

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