

**MEMORANDUM**  
**via Email**

**TO:** Clients and Other Interested Parties **September 25, 2015**

**RE:** Overview of FDA's Final Rule to Implement FSMA's Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

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Following on its October 29, 2013 proposed rule and its September 29, 2014 supplemental proposed rule,<sup>1</sup> the Food and Drug Administration (FDA) published its final rule on Current Good Manufacturing Practices (CGMPs) and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Food for Animals on September 17, 2015.<sup>2</sup> The final rule is one of several new rules intended to implement the FDA Food Safety Modernization Act (FSMA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act). The final animal HARPC rule is largely consistent with the proposed rule that was supplemented in 2014; however, FDA has clarified certain CGMP and HARPC requirements, and has suggested areas where future rulemaking will occur.

The final rule generally applies to facilities that manufacture, process, pack, or hold domestic and imported animal food, i.e., those facilities required to register with FDA under Section 415 of the FD&C Act, with certain exemptions. The notable features of the new rule include the following:

1. The rule establishes for the first time CGMPs for food for animals, which are akin to the CGMPs that have long applied to human food;

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<sup>1</sup> The proposed rule is found at 78 Fed. Reg. 64736 (Oct. 29, 2013), available at <http://www.gpo.gov/fdsys/pkg/FR-2013-10-29/pdf/2013-25126.pdf>. The supplemental proposed rule is found at 79 Fed. Reg. 58524 (Sept. 29, 2014), available at <http://www.gpo.gov/fdsys/pkg/FR-2014-09-29/pdf/2014-22445.pdf>.

<sup>2</sup> The final rule was published in the Federal Register on September 17, 2015. See Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, Final Rule, 80 Fed. Reg. 56170 (Sept. 17, 2015), available at <http://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf>.

2. It requires animal food facilities to develop a written food safety plan that includes a hazard analysis and imposes risk-based preventive controls;
3. It requires the establishment of a supply chain program; and
4. It clarifies the facilities that are subject to CGMPs and HARPC requirements, and the exemptions from these requirements, including exemptions for “farms.”

The final rule is effective November 16, 2015.<sup>3</sup> For the CGMP requirements, food facilities have one year from publication of the final rule (September 19, 2016) to comply. “Small businesses” (a business employing fewer than 500 full-time equivalent employees, regardless of sales) and “qualified facilities” (which includes “very small businesses,” i.e., businesses averaging less than \$2.5 million per year (adjusted for inflation) in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale) have two years (September 18, 2017) and three years (September 17, 2018), respectively, to comply with the CGMPs. For the HARPC requirements, the general compliance date is two years from publication of the final rule (September 18, 2017), while small businesses and qualified facilities (including very small businesses) must comply in three years (September 17, 2018) and four years (September 17, 2019), respectively.<sup>4</sup> In addition, qualified facilities must retain records to support their qualified status by January 1, 2017.

#### I. Key Differences Between Proposed Rules and Final Rule

On the whole, the substance of the CGMP and HARPC requirements for food for animals found in the final rule largely mirrors the proposed rule and supplemental proposed rule. In response to comments on the proposed rules, though, FDA has revised the CGMPs in notable ways to provide greater flexibility for animal food facilities. A non-exhaustive list of differences between the proposed and final rules is set forth below:

- **The Definition of “Farm” Has Expanded:** The final rule distinguishes between two types of farms: “Primary Production Farm” and “Secondary Activities Farm,” as discussed further below. “Farms” are exempt from the requirements of the final rule.
- **Clarification of Requirements for Feed Mills:** Under the final rule, feed mills that are part of a farm are exempt from the CGMP and HARPC requirements for food for

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<sup>3</sup> As exceptions, paragraph (2) of the definition of “qualified auditor” pertaining to an audit agent of a certified body that is accredited in accordance with regulations will take effect at a later date after FDA finalizes its third-party certification rule.

<sup>4</sup> The staggered compliance dates for CGMP and HARPC requirements for qualified facilities (including very small businesses), small businesses, and all other businesses, and compliance dates for the supply-chain program are charted on page 56329 of the Federal Register Notice.

animals, while feed mills that are not part of a farm must register as food facilities and are subject to CGMPs and HARPC.

