

## **Establishing a Fully Integrated National Food Safety System with Strengthened Inspection, Laboratory and Response Capacity**

### **Strategic Vision**

Food safety is a core public health issue even though the U.S. food supply is among the safest in the world. With today's far reaching and complex food supply chain, there is an increasing need to find more effective solutions to better protect American consumers by preventing intentional and unintentional food contamination. Food can become contaminated through many different vehicles at many different steps – at the source on the farm or in harvest water, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, FDA, in cooperation with other food regulatory and public health agencies, has done a great deal to prevent both intentional and unintentional contamination of food at each of these steps. FDA has worked with other federal, state, local, tribal, territorial and foreign counterpart food safety regulatory and public health agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia to strengthen the nation's food safety and food defense system.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population, and an increasingly globalized food supply chain and new pathogens and other contaminants pose challenges that are requiring us to continually update our current food protection strategies.

Recognizing these challenges, President Obama has made a personal commitment to improving food safety. On July 7, 2009, the multiagency Food Safety Working Group (Working Group), which he established, issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. Preventing harm to consumers is the top priority. Too often in the past, the food safety system has focused on reacting to problems rather than preventing harm in the first place. The Working Group recommends that food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures to prevent problems before they occur.

At the Federal level, a number of Agencies are working together to coordinate their efforts and develop short- and long-term agendas to make food safer. As the federal regulatory agency responsible for most of the food supply, FDA<sup>1</sup> is committed to ensuring that the U.S. food<sup>2</sup> supply continues to be among the safest in the world. FDA has the responsibility of establishing enforceable standards to ensure the safety of the food the Agency regulates. These standards will reflect the prevention-oriented public health principles embraced by the Working Group. FDA will set new food

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<sup>1</sup>FDA is the federal agency that is responsible for the food supply except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture (USDA).

<sup>2</sup> For purposes of this document, the term "food" includes human food, animal feed, components (i.e. ingredients) of both food and feed, and dietary supplements for humans, except as otherwise noted.

safety standards and review existing standards in light of what we have learned over the past decade with regard to prevention strategies. In addition, FDA will work with food industry to establish quantitative metrics for the controlling factors affecting food safety by incorporating appropriate measures of success. These metrics, or measures, will improve our ability to verify that certain measures or practices are being carried out and are effective.

This verification requires a systematic, integrated approach to effective risk control and enforcement strategies. Together with our federal and state, local, tribal and territorial partners, FDA will work to plan and implement an inspection and enforcement program to ensure high rates of compliance with the Agency's food safety standards. By working with federal, state, territorial, tribal and local regulatory and public health partners, FDA will establish a fully integrated national food safety system, built on collaboration among all of these partners. The system will encompass inspections, laboratory testing, and response and will place priority on preventing foodborne illness, in both food for humans and animals, through the adoption and uniform application of model programs, such as the Manufactured Food and the Retail Food Regulatory Program Standards and other appropriate program standards. This collaboration will result in 1) better ability to assess potential risk at domestic food facilities and greater and more consistent inspectional coverage of these facilities across the entire food supply chain, 2) greater food surveillance through integration of food facility inspection and testing information, and 3) improved rapid response capacity and efficiency.

Under this system, FDA and federal, state, territorial, tribal and local regulatory agencies will conduct food facility inspections under the same set of standards. FDA will work with its regulatory partners to develop uniform national standards, including inspection, investigation, and testing protocols; training and certification requirements; establish program audit criteria; and create performance metrics to ensure program objectives are met. System integrity and credibility will be maintained through regular program oversight and accountability at all levels. Federal and state inspections will be conducted in accordance with a public health risk driven national work plan that FDA will develop with its regulatory partners. An integrated system will result in more coordinated response efforts to better respond to multi-state outbreaks when they occur.

