# FSMA Facts

FDA FOOD SAFETY MODERNIZATION ACT

## CGMPs and Preventive Controls for Food for Animals

**Summary**

FDA's proposed rule on Current Good Manufacturing Practices (CGMPs) and preventive controls for food for animals focuses on preventing problems in order to improve the safety of these products. The preventive controls provisions of the proposed rule, which are required by the FDA Food Safety Modernization Act, would apply to domestic and imported animal food, including pet food, animal feed, and raw materials and ingredients. Facilities producing animal food would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct problems that arise. The proposed rule would also establish certain Current Good Manufacturing Practices (CGMPs) that specifically address animal food.

FDA is proposing that the requirements be effective 60 days after the final rule is published in the Federal Register. Recognizing that small and very small businesses may need more time to comply with the requirements, FDA is proposing tiered compliance dates based on facility size. The proposed rule will publish on October 29 and comments are due 120 days after publication. FDA is also announcing three public meetings to explain the proposal and provide additional opportunity for input.

**Background**

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011, to better protect human and animal health by helping to ensure the safety and security of the food and feed supply. FSMA embraces preventing food safety problems as the foundation of a modern food safety system and recognizes the need for a global approach to food and feed safety. FDA has proposed three additional rules that are foundational to this preventive approach encompassed by FSMA. In addition to preventive controls for food for animals, FDA has proposed preventive controls for human food; standards for produce safety; and the Foreign Supplier Verification Program for importers, which requires importers to take steps to help ensure that imported human and animal food are as safe as that which is produced domestically. FDA has also proposed to establish a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.

Ensuring the safety of animal food is complex. It involves: (1) ensuring the safety of animal food for animals consuming the food, and (2) ensuring the safety of animal food for humans handling the food, particularly pet food. Through a comprehensive review of the animal food safety system in the U.S., the agency has identified gaps in the regulation of non-medicated animal food. (FDA requires facilities producing medicated feeds to follow current good manufacturing practices (CGMPs) to prevent unsafe contamination of feed with drugs.) One critical gap is the lack of federal regulations, such as Current Good Manufacturing Practices (CGMPs), to provide baseline requirements for producing safe animal food (including pet food, animal feed, and raw materials and ingredients). Another critical gap is the lack of federal regulations relating to hazard analysis and preventive controls.

**Who is Covered?**

With some exceptions, the proposed rule on CGMPs and preventive controls for food for animals would apply to facilities that manufacture, process, pack, or hold animal food and are required to register as a food facility under section 415 of the FD&C Act. This rule does not apply to farms that manufacture food

for their own animals or other food facilities not required to register under section 415 of the FD&C Act. More information about exemptions from this proposed rule can be found in the chart at the end of this fact sheet.

**Highlights of the Proposed Rule**

The proposed rule would establish for the first time Current Good Manufacturing Practices that specifically address the manufacturing, processing, packing, and holding of animal food. FDA considered it important to establish CGMPs for animal food as prerequisite requirements to ensure that these products are manufactured under conditions and practices that protect against contamination. The proposed rule also would establish Hazard Analysis and Risk-based Preventive Controls for Food for Animals to implement the provisions in section 103 of the FDA Food Safety Modernization Act. The new requirements would be called "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals."

**New Current Good Manufacturing Practices**

The proposed animal food CGMPs address similar safety requirements as those contained in the proposed rule to update the human food Current Good Manufacturing Practice (CGMP) regulations. These areas include:

- Hygienic personnel practices and training;
- Facility operations, maintenance, and sanitation;
- Equipment and utensil design, use, and maintenance
- Processes and controls; and
- Warehousing and distribution.

However, the CGMP provisions of the proposed rule for animal food are not identical to the human food CGMPs in the proposed rule for preventive controls for human food. The animal food CGMPs, for example, would not address certain practices that don't pertain to animal food, such as allergen cross-contact.

**Hazard Analysis and Risk-Based Preventive Controls**

Under the proposal, each owner, operator, or agent in charge of a facility (those required to register with FDA under Section 415 of the FD&C Act), with certain exceptions described below, would be required to comply with the hazard analysis and risk-based preventive controls. The preventive controls are **science- and risk-based** in that they would require controls that are necessary to protect human and animal health and exempt certain facilities from requirements or modify requirements for certain low-risk activities. Second, they are **flexible** in that firms can develop preventive controls that fit their products and operations, as long as they are adequate to significantly minimize or prevent all food safety hazards that are reasonably likely to occur.

