

Report to Congress

**Report to Congress on Building Domestic Capacity to Implement the FDA Food Safety
Modernization Act (FSMA)**

Submitted pursuant to FSMA Section 110(a)(1)

U.S. Department of Health and Human Services

Food and Drug Administration

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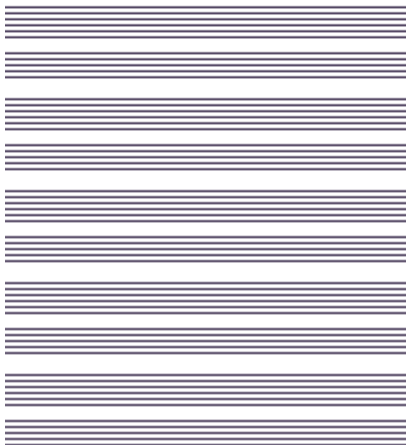
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Ensuring a Safe Food Supply

A Report to Congress Under the FDA Food Safety Modernization Act
Section 110(a)(1)



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INTRODUCTION

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. FSMA directs the building of a new, modernized food safety system that works more effectively to prevent food safety problems and meets the challenges of today's global food system. Among its provisions is a directive to the Secretary of Health and Human Services to submit a comprehensive report to Congress that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illnesses and other food-related hazards that can be addressed through preventative activities. This report fulfills that directive and describes how the nation's capacity to prevent foodborne illness can be strengthened.¹

This report is based on information provided by the Food and Drug Administration (FDA). It reflects the specific elements of the charge from Congress, providing, among others:

- (A) Analysis of the need for further regulations or guidance to industry.
- (B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 109, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.
- (C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.
- (D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.
- (E) Surveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards, including how such systems and networks are integrated.
- (F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies developed under sections 108 and 205.
- (G) The estimated resources needed to effectively implement the programs and practices identified in the report developed in this section over a 5-year period.

¹ 21 USC 2204. Section 110 (a)(1): Building Domestic Capacity. The report is to be submitted in coordination with the Departments of Agriculture and Homeland Security.

(H) The impact of requirements under this Act (including amendments made by this Act) on certified organic farms and facilities (as defined in section 415 (21 U.S.C. 350d).

(I) Specific efforts taken pursuant to the agreements authorized under section 421(c) of the Federal Food, Drug, and Cosmetic Act (as added by section 201), together with, as necessary, a description of any additional authorities necessary to improve seafood safety.

EXECUTIVE SUMMARY

The FDA Food Safety Modernization Act (FSMA) was enacted in response to a series of illness outbreaks and contamination incidents involving both domestic and imported food, which revealed the need to modernize the nation's system of food protection. It passed Congress with broad consumer and industry support and reflects their shared vision that all will benefit from a modernized food safety system that reduces foodborne illness, strengthens public confidence in the safety of our food, and minimizes costly disruptions of the food supply.

To fulfill its vision, FSMA mandates an overhaul and expansion of the FDA's current food safety program and authorities and directs an historic shift from reacting to and solving problems after they occur to preventing contamination of food in the first place, thus preventing human illness. The elements of that overhaul, and of this report, can be summarized as follows:

1) Standard Setting and Guidance – Developing and implementing the new prevention standards mandated by Congress is FDA's most critical activity in the initial phase of its implementation of FSMA; these standards will be the foundation upon which a new food safety system will be built. FSMA requires a sea change in the standards FDA promulgates for assuring safe food production, with three major new areas of focus: a) preventive control standards requiring food processors to identify potential hazards associated with their processes and prevent those hazards from occurring, b) specific risk-based standards for safe production and harvesting of produce that take account of the diversity of sizes and operations, and 3) verification of the safety of foods from foreign suppliers by importers of food.

Progress in the first two years: In January 2013, FDA proposed the first two landmark regulations that set science-based standards for preventing foodborne illness.

2) Communication and Outreach – Providing information and technical assistance to food producers will be key elements of a successful FSMA implementation, particularly for small producers.

Progress in the first two years: FDA has undertaken a major new effort to educate and inform the food industry and other stakeholders about FSMA rules to ensure that they understand and have an opportunity to help shape all new requirements. Extensive outreach to stakeholders is underway to get comments before new rules are proposed and after proposals are issued and to help these stakeholders comply once new requirements are in place. Providing technical assistance to food producers will be a key element of successful FSMA implementation,

particularly for small producers; FDA has already formed three public-private partnerships for this purpose.

3) Inspections and Compliance – While inspections of food processors are just one part of an integrated approach to ensuring that modern preventive controls are applied broadly across the food supply, the disparity in the number of domestic and foreign facilities requiring inspection and the number actually inspected by FDA each year has been one of the greatest concerns of the public and the Congress. **FSMA therefore directs FDA to substantially increase its domestic and foreign inspection frequencies. To implement FSMA effectively and efficiently, FDA must modernize the way it conducts inspections and other compliance activities.**

Progress in the first two years: FDA leadership is rapidly implementing plans to ensure that all domestic facilities producing food are inspected according to the frequency specified in FSMA. The agency has also ramped up the number of inspections of foreign food facilities. Recent funding increases have almost permitted FDA to return to its inspection level of a decade ago domestically, although to fully meet the FSMA mandate for the inspection of foreign food facilities, substantial additional funds will be necessary. Moreover, FDA leaders are modernizing inspection procedures, which should result in more targeted inspections and significant savings in the overall time it takes to complete inspections and inspection reports. This will allow FDA to conduct more frequent and effective inspections overall with the resources available. FDA also is considering procedures, such as use of third-parties, to better leverage public and private resources to achieve high rates of compliance.

4) Federal-State Integration – **A successful, integrated nationwide food safety system will not be possible without the involvement of state, local, territorial and tribal partners, who will work in partnership with Federal agencies to plan and implement consistent national inspection and enforcement programs.** Congress has expressed concern that there is significant variability among state inspection programs and that information is not fully shared between states and Federal partners.

Progress in the first two years: FDA and the states are working together to develop consistent, nationwide standards for human and animal food inspection programs, to implement nationwide training and certification programs for inspectors, and to develop shared data platforms. Subject to the availability of funding to help the states effectuate integration, FDA is pursuing a path toward an integrated national system that includes these components: a) consistent national standards for food safety oversight, b) uniform national training of inspectors and joint inspection planning to make optimal use of state and federal resources, c) further integration and coordination among federal and state laboratories, d) expand sharing of inspection, compliance and lab data among FDA and its state and local partners, e) a coordinated national emergency

response network, and f) performance standards for all parties that are audited for quality and remediation of weaknesses.

5) Imports – FDA must implement an entirely new paradigm for import oversight to succeed in ensuring the safety of food coming into the United States. One of the principal driving forces behind the demand for an improved food safety system is public concern about the safety of imported food, which now comprises 15% of the U.S. food supply (and for some foods, such as fruits and vegetables, a much higher percentage). Food is imported from more than 110,000 food manufacturers located in more than 150 countries, many of which are less developed nations without robust regulatory systems in place. A large percentage of the types of foods exported to the United States are considered high risk by food safety experts. FSMA provides new authorities to FDA that hold great promise, including the authority to hold importers accountable for verifying that their foreign suppliers have adequate preventive controls in place to ensure that the foods imported into the U.S. are as safe as those produced domestically.

Progress in the first two years: In recent years, FDA has taken significant steps to improve the oversight of imported food, including implementing a new risk-based analytics system (PREDICT) to improve screening and targeting at the border; the establishment of foreign offices in China, India, Latin America, Europe, the Middle East and Africa; and efforts to develop joint planning and standard setting with other nations to leverage the food safety activities of these entities (such as a pilot comparability arrangement that has been negotiated with New Zealand).

Since FSMA's enactment, FDA is well along with a series of new efforts that will further transform the regulation of imports: development of the Foreign Supplier Verification Program mandated by FSMA, partnerships with its foreign counterparts to create a global coalition of regulators and strengthen regulatory capacity of foreign countries; and leveraging public and private third parties to more effectively verify that modern preventive measures are being taken at the tens of thousands of foreign manufacturing facilities producing food for the American marketplace.

6) Surveillance and Response – Developing new tools to rapidly identify contaminated food causing a foodborne outbreak, quickly tracing the food to its source and removing the source of illness are the primary goals of U.S. surveillance and response activities. The Centers for Disease Control and Prevention (CDC), the Department of Agriculture (USDA), FDA, and state and local health and agriculture agencies must work closely together to accomplish these goals.

Progress in the first two years: Improved surveillance by health officials in recent years has resulted in an increase in the identification of large, multi-state outbreaks associated with food. The surveillance and response system must be further strengthened by obtaining better data on the foods and pathogens responsible for outbreaks, continued integration of state and Federal data systems, early signal detection capabilities regarding contamination events, the development of tools to quickly detect contaminants in food (such as rapid test kits), improved product tracing of food in the supply chain, and the capability to ensure that we learn from outbreaks to inform future prevention efforts. FDA-specific activities include: (1) establishing a focal point within the agency for outbreak response (Coordinated Outbreak Response and Evaluation Office, or CORE), which is comprised of a chief medical officer and a multidisciplinary staff fully dedicated to managing and coordinating outbreaks with FDA's state, local, and federal partner; (2) providing training and funding to 19 states to develop rapid response teams for foodborne outbreaks; and (3) implementing an interagency analytics consortium with CDC and USDA to provide more specific estimates of foodborne illness by pathogen and food combinations.

7) Science Infrastructure – FDA will need to fill significant gaps that exist between its current science and technical capacities and those needed to implement FSMA. Numerous expert studies have recommended that FDA strengthen its scientific capacity and knowledge about how food contamination occurs and how it can be prevented. FDA needs to improve its laboratory and research capabilities to better detect contaminants and microbes in food samples and to predict human toxicity of new or emerging chemical contaminants. Additional IT capacity is needed to improve FDA's ability to conduct risk analyses and better manage risks.

Progress in the first two years: Major new efforts have begun since FSMA's enactment to develop new risk analytics for targeting foods of most concern, to develop new and innovative detection technologies for microbial and chemical contaminants (in conjunction with academic, federal and private partners) and to improve FDA's ability to use information technology to better manage risks and to communicate risk information to other agencies and to food producers. New internal structures were established to strengthen core science and research capabilities by ranking efforts based on greatest public health benefit. And new information technology systems have been developed that will better track and monitor research efforts and thus improve coordination and accountability.

8) Food Defense - FSMA requires that FDA issue regulations to protect against the intentional adulteration of food. While FSMA is primarily focused on preventing illness from unintentional contamination by chemical and microbiological contaminants, it also contains mandates to strengthen food defense – that is, protecting the food supply from terrorism or other acts of intentional contamination. Several FSMA provisions require FDA to issue regulations to protect against the intentional adulteration of food, and FSMA seeks to bolster state and local capacities to prepare for, respond to, and recover from intentional contamination events.

Progress in the first two years: An interagency working group that includes FDA, USDA, and the Department of Homeland Security has devised a set of specific priorities for addressing any gaps or weaknesses in food defense, as directed by FSMA -- including research priorities, improved preparedness, detection of intentional hazards, emergency response, and recovery from an intentional agriculture or food-related incident. Public comments will soon be sought via an Advanced Notice of Proposed Rulemaking, which will seek industry and other stakeholder advice on how to best ensure protection from intentional contamination

9) Animal Food – Central to developing an effective food safety system is the concept that food for animals, as well as humans, be safe. FSMA provides measures to ensure that food for companion animals and for food-producing animals is safe for the animals and people.

Progress in the first two years: FDA's Center for Veterinary Medicine has established an Animal Food Safety Preventive Controls Alliance with industry and other stakeholders that will ensure that training courses, materials, and other technical assistance are available for the animal food industry once the FSMA-directed preventive controls regulations are promulgated. A May 2011 Notice began the process of acquiring advice from industry and others on the content of those regulations.

10) Resources – The promise of FSMA to reform food safety in the U.S. and to significantly reduce the burden of foodborne illness cannot be realized without additional funding. Taking into account the projected resource needs from the Congressional Budget Office and new funds appropriated from FY2010 through FY2012, FDA will need an additional \$400 million to \$450 million in funds added to its base, to make FSMA a fully successful initiative.

Progress in the first two years: Congress has added \$100 million in the FY 2011 and 2012 FDA budgets, thus making a meaningful start on reaching the goal of ensuring adequate funds to implement the new food safety efforts.

CHAPTER 1 – STANDARD SETTING AND GUIDANCE

A. BACKGROUND

The production of safe food is the responsibility of the food industry, but it is FDA's responsibility to set food safety standards and to ensure that these standards are met. FDA standards and guidance address four major categories of contaminants that have the potential to adulterate foods: chemical, biological, physical and radiological. Section 110 of FSMA directs FDA to provide Congress with an analysis of the need for new standards and guidance for the food industry.

B. BACKGROUND ON STANDARDS AND GUIDANCE DOCUMENTS

The authority for food safety standards is rooted in the Federal Food, Drug, and Cosmetic Act (FD&C Act). Standards, which are set through rulemaking, are binding. In addition to regulatory standards, FDA issues guidance documents, which express FDA's current thinking on topics such as the point at which FDA may consider taking regulatory action or the steps industry can take that FDA would consider acceptable. However, guidance documents are not binding requirements.

Safety Standards

There are two principal types of safety standards that apply to human and animal food safety:

1. "conditions of manufacture" describe the production or processing system, environment and controls that must (or should) be in place (e.g., current good manufacturing practices [CGMP], hazard analysis and critical control point [HACCP] controls, and other preventive controls); and
2. "product standards" are usually numerical and describe the maximum level of a substance (e.g., contaminant, additive, drug residue) that can safely be present in the finished food; or specific processing parameters, such as time and temperature controls for microbial hazards

Safety standards relating to the conditions of manufacture of a food are designed to prevent introduction of potential hazards and to ensure that the product standards that apply to that food are consistently met.

Before the passage of FSMA, performance standards have been an important means by which FDA has sought the end result of "safe food." Emphasis has been placed on verifying/monitoring the end result – the safety and sanitary production of the food that people consume -- rather than on the crucial need for industry to evaluate, institute and verify control measures to ensure that the introduction of hazards is prevented, conditions of manufacture are

appropriate, and their products meet established food safety standards. An exception to this is where FDA has required HACCP (juice and seafood). Commodity-specific regulations have provided additional standards for conditions of manufacture; an example is the recent regulations governing the production, transportation and storage of eggs, prompted by the frequency of egg-associated Salmonella illnesses. Good Manufacturing Practice (GMP) regulations, describing the methods, equipment, facilities and controls for producing processed food also provide an important regulatory control over the safety of the nation's food supply.

Guidance documents

Guidance documents foster industry compliance with a regulation by communicating FDA's best thinking and providing technical information for facilities that have limited food safety technical expertise. In addition, they promote consistency.

For instance, FDA most recently issued the fourth edition of the Fish and Fishery Products Hazards and Controls Guidance, which has been successful in assisting processors of fish products in developing their HACCP plans -- by identifying hazards that are associated with their products and helping them to formulate preventive control strategies.

FDA will develop similar guidance on hazard analysis and preventive controls to explain the requirements of the two proposed preventive control regulations (for human and animal food) and the produce safety rule – directed by FSMA. As part of this preventive control guidance, FDA will also develop guidance documents that are targeted to specific types of food.

C. CHANGES UNDER FSMA

Under FSMA, the product standards described above still are in place but FSMA focuses on having systems in place to prevent problems rather than relying on their detection after the fact. Under FSMA, FDA is required to issue rules establishing a basic framework of prevention-oriented standards, including rules requiring: a) facilities producing food to have preventive controls in place, b) farms to comply with science-based minimum standards for the safe production and harvesting of fruits and vegetables and c) importers to perform risk-based verification of their foreign suppliers to verify that the food is produced in accordance with the same modern prevention standards FSMA establishes for domestically produced food.

- a) Preventive Controls. Hazards in food, whether pathogenic microorganisms, chemical, or other hazards, can be eliminated, reduced or controlled with preventive controls. With FSMA section 103, Congress amended the FD&C Act by adding Section 418 on Hazard Analysis and Risk-Based Preventive Controls. This section requires owners, operators, or agents in charge of human and animal food facilities to develop and implement a written plan that describes and documents how their facilities will implement the hazard analysis and preventive controls required by this section. These requirements include:
 - the identification of hazards (i.e. a hazard analysis) that may be associated with a food facility, those occurring naturally and those that might be intentionally introduced;
 - preventive controls to significantly minimize or prevent identified hazards;

- procedures for monitoring and verifying the preventive controls;
- corrective action procedures if a preventive control fails; and
- recordkeeping.

- b) Standards for Produce Safety. FSMA section 105 amended the FD&C Act by adding section 419, Standards for Produce Safety. This section requires FDA to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables for which it is determined that such standards minimize the risk of serious adverse health consequences or death. FSMA directs FDA to develop a produce safety regulation that requires measures FDA determines are reasonably necessary to prevent the introduction of reasonably foreseeable hazards, and that, among other things, (1) provides sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables, (2) is based on science, and (3) takes into consideration conservation and environmental practice standards.

Section 110 of FSMA also directs FDA to describe the effects of new FSMA-related food safety standards on certified organic farms and facilities. FDA has consulted with technical experts and representatives from the National Organic Program to ensure that its produce safety rulemaking does not conflict with or duplicate requirements of the National Organic Program.

- c) Foreign Supplier Verification Program. FSMA also addresses the safety of imported food by requiring importers to perform risk-based verification of their foreign suppliers to verify that the food is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the FD&C Act, is not adulterated, and is not misbranded with respect to food allergen labeling.
- d) Performance Standards. Section 104 of FSMA directs FDA to determine the most significant contaminants on a biannual basis and to set appropriate performance standards for those contaminants as needed.

Guidances supplement formal regulations and will be an essential part of an effective FSMA implementation, as they will give industry specific information intended to help processors and others understand how to do their part in ensuring the safety of food. As such, guidances will be developed in two ways:

- 1) Specific guidances to accompany the regulations that carry out the intent of Congress in enacting FSMA, such as the produce standards and the new preventive controls regime (as well as commodity-specific guidances, as needed, to clarify how the new FSMA rules apply in specific areas) and
- 2) A significant ongoing guidance effort, over the next decade or more, to clarify and explain requirements as new evidence and techniques of protecting food emerge as a result of the close collaboration between government, academia, and industry.

All FDA rules and guidances will reflect advice and expertise obtained through extensive dialogue with the food industry, scientific experts, the consumer community and other stakeholders.

