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Q&A: The Food Safety Modernization Act

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The U.S. Food and Drug Administration (FDA) has broad authority under the Federal Food Drug and Cosmetic Act (FFDCA) to regulate the safety of food. This authority extends not only to human food, but also to animal food (feed and pet food) and their components, such as grains, oilseeds, animal- and plant-based ingredients, minerals, vitamins and other items.

Further, FDA has general authority to inspect human food, animal food and grain-handling facilities to evaluate whether human food, animal food, and raw agricultural commodities, such as grains and oilseeds, are being held (stored), processed, packed and distributed in accordance with the agency's requirements.

The Food Safety Modernization Act (FSMA) – signed into law on Jan. 4, 2011 – significantly expanded FDA's authorities and regulatory reach, and mandated that the agency issue significant new prevention-orientated regulatory requirements for the human and animal food industries, including facilities in the grain, animal feed and feed ingredient, grain processing, pet food, and biofuels sectors.

Following are responses to some of the most frequently asked questions that have been posed to the NGFA about FSMA and its implementing regulations.

1. *What types of facilities are covered by FSMA?*

A. Most FSMA regulations apply to operations required to register with FDA as food facilities under the Bioterrorism Act of 2002. Among the types of facilities required to register with FDA are grain elevators, feed and feed ingredient and pet food manufacturers, grain processors, and biofuels producers manufacturing co-products like distillers dried grains that are intended for use as animal feed. The regulations also apply to food, feed, and grain products whether they are shipped in interstate or intrastate commerce.

In addition, some of the new regulations implemented under FSMA apply to operations 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 human and animal food apply to entities regardless of whether they are required to register as a food facility.

2. ***What FSMA regulations has FDA issued, and to what types of operations do they apply?***

A. FDA has completed rulemaking for all of the major rules required under FSMA. The following table lists six of the major FSMA rules and, in general, the types of commercial grain, feed, and

processing entities to which they apply. However, this table provides only a summary of general applicability and its contents should not be relied upon to definitively determine whether a specific operation or facility is subject to a given regulation or requirement. Further, several of FDA's regulations include exemptions and/or modified requirements for certain operations and subsets of types of facilities that otherwise would be subject to a given regulation.

Subject of Rule	Type of Operation
Current Good Manufacturing Practice (CGMP) and Preventive Controls for Human Food	• Processing/packing human food **covered** • Holding grain **exempt, if the facility is solely engaged in just holding and distributing grain**
CGMP and Preventive Controls for Food for Animals	• Processing/packing animal food and holding processed animal food **covered** • Holding grain **exempt, if the facility is solely engaged in just holding and distributing grain.**
Foreign Supplier Verification Programs	• Importers of foreign human and animal food **covered** *(see exception below)* • Importers of foreign grain raw agricultural commodities that are solely engaged in the storage of grain intended for further distribution or processing, and grain importers that do not take physical possession of the grain they import but instead arrange for the delivery of the grain to others **exempt**
Accreditation of Third-Party Certification Programs/Auditors	• Importing "high-risk" foreign foods, and foreign foods qualifying for "expedited" entry into U.S. **covered**
Sanitary Transportation of Human and Animal Food	• Shippers/loaders/carriers/receivers involved in truck and rail transportation of human food and animal food, including grain, **covered**
Food Defense/Intentional Adulteration	• Processing/packing/holding human food **covered** • Holding grain **exempt**, if the facility is solely engaged in just holding and distributing grain; processing/packing/holding animal food **exempt**

3. ***What does it mean for a facility to be solely engaged in holding and distributing grain?***

A. A facility is solely engaged in holding and distributing grain when no other food-related activities subject to the FSMA-related rules for CGMP and preventive controls for human and/or animal food are being performed at the facility.

As such, FDA's definition of "facility" is relevant to determining whether a facility is exempt from the rules for CGMP and preventive controls for human food and animal food. FDA defines the term "facility" within its regulations, which states in relevant part: "Facility means any establishment, structure, or structures under one ownership at one general physical location…that manufactures/processes, packs, or holds food for consumption in the United States. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership."

To provide guidance on what constitutes a single facility, FDA states, "one factor for determining whether a business is one or two facilities is through real estate records, because a property line could demonstrate that several buildings are on the same lot, and therefore, are the same facility."

FDA states in its definition of "facility" that one facility could have several operations in separate physical structures. For example, a single facility may store raw agricultural commodities in one structure (e.g., grain elevator) destined for animal food and manufacture animal food in another structure (e.g., feed mill). In this example, FDA says the facility is **not** "solely engaged" in the holding of raw agricultural commodities and, as a result, the grain elevator located at the facility is not exempt from requirements established by the rule for CGMP and preventive controls for animal food.