To be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. It must be sustained through multi-year funding that will be provided to state and local regulatory and public health partners to build the necessary state and local infrastructures, contain adequate legislative authorities to facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that reduces foodborne illness, identifies sources of risk throughout the system, and reduces time to detect and respond to outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

## **Background**

### ***Leveraging with Federal, State, Local, Tribal and Territorial Partners***

The domestic food supply chain is currently overseen by a mix of multiple Federal, State, territorial, tribal, and local regulatory and public health agencies that often work independently from one another, work under different legislative authorities, and are driven by different objectives and

perspectives on priorities. More than 3,000 state, territorial, tribal, and local regulatory agencies have responsibility to regulate the retail food and foodservice industries in the United States. Together, they are responsible for the inspection and oversight of over one million food establishments, including restaurants, grocery stores, cafeterias and other outlets in health-care facilities, schools, and correctional facilities. Specifically, states perform approximately 90% of all food safety inspections conducted at food manufacturing and distribution establishments. At the federal level, FDA oversees more than 150,000 registered domestic food facilities including food manufacturers and processors, food warehouses, and grain elevators. The majority of this oversight responsibility is shared with states. In addition, federal and/or state, territorial, tribal and local authorities oversee more than 2 million farms.

### ***FDA's Role in Setting National Standards***

FDA provides guidance, model codes and other technical assistance to state, territorial, tribal and local regulatory partners to assist them in carrying-out their regulatory responsibilities. Since 1972, FDA has also contracted or entered into partnership agreements with many state regulatory agencies to perform inspections and investigations. FDA currently has 42 state food inspection contracts, providing over 10,500 inspections in the areas of Good Manufacturing Practices (GMPs), sanitation, seafood, juice, and low acid canned foods. In addition, FDA has 35 state contracts providing over 5,000 yearly inspections in the areas of GMPs for licensed medicated feed manufacturers and bovine spongiform encephalopathy (BSE) controls. FDA also has 65 state grants/cooperative agreements in the areas of food protection, food emergency response networks, ruminant feed ban support, rapid response teams, and innovative food defense activities. These contracts and cooperative agreements have established, developed and maintained collaborative relationships with state, territorial, tribal and local regulatory partners, and have been critical in leveraging FDA's food safety resources. These agreements have provided critical support to FDA in terms of regulatory oversight, but there are challenges related to the integration of resources and information sharing that need to be addressed.

### ***Limitations to Current Collaborative Efforts***

Current leveraging efforts have not been sufficient to ensure adequate oversight of the entire food supply chain. Food facilities are not uniformly inspected, food regulatory systems (seafood, dairy, food manufacturing) operate under different standards, data is not uniformly captured on a national basis, and the data we have is not systematically mined for signal intelligence. Neither FDA nor our regulatory or public health partners alone collect and analyze a sufficient number of surveillance samples per year to have confidence in being able to effectively identify all potential areas of concern; combining and then evaluating the data would provide a much greater ability to detect problems. In addition, national response efforts are uneven. The current food safety system hinders our ability to effectively prevent and respond to foodborne safety problems in the food supply. Throughout the years, numerous reports point out that the FDA does not take full advantage of the inspectional and surveillance capabilities of our state, territorial, tribal and local regulatory and public health partners. This situation is due in large part to the varied standards and laws in each state as compared with the federal system, as well as to the lack of interoperable data systems and legal impediments to sharing data among partners.

These combined factors present a challenge in managing and responding to signals of public health concern in the food supply. The currently decentralized U.S. public health and agriculture system results in a situation in which responsibility for surveillance, detection, investigation, response and

recovery to foodborne disease outbreaks is shared across federal, state, territorial, tribal, and local government agencies. Standards for laboratory testing and protocols vary widely, and alignment is needed to effectively manage and conduct multi-state outbreak investigations. Developing the needed standards, providing incentives to state and local food regulatory agencies and promoting uniformity will be important components to an integrated national food safety system.

As noted, various levels of government are working to address food safety problems from the President's Food Safety Working Group to local leaders working through public health and agriculture organizations. At all levels, there is a call for greater integration and coordination between the Federal agencies and the regulatory and public health partners involved in food safety. This document identifies the concrete steps FDA is taking to carry forth this integration and coordination. It describes the necessary actions of the Agency and its partners for development of an integrated, risk-based national food safety system to improve food safety and reduce foodborne illness.

### **Integrated National Food Safety System**

To be successful, an integrated national food safety system must build upon the work currently being done by FDA and our regulatory and public health partners. Additional work is needed in terms of active communication, coordination, and support. One important step towards implementing an integrated national food safety system will entail the adoption and implementation of the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards, which is already well underway<sup>3</sup>. In addition to these existing standards, consideration will be given to the need for additional program standards in order to adequately cover the entire food supply chain. Program standards are important to establish a uniform foundation for the design and management of federal, state, territorial, tribal and local food programs that encompass best practices of a high quality regulatory program. Within the program standards are the critical elements of a regulatory program designed to protect the public from foodborne illness. For example, in the Manufactured Food Regulatory Program Standards, the specific standards cover a state's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, food-related illness and outbreak investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. It is FDA's role and responsibility to not only meet these standards and to collaborate with other food regulatory agencies, but to also assist through incentives or other means state and local regulatory and public health programs working to meet these standards.

