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Dave Fairfield, NGFA Vice President of Feed Services

FDA Publishes Final FSMA Preventive Control Rules

The U.S. Food and Drug Administration (FDA) on Sept. 17 published its final rules mandated by the Food Safety Modernization Act (FSMA) to establish requirements for current good manufacturing practices (CGMPs), hazard analysis and risk-based preventive controls, and supply-chain programs that apply to human food and animal feed.

The two new rules will serve as the “cornerstones” of the new prevention-orientated regulatory framework for food and feed being implemented by FDA under authority provided by FSMA. In addition to these two rules, FDA is under a court order to publish five other major FSMA-related rulemakings by March 31, 2016. Those rules will address produce safety, foreign supplier verification programs, accreditation of third-party auditors, intentional adulteration of food, and sanitary transportation of food and feed.

Overview of FDA’s Final Regulations for Animal Feed and Pet Food: FDA’s final regulations apply to domestic and foreign facilities that manufacture, process, pack or hold animal feed and/or pet food, and ingredients used in such products. Generally, with some exceptions, that means the new requirements apply to facilities that are required to register with FDA under the agency’s existing facility registration regulations implemented as part of the Bioterrorism Act.

Significantly, and as strongly advocated for by the NGFA, FDA has exempted from both its human food and animal feed final rules grain elevators and other facilities that are solely engaged in storing raw agricultural commodities (except fruits and vegetables) intended for further distribution and processing. As such, facilities qualifying for the exemption are not obligated to comply with the rules’ requirements for current good manufacturing practices (CGMPs), hazard analysis and risk-based preventive controls, or supply-chain programs.

Importantly, the grain elevator exemption is available only to facilities that solely store “grain,” as defined by FDA. Examples of products that are included within FDA’s definition of “grain” are barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed). Among the products that FDA classifies as “fruit” are lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peanuts, tree nuts and seeds for direct consumption. Under the rule, facilities that store such “fruits” are exempt from FDA’s CGMP regulations, but are not exempt from the requirements established within the agency’s regulations for hazard analysis and risk-based preventive controls and supply-chain programs.

New Employee Training and Qualification Requirements: Under the final rule, individuals at covered facilities are to have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal feed as appropriate to the individual’s assigned duties. The rule specifically establishes that employees are to be appropriately trained on the principles of animal feed hygiene and animal feed safety, including

the importance of employee health and personal hygiene. Although the rule does not prescribe the content of training or its frequency, FDA expects training to occur before working in production operations and periodic refresher training thereafter. In addition, training records are to be maintained.

Within the preamble of the rule, FDA states that it expects that much of the required training will be provided in-house by knowledgeable employees already at facilities. In addition, FDA states that the training material being developed by the Food Safety Preventive Controls Alliance (FSPCA) will be useful to facilities when conducting in-house training. The NGFA has served as an active member of the FSPCA since its inception in 2011, with NGFA Vice President of Feed Services David Fairfield currently serving as chair of the FSPCA's animal feed-related activities.

The final rule for animal feed and pet food has three distinct subparts that establish requirements for covered facilities to: 1) adhere to specified CGMPs; 2) conduct a hazard analysis and implement risk-based preventive controls; and 3) implement a supply-chain program to verify that its supplier of a raw material or ingredient controls a hazard if the facility relies on the supplier to control such a hazard.

CGMPs: The animal feed and pet food CGMPs establish baseline standards for facility operations and conditions. The new regulation requires covered facilities to address issues such as hygienic personnel practices and training; facility operations, maintenance, and sanitation; equipment design, use, and maintenance; processes and controls; and warehousing and distribution.

Some of the key requirements established by the new CGMPs are:

- Personnel are to maintain adequate personal cleanliness, including washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against animal feed contamination.
- The overall cleanliness of the plant is to be under the supervision of one or more competent individuals assigned responsibility for this function.
- Materials not used in animal feed or those not necessary for plant and equipment maintenance and operation (e.g., fertilizers and pesticides) must be stored in an area of the plant where animal feed is not manufactured, processed, or exposed.
- Raw materials and other ingredients:
 - Must be examined to ensure that they are suitable for manufacturing and processing into animal feed and must be handled under conditions that will protect against contamination and minimize deterioration.
 - Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal feed that can cause injury or illness to animals or humans.

