

The Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food¹

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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) and a hazard analysis. 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 high-risk hazards that have a higher combination of frequency of occurrence and severity of injury or illness. 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 (FSVP), accredited third-party certification, and sanitary transport. The FDA has released a free sanitary transport training for carriers available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/training-carriers-covered-sanitary-transportation-human-and-animal-food-rule>. Trainings for FSVP are also available.

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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, 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. If your facility needs to comply the deadline for all components was September 17, 2019. Inspections have begun on all elements.

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. They do not need to be an employee of the facility or located at the facility, although logistics of being a PCQI remotely are rather arduous. 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/IFAS Department of Animal Sciences (FSMA): <https://animal.ifas.ufl.edu/extension/courses/fsma/>

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

References

21 CFR §1.227. Accessed on September 14, 2016.

9 CFR §225. Accessed on September 14, 2016.

CDC. 2009. “Multistate outbreak of *Salmonella* Typhimurium infections linked to peanut butter, 2008–2009.” Accessed on August 29, 2016. <http://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html>

CDC. 2011. “Multistate outbreak of listeriosis linked to whole cantaloupes from Jensen Farms, Colorado.” Accessed on August 29, 2016. <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html>

FDA. 2016a. “Melamine pet food recall of 2007.” Accessed on August 29, 2016. <http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm129575.htm>

FDA. 2016b. “FSMA final rule for preventive controls for animal food.” Accessed on August 29, 2016. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>

Richardson, S., R. Goodrich Schneider, M. A. Ritenour, M. D. Danyluk, and K. R. Schneider. 2015. *The Food Safety Modernization Act and the FDA Facility Registration Program*. FSHN13-07. Gainesville: University of Florida Institute of Food and Agricultural Sciences. <https://edis.ifas.ufl.edu/fs231>