D. CHALLENGES FOR THE FUTURE

The rules outlined above provide the central framework for the modern, prevention-oriented food safety system mandated by FSMA. Completing these rules and accompanying documents is thus one of FSMA's highest priority challenges. In addition to these rules, FDA is directed to establish standards for safe transportation of food and to prevent intentional adulteration of food. FDA must complete those regulations in the near future as well.

In all areas of standard setting called for by FSMA, FDA is committed to adopting standards that provide flexibility in achieving the goal of prevention based on current knowledge of hazards and interventions, and that can accommodate new knowledge about how to improve food safety that will continue to emerge. To take advantage of this flexibility, FDA must have the technical capacity and expertise to be at the cutting edge of understanding regarding food safety hazards and preventive measures; and must work collaboratively with a broad range of food industry experts to ensure standards are up-to-date, effective, and efficient in protecting the safety of food.

CHAPTER 2 – COMMUNICATIONS, OUTREACH, AND TECHNICAL ASSISTANCE

A. BACKGROUND

FSMA recognizes that communications, outreach and technical assistance are essential to an effective food safety system and serve many functions, depending on the audience. These efforts, many of which are already underway, will:

- Improve the quality and practicality of regulations by engaging stakeholders during the development of regulations so their views can better inform rulemaking;
- Increase compliance by ensuring FDA requirements are understood by the regulated industry through training, technical assistance and other means;
- Ensure coordination and consistency with other public health government agencies at the Federal, state and local levels;
- Educate food handlers along the farm to table chain about their role in preventing foodborne illness; and
- Inform stakeholders at all levels about specific and potential threats to the safety and security of the food supply, such as during foodborne illness outbreaks and food recalls.

B. COMMUNICATIONS AND OUTREACH TO INFORM RULEMAKING

Communications and outreach play an early role as FDA implements the new law's provisions. FDA has conducted extensive outreach to stakeholders so that the rules developed are science-based and reflect the diversity of affected industries. For example, FDA received initial written advice and held public meetings on Preventive Controls, Imports, and Inspection and Compliance, before the development of proposed rules. In addition, FDA held numerous listening sessions with stakeholder groups. The agency also developed a new interactive website with more than 13,000 people signed up to receive email alerts. FDA has visited farms in 14 states and toured facilities, including a pet food operation. FDA has made more than 400 presentations at various meetings and events to keep stakeholders informed of its progress in implementing FSMA. FDA will continue its extensive outreach as proposed rules are published. Investments on the "front end" result in rules that are clear, practical and science-based, and that are well understood and can be implemented by the wide array of affected farmers, processors and handlers of food.

C. PROVIDING TECHNICAL ASSISTANCE ON IMPLEMENTATION OF FSMA RULES

To ensure that the FSMA requirements, such as preventive controls, are implemented and are working properly to protect the public health, the agency recognizes the need to work closely with the food industry and other partners to provide technical assistance and training, particularly to small businesses.

That effort will be assisted greatly by the formation of three “alliances” to help farmers and food companies identify and implement best practices for the safe production and handling of their commodities. The Food Safety Preventive Controls Alliance and the Sprouts Safety Alliance have been created in conjunction with the Illinois Institute of Technology, and the Produce Safety Alliance in conjunction with Cornell University. The alliances are collaborative efforts by industry, academia, and government to support food growers and processors in meeting the requirements of FSMA. To do so, the alliances will develop alliance-specific preventive control training courses and other technical assistance, and generally serve as a resource to industry in providing information and reference tools. A related asset will be upgrading the Center for Food Safety and Applied Nutrition’s SAFEFOOD Nutrition Information Center, which over time will serve as a portal for calls and emails from growers and processors, in addition to other stakeholders.

FDA’s call center for industry inquiries is at 1-888-SAFEFOOD.

The alliances established are public-private partnerships involving government, industry and academia to leverage resources and provide hands-on practical information to the domestic and international industry. FDA, the Department of Agriculture, and Cornell University formed the Produce Safety Alliance in 2010 to develop an important educational component in preparation for the planned rule on the safe growing, harvesting, and packing of produce. The Alliance will provide produce growers and packers standardized training and educational materials about current risk-and science-based best food safety practices and, in the future, about regulatory requirements, with initial emphasis on small and very small scale growers/packers.

The Food Safety Preventive Controls Alliance has been organized in anticipation of rules on preventive controls for food facilities. Focused on small businesses, which need the most assistance, the alliance will develop training materials and establish a network of trainers who can assist industry in complying with the new regulations. Because small businesses have limited resources for travel and training, the alliance will use innovative ways to reach out to them.

The Sprouts Safety Alliance has been organized to develop a core curriculum, training and outreach programs for stakeholders in the sprout production community to enhance the industry's understanding and implementation of best practices for promoting sprout safety, as well as, in the future, relevant regulatory requirements.

D. DISSEMINATING INFORMATION ON THREATS TO THE SAFETY OF THE FOOD SUPPLY

FDA plays an important role as a source of information that others can use to improve food safety. The agency distributes information to the regulated industry and to government partners on potential threats, whether intentional or unintentional, in the food supply and preventive measures in a number of ways. While these activities have long been part of FDA's portfolio of resources available to help protect the food supply, they will be especially important in helping others understand how to best utilize the new FSMA-directed food safety systems.

Press Releases and Social Media - These tools are used widely and often to communicate to the media and to the general public when threat information needs the widest possible distribution.

Letters to Industry - FDA uses letters to industry to inform affected sectors of the industry about safety concerns related to a particular commodity.

Food Defense - FDA serves as co-chair of the Food and Agriculture Sector Government Coordinating Council (GCC), along with USDA and the Department of Homeland Security which constructed and hosts the GCC. DHS, as a non-regulatory agency, facilitates outreach to private sector partners, supports voluntary vulnerability assessments and shares information on deliberate threats. The GCC has now added a co-chair to represent state, local, territorial and tribal partners into the integrated system. The Food and Agriculture Sector uses a series of web-based platforms to ensure message dissemination to stakeholders (government, industry and academia) and to share surveillance information that can be used to identify potential threats, whether intentional (food defense) or unintentional (food safety).

Import Alerts - Import Alerts are used to disseminate information such as problems detected with commodities, shippers and importers to provide for more uniform and effective FDA import coverage. They may be based on adverse health consequences; actionable levels of a pesticide, aflatoxin, or chemical contaminant; trends detected, such as unapproved food colors; or a violative foreign inspection.

Educating Food Workers - Food workers, including consumers, play a role in minimizing contamination and the growth of pathogens through proper handling, preparation and storage of foods. Numerous FDA food safety education programs teach consumers how they can help to prevent illnesses, such as:

- FDA, CDC, USDA, Ad Council campaign - Food Safe Families;

- To Your Health! Food Safety for Seniors;
- Food Safety for Moms-to-Be;
- Preventing Foodborne Illness Associated with Pet Food and Pet Treat, and,
- The school-based Science and our Food Supply.

FDA has also carried out education campaigns for specific threats, such as human pathogens in raw milk, raw produce and fresh-squeezed fruit and vegetable juices; *Vibrio vulnificus* in raw oysters; and reducing the risk of listeriosis in pregnant Hispanic women. The agency works closely with other Federal agencies and public-private partnerships such as the Partnership for Food Safety Education to leverage resources and contributes to FoodSafety.gov, the Federal web site for food safety information.

For retail and foodservice operations, FDA's education and training efforts are directed at state and local regulatory partners, but education materials also are provided to food workers. In addition, FDA offers on-line and face-to-face training courses to state, local and tribal regulatory partners and to industry on retail HACCP, the Food Code, and foodborne illness investigation.

Food defense-related education and training materials are geared more towards industry management and front-line workers than to consumers. However, consumers are encouraged to report suspicious activity and to be vigilant within their communities. FDA, through the Food and Agriculture Sector Government Coordinating Council, continues to provide industry partners information on what they can do to decrease the risk of intentional contamination of food within their control.

E. COMMUNICATION AND COORDINATION RELATED TO OUTBREAK IDENTIFICATION AND RESPONSE

While FSMA focuses on prevention of foodborne illness outbreaks, it also recognizes the importance of improving outbreak detection and response. In recent years, FDA has undertaken significant efforts in this area, including engaging industry and consumer stakeholder groups early in outbreak investigations and in building relationships outside of an emergency outbreak situation. In many recent outbreak investigations, for instance, FDA has reached out to industry when there were several suspect foods and the epidemiological investigation was unable to narrow the source. Too, industry has proactively provided information to aid in the investigation. Outside of outbreak situations, FDA has participated in exercises with CDC and USDA, DHS, and various levels of law enforcement to share and familiarize each other with their respective processes during an outbreak investigation.

In addition, FDA has worked to build partnerships with states, local governments and other Federal partners to improve risk communication during outbreaks. For example, a subgroup of the Partnership for Food Protection is examining ways to improve outbreak response, including communications, and FDA, CDC, and USDA's FSIS have established a Collaboration Workgroup with an outbreak response and communications component.

Acknowledging the importance of research in understanding effective communication in the event of an emergency, FDA now has the capability to analyze social media content at the time of an outbreak or recall to help guide the direction of future messaging and social media outlets to be reached.

In 2011, FDA formed a new outbreak group, the Coordinated Outbreak Response and Evaluation (CORE) Network, with full-time staff to manage surveillance, response, and post-response activities related to incidents of illness linked to FDA-regulated human and animal food. Led by a Chief Medical Officer, a new position, the CORE Network is streamlining incident-related processes, which were previously dispersed throughout the FDA, and enhancing transparency and working relationships with internal and external stakeholders. External communications is central to CORE with an emphasis on sharing findings of outbreak investigations and root cause assessments to ensure they drive further development of preventive food safety strategies.

F. FUTURE NEEDS

FSMA has increased FDA's need to communicate and provide outreach. For the future, FDA will need to obtain, and make strategic use of, resources to provide technical assistance at the scale needed to implement FSMA and other food safety requirements. This will require more assistance than currently provided by FDA and will require that FDA leverage resources with its partners in government, industry and academia through additional collaboration and alliance-building. FDA must consider both domestic and international audiences in its outreach strategy. The diversity of audiences that FDA must reach makes outreach even more challenging and requires that communication be tailored in a variety of ways. For example, outreach efforts must take into consideration the special needs of small businesses, which generally lack the resources to find this information on their own and may need individual assistance in order to meet new requirements. Public and private alliances are critical to success. Attention also needs to be paid to the increasing diversity of business owners, such as the critical need to have resources available in different languages, as well as providing educational materials for individuals with low literacy levels.

CHAPTER 3 - INSPECTIONS AND COMPLIANCE

A. BACKGROUND

FDA inspects food facilities that manufacture, process, pack and hold food to ensure food safety and compliance with the Federal Food, Drug, and Cosmetic Act. Having a strong inspection and compliance process in place is critical for the agency's ability to safeguard the food supply by ensuring that all ingredients used in food are safe and that the food is protected from dangerous pathogens, chemicals or other harmful substances.

FSMA directs FDA to increase its food facility inspection frequency immediately. For example, all high-risk domestic facilities must be inspected within 5 years of enactment and no less than every 3 years after that. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and to double those inspections every year for the next five years.

FSMA also directs FDA to make its inspection program "risk-based" and gives FDA new inspection and enforcement tools to better detect and take swift action to correct failures by firms to implement proper preventive measures. These tools are aimed at providing stronger assurances to consumers that food producers and processors are implementing modern preventive measures on a consistent, daily basis. To take advantage of these new tools, FDA is revamping its approach to inspection and compliance, beginning with a broadening of its purposes.

B. INSPECTION FREQUENCY CONCERNS

The FSMA mandate to adhere to a domestic food facility inspection frequency mandate and the mandate for FDA to conduct much larger numbers of foreign food facility inspections over the next several years were prompted by Congressional concerns over historically poor inspection frequencies in domestic facilities and low numbers of foreign food facility inspections as indicated by the examples that follow:

- In the mid-1990s, FDA conducted approximately 5,000 domestic food inspections annually, and funded the states under contracts to conduct about an equal number.
- Between 2004 and 2008, more than 50% of FDA's domestic food facility inventory was not inspected. While inspection counts of domestic facilities have increased in recent years over the aforementioned historically low numbers, the inventory of domestic firms to be inspected now numbers in excess of 100,000; thus many firms are still inspected infrequently.

- The inventory of foreign food firms that are subject to FDA inspection is estimated to number over 130,000. FDA inspected fewer than 100 foreign food facilities per year prior to FY2010 when the numbers of foreign food inspection began to increase. More specifically, 350 foreign food inspections were conducted by FDA in FY 2010, 1,000 in FY 2011, and over 1,200 in FY 2012, but even at this increased rate it would take FDA years to conduct foreign inspections at all food facilities exporting food to the U.S.

C. PURPOSES OF INSPECTION AND COMPLIANCE

In addition to recognizing the need for adequate inspection frequency, FSMA calls for and empowers FDA to transform its approach to inspection and compliance – shifting from a primary focus on detecting legal violations and building judicial enforcement cases to a focus on ensuring that firms are consistently implementing the modern prevention measures mandated by FSMA.

This shift is based on the now widely shared understanding that the foundation for reducing the risk of preventable foodborne illness in today’s global food system is action by the food industry. Specifically, food safety depends primarily on the food industry working in a continuous improvement mode to: (1) implement science- and risk-based preventive measures at all appropriate points across the farm-to-table spectrum, and (2) manage their operations and supply chains in a manner that provides documented assurances that appropriate preventive measures are being implemented as a matter of routine practice every day.

FDA’s role under FSMA is to foster implementation of such modern preventive measures using a wide range of tools, including education and technical assistance, inspection and other compliance measures to assess and incentivize compliance, and swift action when firms fall short. Inspection with a strong public health prevention focus is a central element of FDA’s FSMA compliance strategy and will be most effective when carried out in the context of a comprehensive effort to foster compliance with modern food safety standards, including:

- Commodity- and sector-specific guidance on implementation of prevention-oriented standards;
- Education and outreach to industry to ensure expectations and requirements are understood;
- Technical assistance to facilitate compliance, especially by small and mid-size operators;
- Regulatory incentives for compliance, such as less frequent or intense inspection for good performers;
- Reliable third-party audits to verify compliance;
- Public education, transparency and publicity to promote compliance and prevention;

- Modernized approaches to inspection and enforcement based on the prevention framework and the enhanced inspection and enforcement tools provided by FSMA.

Under this new FSMA framework, inspection will take a wider array of forms and have a wider range of purposes than in the past, and thereby make a greater contribution to food safety and protection of public health. Examples of the different roles inspection can play in a modernized food safety system include:

- *Efficiently screening firms for food safety performance* as a guide to inspection priority, frequency, depth, and approach.
- *Providing firms incentives for compliance* through enhanced presence and targeted scrutiny of high-risk firms and products and reduced scrutiny of firms with records of demonstrated good performance.
- *Assessing the compliance of individual firms* through a range of inspection and sampling techniques used in a strategic, risk-based way to maximize coverage of priority sectors and firms.
- *Collecting data to inform understanding and analysis* of sector-wide hazards, practices and preventive control deficiencies.
- *Collecting data on compliance rates* to evaluate program performance and plan future efforts.

FDA believes that a more flexible, multi-faceted approach to inspection will not only be more effective but can also be more efficient. For example, as one alternative approach to be used when appropriate, FDA is piloting a focused, shorter “component” inspection model, one in which the investigator reviews in depth one or more of the most critical control systems at the food manufacturing facility during an inspection, as determined through the use of a risk model, as opposed to performing a comprehensive inspection of all systems. FDA believes that such an approach can provide a clear indication of whether the facility has the ability, commitment and systems to successfully implement modern controls. If such an inspection reveals problems, would pursue further inspection and action as needed. Under such a system, however, the current 18-hour average time for domestic food facility inspections could be reduced without compromising food safety.

To carry out this broader approach to inspection and compliance, FDA will expand the skills and capacities of its scientific, technical and operational staff and change its internal operational practices. This includes enhancing capacity and improving internal procedures to enable the agency to make quick decisions and take immediate action when needed to protect public health, using an array of tools, and working more closely with local and state agencies to coordinate compliance and enforcement efforts.

D. FSMA-DIRECTED PROGRAMS AND PRACTICES

Prevention-Based Inspections

FDA's historical model for conducting food facility inspections has been centered around industry's implementation of current Good Manufacturing Practice (cGMP) regulations. CGMPs are focused predominately on sanitation, training of industry personnel, and general requirements that protect food products from contamination with various adulterants. As outlined above, FSMA will require a shift from this inspection model and regulatory paradigm to one that focuses on the adequate implementation of science-based preventive controls for identified hazards.

Under FSMA, food facilities will develop food safety plans for each product they produce. These plans will identify the hazards reasonably likely to occur during the production of the firm's food products. In addition, the plan must specify the preventive controls or practices that will be put in place to mitigate identified hazards. Implementing these food safety plans will require that industry, in part, develop procedures, provide and document employee training, and establish monitoring records that demonstrate the firm is following its plan.

Under FSMA, FDA and state inspectors will still make observations regarding the conditions in the facility on the day of the inspection, but they will also review records to determine if the firm has identified accurately all hazards associated with its processes and has implemented on a continuing basis appropriate controls to prevent the manufacture of unsafe food.

New Enforcement Authorities

To supplement the new inspection models under the preventive controls paradigm, FSMA provides FDA with new administrative enforcement tools that facilitate swift action when preventive control failures result in the production of unsafe food that has the potential to put consumers at risk. These new enforcement tools include:

Expanded Administrative Detention: FSMA amended the criteria for ordering administrative detention to allow FDA to detain a food that it believes is adulterated or misbranded. Administrative detention provides a strong incentive for compliance and a means by which FDA can quickly and effectively remove unsafe food from distribution channels. In certain cases, administrative detention will allow the agency to pursue other enforcement action, while maintaining control of the product of concern.

Suspension of Food Facility Registration: FSMA expressly provides FDA with the authority to suspend the registration of a food facility if the food manufactured, processed, packed, received, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals and other criteria are met. A facility with a suspended registration cannot introduce or offer to introduce food from the facility into commerce in the United States.

Mandatory Recall: Before FSMA, FDA had to rely on a firm's voluntary decision to recall food from the marketplace that was adulterated or misbranded and likely to result in serious illness or death, to human or animal health. Under FSMA, the agency can order a recall under such circumstances if a food firm does not choose to do so voluntarily. Additionally, FDA has launched a new search engine where consumers can quickly and easily check on new and recent recalls.