The proposed hazard analysis and risk-based preventive control requirements are similar to Hazard Analysis and Critical Control Points (HACCP) systems, which were pioneered by the human food industry and are required for juice and seafood. They would require operators of a facility to understand the hazards that are reasonably likely to occur in their operation and to put in place preventive controls to minimize or prevent the hazards. Although this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.

Each facility would be required to prepare and implement a written food safety plan, which would include the following:

- A **Hazard analysis** that would identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility.
- **Preventive controls**, which would be identified and implemented to provide assurances that hazards that are reasonably likely to occur would be significantly minimized or prevented. These preventive controls would need to be appropriate for the facility and the animal food being produced,

and could address, for example, animal food processing, prevention of cross-contamination, and sanitation affecting animal food safety. A recall plan for animal food for which there are hazards that are reasonably likely to occur would be required. It is unlikely that all possible prevention measures and verification procedures would be applied to all animal foods at all facilities. FDA believes a supplier approval and verification program is a risk-based and appropriate control to significantly minimize or prevent hazards from raw materials and ingredients that is consistent with current scientific understanding of food safety practices. Although it is not included in the proposed requirements, it is discussed in the preamble and FDA is seeking comment on such a program.

- **Monitoring** procedures that would provide assurance that preventive controls are consistently performed and records to document the monitoring.
- **Corrective actions** that would be used if preventive controls are not properly implemented. Facilities would be required to correct problems and minimize the likelihood of reoccurrence, evaluate the animal food for safety, and prevent affected animal food from entering commerce. If specific corrective action procedures were not established for the problem, or if a preventive control is found to be ineffective, the facility would also be required to re-evaluate the food safety plan to determine if modifications are needed.
- **Verification** activities to ensure that preventive controls are consistently implemented and are effective. Verification activities might include records review of monitoring, correction actions, or instrument calibration. Preventive controls would also be required to be validated to ensure they are effective in controlling the hazard. In addition, the food safety plan must be reassessed at least every three years and otherwise when necessary. FDA recognizes that product and environmental testing programs are science-based verification activities that are commonly accepted in many sectors of the food industry. Although they are not included in the proposed requirements, they are discussed in the preamble and FDA is seeking comment on these programs. FDA also is asking for comments regarding review of customer and other complaints as part of verification.
- **Recordkeeping**: Firms would be required to keep a written food safety plan, including the hazard analysis. They would also be required to keep records of preventive controls, monitoring, corrective action, and verification procedures.

**Draft Qualitative Risk Assessment of Risk of Activity/ Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm**

Along with the proposed rule, FDA announced the availability of, and is requesting comment on, a draft qualitative risk assessment designed to provide a science-based risk analysis of those on-farm activity/ Animal food combinations that would be considered not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences to humans or animals. Interested persons may submit comments regarding the draft risk assessment to www.regulations.gov, Docket No. FDA-2013-N-1043. The document may also be viewed at available at http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf.

Public comments will be considered in preparing a final version of the risk assessment. The draft risk assessment was submitted to a group of scientific experts external to FDA for peer review, and the draft was revised, as appropriate, considering the comments of those experts. The report from that peer review is available at http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366907.pdf.

**Effective and Compliance Dates and Definitions for Small and Very Small Businesses**

FDA is proposing the following effective and compliance dates for businesses subject to the new requirements. Recognizing that small and very small businesses may

need more time to comply with the requirements, the compliance dates are adjusted accordingly.

**Effective Date:** 60 days after the final rule is published

**Compliance Dates:**

- **Very Small Businesses—**a business having: Option 1 less than $500,000 in total annual sales of animal food; Option 2 less than $1 million in total annual sales of animal food; or Option 3 less than $2.5 million in total annual sales of animal food, adjusted for inflation, would have to comply three years after the publication of the final rule.
- **Small Businesses—**a business employing fewer than 500 persons would have to comply two years after the publication of the final rule.
- **Other Businesses—**a business that is not small or very small and does not qualify for exemptions would have to comply one year after the publication of the final rule.

**Economic Impact of the Proposed Rule**

The proposed rule is aimed at reducing the human and animal health burden by (1) reducing the risk of serious illness and death to animals, and (2) reducing the risk of adverse health effects to humans handling contaminated animal food.

An improved animal food safety system can reduce the number of recalls, reduce the risk of adverse health effects related to contaminated animal food, and reduce the losses of contaminated animal food ingredients and products. The proposed rule has a one-time compliance cost to industry estimated at $100.74 million, and discounting the one-time cost over 10 years at a 7 percent discount rate and adding the annual costs results in a total an annualized compliance cost estimate of $128.75 million. While the many potential benefits of the proposed rule can be identified, the current economic costs of hazards associated with animal food products could not be sufficiently quantified for comparison. The document is available at http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM366905.pdf.

