

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

Article 1. Consumer Information and Recall; Facility Registration and Suspension; Records Access; Prior Notice for Imports; and Other Provisions That Took Effect as of November 2012

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ABSTRACT

The U.S. 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 the FDA with greater powers and direct it to develop regulations that will focus the food industry on the prevention of foodborne illness. This series of articles will describe the legal “basics” for the readers of *Food Protection Trends*. This first article focuses on the first provisions of the new law to take effect, including recall and consumer notification, facility registration and suspension, records access, prior notice for imports, administrative detention, fees for recall and re-inspection, and high-risk food categories. Future articles will examine the provisions of FSMA that govern new preventive control programs, produce safety standards, imported food requirements, lab accreditation, food defense and state surveillance reforms.

A major revision of our nation’s food safety laws was advanced when President Barack Obama signed the FDA Food Safety Modernization Act (FSMA) into law on January 4, 2011. This comprehensive law will reshape the approach taken by the Food and Drug Administration (FDA) from one that was largely reactive to one that focuses on prevention. The law will require the use of food safety plans throughout the food industry, based on the Hazard Analysis and Critical Control Points (HACCP) model already implemented in the seafood, juice, meat and poultry industries. The law gives increased emphasis to surveillance activities, on-farm food safety, and food laboratory accreditation, along with more traditional FDA activities such as inspection and import controls. There are a number of innovative elements in the new law, including reliance on a foreign supplier verification program and third-party certification for imported foods that are unique to FSMA.

This article is the first in a series that will outline the provisions of FSMA and describe the elements and timing of its implementation. The series will provide a primer for non-legal food safety professionals. This first article looks at a number of provisions that have already been implemented by FDA, some of which are based on authorities first granted to the agency under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). There are also several self-executing provisions that are reviewed such as the mandatory recall and new suspension of registration authorities. A law is said to be “self-executing” if its provisions become effective without the need for an agency to issue intervening regulations.

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Future articles will examine the provisions governing preventive control programs, produce safety standards, imported food requirements, lab accreditation, food defense and state surveillance reforms that will occur under FSMA.

The law contains numerous instructions to FDA that require changes to its oversight and regulation of the food industry, including more than 50 different deliverables in the form of new regulations, guidance, and reports to Congress (22). Following an initial burst of activity at FDA, the process slowed to a crawl early in 2012 as deadlines for major rules on preventive controls, import verification and produce safety passed while the proposed rules were in the review process. Despite this delay, FDA has started to implement a number of provisions to improve information available to consumers and the food industry, establish systemic reforms, and expand enforcement powers.

Actions taken to date provide insight on FDA implementation of FSMA's transformative scheme for a preventive food safety system. It is clear that FDA intends to take a building block approach to rolling out FSMA programs, which is consistent with the law's structure. In the Act, Congress set forth a multi-year implementation schedule, coupled with directions for Congressional reports, studies, and public hearings on key programs to assure a cumulative and inclusive process for formulating new regulations.

This article covers seven FSMA provisions (Table 1), many of which became effective within the first year of passage of the Act:

1. Requirement for FDA to develop a consumer friendly web search for locating food subject to a recall;
2. Mandatory recall authority;
3. Requirement for food facilities to register in even numbered years;
4. Requirement for importers to provide notice if food they are importing has been refused entry by another country;
5. Authority for FDA to administratively detain suspect food items;
6. Expanded records access authority during emergencies; and
7. Authority to collect fees to recover the costs of re-inspections or mandatory recalls.

Table 1. Location of Provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S Code

Provision	Location in:		
	FSMA	FDCA	U.S. CODE
1. Consumer friendly web search for locating food subject to a recall. FDA announced it had accomplished this April 4, 2011 (7).	§ 206		21 U.S.C. § 3501 (note)
2. Mandatory recall authority. Self-executing upon enactment of FSMA (9).	§ 206	§ 423	21 U.S.C. § 3501
3. Registration. Self-executing.	§ 102	§ 415	21 U.S.C. § 350d
Food categories. Guidance issued August 2012 (14).			21 U.S.C. § 350d (a) (2)
Biennial registration. Self-executing upon enactment of FSMA (10).			21 U.S.C. § 350d (a) (3)
Suspension of registration. Self-executing 180 days after enactment of FSMA (10).			21 U.S.C. § 350d (b)
4. Prior notice of Imported Food Shipments. Interim final rule issued May 5, 2011 (3).	§ 304	§ 801 (m) (1)	21 U.S.C. § 381 (m) (1)
5. Administrative detention. Interim final rule issued May 5, 2011 (4).	§ 207	§ 304 (h) (1) (A)	21 U.S.C. § 334 (h) (1) (A)
6. Records access. Interim final rule issued February 23, 2012 (5).	§ 101	§ 414 (a)	21 U.S.C. § 350c (a)
7. Re-inspection and mandatory recall fees. First fee schedule issued August 1, 2011 (2).	§ 107	§ 743	21 U.S.C. § 379j-31

Recall and consumer notification (FSMA, Section 206)

Mandatory recall authority was one of the first provisions of FSMA to go into effect. The provision, which ideally will be used rarely, requires FDA to first give companies the opportunity to conduct a voluntary recall when the agency determines food is unsafe or produced under insanitary conditions. This provision, however, makes it clear that FDA has the authority to order a recall if a company fails to respond to the request for a voluntary one.

The mandatory recall section of FSMA establishes the process, powers and limits for using the authority. Although the agency has developed internal guidelines on using this authority, the law does not require the agency to issue guidance or regulations (18).

The legislation mandates that FDA develop a number of communications tools that will help inform consumers about recalls. For example, in one of its first actions to implement FSMA, FDA published a consumer-friendly website to help identify food that is subject to a recall (<http://www.fda.gov/safety/recalls/default.htm>). The website provides searchable, product-specific information for consumers, replacing a recall search engine that was cumbersome and not useful to consumers. In addition, the legislation requires grocery stores to post notices provided by manufacturers that provide specific information on recalls for customers when they are shopping, once FDA identifies “conspicuous locations” within a grocery store for posting such notices.

Currently consumers receive little or no in-store messaging, which leaves many standing in the grocery store wondering whether something they recently purchased was involved in a recall. The list of conspicuous locations for notices will provide targeted recall information at the point of purchase, and may ultimately extend to other types of notification, such as text, phone or email. While the overall goal of FSMA is to prevent food from becoming contaminated in the first place, these provisions will provide some immediate consumer benefits before the prevention components come on-line.

Registration (FSMA, Section 102)

In 2001, when Congress was grappling with the aftermath of the attack on the World Trade Center, concerns were raised by then-Secretary of Health and Human Services Tommy Thompson that our food supply could become a target. In fact, Thompson told Congress that he was most concerned about food as a target because inspections were not adequate (6). In response, Congress included a number of food provisions in the Bioterrorism Act, along with \$100 million for improvements in FDA’s inspection and counter-terrorism programs. Specifically, the Bioterrorism Act gave FDA authority to register domestic and foreign facilities, detain suspect food items, and require prior notice on all imported food shipments. Each of these provisions was enhanced with the passage of FSMA.

FSMA significantly improves the registration provision. When coupled with new authority to suspend that registration, it gives FDA a powerful new enforcement tool. Understanding why requires a review of the provision’s history. Prior to 2002, FDA inspectors went into the field not knowing what companies they should be inspecting. A Government Accountability Office report once noted that FDA inspectors would refer to the Yellow Pages of the local phone book to find food plants in an area (17). The registration provision was adopted by Congress in order to give the agency a comprehensive list, with names, addresses and contact information for the food plants under its jurisdiction.

The initial registration provision under the Bioterrorism Act required registrants to “notify the Secretary in a timely manner of changes to [registration] information,” and required FDA to compile and maintain an up-to-date list of registered facilities. FDA implemented this as a one-time registration, which left facilities on an honor system for updating the registry. As a result of this implementation, the database of food processing facilities soon became out-of-date (19).

FSMA requires food facilities to re-register between October and December of each even-numbered year, starting in October 2012. While the agency does not have to issue guidance before implementing the registration system, the agency indicated it will do so in its announcement of new guidance on food categories (15).

Suspension (FSMA, Section 102)

Authority to suspend the registration of a food facility is perhaps the most important enforcement tools the new law grants the FDA. It allows the agency to effectively shut down a food facility if foods produced there have a reasonable probability of causing illness or death if they are consumed. A facility that packed, received or held the food may also have its registration suspended if it knew or had reason to know of that probability. A facility under suspension cannot import or ship food until the business takes satisfactory corrective action.

To keep FDA from over-reaching, the authority to suspend a registration resides with the Secretary of Health and Human Services, and businesses are provided an opportunity to contest the suspension within two days of its issuance. The Secretary can reinstate the registration when the evidence shows that adequate grounds do not exist for its continuation. A facility must also submit a corrective action plan for FDA approval, and once it is approved, the facility’s registration may be reinstated.

Suspension authority is a powerful new enforcement tool for protecting the public from unsafe food. For example, FDA has stated it may suspend registration based on commission of a prohibited act, such as refusing a records access order (13). This significantly strengthens and expands administrative power to aid enforcement. Prior to FSMA, FDA escalated enforcement actions mainly through the courts.

On November 26, 2012, the FDA exercised its authority to suspend the registration of a food processor for the first time since FSMA was enacted. Products produced by this company, a producer of nuts and nut spreads, were at the heart of a multistate outbreak of *Salmonella* Bredeney infections that sickened 42 people. In the interest of public health, FDA suspended the company’s registration, thereby making it illegal for it to introduce foods into interstate commerce (16).

Records access (FSMA, Section 101)

Another new authority under FSMA is the records access provisions. To gain access to company records under the Bioterrorism Act, FDA needed evidence of adulteration together with evidence of a serious risk to health or life. It also required that record requests be in writing. In a number of highly publicized cases, this delayed FDA's access to critical company records during outbreak investigations. Additionally, the Bioterrorism Act only allowed FDA to access records for the food under investigation, preventing inspectors from following leads to other food lines within the same facility.

The amendment to the Bioterrorism Act's records access provision should not be confused with provisions elsewhere in the law granting FDA new authority to review certain company records. For example, FSMA's preventive controls section gives FDA new authority to access a facility's written food safety plan, together with monitoring and test results, during its regular inspections of the food plant. These records must be made available to "a duly authorized representative of the Secretary upon oral or written request."

This authority will greatly aid FDA in improving the effectiveness of its inspections. No longer will the agency be doing a simple inspection, reflecting only its findings during the time inspectors are in the plant. Through a review of historical records, FDA can transition from "moment in time" inspections to conducting inspections that reflect activities in the plant over a longer time frame.

During an investigation of an outbreak, FSMA's changes to FDA's Bioterrorism Act authority allow the agency to access additional records and expand an inquiry to other food lines within a facility, provided there is a reasonable belief the food processed on them is affected in the same way as the food under investigation. The rule on records access was issued as an interim final rule in February, 2012 (an interim final rule is a regulation that becomes effective on publication without going through the notice and comment waiting period). This provision should be widely discussed with the food industry during the implementation phase, as an Inspector General investigation in 2009 found that 25% of businesses were not aware of the record-keeping requirement and almost 60% had incomplete records (20).

Prior notice for imports; administrative detention (FSMA, Sections 304 & 207)

Two other provisions of the Bioterrorism Act were also enhanced through implementation of FSMA programs. Within four months of FSMA's enactment, FDA issued interim final rules on prior notice requirements for imported food and administrative detention. Under the Bioterrorism Act, prior notice provided FDA with information about imported food, including its source, shipment, expected arrival date and destination. FSMA's prior notice rule simply added an additional reporting requirement for importers to identify any country that had refused entry to the shipment.

Administrative detention under the Bioterrorism Act expanded FDA's ability to detain food, but the power was not used (1). This was in part because the requirement for "credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals" proved too high a standard.

