

# The Food Safety Modernization Act – A Series on What is Essential for a Food Professional to Know

## [ Article 5. Surveillance ]

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### ABSTRACT

The FDA Food Safety Modernization Act (FSMA) is a significant and far reaching update of the laws and subsequent regulations that affect the safety of domestically produced and imported foods regulated by the Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides FDA with greater powers and directs it to develop regulations that will focus the food industry on the prevention of foodborne illness. This series of articles describes the legal “basics” for the readers of *Food Protection Trends*. This fifth article focuses on enhancements to foodborne illness surveillance. Past articles have reviewed FSMA's provisions on preventive controls, food defense, and produce safety standards. Future articles will examine the provisions of FSMA that govern imported food requirements and lab accreditation.

### INTRODUCTION

The FDA Food Safety Modernization Act (FSMA) reshapes the approach taken by the Food and Drug Administration (FDA) in regulating the food supply from one that was largely reactive to one that focuses on prevention. To help build that preventive system, the law places increased emphasis on surveillance activities that will inform every aspect of the new risk-based system FSMA creates. For example, in six sections – Produce Safety Standards (Section 105); Inspections (Section 201); Border Inspections (Section 201); Traceability (Section 204); Importer Verification (Sections 301 and 302); and Importer Certification (Section 303) – the law mandates that FDA regulate specific foods on the basis of the “known food safety risks” of the food. The produce safety and traceability sections specify that in establishing “known risks,” FDA can consider the history and severity of foodborne illness outbreaks and take into consideration data collected by the Centers for Disease Control and Prevention (CDC). The law also requires that FDA review and evaluate health data every two years to determine the most significant contaminants in food and to set performance standards for significant contaminants.

Thus, surveillance activities of the states and CDC provide essential building blocks for implementing FSMA in order to document known food safety risks in foods and identify the most significant

contaminants. Surveillance also provides information on emerging hazards in the food supply and feedback on the effectiveness of preventive controls.

On the response side, recalls are initiated on the basis of epidemiological data. Rapid detection of an outbreak and prompt identification and removal of the food involved can reduce its public health impact.

This is the fifth of seven articles that analyze the text of the relevant FSMA provisions, and review steps taken by FDA to interpret, or in some cases, implement the new law.

This article covers:

- The statutory definition of foodborne illness outbreak,
- Information sharing between Federal and State surveillance systems,
- Specific mandates designed to improve surveillance systems,
- The working group and development of an expert body to recommend continued improvement to surveillance systems,
- State roles and evaluation of capacity and needs, and
- Fitting surveillance into the broader risk-based, preventive food safety system

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**TABLE 1.**

**DESCRIPTION**

**FSMA**

**LOCATION**

**FD&C**

**CODIFIED**

Foodborne illness outbreak defined	§205(a)		21 U.S.C. §2224(a)
Directions to enhance foodborne illness surveillance systems	§205(b)(1)		21 U.S.C. 2224(b)(1)
Working group	§205(b)(2)		21 U.S.C. §2224(b)(2)
Improving food safety and defense capacity at the State and Local level	§205(c)(1)		21 U.S.C. §2224(c)(1)
Review of State and Local capacities and needs for enhancement	§205(c)(2)		21 U.S.C. §2224(c)(2)
<b>Surveillance-based factors used for defining high risk</b>			
Performance Standards	§104		21 U.S.C. §2201
Prioritizing risks for produce safety standards	§105	§419(a)(4)	21 U.S.C. §350h(a)(4)
Defining high-risk facilities for inspection purposes	§201	§421(a)(1)	21 U.S.C. §350j(a)(1)
Defining high-risk foods for targeted border inspections	§201	§421(b)	21 U.S.C. §350j(b)
Identifying high-risk foods subject to enhanced traceability requirements	§204(d)(2)		21 U.S.C. §2223(d)(2)
Level of risk posed by imported food as a factor in importer verification program	§301(c)(3)	§805(c)(3)	21 U.S.C. §384a(c)(3)
Known safety risks as a factor in voluntary qualified importer program	§302	§806(d)	21 U.S.C. §384b(d)
Known safety risks as a factor in import certification requirement	§303	§801(q)	21 U.S.C. §381(q)
Attribution data's role in defining high risk food types for targeting foreign inspections	§306	§807	21 U.S.C. §384c
Requirement to reanalyze food safety plans in response to new hazards	§103	§418(i)	21 U.S.C. §350g(i)
Centers of Excellence role in researching and improving surveillance	§210(b)	[Public Health Service Act §399V-5]	42 U.S.C. 280g-16