- **Clarification of “Holding” Exemption for Bulk Grain Storage:** Based on comments from stakeholders, FDA has exempted from the final rule those facilities that merely hold raw agricultural commodities (RACs). “Holding” includes activities performed incidental to storage of an animal food (e.g., drying, dehydrating, and blending of the same RAC), but other processing activities (e.g., slicing) negate the exemption. With this exemption, typical grain elevators are exempt from the CGMPs/HARPC requirements. Grain elevators with integrated feed mill operations, however, are subject to HARPC.
- **Revised Sanitation Requirements for Bulk Feed Stored Outdoors:** FDA has provided further flexibility for facilities to determine when protective coverings are “necessary and appropriate” to prevent contamination of food.
- **Economic Adulteration:** Hazards that may be intentionally introduced for purposes of economic gain may need preventive controls, particularly where there is a pattern of economic adulteration. Economic adulteration affecting product quality, but not safety, is outside the scope of the final rule.
- **New Definition for “Preventive Controls Qualified Individual”:** FDA has established “preventive controls qualified individual” as a newly defined term under the final rule. The definition provides greater specificity on the requirements for individuals who administer HARPC programs. The definition generally refers to those who have completed certain training on the development and application of risk-based preventive controls, or who are otherwise qualified through job experience.
- **Reliance on Hazard Controls in the Supply Chain:** Under the final rule, FDA allows facilities to forego preventive controls for those hazards that will be controlled by another entity in the supply chain. If a facility’s direct customer or another subsequent entity in the supply chain will control for the hazard, that facility can rely on its customer to provide annual written assurance that the identified hazard will be controlled by a subsequent entity. Labeling is needed to identify that the hazard has not been controlled.
- **Product Testing and Environmental Monitoring:** Product testing and environmental monitoring are included as potential verification activities under the final rule. These steps are required only as appropriate to the facility, the animal food, as well as the nature of the preventive control and its role in the facility’s food safety system.

## **II. Requirements Under the Final Rule**

This memorandum does not provide a detailed description of each requirement included in the final rule. Rather, we set out below a synopsis of key requirements and definitions intended to implement the rule. Specifically, we discuss: (1) CGMPs for food for animals, (2) the HARPC framework; (3) the supply-chain program; and (4) the “farm” definition. FDA has confirmed that it will ultimately develop a guidance document specific to the CGMP and HARPC requirements for food for animals, including a small business compliance guide that will describe the compliance steps that facilities must take.

### **A. CGMPs (Subpart B, 21 C.F.R. § 507.14 – § 507.28)**

One of the most significant impacts of the final rule is the establishment for the first time of CGMPs for food for animals. All establishments required to register with FDA as a food facility must adhere to the CGMPs. The CGMP requirements will be familiar to those who are familiar with the human food CGMP paradigm, as the requirements are somewhat similar. However, the CGMPs for food for animals are designed to provide flexibility to accommodate the various types of facilities that produce this type of food. In particular, the CGMPs address personnel, plant and grounds, sanitation, water supply and plumbing, equipment and utensils, plant operations, holding and distribution, and holder and distribution of human food by-products for use as animal food.

#### **1. Personnel (21 C.F.R. § 507.14)**

Personnel in animal food facilities working in direct contact with animal food, animal food-contact surfaces, and animal food packaging must conform to hygienic practices through adequate personal cleanliness, hand-washing, and other precautions (e.g., removing jewelry).

#### **2. Plant and Grounds (21 C.F.R. § 507.17)**

Animal food facilities must maintain the grounds around a plant so as to protect against contamination of animal food. Moreover, the plant must be suitable in size, construction, and design to facilitate activities that reduce the risk of contamination of such food. In addition, the plant must protect animal food stored outside by effective means.

#### **3. Sanitation (21 C.F.R. § 507.19)**

The buildings, fixtures, and other physical structures of an animal food facility must be clean and in good repair to prevent food from becoming adulterated. Food-contact and non-food-contact surfaces also must be cleaned and maintained to prevent contamination, and the cleaning solutions used for these products must be safe for the intended use. There are limited applications for toxic materials in the animal food plant, including cleaning materials and laboratory testing materials. Other toxic materials, like fertilizers and pesticides, must be stored away from areas of the plant where food is located.

**4. Water Supply and Plumbing (21 C.F.R. § 507.20)**

Water must be “adequate” for the intended use, and derived from an “adequate” source. Specifically, running water is needed to facilitate proper hand-washing and cleaning of utensils and equipment. Water contacting animal food or packaging for animal food also must be safe for the intended use. In addition, plumbing and other drainage concerns are addressed in the final rule.

