

# FOOD PROTECTION OPERATIONS PLAN

Strategic Actions	Strategic Components	Outputs
<b>Food Protection Plan Core Element #1: Prevention</b> <b>\$11,413,778</b>		
<b>Key Prevention Step #1.1: Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses</b>		
1. Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply	Stakeholder outreach on food protection	<b>Output 1a:</b> Meet with wide array of FPP stakeholders and other government partners (Federal, State, and local and foreign) to solicit their input on identifying and implementing preventive approaches to protect the food supply.
	Stakeholder engagement/leveraging in	<b>Output 1b:</b> Draft a plan based on summary of stakeholder input on how best to involve

	implementation of food protection plan	stakeholders in the implementation of the prevention, intervention and response elements of the FPP.
2. Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines	Stakeholder and FDA field support	<b>Output 1c:</b> Develop a list of specialties that would enhance the effectiveness of food inspections. Identify a team of technical experts with capacity to assist rapid response teams in outbreak investigations and provide liaison and training with ORA field staff, state, and local staff that conduct prevention activities.
	Understand industry prevention best practices	<b>Output 2a:</b> Meet with food and feed industry representatives to discuss how to achieve corporate responsibility, understand industry best practices, and identify how and where preventive controls will work best.
	Promote voluntary preventive controls	<b>Output 2b:</b> Promote the adoption of voluntary preventive controls throughout the food supply based on industry best practices by collaborating on training workshops to assist industry in achieving prevention objectives.
3. Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b)	FDA Prevention Guidances/Regulations, Outreach & Training	<b>Output 3a:</b> Develop plan to address other specific high-risk foods of concern from intentional or unintentional contamination.

implement other measures to promote corporate responsibility		<b>Output 3b:</b> -Develop specific guidance and implement guidance through outreach and training.
4. Issue in Spring 2008, a final regulation requiring measures to prevent salmonella in shell eggs and resulting illnesses	Salmonella regulation	<b>Output 4:</b> Work to deliver final regulation defining preventive management practices to salmonella from eggs and resulting illnesses. Implement regulation through outreach and training.
5. Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source	Collaboration with foreign governments	<b>Output 5:</b> Share risk- and life-cycle-based surveillance approaches, examples of corporate food protection plans, and other results of domestic prevention efforts for improving food safety at the source. • Examine best practices around the food safety control systems of other countries as well as increase understanding of the difficulties faced in implementing food protection measures.
6. Provide foreign countries with technical assistance so that they can enhance their regulatory systems	Provide technical assistance to foreign governments	<b>Output 6:</b> Develop mechanisms/protocols to provide technical assistance to foreign countries so that they can enhance their food and drug regulatory systems.

7. Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk	Import Trend Data for Risk Ranking	<b>Output 7:</b> Produce analysis of food import data, including a ranking of food imports according to risk. Work with ORA to update future import inspection work plan based on risk ranking of imports.
8. Focus foreign inspections on high-risk firms and products	FDA Risk-Based Foreign Inspections	<b>Output 8:</b> Formalize the high risk criteria used to identify foreign facilities. Increase foreign inspections of high-risk firms identified by more accurate risk profiling.
9. Improve FDA's presence overseas	FDA Foreign Presence	<b>Output 9a:</b> Establish FDA Field Office in China.
		<b>Output 9a1:</b> Conduct bilateral meetings as agreed to under the China MOA.  <b>Output 9b:</b> Develop a plan to increase FDA presence in other countries/regions of concern, such as India.
<b>Key Prevention Step #1.2: Identify Food Vulnerabilities and Assess Risks</b>		

<p>1. Work with the food industry, consumer groups, and Federal, State, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities</p>	<p>Data Gathering</p>	<p><b>Output 1a:</b> Identify additional information needs to strengthen FDA understanding of food safety and food defense risks and vulnerabilities.</p>
		<p><b>Output 1b:</b> Conduct research and obtain scientific data to identify and counter unintentional and intentional food contamination.</p>
<p>2. Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful</p>	<p>Risk Ranking, aid industry efforts to achieve corporate responsibility</p>	<p><b>Output 2a:</b> Build a team to enhance modeling capability for relative risk ranking.</p>
		<p><b>Output 2a1:</b> Conduct research to evaluate and prioritize risks of food and feed agents that may be harmful.</p>
		<p><b>Output 2b:</b> Determine a ranking of the top priorities for risk evaluation of commodity-agent combinations.</p>
		<p><b>Output 2c:</b> Increase software capacity to assist industry with identifying areas of food safety risk through CARVER-type model for domestic manufacturer and grower use.</p>

