SPECIAL INTEREST PAPER

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 distributers).
- 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 agricultrual 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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