It was only after FSMA was enacted in 2011 that FDA first used its authority to administratively detain food (11). Within six months of the effective date, FDA had exercised its administrative detention authority three times, in one instance completing the action with a court ordered seizure. Under FSMA, the legal standard for exercising this authority changed: rather than having to show credible evidence that the food presented a threat of "adverse health consequences or death," inspectors had to have a "reason to believe" the food was adulterated or misbranded. The change gave inspectors greater latitude in requesting a detention order and broadened it to cover problems analogous to a Class II recall, used when food fails to meet legal standards (a Class I recall is used when food poses a serious risk to consumer health). In fact, the first two orders were based on insanitary conditions – insect and rodent infestations in warehouses – that generally give rise to a Class II recall.

Fees for recall and re-inspection (FSMA, Section 107)

User fees for re-inspection and mandatory recall are the final components of new FSMA authority that could have a significant effect during the earliest implementation phase. The re-inspection fee offsets the costs associated with having FDA inspectors return to facilities that had non-compliance issues in an initial inspection. The fees should improve FDA's rate of re-inspection, which had fallen to 64% of the facilities that had serious violations (21). Fees also serve as an enforcement mechanism by shifting the cost of remedial inspections or mandated recalls onto the facility that created the costs.

FDA has taken a cautious approach to implementing its fee collection program. While the first fee schedule and a request for comments on administering the fee program were issued in the fall of 2011, FDA has delayed invoicing until it publishes guidance on the process for requesting waivers. The agency is also delaying any assessment of fees on importers until it resolves issues that were raised in comments on the program (12).

High risk food categories

Among the tasks FDA must complete, none is as all-encompassing as the requirement for the agency to define which facilities and foods fall into the high-risk category, a condition precedent for meaningful implementation of much of FSMA's risk-based prevention program. The Act requires FDA to define high-risk food or facilities and lays out criteria that the agency is to consider in six provisions affecting prevention programs, inspections, traceability and imports. FDA has developed a model for identifying high-risk facilities based on factors in FSMA's inspection provisions. Information on the process, as well as a decision tree diagram, is available on the agency's website (8). Less well-defined is how FDA will assess the category of risk for foods, which is a pre-requisite to implementing FSMA's enhanced traceability program, and the import certification program. While the agency has not released information on how it makes a high-risk food determination, presentations by agency officials suggest the agency will utilize objective public health data when available, science-based expert elicitations, the Reportable Food Registry (RFR),

and public input. From this information, the agency will likely develop hazard-food category pairings that include consideration of common pathogens and unique processing risks to rank food categories.

CONCLUSION

This article has reviewed the provisions of FSMA that have already taken effect or will shortly. These provisions include improved consumer information during a recall and increased protection from unsafe food, like mandatory recall and record access during an outbreak investigation. The registration provision, which was available to FDA starting in 2002, has been strengthened with the addition of a biennial registration process and suspension authority. Administrative detention and prior notice for imports has also been improved since passage of FSMA. Other provisions, like those governing fees, are poised to be implemented soon, pending additional administrative action. Overall, FSMA takes lessons learned from the last decade to give the FDA enhanced tools for protecting public health.

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

[Article 2. Hazard Analysis and Risk Based Preventive Controls]

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SUMMARY

The U.S. Food Safety Modernization Act (FSMA) is a significant and far reaching improvement over the laws and subsequent regulations governing the safety of domestically produced and imported foods regulated by the Food and Drug Administration (FDA). Through FSMA, the U.S. Congress grants FDA 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 readers of *Food Protection Trends*. This second article focuses on the preventive control programs that food facilities must implement. Future articles will examine the provisions of FSMA that govern new produce safety standards, imported food requirements, lab accreditation, food defense and state surveillance reforms.

INTRODUCTION AND DISCLAIMER

This is a reader’s guide for non-lawyers and food safety professionals for the Hazard Analysis and Risk-Based Preventive Controls section, Section 103, of the Food Safety Modernization Act (FSMA) (Table 1). Section 103 of FSMA, codified in section 418 of the Food Drug and Cosmetic Act (21 United States Code [U.S.C.] 350g), is referred to in this article as “Section 103.”

This article begins by describing what Section 103 requires generally; explains when it takes effect and to whom it applies; and outlines what it says in particular about hazard analysis, preventive controls, monitoring, corrective actions, verification, record keeping, written plans and re-analysis.

The article is meant to promote understanding of what was written in this section and how it interacts with other parts of FSMA or the Food Drug and Cosmetic Act (FDCA). Although the article was written prior to release of proposed or final regulations under this section, many companies had been implementing compliance strategies without waiting for release of regulations.

This article does not purport to provide any legal advice, nor does it reflect the views of the authors’ employer. The reader is advised to consult with his or her own legal counsel and food safety experts in implementing compliance with FSMA.

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TABLE 1. Location of provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA) and the U.S Code

PROVISION	LOCATION		
	FSMA	FDCA	U.S. CODE
Registered food facilities must evaluate hazards and implement preventive controls.	§103(a)	§418(a)	21 U.S.C. §350g(a)
Hazard Analysis. Identify and evaluate known and reasonably foreseeable hazards.		§418(b)	21 U.S.C. §350g(b)
Preventive Controls. Implement preventive controls to significantly minimize or prevent hazards.		§418(c)	21 U.S.C. §350g(c)
Monitoring. Preventive controls must be monitored for effectiveness.		§418(d)	21 U.S.C. §350g(d)
Corrective Actions. Procedures for addressing failures of preventive controls and prevention of affected food from entering commerce.		§418(e)	21 U.S.C. §350g(e)
Verification. Facilities required to verify that preventive controls, monitoring and corrective actions are adequate.		§418(f)	21 U.S.C. §350g(f)
Recordkeeping. Records generated under §§ 418(c)-(f) must be kept for 2 years.		§418(g)	21 U.S.C. §350g(g)
Written Plan and Documentation. Written food safety plan must document and describe procedures used by facility to comply with requirements, and must be available to agency review.		§418(h)	21 U.S.C. §350g(h)
Requirement to Reanalyze. Facilities must conduct a re-analysis after making significant changes in food facility activities, or no less frequently than every 3 years.		§418(i)	21 U.S.C. §350g(i)
Section does not apply to seafood, juice and low-acid canned food facilities that are subject to and in compliance with existing standards and regulations.	§103(a)	§418(j)	21 U.S.C. §350g(j)
Facilities subject to produce safety standards under § 419 of FDCA are exempt.	§103(a)	§418(k)	21 U.S.C. §350g(k)
Certain qualifying small and very small facilities subject to modified food safety requirements.	§103(a)	§418(l)	21 U.S.C. §350g(l)
FDA may provide exemption for facilities engaged solely in producing food for animals, storing raw agricultural commodities for further distribution or processing, or storing packaged foods that are not exposed to the environment.	§103(a)	§418(m)	21 U.S.C. §350g(m)
FDA may provide exemption or modified requirements for certain on-farm facilities.	§103(c)		21 U.S.C. §350d(note)
Section does not apply to dietary supplement manufacturing, processing, packing, or holding.	§103(g)		21 U.S.C. §350d(note)

WHAT FSMA SECTION 103 REQUIRES GENERALLY

Section 103 requires every facility registered under the 2002 Bioterrorism Act (with certain exceptions) to “evaluate the hazards that could affect food manufactured, processed, packed, or held. . . and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated. . . or misbranded . . . monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.”

As a provision of FSMA, the list of prohibited acts in section 301 of the FDCA (21 U.S.C. 331) now includes this amendment: “The following acts and the causing thereof are prohibited: . . . The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title [FSMA Section 103, Hazard analysis and risk-based preventive controls].” Section 303 of the FDCA (21 U.S.C. 333) provides that “any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.”

U.S. Food and Drug Administration (FDA) is required by Section 103 (21 U.S.C. 350g(n)) “to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls.” Section 103 also requires the regulations to be promulgated “not later than 18 months after the date of enactment of [FSMA].”

FDA is also required, among other things, to “provide sufficient flexibility to be practicable for all sizes and types of facilities . . .” and regulations are not to “require a facility to hire a consultant or other third party to identify, implement, certify or audit [preventive] controls. . .” FDA also is required (sub-section (d) of Section 103) to issue a “small entity compliance guide setting forth in plain language the requirements. . . and to assist small entities in complying with hazard analysis and other activities. . .”

WHEN FSMA SECTION 103 TAKES EFFECT

Sub-section (i) of Section 103 provides that it “shall take effect 18 months after the date of enactment of [FSMA].” Though for “small business”, the effective date is delayed until “6 months after the effective date” of the regulations to be issued by FDA under Section 103. Section 103 regulations (21 U.S.C. 350g(n)(1)(B)) are to include a definition of “small business”.

On June 18, 2012, Michael Taylor, Deputy Commissioner for Foods said in a letter that “FDA will expect to enforce compliance with these new FSMA requirements [in particular FSMA Section 103] in timeframes that will be described in the final rules (1).” Before final rules are issued, FDA will release proposed regulations and provide the public a period of time to submit comments to FDA on the proposed regulations.

FACILITIES TO WHICH FSMA SECTION 103 APPLIES

Section 103 (21 U.S.C. 350g(o)(2)) defines “facility” to mean “a domestic facility or foreign facility that is required to register” under the 2002 Bioterrorism Act (section 415). With certain exceptions,

facilities that are required to register under the 2002 Bioterrorism Act are required to comply with Section 103.

FACILITIES SUBJECT TO AND EXEMPT FROM BIOTERRORISM ACT REGISTRATION

Regulations under the 2002 Bioterrorism Act (21 Code of Federal Regulations [C.F.R.] 1.225) require that you register if you are “the owner, operator, or agent in charge of either a domestic or foreign facility. . . and your facility is engaged in the manufacturing/ processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in Sec. 1.226.”

Exemptions to the registration requirements are provided in 21 C.F.R. 1.226 and include:

- a. Foreign facilities where food “undergoes further manufacturing/ processing” (except when further processing is of “a de-minimis nature”)
- b. Farms
- c. Retail food establishments
- d. Restaurants
- e. Nonprofits that serve directly to consumers
- f. Certain fishing vessels
- g. Facilities that are “regulated exclusively, throughout the entire facility” by the USDA by the Federal Meat Inspection Act, Poultry Products Inspection Act or Egg Products Inspection Act.

EXEMPTIONS FOR SEAFOOD, JUICE AND LOW-ACID CANNED FOOD

Section 103 exempts seafood, juice and low-acid canned food facilities subject to and “in compliance with” Hazard Analysis Critical Control Points (HACCP) regulation (21 U.S.C. 350g(j)). FSMA is not intended to amend existing law regulating HACCP in the seafood, juice or low-acid canned food industries, although Section 103, sub-section (f), is explicit that nothing limits the authority of FDA “to revise, issue, or enforce Hazard Analysis Critical Control programs and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.”

Also, the exemption for “thermally processed low-acid foods packaged in hermetically sealed containers,” applies only “with respect to microbiological hazards. . .”

EXEMPTION FOR FACILITIES SUBJECT TO PRODUCE SAFETY STANDARDS

Section 103 (21 U.S.C. 350g(k)) says that the section “shall not apply to activities of a facility that are subject to section 419 [Standards for Produce Safety].” If you are required to register under the Bioterrorism Act but are also subject to the produce safety standards in FSMA, then you will need to comply with the produce safety standards, but not Section 103.

PARTIAL EXEMPTION FOR “QUALIFIED FACILITIES”

Qualified Facilities are not subject to all of the requirements of the rules and regulations under Section 103.

Instead, Qualified Facilities will be required, among other things, to provide FDA “documentation that demonstrates that the . . . facility has identified potential hazards associated with the food produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective.”

Qualified Facilities are those that either (1) meet yet-to-be-published FDA regulations on what constitutes a “Very Small Business” or (2) have a “Limited Annual Monetary Value of Sales.” (21 U.S.C. 350g(l)). Section 103 defines facilities that have a “Limited Annual Monetary Value of Sales” as meaning that the facility must during a 3-year period preceding the applicable calendar year (1) sell more to “qualified end users” than to everybody else and (2) have average annual sales of not more than \$500,000 adjusted for inflation.