### **Recent Actions**

The goal to implement an integrated national food safety system is not new but rather a concept that has been in the works for some time. Since the 1990's, federal, state, territorial, tribal and local agencies have been working together to address specific pieces of a national integrated system. The 1998 National Food Safety Initiative launched a comprehensive approach to food safety and had

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<sup>3</sup> At this time, the Retail Food Regulatory Program Standards and Manufactured Food Regulatory Program Standards have been developed for human food only. FDA has GMPs for the production of medicated animal feeds. FDA is currently developing process control regulations for animal feeds and will investigate the potential for expanding the Retail Food and Manufactured Food Regulatory Program Standards to animal feed.

some success in moving integration forward, but faltered after a few years without adequate federal infrastructure and funding to support the effort. In August 2008, FDA hosted a national meeting, *Gateway to Food Protection*, which reenergized efforts to work together toward an integrated approach in response to addressing the challenges of the growing global food supply. Outcomes of the meeting included the creation of an FDA Federal-State “Partnership for Food Protection Coordinating Committee” made-up of Federal partners (FDA, CDC, USDA, and DHS) and a wide range of representatives from our state, territorial, tribal and local regulatory and public health partners. The committee serves as a strategic and technical committee that advises the Agency on necessary infrastructure and food safety implementation strategies essential to building a national food safety system. The Partnership for Food Protection work groups were also formed under the purview of the Coordinating Committee to focus on specific topics and achieve specific objectives by fall of 2010. The work groups are focusing on improving interactive information technology (IT), training, response, and risk-based work planning. A work group was also formed to facilitate the development of a Pet Event Tracking Network (PetNet). The lessons learned and other results from these groups will be incorporated into the plan for an integrated national food safety system.

These efforts and the necessity to integrate food safety have been recognized and enthusiastically supported by the Obama Administration, which, through an initial investment in the FY 2010 budget of \$14.6 million, will begin to build FDA infrastructure in support of an integrated national food safety system. Specifically, the recent White House Food Safety Working Group Key Findings Report submitted to President Obama on July 7, 2009, identified an integrated food safety system as a priority recommendation where the Federal government will “... *prioritize crucial inspection and enforcement activity across the world, support safety efforts by States, localities and businesses at home; and utilize data to guide these efforts and evaluate their outcomes.*” The Report also recommended the need for a unified incident command structure and adequate provision for sharing data in an emergency, among other specific recommendations to improve state, territorial, tribal and local response capacity and capabilities.

### **Overview of the Approach**

FDA will continue to strengthen the collaboration with its regulatory and public health partners to build an integrated national food safety system. To create a strong and credible system the Agency will:

- Build on collaboration among all regulatory and public health partners to provide comprehensive and well coordinated coverage of the food safety system;
- Develop and implement uniform, national standards and training and certification programs with our regulatory and public health partners;
- Maintain integrity through regular program oversight and accountability at all levels; and,
- Sustain the system through: (1) seeking multi-year funding to state and local regulatory and public health partners linked to defined performance standards; (2) facilitating information sharing and communication for enhanced public health; and (3) creating the infrastructure for national electronic information sharing.

In addition, an integrated national food safety system will require additional staff to support the development of needed programs and approaches and significant expansion of FDA’s current infrastructure. The new system also will require new legislative authorities for FDA to fully implement the data and information sharing aspects of the integrated risk-based national food safety

system. Under an integrated system, each regulatory and public health partner would continue to operate under its own laws and regulations but additional coordination and oversight will be used to create a more unified system.

### **Implementation and Impact**

FDA and its regulatory and public health partners will begin implementing the integrated national food safety system by taking the following actions:

**Establish policies and procedures** to ensure that programmatic objectives and implementation are coordinated across federal, state and local public health and regulatory partners and that Agency actions are transparent to the public by:

- Developing a communications strategy and decision making process to ensure full participation of FDA's state, territorial, tribal and local, regulatory and public health partners in the development of the implementation plan.
- Developing a system organizational oversight and management structure.
- Developing a detailed 5-year implementation plan.

