KEY REQUIREMENTS:
Final Rule on Preventive Controls for Animal Food

- The second major compliance dates for the FDA Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food rule arrived in September 2017.
- The final rule was published in September 2015 and larger animal food facilities were required to comply with the Current Good Manufacturing Practice (CGMP) requirements by September 2016.
- Now larger animal food facilities have been required to comply with the preventive controls requirements since September 18, 2017, and facilities that are small businesses were required to implement the CGMPs by that date.
- Because compliance dates are staggered by the size of the business, the next major compliance dates come in September 2018, when small businesses will also have to meet preventive controls requirements and very small businesses must implement the CGMPs.
- This rule requires animal food facilities to have a food safety plan in place that includes an analysis of hazards to determine which ones need control and risk-based preventive controls to minimize or prevent those hazards.

Jenny Murphy, a consumer safety officer at FDA's Center for Veterinary Medicine, explains what animal food producers can expect in this next phase of implementation. (https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm570439.htm) **VIEW**

Key Requirements

1. COVERED FACILITIES MUST FOLLOW CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) FOR ANIMAL FOOD PRODUCTION.

- The FDA has finalized CGMPs 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 and who are just holding by-product for use as animal food, 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 contamination. Examples of 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.

If the human food facility processes its by-product for use as animal food (e.g., drying, pelleting, heat-treatment), the facility must process the by-product in compliance with CGMPs to help ensure the animal food's safety. The facility can choose to follow either the human food or animal food CGMPs when further processing the by-product. In addition, unless it is a qualified facility or otherwise exempt from 21 CFR part 507, subpart C (hazard analysis and preventive controls), the facility needs to determine whether there are any hazards that 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.

For more information, see the draft Guidance for Industry #239: Human Food By-Products for Use as Animal Food (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf).

2. COVERED FACILITIES MUST ESTABLISH AND IMPLEMENT A FOOD SAFETY SYSTEM THAT INCLUDES AN ANALYSIS OF HAZARDS AND, IF NECESSARY, 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). If the hazard analysis reveals one or more hazards that require a preventive control, the facility must have and implement written preventive controls for those hazards.

- **Preventive controls:** Facilities have flexibility when tailoring preventive controls to address hazards that occur in the products they manufacture. The preventive controls, which must be written, must be implemented to ensure that any hazards requiring a preventive control will be significantly minimized or prevented and help ensure that the food is not adulterated. The rule includes the following preventive controls:
  - **Process controls** include procedures that ensure the control of parameters during certain processing operations such as cooking, refrigerating, and acidifying foods. They must include parameters and values (e.g., parameter values), as appropriate to the nature of the applicable control and its role in the facility's food safety system.
  - **Sanitation controls** are procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to minimize or prevent hazards such as environmental pathogens and hazards from employees handling animal food.
  - **Other Controls** are controls that are not described above but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.

- **Oversight and management of preventive controls:** Once a facility has identified a preventive control for a hazard, the facility must ensure the effectiveness of the control.
  - **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, monitoring of a heat process to kill pathogens would include recording temperature values. Monitoring must be documented.
  - **Corrections:** These are steps taken, in a timely manner, to identify and correct a minor, isolated problem that occurs during food production.
  - **Corrective actions:** These include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected animal food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated. Corrective actions must be documented.
  - **Verification:** These are activities to determine whether a preventive control is operating as intended and to establish the validity of the food safety plan. Examples of verification activities include scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard and calibrating (or checking the accuracy of) process monitoring and verification instruments, such as thermometers. Verification activities also include reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted. Verification activities must be documented.

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

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

3. SOME ANIMAL FOOD FACILITIES WILL NEED A SUPPLY-CHAIN PROGRAM TO ADDRESS HAZARDS IN RAW MATERIALS AND OTHER INGREDIENTS.

- A manufacturer must have and implement a risk-based supply-chain program if its hazard analysis identifies a hazard that (1) requires a preventive control and (2) the control will be applied in the facility's supply chain.

- Manufacturers do not need to have a supply-chain program if they control the hazard in their own facility, or if their customer is a facility that will control the hazard.
- Manufacturers are responsible for ensuring that raw materials and other ingredients requiring a supply-chain-applied control are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw materials are subject to verification activities before being accepted for use. (A manufacturer approves a supplier by considering several factors, such as a hazard analysis of the food, the entity that will be controlling a hazard requiring a supply-chain-applied control, and supplier food safety performance.)
- Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving manufacturer must review and assess that entity's documentation of the supplier verification activities.

4. THE DEFINITION OF A 'FARM' DESCRIBES TWO TYPES OF FARM OPERATIONS. OPERATIONS MEETING THE DEFINITION OF 'FARM' ARE NOT SUBJECT TO THE PREVENTIVE CONTROLS FOR ANIMAL FOOD 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 definition of "farm" allows farms to pack or hold raw agricultural commodities (food in its raw or natural state) that are grown on a farm under a different management. Companies that solely harvest crops from farms are included within the "farm" definition. An operation devoted to raising animals is not subject to the Preventive Controls for Animal Food rule. However, a feed mill that supplies animal food may be a part of a farm or may be subject to the regulation.

  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 a 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(s) 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 harvesting, packing, and holding of grain.

5. FEED MILLS THAT ARE PART OF FARMS (VERTICALLY INTEGRATED OPERATIONS) ARE NOT COVERED BY THE PREVENTIVE CONTROLS FOR ANIMAL FOOD RULE.

- Feed mills that are part of fully vertically integrated farming operations (i.e., where the farm, its animals, and the feed mill are all together under one management) are not subject to the Preventive Controls for Animal Food final rule.
- The FDA remains concerned that not having these feed mills subject to the Preventive Controls for Animal Food final rule leaves a gap in the protection of human and animal health because these feed mills 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 CGMPs established by the Preventive Controls for Animal Food rule.

Business Size	CGMP compliance date	PC compliance date
Business other than small and very small	**Sept. 19, 2016**	**Sept. 18, 2017**
Small business (a business employing fewer than 500 full-time equivalent employees)	**Sept. 18, 2017**	**Sept. 17, 2018**
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).	**Sept. 17, 2018**	**Sept. 17, 2019,** except for records to support status as very small business (January 1, 2017)

COMPLIANCE DATES

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

Compliance dates for some facilities and activities have been extended. For more information, see Compliance Date Extensions and Clarifications for FSMA Final Rules (https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm).

ASSISTANCE TO INDUSTRY

The FDA is committed to educating industry on the new rules while it regulates. The agency is developing guidance on hazard analysis and preventive controls, and has published guidance documents that include:

- Draft guidance on CGMP requirements (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf).
- Draft guidance on Human Food By-Products for Use as Animal Food (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf).
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499202.pdf).
- Draft guidance on Describing a Hazard that Needs Control in Documents Accompanying the Food, as required by Four Rules Implementing FSMA (https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM526490.pdf).
- Draft guidance on Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food) (https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM499509.pdf)

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

- The FSMA Technical Assistance Network (https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm) to provide a central source of information and a web-based system to support industry understanding and implementation of FSMA.
- Collaborating with the Food Safety Preventive Controls Alliance (https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm284406.htm) on training and technical assistance programs.