To meet the Limited Annual Monetary Value of Sales requirement, the facility must count sales to “any subsidiary or affiliate. . . collectively” and “to the subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.” Subsidiary is defined as “any company, which is owned or controlled directly or indirectly by another company.”

“Qualified End-User” is defined to mean:

- a. “a consumer of the food” or
- b. “a restaurant or retail food establishment. . . located in the same State as the qualified facility that sold the food. . . or not more than 275 miles from such facility.”

Qualified facilities also are subject to state and local laws imposing different requirements on the “safe production of food.” Section 103 also does not protect qualified entities from being subject to litigation or liability under state law.

Qualified facilities that do not provide the documentation required by FDA are subject to additional labeling requirements on their food products and/or at point of purchase that include “prominently and conspicuously” labeling “the name and business address of the facility where the food was manufactured or processed.”

DIETARY SUPPLEMENTS

Sub-section (g) of Section 103 states that nothing in Section 103 “shall apply to any facility with regard to the manufacturing, processing, packing or holding of a dietary supplement that is in compliance with. . . 21 U.S.C. 342(g)(2), 379aa-1.”

FDA GRANTED AUTHORITY TO EXEMPT CERTAIN ON-FARM PACKING OR PROCESSING

FDA was required to publish, within 9 months after enactment of FSMA, “a notice of proposed rule-making. . . with respect to activities that constitute on-farm packing. . . holding. . . manufacturing or processing of food that is. . . not grown, raised or consumed on that farm or another farm under common ownership” (sub-section (c) of Section 103). FDA is to do a “science-based risk analysis” and may exempt “certain facilities” from Section 103 or “modify the requirements” as the FDA “determines appropriate” if the FDA determines that these facilities are “engaged. . . In activities that FDA determines to be low risk.”

ADDITIONAL EXEMPTIONS OR MODIFICATIONS FOR CERTAIN ANIMAL FEED AND RAW AGRICULTURAL COMMODITIES

Section 103 provides that the FDA may by regulation create exemptions or modification of requirements for facilities “solely engaged in” (1) “the production of food for animals other than man” or (2) “the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing” or (3) “the storage of packaged foods that are not exposed to the environment.”

WHAT FSMA SECTION 103 SAYS ABOUT HAZARD ANALYSIS, PREVENTIVE CONTROLS, MONITORING, CORRECTIVE ACTIONS, VERIFICATION, RECORD KEEPING, WRITTEN PLAN AND RE-ANALYSIS

HAZARD ANALYSIS

Section 103 (21 U.S.C. 350g(b)) requires the “owner, operator or agent in charge of a facility” to “identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including” the following types of hazards or sources of hazards:

- i. Biological
- ii. Chemical
- iii. Physical
- iv. Radiological
- v. Natural toxins
- vi. Pesticides
- vii. Drug residues
- viii. Decomposition
- ix. Parasites
- x. Allergens
- xi. Unapproved food and color additives; and
- xii. Other hazards that occur naturally or may be unintentionally introduced

Hazard analysis under Section 103 also requires facilities to “identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism.” Note that this provision of FSMA appears to tie closely with Section 106 of FSMA. Section 106 is entitled “Protection Against Intentional Adulteration” and provides, among other things, that FDA shall conduct a “vulnerability assessment” and promulgate regulations “to protect against intentional adulteration of food. . .”

Section 103 hazard analysis also requires a facility to “develop a written analysis of the hazards.” This written analysis is considered under Section 103 as part of the “written plan.” Like other documents called out under Section 103, they “shall be made promptly available to a duly authorized representative of the Secretary [FDA] upon oral or written request” (21 U.S.C. 350g(h)).

Sub-section (b) of Section 103 requires FDA to issue a guidance document related to the [hazard analysis] regulations promulgated by FDA.

PREVENTIVE CONTROLS

Section 103 (21 U.S.C. 350g(c)) requires “the owner, operator, or agent in charge of a facility” to “identify and implement preventive controls, including at critical control points [as defined in 21 C.F.R. 350g(o)(1)], if any, to provide assurances” of the following:

- i. Unintentional hazards identified will be “significantly minimized or prevented”,
- ii. Intentional hazards identified “will be significantly minimized or prevented and addressed consistent with [Section 106 – Protection Against Intentional Adulteration – see above] as applicable,” and
- iii. “[F]ood manufactured, processed, packed or held by such facility will not be adulterated. . . or misbranded.”

Preventive controls are defined in Section 103 (21 U.S.C. 350g(o)(3)) to mean “those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (b) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.”

Examples may include:

- “(a) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.
- “(b) Supervisor, manager, and employee hygiene training.
- “(c) An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.
- “(d) A food allergen control program.
- “(e) A recall plan.
- “(f) Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations).
- “(g) Supplier verification activities that relate to the safety of food.”

Section 103 (21 U.S.C. 350g(n)(4)) provides that FDA does not have the authority to “prescribe specific technologies, practices, or critical controls for an individual facility.”

MONITORING OF EFFECTIVENESS

“The owner, operator, or agent in charge of a facility” is required to “monitor the effectiveness of the preventive controls. . . to provide assurances that the outcomes. . . shall be achieved.” (21 U.S.C. 350g(d)).

CORRECTIVE ACTIONS

“The owner, operator, or agent in charge of a facility” also is required under Section 103 (21 U.S.C. 350g(e)) to “establish procedures to ensure that, if the preventive controls. . . are not properly implemented or are found to be ineffective—

- “(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;
- “(2) all affected food is evaluated for safety; and
- “(3) all affected food is prevented from entering into commerce if. . . the facility cannot ensure that the affected food is not adulterated. . . or misbranded. . .”

VERIFICATION

In addition to monitoring preventive controls for effectiveness and taking appropriate corrective actions, Section 103 (21 U.S.C. 350g(f)) requires that “the owner, operator, or agent in charge of a facility” must “verify that—

- “(1) the preventive controls. . . are adequate to control the hazards identified. . . ;
- “(2)[they are] conducting monitoring. . . ;
- “(3)[they are] making appropriate decisions about corrective actions. . . ;
- “(4) the preventive controls. . . are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and
- “(5) there is documented, periodic reanalysis of the plan. . . to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.”

RECORDKEEPING

Section 103 (21 U.S.C. 350g(g)) requires that the “owner, operator, or agent in charge of a facility. . . maintain, for not less than 2 years, records documenting the monitoring of the preventive controls . . . , instances of nonconformance material to food safety, the results of testing and other appropriate means of verification. . . , instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.”

FOOD SAFETY PLAN AND RECORDS ACCESS

In addition to requiring record keeping, Section 103 (21 U.S.C. 350g(h)) provides that “the owner, operator, or agent in charge of a facility” must “prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of [Section 103], including analyzing the hazards. . . and identifying the preventive controls. . .” The written plan and the other records required under Section 103 also must be “made promptly available” to FDA “upon oral or written request.”

REQUIREMENT TO REANALYZE

Section 103 (21 U.S.C. 350g(i)) requires that the “owner, operator, or agent in charge of a facility shall conduct a reanalysis. . . whenever a significant change is made in the activities conducted at a facility . . . if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard. . .” Reanalysis is also required not less than “once every 3 years.”

Reanalysis must “be completed and additional preventive controls . . . implemented before [a] change in activities at the facility is operative.” If it is concluded that “no additional or revised preventive controls are needed,” the written plan must reflect the basis for the conclusion that no additional preventive controls are needed.

FDA also “may require a reanalysis under this section to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.”

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REFERENCES

1. FDA. 2012. Response to letter from Grocery Manufacturers Association concerning FDA's plans regarding the preventive controls and foreign supplier verification provisions in Sections 103 and 301 of the Food Safety Modernization Act (FSMA). Available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm310084.htm>. Accessed 7 January 2013.

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INTERNATIONAL ASSOCIATION FOR FOOD PROTECTION

General Fund Statement of Activity For the Year Ended August 31, 2012

Revenue:

Advertising	\$155,867
Membership & Administration	517,408
Communication	635,313
Annual Meeting	1,532,382
Workshops & Symposia	119,011
International Symposia	210,686
Total revenue	\$3,170,667

Expense:

Advertising	110,228
Membership & Administration	907,763
Communication	658,199
Annual Meeting	993,903
Workshops & Symposia	80,087
International Symposia	209,962
Total expense	\$2,960,142

Change in General Fund \$210,525

Net Assets as of 8/31/12:

General Fund	1,004,937
Foundation Fund	979,338
Restricted Fund	26,510
Speaker Travel Fund	169,778
Total net assets	\$2,180,563

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

[Article 3. Food Defense]

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ABSTRACT

This is article three in a series of seven articles being published in *Food Protection Trends* to provide basics on the Food Safety Modernization Act (FSMA). This article focuses on the main provisions of FSMA that pertain to Food Defense, which include hazard analysis and risk-based control, protection against intentional adulteration, national agriculture and food defense strategy, and the Food and Agriculture Coordinating Councils. It also includes discussion of activities covered by parts of additional sections of the Act that play a part in Food Defense: building domestic capacity, maintaining a food emergency response network, integrating a consortium of laboratory networks, and improving food defense capacity at the state and local levels.

INTRODUCTION

To begin an article on food defense, some definitions are first necessary to ensure a common understanding of key concepts. Per the United States Food and Drug Administration (FDA) Web site, under FSMA Frequently Asked Questions (FAQs), “**Food Defense** is the effort to protect the food supply against intentional contamination due to sabotage, terrorism, counterfeiting, or other illegal, intentionally harmful means. Potential contaminants include biological, chemical and radiological hazards that are generally not found in foods or their production environment. Food Defense differs from **Food Safety**, which is the effort to prevent unintentional contamination of food products by agents reasonably likely to occur in the food supply (e.g., *E. coli*, *Salmonella*, *Listeria*)” (27). **Food Security**, as defined by the World Health Organization (WHO), exists “when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life” (30).

This article is focused specifically on those sections within FSMA that pertain to Food Defense, based on the FDA definition. It also

focuses on authorities first granted to the agency under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (1) as well as several Homeland Security Presidential Directives (HSPDs) and Presidential Policy Directives (PPDs) that initiated key food defense actions, beginning in 2003.

Intentional adulteration of food or feed in the U.S. has occurred through the actions of disgruntled employees, as demonstrated by the poisoning of 200 pounds of meat with insecticide by a supermarket employee in Michigan in 2003 (2), by the actions of politically motivated groups, such as the spraying of *Salmonella* on a salad bar to make people ill and reduce voter turnout in Oregon in 1985 (5), and as a result of economically motivated actions, such as replacement of melamine for protein in pet foods entering the U.S. from China in 2007 (20). Intentional acts such as these result in significant consequences that affect the economy and public health as well as having psychological and political ramifications.

U.S. farms, foods, and agriculture systems account for about 13 percent of the nation’s gross domestic product and 18 percent

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of domestic employment (19). Any act of intentional adulteration or terrorism occurring in any part of the food supply chain can affect thousands of lives and potentially cost billions of dollars in investigation, health care, lost wages, recall, and recovery. There is also a psychological cost, as learned painfully through the loss of life of humans and beloved pets from melamine in pet food and milk. Trust, once lost, is very hard to regain.

Homeland Security Presidential Directive 7 (HSPD 7), signed on 17 December 2003 was the first to establish a national policy for Federal departments and agencies to identify and prioritize U.S. critical infrastructure and key resources and to protect them from terrorist attacks (14).

FSMA delineates additional requirements to the agencies regarding Food Defense. Four main provisions under FSMA focus on Food Defense:

1. Requirement for facilities to identify hazards that may be intentionally introduced, including by acts of terrorism;
2. Requirement for FDA to conduct a vulnerability assessment of the food system and determine the types of mitigation strategies necessary to protect against intentional adulteration of food;
3. Requirement for FDA in coordination with United States Department of Agriculture (USDA) and Department of Homeland Security (DHS) to make available, via Internet, a National Agriculture Food Defense Strategy;
4. Requirement for FDA in coordination with USDA and DHS to make available, via Internet, a report of activities of the Food and Agriculture Coordinating Councils.