Inspection Frequency

As noted earlier, FSMA requires the inspection of all domestic high risk food firms not less often than once in the first five year period following the enactment of FSMA, and not less often than every three years thereafter. FSMA also requires the inspection of all domestic non-high risk food firms within the first seven years following the enactment of FSMA and once every five years thereafter. Lastly, FSMA requires the agency to conduct not fewer than 600 foreign food facility inspections the first year following the date of enactment of the law, and to double that number each year through 2016; in 2016 FDA is required under FSMA to perform not less than 19,200 foreign food facility inspections.

FDA has developed a working definition for high and non-high risk facilities, which takes into account the criteria defined within the law², including the known safety risk of the food, the compliance history of the facility, and the firm's practices and preventive controls already in place. Using that definition, the agency estimates that there are 22,325 high risk food manufacturing facilities in the United States³. See Diagram 1 for a depiction of the decision tree FDA uses for identifying high risk facilities.

² Section 421 of the Food, Drug and Cosmetic Act mandates inspection of food facilities based on risk and provides criteria for the designation of facilities as "high risk."

³ FSMA also requires that animal feed manufacturers be classified as high risk or non-high risk, and that categorization is underway, which will result in the identification of several hundred high risk animal feed facilities.

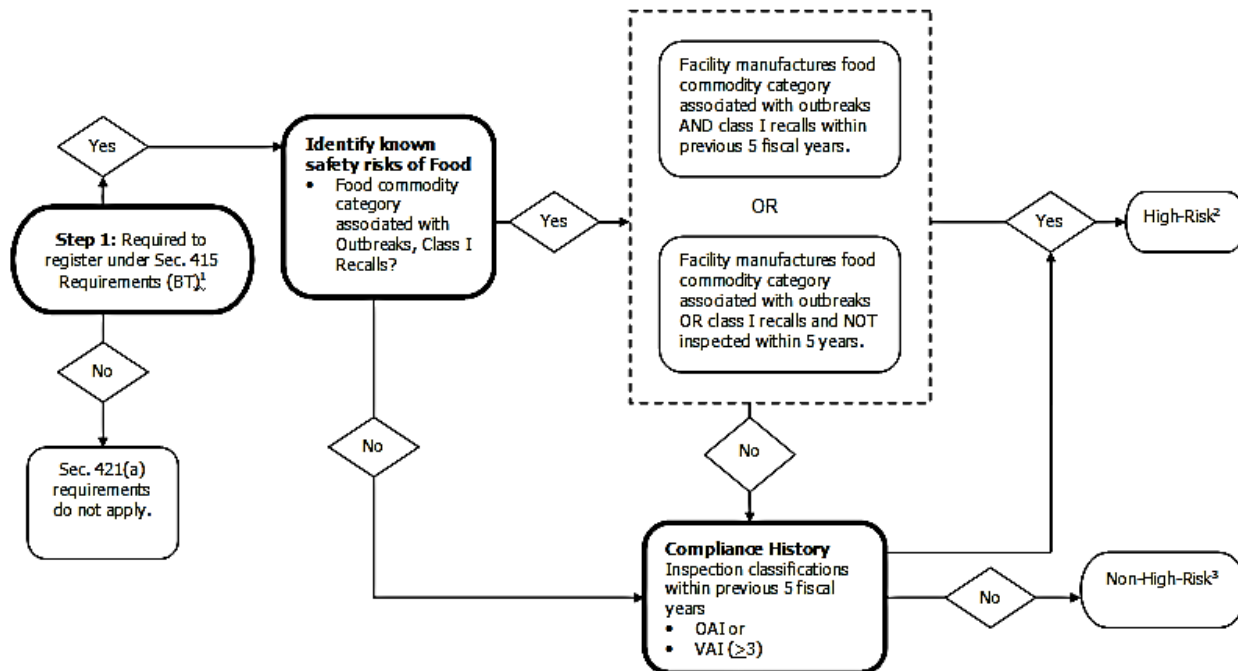


Diagram 1. FY12 FSMA Domestic Facility Risk Category

1. FY12 based on data from agency's Official Establishment Inventory. Resources are allocated for facilities not required to register.

2. Inspect within three-year period.

3. Inspect within seven-year period.

For **domestic inspections**, the agency plans to inspect more than 23,000 facilities per year in the coming years, either by an FDA inspector or by a state inspector under contract to FDA. At that rate, all high risk facilities will be inspected within the first 3 years (about 7400 per year), and all non-high risk within the first 7 years.⁴ Although FSMA requires inspection of domestic high risk facilities within 5 years following enactment, FDA has determined it can inspect all high risk facilities within the first 3 years.

For **foreign** inspections, FDA has increased its coverage to 1000 foreign food facilities in FY 2011 and 1200 foreign inspections in FY 2012. The agency does not expect to go significantly beyond that level in the foreseeable future. Reaching the goal of 19,200 foreign inspections called for by FSMA would require hundreds of millions of dollars in new funding, which the agency cannot realistically expect to receive. Moreover, the agency believes that any additional funding it receives for imported food safety would be better spent over the next few years implementing the FSMA tool kit for imports, which will leverage both FDA and private sector resources more effectively to ensure the safety of foods exported to the U.S. by foreign firms.

For example, as discussed more fully in Chapter 5, the Foreign Supplier Verification Program created by FSMA will be the foundation of a new system under which importers will take greater responsibility for ensuring that foreign manufacturers produce food in compliance with U.S. safety requirements. Another import-related program, the Voluntary Qualified Importer

⁴ An additional 8,000+ animal feed facilities will be inspected annually in the coming years.

Program, will make it easier for participants in the program to import items into the U.S., based on demonstrated high-performance on food safety, and enable FDA to better focus its resources on potentially higher risk imports. FSMA also directs FDA to establish an accredited third party inspection program, under which third party auditors can assure importers and FDA that foreign producers are using effective preventive controls.

In addition, the agency will expand its collaboration with foreign governments to use their inspection information to gain knowledge about the safety of foreign exports that will allow FDA to focus its own resources more efficiently. One way the agency can ensure a foreign government's information is reliable is through a formal assessment of the foreign food safety system to determine if it offers a comparable level of public health protection. FDA has already⁵ begun to engage in such comparability assessments. Finally, FDA will also engage in capacity building to help foreign governments and facilities meet FDA standards. The establishment of foreign offices, staffed by FDA experts, will help facilitate both information sharing and capacity building.

As discussed in Chapter 5, this multi-faceted tool kit sharpens private sector accountability for import safety, leverages private sector resources, and takes advantage of what foreign governments can do to elevate assurances that food coming into the United States meets FSMA's new prevention-oriented standards. FDA is committed to implementing its new import mandate in a comprehensive and balanced way. Foreign inspections are an important part of the tool kit, because they provide direct accountability for inspected firms, incentives for all foreign firms to comply with U.S. requirements, and critical intelligence for FDA concerning foreign food safety practices. In coming years, FDA will be better targeting its foreign inspections to increase their food safety impact and increasing their number as resources permit.

Facility Registration

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) required domestic and foreign facilities that manufacture, process, pack or hold food for consumption in the U.S. to register with the FDA by December 12, 2003. While the registration system has been important in helping to provide FDA with information on the origin and distribution of imported food, it has been limited, in that before FSMA, facilities were only required to register once with the agency. Even though food facilities are required to update required registration information in a timely manner, FDA does not have up-to-date information on facilities, including facilities that may have moved or changed names, and some facilities have registered more than once. Thus, there are varying estimates of the "inventory" of firms to be inspected:

- The number of facilities registered under the current registration system is 167,000 domestic firms, and 254,000 foreign facilities, for a total of 421,000 locations that would be subject to inspection.

⁵ An agreement was recently signed with New Zealand under which the two countries recognize each other's food safety systems as "comparable," thus facilitating trade in food between them.

- Because of the inaccuracies in the current registration system, FDA has accessed private data sources (Dun and Bradstreet) for estimating the number of facilities, and those data suggest that about 106,000 domestic facilities and 130,000 foreign facilities are subject to inspection, for a total of 236,000 facilities. In addition, approximately 17,950 domestic and 4340 foreign animal food facilities have been identified.

Because FSMA requires food facilities to renew their registration with FDA every other year, and thereby facilities will review and confirm their registration information with FDA on a regular basis, the agency should have more up-to-date and accurate food facility information, including the number of total facilities subject to inspection. Under FSMA, the first renewal of registration was October-December 2012, which FDA extended to January 31, 2013. Further, section 102 of FSMA provided FDA with additional authority to strengthen the food facility registration system. Under the new law, FDA is authorized to require food facilities to provide more detailed information about the types of food products manufactured, processed, packed or held at the facility. FDA is engaged in dialogue with the food industry and other stakeholders on how to implement this system.

Reportable Food Registry

The Reportable Food Registry (RFR), which Congress mandated in the Food and Drug Administration Amendments Act of 2007, is an electronic system through which industry must, and public health officials may, submit reports to FDA regarding reportable food (an article of human or animal food for which there is reasonable probability that use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals). Reportable food does not include dietary supplements or infant formula. The RFR helps FDA better protect public health by tracking patterns and targeting inspections, and has provided FDA with valuable, real time information on product deficiencies. The majority of these events result in, or are related to, Class 1 recalls. FDA and the National Institutes of Health have created a Safety Reporting Portal – an online reporting format – that allows reporting for the RFR as well as other product safety reports (such as animal drugs).

One of the limitations of the RFR has been that information regarding reportable foods from the RFR may not get directly to consumer. FSMA attempts to address this issue by allowing FDA to require responsible parties to submit consumer-oriented information regarding a reportable food to FDA. When this provision is fully implemented, one-page summary information will be prepared and published on the web by FDA and for use by grocery stores.

E. FUTURE NEEDS FOR A MODERNIZED INSPECTION AND COMPLIANCE PROGRAM

Implementing the modernized inspection and compliance program needed to implement FSMA and achieve its public health goals requires a range of investments in training, capacity, and infrastructure. This will include:

- A more data-driven, risk-based prioritization system for inspection and compliance activities that enables FDA to better focus its inspection and compliance resources on facilities and foods that are most likely to pose a threat to health.
- Enhanced, interoperable internal/external data systems that capture data on, among other things, the risks of specific pathogens in specific foods; data for inspections conducted by other regulatory partners and by private, third-party organizations; and the compliance history of food facilities subject to inspection.
- Training for FDA and state inspectors in preventive controls and the new systems and prevention-oriented approach to inspections and compliance. FSMA calls for a transformation in FDA's food safety oversight role, which will succeed only if FDA is able to adequately train its frontline workforce.
- Stronger and more timely technical support for inspectors from FDA's food safety experts to enhance the scientific quality of inspection and compliance decisions, which requires expanding expert capacity at FDA headquarters and in the field.
- New information technology tools for inspectors, such as handheld inspection recording devices and "intelligent questionnaires" to shorten and promote consistency in the conduct of food facility inspections and inspection report writing. Less time expended on report writing, in particular, may permit more timely reporting of adverse findings to compliance officers, resulting in speedier administrative and regulatory actions, when warranted. And implementing described strategies to make more efficient use of resources.

CHAPTER 4 - FEDERAL – STATE INTEGRATION

A. BACKGROUND

While FDA has the broadest food safety jurisdiction within the Federal government, covering about 80% of the food supply and most food imports, a successful nationwide food safety program will not be possible without harnessing and leveraging the efforts of state, local, territorial and tribal regulatory and public health partners, who already play key roles in food safety and are willing to work with Federal agencies to plan and implement a public health-focused, integrated national food safety system. The result will be a more unified and efficient system for protecting the domestic food supply via leveraging of inspectional and laboratory resources to reduce duplication, better information sharing and coordination, increased capacity and capability at the state, local, tribal and territorial level, greater inspectional coverage with a primary focus on preventing illnesses, and improved rapid response when foodborne disease outbreaks or food contamination events occur.

B. PATH TO AN INTEGRATED NATIONAL FOOD SAFETY SYSTEM

FDA has been working with its state and local partners for over a decade to develop an Integrated National Food Safety System (IFSS). FSMA included several provisions aimed at carrying forward this partnership and effort:

- Section 201 authorizes FDA to rely on certain inspections conducted by state and local agencies in meeting FSMA’s inspection frequency mandate, which is a central part of FDA’s strategy for making optimal use of public resources to improve food safety.
- Section 202 directs FDA to include state laboratories in FSMA’s new lab accreditation program and to continue building, in partnership with the states. It also directs FDA (in coordination with other agencies) to report on progress in implementing a national Food Emergency Response Network that coordinates the state the capacity of state and local laboratories to be integrated with federal laboratories to respond to food-related emergencies.
- Section 205(c) directs FDA to leverage and enhance the food safety and defense capacities of the states to improve outbreak response and investigation, build state inspection capacity and coordination with FDA, and better share information among federal and state agencies.
- Section 209 directs FDA to administer programs to improve the training of state and local food safety officials. It also authorizes and encourages FDA to partner with state and local officials on inspections and other efforts to ensure compliance with the food safety requirements under the Federal Food, Drug, and Cosmetic Act.

- Section 210 authorizes FDA to make grants to the states and local governments to support their capacity to improve food safety and partner with FDA.

Toward this end, FDA and its state and local partners are working to develop:

- 1) National standards for state food and feed regulatory programs, which establish a uniform foundation and requirements for Federal, state, local, tribal and territorial food and feed programs.

Historically, an obstacle to creating an IFSS has been widely varying approaches of food safety programs among Federal and state agencies. The solution will be implementation of national food and feed regulatory program standards that provide clear, consistent minimum foundational requirements for a high quality regulatory program. The critical elements of regulatory program standards, which have been or are being developed collaboratively by FDA and its state and local partners, include: the regulatory foundation, training, inspection, quality assurance, response to food-related illness and outbreaks, compliance and enforcement, and laboratory resources among others. 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. Implementation of these regulatory program standards will ensure uniformity of inspectional coverage and allow partner regulatory agencies to rely on each other's data to protect public health. FSMA provides FDA with the authority to rely on inspections completed by partner agencies to meet the inspection mandate established by FSMA. In turn, there will be more and better information about the state of the food supply chain, and improved reactions when problems occur.

Current regulatory program standards include the Manufactured Food Regulatory Program standards for regulatory agencies that inspect food processors, Voluntary National Retail Food Regulatory Program standards for regulatory agencies that inspect supermarkets and other retailers, and under development are the Animal Feed Regulatory Program Standards for animal food.

Uniformity and consistency among laboratories that support the regulatory programs are other important components of IFSS. Laboratory accreditation and the support of laboratories seeking to obtain and maintain accreditation is essential to the acceptance of state laboratory results to support recalls and other enforcement actions. It will be necessary to develop uniform data standards for the exchange of data among Federal and state laboratories, which will greatly enhance the collective ability to identify food safety threats, react quickly with accurate information, and provide advice on necessary corrective actions. The Partnership for Food Protection's Laboratory Work Group has developed a manual that is a resource aimed to assist laboratories with meeting the expectations of food regulatory agencies with respect to the acceptance of analytical data. Key pieces of the manual include information on accreditation, sampling, methods, analytical worksheet packages, proficiency testing, and reporting.

National standards for the compilation and sharing of regulatory data among state and Federal agencies are critical needs for partner agencies. This includes the ability to share inspectional findings, processor registration information, recall updates, distribution of contaminated foods, and similar important signal intelligence that can help identify risks and make the most of the resources applied to protect the food supply. FDA, working with its regulatory and public health partners, will develop IT solutions to allow all appropriate parties to access data rapidly and electronically, as permitted under statutory and regulatory restrictions on sharing non-public information.

2) Uniform, national training and certification programs.

A common concern echoed by food manufacturers and members of Congress has been the observation that regulatory activities, especially inspections and data collection, appear at times to differ among the many agencies at the state and Federal level. Thus, the need for consistent training and certification is evident, and FDA intends to make that a focus of its national integrated food safety system strategy.

Already, FDA's Office of Regulatory Affairs has developed classroom and web-based training for state and local retail food inspectors, and in 2009 over 2,000 state and local participants attended classroom training and over 11,000 enrolled in online training. That work is being expanded and enhanced by a joint effort with the International Food Protection Training Institute (created by the Kellogg Foundation, with additional specific funding from Congress provided for one year). A goal will be a nationwide set of baseline training and certification requirements for regulatory and public health partners at varying stages of their career and specialization; followed by the creation of a network of food safety training programs, provided through Centers of Excellence among academic institutions, states and professional associations.

Training will be broad and cover all aspects of an integrated food safety oversight system – scientific expertise, best practices in conducting inspections, administrative processes and procedures, appropriate sampling and laboratory analysis methodology, and effective development of enforcement actions that will withstand legal challenges.

As training expands, certification and proficiency testing programs will also need to expand, to ensure that state and local regulators can adequately demonstrate that they can perform the necessary core competencies. An accreditation approach will also be devised to ensure the quality of the training and that it is comparable and competent among all training providers.

3) An integrated, coordinated national emergency preparedness and response network.

While the primary goal of an integrated system is to prevent foodborne disease in the first place, no prevention program can be 100% effective. A recognized need of the current food safety infrastructure is to have all Federal, state and local agencies working closely together to stop the exposures to contaminated foods, identify the root cause of the contamination, and develop appropriate preventive controls to minimize the risk of recurrence of an outbreak, thus minimizing deaths, illnesses and their associated costs to the public and the food industry.

FDA has already begun to establish several new mechanisms for more rapid and effective emergency response. Nineteen states have received funding from FDA to create Rapid Response Teams to coordinate outbreak response with FDA, CDC and USDA. The Rapid Response Teams cooperative agreements provide funding to support the development of improved standard operating procedures, improved interagency communication, training in the concepts and implementation of Incident Command Systems, development of interactive data sharing platforms, transparent posting of findings from investigations and analytical findings, and increased interagency collaboration and leveraging across disciplines and jurisdictions in food safety. This includes regulatory, health, laboratory, law enforcement, and emergency management partners among all levels of government (federal, state, and local), associations and other national initiatives.

There will be regular training and joint exercises to build strong working relationships and common procedures, and concomitantly the development of uniform data sharing across all jurisdictions.

4) Performance standards, oversight and accountability.

Coordinating the development of a national integrated food safety system -- involving scores of state, local and Federal agencies and organizations -- will require a substantial level of support and oversight. Knowing how well it is working and ensuring constant improvement will be absolutely necessary. Thus, FDA will provide an internal structure to audit and verify performance against program standards – to assist partners in assessing progress and to determine areas of strengths and weaknesses. This will include audits of state and local inspections to ensure adherence to national standards; sample collection and analysis procedures; enforcement procedures; and laboratory quality control. Moreover, a remediation program will be needed for states or local agencies that do not meet program standards.