The enhanced surveillance and response capacity called for in FSMA is poised to transform the food safety systems in the United States at the local, state and federal levels. These improvements could ultimately prevent illnesses and mitigate problems earlier in the farm to fork continuum through improved foodborne illness surveillance activities.

According to CDC, “Inherent in the legislation is the potential to increase overall capabilities and provide new opportunities for

detecting more problems sooner, responding to them faster, and more efficiently monitoring the effectiveness of interventions to prevent foodborne illness and providing data to guide food safety policy” (7). The need for data-driven prevention is a key premise of the improvements to surveillance outlined in FSMA. Enhancements in foodborne illness surveillance systems include improvements in the collection, analysis, reporting, and usefulness of foodborne illness data.

FSMA defines an outbreak of foodborne illness as “the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a certain food” (2). That writes into statute the same definition CDC and the states are already using.

### **Foodborne Illness Surveillance Systems**

State, county and local governments operate the primary system for foodborne illness surveillance. This “bottom up” system allows for considerable innovation at the state and local levels, but also results in a fragmented system in which surveillance programs vary widely from state to state (8). FSMA’s provisions addressing surveillance recognize that strong state and local public health programs provide essential information to identify food safety risks for specific foods and pathogens and feed that information that can be integrated at CDC to identify the known food safety risks for specific foods and pathogens. State and local programs give that information to CDC so it can be integrated to identify the known food safety risk for specific foods and pathogens.

But given the necessity that different levels of government play a role, improving the systems is challenging. At the local level, there is a need for public health nurses or trained epidemiologists to collect food consumption history from confirmed cases of illness, or intake complaints reported by consumers to local health departments. At the state level, data from local agencies is aggregated and some states also operate a centralized system to conduct intake history and manage consumer complaints. State public health authorities conduct foodborne illness outbreak investigations, and when needed will ask for the assistance from federal public health authorities at CDC. CDC operates a number of surveillance systems including PulseNet, FoodNet, and the National Notifiable Diseases Surveillance System (NNDSS) and also coordinates with states and federal regulatory agencies to help identify contaminated foods during an outbreak investigation.

PulseNet and FoodNet were both launched in the late 1990s. The PulseNet surveillance system catalogues bacterial isolates’ Pulse Field Gel Electrophoresis (PFGE) patterns, a “fingerprint” of sections of bacterial DNA, and can spot outbreaks when two or more cases of an indistinguishable “fingerprint” occur. PulseNet has greatly increased the number and type of multi-state outbreaks that are detected, but the culture-based PFGE process has the disadvantage of being time consuming. More rapid culture-independent pathogen identification systems that are starting to replace culture-based diagnostic tests in health care settings will likely necessitate FSMA driven revisions to PulseNet.

FoodNet reports the annual incidence rates for nine pathogen species and provides historical trend analysis. FoodNet provides data for measuring the overall progress in foodborne disease prevention, for the diseases it has under surveillance. It also provides limited information on the foods linked to those illnesses through case-control studies. Thus, it can help with FSMA’s requirement that FDA identify the most significant contaminants, but is limited in its ability to help identify known safety risks for specific foods.

FoodNet has sites in 10 states across the country that collect results from all laboratory samples in those areas, providing popula-

tion-based surveillance for laboratory-confirmed cases. Differing from other public health surveillance systems that are passive, FoodNet is an active system that routinely communicates with more than 650 clinical laboratories to identify new cases and conduct periodic audits to ensure all confirmed cases are captured. This program provides information on seven bacterial and two parasitic foodborne pathogens, while also identifying pediatric cases of Hemolytic Uremic Syndrome. Once a case is identified through FoodNet, information is gathered on food intake, exposures, hospitalizations and travel, and is electronically entered and transmitted to CDC on a monthly basis.