HAZARD ANALYSIS (Section 103(b))

Prior to the passage of FSMA, there were no requirements for food facilities under the regulatory jurisdiction of FDA to implement mitigation strategies or measures to protect against intentional contamination. Now, under FSMA Section 103 (Section 418 of the FDCA), facilities are required to conduct a hazard analysis, implement preventative controls, and have a written food safety plan for all identified hazards, including hazards that may be intentionally introduced, or for types of hazards that could be introduced through acts of terrorism. This applies to businesses that are already required to register under section 305 of the Bioterrorism Act.

Included under Section 103 (21 U.S.C. § 350g(i)) is the requirement to *reanalyze* processes whenever a significant change is made, particularly if the change created a “reasonable potential” for a new hazard or a “significant increase” in a previously identified hazard. This reanalysis is required to take place at least once every three years. In addition, this provision provides FDA authority to *require* reanalysis in response to new hazards and developments in scientific understanding, including, as appropriate, results of the DHS biological, chemical, radiological, or other terrorism risk assessments.

Proposed rules for the hazard analysis and preventive controls have not yet been implemented. FDA could implement the law without regulations but has chosen not to do so, stating on their FSMA Web site “FAQs” page that “the hazard analysis and preventive controls requirements would become effective when the agency issued final rules” (28).

PROTECTION AGAINST INTENTIONAL ADULTURATION (Section 106)

FSMA adds to FDCA Section 420, which requires FDA to conduct a vulnerability assessment of the food system and determine mitigation strategies necessary to protect against intentional adulteration of food, to include per DHS biological, chemical, radiological or other terrorism risk assessments.

TABLE 1. Provisions within the FSMA, Food Drug & Cosmetic Act (FDCA) and U.S. Code

PROVISION	LOCATION		
	FSMA	FDCA	U.S. CODE
Hazard analysis must evaluate hazards that occur from intentional adulteration, including by acts of terrorism.	§103(b) §105(3c)	§104(b)(2)	21 U.S.C. § 350g(b)(2)
Protection Against Intentional Adulteration	§106	§420	21 U.S.C. § 350i
National Agriculture and Food Defense Strategy	§108		21 U.S.C. § 2202
Food and Agriculture Coordinating Councils	§109		21 U.S.C. § 2203

Not later than 18 months after the date of enactment, FDA, in coordination with DHS and in consultation with USDA, is required to promulgate regulations to protect against the intentional adulteration of food. These regulations are to specify appropriate science-based “mitigation strategies or measures” to protect the food supply. They will apply only to food with a high risk of intentional adulteration, as determined by FDA in consultation with DHS.

No later than one year after enactment, FDA, in consultation with DHS and USDA, is required to issue guidance documents related to protection against intentional adulteration of food. These requirements will not apply to farms (with the exception of dairy farms).

In the interest of national security, both the assessments of food system vulnerability and the issuance of some created guidance documents is, per Section 106, left to the determination of FDA, in consultation with DHS.

FDA already has provided a number of resources on their Food Defense Web site to provide support for industry, state and local stakeholders to help identify areas that may be vulnerable to intentional adulteration and to provide possible strategies for mitigation:

1. **Carver + Shock:** (22) developed by the U.S. military to identify areas vulnerable to an attacker; adapted by FDA and USDA for the food and agriculture sector:

- **Criticality:** What impact would an attack have on public health and the economy?
- **Accessibility:** How easily can a terrorist access a target?
- **Recuperability:** How well could a system recover from an attack?
- **Vulnerability:** How easily could an attack be accomplished?
- **Effect:** What is the direct loss from an attack, as measured by loss in production?
- **Recognizability:** How easily could a terrorist identify a target?
- **+ SHOCK:** the psychological impacts of an attack, or “shock” attributes of a target

2. **ALERT:** (21) intended to raise awareness of state and local government and industry representatives regarding food defense issues and preparedness:

- **Assure** – supplies and ingredients you use are from safe and secure sources
- **Look** – after the security of the products and ingredients in your facility
- **Employees** – know the people coming in and out of your facility
- **Reports** – about the security of your products while under your control
- **Threats** – what you do and whom you notify if you have an issue, including suspicious behavior

3. **Employees FIRST:** (23) an FDA initiative that food industry managers can include in ongoing employee food defense training:

- Follow company food defense plan and procedures
- Inspect your work area and surrounding areas
- Recognize anything out of the ordinary
- Secure all ingredients, supplies and finished product
- Tell management if you notice anything unusual or suspicious

4. **Preventative Measures Guidance** (24) – outline of measures to consider

5. **Food Defense Mitigation Strategies Database** (25) – examples of “easily accessible” areas

6. **Vulnerability Assessment** (26) – software tool

NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY (Section 108)

FSMA Section 108 requires the Department of Health and Human Services (DHHS), in coordination with USDA and DHS, to develop, submit to Congress, and make available on the Internet, a National Agriculture and Food Defense Strategy (4). This strategy must be revised and re-submitted to Congress every four years, must include an implementation plan, and a coordinated research agenda, and must be consistent with other Agency plans that already exist:

1. **National Incident Management System:** nationwide system that enables government, private sector, and nongovernmental organizations to work together to prepare, prevent, respond, recover and mitigate effects of national incidents (16);
2. **National Response Framework:** an outline of key response principles that delineates participants, roles and structures to guide operations for response to national incidents (15);
3. **National Infrastructure Protection Plan:** a framework designed to enhance the safety of our nation’s critical infrastructure. Food & Agriculture is 1 Sector out of 18 critical infrastructure Sectors identified in this plan (13);
4. **National Preparedness Goals:** (18) identification of core capabilities and targets necessary to achieve nationwide preparedness across 5 mission areas laid out under Presidential Policy Directive 8: prevention, protection, mitigation, response and recovery (17); and
5. Other relevant national strategies.

In the interest of national security, FSMA allows FDA, USDA and DHS to determine the manner and format in which the National Agriculture and Food Defense strategy is made publicly available on each Agency’s Internet site

FOOD AND AGRICULTURE COORDINATING COUNCILS (Section 109)

The Food and Agriculture Government Coordinating Council (GCC) and Sector Coordinating Council (SCC) (3) were formed in 2004. The GCC consists of federal, state, local and tribal government agency members. The SCC consists of trade associations and industry members (including multinational corporations) and serves as the primary interface with federal, state, local and tribal agencies to bring forward needs and requests from this sector on national security matters. These two Coordinating Councils were formed as a result of HSPD 7, in which the role for these joint councils was established to provide a public-private forum for effective coordination of agriculture and food defense strategies and activities, policy, and communications across the Food Agriculture sector to support the nation’s homeland security mission.

FSMA section 109 requires that DHS, in coordination with USDA and FDA, submit to Congress a report on the activities and progress of these two Food and Agriculture Sector Councils, and that this report is then made publicly available on the DHS Web site.

Additional sections within FSMA containing food defense components

In addition to the four main provisions on Food Defense just described, additional sections within FSMA include some provisions related to food defense. These are primarily concerned with actions and reports to be addressed by the Agency, but they feed back into or support already established food defense programs and have ramifications for food safety professionals at both the state and local level.

These additional provisions within FSMA include:

1. requirements to establish programs and practices to promote food safety and supply chain security,
2. requirement to report on progress with USDA and DHS to implement a national food emergency response laboratory network,
3. requirement for DHS to coordinate with FDA, USDA, DOC and Environmental Protection Agency (EPA) to identify and implement processes to support an integrated response during emergencies, and
4. requirements to develop and implement strategies to improve food safety and defense at the state and local level.

BUILDING DOMESTIC CAPACITY (SECTION 110 A-E, G)

As has been mentioned, FDA, USDA and DHS have been working together on domestic capacity building as required within the framework of food defense provisions cited in other Acts, Codes of Law, PPDs and HSPDs. FSMA now requires FDA, in collaboration with USDA and DHS, to provide a *comprehensive* report to Congress (at 2 years, post signing of FSMA) on the progress of many of these activities, to include the following, as well as an estimation of the resources needed to effectively implement these programs over a 5-year period:

- analysis of needs for additional regulations and guidance;
- identification of potential sources of emerging threats and systems to share preventative strategies;
- surveillance and integration of systems and lab networks to rapidly detect, coordinate and respond to hazards (including consideration of commercially-available methods, specifically for use at ports of entry and FERN labs);

TABLE 2. Provisions within the FSMA, Food Drug & Cosmetic Act (FDCA) and U.S. Code

PROVISION	LOCATION		
	FSMA	FDCA	U.S. CODE
Building Domestic Capacity	§110		21 U.S.C. § 2204
Reports on programs and practices to promote safety and supply chain security	§110(a)-(e)		21 U.S.C. § 2204(a)-(e)
Biennial Food Safety and Food Defense Research Plan	§110(g)		21 U.S.C. § 2204(g)
Food Emergency Response Network	§202(b)		21 U.S.C. § 2221
Integrated Consortium of Laboratory Networks	§203		21 U.S.C. § 2222
Improve food defense capacity at state and Local levels	§205(c)		21 U.S.C. § 2224(c)

- progress on integration of information management (IT) systems to allow data sharing between all lab networks both domestic and foreign, and include integration of the facility registration system into the IT systems used by the federal government for processing food imports;
- and description of progress toward developing and improving an automated risk assessment system for food safety surveillance and allocation of resources.

FDA is directed to “*promptly* undertake those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.”

And finally, under this section, biennially, the agencies are to submit to Congress a joint food safety and food defense research plan that lists and describes the research projects conducted over the past 2 years, as well as those projects planned to be researched over the next 2 years.

FOOD EMERGENCY RESPONSE NETWORK (Section 202(b))

Homeland Security Presidential Directive 9 (HSPD-9) (12), issued in January 2004, established a national policy to defend the national food supply against terrorist attacks, major disasters, and other emergencies. The Food Emergency Response Network (FERN) (8) was developed as a result, to integrate the nation’s food testing laboratories at all levels (federal, state, local and tribal), into a network that would be able to respond to emergencies involving biological, chemical, or radiological contamination of food. FERN is coordinated by both FDA and the USDA Food Safety and Inspection Service (FSIS).

FSMA Section 202(b) requires FDA, in coordination with USDA, DHS, and state, local and tribal governments, to submit a report to Congress on the progress and implementation of FERN. The first report was to be submitted 18 months post enactment of FSMA, and biennially thereafter; these reports are to be made publicly available on the FDA Web site.

As specifically listed within FSMA (Section 202(b)), these reports are to include updates on

- ongoing surveillance, rapid detection, and surge capacity for the large-scale food-related emergencies, including international adulteration of the food supply;
- coordination of the food laboratory capacities of state, local and tribal food labs, including the adoption of novel surveillance and identification techniques and the sharing of data between federal agencies and state labs to develop national situational awareness;
- provision of accessible, timely, accurate, and consistent food lab services throughout the U.S.;
- development and implementation of a methods repository for use by federal, state, and local officials;

- response to food-related emergencies; and
- integration with relevant lab networks administered by other federal agencies.

INTEGRATED CONSORTIUM OF LABORATORY NETWORKS (ICLN) (SECTION 203)

The Integrated Consortium of Laboratory Networks (ICLN) (10) was established in 2005, by a Memorandum of Agreement (MOA) signed by senior officials from a number of federal agencies: USDA, DHHS, DHS, Department of Commerce (DOC), EPA, Department of Energy, Department of Interior, Department of Justice, and Department of State (11). The DHS was established as the lead agency, which would coordinate the work of the ICLN.

The goal of the MOA was to create the basis for a system of laboratory networks capable of integrated and coordinated response to acts of terrorism and other major incidents requiring laboratory response capabilities. Establishing a laboratory network system to strengthen early detection and consequence management was consistent with Homeland Security Presidential Directives 9, 10, 21 and 22 (6, 7, 9).

Per FSMA Section 203, DHS in coordination with FDA, USDA, DOC and EPA is required to maintain the agreement and continue to work on optimization of national laboratory preparedness with the relevant laboratory network members in the ICLN. In addition, FSMA requires the DHS to report progress of the integrated lab network on a biennial basis to Congress as well as make this information available on the DHS Web site.