Therefore, if a facility consists of a grain elevator plus other food-related operations that involve more than holding and distributing raw grains or oilseeds (e.g., grain processing, feed processing, human food processing) that are subject to FSMA-related regulations for CGMP and preventive controls, then FDA does **not** consider such a facility to be "solely engaged" in holding and distributing grain. As such, the grain elevator (and other food-related activities) at the facility is **not** considered to be exempt from requirements established by the rules for CGMP and preventive controls for human food and/or animal food.

4. ***I operate a grain elevator that is located at a facility solely engaged in holding and distributing grain. What FDA/FSMA requirements apply to my operation?***

A. FSMA's rule for Sanitary Transportation for Human and Animal Food apply to the grain elevator if it distributes grain by truck or rail. Other FDA requirements that likely apply to the grain elevator include: 1) general provisions of the FFDCA that require grain to be held under sanitary conditions; 2) FDA action and guidance levels for mycotoxins that may be present in grain; 3) FDA regulations designed to prevent Bovine Spongiform Encephalopathy (BSE) that

cover grain intended to be fed to cattle or other ruminants; 4) establishing and maintaining traceability records as required by the 2002 Bioterrorism Act; and 5) reporting to the FDA via the Reportable Food Registry if grain is distributed that has the potential to cause serious adverse health consequences or death to humans or animals.

5. *Does FDA have authority to inspect my grain elevator if my facility is solely engaged in holding and distributing grain?*

A. Yes. FDA's authority provides the agency's investigators with the right to inspect facilities to evaluate whether human and animal food, including grain, is being stored, processed, packed and distributed in accordance with provisions of the FFDCA and its associated regulations.

It is a "prohibited act" for regulated facilities to refuse to permit access to or copying of any record required under FDA's regulations, or to refuse to permit an FDA investigator entry or inspection of a facility or vehicle. FDA is not obligated to have a warrant for conducting an inspection.

Under its inspection authority, FDA is authorized to: 1) enter "any factory, warehouse, or establishment in which food [is] manufactured, processed, packed, or held …" and "any vehicle….;" 2) inspect "at reasonable times and within reasonable limits and in a reasonable manner;" and 3) inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling thereon."

6. *Are farms covered by FSMA?*

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.

FDA defines a "primary production farm" in the following manner. A *primary production 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.

FDA's definition for "farm" can be found at Title 21 Code of Federal Regulations Part 1.227.

7. *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 are not covered by FDA's rules for CGMP and preventive controls, foreign supplier verification programs and food defense/intentional adulteration.

However, FDA's rule for Sanitary Transportation of Human and Animal Food does apply to truck and rail transporters and establishes a variety of requirements associated with the safe transportation of food, feed and grain products. Significantly, transportation of food by water and air is exempt from the rule.

8. *My facility is involved in distributing animal feed and grain and subject to the rule for Sanitary Transportation of Human and Animal Food. What does this rule require me to do?*

A. The rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food. Depending on the activities you perform, you may be one or more of these entities as defined by the rule.

In general, the rule establishes requirements for the following key areas:

- **Vehicles and transportation equipment**: The design and maintenance of vehicles and transportation equipment are to ensure that food being transported does not become unsafe. For example, they must be suitable and adequately cleanable for their intended use for the safe transport of food.

- **Transportation operations:** The measures taken during transportation are to ensure food safety, such as preventing contamination of ready-to-eat food from touching raw food, protection of food from contamination by non-food items in the same load or

previous load, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.

- **Training:** Documented training of carrier personnel in sanitary food transportation practices is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport. FDA has developed an on-line video to assist carriers in complying with this requirement.

- **Records:** Records of written procedures, agreements and training (carriers) required by the rule are to be established and maintained. The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.

Provisions within the rule establish specific requirements for shippers, loaders, carriers and receivers for each of these key areas. Please see the rule for Sanitary Transportation of Human and Animal Food for more information.

9*. I operate an animal food manufacturing facility that is subject to the rule for CGMP and Preventive Controls for Food for Animals. What does this rule require?*

A. The rule for CGMP and Preventive Controls for Food for Animals requires large and small businesses to: 1) comply with current good manufacturing practice requirements that establish necessary conditions and practices to ensure the safety of animal food that is manufactured, packed or held; and 2) develop and implement a written food safety plan that includes a hazard analysis of "known or reasonably foreseeable hazards" associated with the facility and type of animal food and use of preventive controls, as necessary, to ensure that hazards requiring a preventive control are significantly minimized or prevented.

Animal food facilities that are "very small businesses" are to comply with CGMP requirements and submit attestations to FDA that they are controlling hazards or complying with applicable state, local, tribal or other non-federal food safety law.