**5. Equipment and Utensils (21 C.F.R. § 507.22)**

Equipment and utensils used with food for animals must be designed and constructed so as to avoid adulteration of the food, and to facilitate their cleaning. Food-contact surfaces must be constructed with non-toxic materials to withstand the intended use, including cleaning and sanitizing. Specific requirements also apply for instruments and controls used to regulate the environment for the animal food.

**6. Plant Operations (21 C.F.R. § 507.25)**

The final rule has detailed requirements related to the operations of animal food plants. These include the requirement to appropriately store and clean raw materials, requirements applicable to work-in process and rework, and the supervision of cleanliness of the plant.

**7. Holding and Distribution (21 C.F.R. § 507.27)**

Steps must be taken to protect animal food that is held for distribution from contamination and deterioration. The food labeling must contain instructions on the safe use of the animal food for the intended species. Shipping containers must be examined to ensure they do not contribute to contamination of the food. In addition, unpackaged and bulk food must be held in a manner to prevent cross-contamination.

**8. Holding and Distribution of Human Food By-Products For Use as Animal Food (21 C.F.R. § 507.28)**

In cases where facilities already implement the applicable safety requirements for human food, the requirements of the final rule for animal food do not need to be implemented for human food by-products that are diverted to animal food uses, except to prevent contamination during holding and distribution of the by-product. In the event that the human food by-product is further processed, animal food CGMPs must be observed, and HARPC provisions also must be implemented, unless the facility is otherwise exempt from such provisions. FDA has confirmed that it will develop a guidance document specific to human food by-products used as animal food.

**B. HARPC Framework (Subpart C, 21 C.F.R. § 507.31 – § 507.55)**

As found in the proposed and supplemental proposed rules, the final rule imposes HARPC requirements for domestic and foreign facilities that manufacture, process, pack, or hold

food for animals distributed in the United States. In general, the HARPC provisions require facilities to implement a written food safety plan, hazard analysis, preventive controls, monitoring, corrective actions, verification, a supply-chain program, a recall plan, and record-keeping. Certain facilities and activities, however, are exempt from HARPC compliance or are subject to modified HARPC requirements, as summarized in the table below:<sup>5</sup>

Facility Type	21 C.F.R. Reference	Applicability of HARPC Requirements
<p>“Qualified facility”<sup>6</sup></p> <ul style="list-style-type: none"> <li>- Very small business</li> <li>- Average annual sales &lt;\$500,000 and at least 50% of sales directly to consumers or to local retailers or restaurants (within the same state or within 275 miles of facility)</li> </ul>	<p>§ 507.5(d)</p>	<p>Modified HARPC requirements (described in 21 C.F.R. § 507.7)</p> <p>A qualified facility must:</p> <ul style="list-style-type: none"> <li>- Notify FDA about its status; and</li> <li>- Either:                             <ul style="list-style-type: none"> <li>o Notify FDA that it is addressing hazards through preventive controls and monitoring; or</li> <li>o Notify FDA that it complies with applicable non-federal food safety regulations and notify consumers of the name and complete address of the facility where the food was manufactured or processed</li> </ul> </li> <li>- Notification takes the form of an “attestation” which must be submitted to FDA every 2 years</li> </ul>
<ul style="list-style-type: none"> <li>- Low-risk, on-farm activities performed by small business (&lt; 500 full-time equivalent</li> </ul>	<p>§ 507.5(e)</p>	<p>Small and very small on-farm businesses conducting only the specified low-risk activities are exempt from the requirements for hazard analysis and risk-based preventive</p>

<sup>5</sup> The table can also be found in the final rule at page 56175.

<sup>6</sup> FDA has the authority to withdraw a qualified facility exemption in the event of an active investigation of a foodborne illness outbreak directly linked to the qualified facility or if the Agency determines that it is necessary to protect the public health, and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food handled at such facility. (21 C.F.R. § 507.60 (“Circumstances that may lead FDA to withdraw a qualified facility exemption”). Procedures governing the withdrawal of a qualified facility exemption are specified in 21 C.F.R. § 507.62 – 507.65.