A complementary effort will be the development of a national food safety “workplan,” that will allow all partners in this endeavor to use a uniform risk-based approach which will ensure coverage of the highest risks and reduce any unnecessary duplication by sharing information. By developing uniform standards for inspections and sharing information, the new system will establish mutual reliance that effectively leverages both Federal and state resources, increases efficiency, and avoids duplicate inspections and other redundancies.

5) Capacity Building

FSMA required FDA to assess current capabilities and develop capacity of partner agencies to carry out food safety and defense activities, including staffing levels, laboratory capacity, and information systems. In partnership with state and local representatives, FDA has been developing initial strategies to develop capacity. However, additional data is needed to determine what future strategies will be developed to address capacity of partner agencies. A review of current Federal, State, local, and trade association surveys was conducted by a workgroup under FDA’s FSMA Federal-State Integration team. The current surveys did not fulfill the needs outlined in FSMA, specifically in the areas of information technology,

laboratory, food safety, and food defense. The workgroup has developed a survey that will enable FDA to determine what gaps exist in State and local capacities. The survey has been developed and is undergoing appropriate clearances, with a target for distribution in 2013. Once the responses have been received and analyzed, the information will be used to further develop and improve strategies and procedures, called for under FSMA section 205(c)(1), which directs FDA to implement strategies to “leverage and enhance” state and local food safety capacity for purposes of improving foodborne illness outbreak response, accelerating foodborne illness surveillance, carrying out inspections and enforcement, improving effectiveness of partnerships to coordinate food safety and defense resources, and sharing information among partner agencies in a more timely manner.

C. WHAT IS NEEDED TO ACCOMPLISH AN INTEGRATED NATIONAL FOOD SAFETY SYSTEM?

While FDA has made developing and implementing an integrated national food safety system a high priority, achieving FSMA’s vision of a well-coordinated and integrated national food safety system will require additional investment in FDA’s capacity to support and oversee such a system.

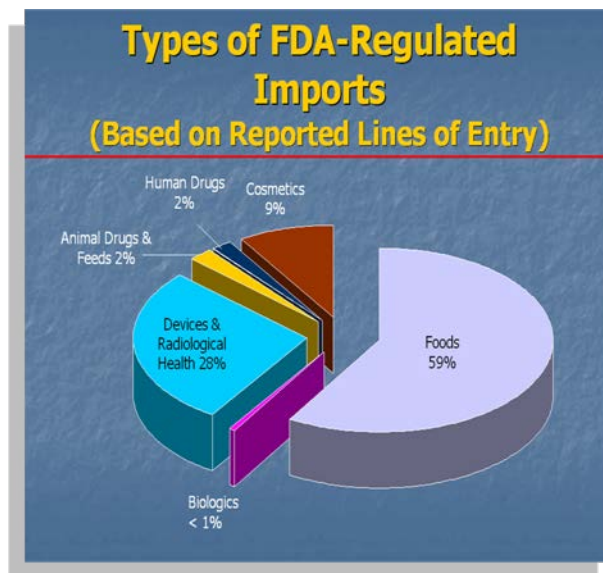
More significantly, funding will be necessary to assist many of the state, local, territorial and tribal programs in developing their own infrastructure and meeting the national food safety program standards referred to earlier in this chapter. A central and significant element of this investment will be in the training of state and local inspectors to meet national standards and inspect effectively within FSMA’s new preventive controls framework.

Finally, to enhance performance by FDA and its state and local partners, investment is needed in interoperable data sharing networks, backed up by clarified authority and improved procedures for sharing sensitive data among government food safety partners.

CHAPTER 5 - IMPORTS

A. BACKGROUND

We live in a nation that increasingly relies on other countries to produce the food we consume. 15% of all food consumed by U.S. households each year is imported from abroad. This food comes from approximately 130,000 manufacturers in more than 150 countries. For some food categories, more food is imported than produced domestically. For example, 50% of fresh fruits, 20% of fresh vegetables and 80% of seafood consumed by Americans are produced outside of the U.S. A plethora of ordinary food ingredients – such as wheat gluten, citric and ascorbic acid, soy and rice protein, carrageenan, gum acacia and more – are primarily sourced from overseas, often from developing nations. Foods make up the largest share of FDA-regulated imported product categories, accounting for 59% of reported lines of entry (see Exhibit 1).



B. THE EFFECTS OF GLOBALIZATION

Food imports have grown by an average of nearly 10% annually from 2002-2009 (see Exhibit 2). Along with the dramatic increase in food imports, the nature of food imports has also changed over time. Traditionally, the bulk of food imports consisted of unprocessed food ingredients, where subsequent processing of those ingredients took place in FDA-regulated domestic facilities. Today, finished, ready-to-eat food products and fresh produce account for an

increasing proportion of all imported food products. These finished products are also following ever-more complex paths through multi-step supply chains with increasing numbers of processing steps and entities to reach the United States. Canned tuna provides a stark illustration of this (see Exhibit 3). This increased complexity of production has resulted in a greater proportion of higher-risk products. Between 2000 and 2007, between 70% and 85% of import refusals of produce and seafood -- the two largest categories of food imports -- were for potentially dangerous violations including the presence of pathogens, chemical contamination, and "other sanitary violations."

Increasing pressures to reduce costs and augment food production are also encouraging shifts in manufacturing and production to lower cost countries with often less developed regulatory systems for overseeing food manufacturing. This disparity is likely to continue in the future. China and India, for example, are each expected to experience 9% annual growth in food exports between 2010 and 2020.

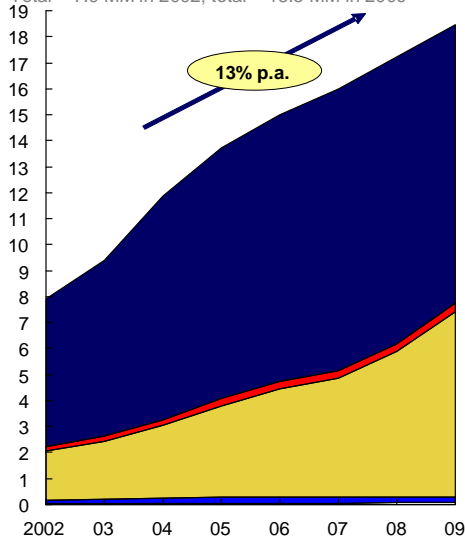
The sheer growth of imported products and foreign facilities supplying the United States has created enormous challenges for the FDA in identifying foreign food facilities and protecting the food supply. Shifts in global production have intensified these challenges, as countries such as Mexico and China that account for high percentages of food imports, account for even higher percentages of import refusals. At the same time, increased fragmentation of supply chains and a growing complexity of products have made it ever-more difficult for FDA to identify the source of contamination or to prevent and detect intentional efforts by some importers to manipulate the system and avoid scrutiny. And as highly-publicized incidents such as melamine-tainted pet food have shown, globalization has created the conditions for greater incentives and opportunities for economically-motivated adulteration and intentional fraud.

Exhibit 2

Import shipments of FDA-regulated products have been growing at 13 percent per year

Imported lines¹ (millions)

Total = 7.9 MM in 2002; total = 18.5 MM in 2009



**Combined Annual Growth Rate (CAGR)
2002-09 Explanation of center's products**

Product Category	CAGR	Explanation
Foods	9.5%	<ul style="list-style-type: none"> Articles for cleansing, beautifying, promoting attractiveness of body Food products for human, animal, pet use, except meat and poultry
Drugs	12.9%	<ul style="list-style-type: none"> Prescription and OTC drugs for human
Devices	20.8%	<ul style="list-style-type: none"> Medical devices for human use Products that emit radiation (e.g., microwaves, lasers, x-ray machines)
Veterinary products	6.7%	<ul style="list-style-type: none"> Drugs, devices, and food additives for animals and pets
Biologics	15.8%	<ul style="list-style-type: none"> Blood products, vaccines, and tissues for transplantation



¹ An import line represents the portion of a shipment listed as a separate item on an entry document. The number of units can vary
Source: FDA

Over the past decade FDA has embarked on a significant conceptual shift in the way it addresses import safety – a shift toward a system that emphasizes prevention of food safety hazards at the source of production and where the border is seen as the final checkpoint to ensure the safety of imported food, rather than the primary line of defense. These efforts are also focused on moving to a more comprehensive, risk-targeted approach. Following are examples of programs and practices that FDA has put into action to respond to the challenges of globalization.

PREDICT: The Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) uses risk-based data and analytics to help inform entry admissibility decisions, rather than just relying on border examinations. Launched in 2007, the program works by “scoring” food entries on the basis of a wide range of risk factors, including inherent risks of the product (such as inherent health risks or risk of the product being the target of economic adulteration), facility inspections and compliance history, data anomalies, admissibility history, and intelligence pertaining to the manufacturer, foreign locale, or product. Lower-risk lines receive automated “may proceed” release, while those with higher risk scores are flagged for further review. FDA is complemented in this effort by collaboration with the DHS Commercial Targeting Analysis Center, which gives FDA access to Customs and Border Protection targeting systems that attempt to identify imports that might be problematic from a national security standpoint.

Establishment of Foreign Posts: Since 2007, FDA has established and staffed thirteen posts in strategic locations around the globe, including China, India, Latin America, Europe, the Middle

East, and Sub-Saharan Africa. An expanded overseas presence has allowed FDA to improve its collaborative working relationships with its counterpart agencies and to learn more about their procedures and capacities, and to better enable FDA to help other nations build their capacity to better protect food made in their countries. FDA's presence in these regions has also allowed for greater engagement with foreign governments and industry, including helping to ensure that they understand more fully FDA's requirements regarding FDA-regulated products. Finally, having investigators overseas also allows the agency to more readily perform inspections of foreign facilities, especially emergency inspections and inspections of high-risk facilities, and gives FDA the opportunity to conduct joint inspections with other countries.

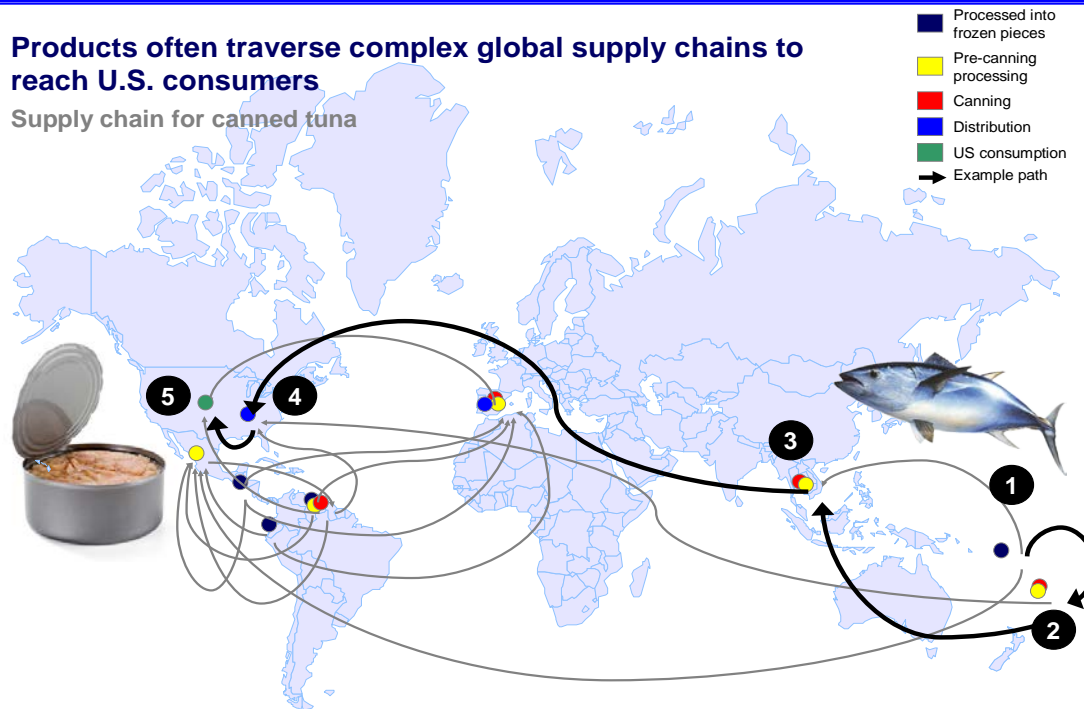
Bilateral and Multilateral Workplans and Standards: Efforts to develop bilateral and multilateral workplans and standards have been immensely helpful in building positive working relationships with a number of different countries and have given FDA valuable insight into the challenges that others have been facing. For example, FDA has had a longstanding involvement with the Codex Alimentarius Commission, a United Nations intergovernmental organization that develops food safety and quality standards to protect the health of consumers and to ensure fair practices in food trading. FDA is committed to international harmonization of food safety standards through Codex Alimentarius and other channels as fully as possible, in keeping with U.S. food safety mandates and FDA's public health mission.

Global Outreach and Capacity Building: Because a substantial portion of the U.S. food supply is imported, FDA conducts outreach to build the capacity of its trading partners to improve the safety of imported food. FDA seeks to raise global awareness about non-intentional and intentional contamination of the food supply and build relationships with counterparts in foreign governments, the private sector and academia. FDA provides training, outreach and capacity building in areas such as preventive controls, U.S. regulatory requirements, risk assessment, laboratory capacity, among others; and for food defense, vulnerability assessments, mitigation strategies, response and recovery, and ensuring food safety and defense at international events.

Analytical Tools Initiative: FDA is exploring new or previously unused rapid analytical tools for use in field investigations or in the laboratory – that will be particularly useful for screening of imports. For example, FDA is currently training staff on the use of a portable X-ray Fluorescence (XRF) device capable of detecting toxic elements – especially lead, cadmium, mercury, arsenic, and selenium -- in imported foods, including dietary supplements.

Products often traverse complex global supply chains to reach U.S. consumers

Supply chain for canned tuna



Source: <http://www.ilo.org/public/english/dialogue/sector/techmeet/tmfce07/tmfce-r.pdf>

D. NEW AUTHORITIES

Until FSMA's enactment, FDA's ability to realize a needed paradigm shift in the import arena has been significantly hindered by its limited and outdated regulatory authorities. FSMA addressed many of these limitations by providing the agency with significant new authority to better ensure that imported food products meet U.S. standards and are safe for U.S. consumers. These authorities are based on FSMA's overall prevention strategy and on leveraging the primary responsibility and capacity of the private sector to ensure the safety of food, whether sourced domestically or overseas. They include:

- **Foreign Supplier Verification:** For the first time, importers will have a clearly defined responsibility and accountability for the safety of the food they import. Importers will need to provide adequate assurance that imported foods have been produced under appropriate risk-based controls that provide the same level of public health protection as those required of our domestic food industry.

- **Accredited Third Party Certification:** FSMA establishes a program through which accredited third parties can certify that foreign food firms or facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports. Under FSMA, foreign governments, foreign cooperatives, and other third parties, including private parties, are eligible to be considered for accreditation as third-party auditors.
- **Certification for High Risk Foods:** FSMA provides FDA with the discretionary authority to require that, based on risk, certain imported foods be accompanied by a credible and accredited third party certification or other assurance of compliance as a condition of entry into the U.S. The certification or assurance can be obtained by an accredited third party auditor or a representative of the government of the exporting country, designated by FDA.
- **Voluntary Qualified Importer Program:** FSMA directs FDA to establish a voluntary program to expedite entry into the U.S. of food from eligible, qualified importers. To be eligible, an importer must offer food for importation from a facility that has a certification by an accredited third party. This program will provide incentives for importers to take added safety measures.
- **Authority to Deny Entry:** FDA may refuse entry into the U.S. of food from a foreign facility if FDA (or other individuals duly designated by FDA) is denied access by the facility or the country in which the facility is located.

FSMA also directs FDA to do more inspections in foreign countries to verify compliance with U.S. standards.⁶ And FSMA requires FDA to develop a plan for international capacity building and collaboration for food regulation that will include, as appropriate, recommendations for bilateral and multilateral arrangements and agreements, provisions for secure electronic data sharing, provisions for mutual recognition of inspection reports, training of foreign governments and food producers on U.S. food safety requirements, recommendations on whether and how to harmonize requirements under the Codex Alimentarius, and provisions for multilateral acceptance of lab methods and testing and detection techniques.

E. ADDRESSING FUTURE CHALLENGES

The manufacturers and producers that FDA regulates will continue to face intense pressures to lower costs and improve productivity, fueling a cycle in which the quest for efficiency leads to increased production abroad and higher volumes of imported products to regulate. Goods entering the U.S. will come from new and different markets, flowing through long-multi-step processes. The shift in global product flows will make it increasingly difficult to identify the source of a product and to ensure that all players along the supply chain meet their safety and quality responsibilities. And increasingly, the agency will need to contend with ever more sophisticated threats of fraud and product adulteration.

⁶ The new law required FDA to inspect not fewer than 600 foreign facilities in 2011, and calls for a doubling of the number of facilities inspected each year for the subsequent 5 years.

Implementing the new authorities and mandates provided by FSMA will be key to enabling the agency to start to address these challenges, and meeting them will extend well beyond the development of regulations and guidances. Enforcement will be complicated and resource-intensive. Investments will be needed for recruiting and training a cadre of staff to audit the Foreign Supplier Verification Program, to oversee the Voluntary Qualified Importer Program and the third party accreditation process, and to develop the information systems that will support effective risk-based decision making.