IMPROVE CAPACITY AT STATE AND LOCAL LEVELS (SECTION 205(C))

Prior to the signing of FSMA, FDA had already introduced several training programs for improving awareness and capacity at state and local levels. In 2008, FDA launched the **ALERT** program, mentioned previously under Section 106: PROTECTION AGAINST INTENTIONAL ADULTURATION, as a program to raise the awareness of state and local government and industry representatives regarding food defense issues and preparedness.

In 2011, FDA launched **FREE-B: Food Related Emergency Exercise Bundle** (FREE-B) (29), which was developed in cooperation with the Centers for Disease Control and Prevention (CDC), USDA FSIS and USDA Animal and Plant Health Inspection Service. FREE-B is a compilation of scenarios based on both intentional and unintentional food contamination events designed to assist government regulatory and public health agencies to participate in “scenarios” to assess existing food emergency response plans, protocols and procedures independently. Both ALERT and FREE-B training programs are available on the FDA Food Defense Web site at no cost.

Section 205(c) focuses on the FDA putting into place strategies to help leverage and enhance the food safety and defense capacities of state and local agencies to achieve the following goals:

- Improve foodborne illness outbreak response and containment;
- Accelerate surveillance and outbreak investigations via rapid shipment of isolates and more standardized illness outbreak interviews;
- Strengthen capacity to conduct inspections and enforce standards;
- Improve effectiveness of partnerships to coordinate resources and reduce incidence of illness;
- Share information on a timely basis among agencies, industry, health care providers and the public; and
- Strengthen capacity of the agencies to achieve goals as laid out in FSMS Section 108: NATIONAL AGRICULTURE and FOOD DEFENSE STRATEGY.

As part of developing strategies to achieve these goals, FDA is required to complete, within 1 year after the date of FSMA enactment, a review of state and local capacities and needed enhancements, which may require surveys to best determine:

- Staff levels and expertise available to perform food safety & food defense functions;
- Lab capacity to support surveillance, outbreak response, inspection and enforcement activities;
- IT systems for data management and information sharing between federal, state and local agencies; and
- Other state and local activities and needs as deemed appropriate.

CONCLUSION

Food Defense hazards are focused on **intentional** versus unintentional (food safety) hazards. Prior to 2004, food defense was not a key focus of monitoring for hazards within the food supply chain. The Bioterrorism Act, HSPD-7, and HSPD-9 initiated dramatic changes in how we began to scrutinize our nation's food supply chain, and in how the various federal agencies began to work more closely together to monitor, assess and implement these initiatives at the federal level and to some degree also at the state and local levels. The provisions within FSMA are consistent with efforts already established over the past 10 years, and FSMA continues to direct collaboration between the agencies at all levels, with additional requirements now to update and report progress to Congress and Agency Web sites as appropriate.

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ILSI North America Future Leader Award Call for Nominations

The North American Branch of the International Life Sciences Institute (ILSI N.A.) is soliciting nominations of individuals to be considered to receive its 2013 Future Leader Award.

The ILSI N.A. Future Leader Award, given to promising nutrition and food scientists, allows new investigators the opportunity to add to an existing project or to conduct exploratory research that might not receive funding from other sources or add to an existing project. Consideration will be given to individuals proposing research in the areas of experimental nutrition, nutrition and toxicology, and nutrition and food science.

Nominees for the Future Leader Award must meet the following criteria:

- Within 5 years of 1st tenure track position, or stable employment at a reputable research institute.
- Permanent resident of Canada or the United States.
- Show potential for future scientific leadership in nutrition, nutrition and toxicology, or nutrition and food science, based on the recommendations of 3 senior colleagues.
- Doctoral degree

Potential candidates should:

- Request that three (3) letters of nomination be submitted to ILSI N.A. by the department head and two other senior faculty or former professors. Letters should include specific information on the nominee's leadership qualities, area of interest, and special capabilities.
- Send a one-page cover sheet to ILSI North America that includes complete contact information for the nominee and an indication from whom ILSI N.A. should expect to receive letters of nomination. A current curriculum vitae should be attached.

**The deadline for receipt of all letters is Friday, June 15, 2013.
It is the nominee's responsibility to ensure that all materials arrive
at ILSI North America by the deadline.**

**For further information contact:
ILSI North America; Courtney Kelly; ckelly@ilsa.org**

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

[Article 4. Produce Safety Standards]

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ABSTRACT

The U.S. 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 the 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 will describe the legal “basics” for the readers of *Food Protection Trends*. This fourth article focuses on the produce safety standards that farms must implement. Future articles will examine the provisions of FSMA that govern imported food requirements, lab accreditation, food defense and state surveillance reforms.

INTRODUCTION

On January 4, 2011, the most significant revision of our nation’s food safety laws in many decades was signed into law. The FDA Food Safety Modernization Act (FSMA, or “the Act”) was the product of several years of efforts within Congress to reform the U.S. Food and Drug Administration (FDA). FSMA gives FDA new powers and transforms the nation’s food safety system from one that is reactive to one that is more pro-active. FSMA outlines the type of preventive control methods the industry will be responsible for implementing and documenting to help ensure the safety of the nation’s food supply.

This article, focusing on the FSMA-mandated produce safety standards, is one in a series of *Food Protection Trends* articles outlining several of the most impactful provisions of FSMA and describes the elements and timing of its implementation. The series will provide a primer for food safety professionals who do not have a strong food law and regulations background. Although FDA released the proposed rule on January 16 this year, the focus of this article will be primarily on the statute.

Impetus for FSMA produce safety standards

Currently, FDA has very little oversight of the fresh produce industry, and what it does have is largely through voluntary guidance, including the good agricultural practices (GAPs) guide, “Fresh-Cut Guide,” and draft commodity-specific guidance documents. The fresh produce industry has been hit hard, however, over the past several years with a series of large recalls and outbreaks of illness linked to various items, including spinach, cantaloupes, mangoes, romaine lettuce and sprouts. Despite the rise in industry-driven efforts to improve produce safety, including third-party audits and certification of good agriculture practices, Global Food Safety Initiative (GFSI)-related food safety schemes (e.g., GlobalGAP, SQF), and the development of product-specific safety standards, such as the California Leafy Greens Handlers Marketing Agreement, outbreaks and recalls have continued.

After numerous calls for the FDA to step in and set more stringent food safety requirements for the entire fresh produce industry, essentially “raising the bar” for all producers—both foreign and domestic—wishing to sell product in the U.S., the U.S. Congress included *Section 105 – Standards for Produce Safety* into the FSMA.

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However, recognizing that not all fresh produce items are equal, section 105's requirements are limited in scope to those products that FDA deems higher risk. Nevertheless, the new produce safety regulations deriving from FSMA will be FDA's first mandatory regulation of the produce industry.

Standards for produce safety (FSMA, Section 105)

One of the most significant provisions within FSMA is the requirement for FDA to develop produce safety standards, which will be founded, to some extent, on the principles of "preventive controls," as detailed in an earlier article in this series. Under FSMA's section 103 on hazard analysis and preventive controls, each registered facility will be required to conduct a hazard evaluation to identify "known or reasonably foreseeable hazards," including "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food and color additives," and "hazards that occur naturally or may be unintentionally introduced." Each registered facility is then required to implement preventive controls (including at critical control points, if any) to provide assurances that the identified hazards would be significantly decreased or prevented and that the food will not be adulterated or contain an undeclared allergen.

According to FSMA, within a year of the bill's enactment, FDA, in consultation with USDA, state departments of agriculture, and the Secretary of Homeland Security, was required to publish a proposed rule establishing science-based standards for the safe production and harvesting of those types of fruits and vegetables (including mixes or categories of fruits and vegetables) for which FDA has determined that such standards would "minimize the risk of serious adverse health consequences or death."

Furthermore, FSMA mandates that, once the proposed rule is released, FDA allows for a public comment period and must conduct at least three public meetings in diverse geographical areas to allow stakeholders a chance to voice concerns and/or propose recommendations for consideration by the agency. According to FSMA, a final rule will be required within a year of the closing of the comment period on the proposal.

The scope of the produce provisions within the Act itself includes: (1) fresh fruit and vegetables; (2) mushrooms; (3) sprouts; and (4) peanuts and tree nuts (1). FDA is instructed to prioritize regulations for fruits and vegetables that have been associated with foodborne illness outbreaks. FDA is required to allow flexibility in the ways in which different types of facilities can meet the standards, including farms that sell directly to consumers, as well as to consider conservation practices and organic production requirements. Although many farms will seek advice from food safety experts in developing appropriate food safety programs and may utilize second- or third-party auditors in order to evaluate the programs put into place, FDA cannot require a facility to hire such experts.

Section 105 does not apply to facilities that are subject to the preventive controls section or to persons who grow food for their own personal consumption. FSMA also provides FDA the discretion to exempt or modify the requirements for small and very small businesses

that produce and harvest low-risk fruits and vegetables. FDA must also acknowledge differences in risk and minimize the number of separate standards that apply to separate foods. Specifically, within 180 dates after the regulations are promulgated, FDA is required to issue a Small Entity Compliance Guide. FDA will have to define, by regulation, "small business" and "very small business." The statute describes the compliance date for small businesses and very small businesses as 1 year and 2 years, respectively, from the date the final rule is released.

FIGURE 1. Exemptions for small and very small farms

FSMA provides an exemption from mandatory produce standards for qualifying very small farms with limited size and limited scope of distribution.

- The limited size is for annual sales (3-year average) of less than \$500,000.
- The limited scope of distribution is either intrastate or within a 275 mile radius (includes Canadian or Mexican imports).
- A majority of the distribution must be directly to qualified end-users – directly to consumers or directly to restaurants or retail food establishments (i.e., not through distributors).
- The product label (if it has one) must include the name/place of business, or if there
- is no label, this information must be provided in a written placard or by some other suitable means.
- The exemption can be withdrawn by FDA, on a facility basis, if the food is directly linked to a foodborne illness outbreak.

The regulations must allow states and foreign governments to seek variances from the requirements, which might be appropriate under certain unique and/or different circumstances that call for such exceptions. FSMA also requires FDA to coordinate education and enforcement activities with state and local government and, where appropriate, with USDA to ensure compliance.

Challenges for FDA in developing regulations and guidance

FDA faces challenges in several areas in developing both the produce safety regulations and the accompanying industry guidance. These areas are highlighted in *Fig. 2* below:

FIGURE 2. FDA challenges in developing regulations and guidance

Considerations for defining risk categories for commodities by outbreak/illness data:

- Interplay of number, extent and severity of outbreaks
- Timeframes for baseline period
- Effect of consumption/exposure on illness data
- Effect of identifying (or not) food vehicle on illness data

Considerations for defining risk categories for commodities by positive sampling data:

- Availability of contamination data by commodity is highly variable.
- Contamination testing is driven, in part, by perceived risk.