- Water must be adequate for the facility's operations, must be derived from an adequate source, and must be safe for its intended use.
- Plumbing must be designed, installed, and maintained to avoid being a source of contamination to animal feed, water supplies, equipment, or utensils, or creating an unsanitary condition.
- Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal feed must be examined prior to use to protect against the contamination of animal feed from the container or vehicle.
- Animal feed returned from distribution must be assessed for animal feed safety to determine the appropriate disposition. Returned animal feed must be identified as such and segregated until assessed.

Significantly, the new CGMPs are an overarching set of requirements for all animal feed and pet food. Therefore, facilities producing medicated animal feeds are subject to both the new CGMPs and FDA's existing CGMP regulations for medicated feeds.

As previously noted, FDA's CGMP regulations generally apply to facilities that are required to register with FDA under the agency's existing facility registration requirements. As such, farms, as defined by FDA, are exempt from the CGMPs. However, FDA has expressed concern that certain feed manufacturing operations associated with vertically integrated farms are exempt from the regulation.

Therefore, FDA has announced that it intends to publish a proposed rule in the future that would require some feed mill operations that currently are part of a farm to implement the CGMPs established by the final rule. FDA officials have stated that a rulemaking process to address this topic may occur within the next two years.

Hazard Analysis and Risk-Based Preventive Controls: The final rule requires covered facilities to establish and implement an animal feed safety system that includes an analysis of hazards and implementation of risk-based preventive controls. To do so, the rule requires a "preventive controls qualified individual" to develop and implement a written animal feed safety plan for the facility.

The rule defines a "preventive controls qualified individual" to mean a "qualified 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 is otherwise qualified through job experience to develop and apply a food safety system." Therefore, a "preventive controls qualified individual" may be qualified by successfully completing training under a standardized curriculum recognized as adequate by FDA or by job experience. The standardized curriculum referred to within the definition is that currently being developed by the FSPCA.

The required written animal feed safety plan mandated by the rule is to include:

- **Hazard Analysis:** A hazard analysis is to be conducted by the facility to identify and evaluate “known or reasonably foreseeable hazards” within their operation. The hazard analysis is to include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
- **Preventive Controls:** Preventive controls are required to be implemented for those identified hazards that the “preventive controls qualified individual” determines require a preventive control to be minimized or prevented. Significantly, this determination of whether a hazard requires a preventive control governs whether a facility needs to comply with other requirements within the preventive controls regulation. If a facility conducts a hazard analysis and appropriately determines that the facility has no hazards requiring a preventive control, then the facility has complied with all of its obligations under the preventive controls regulation. The NGFA will be interacting extensively with FDA to gain further clarification on how facilities are to determine whether a hazard within their operation requires a preventive control.
- **Recall Plan:** For animal feed and/or pet food with a hazard requiring a preventive control, the facility is required to establish and implement a recall plan to effectively withdraw products from the market and notify consumers if a safety concern associated with the product arises.
- **Oversight and Management of Preventive Controls:** For hazards determined to require a preventive control, the rule requires that management controls be implemented to ensure the effectiveness of the preventive control. As appropriate to the preventive control, such management controls are to include:
 - **Monitoring Procedures:** These procedures are to be designed to provide assurance that preventive controls are consistently performed.
 - **Verification Activities:** These activities are required to ensure that preventive controls are consistently implemented and effective. They are to include validating with scientific evidence that the control is capable of effectively controlling an identified hazard; confirming implementation and effectiveness; and verifying that monitoring and corrective actions (if necessary) are being conducted.
 - **Corrective actions and corrections:** Corrections are steps to be taken to timely identify and correct a minor, isolated problem that occurs during animal feed production. Corrective actions include actions to be taken to identify a problem with preventive control implementation, reduce the likelihood the problem will recur, evaluate affected animal feed for safety, and prevent it from entering commerce.