employees) - Low-risk, on-farm activities performed by a very small business (dollar threshold of \$2,500,000, as described above)		controls. Low-risk, on-farm activities that qualify for the exemption, including the specific animal foods to which they relate (such as re-packing roughage products, or cracking grains).
Activities subject to low-acid canned food (LACF) requirements of 21 C.F.R. Part 113.	§ 507.5(b)	<ul style="list-style-type: none"> <li>- The exemption applies only with respect to microbiological hazards regulated under Part 113.</li> <li>- The facility must be in compliance with Part 113.</li> </ul>
Activities of a facility that are subject to Section 419 of the FD&C Act (Standards for Produce Safety)	§ 507.5(c)	These activities will be established in FDA’s forthcoming rule for produce safety.
Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing.	§ 507.5(g), (h)	A facility that stores RACs that are fruits and vegetables is not exempt.
A facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, production.	§ 507.5(f)	Modified requirements apply for the storage of unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

Preventive controls are not needed for animal food under certain circumstances. For example, if a facility determines and documents that the animal food could not be consumed without applying an appropriate preventive control, the facility will not need to adhere to the HARPC requirements. A facility also may rely on its customer to address any hazards that may exist, provided appropriate written assurances are obtained from the customer on an annual basis, and the product is labeled to indicate that preventive controls have not been established to address the hazard. 21 C.F.R. § 507.36. FDA has indicated that alfalfa cubes, vegetable oils, and molasses are examples of foods for animals for which a facility may determine there are no hazards requiring preventive controls.

The final rule requires that a “preventive controls qualified individual” prepare and implement a written food safety plan that includes a hazard analysis, preventive controls, a supply-chain program, a recall plan, procedures for monitoring and implementing preventive controls, corrective action procedures, and verification procedures. 21 C.F.R. § 507.31. Below

we provide further detail on the elements of the food safety plan, each of which is associated with recordkeeping obligations (21 C.F.R. § 507.200 - § 507.215):

**1. Hazard Analysis (21 C.F.R. § 507.33)**

Based on experience, illness data, scientific reports, and other information, facilities must identify known or reasonably foreseeable hazards (e.g., biological, chemical, and physical hazards) that may be present for each type of animal food manufactured, processed, or held at a facility in order to determine if these hazards require a preventive control. Hazards may be naturally occurring, unintentionally introduced, or intentionally introduced for economic gain. Facilities must assess hazards both for animals consuming the food and for humans based on the intended use of the animal food. The hazard evaluation must consider the formulation of the food, the facility and equipment used to manufacture the food, raw materials and ingredients of the food, transportation practices, manufacturing and processing procedures, storage and distribution activities, intended and reasonably foreseeable use of the food, sanitation activities, and other relevant factors, such as natural toxin levels.

**2. Preventive Controls (21 C.F.R. § 507.34, § 507.36)**

Based on the hazard analysis discussed above, facilities must identify and implement written preventive controls to assure that any hazards requiring preventive controls will be significantly minimized or prevented, and that food manufactured, processed, packed, or held by the facility will not be adulterated under the FD&C Act. As appropriate to the facility, preventive controls may include process controls, sanitation controls, supply-chain controls, and other necessary measures (e.g., hygiene training). In particular, the final rule clarifies that process controls depend on the role of the process control in the food safety system.

The final rule also clarifies when a facility is not required to implement a preventive control (21 C.F.R. § 507.36), namely under the following circumstances:

1. Where the food could not be consumed without application of an appropriate control;
2. Where the facility relies on a customer (regardless of whether the customer is subject to HARPC requirements) to ensure that the identified hazard will be significantly minimized or prevented provided the documents accompanying the product identify that preventive controls have not been implemented, and the facility annually obtains written assurance from its customer that preventive controls (if applicable) or other food safety requirements are being implemented by the customer;
3. Where the facility relies on a customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the supplier, subject to the disclosure and annual written assurance requirements noted above, and with additional procedures to obtain assurance that the hazard is being controlled; or



4. Where the facility has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product distributed by that facility and where the facility documents the implementation of that system.

FDA also has clarified that where a specific aspect of CGMP compliance serves as a preventive control for a hazard – and thereby becomes part of the HARPC plan – the HARPC requirements such as monitoring, corrective action, verification, etc., must be applied to the CGMP, as it would for any other preventive control.

### **3. Recall Plan (21 C.F.R. § 507.38)**

For animal food posing a hazard requiring a preventive control, a written recall plan must be established, and responsibility for performing the recall plan must be assigned. The final rule specifies that the recall plan must describe the steps to perform during a recall, including: (1) notifying direct consignees of the animal food being recalled with information on how to return or dispose of the food; (2) notifying the public about any hazard presented by the food as needed to protect public health; (3) conducting effectiveness checks to verify that the recall is carried out; and (4) appropriately disposing of recalled food.