TABLE 1. Location of provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA) and the U.S. Code

PROVISION	LOCATION		
	FSMA	FDCA	U.S. CODE
FDA required to develop produce safety standards for high-risk fruits and vegetables that are raw agricultural commodities	§105(a)	§419(a)-	21 U.S.C. § 350h(a)
FDA has discretion to exempt small businesses that produce low-risk raw agricultural commodities		§419(a)(1)(B)	21 U.S.C. § 350h(a)(1)(B)
FDA required to conduct not fewer than 3 public meetings after publication of proposed rule		§419(a)(2)	21 U.S.C. § 350h(a)(2)
Regulations must provide flexibility and consider conservation, environmental practice standards, and organic program requirements		§419(a)(3)	21 U.S.C. § 350(a)(3)
Rule implementation must prioritize raw agricultural commodities with known risks, including a history of causing foodborne illness outbreaks		§419(a)(4)	21 U.S.C. § 350h(4)
Final regulation must provide for coordination of education and enforcement with State and local officials		§419(b)(2)	21 U.S.C. § 350h(b)(2)
Regulations apply to small business after 1 year and very small businesses after 2 years		§419(b)(3)	21 U.S.C. § 350h(b)(3)
Regulations cannot require a business to hire consultants		§419(c)(1)(E)	21 U.S.C. § 350h(c)(1)(E)
Regulations must provide for variances if necessary		§419(c)(1)(F)&(2)	21 U.S.C. § 350h(c)(1)(F)&(2)
FDA must coordinate enforcement with USDA and States		§419(d)	21 U.S.C. § 350h(d)
FDA must publish guidance and conduct not fewer than 3 public education and outreach meetings		§419(e)	21 U.S.C. § 350h(e)
Farms smaller than \$500,000 in sales that directly market to consumers, and to restaurants and grocery stores within 275 miles, are exempt from produce safety provisions		§419(f)	21 U.S.C. § 350h(f)
Produce safety standards do not apply to produce grown for personal consumption		§419(g)	21 U.S.C. § 350h(g)
Activities of a facility that are subject to preventive controls rule (§ 418 fo the FDCA) are exempt from produce safety standards		§419(h)	21 U.S.C. § 350h(h)
FDA required to publish a plain language Small Entity Compliance Policy Guide within 180 days of issuing final regulations	§105(b)		21 U.S.C. § 350h note
Failure to comply with produce safety standards is a prohibited act	§105(c)	§301(vv)	21 U.S.C. § 331(vv)
Produce safety standard provisions have no effect on HACCP authority	§105(d)		21 U.S.C. § 350h note
Importers must verify that suppliers are in compliance with applicable produce safety standards	§301(a)	§805(a)	21 U.S.C. § 384a(a)

- Outbreak ranking is not static and could require moving commodities from one risk category to another, based on new data.
- Operations with multiple commodities in different risk categories, but with similar practices and conditions, could be subject to multiple standards and control regimes at a single farm.

Additional challenges:

- Risk associated with a given commodity varies depending upon practices employed (e.g., regional practices and conditions).
- Practices may change over time for a given commodity.

Helping industry comply

Congress realized that for many producers, compliance with the new regulations and standards could be difficult and may require significant FDA assistance and outreach. FSMA states that within a year of enactment, FDA is directed to publish guidance updating its current good agricultural practices (GAPs). FDA's GAPs are currently presented in the 1998 FDA/USDA "Guidance for Industry – A Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (2). FDA will be required to hold at least three public meetings to conduct education and outreach regarding the guidance.

FIGURE 3. *In addition to this guidance, FDA has plans to:*

1. Publish a "hazards guide" to assist producers in designing preventive controls;
2. Allow reasonable time periods for implementation, taking into account firm size;
3. Cooperate with USDA, state and local extension, and industry-sponsored education efforts to foster understanding and implementation of the regulation;
4. Help support and leverage the Produce Safety Alliance* to train producers;
5. Continue to cooperate with the industry and other food safety partners to identify and implement best practices; and
6. Conduct and foster applied, problem-solving research both to better understand produce safety hazards and to develop the preventive controls needed to minimize them.

** The Produce Safety Alliance was formed shortly before FSMA was made law and is made up of representatives from government, academia and industry who are developing a nationwide training curriculum to increase understanding of the principles of Good Agricultural Practices and to facilitate the implementation of food safety practices on fresh fruit and vegetable farms and in packinghouses.*

FDA progress to date

In preparing for and drafting the proposed rule, FDA worked very closely with the U.S. Department of Agriculture and its agencies, the Environmental Protection Agency, state departments of agriculture, consumer groups, and the industry. FDA and USDA technical experts, scientists, and other staff participated in listening sessions and meetings in 13 states. The agency also solicited public comments through an open docket on the Regulations.gov Web site.

More than 800 comments were received from all parts of the country, which, according to FDA, was an unprecedented number in an FDA produce-related rulemaking action. Comments were submitted from growers of all sizes; environmental groups; state and local government agencies; retail food chains; academia; consumers; and others.

Finally, on January 4, 2013, FDA released its proposed rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Public comments were due to FDA by May 16, 2013. As already noted, the focus of this article is simply on the language and requirements in the Act itself. A separate article providing an overview and deeper analysis of FDA's proposed rule will be published later.

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The author is grateful for the assistance and contributions of fellow IAFP Food Law Professional Development Group members: DeAnn L. Benesh of the 3M Food Safety Department, Erica Sheward of the University of Central Lancashire, and Caroline Smith DeWaal and David Plunkett of the Center for Science in the Public Interest.

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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)
Surveillance-based factors used for defining high risk			
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.

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The Food Safety Modernization Act —

A Series on What is Essential for a Food Professional to Know

[*Article 6. Imported Food*]

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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 sixth article focuses on FSMA's provisions that apply to imported food. Past articles have reviewed FSMA's provisions on preventive controls, food defense, produce safety standards, and foodborne illness surveillance. A future article will conclude the series by discussing the provisions of FSMA that govern lab accreditation.

INTRODUCTION

Many aspects of the FDA Food Safety Modernization Act (FSMA), like registration of food facilities and preventive controls, build on a foundation already in place through previous regulatory or legislative initiatives, but the elements of the law covering imported foods are largely new constructions. Through FSMA, FDA will extend its reach to the foreign growers and manufacturers who ship 10 million line items of food to the United States annually. It does this with a comprehensive program to verify that the preventive controls requirements covering food processors and the produce safety standards covering many high risk agriculture products are being complied with by companies that import food to U.S. markets. These new programs for importers are further verified by improvements to foreign and border inspections and a more systematic approach to working with foreign governments. FDA can reward companies that demonstrate good practices with an expedited entry program, and FSMA also establishes a risk-based inspection program that allows the agency to compel certification of high-risk imports or those coming from high-risk countries.

Title III of FSMA contains the imported food provisions, but foreign producers must be aware of the full contents of the statute and the regulations that will implement it. Cross-cutting provisions, like Section 101 on records access and Section 306 on foreign inspections, must be understood together. Registration and suspension under Section 102 has

consequences for the Foreign Supplier Verification Program. Section 103 applies preventive controls to any covered food facility, whether foreign or domestic. Importers in Title III are covered by the mandatory recall provisions in Section 206 of Title II. FDA has the ability to recover certain costs associated with enforcement actions from importers under a provision in Section 107 of Title I. This interweaving of parts means that businesses which rely on foreign suppliers, and regulators who oversee the import system must be aware of the full scope of FSMA's provisions.

This is the sixth of seven articles that analyze the text of the relevant FSMA provisions. This article covers seven FSMA provisions affecting imports:

1. Requirements on foreign suppliers,
2. Importer verification requirements,
3. Certification of high-risk imports,
4. Expedited entry under VQIP,
5. International capacity building,
6. Accreditation of third party auditors, and
7. FDA's oversight role.

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TABLE 1. Location of Imported Food Provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S. Code

DESCRIPTION	LOCATION		
	FSMA	FDCA	U.S. CODE
INSPECTION OF RECORDS.	§ 101	§ 414	21 U.S.C. § 350c
REGISTRATION.			
United States agent and biennial registration.	§ 102(a)	§ 415(a)	21 U.S.C. § 350d(a)
Suspension of registration.	§ 102(b)	§ 415(b)	21 U.S.C. § 350d(b)
Effect of suspension on imported food.	§ 102(b)(3)	§ 801(l)	21 U.S.C. § 381(l)
PREVENTIVE CONTROLS REQUIREMENTS APPLY TO FOREIGN FOOD FACILITIES.	§ 103(a)	§ 418(o)(2)	21 U.S.C. § 350g(o)(2)
PRODUCE SAFETY STANDARDS			
Process for requesting variances from produce safety standards.	§ 105(a)	§§ 419(c)(1)(F) & (2)	21 U.S.C. §§ 350h(c)(1)(F) & (2)
Requirement to issue guidance for importers (and others).	§ 105(a)	§ 419(e)	21 U.S.C. § 350h(e)
FEES			
Cost recovery fees for reinspection and mandatory recall apply to importers.	§ 107	§ 743(a)	21 U.S.C. § 379j-31(a)
Voluntary Qualified Importer Program.	§ 107	§§ 743(a)(1)(C) & (b)(2)(B)	21 U.S.C. §§ 379j-31(a)(1)(C) & (b)(2)(B)
NOTIFICATION REGARDING “PORT SHOPPING.”	§ 115		21 U.S.C. § 381(note)
EXEMPTIONS FOR ALCOHOLIC BEVERAGE IMPORTERS.	§ 116		21 U.S.C. § 2206
RISK-BASED TARGETING OF FOREIGN FACILITY AND BORDER INSPECTIONS.	§ 201	§ 421	21 U.S.C. § 350j
ACCREDITATION OF FOREIGN LABORATORIES.	§ 202	§ 422(a)(5)	21 U.S.C. § 350k(a)(5)
ACCREDITED LABORATORY REQUIRED FOR TESTING IMPORTED FOOD IN SUPPORT OF ADMISSION UNDER SECTION 801(A).	§ 202	§ 422(b)	21 U.S.C. § 350k(b)
ENHANCED TRACKING AND TRACING OF IMPORTED FOOD.			
Traceability system applies to imported food.	§ 204(c)		21 U.S.C. § 2223(c)
Importing food without traceability information prohibited.	§ 204(j)(2)	§ 801(a)	21 U.S.C. § 381(a)
MANDATORY RECALL APPLIES TO IMPORTED FOOD.	§ 206	§ 423(b)(1)(B)	21 U.S.C. § 350l(b)(1)(B)
FOREIGN SUPPLIER VERIFICATION PROGRAM.	§ 301	§ 805	21 U.S.C. § 384a

TABLE 1. Location of Imported Food Provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S. Code (cont.)

DESCRIPTION	LOCATION		
	FSMA	FDCA	U.S. CODE
VOLUNTARY QUALIFIED IMPORTER PROGRAM.	§ 302	§ 806	21 U.S.C. § 384b
AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS.	§ 303	§ 801(q)	21 U.S.C. § 381(q)
PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.	§ 304	§ 801(m)(1)	21 U.S.C. § 381(m)(1)
BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD SAFETY.	§ 305		
INSPECTION OF FOREIGN FACILITIES.	§ 306	§ 807	21 U.S.C. § 384c
ACCREDITATION OF THIRD-PARTY AUDITORS.	§ 307	§ 808	21 U.S.C. § 384d
FOREIGN OFFICES.	§ 308		21 U.S.C. § 2242
SMUGGLED FOOD.	§ 309		21 U.S.C. § 2243
COMPLIANCE WITH INTERNATIONAL AGREEMENTS.	§ 404		21 U.S.C. § 2252.

FSMA Requirements Apply to Foreign Food Suppliers

All laws that cover food safety for domestic growers or food processors apply to foreign growers and processors who want to import food to the United States. This includes registration requirements under § 102; produce safety standards under § 105; and process control standards under § 103.

Verification: The Importer's Essential Role

Under § 301, FSMA establishes a mandatory requirement for importers to ensure that the food they bring into the U.S. market meets the requirements of the Act. This means that importers conduct "verification activities" to confirm that food is subject to preventive control systems and meets produce safety standards. Further, importers must verify that the food is not adulterated or misbranded. FSMA defines importers of food as either the owner (or consignee) of the food when it enters the U.S. or the agent or representative of the foreign owner (or consignee) of the food at the time it enters the U.S.

To implement this provision, FDA is required to develop regulations describing the types of activities importers can use to assure imported food meets the same level of public health protection required under the Act, and to verify that "food imported into the United States is as safe as food produced and sold within the United States." In contrast to several sections of FSMA that limit FDA's ability to regulate, when it comes to food imports, FDA has a great deal of latitude.

FDA must consider differences in importers and types of imported foods, including the level of risk posed by the food. Verification activities prescribed by the regulation may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk based preventive control plan of the foreign supplier, and periodically testing and sampling shipments. FSMA requires that importers maintain records to document these activities for at least two years. These records are subject to inspection by FDA on request.

There are exemptions from the Foreign Supplier Verification Program for several industries that have been operating under preventive controls regulations for some time. These include seafood, juice and low-acid canned foods processors that are in compliance with Hazard Analysis Critical Control Points (HACCP) regulations for those sectors. Food imported in small quantities for research, evaluation or personal consumption is also exempt as long as it is not sold or distributed to the public.

