

Strengthening Food Safety **+\$10,664,000, + 15 FTE**

1. Why is this initiative necessary?

Preventing foodborne illnesses is a major public health challenge. More than 250 different foodborne illnesses are food safety threats. Based on CDC estimates, 76 million Americans become sick, more than 300,000 are hospitalized, and 5,000 die each year from foodborne illnesses.

Recent high profile outbreaks highlight the need for increased resources to strengthen food safety and enhance FDA's ability to reduce and respond to foodborne outbreaks. These include three outbreaks of *E. coli O157:H7* (associated with chopped lettuce served in Taco Bell and Taco John restaurants and an outbreak associated with bagged spinach), an outbreak of botulism associated with commercially manufactured carrot juice, and an outbreak of norovirus linked to imported raw oysters.

The following table identifies spending for the proposed increase for FDA centers and offices that participate in the Strengthening Food Safety Initiative and the history of spending on food safety.

Table: Food Safety Spending History

Program	FY 2006 Actuals	FY 2007 President's Budget	FY 2008 Initiative	
			FY 2008 Total ¹	+/- FY 2007 PB
Foods	\$280,299,000	\$276,090,000	\$285,590,000	\$9,500,000
Animal Drugs	\$66,235,000	\$70,558,000	\$70,558,000	\$0
NCTR	\$1,804,000	\$1,351,000	\$1,851,000	\$500,000
HQ/OC	\$27,888,000	\$26,907,000	\$27,551,000	\$644,000
Total Food Safety	\$376,226,000	\$374,906,000	\$385,550,000	\$10,644,000

¹ FY 2008 Food Safety total is \$391.021 million including pay increase and Animal Drugs research reduction.

2. How does this initiative support important public health priorities?

As shown in the table below, the Enhancing Food Safety Initiative advances five HHS and FDA goals and objectives.

HHS OBJECTIVE	FDA STRATEGIC GOAL	FDA OBJECTIVE
17. Enhance Emergency Response and Renew the Commissioned Corps	1. Enhance Patient and Consumer Protection and Empower Them with Better Information about Regulated Products	1.3. Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.
	3. Improve Product Quality, Safety, and Availability Through Better Manufacturing and Product Oversight	3.2. Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products through efficient and effective risk targeting, external partnering, effective internal processes and collaboration.

3. What are the risks of not funding this initiative?

If FDA does not receive funding for this initiative, FDA will make limited progress on preventing and reducing foodborne illness. FDA also will not make significant progress preventing or reducing foodborne outbreaks, illness, and death due to contaminated food. In addition, FDA will have difficulty bolstering public confidence in the safety of fresh produce. Health experts and the U.S. Government encourage consumption of fresh produce as part of a healthful diet.

Foodborne illness outbreaks attributed to fresh produce have increased in the past several years. There are at least four possible explanations for this trend:

1. increased consumption of fresh produce
2. improved detection of outbreaks and increased awareness of fresh produce as a vehicle for foodborne illness
3. increased complexity and reach of food distribution systems
4. increased numbers of consumers at high risk of foodborne disease, such as the elderly and individuals with compromised immune systems.

Produce is often consumed raw, without any intervention such as cooking to reduce or eliminate pathogens (if present), which contributes to its potential as a source for outbreaks of foodborne illness.

4. What activities will these funds support?

The Strengthening Food Safety Initiative provides funding to four FDA components: the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Regulatory Affairs (ORA), the National Center for Toxicological Research (NCTR), and the Office of Crisis

Management (OCM). The components of the initiative will improve food safety, increase the FDA's ability to respond to foodborne outbreaks, and protect the health of American consumers.

CFSAN +\$4,000,000

Methods Development

CFSAN will invest funds to develop better methods to rapidly detect and attribute foodborne illness outbreaks related to produce. Developing better methods and better sampling protocols will permit FDA and its public health partners to more rapidly detect disease-causing microorganisms in fresh produce. The result will permit quicker intervention to reduce illnesses and deaths from contaminated food. Improved methods development will also allow industry to more rapidly to resume marketing of uncontaminated food.

Surveillance

CFSAN will invest funds to expand its traceback capabilities. Traceback involves tracking food contamination to its source. CFSAN will hire environmental epidemiologists to work with FDA and state and local agencies, including teams of federal and state experts convened for investigations, to facilitate traceback and on-farm investigations. FDA staff will also train state and local agencies and provide assistance analyzing the data collected. FDA staff will also participate in investigations of farms, packing facilities, and processors. Staff will develop reports that identify sources of contamination and make recommendations for preventing future contamination.

CFSAN will also conduct sampling surveys of imported and domestic produce to examine the incidence of contamination of produce with pathogens.

Regulations and Guidance

CFSAN will develop cost-effective regulations and guidance to prevent or reduce outbreaks, thus reducing illnesses and death. This activity will also minimize risks of economic disruptions resulting from foodborne outbreaks.

Produce Experts

CFSAN will hire individuals with expert knowledge of the production and processing of fresh produce, with particular emphasis on microbiological safety issues. These experts will establish the scientific foundation for regulations, guidance, outreach, training, and other activities to prevent or reduce outbreaks and the resulting illnesses and death.

ORA +\$5,500,000

Outbreak Traceback (\$3,500,000)

ORA will develop the capacity for more rapid traceback of produce-related outbreaks and the capacity to determine the root cause of an outbreak. ORA will develop teams trained in traceback technologies, incident command, and root cause analysis. ORA will strategically position these teams in areas with large produce-growing regions. In addition, ORA will provide training, equipment, and other assistance to States so that they can be full partners with FDA in responding to and preventing produce-related outbreaks. After the first year,

ORA will have 12 fully equipped and trained FTEs with traceback equipment, such as hand-held GPS devices that can be used with geographic information systems to facilitate investigations of outbreaks.

Import Risk-Based IT (\$2,000,000)

ORA will develop an import decision-making system capable of detecting high risk shipments of FDA-regulated products before they are admitted or released into U.S. commerce. ORA will begin formal integration of this technology into the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. This feature will replace outdated legacy systems that are not capable of integrating risk management information with ORA operations.

NCTR +\$500,000

New Methods to Rapidly Detect Foodborne Pathogens, Select Agents, and Toxins

NCTR will direct \$165,000 to provide additional staff and \$335,000 for supplies and services to improve methods for rapid screening and complete identification of foodborne pathogens. NCTR will also develop a genomic database to identify and assess the biological threat of foodborne pathogens.

OCM +\$644,000

Enhancing Geographic Information System (GIS) Mapping and Emergency Operations Center Management

FDA will hire a GIS mapping specialist to address the agency's mapping needs for emergency preparedness and response activities. This will further enhance and support FDA efforts to respond during emergencies and allow FDA to align further with HHS and CDC emergency response structures. OCM will also hire staff to manage the FDA Emergency Operations Center infrastructure. This will strengthen FDA's functional capability to respond to an emergency or event. The request includes the cost to OCM staff on GIS mapping and advanced emergency response.

5. *What results will FDA achieve?*

The projects supported by these funds will produce at least four FY 2008 deliverables:

1. methods to reduce the time required to screen and identify foodborne pathogens by hours or days
2. regulation and guidance to prevent or reduce outbreaks, illnesses, and death
3. a genomic database that will enable FDA to assess the threat of foodborne pathogens from imported food and feed products
4. an import decision making system capable of detecting high risk shipments.