FTE**

1. Why is this funding necessary?

A. Background

The U.S. food supply has changed dramatically in recent years due to consumer demand, changes in processing and distribution practices, and increasing globalization of the food market. The result is faster and more widespread distribution of food and increasing specialization in the manufacture of food ingredients.

At the same time, the volume of imports continues to outpace FDA's ability to respond. Imports have doubled during the past five years. The volume of FDA-regulated foods now exceeds 9.5 million import entries annually.

To respond to these challenges, FDA must shift to a comprehensive, preventative, and risk-based approach to safeguard the food supply and the American homeland. FDA also must reengineer domestic and import-related policies and procedures. These changes must focus on the most important food defense and food safety considerations throughout the entire product life cycle – from production through consumption.

On November 6, 2007, FDA issued the Food Protection Plan, *An Integrated Strategy for Protecting the Nation's Food Supply* (FPP). The FPP 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 identifying potential food defense and food safety threats and counteracting them before they harm consumers.

Today, FDA devotes most of its food-related resources to post-market surveillance and to responding to food contamination events. Under the FPP, FDA will continue to invest in post-market activities and maintain the capability to respond rapidly to incidents of food contamination when they surface. However, FDA will also invest more resources to prevent intentional and unintentional food contamination before problems appear. Only by focusing greater attention on food production and food handling sites – wherever they are located – can FDA protect the American homeland and the U.S. economy from food safety and food defense threats.

B. FDA's Food Protection Plan

FDA is responding to food defense and food safety challenges with FPP, a risk-based, production-to-consumption strategy to ensure the safety of domestic and imported food. FPP integrates food and feed safety with food and feed defense.

The three core elements of FPP – prevention, intervention, and response – are based on a rigorous science and information technology infrastructure. The FPP strategy focuses on

preventing foodborne illness outbreaks, intervening when vulnerabilities surface or problems emerge, and rapidly responding to threats. With the investments in this FY 2009 initiative, FDA will work with the Department of Homeland Security, the U.S. Department of Agriculture, the Centers for Disease Control and Prevention, state, local, and foreign governments, and the domestic and international food industry to safeguard America's food and the national infrastructure of vital food commodities.

FDA has prepared an Implementation Plan for FPP that appears in the exhibit section of this Congressional Justification document. The Implementation Plan contains additional details of the steps that FDA is taking to implement the FPP.

C. Import Safety Action Plan

In conjunction with the November 6 release of the FPP, the Administration announced the release of the Import Safety Action Plan. The Import Safety Action Plan includes short- and long-term recommendations to improve the safety of imports entering the United States. Implementing the Import Safety Action Plan recommendations in conjunction with FPP will result in a system that builds safety into imported foods every step of the way.

D. Cost of Living Pay Increase for FDA Food Defense and Food Safety Programs

FDA regulates a diverse and complex portfolio of products that account for 20 percent of U.S. consumer spending. FDA can only accomplish these responsibilities if it has sufficient resources to pay the scientific, professional, and technical staff that is essential to FDA operations.

Performing the FDA mission is a personnel-intensive agency. FDA delivers its public health mission through a highly trained professional workforce. Personnel and related costs account for 80 percent of FDA's annual expenditures. To maintain a strong scientific capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

The Protecting America's Food Supply Initiative includes funds for the cost of living pay increase for employees who contribute to FDA's food defense and food safety programs. If FDA does not receive the resources to pay these costs, FDA cannot fulfill its fundamental mission to the American public. Providing funds to meet the annual pay increase allows FDA to achieve performance commitments and ensures that FDA can anticipate and respond to public health emergencies.

2. What activities will the funds support?

A. Funding Table

The table below displays the distribution of funds for this initiative across FDA programs.

Protecting America's Food Supply

Dollars in millions

Program	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	+/- FY 2008
Foods	\$453.700	\$505.110	\$537.777	+\$32.667
Center	157.631	169.588	179.640	+\$10.052
Field Activities	296.069	335.522	358.137	+\$22.615
Animal Drugs and Feeds	74.833	76.653	82.271	+\$5.618
Center	40.265	41.219	45.305	+\$4.086
Field Activities	34.568	35.434	36.966	+\$1.532
National Center for Toxicological Research	3.441	4.323	6.056	+\$1.733
Headquarters and OC	31.559	33.526	35.740	+\$2.214
Total, Budget Authority	\$563.533	\$619.612	\$661.844	+\$42.232

¹ Includes funds for Dietary Supplements and Nutrition/Food Labeling activities (FY 2007=\$23.686 M, FY 2008 and FY 2009=\$27.220M)

B. Specific Activities Funded by this Initiative

FDA's FY 2009 budget proposes the following investments to protect America's food supply:

i. Prevention—

Prevention is the cornerstone of an effective, proactive food defense and food safety strategy. Assisting industry to implement preventive control measures is essential to prevent intentional or unintentional contamination of the food supply. The prevention element of the FPP allows FDA to support industry with scientific and analytical tools to better identify and understand food defense and food safety risks and the effectiveness of control measures used to protect the food supply.