Anticipating the need for an extended effort to reposition the agency in a truly global world, FDA issued a report on the Pathway to Global Product Safety and Quality in 2011. This report, which relates to all FDA-regulated products, recognizes that ensuring import safety will involve sustained efforts on the part of the agency in four areas:

- 1) Partnering with foreign counterparts to form global coalitions of regulators: Bilateral and multilateral efforts have been instrumental in improving our food safety system, but ultimately, strong collaboration and coordination among nations is required to meet the demands of a regulatory environment in which product safety and quality knows no borders. In order to realize this effort, FDA needs to make faster progress in capacity building and developing cooperative relationships with foreign counterparts. Strengthening the regulatory capacity of other countries will be a major focus of FDA's international efforts. An example under way is a public-private partnership (i.e., the Global Food Safety Partnership) that the World Bank recently launched to enhance the capacity of food safety systems from farm to fork focusing on developing and middle income countries.
- 2) Building a global data-information system: A global data information system and network needs to be developed that can allow regulators worldwide to regularly and proactively share real-time information and resources. FDA must work with coalition partners to identify critical data elements needed to inform risk models and standardize the reporting of this information to allow for the seamless and automated flow of data. Internally, it should work to make necessary changes and build new capabilities.
- 3) Becoming an intelligence gathering and data-driven organization: With current resource levels and an ever-growing roster of product manufacturers to monitor, FDA will need to expand its capabilities in intelligence gathering and use, with an increased focus on data-driven risk analytics and thoroughly modernized IT capabilities. To enhance its analytics capabilities, FDA must work to provide advanced training to current analytics experts as well as bring in new employees with significant analytical talent and experience. To build the necessary support infrastructure, FDA must create or identify IT tools that will allow experts to quickly access and analyze data across the various information resources available.
- 4) Leveraging public and private sector third parties and more effectively allocating FDA resources: FDA will simply not have the resources or staff to keep pace with rising imports through its efforts alone, and thus must make major improvements in its ability to allocate its resources based on risk and to leverage the combined efforts of government, industry and public- and private-sector 3rd parties. FSMA directs FDA to establish the Foreign Supplier Verification

Program and an accredited third party inspection program, and these will harness private efforts to help ensure foreign producers are using effective preventive controls. In addition, the agency will expand its collaboration with foreign governments to rely, where appropriate, on their inspection information about the safety of products exported to the U.S., which will allow FDA to focus its own resources more efficiently. To make such information most useful, FDA must expand its investment in systems recognition arrangements with foreign governments, under which FDA does a formal assessment of the foreign food safety system to determine if it offers a comparable level of public health protection to that of the U.S. food safety system. If successful, these and other collaborative efforts will result in a global food safety system that is both efficiently protective of consumers and facilitates the trade of safe food, providing consumers in the U.S. and ultimately worldwide with a wide array of safe and economical food choices.

CHAPTER 6 - SURVEILLANCE AND RESPONSE

A. BACKGROUND

Food can become contaminated at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. No system of prevention will be perfect. Thus, having an effective surveillance system in place helps to ensure that potential threats to the food supply are identified quickly so that harm to the public health can be prevented as much as possible and economic disruption of the food supply minimized. Once problems are identified, FDA works with other agencies at the Federal and state levels, as appropriate, to respond. This chapter examines current surveillance and response mechanisms and discusses how they will be improved as part of FSMA implementation.

Presently, FDA conducts surveillance of the food supply by performing inspections at domestic and foreign food facilities that manufacture, process, pack, hold and/or distribute foods; collecting and analyzing samples of food ingredients, finished food products and/or environmental samples; and through the review of entry documents and the physical examination and/or sampling of food products offered for import into the United States. In addition, FDA works with other Federal and state agencies to identify foodborne illness outbreaks and other food-related contamination events or hazards.

When contamination problems or outbreaks are identified, FDA generally works not only with other Federal and state agencies but also with law enforcement agencies, intelligence-gathering agencies and industry to respond. In the case of foodborne outbreaks, response activities may include performing traceback activities; conducting investigations, including environmental assessments and root cause analyses, at various points along the food supply chain; and sampling and analytical testing. The aforementioned routine surveillance and response activities have resulted in a greater awareness of potential vulnerabilities, the creation of more effective surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness and contamination incidents. However, factors such as changing industry practices and the rising volume of imports continue to pose significant challenges for FDA in monitoring the food supply and ensuring that contaminated products are quickly identified and removed from the market, as necessary

B. SURVEILLANCE

Identification of hazards and potential threats to the food supply can occur in a number of ways including through two types of surveillance: 1) surveillance of the food supply; and 2) surveillance of foodborne illness.

Surveillance of the Food Supply

Inspections, sample analyses, and review of documentation and/or the physical examination of imported foods are all ways that FDA works to monitor the food supply.

Inspections: FDA inspects regulated food facilities, and performs field examinations or inspections of imported products offered for entry into the U.S that may or may not result in sample collections. For fiscal year 2012, FDA, and states under contract with FDA to conduct inspections on FDA's behalf inspected over 23,000 domestic food facilities. In addition, FDA inspected over 1200 foreign food facilities. These inspections were carried out, as mentioned, by states under contract and by staff working in FDA's 5 Regional Offices, 20 District Offices, 13 Laboratories, more than 150 Resident Posts and Border Stations, and 13 foreign posts. FDA provides funding to states through contracts, grants and cooperative agreements. This funding is used, in part, to reimburse states that conduct food facility inspections on behalf of FDA and to assist states establish the infrastructure needed to meet voluntary food safety standards and respond efficiently and effectively to food contamination events. FDA also provides technical assistance to the states in such areas as milk, food, and shellfish safety.

Sample Analyses: Random and targeted surveillance product sampling can be helpful in determining the hazards associated with a specific food or food component as well as for understanding how widespread a particular problem might be in the food supply. FDA conducts surveillance sampling – random and targeted for both domestic and imported foods. In addition, FDA conducts for cause sampling to support administrative and judicial regulatory actions relative to both domestic and imported foods/food facilities.

Targeting of Import Examinations: FDA has implemented nationally its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system, a screening engine used by FDA's import entry reviewers in the field to gain information, including risk scores and the rationale for elevated risk scores, associated with line entries of imported food products. PREDICT assists FDA, in part, to target its physical examinations on those shipments that pose the greatest risk, while streamlining the release of lower risk products (see Ch. 5).

The Use of Sample Analyses in Addressing Melamine Contamination

As part of FDA's Food Defense Surveillance Assignment, the agency proactively reviewed protein sources being imported into the U.S. in response to the investigations of the pet deaths in the U.S. that were associated with the consumption of pet food contaminated with melamine, cyanuric acid, ammelide, and ammeline. The same protein sources being used for pet foods could also be used as protein sources for human food. The purpose of this effort was to ensure that the contamination found in pet food was not a more widespread problem in the food and feed system. Throughout the duration of the project, more than 200 inspections were made throughout the country at various points in the supply chain including importers, warehouses, and manufacturers, and more than 220 samples were analyzed by eight Food Emergency Response Network (FERN) laboratories.

In addition to the approaches described above for monitoring the food supply, FDA cooperates with other Federal and state agencies to monitor the safety of food through a system of coordinated laboratory networks and web-based reporting systems:

Safety Reporting Portal (SRP): In May 2010, FDA and the National Institutes of Health launched the SRP for reporting various product safety issues, including problems related to food. More specifically, there is a requirement that those who manufacture, process or hold food for consumption in the U.S. report to FDA, within 24 hours, when they determine that there is a reasonable probability that an article of food under their control could cause severe health problems or death to a person or animal – a requirement known as the Reportable Food Registry. The SRP provides industry with a mechanism to easily meet this reporting requirement and provides FDA a tool to quickly learn about trends and respond, when necessary, to food safety problems. The SRP provides a system that can be used to support similar required reporting for other FDA regulated products.

National Antimicrobial Resistance Monitoring System (NARMS): NARMS is a national program jointly operated by FDA, CDC and USDA that is designed to monitor antimicrobial resistance against foodborne bacteria in humans, retail meat, and animals. Isolates are collected from samples of raw retail meats, food animals, and human clinical cases nationwide, and strain types are entered into the CDC PulseNet database. For example, in 2011, NARMS was instrumental in implicating ground turkey as a likely source of infection ultimately leading to a specific factory where the meat was processed, following a CDC announcement of a multistate outbreak investigation of human *Salmonella* Heidelberg infections. Thus, several agencies were able to work together rapidly and effectively to limit the effects of a life-threatening food contamination event.

Electronic Laboratory Exchange Network (eLEXNET): eLEXNET is a secure web-based application that allows for the storage and sharing of food testing information from Federal, state and local labs through a searchable database. Currently, eLEXNET has more than 250 registered labs, more than 1,800 users, and the database contains over 500,000 sample data submissions. eLEXNET is funded by the FDA with support from USDA and DHS. eLEXNET provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess scope and risks and to analyze trends. FDA monitors the food sample results in eLEXNET on a daily basis for anomalies and also uses this system to identify patterns or potential trends of contamination that may help determine food surveillance policies.

Surveillance of Foodborne Illness

The CDC conducts foodborne illness surveillance through disease monitoring and epidemiological investigations. Central to this effort is FoodNet, the Foodborne Diseases Active Surveillance Network, a sentinel surveillance system that collects information from sites in 10 states about diseases that are caused by any of seven bacteria and two parasites commonly transmitted through food. Investigators seek out laboratory confirmed cases of illness in an attempt to detect every person in the 10 sites who went to a doctor's office, had a sample tested, and was diagnosed with one of these infections. These data are used to conduct analyses and epidemiologic studies designed to help public health officials better understand the

epidemiology, incidence, and trends of foodborne diseases in the US. FoodNet is a collaborative program among CDC, USDA, FDA, and health departments in Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, California, Colorado, and New York.

Most foodborne outbreaks are identified and investigated by local and state health departments. CDC provides consultation on select cases, as well as assistance for outbreaks that are particularly large, unusual, or severe. CDC also collects reports of foodborne outbreaks due to enteric bacterial, viral, parasitic, and chemical agents. State, local and territorial public health agencies report these outbreaks through the National Outbreak Reporting System. CDC conducts analyses of these data to improve understanding of the human health impact of outbreaks and the pathogens, foods, and contributing factors involved in these outbreaks.

In recent years, detection of large, multi-state outbreaks has become increasingly common. This is due, in part, to improvements in surveillance, especially PulseNet (see below) that have allowed for identification of outbreaks that would previously have been missed, but is also the result of an increasingly centralized and inter-connected food supply that allows for a food contaminated in production to be rapidly distributed for consumption. During a multi-state foodborne illness outbreak, CDC serves as lead coordinator between public health partners to detect the outbreak, define its size and extent, and to identify the food causing illness.

FSMA further enhances CDC's role in foodborne disease surveillance by directing that agency "to improve the collection, analysis, reporting and usefulness of data on foodborne illness. . ." CDC will do that by a number of means described in FSMA, including strengthening Federal/state/local coordination of surveillance systems, improving epidemiological tools, and allowing greater public access to surveillance data.

A significant tool in illness surveillance is PulseNet, the national molecular subtyping network for foodborne disease surveillance coordinated by CDC and the Association of Public Health Laboratories. The network consists of: state health departments, local health departments, and Federal agencies (CDC, USDA/FSIS, FDA). PulseNet participants perform standardized molecular subtyping (or "fingerprinting") of foodborne disease-causing bacteria, which can be used to distinguish strains of organisms such as Shiga toxin-producing *Escherichia coli* (STEC), including O157:H7, *Salmonella*, or *Listeria* at the DNA level. DNA "fingerprints" are submitted electronically to a database at the CDC. These databases are available on-demand to participants, allowing for rapid identification and comparison of emergent patterns.

C. OUTBREAK RESPONSE

When a potential multi-state outbreak has been detected, CDC's Outbreak Response Team collaborates with a national network of epidemiologists and other public health officials to ensure rapid, coordinated detection and response to the outbreak. PulseNet laboratories strengthen detection capabilities by conducting ongoing surveillance to identify new cases, conducting advanced laboratory testing of disease-causing microbes, testing suspect foods, and providing other technical support to the Outbreak Response Team as part of the investigation. During recent years, CDC investigations of foodborne outbreaks have identified more than 15

new, previously unrecognized food items associated with human illness due to pathogens such as STEC, Salmonella, and Listeria. This data has helped identify additional high risk foods for evaluation. Once a contaminated food source has been identified, public health action to control the outbreak can be taken by FDA and other regulatory agencies. At this stage, CDC continues to investigate potential sources of illness and monitors for additional illnesses to determine when the outbreak is over and when public health interventions have been effective. CDC also advises the public about what they can do to protect themselves, advises the medical community about how to treat the infections, and works closely with the regulatory agencies and industry to learn how to prevent similar outbreaks in the future.

Product Tracing

A key component to responding to a foodborne illness outbreak is to identify the source of the outbreak and subsequently remove contaminated food from the marketplace; identification of the source, at times, can be accomplished through product tracing. A *traceback investigation* may be initiated to identify the source of contamination. Starting at a common point where ill individuals purchased or consumed contaminated food, FDA works with industry and state and local agencies to conduct traceback and environmental investigations that typically examine each point throughout the supply chain in an attempt to determine where the contamination likely occurred. This may involve examinations of facilities, ingredients, finished products, packaging, and food handling practices (such as how long food is held prior to shipment, what specific processing steps were completed, and whether finished products or ingredients are shared or exchanged with other facilities). If a source or sources is identified, FDA initiates a *trace forward operation* to determine the distribution of all contaminated or potentially contaminated food from an implicated farm, processing facility, or importer. Quick action is often necessary to identify all of the food that needs to be removed from the market to prevent additional illnesses. However, current industry tracing systems are not standardized and many are not available in an electronic format; and it is often not possible to trace a contamination back to a source.

Response Networks

FDA operates a number of networks that play critical roles in responding to foodborne illness outbreaks:

Emergency Operations Network: The FDA Emergency Operations Network Incident Management System captures incidents regarding FDA regulated products that may be responsible for causing injury or illness. When an emergency response to an incident is required, the system also captures the large volume of information the response may generate, including early investigational activities and analytical findings. The system also generates Geographic Information System (GIS) maps related to emergency response activities and creates a historical record of response related information.

Coordinated Outbreak Response and Evaluation (CORE) Network: FDA enhanced its role in outbreak response and prevention in September 2011, with the launch of the CORE Network. Staffed, in part, by experts in epidemiology, consumer complaints, statistics, and veterinary medicine, CORE's principal function is to streamline FDA decision-making during foodborne

outbreak/food contamination event responses, ensure seamless coordination and enhanced communication within FDA and with other Federal-state agencies, and assure FDA becomes ever more efficient and effective in food safety related response activities. In addition, CORE has staff dedicated to performing surveillance, data mining, and monitoring data in internal and external surveillance systems. Information gleaned through such surveillance is used to identify long and short term trends and sudden elevations in human illness, for example, which may signal a potential emerging problem.

Lastly, CORE has staff dedicated to handling post outbreak/contamination response activities, including: conducting hot washes to assess what went well during a response and where there are opportunities for improvement; determining the need for an environmental assessment or root cause analysis; if root causes have been identified relative to an outbreak/contamination event, facilitating the development and implementation of preventive food safety strategies; and to driving enhanced surveillance of a segment of the industry, when warranted.

FERN: The Food Emergency Response Network (FERN) is an integrated, secure laboratory system for Federal, State, and local government agencies engaged in food safety and defense activities. Consisting of 172 Federal, state and local laboratories, FERN plays a critical role in food safety and defense by integrating these food-testing laboratories into a network that is able to detect, identify, respond to, and aid in the recovery from emergencies involving biological, chemical, or radiological contamination of food. FERN's strength lies in allowing participating government agencies to compare, share and coordinate laboratory analytical findings. It also strengthens the capacity of State and local laboratories, facilitating the ability of these laboratories to serve as first responders during food emergencies. FERN interacts with other lab networks through the Integrated Consortium of Laboratory Networks, which aims to improve coordination of laboratory response to incidents and to identify gaps in laboratory preparedness and response. FERN is jointly operated by FDA and FSIS.

D. ADDRESSING FUTURE CHALLENGES

Substantial progress has been made in recent years at the Federal, state, and local levels in food-related surveillance and outbreak response. Scientific knowledge about pathogens in food has been improved greatly and government health agencies work much more collaboratively together than in the past to resolve problems quickly. Nevertheless, many improvements remain to be made, and implementation of the authorities provided by FSMA will help achieve such needed improvements directed or envisioned by FSMA including:

- Better data on the specific food-pathogen combinations responsible for outbreaks of foodborne illness, known as attribution data, are needed to better link regulatory activities with public health outcomes. This requires staff at the state and local levels to identify clusters of illness faster, conduct case interviews and obtain food exposure information quickly, and collect samples of implicated products for laboratory testing. Epidemiologists and risk assessors are needed at the Federal level to compile and analyze information to improve FDA's ability to attribute illnesses to specific food-pathogen combinations.

- The further integration of data systems in outbreak investigations, including epidemiology, laboratory, environmental, and traceback data is improved; but real time data sharing among food safety agencies at the Federal, state, and local levels must be further enhanced. Current pilot projects, underway at CDC, FDA and in states, should be expanded if successful.
- Targeted data on the prevalence of pathogens in FDA-regulated foods is needed to provide baseline data against which future data can be compared to measure improved food safety performance and the effectiveness of regulatory interventions.
- Expanded use of in-depth environmental assessments and root cause investigations can create a feedback loop through which this information can be used to inform prevention activities. This is beginning to occur through the newly-formed CORE Network but on a very limited basis with current resources.
- Enhanced product tracing of food in the supply chain is needed by both industry and government to remove contaminated products from the marketplace more quickly and reduce the impact of outbreaks of foodborne illness. Under FSMA, FDA has established and completed pilot studies in coordination with the food industry to explore methods to rapidly and effectively trace foods in the supply chain to prevent or mitigate foodborne illness and will be working with industry and conducting rulemaking to improve traceability. Goals for the future include fewer paper records, standardized electronic data elements that rapidly link shipments of implicated product in the supply chain, and new technology to analyze and visually display data to find the common source in a traceback. FSMA also directs FDA to propose regulations to establish recordkeeping requirements for high risk foods to help in tracing products.
- Tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods, are needed, that allow for rapid, on-site analysis of a particular sample. Rapid contamination detection technology could be expanded to cover new agents and new food types, and could reduce analysis times from days to hours (or even minutes), allowing for an enhanced emergency response capability. In addition, integrated automated laboratory management systems would improve information and data flow.

CHAPTER 7 – SCIENCE INFRASTRUCTURE

A. BACKGROUND

FSMA mandates a new approach to FDA’s current food safety system, emphasizing prevention and risk-based priority setting and resource allocation to address the challenges of the twenty-first century. However, resources have not increased in proportion to the additional demands and responsibilities placed on the agency and the scientific challenges continue to magnify: rapidly changing technologies and new scientific breakthroughs; emergence of new foodborne pathogens as well as familiar pathogens in foods not traditionally associated with illness; increasingly global and complex food production environments and processes; as well as an increase in the percentage of the U.S. population who are most at risk for foodborne illness. It is imperative that FDA ensures a strong science infrastructure, clearly identifying its public health research priorities while allocating its resources accordingly, and collaborates with other public health and research agencies in federal and state governments, as well as academia, and private industry. Two principal categories of infrastructure development within FDA must be strengthened if FSMA’s challenge to address those gaps is to be met:

B. NEW RISK ASSESSMENT TOOLS AND IMPROVED LABORATORY METHODS

Current food safety evaluation and testing methods, computational science capabilities, and data availability hamper FDA’s ability to quickly respond to, and remove, contaminants in the food supply. If resources are provided to improve these capabilities, FDA will invest in a wide range of research and laboratory investigations with concrete goals, such as:

- Faster screening and confirmatory methods to detect microbial and chemical contaminants in food,
- Portable, on-site hazard detection tools for inspectors, that will greatly reduce the time it takes to locate and isolate the causes of outbreaks,
- Mobile Testing Platforms to provide on-site analysis for inspectors in emergency situations,
- New technologies for assessing toxicity of newly identified or unknown chemical and microbiological contaminants,
- Improved capability to identify and assess biological threats that may result from deliberate contamination,

- The capacity to make rapid assessments of risk from a given contaminant on a given food (e.g., baseline data on contamination in lettuce in different regions and seasons),
- Improved capability to assess the health implications of new food technologies, such as nanotechnology and genetically engineered foods,
- Improved capability to find new and unexpected contaminants in food (e.g., melamine in infant formula).

