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Q&A: The Food Safety Modernization Act

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Given the U.S. Food and Drug Administration's (FDA) on-going activities to implement the expansive Food Safety Modernization Act (FSMA), signed into law on Jan. 4, 2011, the NGFA is receiving numerous inquiries pertaining to how various provisions may affect the grain, feed, processing and export industry.

For that reason, the NGFA is providing the following responses to some of the most frequently asked questions. Because FDA has yet to issue final regulations for most of FSMA's key provisions, the information provided is based on the statutory language of the act and regulatory language that has been proposed to date by the agency.

1. What does FSMA require FDA to do?

A. FSMA greatly expands FDA's authority to regulate the U.S. food and feed supply. The law requires FDA to issue more than 50 regulations, guidance documents and reports pertaining to various food/feed safety issues. Many of FDA's FSMA-related activities will affect the grain, feed, processing and export industry.

2. What types of facilities are covered by FSMA?

A. Many of the provisions within the law apply to facilities required to register with FDA under the Bioterrorism Act of 2002. Under the Bioterrorism Act, facilities – both domestic and foreign – that manufacture, process, pack or hold (store) food are required to register.

Importantly, the law covers "food," as defined in the federal Food, Drug and Cosmetic Act, as products intended for consumption by humans or animals in the United States. It also applies to such products regardless of whether they are shipped in interstate or intrastate commerce.

Thus, under this broad umbrella, the law applies to, among others, grain elevators, feed and feed ingredient and pet food manufacturers, grain processors, biofuels producers manufacturing co-products like distillers dried grains for use as feed ingredients, and exporters of grains, feed and feed ingredients, and processed commodities.

In addition, some of the new regulations mandated by FSMA will affect facilities and entities that are not required to register with FDA as a food facility. For example, FDA's rules for foreign supplier verification programs and sanitary transportation of food/feed will apply to entities regardless of whether they are required to register as a food facility.

Based on FDA's proposals, the following table indicates the types of commercial grain, feed, processing and export facilities/entities that would be covered by FSMA-related rules:

Subject of Rule	Anticipated Coverage - Who/What Will be Affected
Current Good Manufacturing Practice (CGMP) and Preventive Controls for Human Food	• Grain processors producing human food **covered** • Grain elevators solely "holding" grain **exempt**
CGMP and Preventive Controls for Animal Feed and Pet Food	• Animal feed/pet food manufacturers **covered** • Grain elevators solely "holding" grain **exempt**
Foreign Supplier Verification Programs	• Importers of foreign food/feed/grain **covered** • Grain elevators importing foreign grain **likely covered**
Accreditation of Third-Party Auditors	• Facilities/entities importing "high-risk" foreign foods, and foreign foods qualifying for "expedited" entry into U.S. **covered**
Sanitary Transportation of Food/Feed/Grain	• Shippers/carriers/receivers involved in truck and rail transportation of food/feed/grain **covered**
Food Defense/ Intentional Adulteration	• Grain processors producing human food **covered** • Grain elevators solely "holding" grain, animal feed and pet food facilities **exempt**

3. Does FSMA cover farms?

A. Farms, as well as restaurants and retail food establishments, are not required to register with FDA under the Bioterrorism Act. Therefore, aside from the FSMA-mandated produce safety rule that applies to fruits and vegetables, the law does not apply to farms that are exempt from the registration requirement.

Importantly, under FSMA, FDA has proposed to define "farm" in the following manner. Farm means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities:

1. Pack or hold raw agricultural commodities;
2. Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (3)(ii)(A) of this definition; and
3. Manufacture/process food, provided that:

    i. All food used in such activities is consumed on that farm or another farm under the same ownership; or

ii. Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

A. Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
B. Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

4. What about transporters like trucking firms, barge operators and railroads? Are they covered by FSMA?

A. Transporters are not required to register as a food facility under the Bioterrorism Act since they hold food only to transport it from one location to another. Since transporters are not required to register as a food facility, they will not be covered by FDA's rules for Current Good Manufacturing Practice (CGMP) and preventive controls, foreign supplier verification programs and food defense/intentional adulteration.

However, FSMA directed FDA to reinitiate rulemaking associated with the Sanitary Food Transportation Act of 2005, which will apply to truck and rail transporters and address various issues associated with the safe transportation of food, feed and grain products. Significantly, transportation of food by water (e.g. barge and vessel) or air will not be covered by FDA's rule.