A list of importers participating under the Foreign Supplier Verification Program is to be published on a website for the public and failure to participate is considered a prohibited act under the Federal Food, Drug and Cosmetic Act. While Congress prescribed that this section of FSMA should become effective two years after the date of enactment, it has not yet been implemented; regulations to implement this section were released for public comment in July 2013.

Certification of Imports

While the Foreign Supplier Verification Program establishes a mandatory requirement on importers, FSMA gives FDA and importers other tools to help assess the safety of imports. Import certification is an important innovation contained in § 303 and § 307 of FSMA. Certification is the concept of using a third party, specifically a foreign government or third party auditor, to provide assurance that the requirements of the law have been met. It was added to FSMA to respond to concerns that FDA did not have the capacity to inspect the large number of foreign companies that registered as importers after registration became required in 2003.

Under FSMA, certification is recognized in two contexts. First, under § 303, FDA can mandate certification for imported foods based on the “risk of the food.” This is determined by analysis of the known food safety risks associated with the food or the country, territory, or region where the food originates. FDA can also require certification if it finds that the food safety programs in the country of origin are not adequate to ensure that the food is as safe as a similar product produced domestically, and that the certification would assist the Secretary in either admitting or refusing entry of the food. When the food safety programs in a specific country are found to be deficient, FDA must establish a system to allow the foreign government to inform the agency when improvements are implemented, and to demonstrate that they are adequate to ensure the food “is as safe as a similar article of food that is manufactured . . . in the United States in accordance with this Act.”

Voluntary Qualified Importer Program

Under § 302, FSMA also allows for the use of certification in the Voluntary Qualified Importer Program (VQIP). This program provides for expedited review and importation of food by importers who opt to participate. Participation in the program follows an application to the FDA, and must be consistent with requirements of the certification section of the Act, as each facility that qualifies must have certification. FDA can manage the program under a guidance that controls the participation of companies, and sets out the standards for compliance with the program, together with revocation and reinstatement in the program, where necessary. Imported food that comes in under the VQIP program must have proof that it is from a certified facility.

FDA reviews applications to VQIP and makes determinations based on criteria outlined in FSMA, such as (1) the known food safety risks of the food; (2) the compliance history of foreign suppliers; (3) the capability of the regulatory system of the country of export; (4) the importers’ compliance with the Foreign Supplier Verification Program; (5) practices of the importer, including recordkeeping, testing, inspection and audits of the facilities, traceability of the food, temperature controls, and sourcing practices; (6) the potential risk for intentional adulteration; and (7) any other factor the Secretary determines is appropriate. Reevaluation of the company’s fitness for VQIP is done at least once every three years.

Cooperation: International Capacity Building and Cooperation

Under § 305, FSMA requires FDA to establish a plan for building the food safety capacity of foreign governments, including the technical, scientific, and regulatory capacity of governments that export food to the U.S. The plan should outline FDA’s recommendations for bilateral

and multilateral arrangements; provisions for secure electronic data collection and mutual recognition of inspection reports; training for foreign governments and food producers; recommendations for harmonization with Codex Alimentarius requirements; and international acceptance of laboratory methods, testing and detection techniques.

Accreditation of Third-Party Auditors

Under § 307, FSMA recognizes in statute the role of auditors as part of the regulatory system. This is a significant departure from the normal regulatory approach that accepts findings following an on-site U.S. government inspection. Importantly, “third-party auditors” can be foreign governments, agencies of a foreign government, foreign cooperatives or other third parties that the FDA determines are appropriate in this context. Audits permitted under this section must be performed by an auditor that is accredited by FDA or an accrediting body it has recognized for that purpose. They also should be unannounced and conducted in a manner to minimize conflicts of interest.

To be accredited under FSMA, an auditor must be capable of conducting food safety audits to certify that the company or facility is in compliance with the requirements of FSMA, and be willing to certify to that compliance, either for the purposes of mandatory certification or VQIP. If an auditor discovers a condition that could lead to a risk to public health, the law obligates the auditor to notify FDA. The law also prescribes a number of limitations and conflicts of interest for third party auditors.

Auditors must be able to issue a written and electronic food certification, as needed, or a facility certification to accompany each food import shipment. Certificates can only be issued after conducting a regulatory audit and such other activities as are needed to establish compliance. The Act describes the purpose of certification as both to approve specific food shipments and also to determine if the facility meets eligibility for the VQIP.

Auditors can lose their accreditation if the food they certify is linked to an outbreak of foodborne illness that can cause serious illness or death in humans or animals or if FDA finds that the auditor no longer meets the requirements. Accreditation also is contingent on FDA’s ability to review audits or investigations of the auditor.

FDA has the authority to recognize accreditation bodies to assist the agency in identifying qualified auditors and the authority to both revoke and reinstate that recognition. FSMA gives FDA the authority to prescribe the type of audit reports that meet the requirements of the Act, including the date and scope of the audit, and name of the person at the facility responsible for meeting the requirements of the Act. Regulatory audit reports are accessible to FDA at any time. FSMA also sets out specific requirements for different types of recognized auditors, including foreign governments, foreign cooperatives and other third parties. FDA must maintain a public registry of accredited auditors and accreditation bodies approved by the agency and periodically (no less than once in 4 years) reevaluate those approvals.

Oversight: FDA’s Role

In addition to FDA’s role in designing and administering the import programs described above, the agency also has responsibilities to improve foreign and border inspections, and establish a presence in

regions from which much of our imported food comes. In § 201 of FSMA, the agency is required to double the number of foreign inspections each year for five years. While meeting this mandate will be dependent on annual funding levels approved by Congress, it establishes a clear direction for the agency to more closely monitor conditions in exporting countries. FDA inspected 995 foreign facilities in fiscal year 2011 (1) a significant increase over its lowest point of 96 foreign inspections conducted in 2007 (2). At the border, FDA is required to conduct risk-based inspections. In addition to the known risk of the food item, it also must evaluate the country or region it originates from, the compliance history of the importer, and any certification provided under the VQIP or mandatory certification program.

FSMA also authorizes establishment of foreign offices to assist foreign governments with measures to provide for the safety of foods they export, and to conduct direct inspections. FDA had begun setting up these offices prior to FSMA's passage. Consistent with § 308, the agency expanded the program and now has 13 offices in 10 countries (1).

CONCLUSION

The imported food program under FSMA makes major changes to the way FDA regulates imported food. It places new responsibilities on importers to make sure their suppliers are complying with U.S. food safety standards. In the case of high-risk foods, it establishes a new program for accredited auditors to certify the safety of the product

before it leaves the country where it was manufactured. These two provisions ease pressure on the border inspection system by moving safety assurances back to the exporting country. Together, the new provisions provide a comprehensive system that emphasizes prevention, supported by more frequent foreign inspections and border checks to verify FSMA is working to protect consumers.

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In Memory

John H. Fritz
Silver Springs, MD

IAFP would like to extend our deepest sympathy to the family of John H. (Jack) Fritz who recently passed away. IAFP will always have sincere gratitude for his contribution to the Association and the profession. Mr. Fritz was President of the Association in 1964.



The Food Safety Modernization Act – A Series on What is Essential for a Food Professional to Know Article 7. Laboratory Accreditation

ABSTRACT

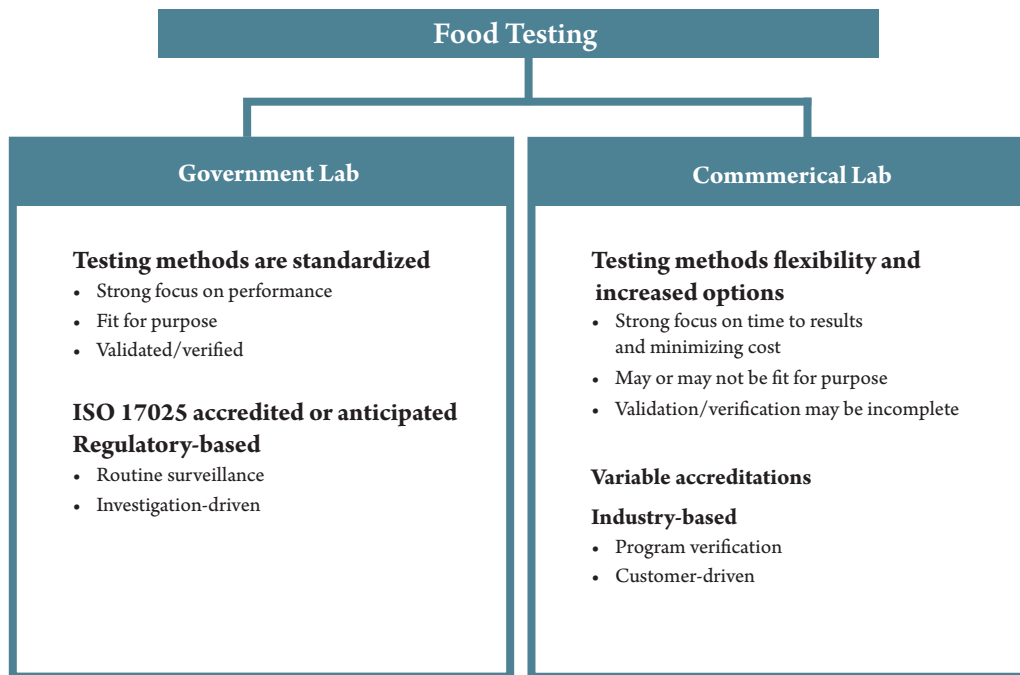
The FDA Food Safety Modernization Act (FSMA) is a significant and far-reaching update of the laws and subsequent regulations that affect the safety of foods regulated by the United States Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides FDA with greater powers and directs the agency to develop regulations that will focus the food industry on the prevention of foodborne illness, instead of the historical reactionary approach. This document is the last in a series of articles describing the legal fundamentals for food professionals and focuses on the provisions within FSMA that apply directly to laboratory accreditation, as FDA increases domestic and foreign laboratory capacity surrounding the sampling and testing of food products. The current understanding of the rule and applicability to the food testing industry, in general, is discussed.

INTRODUCTION

The FDA Food Safety Modernization Act (FSMA) is the first update to antiquated U.S. food safety laws in more than 70 years. FSMA and its subsequent regulations aim to improve the safety of domestically produced and imported foods regulated by the U.S. Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides FDA with greater powers and directs the agency to develop regulations that will allow the food industry to prevent the on-going problem of foodborne illness. In America, it is estimated that 1-in-6 people will contract a foodborne illness, causing 125,000 hospitalizations and 3,000 deaths each year (2).

This document is the last in a series of articles describing the legal essentials within FSMA, pertinent for food professionals. Previous articles in this series have reviewed implemented provisions, preventive controls, food defense, produce safety standards, foodborne illness surveillance, and imported food, under the context of the new law. This final article focuses on the provisions within FSMA, as shown in *Table 1*, that apply to accreditation of laboratories that

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The goal of every lab should be reliable results, which are achieved by proper sampling, sample preparation, test method utilization, technician competence and strong ethics.

FIGURE 1. Overall dynamics of the food testing industry.

conduct sampling and food testing for regulatory purposes. It also draws attention to other provisions in FSMA that have an impact on laboratory accreditation.

Laboratory accreditation offers a mechanism to support the generation of reliable data, based on a structured and independently verified quality assurance program. When combined with meaningful sampling plans, properly trained and competent laboratory technicians, scientifically sound analytical procedures and ethically responsible management personnel, it should ensure that associated laboratory data are accurate and reproducible. Such data serve as an important tool in supporting informed decisions about the safety and quality of direct human contact items, including food, pharmaceuticals, dietary supplements, drinking water, environmental samples, cosmetics, toiletries, household items, and toys.