C. INFORMATION TECHNOLOGY

“The FDA cannot fulfill its mission because its information technology (IT) infrastructure is inadequate” – FDA Science and Mission at Risk: Report of the Science Board (2009).

As the above statement of FDA’s advisory committee of outside experts notes, the agency’s IT infrastructure is not commensurate with the agency’s current responsibilities, and the enactment of FSMA imposes new challenges that will create yet more gaps between capacity and need. For example, inadequate computational science capabilities presently limit the ability of FDA to identify current and emerging microbial and chemical hazards. This gap hampers the agency’s ability to quickly identify, respond to, and remove contaminants in the food supply.

The Science Board noted that FDA’s IT problem is largely resource-driven, as the agency has simply not invested in IT upgrades that can give it modern information systems. If resources were provided, however, FDA can be far more efficient and effective, for example, by:

- Creating web-based information systems to allow states and Federal agencies to view and analyze real-time inspection, laboratory, geographic, epidemiologic, and environmental investigation data during outbreak investigations, thus shortening the time it takes to resolve an outbreak and thus reducing illness and economic impacts on industry,
- Integrating FDA’s food-related data bases to improve predictive capabilities and risk management, thus enabling FDA to focus on the greatest risk –more rapidly and more effectively,
- Expanding communications and mobile infrastructure to provide rapid sharing of inspection, laboratory data among FDA investigators, other Federal agencies, and state and local health agencies,
- Implementing dedicated technical support experts and knowledge systems for state and federal inspectors utilizing modern technologies that allow inspectors to immediately record and upload findings and to ask questions of subject matter experts before, during, and after inspections, thus substantially increasing inspector efficiency.

- FDA has contracted with IT experts who are working with agency IT staff to conduct a comprehensive assessment of the food program's IT capabilities and needs, in light of the science board conclusions. That evaluation and proposed remedies will be included in the next required report to Congress.

CHAPTER 8 - FOOD DEFENSE

The term “food defense” can be summarized as the effort to prevent **intentional** contamination of the food supply. The contaminants that could be used in an intentional contamination incident can be biological, chemical, radiological, or even physical, and are not well studied in food. This differs from “traditional” food safety, which is the effort to prevent unintentional contamination of food products by hazards (e.g., *E. coli*, Salmonella, Listeria).

While FSMA is primarily focused on preventing illness from unintentional contamination, it also contains mandates to strengthen food defense – that is, protecting the food supply from terrorism or other intentional contamination. FSMA requires FDA to issue regulations to protect against the intentional adulteration of food. For example, FDA is required to promulgate regulations specifying appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain from intentional adulteration at specific vulnerable points. In addition, FSMA requires FDA to issue regulations regarding hazards related to food, including those hazards that may be intentionally introduced, to establish standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of preventive controls. Further, FSMA requires FDA to establish science-based minimum standards for the safe production and harvesting and those types of fruits and vegetables that are raw agricultural commodities for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death, including from hazards that may be intentionally introduced. Issuance of regulations to protect against intentional contamination will mark a shift from the current system. This shift presents a number of challenges to the agency and its stakeholders. It will begin with public comments to an Advanced Notice of Proposed Rulemaking, which will seek industry and other stakeholder advice on how to best ensure protection from intentional contamination. Such “ANPRs” are an effective mechanism to ensure adequate dialogue before rules are developed and in this case can help FDA determine the proper role and scope of regulatory standards for food defense.

To manage this shift, FSMA directs the development of a National Agriculture and Food Defense Strategy under which FDA, USDA, DHS, EPA, CDC, and state, local and tribal health authorities can work together to protect the food supply from hazards that might be intentionally added to food in the United States. An interagency working group that will develop the Strategy has devised a set of specific priorities for addressing any gaps or weaknesses in food defense, as directed by FSMA -- including research priorities, improved preparedness, detection of intentional hazards, emergency response, and recovery from an intentional agriculture or food-related incident.

Further, in 2003, DHS identified the Food and Agriculture Sector –that is, the complex production, processing, and delivery systems for feeding the population – as a critical infrastructure for national security. At the Federal level, USDA and FDA lead efforts to identify infrastructure vulnerabilities and develop plans to address them.

While defense of some of the Food and Agriculture Sector involves physical protection of food manufacturing, many Sector assets defy traditional physical security practices because they are not “brick and mortar” entities, like buildings, bridges, or dams. Instead, they are open areas (i.e., farms, ranches, or livestock transport areas) and complex systems that span the globe. Sector assets, including processing and distribution facilities and farms, are vulnerable to livestock and crop diseases, food-borne pathogens, pests, or poisonous agents that occur naturally, are unintentionally introduced, or are intentionally delivered by acts of terrorism. Sector partners have acknowledged the importance of early awareness of any threat agent within the Sector’s systems. The Sector can improve its food safety and food defense posture through improved laboratory capacity, better threat surveillance, and enhanced Federal cooperation with State, local, tribal and territorial partners as well as the private sector. The need for an improved food defense infrastructure is extensively documented within the 2011 Sector Critical Infrastructure Protection Annual Report for the Food and Agriculture Sector.

FSMA specifically directs a description in this report on “outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 109, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.” The Critical Infrastructure Partnership Advisory Council Annual Report provides an ongoing description of those outreach activities through Council membership of many of the largest food producers and food trade associations in the US. That report can be accessed at: www.dhs.gov/xlibrary/assets/cipac/cipac-annual-2011.pdf. Of particular note is a DHS project called “CoreSHIELD,” created by the National Center for Food Protection and Defense at the University of Minnesota. CoreSHIELD, which is co-funded by FDA, DHS, USDA and others, provides an IT gateway for communication, collaboration, education and training among all stakeholders responsible for the nation’s food supply, and thus allows food manufacturers, Federal agencies, and state and local agencies to communicate and respond to untoward events in a secure online environment.

CHAPTER 9 - ANIMAL FOOD

The Food, Drug and Cosmetic Act (FD&C) defines “food” as articles used for food or drink for man or other animals. Thus, when Congress amended the FD&C Act with FSMA, the new food safety authorities and responsibilities include animal foods, including pet food and feed for food-producing animals. Animal food (or feed) safety is important both for the animals that consume the food as well as for human food safety. The human food safety issue arises from two main sources: possible exposure to feed-derived contamination of edible products from food producing animals, and exposure to pathogens stemming from direct contact with contaminated pet food or inadequate hygiene practices following handling of pet food products. FDA’s Center for Veterinary Medicine (CVM) implements the provisions related to animal food safety. Accordingly, CVM carries out a number of programs and practices intended to promote the safety and supply chain security of food. While CVM participates in many of FDA’s food safety initiatives, and throughout this report the safety of human and animal food are usually considered one and the same, some activities are specific to veterinary medicine, as described below.

A. SURVEILLANCE AND RESPONSE

CVM tracks and responds to pet food related illnesses using a multi-component system referred to as the Pet Food Early Warning and Surveillance System (PFEWSS). The PFEWSS includes monitoring several electronic systems and FDA’s consumer complaint system. Two of the individual components of the PFEWSS are PETNet and Vet-LIRN. PETNet, the Pet Event Tracking Network, is a secure, web-based network that allows information to be exchanged more freely and efficiently between FDA and other Federal and state regulatory agencies.

PETNet provides for the exchange of information about pet-food related incidents, such as illness associated with the consumption of pet food or pet food product defects. PETNet is only accessible to government employees who are given membership rights, and each member has equal access to the data in the system. Using the shared information, state and Federal agencies can work together to quickly determine what regulatory actions are needed to prevent or quickly limit adverse effects associated with pet food products. PETNet was launched on August 1, 2011. At launch, there were over 150 members representing: 50 states, 4 Federal agencies (FDA, DHS, USDA, CDC), and 3 U.S. territories. The principal purpose of PETNet is to serve as a mechanism to share information quickly in early alert scenarios, a mechanism that is meant to provide similar benefits during feed safety emergencies for food-producing animals. In 2013, CVM intends to work through the Partnership for Food Protection (PFP) to expand the PETNet system to include livestock animals.

The Vet-LIRN, Veterinary Laboratory Investigation and Response Network, coordinates the facilities, equipment and professional expertise of veterinary diagnostic laboratories to respond to high priority chemical and microbial animal food/feed and drug contamination events. This

network, created by CVM, examines data in reportable food registries and other FDA portals to facilitate early detection of animal food adulteration. Such veterinary cases or diagnostic samples are unlikely to be encountered by public health or food testing laboratories.

CVM also plays a key role in the National Antimicrobial Resistance Monitoring System (NARMS), a national program jointly operated by FDA, CDC, and USDA, designed to monitor foodborne bacteria in humans, retail meat, and animals. Laboratory isolates from samples of raw retail meats, food animals, and human clinical cases nationwide are collected, strain types determined and subsequently entered into the CDC PulseNet database for analysis.

B. INSPECTIONS AND COMPLIANCE

The FSMA directive for increased inspection of food manufacturing facilities applies equally to animal food producers, of which there are 17,950 in the United States and 4340 in foreign countries making animal food for consumption in the U.S. FDA inspected almost 6000 domestic facilities in FY2012, and 7 foreign facilities, with the ultimate goal of inspecting all high-risk facilities every 3 years and non-high-risk facilities every 7 years. To assist the animal food industry in being compliant with FSMA, the agency is participating with the animal food industry, academia, and the state and local animal food regulatory officials, through the Animal Food Safety Preventive Controls Alliance, to develop training courses and materials on implementing preventive controls.

C. STANDARD SETTING AND GUIDANCE

This report describes the need for new rules and procedures for preventing foodborne illness through the use of preventive controls in the production of human foods. The Animal Feed Safety System (AFSS) is a program for animal food, created by FDA, aimed at protecting human and animal health by ensuring production and distribution of animal food that is safe. The AFSS covers the entire continuum of agency activities, such as: pre-approving additives for use in animal feed; establishing limits on feed hazards; providing education and training; conducting research; performing inspections, taking enforcement for ensuring the removal of unsafe feed from the marketplace and to ensure compliance with agency regulations; and establishing partnerships with other agencies with responsibility for animal food safety. Furthermore, the AFSS encompasses regulations and guidance pertaining to oversight of animal food production, including manufacturing, labeling, storing, distributing and using all animal food at all stages of production and use, whether at commercial or non-commercial establishments.

Currently, FDA has regulations governing the controls for manufacturing, processing, packing, and holding of drug premixes and medicated feeds. However, a broader regulatory approach is required that addresses animal food safety issues associated with the manufacturing, processing, packing, and holding of animal food, including pet food, food for food-producing animals, and raw materials and ingredients. FSMA modified the FD&C Act by adding section 418, “Hazard Analysis and Risk-Based Preventive Controls.” The section provides FDA with the authority, in

part, to develop regulations for a risk-based, preventive controls food safety system intended to prevent unsafe animal food containing hazards, which may cause illness or injury to animals or humans, from entering into the food supply. As directed by Congress under FSMA, CVM drafted preventive control regulations for animal food which FDA expects to publish for public comment soon. The regulations to be drafted under FSMA will require written food safety plans for facilities that are required to register with FDA under section 415 of the FD&C Act. FDA's proposed regulations will also include Good Manufacturing Practices for animal food. FDA published a notice in the *Federal Register* in May 2011, seeking public comment on preventive control measures in order to help develop guidance for food facilities. CVM also will develop the accompanying guidance documents for the preventive control regulations for animal foods.

CVM also has an active role in the Food Safety Preventive Controls Alliance (FSPCA) that is designed to develop training courses and materials on preventing contamination for both human and animal food during production. The materials to be developed by the alliance will help industry—particularly small- and medium-sized companies-- comply with the new preventive control rules. The alliance is composed of members from the FDA, local and state food protection agencies, the food industry, and academia. CVM will assist the alliance with developing materials to support the preventive control regulations for animal food. The alliance will:

- develop standardized hazard analysis and preventive controls training and distance education modules for food industry and regulatory personnel;
- design and deliver a state-of-the-art distance learning training portal;
- develop “train-the-trainer” materials and student education delivery systems;
- create a technical assistance network for small- and medium-sized food companies;
- develop commodity/industry sector-specific guidelines for preventive controls;
- assess knowledge gaps and research needs for further enhancement of preventive control measures; and
- identify and prioritize the need for, and compile, critical limits for widely used preventive controls.

As described in Chapter 4 of this report, FDA is actively designing an Integrated Food Safety System (IFSS) under which FDA and its state partners will implement a unified Federal-state food safety system. One of the key principles of an IFSS is the uniform application of model programs so that regulatory agencies conduct inspections under the same set of standards. FSMA encourages this principle by supporting enhanced partnerships with state and local government agencies, and the integration of these regulatory programs to support a national food and feed safety system. Presently, there are no recognized uniform standards for state feed regulatory programs. As the United States moves towards integrating food safety resources, uniform standards across feed regulatory programs are needed. In 2011, FDA and the

Association of American Feed Control Officials entered into a joint partnership to develop the Animal Feed Regulatory Program Standards (AFRPS). These standards are designed to integrate the regulatory activities of partner agencies into an efficient and effective process for improving food and feed safety in the United States. The AFRPS will provide a framework that every state can use to determine the strengths and needs of its program. Implementation of these standards will build uniformity and consistency among state feed regulatory programs and further efforts to develop an IFSS. The current draft of the AFRPS is composed of eleven standards that would serve as an objective framework to evaluate and improve components of a state feed program. The AFRPS are currently undergoing review and clearance. CVM also participates in international harmonization and collaboration efforts and is currently serving as the chair of the U.S. Delegation to the ad hoc Intergovernmental Codex Task Force on Animal Feeding, charged with the task of developing guidelines on the application of risk assessments for feed hazards with regard to the safety of food produced from animals.

Codex also charged this Task Force with developing a prioritized list of hazards associated with animal feed. The Task Force determined a better approach would be the development of guidance for nations or regions on how to establish their own prioritized lists of feed hazards. The Task Force therefore changed its charge and is creating a document titled “Guidance for use by governments in prioritizing their national feed hazards.” This Codex Task Force is expected to meet again in February 2013; CVM will again serve as the chair of the U.S. delegation.

CHAPTER 10 – RESOURCES

A. BACKGROUND

FSMA directs FDA to provide Congress with an estimate of the resources the agency will need “to effectively implement the programs and practices identified in the report over a 5-year period.” Prior to the enactment of FSMA and the resultant significant expansion of FDA’s regulatory responsibilities in food safety, Congressional and expert reports noted the disparity existing between FDA’s vast responsibilities for protecting America’s food supply and the available resources. With a headquarters staff of about 900 and a field staff of 2,600 comprised of inspectors and other compliance staff, FDA is expected to oversee:⁷

- 80% of the U.S. food supply, including most food imports⁸;
- a \$1.1 trillion food processing industry;
- over 100,000 domestic food manufacturing facilities and an even larger number of foreign facilities;
- more than 150,000 fresh produce growers; and
- 10 million annual shipments of imported food, with continued increases anticipated.

B. THE RECENT PAST – DECLINING RESOURCES, GROWING DEMAND

For most of FDA’s history, its food program comprised almost half of the agency’s budget, reflecting the vast size of the food industry and the enormous diversity of food products that FDA is charged with regulating. In recent years, however, that percentage has been steadily declining, and today the food program makes up only 23% of FDA’s overall budget, including the increases of \$324 million in appropriations that Congress added in fiscal years 2008, 2009, and 2010. Additional appropriations increases targeted specifically for food safety in FY 2011 and 2012 allowed the food program to near its earlier resource levels.⁹

Thus, while the budget provided increases in recent years, they had the effect of only allowing FDA’s food program to begin a return to staffing levels of earlier years. Meanwhile, various metrics of FDA success in the food safety arena during this time period and prior remained substantially degraded or unimproved, for example:

⁷ An additional 800 headquarters and field staff oversee veterinary drugs and the safety of animal food.

⁸ By contrast, USDA’s Food Safety Inspection Service has a 9,000-person staff to regulate 20% of the U.S. food supply (meat and poultry), and a comparatively low volume of meat products imported into the United States.

⁹ The FY2013 Continuing Resolution also provided FDA with \$40 million in “one-time” funding for food safety, which will help offset the effects of sequestration for that year.

- Import inspection rates were below 2%, meaning that most imported foods entered the United States with no physical inspection at the border;
- Inspection rates of foreign facilities were consistently below 100 per year, a tiny fraction of the facilities making food for the U.S. market;
- Instances of foodborne disease outbreaks had climbed since the 1990s, involving a wide range of commodities, including eggs, peanut butter, spinach, lettuce, cantaloupes, peppers and many other foods; some of these outbreaks were and continue to be caused by pathogens new to science and about which little is known; and
- The economic costs of disease outbreaks to consumers, farmers and food processors continued to soar, with estimates of total annual costs well over \$100 billion per year¹⁰.

Against this background of fluctuating and overstretched resources, FSMA places broad new demands on FDA to build and implement a modern, new food safety system that includes sweeping overhaul of the regulatory framework; new inspection frequency mandates; enhancement of state and local capacity; and the construct of a new import food safety system commensurate with the demands of today's global food system. FSMA cannot be fully implemented in a timely and effective manner without additional resources.