5. Will small companies be exempt from FSMA requirements?

A. One of the most significant FSMA-related rules – CGMP and preventive controls for animal feed/pet food – will require most covered facilities to develop and implement a written food safety plan in which the facility implements controls to prevent significant hazards from causing feed/pet food products to be adulterated or misbranded. FSMA requires FDA to establish modified hazard analysis and preventive controls requirements for "qualified facilities." In general, as proposed by FDA, a qualified facility would be a very small business – one with less than $2.5 million in total annual sales of animal feed/pet food.

Within the CGMP and preventive controls rule, FDA has proposed that qualified facilities would need to identify potential hazards associated with the animal feed/pet food manufactured, processed, packed, or held at the facility, and demonstrate that identified hazards are being controlled. However, the required level of recordkeeping and documentation associated with the control of such hazards would not be as extensive as those required for facilities that do not meet the definition of a qualified facility.

6. Doesn't FSMA contain language that exempts facilities that only store and distribute grains and oilseeds from the hazard analysis and preventive controls requirements?

A. FSMA contains language that states FDA may, by regulation, exempt or modify the requirements for compliance under the hazard analysis and preventive controls section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other

than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.

Within its supplemental CGMP and preventive controls rules for human food and animal feed/pet food, FDA has proposed that facilities solely engaged in storing raw agricultural commodities – such as grains and oilseeds – would be exempt from the regulations' requirements. In doing so, FDA clarified that being "solely engaged in storage" encompasses activities that grain elevators perform to safely and effectively store grains and oilseeds. For example, FDA's current position is that, among others, the activities of drying, screening, blending and fumigation of grains and oilseeds inherently are associated with being "solely engaged in storage."

7. What food/feed safety hazards will covered facilities need to address within their food and feed safety plans?

A. FSMA requires facilities "to identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility." Within FDA's proposed animal feed/pet food rule, the agency defines "hazard" to mean "a biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in humans or animals in the absence of its control."

Sources of information concerning hazards that facilities likely will need to consider include:

- Hazards for which FDA already has established tolerances or action levels;
- Hazards associated with recalls and reports submitted to FDA's Reportable Food Registry; and
- Further FDA hazard guidance currently under development.

Within the hazard analysis provisions in the proposed rule, facilities first would be required to identify known or reasonably foreseeable hazards associated with the facility. Next, facilities would need to narrow identified hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal feed/pet food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in animal feed or pet food, as well as components to manage those controls. Such resulting hazards, if any, would be designated as "significant" and be subject to FDA's preventive controls requirements. If, through the hazard analysis, no "significant" hazards are identified, then the facility would have no further obligations under the preventive controls regulation.

8. What preventive controls will be deemed to be effective in controlling identified "significant" hazards?

A. Within its proposed animal feed/pet food rule, FDA defines "preventive control" to mean "those risk-based, reasonably appropriate procedures, practices, and processes that a [knowledgeable] person would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding at the time of the analysis." FDA is developing further guidance for this topic.

9. For covered facilities, will FDA's hazard analysis and preventive controls requirements require a hazard analysis and critical control point (HACCP) plan?

A. Within FDA's proposed CGMP and preventive controls rule for animal feed/pet food, the agency states, "FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 [hazard analysis and preventive controls] of FSMA." However, one distinction that FDA has proposed to make between its hazard analysis and preventive controls requirements and HACCP is that covered facilities would not need to perform and document the five preliminary steps typically associated with developing and implementing a HACCP plan.

Significantly, and as addressed in question 7, if a facility conducts the required hazard analysis and identifies no "significant" hazards, then the use of preventive controls, along with associated management activities, would not be required under the regulation. However, if a facility does identify a "significant" hazard within its operation, then the facility would need to implement preventive controls in accordance with the regulation, which consists of the use of HACCP-like principles.

10. Will covered facilities need to have their written food safety plans "certified" by a third-party auditor?

A. Absolutely not. FSMA specifically states that the regulations to be developed by FDA "shall not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party."

11. Within its proposed CGMP and preventive controls rule for animal feed/pet food, FDA proposes that a "qualified individual" perform or oversee activities associated with the required food safety plan. Who is a "qualified individual?"

A. FDA proposes that a "qualified individual" would be one who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or be otherwise qualified through job experience. FDA also has proposed that the qualified individual may be, but is not required to be, an employee of the facility.

Related to this proposed requirement, FDA currently is funding activities associated with the Food Safety Preventive Controls Alliance, which is responsible for developing the standardized curriculum that FDA will recognize as being adequate for training purposes. The NGFA serves on the Alliance's organizing and steering committees, and is actively involved in developing the curriculum, which will be made available in early 2016.