Supply-Chain Program: The final rule requires that an animal feed facility have a risk-based supply-chain program for those raw materials or other ingredients for which the facility has identified a hazard requiring a preventive control that will be controlled by the supplier of the raw material or ingredient. Animal feed facilities that control such a hazard requiring a preventive control within their own operations, or who follow requirements applicable when relying on a customer to control such a hazard, do not need to have a supply-chain program for that hazard.

If there is a hazard requiring a preventive control associated with a supplier's raw material or ingredient and the facility relies on the supplier to control the hazard, the rule requires that the facility:

- Receive that raw material or ingredient only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw material or ingredient are subject to verification activities before being accepted for use.
- Perform activities to verify that the supplier is adequately controlling the hazard, including, as appropriate to the raw material or ingredient and its supplier:
 - Conducting onsite audits of the supplier's operations.
 - Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.
 - Review of the supplier's relevant feed safety records.
 - Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

Significantly, for a raw material or ingredient with a hazard requiring a preventive control and for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the supply-chain program regulation requires that an onsite audit be conducted of the supplier. The onsite audit is to be conducted annually by a qualified auditor unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazard is controlled. The required audit may be conducted by a qualified auditor that is an employee of the facility or a separate third-party organization.

Recordkeeping Requirements: Facilities are required by the final rule to document its hazard analysis and the management activities associated with controlling hazards that require a preventive control as part of its written feed safety plan. If a facility relies on a supply-chain program to control a hazard requiring a preventive control, then verification activities performed to control the hazard are to be documented. In addition, facilities are to document required training of employees.

All records required by the regulations are to be retained at the facility for at least two years after the date they were prepared. However, except for the animal feed safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The animal feed safety plan is to remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location. Importantly, and as strongly advocated for by the NGFA, the rule also provides that records established or maintained to satisfy the requirements of the rule are exempt from FDA’s onerous Part 11 electronic record requirements.

All records required by the rule are to be made promptly available to an authorized representative of FDA for official review and copying upon oral or written request.

Very Small Businesses: Under the final rule, facilities that meet the definition of a “very small business” (as detailed below) are subject to modified requirements for hazard analysis and risk-based preventive controls and supply-chain programs. However, a very small business still is obligated to comply with the rule’s CGMP requirements.

In general, under the regulations for hazard analysis and risk-based preventive controls and supply-chain programs, a facility that is a very small business is required to:

- Attest the facility is a very small business; and
- Attest that the facility has identified hazards and that preventive controls have been implemented and are being monitored; or
- Attest that the facility is in compliance with an applicable non-federal feed safety law.

Compliance Dates: Covered facilities have a staggered number of years to comply with the rule’s requirements, based on business size. Also, as strongly advocated for by the NGFA, the rule establishes staggered compliance dates between the CGMP requirements and the hazard analysis and risk-based preventive controls requirements. The following table shows the compliance dates established for various business sizes and regulations.

Business Size	CGMP Compliance Date	Preventive Controls Compliance Date
Business other than Small and Very Small	Sept. 19, 2016	Sept. 18, 2017
Small Business	Sept. 18, 2017	Sept. 17, 2018
Very Small business	Sept. 17, 2018	Sept. 17, 2019

To define business size, the rule establishes the following definitions:

- **Small Business:** A business employing fewer than 500 full-time equivalent employees. The rule specifies that all employees within the business and all of its subsidiaries and

affiliates, regardless of whether an employee is involved in animal feed-related activities, is to be counted in this determination.

- **Very Small Business:** A business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal feed plus the market value of animal feed manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

FDA Public Meeting: FDA has scheduled a public meeting on Oct. 20 in Chicago to discuss the requirements established within its human food and animal feed rules. FDA will provide more information about the meeting, including registration details, later this month. The NGFA will inform members of this information when it is available.

NGFA Webinar: The NGFA is partnering with *Grain Journal* to provide a free webinar to provide an overview of FDA's new regulations and address specific details of FDA's final FSMA rules that are important to the grain and feed industry. The webinar is scheduled for Oct. 5 at 2 p.m. central. Information will be provided in the near future about how to register for this event.

The NGFA is actively engaged with FDA to gain clarifications on a variety of compliance issues associated with the rules, and will provide additional updates on requirements in the future. NGFA members with questions about the rules may contact David Fairfield at dfairfield@ngfa.org or (712) 243-4035.