In order to demonstrate how states can improve outbreak detection and response, CDC launched the FoodCORE (Foodborne Disease Centers for Outbreak Response Enhancement) collaborative network. Currently seven centers, covering about 13 percent of the U.S. population, participate in FoodCORE. These centers bring together public health laboratory, epidemiology, and environmental health expertise at state and local health departments.

FoodCORE has developed a set of performance metrics that are designed to demonstrate successes and identify gaps in the process of detection and investigation of enteric diseases and outbreaks. Reporting is based on the guidelines of the Council to Improve Foodborne Outbreaks Response with each center providing information on the burden, timeliness, and completeness of disease detection and investigation activity. FoodCORE centers collaborate on ways to implement better methods to detect, investigate, respond to, and control multistate outbreaks.

CDC oversees the NNDSS, a program that supports the activity of collecting and monitoring disease data, including policies, laws, people, partners, information systems, processes and resources at the local, state, and national levels. Each state has laws mandating that health care providers report cases of certain foodborne diseases to state and /or local health departments and this delivers important information into the NNDSS (6). To improve the utility of this information, NNDSS functions through the National Electronic Disease Surveillance System which provides data and information technology standards, and support to state, local and territorial health departments. These health departments then provide CDC with data on nationally notifiable disease and conditions.

### **Strengthening the Links in Our Surveillance System (§ 205(b)(1))**

Given its fragmented structure, surveillance relies on communication links between many partners. Section 205 of FSMA sets in place measures to strengthen the links in the national foodborne illness surveillance system. It calls for improved coordination among federal, state and local authorities. Oversight of these improvements falls under the Secretary of Health and Human Service acting through the CDC Director. The goal of FSMA’s surveillance section is to improve the collection, analysis, reporting and usefulness of data on foodborne illness.

Section 205(b)(1)(A) requires federal, state and local surveillance systems to be coordinated, and includes specific mention of complaint systems.

Complaint and notification systems allow the responsible public health agency to receive and respond to suspected illnesses associated with food and dining establishments reported from the public. Currently the processing of complaints varies by local, state, and federally run agency. Although complaint systems are responsible for detecting 75 percent of all foodborne outbreaks, they have received little systematic attention with respect to how they function or how they might be improved (9).

Also called for under the coordination provision are increased in local and state participation in national networks of public health and food regulatory agencies and laboratories. These improvements should result in better sharing of collected data and information among federal agencies.

Facilitating sharing of surveillance information among federal governmental agencies – specifically the Food and Drug Administration, the Department of Agriculture, the Department of Homeland Security – and state and local agencies, and with the public is the next of several specified improvements under section 205(b)(1).

Continuing the list of areas for strengthened efforts under section 205, the development of improved epidemiological tools for obtaining quality exposure data is intended to provide additional progress towards enhanced surveillance. Food consumption and exposure questionnaires, and their administration, are mainly coordinated by state and local health departments. Questionnaires that collect exposure data vary by pathogen, and by state and there are many discrepancies on what and how intake data is then analyzed. Coordinating epidemiologic surveying and statistical analysis tools should produce better quality exposure data.

Microbiological methods for classifying cases are also rapidly changing. To keep up with the changes, public health laboratory practice standards will need to anticipate and coordinate non-culture based rapid microbiologic identification for classifying cases. Augmentations of microbiologic and epidemiologic tools could improve attribution of foodborne illness outbreaks to specific food items. In particular, improved exposure assessments will be needed to compensate for potential losses of microbiological specificity with the increased use of non-culture-based diagnostic tests.

In order to reach the goal of section 205(b)(1)(E) for rapid case identification, FSMA requires that standardized information is to be submitted to a centralized database. Harmonizing rapid pathogen identification laboratory technologies is another area where FSMA calls for enhanced efforts. While expanding the capacity of many surveillance systems, FSMA urges working toward innovations, including software that is programmed to automatically search databases for identifying outbreaks more rapidly. Expanding the information technology capacity of public health surveillance systems will be necessary to other FSMA provisions discussed later.