12. Will covered facilities need to submit their written food safety plans to FDA in advance of an inspection?

A. FDA did not propose this requirement in its CGMP and preventive controls rules. The agency previously had expressed interest in this concept, but has not attempted to move it forward through its proposed regulations.

13. Does FSMA expand the traceability requirements for food?

A. FSMA requires FDA to initiate rulemaking on enhancing the tracking and tracing of "high-risk" foods to evaluate whether additional recordkeeping requirements would assist in preventing or mitigating outbreaks of foodborne illnesses. FDA has yet to define "high-risk" foods, but when doing so is required to consider known safety risks of a food based on foodborne illness data and the likelihood that a particular food has a high potential risk for contamination. FDA has conducted two pilot projects pertaining to enhanced traceability of foods, and has sought comments on recommendations emanating from the projects.

Importantly, FSMA expressly prohibits FDA from imposing recordkeeping requirements that would limit the commingling of raw agricultural commodities (except raw fruits and vegetables), a legislative provision that the NGFA assisted in drafting. Further, FSMA states that facilities handling such raw commodities (like grains and oilseeds) on a commingled basis are subject to the existing Bioterrorism Act requirement to maintain records sufficient to identify the immediate previous source and immediate subsequent recipient of the commodity(ies). Thus, it is anticipated that the law's potential enhanced product-tracing and recordkeeping requirements will have a negligible, if any, impact on facilities storing raw grains and oilseeds, as well as on most manufacturers of feed and feed ingredients – given the requirement that it be applied only to "high-risk" products.

14. Will covered facilities be required to have supplier verification and approval programs?

A. FDA's supplemental CGMP and preventive controls rules included proposed requirements for supplier verification and approval programs. However, such requirements only would apply when a hazard analysis identifies a "significant" hazard associated with the supplier's product.

15. When will FDA complete its FSMA-related rulemakings? And when will covered facilities/entities need to comply with the requirements?

A. In response to the court settlement reached by FDA in a lawsuit filed by consumer groups concerning dates for finalizing the FSMA-related food and feed safety rules, deadlines have been established for issuing the major FSMA-related final rules. The table on the following page indicates the deadlines for issuing final rules, along with the proposed compliance timeframes for covered facilities/entities.

16. How can I get more information about FSMA?

A. FSMA-related questions may be directed to NGFA Vice President of Feed Services David Fairfield at (712) 243-4035 or dfairfield@ngfa.org.

Subject of Rule	Deadline for Publishing Final Rule	Proposed Compliance Dates for Covered Facilities/Entities
Produce Safety (applies to farms/businesses producing fruits, vegetables)	**Oct. 31, 2015**	• **Four years** – very small businesses (more than $25,000 but no more than $250,000 in annual produce sales) • **Three years** – small businesses (more than $250,000 but no more than $500,000 in produce sales) • **Two years** – all other farms/businesses • Compliance dates for water quality standards, and related testing and recordkeeping provisions would be an additional two years beyond the compliance dates for the rest of the final rule
Current Good Manufacturing Practice (CGMP) and Preventive Controls for Human Food	**Aug. 30, 2015**	• **One year** – large businesses (500 employees or more) • **Two years** – small businesses (less than 500 employees) • **Three years** – very small businesses (less than $1 million annual sales of human food)
CGMP and Preventive Controls for Animal Feed and Pet Food	**Aug. 30, 2015**	• **One year** – large businesses (500 employees or more) • **Two years** – small businesses (less than 500 employees) • **Three years** – very small businesses (less than $2.5 million annual sales of animal feed/pet food)
Foreign Supplier Verification Programs	**Oct. 31, 2015**	Importers will be required to comply six months after the foreign supplier of food is required to comply with CGMP and preventive controls rule for human food and/or animal feed/pet food.
Accreditation of Third-Party Auditors	**Oct. 31, 2015**	The FDA intends to implement this program as soon as possible after publication of the final rule and the final Model Accreditation Standards, which will be published separately.
Sanitary Transportation of Food/Feed/Grain	**March 31, 2016**	• **Two years** – small businesses (less than 500 employees) and small motor carriers (who are not also shippers and/or receivers and have less than $25.5 million in annual receipts) • **One year** – businesses and motor carriers that are not small
Food Defense/ Intentional Adulteration	**May 31, 2016**	• **Three years** – very small businesses (less than $10,000,000 in total annual sales of food) • **Two years** – small businesses (less than 500 employees) • **One year** – other businesses that are not “small” or “very small” and do not otherwise qualify for exemptions