In FY 2009, FDA will make priority prevention investments in the following areas:

- FDA will **Facilitate Corporate Responsibility** by working with domestic and international partners to support industry efforts to institute corporate prevention

responsibilities and objectives. This component of the prevention strategy facilitates appropriate food defense and food safety standards for all phases of food production.

- FDA will **Determine Vulnerabilities and Areas of Risk** through improved surveillance systems, risk assessments and risk modeling, and statistical sampling. FDA will establish the capacity to target high-risk food defense and food safety threats.
- FDA will **Establish an FDA Office in China** to better protect American consumers from unsafe products. As recent events highlight, China is a leading source of food imports into the United States. A full-time office in China is necessary due to the increased risk and volume of food and feed imports arriving from China.
- FDA will **Expand Science** that identifies food safety threats, sources of contamination, their mode of spread, and options to prevent contamination. A risk-driven, science-based approach to understanding threats to the food supply is the foundation of FDA's food protection strategy.

ii. Intervention–

Risk-based intervention supplements the protection element of the strategy by monitoring the success of, and identifying weaknesses in preventive measures. Intervention augments prevention through inspection and sampling techniques that use modern detection technology.

FDA will strengthen the information technology systems that support intervention activities. Modern IT systems improve FDA's ability to target and conduct inspection and surveillance, perform laboratory analysis, and achieve reliable 24/7 operations.

In FY 2009, FDA will make priority intervention investments in the following areas:

- FDA will **Ensure Adequacy of Industry Prevention Strategies** through increased risk based inspections, audits of controls designed to prevent contamination, and sampling at the source.
- FDA will **Conduct Expanded Risk-Based Surveillance** across the food and feed chain to identify gaps in detecting food and feed threats and to institute corrective action before illness or injury occurs.
- FDA will **Enhance the Ability to Detect** and quickly identify risk signals by deploying new rapid screening tools and methods to identify pathogens and other contaminants in food and feed.
- FDA will **Increase Food and Feed Sampling and Testing** through improved laboratory analysis. FDA must increase surveillance of animal food and feed ingredients to protect consumers from intentional and unintentional threats to vital components of the food chain.

iii. Response–

The response element of the strategy will reduce the length of time between detecting and containing foodborne illness. FDA’s recent experience with spinach and leafy greens, melamine, peanut butter, and other contaminated products demonstrates the need for more effective response strategies. FDA must respond faster, communicate more effectively to consumers and FDA food safety partners, and limit economic consequences for affected industries. FDA also must strengthen its response systems and further integrate them with state, local, federal, and international agencies.

In FY 2009, FDA will make priority response investments in the following areas:

- FDA will **Enhance Rapid Response Capacity** by leveraging state resources and strengthening FDA and state rapid response capability.
- FDA will **Upgrade Emergency Response** and traceback capabilities and systems. These systems are critical for quick response during an outbreak of foodborne illness.
- FDA will **Improve Risk Communication** to rapidly and effectively respond to consumer concerns during and after an event, and educate consumers about food safety issues.

iv. Food Defense and Food Safety IT Investments–

To support all three elements of the strategy to Protect American’s Food Supply, FDA will upgrade IT systems to rapidly identify food importers and facilitate FDA’s ability to maintain, update, and search records and data on food establishments and shipments. FDA will collaborate with Customs and Border Protection on systems to accurately identify firms involved in the food import supply chain.

v. Cost of Living Pay Increase for Food Defense and Food Safety Programs–

Funding the cost of living pay increase allows FDA to retain its professional workforce by paying salary increases that track the cost of living. Without these funds, FDA must reduce the number of inspectors, consumer safety officers, food defense researchers, food safety technologists, and other health experts that perform essential functions in FDA’s mission to protect and promote public health.

3. *What are the risks of not proceeding with the initiative?*

A. FDA Food Defense and Food Safety Programs

Not funding this initiative threatens the Federal government’s ability to protect the American public from unsafe food. Not funding this initiative also diminishes FDA’s ability to prevent or respond to a terrorist attack or a public health emergency related to food. Not providing sufficient resources to launch the Protecting American’s Food Supply strategy will have far-reaching consequences:

- Significant outbreaks of foodborne illness will continue in the United States because FDA does not have the scientific- and risk-based techniques to identify and eliminate foodborne hazards and prevent contaminated foods from reaching American consumers.
- Imported foods will remain a safety and security threat. Products from countries with high-risk food production, manufacturing, and distribution systems will continue to enter U.S. commerce without appropriate surveillance.
- FDA and our industry partners will not achieve the ability to rapidly trace the origin of foods implicated in intentional or unintentional adulteration.
- American consumers will continue to suffer significant adverse health consequences, including morbidity and death, because FDA cannot establish a strong, science-based regulatory framework with prevention standards to ensure the safety and defense of food.
- The confidence of American consumers in the safety and security of the food supply will remain low. Consumers will avoid certain foods such as fruits and vegetables and will not fully benefit from foods that are essential to a healthy diet. This will increase morbidity and mortality from chronic diseases and impose significant public health impact and costs.