Improvements are required in order to identify new or rarely documented causes of foodborne illnesses, as well as being able to better attribute food sources in sporadic cases of illness. Requiring the coordinated surveillance system to share aggregated de-identified surveillance data more rapidly, while maintaining confidential information protected by the Health Insurance Portability and Accountability

Act, will allow for more rapid response to outbreaks, helping to prevent illnesses and deaths from foodborne pathogens.

While increasing public awareness and knowledge is an overarching theme, so is engaging academic research. Section 205(b)(1)(H) specifically calls for the establishment of more flexible mechanisms for quickly initiating studies at universities and academic institutions.

Sharing foodborne illness surveillance data with the National Bio-surveillance Integration Center is also required. Foodborne illness data and overall surveillance systems will be integrated with other biosurveillance capabilities at the federal, state, and local levels. Improved integration through enhanced exchange of foodborne illness data and surveillance findings for situational awareness will aid in public health response operations. Other surveillance activities selected by the Secretary may be enacted allowing flexibility for future unforeseen needs.

In development of the strategies to achieve FSMA's food safety and food defense goals, there is also a requirement in section 205(c) for Secretarial review of current state and local capacities and their needs for enhancement. This review may include a survey of staffing levels and expertise available to perform food safety and defense functions. Laboratory capacity to support surveillance activities, outbreak response, inspection, and enforcement will also be gauged. Data management systems and informational technology systems' needs will be measured for their ability to support the sharing of food safety and defense information to the federal level from state and local agencies.

The Secretary may also choose to review other state and local activities and needs to complete the work outlined in FSMA. This review of current food safety capabilities was to be presented to Congress two years after the date of enactment, on January 4, 2011. Although no such report to Congress has been issued, a Federal Register Notice on February 24, 2012, elicited public comments on the proposed collection of information. The agency received six comments, a number of them from the National Association of County and City Health Officials, and responded to those comments mentioning that the agency has, through a cooperative agreement with Association of Food and Drug Officials, a mechanism to deliver the survey (5).

### **Food Safety Working Group (§ 205(b)(2))**

The Secretary also has a mandate to create a working group of experts and stakeholders from federal, state, and local food safety and health agencies as well as food and food testing industries, consumer organizations, and academia. The working group is required to meet annually, if not more frequently.

Through an annual public report, the working group will advise the Secretary on an ongoing and regular basis regarding the improvement of foodborne illness surveillance and implementation of recommendations outlined in FSMA. Guidance from the working group has already been given to CDC regarding selection criteria for the Centers of Excellence.

CDC has designated five Integrated Food Safety Centers of Excellence in fulfillment of its role in implementing a provision in section 210 of FSMA (3). State health departments and their affiliated university partners located in Colorado, Florida, Minnesota, Oregon and Tennessee

were chosen through a competitive process. The centers will provide technical assistance and training for disciplines critical to surveillance activities: epidemiology, laboratory and environmental investigations and associated analysis, and will assist neighboring states in making improvements. These centers will identify and implement best practices in foodborne disease surveillance, serving as a resource for public health professionals at the state, local, and regional levels.

Another function of the working group is providing input to the Interagency Food Safety Analytics Collaboration in the development of its strategic plan for attribution.

### **Ongoing Improvement through the FSMA Working Group (§ 205(b)(2) (A)-(F))**

Additionally, the surveillance working group was charged with providing advice and recommendations on priority data needs of partners related to foodborne illness and its causes. It will give advice on how to improve the effectiveness, coordination, and integration of foodborne disease surveillance, and on how to improve timeliness of data collection and access to surveillance data. Solutions are to focus on overcoming barriers to improving surveillance and disease prevention.

The working group is also charged with identifying the capacities needed for automatic electronic searches of surveillance data, and specific actions to improve foodborne disease surveillance. In response to this charge the working group has thus far identified the safety of imported food items as a challenge area. Its recommendation calls for improvements to accessing data from partner agencies in other countries, including information on the source of food products, and inclusion of this data in the outbreak reporting system. Working group members also identified information gaps, including identification and reporting on the original source of contaminated food.