		<b>Output 2d:</b> Using findings from the research of Salmonella strains, initiate development of an integrated genomic database to be used for the risk assessment of foodborne pathogens.
3. Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease	Risk-Based Process for Targeting FDA actions/resources	<b>Output 3a:</b> Develop a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.
4. Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated	Better attribution data collected	<b>Output 4a:</b> In collaboration with CDC, identify data needed for optimal attribution needs. Work with CDC to help design better tools for use by States and locals in conducting epidemiological investigations to obtain the data.
	Data analysis, real time reporting of data, risk communication	<b>Output 4b:</b> Work with CDC on analysis of the data that CDC acquires and provides.
	Risk ranking, apply findings to review of product life cycle	<b>Output 4c:</b> Determine which food/pathogen pairs present the highest risk, i.e. develop a risk ranking of food/pathogen pairs.
<b>Key Prevention Step #1.3: Expand the Understanding and Use of Effective Mitigation Measures</b>		

<p>1. Focusing on higher risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination</p>	<p>Identify research needs for high risk foods</p>	<p><b>Output 1a:</b> For higher risk foods, work to understand, identify and target effective mitigation strategies through the development of a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination for higher risk foods.</p>
<p>2. Research, evaluate, and develop new methods to detect food contaminants</p>	<p>Conduct basic research</p>	<p><b>Output 2a:</b> Based on research plan for high risk foods, initiate basic research and leverage with outside organizations to determine possible mitigation steps to identifying and mitigate unintentional and intentional food contamination.</p>
<p>3. Encourage outside development of new contamination detection and prevention technologies</p>	<p>Develop new platform technologies</p>	<p><b>Output 3a:</b> Encourage the development by outside parties of new and innovative platform technologies for detecting contaminants in foods. Meet with various outside groups to encourage development of microarray, optical mapping, and biosensors for detect and ID of enteric bacteria that may be accidental or intentional contaminants in the food supply.</p>
	<p>Develop better detection tools</p>	<p><b>Output 3b:</b> Encourage the development by outside parties of hand held rapid detection tools to identify an increased number of foodborne pathogens.</p>
<p>4. Develop websites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities</p>	<p>Communicate research results, aid industry efforts to achieve corporate responsibility</p>	<p><b>Output 4a:</b> Produce website for disseminating research results and guidance to industry on effective steps to mitigate vulnerabilities.</p>

<b>Food Protection Plan Core Element #2: Intervention</b> <b>\$15,606,555</b>		
<b>Key Intervention Step #2.1: Focus Inspections and Sampling Based on Risk</b>		
1. Focus food and feed safety inspections and sampling based on risk	Focused, risk-based inspections and sampling	<b>Output 1a: Domestic inspection and sampling activities.</b> •Target domestic food field exams.
		<b>Output 1b: Foreign / import inspection and sampling activities.</b> • Target import food field exams. • Reengineer Foreign Inspection Program inspections to be based on risk.
	Enhance State inspections	<b>Output 1c: Prioritize inspections based on risk</b> using tools that include FDA and State inspection and enforcement data.
		<b>Output 1d: Improve State access</b> (current 40 states food and BSE) to eSAF (electronic State Access to FACTS) to include elimination of duplicate entry, electronic Seafood HACCP forms, better work planning, and assignments. View other state inspection data.



<p>2. Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample</p>	<p>Rapid Detection and Testing</p>	<p><b>Output 2a:</b> Choose and evaluate methods appropriate for detecting contaminants in foods.</p> <ul style="list-style-type: none"> <li>• Develop enhanced screening kits and new methods to address new pathogens and speed analysis.</li> <li>• Develop fast and inexpensive techniques using microarray technology to detect antibiotic resistance markers in Salmonella and E-coli 157:H7.</li> </ul> <p><b>Output 2b:</b> Initiate work with industry and States to establish the means to rapidly determine exact sources of contamination and halt further distribution.</p>
<p>3. Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspectional strategies</p>	<p>Inspector Training</p>	<p><b>Output 3a:</b> Update existing FDA and state investigator training to incorporate new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment and modern inspectional strategies.</p> <ul style="list-style-type: none"> <li>• Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspectional strategies.</li> <li>• Develop a training program to ensure feed inspections conducted by our state counterparts meet FDA standards for inspections.</li> </ul>