B. Cost of Living Pay Increase for Food Defense and Food Safety Programs

Failing to fund this initiative means that FDA must reduce core public health programs, including our professional staff that performs the FDA mission. Failing to fund the cost of living pay increase will result in an FDA-wide loss of 90 FTEs. This total includes 54 Field FTEs who perform work in food protection program areas.

If FDA does not receive these funds, FDA must reduce staff so that FDA can pay mandatory cost of living increases for the remaining staff. The loss of these scientific and technical experts will impair FDA's ability to fulfill its public health responsibilities and to recruit, train, and retain a world-class scientific workforce. A diminished FDA workforce will limit FDA's ability to reduce food defense and food safety threats, secure the homeland, and to protect the health and security of the American people.

4. How does this initiative support Executive Branch public health priorities?

The FDA Protecting America's Food Supply Initiative implements the Food Protection Plan, the Import Safety Action Plan, the December 11, 2007 agreements with China on food protection, and elements of the Food and Drug Administration Amendments Act. This initiative also secures the homeland and strengthens the nation by improving food safety and food defense through better oversight of manufacturing, production, and distribution here and abroad. The strategy achieves core FDA responsibilities under Homeland Security Presidential Directive 7 (Infrastructure) and Homeland Security Presidential Directive 9 (Food Defense).

5. What will FDA accomplish with this initiative?

The Protecting America's Food Supply strategy will allow FDA to achieve significant near-term food protection accomplishments in FY 2009. These accomplishments will provide a foundation for substantially reducing illnesses caused by contamination of the food supply in the following years.

The foundation of this strategy is a risk-focused science-based approach that builds new and greater food protection capabilities over several years. While there are significant early benefits to this comprehensive approach, FDA and its partners will achieve even greater reductions in risk to the food supply as the prevention strategies mature and FDA implements risk-based improvements to field operations.

During FY 2009, FDA will achieve significant results that contribute to food protection:

A. Prevention–

FDA will begin to provide industry with new control measures throughout all levels of the food production and processing chain. For example, control measures will include practices and intervention steps to prevent or reduce the growth and survival of pathogens on produce.

By establishing an FDA presence in China, FDA will more effectively implement the December 11, 2007 Agreement with China to improve the safety of food and feed. An office in China is an essential platform to conduct training, audits, and technical assistance in China to better protect American consumers.

FDA will develop the food safety and food defense science upon which regulatory decisions and enforcement rely. FDA will also increase food safety and food defense technical assistance to industry groups, other agencies, and FDA's international partners.

FDA's Animal Drugs and Feeds Program will improve the animal feed safety system to better safeguard animal feed and feed ingredients from food defense and food safety threats. FDA will also protect animal feeds from harmful ingredients, tampering, and contamination.

B. Intervention–

FDA's field operations will ensure the adequacy of industry prevention strategies through increased risk based inspections, audits of controls designed to prevent contamination, sampling, and surveillance. Specifically, FDA will conduct the following field operations with base funding and the FY 2009 increase proposed in this initiative:

- 20,000 additional import food field exams
- 1,057 additional domestic food safety inspections
- 50 additional foreign food inspections
- an additional 30 domestic and 30 import food sample collections and analyses
- an additional 30 domestic and 35 import animal feed sample collections and analyses

- 90 additional imported and domestic cheese program inspections
- 92 additional domestic low acid canned food inspections
- 50 additional domestic fish and fishery Hazard Analysis and Critical Control Point (HAACP) inspections
- 85 additional juice HAACP inspections.

C. Response–

FDA will strengthen its emergency response infrastructure to respond to incidents. FDA will also enhance the functionality of essential systems to respond to emergencies.

FDA's field operations will develop three cooperative agreements to support state food defense and food safety infrastructure. FDA's field operations will develop and maintain rapid response teams.

FDA will begin to develop a Risk Communication Program to provide transparent outreach to consumers via website, press releases, and other means of communication to ensure that FDA shares information with consumers and industry in a timely and efficient manner.

D. Cost of Living Pay Increase for Food Safety and Food Defense Programs–

Funding the annual cost of living increase allows FDA to extend through FY 2009 the strong performance levels that FDA has targeted for FY 2008. In contrast, failing to fund the cost of living pay increase will cause deterioration in performance across all FDA program areas.