**Continue to develop national standards** in cooperation with state and local food regulatory agencies to ensure uniformity in inspectional coverage and the collection and analyses of compliance, surveillance, and environmental samples to enable both FDA and states to make greater use of each other's laboratory analytical and inspection data in pursuing advisory, administrative, or judicial actions by:

- Continuing the development and expansion of national program standards such as the Manufactured Food Regulatory Program Standards and Retail Food Regulatory Program Standards
- Developing a national laboratory proficiency testing program and a remediation program for states that do not meet the national program standards.
- Creating shared data standards that enable the exchange of public health and agricultural laboratory data as well as enforcement data among FDA and our regulatory and public health partners for faster identification of food safety threats and information on corrective actions.
- Leveraging the work of the Partnership for Food Protection IT Work Group to make necessary IT improvements for interconnectivity between Federal, state, territorial, tribal and local regulatory and public health partners.

**Create a national work plan** to improve and expand inspection and sample collection coverage to verify industry performance in implementing food safety measures while reducing redundancies in the current system through better coordination of work planning by FDA and our state, territorial, tribal and local partners by:

- Developing a process to work with all regulatory and public health partners to create an approach for the ranking of food categories by public health risk.
- Developing systems, staffing, tools, policies and procedures for moving forward with the creation of a national risk-based work plan. FDA will seek lessons learned from the pilot project underway by the Partnership for Food Protection Risk-Based Work Planning Work Group.

**Develop training and certification programs** to achieve a high level of scientific quality in data collection and inspections, ensure uniform and consistent approaches to food safety throughout the national system and help build capacity across state and local agencies by:

- Developing and implementing training for regulatory and public health partners, including certification of proficiencies and work with one or more international food protection training institutes.
- Working collaboratively with Federal, state, territorial, tribal and local partners to develop and deliver classroom and web-based courses to improve the quality of inspections, investigations, sample collections and analyses, enforcement, emergency response and recovery activities, communication, and outreach.
- Developing and administering food certification programs for inspectors, investigators, and analysts at FDA and our regulatory partners to ensure that all parties are performing to the national standards.
- Leveraging the work being done by the Partnership for Food Protection Training Work Group to perform competency assessments and to develop a framework for certification.
- Working with outside parties on the creation of one or more international food safety training academies as a forum to provide the training

**Coordinate emergency response** to enable faster and more effective response to food safety events by:

- Working with the Council to Improve Foodborne Outbreak Response (CIFOR) to implement guidelines for multi-jurisdictional outbreak response.
- Continuing to improve outbreak response by increasing the number of cooperative agreements to fund Rapid Response Teams (RRT) and to fund additional laboratories in the Food Emergency Response Network (FERN) to integrate an all-hazards response capability for food and foodborne illness responses and to react more rapidly to potential threats to the food supply.
- Leveraging the Partnership for Food Protection Response Work Group's work on improving recall effectiveness checks through a series of pilots and development an inventory of Incident Command System (ICS) models and best practices.
- Working with regulatory and public health partners to develop guidelines to use that will improve traceback speed and accuracy.
- Developing a system for rapid analysis and integration of consumer complaints to facilitate early detection of food problems
- Beginning to work collaboratively to address recovery issues after an outbreak has occurred

**Provide program oversight** to measure performance against the program standards and maintain the credibility of the program by:

- Conducting audits of our regulator partners to measure their performance against the program standards. Audits will include reviews of inspection, investigation, sample collection and analysis, enforcement, response, recovery, and outreach activities.

**Develop performance outcomes and measures** to assess the success of the program in terms of the reduction of foodborne illnesses and other public health focused criteria, industry compliance rates, resource efficiencies, and other applicable criteria.

## **Conclusion**

The safety of the U.S. food supply depends on preventive and collaborative approaches throughout the food supply chain. We look forward to continuing to work with our federal, state, territorial, tribal and local regulatory and public health partners along with industry, consumer groups, academia, and others to help FDA reduce the incidence of foodborne illness to the lowest level possible. The development of a fully-integrated national food safety system over the next five years is a critical component within the President's overall public-health-focused food safety framework for maintaining a safe food supply for U.S. consumers.

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