

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**