<p>4. Collaborate with foreign authorities to reduce risk of imported food</p> <p>5. Voluntary certification programs for foreign firms and importers</p>	<p>Leverage with Foreign Counterparts</p> <p>Voluntary Certification</p>	<p><b>Output 4a:</b> Review and enhance existing information sharing agreements and explore developing new information sharing agreements with foreign authorities to leverage their inspection and certification data. Plan to prioritize information sharing agreements based on the value of such agreements to FDA and consumer protection.</p> <p><b>Output 5a:</b> Work to understand existing standards and certification programs and consider incentives to encourage broader participation.</p>
<p><b>Key Intervention Step #2.2: Enhance Risk-Based Surveillance of Imported Foods at the Border</b></p>		
<p>1. Further enhance FDA’s ability to target imported foods for inspection based on risk and publish the <i>Prior Notice of Imported Foods</i> Final Rule by the end of 2007 as part of Bioterrorism Act implementation</p>	<p>Tools to target high-risk foreign firms</p>	<p><b>Output 1:</b> Work to publish the Prior Notice of Imported Foods Final Rule as part of Bioterrorism Act implementation.</p>

2. Conduct foreign food and animal feed inspections more efficiently using the tools designed to target high-risk firms		<p><b>Output 2a:</b> Enhance FDA Import Programs to focus on imported product life-cycle.</p> <ul style="list-style-type: none"> <li>• Update the inspection work plan to use the tools designed to target high-risk firms.</li> </ul>
3. Use advanced screening technology at the border	Automated screening technologies	<p><b>Output 3:</b> Identify and deploy advanced screening technology for border control.</p> <ul style="list-style-type: none"> <li>• Identify advanced screening technologies that would have a big impact in terms of improving risk-based screening of food imports at the border. Compare these screening technologies against PREDICT and choose the technology to be deployed widely.</li> <li>• Expand software capacity for risk-based sampling strategies (PREDICT model or other) for imported products and domestic retail.</li> <li>• Expand staff to redesign sampling strategies.</li> <li>• Deploy advanced screening technology, contingent on availability of risk-based criteria and maturity of PREDICT.</li> </ul>
4. Improve data quality and handling capacity for food imports	Better data on food imports	<p><b>Output 4a:</b> Enhance data capture for imports</p> <ul style="list-style-type: none"> <li>• Increase access to data across agencies (e.g. USDA, Customs), contingent upon IT integration at FDA and participation of other agencies.</li> </ul>
	Import Alert System	<b>Output 4b:</b> Improve Import Alert System

<p>5. Enhance information sharing agreements with key foreign countries</p>		<ul style="list-style-type: none"> <li>• Automate the Import Alert/Bulletin System to receive recommendations; shorten the development, clearance and implementation timeframes; include mandatory time frames for the clearance process.</li> <li>• Develop a system that will allow Import Alerts (IA's) and Import Bulletins (IB's) to be written, issued, and stored in a manner that would allow easy search, tracking, and trending capability.</li> <li>• Develop an automated system to cross reference various agency databases.</li> <li>• improved data quality and handling capacity for imports.</li> </ul>
<p><b>Key Intervention Step #2.3: Improve the Detection of Food System “Signals” that Indicate Contamination</b></p>		
<p>1. Deploy new rapid detection tools and methods to identify pathogens and other contaminants</p>	<p>Deployment of new rapid detection tools and methods</p>	<p><b>Output 1a:</b> Train analysts and investigators on new tools and methods.</p> <p><b>Output 1b:</b> Evaluate and identify additional inspection tools; conduct inspections and investigations using these new rapid detection tools and methods.</p>

<p>2. Improve FDA's Adverse Event and Consumer Complaint Reporting System, including capturing complaints made to food manufacturers and distributors</p>	<p>Trace-back software</p>	<p><b>Output 2a:</b> Enhance and test software for mapping adverse events to causes.</p>
	<p>Adverse event and consumer complaint reporting</p>	<p><b>Output 2b:</b> Improve the Consumer Complaint Reporting System so that it captures complaints made to food manufacturers and distributors.</p>
	<p>Dietary Supplements</p>	<p><b>Output 2c:</b> Develop and implement a plan to enhance surveillance of dietary supplements.</p>