C. MAKING OPTIMAL USE OF CURRENT FDA RESOURCES

In addition to highlighting the need for new resources, FSMA challenges FDA to make optimal use of current resources, including a mandate for FDA to set risk-based priorities for use of its resources. To that end, the agency has started several initiatives that are expected to make better use of existing resources and thus lessen the demand for new funding. While those initiatives may themselves require funding, they hold great promise for increasing FDA efficiency and effectiveness. The initiatives are summarized as follows:

- 1) Data-Driven, Risk-Based Resource Allocation – The foods program is developing new tools that will provide the information needed to focus decisions and resources on areas of greatest risk to health. This includes new tools for ranking risks, prioritizing program activities based on opportunities to reduce risk, and linking risk-based priorities more clearly with budget formulation and execution. This will improve FDA's productivity in all areas, including research and standard setting, inspections, and technical assistance to industry.
- 2) Increased Inspection Efficiency and Productivity – FDA is making changes to improve its inspection efficiency. For example, FDA will enhance targeting of facilities and key systems within facilities based on risk and further streamline the inspection process by

¹⁰ Robert L. Scharff, March, 2010, for the PEW Produce Safety Project at Georgetown University

developing new inspection approaches and providing inspectors improved electronic information tools to increase their productivity.

- 3) Leveraging the Expertise and Resources of Others – One of the concerns raised by Congress is the appearance of duplication of efforts by FDA with other agencies. A focal point for FSMA implementation will be information sharing and coordination with USDA, the National Marine Fisheries Service, the Defense Department, states, foreign governments, and private, third-party certification organizations. FDA will also be working with the food industry on building training programs, and to create a third-party audit system that will allow the private sector to be an active partner with government in assuring food safety.

D. FDA'S RESOURCE NEEDS TO IMPLEMENT THE FDA FOOD SAFETY MODERNIZATION ACT

The Congressional Budget Office (CBO) has concluded that there is a wide gap between FDA's current food safety resources and the level of funding that will be needed to implement FSMA. At the time FSMA was enacted, CBO estimated that FDA would need an additional **\$583 million** over its FY 10 base appropriation by 2015 to implement FSMA, although the CBO estimates did not include investments in FDA's technical capacity and training, Federal-state integration, and building a new import system that harnesses private sector supply chain management capacity and responsibility. CBO also assumed FDA would seek the annual doubling of foreign inspections, which FDA considers cost-prohibitive given reasonably foreseeable resources. Nevertheless, the CBO estimates remain relatively accurate for the long-term investments necessary to implement such a major reform of the U.S. food safety system.

With additional funding already provided by Congress in the FY 11 and FY 12 appropriations of almost \$100 million in budget authority, realistic and effective implementation of FSMA will require an increase of perhaps **\$400 - \$450 million** in FDA's FY 2012 funding base by FY 2017.

More specifically, the FSMA funding gap identified by CBO can be closed over a five-year period (2013-2017), with a \$400 - \$450 million addition to its 2012 base funding for food safety activities. When taking into account funds provided in FY 2013, and new resources, including new user fees proposed in the FY 2014 President's budget, well over half of the additional funds needed for implementing FSMA would be available if Congress accepts the President's FY 2014 request.

With respect to user fees, to help finance the building of an effective food safety program, Congress has shown past interest in enacting a processing facility registration user fee similar to the registration fees paid by pharmaceutical and medical device manufacturers. Another user fee model that some countries use to fund their import inspection activities is an import entry fee, in which importers pay a fee for each food entry, the proceeds of which are dedicated to improving oversight over imported food. FDA has been discussing such fee options with the many food safety stakeholders to determine if any fee options might be practicable and acceptable. FSMA

provided some limited user fees in the food area, but they are not expected to be a substantial source of revenue to build a modern food safety system. The President's FY 2014 budget requests authority to generate user fee revenue for food safety in the amount of \$225 million.

If provided, those new funds would be spent on the following new and expanded activities:

- 1) **Regulations and Guidance** - Set new prevention standards for the production of food that are science- and risk-based and are flexible enough for the diversity of products and production methods found in the food industry; provide technical assistance to food producers in adopting those standards; develop the scientific underpinning for preventive controls to ensure they are science-based and maximally effective.
- 2) **Domestic Inspections** - Improve and expand FDA's inspectional effort, with a focus on re-training FDA inspectors and its state and local public health partners to the new prevention standards.
- 3) **Imports** - Implement the new import food safety system mandated by FSMA, including oversight of the new Foreign Supplier Verification Program, improved border screening with better risk data and assessments of incoming imports, improved foreign government capacity to assure the safety of their food exports, private audits by accredited third party inspectors for foreign manufacturing facilities, and more foreign inspections by FDA inspectors.
- 4) **Science for Food Safety** – Improve the agency's science infrastructure to support all aspects of food safety protection; expand research capacity to better detect contaminants in food; improve scientific knowledge on how food contamination occurs and can be prevented.
- 5) **Integrated Federal-State Food Safety System** - Develop an integrated national food safety system that allows FDA and the states to respond more rapidly to food safety problems, eliminates any unnecessary duplication of regulatory activities by sharing information, and establishes standardized training and regulatory standards to ensure consistent oversight on a level playing field for food producers.
- 6) **Planning and Response** – Expand FDA's outbreak response capacity to identify sources of foodborne disease more rapidly and thus greatly reduce the impact of such outbreaks on public health and on the food distribution chain; increase communications among Federal and state agencies and with the public, so as to rapidly contain outbreaks when they occur.
- 7) **Risk Analysis** - Implement the recommendation of the Institute of Medicine to establish a risk-based resource allocation system so that FDA will have the tools to focus on the greatest risks and the greatest opportunities to reduce risk, and in turn adopt the most effective and efficient interventions (i.e., research, regulation, or education).
- 8) **Information Technology for FSMA Implementation** - Develop a modern Information Technology capacity to best utilize risk analysis techniques, track and analyze domestic

and foreign inspection data, respond to information provided by third-party inspectors, share information with state and foreign counterparts, and manage an effective resource allocation process.

- 9) **Food Defense** – The Department of Homeland Security notes that every dollar spent through FSMA to speed the rapid recognition, recall and protection of the public health from contaminated food will also pay dual dividends toward the national security defenses of the United States against the threat of a deliberate food-borne attack with chemical or biological weapons.

E. THE CONSEQUENCES OF NOT HAVING RESOURCES TO IMPLEMENT FSMA

If FDA does not have sufficient resources to modernize and reform food safety, the agency will be unable to meet the expectations of Congress, the food industry and the public to build a modern food safety system that better protects both consumers and the food industry from the health and economic consequences of foodborne illness and other hazards. While specific impacts are difficult to quantify, numerous negative results can reasonably be predicted:

- The United States will not move from the antiquated “chase problems after they occur” system of the past to one based on good science and prevention of problems before they happen;
- The safety of imported food will remain largely unverified, and foreign government capacity and oversight unmonitored, leaving both consumers and food processors in the U.S. vulnerable to the production and protection systems of other countries;
- Outbreaks of foodborne disease, and their associated disruptions to commerce and the food supply chain, will likely continue, along with their estimated 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths; and the estimated \$100 billion plus annual economic toll;
- Traceback of food contamination sources will remain inefficient and slow;
- Improvements in the technology and science for understanding and combating food contamination will go unrealized; and
- State and FDA inspectors will continue to be unable to adopt uniform, consistent regulatory practices.

APPENDIX 1

Background on the FDA Food Safety Modernization Act

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable and that Congress has directed FDA to address through new legislation.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. Some authorities went into effect quickly, such as FDA's new authority to order companies to recall food, and others require FDA to prepare and issue regulations and guidance documents. The funding the agency gets each year, which affects staffing and vital operations, will also affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

The following are among FDA's key new authorities and mandates. Specific implementation dates specified in the law are noted in parentheses:

Prevention

For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

- **Mandatory preventive controls for food facilities:** Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise. (*Final rule due 18 months following enactment*)
- **Mandatory produce safety standards:** FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as composted manure), hygiene, packaging, temperature

controls, animals in the growing area and water. *(Proposed regulation due 1 year following enactment; final regulation due 1 year following close of comment period on proposed regulation)*

- **Safe Food Transport:** FSMA added a timeline to regulations Congress had directed the agency to issue, in the 2005 Sanitary Food Transportation Act (SFTA), to establish sanitary transportation practices for all persons engaged in the transport of food.
- **Prevention of intentional contamination:** FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. *(Final rule due 18 months following enactment)*

Inspection and Compliance

FSMA recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge. FSMA provides FDA with important new tools for inspection and compliance, including:

- **Mandated inspection frequency:** FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.
- **Records access:** FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- **Testing by accredited laboratories:** FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that U.S. food testing laboratories meet high-quality standards. *(Establishment of accreditation program due 2 years after enactment)*
- **Expanded administrative detention:** The FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).
- **Suspension of food facility registration:** FDA can suspend the registration of a food facility if the agency determines that the food manufactured, processed, packed, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals and other criteria are met. A facility that is subject to suspension order is prohibited from introducing or offering to introduce food into commerce. *(Effective 6 months after enactment)*

Response

The FSMA recognizes that FDA must have the tools to respond effectively when problems emerge despite preventive controls. New authorities include:

- **Enhanced product tracing abilities:** FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. *(Implementation of pilots due 9 months after enactment)*
- **Improved Illness Surveillance:** FSMA directs that surveillance of foodborne illness be strengthened through the Centers for Disease Control and Prevention and to include enhanced data collection, analysis and reporting; and improved coordination between Federal agencies and state and local health officials.
- **Additional Recordkeeping for High Risk Foods:** FDA is directed to issue proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods. *(Implementation due 2 years after enactment)*.
- **Mandatory recall:** FSMA provides FDA with authority to order a mandatory recall in certain circumstances when a company fails to cease distribution and voluntarily recall certain food after being provided with an opportunity to do so by FDA.

Imports

FSMA gives FDA significant new authority to better ensure that imported products meet U.S. standards and are safe for U.S. consumers. New authorities include:

- **Importer accountability:** For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe. *(Final regulation and guidance due 1 year following enactment)*
- **Accredited Third Party Certification:** The FSMA establishes a program through which accredited third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports. *(Establishment of a system for FDA to recognize accreditation bodies is due 2 years after enactment)*
- **Certification for high risk foods:** FDA has the authority to require that high-risk imported foods be accompanied by a third party certification or other assurance of compliance as a condition of entry into the U.S.
- **Voluntary qualified importer program:** FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities. *(Establishment due 18 months after enactment)*
- **Authority to deny entry:** FDA can refuse entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

Enhanced Partnerships

FSMA builds a formal system of collaboration with other government agencies, both domestic and foreign. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals. The following are examples of enhanced collaboration:

- **State and local capacity building:** FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies. FSMA provides FDA with a new multi-year grant mechanism to facilitate investment in State capacity to more efficiently achieve national food safety goals.
- **Foreign capacity building:** The law directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. food safety requirements.
- **Reliance on inspections by other agencies:** FDA is explicitly authorized to rely on inspections of other Federal, State and local agencies to meet its increased inspection mandate for domestic facilities. FSMA also allows FDA to enter into interagency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

Additional partnerships are required to develop and implement a national agriculture and food defense strategy, to establish an integrated consortium of laboratory networks, and to improve foodborne illness surveillance.

APPENDIX 2

Analysis of Foodborne Illness Outbreaks involving Fruits and Vegetables, 2006-2010.

Section 110 of FSMA requires a report on traceback and surveillance for fruits and vegetables, to wit:

"(f) TRACEBACK AND SURVEILLANCE REPORT. -- The Secretary shall include in the report...an analysis of FDA's performance in foodborne illness outbreaks during the 5 year period preceding the date of enactment of this Act involving fruits and vegetables that are raw agricultural commodities (as defined in section 201(r) (21 USC 321(r)) and recommendations for enhanced surveillance, outbreak response, and traceability. Such findings and recommendations shall address communication and coordination with the public, industry, and State and local governments, as such communication and coordination relates to outbreak identification and traceback."

While raw fruits and vegetables continue to be an important part of a healthy diet, the risk of becoming ill as a result of consuming these commodities exists. With no treatment step, such as heat, to reduce the potential pathogen contamination, produce can and does become contaminated resulting in foodborne illness outbreaks. For over a decade, FDA has been involved in efforts to guide industry in ways to minimize the risk of contamination of produce. Foodborne illness outbreaks have continued over the years to be associated with fruits and vegetables that are raw agricultural commodities.

Each year multiple illness events associated with FDA regulated products are reported. FDA along with CDC and state and local health departments, collaborate to compile, track, and summarize data pertaining to outbreaks.

Illness events are reported to FDA by state and local health departments and the CDC. Events are entered into the database if an FDA-regulated product (product in interstate commerce) is implicated in causing human illness. The information presented below (Tables 1 and 2) represent the reported number of outbreaks and illnesses associated with FDA-regulated fruits and vegetables, and do not include illnesses and/or deaths that may have occurred but were not captured by the outbreak reporting process.

Table 1: FDA-Regulated Fruits and Vegetables Associated with Foodborne Illness Outbreaks by Vehicle, 2006 – 2010.

Vehicle	Number of Outbreaks	Number of Cases	Number of Hospitalizations	Number of Deaths
Berries	4	111	6	0
Leafy Greens	10	527	220	5
Melons	4	158	28	1
Tomatoes	7	581	47	0
Jalapeno/Serrano peppers	1	1495	315	9
Cucumber	1	118	0	0
Sprouts	8	496	67	0
Celery	1	10	5	5
Unknown	4	528	82	0
Total	40	4024	770	20

Table 2: FDA-Regulated Fruits and Vegetables Associated with Foodborne Illness Outbreaks by Agent and Vehicle, 2006 – 2010.

Agent	Number of Outbreaks	Vehicle
Bacterial		
<i>E. coli</i> O157:H7 and non- <i>E. coli</i> O157:H7	9	Leafy greens (8) Sprouts (1)
<i>L. monocytogenes</i>	2	Celery (1) Sprouts (1)
<i>Salmonella</i>	27	Melon (3), sprouts (5), tomatoes (6), berries (2); Serrano/jalapeno peppers (1)
Parasitic		
<i>Cyclospora</i>	2	Berries

FDA’s Performance in produce related foodborne illness outbreaks, 2006-2010

FDA’s goal in food surveillance and outbreak response continues to be to protect public health and reduce risk of illness from contaminated food products (*Note:* alternatively, replace latter with “ensure safety of food supply”). During this time period, FDA demonstrated this commitment by rapidly responding to foodborne outbreaks, instituting organizational and process changes to enhance surveillance, response, and prevention efforts, and implementing

intervention strategies to prevent further illnesses, and better communicating with industry, government, and public partners. FDA has a philosophy for continuous improvement, thus, many areas that have been strengthened will continue to be enhanced. In reviewing the last five years of outbreaks, several challenges became evident and need for improvements identified, such as product tracing. Also evident in this review was the affirmation that surveillance and outbreak response and prevention efforts are a shared responsibility and improvements in one area will enhance another partner agency's effectiveness and better protect public health in responding to and preventing foodborne outbreaks.

Surveillance:

The Centers for Disease Control and Prevention (CDC) along with state and local health departments have the primary responsibility for human disease surveillance including foodborne illnesses and outbreaks in the United States. All illnesses and outbreaks begin as a local or state issue and responsibility and the majority are confined to the local or state level. Local agencies and states investigate foodborne outbreaks, take appropriate actions and submit reports to the CDC. .

From a food surveillance perspective, FDA has continued to submit pulsed-field gel electrophoresis (PFGE) patterns of disease causing bacteria isolated from foods into the PulseNet database. These genetic fingerprints can then be compared to the PFGE pattern of bacteria isolated from human clinical samples to determine if there's a potential link, thereby accelerating detection of a potential outbreak.

Previously, FDA would be notified by CDC when the epidemiological and laboratory investigation was complete and clearly implicated a specific FDA regulated product. Over the past several years, FDA engagement has occurred much earlier when discussions between CDC and states are underway on the potential suspect foods. In January of 2010, CDC and FDA began joint weekly conference calls to discuss emerging illness clusters with the potential to be associated with FDA regulated products – produce was often a topic of these calls. This earlier engagement enables FDA to get ahead of the curve and also support CDC and the states by providing seasonality, historical sampling data, and food practices/production information for foods that may be suspect to help narrow the focus of the epidemiologic investigation. Interventions by FDA are primarily enabled when the investigation narrows the foods suspected of causing illness to a single food or ingredient. To increase communication and coordination between FDA and CDC, FDA has had a full time employee physically located in CDC's Outbreak Response and Prevention Branch in Atlanta since approximately 2003. This enables rapid and constant communication on outbreak investigations and collaborative sharing of information which is key to both the epidemiologic investigation conducted by CDC, state, and local public health officials and the product investigation led by FDA and state and local food regulatory authorities.

In the last several years, foodborne outbreaks, particularly those associated with produce, have taken on a slightly different picture than previously. The ability to detect illness clusters sooner than previously capable has resulted in less food exposure data to apply in tracing produce in the supply chain. While this is an advance for public health, it makes it more difficult to determine the food or ingredient causing illness using traditional epidemiologic methods. It also has an adverse impact on product tracing. Ironically, requests by CDC and state public health officials to conduct a traceback to inform the epidemiologic investigation has increased in this new paradigm, while these types of outbreaks are often characterized as having few, if any, exposures of high value to traceback. New tools and epidemiologic approaches are needed to determine the food or ingredient causing illnesses. This is particularly pertinent for produce related outbreaks, given their short shelf life and the challenges of multiple produce items suspect in a single menu items (e.g. tacos and/or sandwiches all with lettuce and tomato as ingredients).

To begin to address this trend and the challenges associated, FDA in cooperation with CDC, hosted a workshop in early 2011 entitled, “Outbreak Challenges and Future Approaches.” Representatives from several states both public health and food regulatory agencies attended along with USDA FSIS, and CDC. Topics that were explored along with potential solutions included, but were not limited to, product tracing, environmental assessments, supply chain characterization, and economic supply and demand considerations.

Response and Product Tracing:

Nationally Integrated Food Safety System

Response to foodborne illness outbreaks involves state, local, and tribal partners as well as other federal agencies. Typically, state and local public health officials initiate the response early in the investigation to gather information on food exposures, product shipments, and handling and storage practices at retail to aid in determining the food involved. Between 2006 and 2010, there were significant advances in coordinating and managing FDA’s response to produce related foodborne outbreaks. This is evident in the increased level of training of FDA field and headquarters staff and management in the principles of the national incident management system and also implementing these principles in a response effort.

Another important advance in achieving a nationally integrated food safety system is the establishment of 19 state Rapid Response Teams (RRTs) which respond to large, multistate foodborne outbreaks and other emergencies with FDA field offices. States and FDA staff train together and respond as a coordinated unit. These teams were initiated in 2009/2010 through FDA cooperative grants with state food regulatory agencies. In concert with state RRTs, which are focused on the prompt removal of contaminated products from commerce and the

investigation of how and where the product became contaminated from where the food was served, to the food manufacturing facility, and back to the farm or origin.

