

KEY REQUIREMENTS:

Final Rule on Preventive Controls for Animal Food

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. This outreach began before the rule was proposed in October 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both preventive controls proposals.

Below are the key requirements and compliance dates.

1. CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) ESTABLISHED FOR ANIMAL FOOD PRODUCTION.

- The FDA has finalized baseline CGMP standards for producing safe animal food that take into consideration the unique aspects of the animal food industry and provide flexibility for the wide diversity in types of animal food facilities.
- Processors already implementing human food safety requirements, such as brewers, do not need to implement additional preventive controls or CGMP regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except to prevent physical and chemical contamination when holding and

distributing the by-product. Examples of physical and chemical contamination include placing trash or cleaning chemicals into the container holding the by-products. This regulation applies to human food facilities that donate or sell a by-product for use as animal food.

Further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) requires companies to process the by-product in compliance with CGMPs to ensure the animal food's safety and to make sure that the processing does not introduce hazards to the animal food. The company can choose to follow either the human food or animal food CGMPs when further processing the by-product. In addition, unless they are a qualified facility or otherwise exempt from subpart C (hazard analysis and preventive controls), the facility needs to assess its process and determine whether there are any hazards that would require a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control would document such a determination in its hazard analysis but would not need to establish preventive controls.

2. COVERED FACILITIES MUST ESTABLISH AND IMPLEMENT A FOOD SAFETY SYSTEM THAT INCLUDES AN ANALYSIS OF HAZARDS AND RISK-BASED PREVENTIVE CONTROLS. THE RULE SETS REQUIREMENTS FOR A WRITTEN FOOD SAFETY PLAN THAT INCLUDES:

- **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).
- **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented.

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■ Oversight and management of preventive controls

controls: The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

- **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, proper refrigeration could be documented with either affirmative records demonstrating temperature is controlled or “exception records” demonstrating loss of temperature control.
- **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They 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.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility’s food safety system.

- **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during animal food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected animal food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.

- **Recall plan:** Every facility that produces animal food with a hazard requiring a preventive control must have a recall plan.

3. SUPPLY-CHAIN PROGRAM IS MORE FLEXIBLE, WITH SEPARATE COMPLIANCE DATES ESTABLISHED.

- The rule mandates that an animal food manufacturing/processing facility have a risk-based supply chain program for those raw materials and other ingredients for which it has identified a hazard

requiring a supply-chain-applied control. Animal food facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to controls hazards, do not need to have a supply-chain program for that hazard.

- Animal food facilities are responsible for ensuring that raw materials and other ingredients with a supply-chain-applied control are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
- A facility will not be required to implement a preventive control when an identified hazard will be controlled by another entity in the distribution chain, such as a customer or other processor. The receiving facility will have to disclose that the food is “not processed to control (identified hazard)” and obtain written assurance from its customer regarding certain actions that customer agrees to take.
- Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for animal food rule or the produce safety rule.

4. THE DEFINITION OF A ‘FARM’ IS CLARIFIED IN THE PREVENTIVE CONTROLS FOR HUMAN FOOD FINAL RULE TO COVER TWO TYPES OF FARM OPERATIONS. OPERATIONS MEETING THE DEFINITION OF ‘FARM’ ARE NOT SUBJECT TO THE PREVENTIVE CONTROLS RULE.

- **Primary Production Farm:** This is 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.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of “farm”

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to allow farms to pack or hold raw agricultural commodities (food in its raw or natural state) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

For example, a farm that raises beef cattle may own and operate a feed mill. The feed mill is considered part of the farm and is not subject to the preventive controls for animal food rule if the feed mill is managed by the farm or the same company as the farm, is in the same general physical location, and produces animal food that is fed only to the animals on that farm or another farm under the same management.

In another example, a poultry processor may own a feed mill but contract the raising of the poultry to a third-party farmer. The poultry processor and its feed mill are under different management than the farm raising the poultry. The feed mill owned by the poultry processor does not qualify as a farm and is subject to the preventive controls for animal food rule because it manufactures food for animals that are on a farm that is not under the same management as the feed mill.

- **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing, and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities that are harvested, packed, or held by the Secondary

Activities Farm. The secondary activities farm definition has very limited application to animal food beyond the packing and holding of grain.

5. FEED MILLS ASSOCIATED WITH FARMS (VERTICALLY INTEGRATED OPERATIONS) NOT COVERED.

- Feed mills associated with fully vertically integrated farming operations (i.e., farms where the feed mill, animals, land, and establishment are all owned by the same entity) generally meet the definition of a farm and are therefore not subject to the Preventive Controls for Animal Food final rule.
- The FDA remains concerned that not having these operations subject to the Preventive Controls for Animal Food final rule leaves a gap in the protection of human and animal health because these feed mill operations manufacture significant amounts of animal food.
- The FDA 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 current good manufacturing practices established by the Preventive Controls for Animal Food rule.

COMPLIANCE DATES

Businesses have a staggered number of years after publication of the final rule to comply, based on business size. In addition, there will be staggered compliance between the CGMP requirements and the Preventive Control Requirements:

Business Size	CGMP compliance date	PC compliance date
Business other than small and very small	1 year	2 years
Small business (a business employing fewer than 500 full-time equivalent employees)	2 years	3 years
Very small business (a business 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 food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).	3 years	4 years, except for records to support its status as a very small business (January 1, 2017)

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will be subject to CGMPs but not to preventive controls:** six months after the receiving facility's supplier is required to comply with the CGMP requirements of this rule.
- **Receiving facility is not a small or very small business and its supplier will be subject to CGMPs but not to preventive controls:** six months after the receiving facility's supplier is required to comply with the CGMP requirements of this rule.
- **Receiving facility is a small business and its supplier is subject to the preventive controls for animal food final rule:** Three years after the rule's publication date or six months after the supplier is required to comply with the rule, whichever is later.
- **Receiving facility is not a small or very small business and its supplier will be subject to the preventive controls for animal food final rule:** Two years after the rule's publication date or six months after the supplier is required to comply with the rule, whichever is later.

ASSISTANCE TO INDUSTRY

The FDA is committed to educating industry on the new rules while it regulates. The agency is developing several guidance documents that include:

- CGMP requirements
- Hazard analysis and preventive controls

- Human Food By-Products for Use as Animal Food
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule

Plans for training and technical assistance are well under way. They include:

- Establishing a Food Safety Technical Assistance Network within the agency to provide a central source of information and a call center to support industry understanding and implementation of FSMA.
- Collaborating with the Food Safety Preventive Controls Alliance to establish training and technical assistance programs.

MORE INFORMATION

Federal Register
www.regulations.gov

Frequently Asked Questions
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#PC_Rules

FDA Food Safety Modernization Act
www.fda.gov/fsma

FDA's FSMA Technical Assistance Network
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>