Another recommendation the working group put forward is to expand FoodCORE in order to improve outbreak investigations and facilitate capacity building at the state level. Also CDC is urged to consider efforts for improving access to pre-existing surveillance training tools, while limiting duplication and improving dissemination to public health practitioners (4).

Section 205(b)(2) also requires the working group to outline the priority information and analysis needs for the regulatory agencies, the food industry, and consumers regarding causes of foodborne illness. The working group will seek to identify opportunities for improvements in the effectiveness of coordination and integration of activities among federal agencies, and between the federal, state and local levels of government.

Surveillance activities are also described in the Joint Food Safety and Food Defense Research Plan outlined under section 201. This section aids in designating high-risk foods based in part on the history of foodborne illness outbreaks attributed to such foods, establishes a working group to provide advice on the improvement of surveillance collection, access and use, and develops guidelines for individuals to manage the risk of food allergy and anaphylaxis in schools and the early childhood education programs (1).

### **Use of Surveillance Data in FSMA's Implementation**

Very appropriately, section 205 rests almost at the center of FSMA's 88 page text. In many ways, the enhanced programs support every major safety reform in the new law. Identifying, defining and/or prioritizing risk is required in at least eight separate sections within FSMA. A brief summary of these provisions demonstrates the reach of surveillance in the modern preventive food safety system.

Section 104 of FSMA establishes performance standards for reducing the risk of serious illness caused by contaminated food. The standards will be developed following a recurring review of relevant health data, including epidemiological studies to identify the most significant foodborne contaminants. The improvements to data collection and analysis in section 205(b)(1) will be critical to facilitate this biennial review.

FDA must define high-risk foods as part of its implementation of traceability requirements for these foods in section 204. The history and severity of foodborne illnesses attributed to a food, based on surveillance data collected by CDC, is one of the six factors directly related to information gathering under section 205 that must be considered in designating a food as high-risk.

A number of provisions in FSMA require FDA to prioritize its efforts based on risk. The history and severity of foodborne illness outbreaks must be considered in prioritizing produce safety standards under section 104. FDA is directed to prioritize inspections under section 201 based on known safety risks of specific foods, a function that will depend on attribution data gathered under the surveillance section.

Surveillance data is critical to the import title of FSMA as well. The Foreign Supplier Verification Program in section 301 and Voluntary Qualified Importer Program require importers to take known safety risk into consideration. The definition of high-risk food will dictate when imported food must be accompanied by a third-party certification under section 303. Finally, FDA must make a special effort to direct resources to the inspection of high-risk foreign facilities under section 305. In every instance, it will be the data and analysis under section 205 that will aid in making these determinations.

In addition to informing risk determinations, information on emerging pathogens and new hazards gathered through surveillance activities will factor into food safety plans under section 103. As new hazards are identified, FDA has authority to order facilities to reanalyze and if necessary revise their food safety plan to address the hazard.

### **A Broad Goal for Enhanced Surveillance**

At its heart the surveillance provisions in section 205 are intended to "improve the collection, analysis, reporting and usefulness of data on foodborne illnesses." This broad goal is important to attribution of outbreaks to specific food items. Robust foodborne illness surveillance data are needed to inform targeted prevention interventions. Looking to the leadership of CDC, FSMA directs the agency to (1) improve coordination and data sharing with public health partners and the public; (2) increase state and local participation in national surveillance networks; (3) expand and integrate national surveillance systems; (4) enhance laboratory and epidemiological methods for agent

identification, outbreak detection and investigation; and (5) improve the attribution of specific illnesses to specific foods.

CDC is directed to support the implementations of FSMA and work closely with FDA and other agencies in implementing the enhanced surveillance system outlined in FSMA's provisions.

But none of the work that is outlined can be completed without strong investment in the agencies tasked with oversight of the work. As such there is an authorization of \$24,000,000 appropriated for each fiscal year 2011 through 2015.

## ACKNOWLEDGMENTS

The author is grateful for the advice assistance and contributions of fellow IAFP Food Law Professional Development Group members.

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