Please see the rule for CGMP and Preventive Controls for Food for Animals for more information.

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

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

11. ***When do I need to comply with the new FSMA rules?***

A. The following table lists compliance dates established for the major FSMA rules that are most likely to impact facilities involved in the grain and feed industry. In general, compliance dates were established based on business size, with smaller firms being given more time to comply. Note that all compliance dates for the rules have already passed. As such, if a new food/feed facility begins operation, FDA expects such a facility to be in compliance with applicable rules at the time of start-up. That is, FDA provides no compliance "grace" period for new operations.

Final Rule	Date Issued	Compliance Date		
		Large Business*	Small Business**	Very Small Business***
CGMP and Preventive Controls for Human Food	Sept. 17, 2015	Sept. 19, 2016	Sept. 18, 2017	Sept. 17, 2018
CGMP and Preventive Controls for Food for Animals	Sept. 17, 2015	Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PCs)	Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PCs)	Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PCs)
Foreign Supplier Verification Program	Nov. 27, 2015	May 30, 2017§	Not applicable	Not applicable
Sanitary Transportation of Human and Animal Food	April 6, 2016	April 6, 2017	April 6, 2018	Not applicable
Food Defense/Intentional Adulteration	May 27, 2016	July 26, 2019	July 26, 2020	July 26, 2021

*** Large Business Definitions:** *All Rules* – Business that does not meet the definitions for "small business" or "very small business"

**** Small Business Definitions:**

- *CGMP and Preventive Control Rules for Human and Animal Food* – Business with less than 500 full-time equivalent employees
- *Sanitary Transportation* – Business, other than a motor carrier who are not also shippers and/or receivers, employing fewer than 500 persons and motor carriers having less than $27.5 million in annual receipts
- *Food Defense/Intentional Adulteration* – Business with less than 500 full-time equivalent employees

***** Very Small Business Definitions:**

- *Preventive Controls Human Food* – Business with less than $1 million in annual human food sales plus market value of human food not sold;
- *Preventive Controls for Animal Food* – Business with less than $2.5 million in animal food sales plus market value of animal food not sold;
- *Food Defense/Intentional Adulteration* – Business averaging less than $10,000,000 in annual human food sales plus market value of human food not sold

§ FSVP: All importers are to comply with FSVP requirements 18 months after the final rule or six months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later. "Very small importers" (importers with average annual sales of less than $1 million for human food and $2.5 million for animal food plus market value of human food or animal food not sold) and "importers of food from very small foreign suppliers" are subject to modified requirements.

12. *Within the rule for CGMP and Preventive Controls for Food for Animals, FDA requires that a "preventive controls qualified individual" or "PCQI" perform or oversee activities associated with the required food safety plan. Who is a "PCQI*?"

A: FDA defines a "PCQI" as an individual 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's rule states that a PCQI may be, but is not required to be, an employee of the facility.

The Food Safety Preventive Controls Alliance (FSPCA) has developed the standardized animal food curriculum that FDA recognizes as being adequate for PCQI training purposes. The FSPCA PCQI training course consists of about 20 hours of instructional content that is delivered by FSPCA Lead Instructors in either face-to-face, virtual, or blended (virtual and face-to-face) format. NGFA is active within the FSPCA and frequently conducts PCQI training courses.

13. *Are facilities covered by the FSMA rules for CGMP and preventive controls required to have supplier approval programs?*

A: FDA's CGMP and preventive controls rules include requirements for supplier approval and verification programs. However, such requirements only apply when the facility's hazard analysis identifies a hazard requiring a preventive control in a raw material or ingredient and the facility relies upon its supplier of the raw material or ingredient to control the hazard prior to receipt by the facility.

14. *Did FSMA expand the traceability requirements for food?*

A: FSMA required 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. In response, FDA on Nov. 15, 2022, issued a final rule to establish additional traceability requirements for certain foods. The final rule standardizes the data elements and information covered entities are to establish, maintain, and communicate to the next entity in the supply chain to facilitate rapid and accurate traceability of foods identified within FDA's "Food Traceability List" (FTL). Among the foods included by FDA within the final FTL are soft and semi-soft cheeses, leafy greens, fresh cut fruits and vegetables, some types of fish, shell eggs, and nut butters. Grains and oilseeds are not included in the FLT. Significantly, the final rule does not establish additional traceability requirements for animal feed or pet food. Nor do the additional traceability requirements apply to animal foods that contain foods (or by-products from the production of food) identified in the FTL.

15. *How can I get more information about FSMA?*

A. FSMA-related questions may be directed to NGFA Senior Vice President David Fairfield at dfairfield@ngfa.org.