### **4. Monitoring (21 C.F.R. § 507.40)**

As a component of preventive control management (21 C.F.R. § 507.39), animal food facilities must take the following steps (as appropriate to the nature of the preventive control and the role in the facility):

- Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.
- Monitor the preventive controls with adequate frequency to provide assurance they are consistently performed.
- Document the monitoring of preventive controls.

### **5. Corrective Actions and Corrections (21 C.F.R. § 507.42)**

Animal food facilities must have written procedures for corrective actions in the event that preventive controls are not properly implemented, such as where product testing demonstrates the presence of an indicator organism in animal food. A facility must take action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent adulterated food from entering commerce.

### **6. Verification (21 C.F.R. § 507.45, § 507.49)**

To verify the effectiveness of preventive controls implemented to address hazards in animal food, verification activities are required under the final rule. These include validation of

preventive controls (discussed below), monitoring, appropriate decision-making regarding corrective actions, and reanalysis. Verification steps must be taken as appropriate for the facility, the type of animal food, and the nature of the preventive control, which may include calibration of instruments, environmental monitoring, product testing for pathogens, and review of records. Verification activities must be documented.

**7. Validation (21 C.F.R. § 507.47)**

Animal food facilities also must validate that preventive controls are adequate to control hazards that are identified for animal food. To this end, the validation activities must be carried out by a preventive controls qualified individual prior to implementation of a food safety plan, and upon changes to or reanalysis of the food safety plan. Certain controls, such as the sanitation controls, the recall plan, and the supply-chain program, are not subject to validation requirements.

**8. Reanalysis (21 C.F.R. § 507.50)**

The final rule requires reanalysis of the food safety plan at least once every three years. Reanalysis may be needed sooner if production changes occur, there are changes in the hazard profile, or issues are observed during implementation of the current plan.

**C. Supply-Chain Program (Subpart E, 21 C.F.R. § 507.105 - § 507.202)**

The final rule requires manufacturing and processing facilities to establish and implement a risk-based supply-chain program to control for hazards in raw materials and other ingredients where preventive controls are applied before receipt by the manufacturing and processing facilities. The supply-chain program entails: (1) using approved suppliers; (2) determining appropriate supplier verification activities; (3) conducting supplier verification activities; (4) documenting supplier verification activities; and (5) verifying a supply-chain-applied control performed by an entity other than the facility's supplier and documenting that verification was performed by another entity (when applicable).

The rule also provides appropriate supplier verification activities for raw materials and other ingredients, which include onsite audits, sampling and testing of raw materials or other ingredients, review of the supplier's food safety records, and any other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient. Generally speaking, the supply-chain program must provide assurance that hazards requiring supply-chain-applied controls have been significantly minimized or prevented. 21 C.F.R. § 507.110. Adequately detailed records must be kept to document the supplier verification activities. 21 C.F.R. § 507.202.

Separate compliance dates have been established for supply-chain program provisions that extend one year beyond the compliance date for CGMPs; the compliance dates for the supply-chain program are expected to be further clarified by FDA.

**D. Farm Definition (21 C.F.R. § 1.227)**

As noted above, FDA has clarified the definition of “farm,” which is central to determining who must register as a food facility and be subject to the HARPC requirements. The farm definition is consistent between the separate CGMP and HARPC rules that apply to food for humans and animals. FDA recognizes two types of farm:

- **Primary Production Farm:** An operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.
- **Secondary Activities Farm:** An operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding RACs. It must be majority owned by the Primary Production Farm that supplies the majority of the RACs harvested, packed, or held by the Secondary Activities Farm.

Under this definition, feed mills that are part of a farm are exempt from registering as food facilities and are not subject to the rule, while feed mills that are not part of a farm are required to register as a food facility and are subject to the rule. FDA has noted that this leaves a large gap in regulation of feed mills, and the Agency intends to publish a proposed rule that would require some feed mill operations that currently are part of a farm to comply with CGMPs. Based on the Agency’s recent comments, we understand that it will be some time before this proposed rule is developed. In addition, farms conducting activities related to produce that are covered by the standards for produce safety will be required to comply with the produce safety rule once final.

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We will continue to monitor and report on implementation of the HARPC requirements and other FSMA related activities.