Understanding FSMA - The Preventive Controls for Animal Food Rule

The FSMA Preventive Controls for Animal Food Rule requires many animal food businesses to follow basic sanitation standards, conduct a hazard analysis, and write a preventive controls food safety plan.

The Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act (FSMA) is the most sweeping reform of food safety laws in more than 70 years. FSMA shifts the focus away from merely responding to contamination events toward establishing systems to prevent them from occurring. The law directed the U.S. Food and Drug Administration (FDA) to write seven regulations, each of which affects the vast and complex food and feed system in the U.S.

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulation, often shortened to the Preventive Controls for Animal Food Rule, is the FSMA regulation that requires all FDA regulated animal food businesses to comply with current good manufacturing practices (GMP) (Subpart B). Businesses that manufacture, process, pack, or hold animal food also may be required to establish and implement a food safety plan that includes a hazard analysis and a preventive controls food safety plan (Subpart C) in addition to developing a Supply-Chain Program (Subpart E). Businesses that are required to comply with some or all aspects of this rule include pet food manufacturers, feed mills, and other animal food processing facilities.

Coverage

Businesses that manufacture, process, pack, or hold food for consumption by animals in the United States are covered. This includes feed mills, animal feed and pet food manufacturers and processors, and holding facilities. FDA defines the terms manufacturing and processing to mean making food from one or more ingredients or chemically or physically modifying food ingredients to create new products. Examples include: Baking, boiling, bottling, canning, cooking, cooling, cutting, dehydrating to create a distinct commodity, distilling, formulating, freezing, grinding, milling, mixing, packaging, pasteurizing, pelleting, and rendering.

Certain types of animal food operations are not subject to the rule. Farms that only grow crops used for animal food are not covered under this regulation. 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 rule. Retail establishments that sell animal feed or pet food directly to consumers and home-based producers of pet foods are also not subject to this federal regulation, although they may be covered under local and state regulations.

**Key Requirements**

As the longer name of the rule suggests, the regulation includes two main requirements, 1) Current Good Manufacturing Practices (GMP) (Subpart B) and 2) Hazard Analysis and Risk-based Preventive Controls. Together, these make up the Food Safety System. The Hazard Analysis and Risk-based Preventive Controls (Subpart C) and the Supply-Chain Controls program (Subpart E) are components of the Food Safety Plan that becomes an integral part of the complete Food Safety System.

1. Current Good Manufacturing Practices (GMPs) for animal food production.

GMPs are baseline food safety and sanitation standards for preventing contamination of animal foods with harmful microorganism and toxic compounds. They include health and sanitation standards for personnel, plant and grounds, cleaning and sanitizing, water supply, equipment and utensils, plant operations, holding and distribution of animal foods, and holding and distribution of human food by-products to be used for animal food.

2. Hazard Analysis Preventive Controls

Food Safety Plan

Required components of a preventive controls animal food safety plan are as follows.

**Hazard Analysis.** The first step in the food safety plan is to identify potential hazards that might occur as the animal food is produced. Hazards can be grouped into biological (e.g. *Salmonella* spp., *Listeria monocytogenes*), chemical (e.g. mycotoxins, toxic compounds, nutrient deficiencies), or physical (e.g. metal, stones, glass). They may occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain. A risk-based hazard analysis is then conducted to determine how best to prevent any known or foreseeable animal food safety hazards from occurring. Hazards are ranked depending on their probability of occurrence and severity. Lower risk hazards may be controlled through GMPs, other quality and safety systems in place (i.e. prerequisite programs) while those identified as higher risk are controlled by more rigorous sanitation, process, or supply chain preventive controls.

**Preventive controls:** Written preventive controls must be implemented to ensure that any hazards requiring a preventive control will be significantly minimized or prevented in order to prevent contamination of animal food. The food safety plan must include how they intend to implement those preventive controls for each hazard.

**Types of preventive controls include**

- **Process Controls** are procedures in place that ensure process parameters or values are adequately controlled during activities and include cooking, refrigerating, and acidifying animal foods. Process parameters and values (e.g. temperature, time, pH) must be 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 in order to minimize or prevent hazards such as environmental pathogens and contamination from employees who handle animal food.

- **Supply-Chain Controls** are put into place prior to a facility receiving raw materials or ingredients from suppliers. Some animal food facilities must develop this program as part of their food safety plan. The receiving facility must have in place written procedures, verification activities, and adequate documentation to assure that the hazard associated with that material or ingredient has been controlled before it is received. There are certain situations and circumstances that do not require a supply chain preventive control such as if there is no foreseeable hazard associated with that ingredient, if the hazard will be controlled by the receiving facility, or if the supplier is following the requirements under another FSMA regulation, the Foreign Supplier Verification Program (FSVP).

Other controls not described above but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented may also be developed and implemented.

**Oversight and management of preventive controls.** Once a facility has identified a preventive control for a hazard, additional steps in the food safety plan are needed to ensure that they are continuously and effectively carried out.

**Monitoring:** These are procedures 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. The results of monitoring activities 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. A recall plan is a written plan that details the actions to be taken if an animal food product needs to be removed from commerce. The plan includes the method for notifying consumers and the public, a measure of the effectiveness of removing the product from commerce, and steps for disposal of the product along with assigning responsibility for carrying out these actions.

Training requirements

Each individual must have the education, training, or experience necessary to safety manufacture, process, pack, or hold animal food appropriate to their duties. They must be knowledgeable on the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene as appropriate to the animal food and their assigned duties.