In 2009, CDC established a pilot program called FoodCORE, with grants to 7 state/local public health agencies. FoodCORE sites focus upon improving the surveillance and epidemiologic investigation of foodborne outbreaks to identify the specific food vehicle faster. Innovative approaches such as using students from nearby public health schools. Both RRT and FoodCORE grants have enhanced surveillance and response to outbreaks and not only promote but require a greater degree of collaboration and communication between epidemiologists, food regulatory officials, and laboratorians. This is a critical aspect to improving outbreak investigation. Communication and collaboration among these three disciplines is key to solving the outbreak puzzle, and also vital in making better risk informed decisions, and preventing further illness.

Interventions

In examining FDA response to produce related outbreaks, it's also apparent that public health interventions were instituted quickly by FDA, when applicable. Because of the inherent delays in reporting foodborne illnesses, coupled with the short shelf life of most produce, contaminated produce may no longer be in commerce when the specific food item is implicated. Given this, a recall and or consumer warning will not likely result in greater public health protection. However, in most produce related outbreaks where the contaminated food or ingredient was identified and the implicated food was still in commerce, FDA implemented several intervention strategies. These interventions ranged from working with a firm to remove the product from the market and announce the recall, detaining suspect product at the U.S. border, increasing food sampling surveillance, to leveraging state authorities to immediately detain product. Often FDA issued a consumer warning in addition to a food firm's recall announcement to ensure a wider distribution of the warning to consumers. Also evident in the evolution of FDA's intervention strategies is in the early engagement of industry as well as transparency to the public about the investigation even when not all the facts are known and information continues to evolve. A few examples of this include *Salmonella* Saintpaul in 2008, *E. coli* O157 in X, and XX. In spring of 2008, FDA attended a workshop sponsored by USDA to foster communications among industry, consumer groups, and state, local, and federal agencies during foodborne outbreaks. Based on that workshop, FDA instituted a practice of engaging industry earlier in an outbreak to better prepare the industry and also benefit from the commodity and supply chain knowledge of the industry in the investigation.

Challenges:

Outbreak investigations are not without their challenges. There are many areas where improvements continue to be needed even where gains have been accomplished. Coordination and communication among state, local, tribal and federal officials continues to be an area to

strengthen. One critical aspect of this is information sharing. FDA is limited by statute in its ability to share certain types of information even with our state and local partners. Some mechanisms exist to share certain types of information with states, however, many states have not taken this opportunity or maintained agreements current. Recognizing this gap, FDA's Office of Partnerships in 2011 have focused outreach efforts with states to establish agreements that allow for information sharing of commercial confidential information. While expanding the number of states with these types of information sharing agreements will facilitate outbreak investigations, legislative changes to our ability to share critical information during an emergency may be necessary.

Product Tracing

Significant challenges exist in tracing produce and other foods in an outbreak. There are several reasons for this including drastic cuts in state and local budgets limiting resources and inconsistent adoption of voluntary industry led programs, but most importantly is the lack of a uniform supply chain system for tracing that is comprised of uniform data elements and a means to link products as they move through the supply chain. A traceback is typically needed to pinpoint the common source where contamination likely originated. Delays in determining the common source result in further illnesses and adverse economic impacts.

FDA cannot be in the position of requiring or approving a specific tracing system or systems. The produce industry has appropriately taken a leadership role with instituting several initiatives to improve tracing produce through the supply chain; however, there is inconsistent adoption by industry. It was clear in reviewing the past five years of outbreaks, that product tracing is a critical step in identifying the common source in the supply chain and until that occurs contaminated produce remains in distribution and in consumer's home. FSMA Section 204 mandates that additional record keeping requirements be established for high risk foods. With this new authority to establish regulations, it is FDA's expectation that significant strides will be accomplished in establishing a foundation for a national uniform tracing system and will result in increased speed and accuracy of tracking foods designated as high risk. Along with the new authority in FSMA Sec. 204, many statutory limitations limit FDA's abilities in this area.

Knowledge Management and technology

As industry and government exponentially collect data, there's a significant challenge in managing the information and identifying key information among the background noise. A unique challenge in outbreak situations, especially involving produce due its complex distribution system and short shelf life, is the rapid barrage of information received by FDA in a fairly short time span and the need to have appropriate systems in place to analyze the information. The need to better manage information, especially in outbreak settings, is not only important to help improve the overall management of the outbreak but also to facilitate information sharing with state and federal partners, and for streamlining and conducting more

rapid tracing of produce items. Currently, FDA is exploring a platform with greater analytic and data sharing potential, Palantir Technologies. However, improvements in this technology will require additional resources, especially for state and local agencies.

Priority Setting and Risk Based Resource Allocation:

Clusters of illness and foodborne outbreaks are being detected more frequently than ever before. With this comes the need to prioritize resources. In reviewing the last five years of produce related outbreaks, it was apparent that FDA needed to assess its resource allocation depending on the size, scope, and severity of the outbreaks ongoing at any one time. For example, during the shell egg outbreak in 2010, FDA activated its Emergency Operations Center and established an incident management group in headquarters and also teams in the field. At the same time, an outbreak of Salmonella with six individuals ill was being investigated by two states; the outbreak was linked to blueberries shipped interstate. FDA resources were stretched in extending support to our state partners as many FDA resources were devoted to the *Salmonella Enteritidis* outbreak linked to shell eggs. In examining some of these challenges, FDA established the CORE Network in 2011 which is intended to streamline some of the organizational structure and process issues and institute more consistent procedures for outbreak investigations including those that are produce associated. Additionally, FDA is currently implementing a more systematic priority setting process for the FDA Foods and Veterinary Medicine program based on public health risks and other factors. This process is also intended to align resources with public health risks and tie public health outcomes to strategic planning.

Communication:

Communication has been covered in section XX of this report but to touch on this with respect to the analysis of the last five years of FDA's performance in surveillance, response, and product tracing of produce related foodborne outbreaks, one area strikingly improved is the coordination with press releases with the CDC. In examining the communication in 2006 and a few outbreaks in 2008 and 2010, the consistency and timing of messaging has greatly improved. This is critical for consumers to have confidence in the federal government's ability to provide consistent, science based messages to consumers.

Prevention - Learning from outbreaks

As FSMA focuses FDA on prevention efforts, outbreaks represent valuable learning opportunities to identify contributing factors, put in place additional prevention based measures, and thus decrease the probability of similar outbreaks. There are two major types of learning from outbreaks – those that are more technical in nature and those that are more process oriented. Both affect FDA's ability to limit and prevent illnesses in a foodborne outbreak including those that are linked to produce.

With respect to process improvements, FDA has held lesson learned activities for major produce associated outbreaks ranging from hot washes to formal after action reporting. Some of the knowledge gained was in areas of communication, coordination, decision making, and process improvements. To the degree resources and organizational structure permitted, FDA instituted changes to reflect the lessons learned over the last five years.

From a more technical perspective, FDA has strived for capturing the practices and conditions that lead to product contamination through investigational observations, reports, and sampling. In most produce related outbreak where a food has been implicated and a common source identified in the supply chain, the contamination likely occurred at production or packing and contamination may have been further spread by various means such as equipment and water uses. FDA has consistently conducted investigations at production and packing facilities both domestically and internationally. These investigations are resource intense and require training not typical of FDA routine inspection processes for this time period. FDA designed a produce farm investigation training course to better prepare FDA and state investigators. However, there was limited number of courses offered between 2006 and 2009. In 2012, FDA increased the number of these course offerings. Building FDA capacity in this area will increase FDA's ability to identify and capture practices and conditions that led to the contamination and resulting product associated outbreak. Additionally, FDA is currently expanding the intensity and depth of these types of environmental investigations to increase FDA understanding of the probable cause(s) of the contamination, the role of the environment, and long term strategies for prevention.

Even with well-trained investigators and adequate resources, major barriers exist in capturing the contributing factors of a contamination event. There is a time lag from when the contamination of the food occurs to when someone becomes ill, to detecting the outbreak itself. Once the outbreak is detected then the epidemiologic investigation by local, state, and CDC ensues to determine the food or ingredient causing illness (Is it the salad or the steak? If it's the salad, is it the lettuce, tomatoes, or cheese?). This may take weeks or sometimes months. After the food or ingredient is identified, FDA working with state and local partners traces the food to reach the point in the supply chain where the contamination likely occurred. This also takes time. Reductions in time delays are possible in some or all of these areas, particularly in product tracing. However, enhanced surveillance and new approaches in epidemiologic investigations to identify the food is the first critical step.

With all of these challenges, FDA has been successful in gathering information on contributing factors that likely led to the contamination of the produce. Examples include the 2006 *E. coli* O157 outbreak linked to bagged spinach, 200 *E. coli* O145 outbreak linked to bagged lettuce, 200 S. Litchfield outbreak linked to cantaloupe FDA shared its finding with industry to facilitate changes in practices by industry that may minimize opportunities for contamination. Consistent with the approach to gain knowledge of factors contributing to contamination of produce and to focus efforts based on risk, FDA launched two special initiatives for produce items consistently

associated with outbreaks – leafy greens and tomatoes (www.fda.gov/Food/FoodSafety). The knowledge gained from outbreak investigations and the proactive initiatives contributed to the development of policy and regulations to improve produce safety.

In the last few years, FDA has focused efforts on enhancing outbreak investigation at food firms to better capture the practices and conditions that led to contamination and also to more systematically and consistently conduct these types of investigation. This is an ongoing process and continues to be under development. A significant accomplishment, and recognition of the need for this, is the establishment of a Post-Response Team in FDA CORE that is responsible for systematically capturing and communicating lessons learned from produce and other FDA-regulated products associated with foodborne illness outbreaks. The extent this CORE team is able to accomplish this aspect of their mission is dependent on several factors including resources; however, the first step to success is having a dedicated team for this effort currently advancing FDA and our stakeholders' knowledge that contributes to preventive food safety policies and practices.

Summary

An analysis of the five years preceding enactment of FSMA identified areas where FDA's performance has greatly improved. These include, but are not limited to: surveillance with earlier engagement in detecting outbreaks, communications on outbreaks early on, coordination of public messaging with CDC, process improvements by streamlining and enhancing efficiencies in outbreak response using incident management structures, and learning from outbreaks during this time period to design and launch FDA's CORE Network in 2011. FDA will continue efforts to improve coordination and communication with all its partners as an essential component of surveillance, product tracing, and the overall response to outbreaks.

A few critical areas remain central to improving FDA's performance, namely, data collection to support and inform risk priority setting, information and knowledge management, product tracing, technologic applications, and risk informed decision making. Areas where FDA's ability to impact changes but improvement will increase public health protection in outbreaks include exploring new epidemiologic tools to identify the food involved in an outbreak that enables FDA to take action and more consistent collection by states and local public health authorities of outbreak data for product tracing.

State, local, and federal agencies continued dialogue and efforts through the Partnership for Food Protection, Rapid Response Teams, FoodCORE sites, and CDC's Center for Excellence for a more nationally integrated food safety system will improve surveillance, response, and product tracing in produce related foodborne outbreaks. As FDA improves tracking and tracing procedures for high risk foods, a solid foundation will be laid for establishing a uniform system for tracing produce through the food supply chain.

Recommendations:

FSMA directs the consideration of recommendations for improving traceback and surveillance for fruits and vegetables. The following ideas might be considered for future development.

Surveillance

- Increase baseline knowledge of the prevalence and level of contamination and practices contributing to contamination of produce. Focus resources on produce items with increased risk.
- CDC and states, in cooperation with FDA, explore epidemiologic, sampling, and environmental methods to enhance identification and speed to identify the food causing illness.
- Promote adoption and implementation of CIFOR Guidelines, including performance measures, by state and local public health and food regulatory agencies.
- FDA obtain funding and resources to support technological advances for food surveillance to detect emerging trends. Collaborate with state, local, and federal government and industry partners.

Response:

- Promote adoption and implementation of CIFOR Guidelines, including performance measures, by state and local public health and food regulatory agencies.
- Continue support for a nationally integrated food safety system including the outbreak response workgroup of the Partnership for Food Protection.
- Obtain funding and resources to enhance FDA's knowledge management capabilities and risk informed decision making; improve information sharing through technology advancements.
- Increase the speed that FDA conducts product tracing through technology advancements.
- Continue support and expand the number of state Rapid Response Teams and FoodCORE sites. Promote mechanisms that integrate epidemiology, environmental, tracing, and laboratory data in outbreak investigations and increase communication and coordination among public health, laboratory, and food regulatory officials.
- Determine if additional or changes in legislative authority is needed to enable information sharing between FDA and state and local public health and regulatory partners.

Product Tracing:

FDA will continue to implement FSMA Section 204 to enhance tracking and tracing of FDA regulated foods and promulgate rulemaking for additional record keeping for high risk foods. However, the limitations in this section of the law hinder FDA's ability to significantly increase

the speed of tracing and the scope of public health protection. In the short term, advances in product tracing may be achieved by the following:

- Increase consistency of data collection by state and local officials for product tracing
- Expand training of FDA and state and local officials in product tracing for regulatory purposes.
- Increase adoption and support by the farm to table supply chain of industry led initiatives to improve product tracing for produce.
- Increase awareness and preparedness of industry on FDA's information needs for product tracing.
- Implement technologic advances to increase speed of product tracing both for receiving and analyzing data.

APPENDIX 3

FSMA directs that this report include a summary of certain seafood safety activity being undertaken by FDA, with:

“Specific efforts taken pursuant to the agreements authorized under section 421(c) of the Federal Food, Drug, and Cosmetic Act (as added by section 201), together with, as necessary, a description of any additional authorities necessary to improve seafood safety.”

FDA had several agreements that were necessary and appropriate to improve seafood safety prior to FSMA’s enactment.

Applicable agreements include:

MOU No.	Purpose	Parties	FDA Lead Center or Office/ Contact	Effective Date	Expiration Date
225-04-4001	Allows FDA to commission Custom and Border Protection Officers.	DHS	ORA Domenic Veneziano (301) 443-6553	12-03-2003	Indefinite
225-09-0008	Agreement regarding inspection programs for fishery products.	DoC	CFSAN William Jones (301) 436-2300	10-09-2009	Indefinite
225-79-4003	Cooperative enforcement of the FD&C Act between USCS and FDA	DHS	ORA Joe McCallion (301) 594-1218	08-14-1979	Indefinite
225-72-2009	Cooperation and information sharing in the inspection of food products and establishments. This MOU supersedes Agreement No. 225-72-	Agriculture	ORA David Glasgow (301) 796-5403	03-04-11	Indefinite

	2009 dated June 25, 1975.				
<u>225-86-2000</u>	Enforcement of laws against illegal harvest, transport, export, import, sale, and purchase of molluscan shellfish.	DoC	CFSAN Donald Kraemer (301) 436-2300	07-24-1986	Indefinite
<u>225-99-2001</u>	To facilitate an exchange of information between FDA and FSIS about establishments and operations that are subject to the jurisdiction of both agencies.	Agriculture	ORA Jeanne Roman (301) 827-0947	02-23-1999	Indefinite

With regard to specific efforts taken pursuant to the agreements:

The Memorandum of Understanding between the U.S. Department of Commerce National Oceanic and Atmospheric Administration and U.S. Department of Health and Human Services Food and Drug Administration regarding inspection programs for fishery products (MOU No. 225-09-0008 above).

FDA continues to maintain guidance documents on its website which NMFS can use to help evaluate an establishment's compliance with FDA's Current Good Manufacturing Practice regulations and seafood HACCP regulation and to assist NMFS in determining whether a product may be regarded as adulterated or misbranded under the Act. For example, on April 28, 2011, FDA released the Fourth Edition of the Fish and Fishery Products Hazards and Controls Guidance and made it available on the FDA website. The guidance is intended to assist processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (HACCP) plans and to serve as a tool to be used by federal and state regulatory officials in the evaluation of HACCP plans for fish and fishery products. In addition, in January 2009, FDA issued guidance to industry about what FDA considers to be acceptable market names for seafood sold in interstate commerce and to assist manufacturers in labeling seafood products and made it available on the FDA website. The guidance defined the different categories of names found in "The Seafood List" and outlines principles that can be used to label seafood species sold in the United States (U.S.) with an appropriate, non-misleading statement of identity. The Seafood List is updated regularly.

FDA continues to maintain a list of domestic seafood establishments that seek to export fish and fishery products to the European Union (EU) and that meet the criteria for inclusion on the list, on its website, which NMFS can use in determining whether to issue public health safety certifications for establishments exporting fish or fishery products to the EU. This list is used by the EU to develop its Official EU List of EU approved Fishery Products establishments. This list is updated regularly by CFSAN and sent to the EU on a quarterly basis.

On October 31, 2011, FDA implemented a new ORA-wide procedure that described the steps to be taken and assigned responsibility for each step to ensure that cooperation and information sharing relative to the inspection of fish and fishery products was executed as defined in the MOU.

On February 13, 2012, FDA implemented a new CFSAN procedure that described the steps to be taken and assigned responsibility for each step to ensure that cooperation and information sharing relative to the inspection of fish and fishery products was executed as defined in the MOU.

FDA continues to notify NMFS in writing when FDA has sent a Warning Letter to a fish or fishery product establishment in accordance with the MOU.

FDA continues to maintain close working relations with NMFS. FDA personnel continue to meet with NMFS personnel on a regular basis.

FDA continues to participate in meetings with industry to promote better communication and understanding of regulations, policy, and statutory responsibilities. For example, FDA continues to staff a booth at the International Boston Seafood Show each year. Nearly 20,000 industry representative attended last year's International Boston Seafood Show. In addition, FDA also participated in the 4th Trans-Atlantic Fisheries Technology Conference (October 30-November 2, 2012), a joint meeting of the Atlantic Fisheries Technology Conference (AFTC) and the Western European Fish Technologists Association (WEFTA) hosted in 2012 by the Seafood Science and Technology Society of the Americas (SST), to provide a Regulatory Perspective on Moisture Control.

During the Gulf Oil Spill, FDA took advantage of the inspectional capabilities of the NMFS to achieve the maximum utilization of resources. The National Oceanic and Atmospheric Administration (NOAA) in consultation with the U.S. Food and Drug Administration (FDA), the Environmental Protection agency and state health and fisheries agencies in the Gulf region have established a protocol for use in re-opening oil-impacted areas closed to seafood harvesting. In order to avoid overloading laboratory capacities, seafood samples had to pass the sensory testing (smelling and tasting) by expert panels at NOAA's seafood testing laboratory in Pascagoula, MS, before being sent for chemical testing, under this reopening protocol.