A variety of accreditation programs exist, with guidance on best practices, available to both regulatory and commercial laboratories. Testing method guidance is based on the item or items to be tested and the purpose for and/or intended recipient of the data. Since regulatory agencies typically do not have legislative authority over private laboratories, there is opportunity for a broad range of interpretation and implementation in the technical analysis conducted, as well as reporting of associated data – unless the testing is conducted directly for regulatory purposes and prescriptive procedures are available. While the FDA Office of Regulatory Affairs interacts with and provides expectations for private laboratories via imported food items and mandated compliance with the Food, Drug, and Cosmetic Act as part of the detention without physical examination program, laboratory accreditation is not currently specified under either. Rather, it is the responsibility of the importer to ensure that the laboratory is providing technically sound and reliable data.

In the event FDA questions the integrity of the sampling and/or testing program, FDA is authorized to conduct on-site visits and review laboratory procedures. However, this type of action would not be considered an “official inspection” by FDA and participation by the private laboratory is considered voluntary (4).

It is important to draw a distinction between commercial (or private) food testing and testing conducted for regulatory purposes. (See Fig. 1 for an illustration of these differences.) The majority of food testing performed in the U.S. is considered private in that it is initiated by industry as a tool to verify the effectiveness of food safety programs, such as Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practices (GMPs), microbial intervention programs, raw material supplier performance, sanitation programs, and/or environmental control programs. Such testing often occurs internally within a company-owned laboratory or by a third-party commercial laboratory. In this case, testing data are used to make various process-associated decisions ranging from the effectiveness of a sanitation program, to product disposition, to compliance with customer expectations. Commercial testing encompasses a variety of procedures with differences largely based on cost, turn-around time, and validated performance.

Independent of commercial testing is regulatory testing, which is driven by routine surveillance programs or foodborne illness investigations. Regulatory testing is most often conducted by federal- and state-level government laboratories following standardized procedures, but may occur at a private laboratory under specific, contracted procedures. Regulatory testing methods are most often performance-driven.

While government laboratories have already pursued laboratory accreditation programs, adoption of such programs by commercial laboratories varies widely. The International Organization for Standardization (ISO) 17025 standard has

been used since 1999 as a basis for the accreditation of testing and calibration laboratories, including food-testing laboratories. ISO 17025 provides a framework upon which laboratories can build quality management systems to ensure data reliability. An ISO 17025 standard interpretation aid, issued by the Association of Analytical Communities International Analytical Laboratory Accreditation Criteria Committee (1), has served as an important tool for laboratories seeking accreditation, as well as for accrediting bodies to assure compliance and competency. While several local, state, and federal government laboratories have sought and achieved ISO 17025 accreditation, the population of commercial laboratories with ISO 17025 accreditation is relatively small. Increasing awareness of the importance of reliable data in supporting food safety programs has placed a spotlight on both laboratory competence and the use of validated, “fit for purpose” testing methods. Accordingly, food manufacturers and regulatory agencies are expressing competency and method expectations beyond those included in the ISO 17025 standard. However, such expectations are expressed with variable levels, based on whether the analysis is conducted on a commercial, third-party basis, or for regulatory purposes. Moreover, expectations that laboratory analysis is conducted according to ISO 17025 or analogous standards (such as those stated in the current Global Food Safety Initiative guidance) may lead to variations in the interpretation of equivalency. As expectations continue to evolve, guidance for establishing standards beyond ISO 17025 is warranted. This approach is needed to ensure laboratory competency and method performance, which in turn, will drive the generation of reliable data used to manage food safety programs worldwide.

The laboratory accreditation program, included as part of FSMA, is intended for laboratories that conduct regulatory testing on behalf of FDA, but may also include private laboratories. It is possible that the FSMA-directed accreditation program will encompass much of the ISO 17025 standard, although it is unclear at this time as to whether such an accreditation will sufficiently address FDA expectations. The relevance of laboratory accreditation per FSMA for private laboratories and non-regulatory food testing is currently unknown, as is whether expectations could potentially evolve into something similar to those for the pharmaceutical industry in that laboratory analysis is considered part of current Good Manufacturing Practices and thereby under the legal authority of FDA.

By comparison, non-regulatory testing for food items regulated by the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS), including meat, poultry, and processed egg products, also is conducted by commercial in-company or third-party laboratories without regulatory oversight. However, FSIS has recently issued guidance documents for regulated establishments to assist in the selection criteria for private laboratories, based on accreditation, technical competence, and validity of test methods. A recently updated guidance entitled “Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory,” is intended to provide free, easy-to-interpret information, including a laboratory assessment checklist for food processors to determine if the

laboratory, and associated data, are reliable (3). This guidance document highlights that FSIS laboratories are ISO 17025 accredited and that ISO 17025-accredited laboratories would meet their recommended guidance. The document also states that while laboratory accreditation is not a specific requirement, accreditation provides an increased level of confidence in the accuracy and quality of test results.

Laboratory accreditation per FSMA: Expanding FDA’s ability to test food, with quality and reliability

Section 202(a) of FSMA requires FDA to establish a testing program that uses accredited laboratories to augment the thirteen field laboratories currently operated by the agency and to utilize them to analyze samples in an effort to protect public health. The stated goal of Section 202(a) is to increase the number of laboratories that are qualified to perform testing of food. By expanding both the domestic and foreign capacity of food testing via accredited laboratories, an increased level of testing for routine surveillance, importing compliance, and foodborne illness investigations can exist. Additionally, the accreditation requirements are aimed to advance quality assurance and scientifically sound sampling programs, thereby driving the collection of reliable data more effectively. Quality is further enhanced by a grant program, under Section 210, which is designed to improve the capacity of laboratories to detect disease agents. Meanwhile, reliability is assured through direct reporting of test results to FDA, along with FDA review and periodic re-evaluation of accrediting bodies, and oversight of the laboratories they accredit, as described below.

Process of laboratory accreditation per FSMA

Under the program, FDA recognizes third-party, accrediting bodies that will accredit government and private laboratories to test food for regulatory purposes. These accredited labs will report results of public health concern directly to FDA. The agency is required to establish a registry of accrediting bodies and accredited laboratories that includes laboratory contact information. The accrediting body or the accredited laboratory is responsible for reporting any changes that would affect the recognition of the accrediting body or the accreditation of the laboratory.

What laboratories qualify for accreditation per FSMA?

Accredited laboratories may be government-operated or privately run. The only eligibility requirement is a demonstrated capability to conduct one or more sampling and analytical testing methodologies for food. Overseas laboratories also can be accredited, provided they meet the same standards applicable to laboratories located in the U.S.

Laboratories must be accredited for the particular sampling or analytical testing methodologies they use for analysis conducted for regulatory purposes. The scope of accreditation could be noted on the registry, enabling businesses to identify whether the laboratory is appropriate for the testing they are seeking.

An exception to this limitation is provided in cases where a new methodology has been developed and verified, but the laboratory has not yet been accredited to perform it, but only if the use of the new methodology is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak. This

approach ensures that the most advanced testing methodologies are available when needed, even if the accreditation process has yet to catch up with the advancement in methodologies.

Program expectations and accountability reviews

FDA is required to develop model sampling techniques and analyzing standards that an accredited laboratory must follow. The standards must include methods to ensure that appropriate sampling, analytical procedures, and commercially available techniques are followed. Reports of analyses must be certified as true and accurate. Other standards will ensure use of internal quality systems, procedures to evaluate and respond promptly to complaints regarding analyses, and employment of qualified personnel to perform the sampling and analysis. In addition to these specific requirements, FDA may establish other criteria.

To ensure the system remains accountable, FDA must review whether an accrediting body meets the requirements for recognition, no less than once every five years. The accreditation review may require that agency personnel accompany auditors from the accrediting body to assess whether or not the laboratory meets the criteria for recognition.

The agency is required to revoke its status if an accrediting body does not comply with FDA-mandated criteria. This approach may also result in laboratories losing their accreditation status as well. FDA is to specify terms and conditions that would allow an accredited laboratory to continue to perform testing under these circumstances.

FSMA-regulated food testing

Six months after establishing the accreditation program, food testing conducted for regulatory purposes (e.g., routine surveillance, importation, and foodborne illness outbreak investigation), must be performed by an accredited laboratory that is listed on FDA’s registry.

Circumstances when testing must be done by an accredited laboratory are when testing is conducted:

1. By or on behalf of the food’s owner or consignee in response to a specific testing requirement under the Food, Drug, and Cosmetic Act or its implementing regulations, or as required by FDA, when applied to address an identified or suspected food safety problem; and,
2. On behalf of the food’s owner or consignee in support of admission of an imported article of food, or as part of consecutive testing to resolve an import alert.

FDA has not issued proposed regulations on FSMA’s laboratory accreditation provisions; thus, it is unclear as to whether accredited in-company laboratories and/or third-party laboratories hired by a company, will be eligible to conduct such testing.

Reporting of results and other FSMA provisions

FSMA requires the accredited laboratory to send test results directly to FDA. The agency can waive this requirement if it determines the results do not contribute to the protection of public health. This requirement keeps the reporting system

TABLE 1. Location of laboratory accreditation provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S. Code

Description	Location		
	FSMA	FDCA	U.S. CODE
Domestic Capacity Building	§ 110		21 U.S.C. § 2204
Initial Report Describing Laboratory Networks	§ 110(a)(1)(E)		21 U.S.C. § 2204(a)(1)(E)
Report on Laboratory Capability, Progress toward Accreditation	§ 110(c)		21 U.S.C. § 2204(c)
Laboratory Accreditation	§ 202(a)		
Recognition of Accreditation and Program Requirements		§ 422(a)	21 U.S.C. § 350k(a)
Testing Procedures and Reporting		§ 422(b)	21 U.S.C. § 350k(b)
Food Emergency Response Network	§ 202(b)		21 U.S.C. § 2221
Grants to Build Laboratory Capacity	§ 210	§ 1009(a)(3)	21 U.S.C. § 399(a)(3).
Mutual Recognition of Foreign Laboratory Methods and Testing	§ 305(c)(6)		

from being overwhelmed with test results that fail to call attention to real or potential food safety problems. The waiver must be issued through regulations, suggesting this authority is not meant to be a case-by-case waiver.

FSMA does include a specific requirement for FDA to review testing by accredited state or local government laboratories if the results led the state to order a food recall. The review would be for the purpose to determine whether a national recall is warranted, or if FDA needs to take other compliance or enforcement actions.

Food emergency response network

While not a part of the accreditation program, Section 202(b) of FSMA requires FDA to report biennially on the implementation of a Food Emergency Response Network. This network is intended to provide surveillance, rapid detection, and surge capacity in cases of a bioterrorism attack on the food supply or other large-scale food-related emergency.

Final issuance of the rule

FSMA set a deadline of Jan. 4, 2013, for establishing the accreditation program with a requirement to use accredited laboratories, beginning six months later. FDA missed the statutory deadline. Presently, it is unclear when the program will start.

What does this rule mean for consumers?

Testing doesn't make food safe; food safety programs, processes, and associated verifications drive quality and safety of food production. Verifications often include testing; but finished product pathogen testing is rarely a meaningful avenue of verification. This discrepancy may be due to the inadequacy

of population sampling, as it relates to a very low incidence of the defect (i.e., pathogen) meant to be detected.

FSMA has given FDA more tools to regulate the foods under FDA's purview, making the agency more robust. It is anticipated that this approach will lead to fewer outbreaks, illnesses, and deaths attributable to foodborne pathogens in the U.S. Having the ability to establish, implement and oversee laboratory accreditation guidelines, as well as broaden domestic and foreign laboratory capacity, will support more efficient production of reliable data, and therefore, support FDA's efforts to protect public health.

What does this mean for food safety professionals?

Placing greater emphasis on laboratory expectations, including third-party accreditation, quality programs, technical competence, and use of validated methods allows for more clarity, and thereby, improved consistency across the industry in producing reliable data. Since FSMA currently applies to regulatory testing, commercial labs may or may not choose to implement such practices on all testing conducted at the facility, since testing would still be voluntary. Ideally, companies performing and/or requesting food testing to support important decisions about their process and products, including compliance with regulatory and global quality standards, demonstrate the value of providing specific laboratory expectations and for laboratory accreditation across the industry.

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