**Rulemaking Process and How to Submit Comments**

The proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," is published in the Federal Register so that the public can review it and submit comments. FDA considers comments received during the comment period on the proposed rule and then considers revising the rule, based on its review of the comments, before issuing a final rule. The proposed rule and supporting documents are filed in FDA's official docket on http://www.regulations.gov and also can be accessed at www.fda.gov/fsma. Comments are due 120 dates after the publication date.

FDA has conducted extensive outreach to industry, the consumer community, other government agencies, and the international community to gain input and perspective on how best to implement this and other proposed rules required by FSMA. That input and perspective shaped the proposed rule in a way that will help to ensure they are practical, flexible and effective. FDA will hold three public meetings on Nov. 21, 2013 in College Park, MD., on Nov. 25, 2013 in Chicago, and on Dec. 6 in Sacramento, CA. FDA will also participate in several additional meetings during the comment period.

**Assistance to Industry**

FDA will publish within six months of publication of the final rule a guidance document that provides the requirements in plain language to help businesses, particularly small businesses, comply with the hazard analysis and preventive controls requirements. In addition, FDA has established a Food Safety Preventive Controls Alliance, with a specific subcommittee dedicated to animal foods, to disseminate information on hazards and controls to help industry, particularly small and very small businesses, comply with the new requirements.

**For Additional Information**

- (Link to Federal Register notice)
- FDA Food Safety Modernization Act web site
- Fact Sheet: Preventive Controls for Human Food
- Fact Sheet: Standards for Produce Safety
- Fact Sheet: Foreign Supplier Verification Program for Importers of Food
- Fact Sheet: Accreditation of Third Party Auditors
- The Food Safety Law and the Rulemaking Process: Putting FSMA to Work
- Video: The Rulemaking Process: A Primer by FDA
- Video: FDA Food Safety Modernization Act: A Primer by FDA

*Updated: 10/23/13*

**Exemptions and Modified Requirements for Preventive Controls for Food for Animals***

| Type of facility or operation | Hazard Analysis and Risk Based Preventive Control Requirements | Current Good Manufacturing Practices (CGMPs) |
|---|---|---|
| A facility that has animal food sales averaging less than $500,000 per year during the last three years. In addition, sales to qualified end users must exceed sales to others. A qualified end-user is either a consumer (in any location), or a restaurant or retail food establishment purchasing the animal food for sale directly to consumers that is located in the same State or not more than 275 miles away. | **Modified Preventive Control Requirements Apply:** Facility must certify that it is a "qualified facility" and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications. | Must comply |
| A very small business with total annual sales of animal food, adjusted for inflation is (three options are being proposed):<br>• Option 1: Total annual sales of < $500,000<br>• Option 2: Total annual sales of < $1,000,000<br>• Option 3: Total annual sales of <$2,500,000 | **Modified Preventive Control Requirements Apply**: Facility must certify that it is a "qualified facility" and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications. | Must comply |
| Animal foods subject to the low-acid canned food (LACF) regulation. The exemption for facilities producing low-acid canned food applies only to those microbiological hazards addressed by LACF regulation. | Exempt | Must comply |
| Activities within the definition of "farm," including farm activities that are covered by the proposed rule "Standards for the Growing, Harvesting, Packing and Storing of Produce." | Exempt | Exempt |

**Exemptions and Modified Requirements for Preventive Controls for Food for Animals***

| Type of facility or operation | Hazard Analysis and Risk Based Preventive Control Requirements | Current Good Manufacturing Practices (CGMP) |
|---|---|---|
| Certain low-risk manufacturing/processing activities, packing or holding activities that are conducted by small or very small businesses on farms for specific animal foods. Examples including conveying/weighing/sorting/culling/grading grain, oilseed, grain and oilseed by-products, and forage (hay and ensiled material). | Exempt | Must comply |
| Facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables, which are covered under the produce safety rule) intended for further distribution or processing. | Exempt (provided they are solely engaged in such storage) | Exempt |
| Facilities, such as warehouses, that only store packaged animal foods that are not exposed to the environment<br>• Packaged animal food for which refrigeration is not required for safety<br>• Packaged animal food for which refrigeration is required for safety | Exempt<br><br>**Modified Preventive Control Requirements Apply:** Requirements concerning temperature controls, including monitoring, verification, and records. | Must comply |

- This chart does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult the proposed rule for specific requirements.