Each covered facility must have at least one Preventive Controls Qualified Individual (PCQI) who is responsible for writing and overall management of the food safety plan. Attending a formal training course is not specifically required in the rule; however, it is strongly recommended and will provide evidence that the PCQI has adequate knowledge of the rule and its requirements. A standard 2½- day course Preventive Controls for Animal Food course was developed by the Food Safety Preventive Controls Alliance is offered regularly by Penn State Extension instructors.

Exemptions to the Rule and Modified Requirements

Some animal food facilities may be eligible for exemption from some parts of the Animal Food Rule. The following is a list of available exemptions.

1) Qualified facility exemption.

A "qualified facility" exemption is available to facilities having 1) less than $2,500,000 in average annual total food sales, calculated over the previous 3 years, plus inventory (adjusted annually for inflation) or 2) less than $500,000 (also inflation adjusted) in previous 3-year average annual sales provided that the average monetary value of all food sold directly to qualified end users is greater than that sold to other purchasers. A qualified end-user means 1) the consumer of the food, or 2) a restaurant or retail food establishment located in the same state or Indian reservation or no more than 275 miles from the qualified facility and is purchasing the food for sale direct to consumers.

Qualified exempt facilities must comply with GMPs (Subpart B) but are not required to write a written preventive controls food safety plan (Subpart C) or develop a Supply-Chain Program (Subpart E) nor are they required to meet the full record keeping provisions in the rule.

However, exemptions are not automatic. Every 2 years, the manufacturer must submit a form to FDA that discloses their 3-year average annual sales figures and/or sales distribution information determined from tax documents, invoices, or other accounting documents. They must also attest that they have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective, or that they are in compliance with state regulations on animal food. FDA can withdraw a qualified exemption at any time if the product is under investigation for a foodborne illness linked to the facility or if is otherwise necessary to protect the public health.

2) Mixed type facility exemption.

Mixed type facilities both grow crops for animals and conduct animal food processing and manufacturing activities. This exemption is available only to facilities with less than 500 full-time employees or with previous 3-year average annual feed sales plus the value of the inventory less than $2,500,000 and only if all of animals that consume all of the feed are at the same location and under the same ownership or management. To obtain the exemption, all products and processes must be in the low risk category as determined by FDA.

Low risk products include roughage like alfalfa meal or pulp, plant protein meal, grain by-products such as bran, flour, middlings, and brewer's or distiller's grain, oilseed products, molasses, animal protein meal, milk products including casein or lactalbumin, animal tissue products, vitamins, minerals, concentrates, and processing aids. Processes that are considered low risk include chopping or shredding hay, cracking or shelling grain, crushing, grinding, rolling, or milling grain, making silage or haylage, and labeling or packaging certain products.

Facilities that meet the requirements for this exemption are not required to comply with the Preventive Controls (Subpart B) section of the rule or the Supply-Chain Program (Subpart C) section. However, compliance with GMPs is required (Subpart B)

3) Holding and storage exemptions.

Facilities that only store packaged animal food that does not require time and temperature controls to prevent or minimize the growth of pathogens, such as refrigeration, are not required to conduct a hazard analysis and implement preventive controls (Subpart C) or to develop supply chain controls (Subpart E). However, facilities that only store packaged animal food that does require time and temperature
controls to keep it safe are required to implement a plan to meet temperature controls that includes monitoring, corrective actions, verification, and implementation records. GMPs (Subpart B) must be followed when storing packaged animal food whether or not time and temperature controls are needed.

Finally, facilities where only raw agricultural commodities are stored are eligible for this type of exemption. These are businesses that solely engage in holding or transporting raw agricultural commodities, hulling, shelling, drying, packing, and holding nuts and hulls, or the ginning of cotton. Businesses under this exemption do not have to comply with GMPs, conduct a hazard analysis and implement preventive controls or supply chain controls.

4) Low-acid canned foods exemption. Commercial establishments that produce low-acid canned animal foods, such as pet food, are not subject to the preventive controls (Subpart C) section of the regulation for microbiological hazards that are already controlled under FDA low acid canning regulation (21 CFR Part 113). Nor are they subject to the Supply Chain Program (Subpart D) section of the rule. However, compliance with GMPs (Subpart B) is required.

Required Records

In general, activities that are part of a facility’s GMP program do not have require records. However, many other activities may require records, including those that establish a preventive control, monitor the performance of preventive controls such as receiving and batching, corrective action activities, and verification activities which could include calibration of instruments. Also, all training should be documented through records including on-the-job and formal training.

Deadlines for Compliance

The deadline for very small businesses, with average annual sales less than 2.5 million dollars, were required to comply with the rule by September 17, 2019. Small businesses, with less than 500 full time employees, had until September 17, 2018 to comply. All other larger businesses were required to comply by September 18, 2017. Deadlines for implementing current Good Manufacturing Practices (Subpart B) were 1 year before each of above deadlines.

Further resources

- The Penn State Extension FSMA website has information on all of regulations issued under the Food Safety Modernization Act, including the Preventive Controls for Animal Food Rule. Visit this site regularly to keep up-to-date on the latest regulatory developments, compliance issues, and when and where training sessions will be offered.
- The full text of the rule and industry guidance documents are available on the FDA FSMA website.

• Home-based animal food manufacturers should contact the Pennsylvania Department of Agriculture (PDA) to determine what state regulations are in place for them.

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