<p>3. Work to create a Reportable Food Registry for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]; under FDAAA, industry is expected to report such situations to the FDA within 24 hours</p>	<p>Reportable Food Registry</p>	<p><b>Output 3a:</b> Establish a <i>Reportable Food Registry</i> for industry reports of certain adulterated foods.</p>
<p>4. Work to create an Early Warning Surveillance and Notification System to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)].</p>	<p>Pet food safety database</p>	<p><b>Output 4a:</b> Establish an early warning surveillance and notification system to identify adulteration of pet food supply and outbreaks of illness associated with pet food.</p> <p><b>Output 4b:</b> Develop a centralized database for veterinarians that captures data on food safety incidents and causes.</p>

<b>Food Protection Plan Core Element #3: Response \$3,173,667</b>		
<b>Sub-Element #3.1: Improve Immediate Response</b>		
<p>1. Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System</p>	<p>Emergency Operations Network Incident Management System</p>	<p>Output 1: Improve data collection and incident reporting.</p> <ul style="list-style-type: none"> <li>• Enhance mapping capability of emergency response resources, in coordination with the HHS Office of the Secretary and other HHS agencies.</li> </ul>
<p>2. Working with stakeholders, develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients</p>	<p>Track-back process</p>	<p><b>Output 2a:</b> Working with stakeholders, develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.</p> <p><b>Output 2b:</b> Improve trace-back process protocol.</p>

<p>3. Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions (ISAP lead with FPP coordination)</p>	<p>Emergency response coordination</p>	<p><b>Output 3a:</b> Enhance FDA's ability to coordinate a comprehensive FDA response to foodborne illness events, outbreaks and emergency situations by reviewing and improving the protocol and roles and responsibilities for emergency coordination.</p> <ul style="list-style-type: none"> <li>• Acquire staffing resources to provide optimal Agency response (OCM).</li> <li>• Hire and train emergency coordination staff (CVM).</li> <li>• Coordinate Agency participation in exercises and workgroups related to emergency preparedness, response and counterterrorism, such as the TOPOFF 5 Exercise.</li> </ul> <p><b>Output 3b:</b> Work with states to initiate the establishment of state and regional rapid response teams.</p>
<p>4. Enhance information technology networking with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members</p>	<p>IT networking with partners</p>	<p><b>Output 4a:</b> Enhance information technology networking with selected federal, state, and local testing labs to communicate timely testing results among FDA and lab members, contingent on training.</p>
	<p>Lab capacity</p>	<p><b>Output 4b:</b> Expand FDA, State, and foreign lab capacity, contingent on availability of FERN training and equipment for disciplines in biological, chemical, and radiological methods.</p>



<b>Sub-Element #3.2: Improve Risk Communications to the Public, Industry and Other Stakeholders</b>		
1. Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies	Communication working group and research	<b>Output 1:</b> Consider appropriate methods for consumer communications.
2. Based on that research, update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers	Updated communication plan	<b>Output 2:</b> Update the Food Protection Risk Communication Plan using the most effective strategies for sharing information with consumers. <ul style="list-style-type: none"> <li>• Improve current process for handling consumer complaints and inquiries based on needs assessment.</li> <li>• Review and improve food protection communication process to increase timeliness of food protection messages.</li> </ul>
3. Build a consumer website to communicate relevant food protection information	Food protection website for consumers	<b>Output 3a:</b> Build a consumer website to communicate relevant food protection information.
		<b>Output 3b:</b> Strengthen interagency coordination and public communications during food recalls.
4. In a food-related emergency, implement this communications plan, including utilizing all	Communication plan implementation, monitoring and	<b>Output 4a:</b> Establish a monitoring system to assess whether communication plan was

<p>relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and thus more resilient population</p>	<p>continuous improvement</p>	<p>followed. <b>Output 4b:</b> Develop a continuous process improvement infrastructure for the communication plan.</p>
<b>Subtotal</b>		<b>\$30,194,000</b>
<b>Cost of living pay increase for onboard food protection employees</b>		<b>\$12,038,000</b>
<b>Total</b>		<b>\$42,232,000</b>