UF IFAS Extension UNIVERSITY of FLORIDA

AN330

The Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food[1]

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The Food Safety Modernization Act (FSMA) was signed into law in January of 2011 and is considered the most sweeping reform of food safety regulations in 70 years. The impetus behind this legislation included a few major incidents, such as a *Salmonella typhimurium* outbreak in peanut butter from the Peanut Corporation of America (CDC 2009), a *Listeria monocytogenes* outbreak in cantaloupes (CDC 2011), and a massive recall of pet food due to melamine (FDA 2016a). The human food regulations were composed first and, with significant input from industry, academia, and consumer groups as well as other agencies, were then modified to better suit animal food production.

In Florida, these new regulations apply to facilities that manufacture, process, pack, or hold food or food ingredients for animals. The Food and Drug Administration uses the term "food." However, "feed" may be substituted as appropriate. These facilities may include pet food manufacturers, renderers, ethanol distillers, feed mills, distributors, and others. The primary goal of these regulations is to ensure safe food for the animals, people who handle the feed, and people who consume the final animal products.

What does the rule require?

Facilities subject to the rule must establish a food safety plan. This plan must include written current good manufacturing practices (CGMPs), a hazard analysis, and preventive controls (when needed). CGMPs are practices used by the facility to ensure general facility cleanliness, training of personnel, and proper plant operations. Examples may include procedures for employee hand washing, equipment maintenance, pest control, or equipment cleaning. The hazard analysis identifies and evaluates known or reasonably foreseeable hazards associated with each produced, packaged, or held food that may cause illness or injury to humans or animals. Hazards are categorized as biological, chemical, or physical. They include, but are not limited to, pathogens, nutrient deficiencies, and metal fragments. CGMPs may help manage these hazards. However, the facility may choose to implement preventive controls specifically targeting hazards that occur frequently and have a strong probability of continuing. These controls may include a specific step in the process, sanitation controls, or controls placed on the supply chain. These basic components are coupled with monitoring, validation, and recordkeeping procedures.

In addition to preventive controls, there are three other major components to the rule: foreign supplier verification programs, accredited third-party certification, and sanitary transport. Foreign supplier verification, which may affect only a small percentage of facilities, is the second most immediate concern after preventive controls.

Does this rule apply to my facility?

The answer to this question depends on the specifics of your operation. If your facility is already registered with the FDA as a domestic or foreign facility that manufactures,

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processes, packs, or holds food as defined in 21 CFR 1.227 (https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol1/CFR-2012-title21-vol1-sec1-227/content-detail.html) (Richardson et al. 2015), it will most likely be expected to be in compliance.

There are certain exceptions. For instance, if a feed mill is exclusively used to manufacture feed for the animals on the farm where it is located, it may meet the definition of a primary production farm and be exempt from the rule. However, if your farm produces feed for your own livestock but delivers to contract growers, it may need to comply since different management is overseeing the livestock. If your facility produces animal feed ingredients as a by-product of human food production (such as citrus pulp from an orange juice manufacturer), it may already be covered by CGMPs for human food production. In this case, the facility has the choice of implementing a separate plan for the animal feed or keeping it under the human food plan. There are other situations that may result in exemption from all or part of the rule. However, it is important to review the specifics of your facility and determine if it meets the criteria spelled out in the law. Keep in mind that instituting CGMPs is a good practice even if your facility is exempt.

When does my facility need to be compliant?

The FDA has established a timeline for when establishments must be compliant with different aspects of the law (Table 1). Large businesses have a shorter timeline than small or very small operations. For all businesses, the deadline for establishment of CGMPs is a year before the deadline for establishment of hazard analysis and risk-based controls.

Table 1.

Business Size	Subpart B Current Good Manufacturing Practices	Subpart C Hazard Analysis and Risk-Based Preventive Controls
All Others	September 19, 2016	September 18, 2017
Small Businesses (< 500 FTE)	September 18, 2017	September 17, 2018
Very Small Businesses (< $2.5 million/year)	September 17, 2018	September 17, 2019
FTE = Full-time equivalent employee (FDA 2016b)		

Who is responsible for writing a food safety plan at my facility?

A preventive controls qualified individual (PCQI) is responsible for developing the food safety plan. This person should have the education, experience, or both to develop and implement risk-based preventive controls. It is good practice to have a food safety team incorporating personnel from throughout the facility involved in the development and maintenance of the food safety plan. This helps ensure the comprehensiveness of the food safety plan as well as familiarity with the overall plan among personnel throughout the facility. The owner, operator, or agent in charge is accountable for the food safety program and should make sure the PCQI and food safety team are appropriately selected.

What experience and education are necessary to be a preventive controls qualified individual (PCQI)?

There are multiple ways to become qualified to be a PCQI. The Food Safety Preventive Controls Alliance (FSPCA) worked with the FDA to develop a standardized curriculum as one way to meet requirements. This course is designed to teach the concepts necessary to design a food safety plan. Alternatively, there may be equivalent training programs. Experience can also be gained on the job working with a risk-based preventive controls food safety plan. This experience should be documented as justification that a training program was not needed.

We already have good manufacturing practices in place. Do we have to start over?

No, but current practices should be reviewed to determine how they fit into a food safety plan and whether modifications are needed. For example, feed manufacturers producing medicated feed already need to be in compliance with CGMPs for medicated feeds (9 CFR 225). In most cases, these established CGMPs will fit into a food safety plan with little to no modification.

Is writing a food safety plan a one-time occurrence?

No. It is expected that the food safety plan will be treated as a "living document." It should be reviewed and revised whenever the product or process changes, an outbreak of a foodborne illness occurs in a similar product, or frequent corrective actions are made. The safety plan should also be reviewed and revised at least every three years. It is acceptable for a review to result in no revisions if the plan is found to be robust enough to address new concerns and both the completed review and reasons for the lack of changes are documented for the FDA.

For more information, visit the following websites.

FDA (key requirements for preventive controls for animal feed): http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461884.pdf

FDA FSMA (animal feed overview): http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm347941.htm

UF Department of Animal Sciences (FSMA): http://animal.ifas.ufl.edu/FSMA/index.shtml

Food Safety Preventive Controls Alliance (FSPCA): https://www.ifsh.iit.edu/fspca

Southern Center for FSMA Training: http://sc.ifas.ufl.edu/

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