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food industry lawflash

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FDA Releases Good Manufacturing Practices for Animal Food

Proposed requirements dictate a substantial upgrade of the current regulatory standard of care.

On October 29, the U.S. Food and Drug Administration (FDA or the Agency) issued a proposed rule—Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Rule)—which establishes, for the first time, current good manufacturing practices (GMPs) that specifically address the manufacturing, processing, packing, and holding of animal food.[1] The 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's Food Safety Modernization Act (FSMA).

Collectively, the proposed requirements would dictate a substantial upgrade of the regulatory standard of care currently being imposed upon both feed manufacturers and the ingredient suppliers of such manufacturers. In the near term, its publication should also significantly alter expectations throughout the supply chain for such products by bringing them closer to those required for human food products.

Background

The Rule would not only establish certain GMP provisions to ensure the safety and suitability of animal food,[2] but it would also implement the requirements of section 103 of FSMA for animal food facilities that must register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 350d, to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. More specifically, the Rule would establish requirements for the following:

- A written food safety plan
- Hazard analysis
- Preventive controls for hazards that are reasonably likely to occur
- Monitoring
- Corrective actions
- Verification
- Associated records

The application of the preventive controls, however, would be required only in cases where facilities determine that hazards are reasonably likely to occur.

1. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (proposed Oct. 29, 2013) (to be codified at 21 C.F.R. pts. 16, 225, 500, 507, and 579), *available at* http://www.gpo.gov/fdsys/pkg/FR-2013-10-29/pdf/2013-25126.pdf.

2. Under the Rule, "animal food" would be defined as "food for animals other than man, and includes pet food, feed, and raw materials and ingredients." "Animal food" does not refer to food derived from animals that is intended for human consumption.

Covered Entities

Generally, the Rule would apply to facilities that manufacture, process, pack, or hold animal food and that are required to register as a food facility under section 415 of the FD&C Act. The Rule would not apply to farms that manufacture food for their own animals or other food facilities that are not required to register under section 415 of the FD&C Act. Under the Rule, each owner, operator, or agent in charge of a facility, with certain exceptions noted in the Rule, would be required to comply with the hazard analysis and risk-based preventive controls.

New GMPs Under the Rule

In the Rule, the Agency proposes a number of new GMPs that contain safety requirements similar to those in FDA's proposed rule to update its preventive control requirements for human food. These include the following:

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

However, as the Agency notes in guidance on the Rule, the GMP provisions of the human food and animal food proposed rules are not identical. For example, the Rule does not address allergen cross-contact, as such practices do not pertain to animal food.

Hazard Analysis and Risk-Based Preventive Controls

While the Rule's proposed hazard analysis and risk-based preventive control requirements are somewhat similar to Hazard Analysis and Critical Control Points (HACCP) systems, the Rule differs from HACCP systems in that animal food preventive controls may be required at points other than at critical control points, and critical limits would not be required for all such preventive controls.

The Rule would require that each covered facility prepare and implement a written food safety plan, which must 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** that 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.
- **Monitoring procedures** that would provide assurances that preventive controls are consistently performed along with 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 reevaluate 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 may 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.

- **Recordkeeping requirements** mandating that firms keep a written food safety plan, including the hazard analysis. Firms would also be required to keep records of preventive controls, monitoring, corrective action, and verification procedures.

Exemptions and Modified Requirements for Preventive Controls

The Rule would establish a series of exemptions (including modified requirements in some cases) from the requirements for hazard analysis and preventive controls. For example, under the Rule, modified preventive control requirements would apply to the following:

- Certain facilities having animal food sales averaging less than $500,000 per year during the last three years and for which sales to "qualified end users" exceed sales to others.
- Entities that meet the Rule's definition of a "very small business."
- Facilities, such as warehouses, that only store packaged animal foods that are not exposed to the environment (e.g., packaged animal food for which refrigeration is required for safety).

While the above are only a few examples of the Rule's proposed exemptions and modified requirements, the Agency's guidance on the Rule provides a detailed summary of all of the proposed exemptions and modified requirements.[3]

Draft Qualitative Risk Assessment

In addition to issuing the Rule, FDA announced the availability of, and is requesting comment on, a draft qualitative risk assessment. The risk assessment is 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.[4] Public comments will be considered by the Agency in preparing a final version of the risk assessment.

Contacts

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3. FDA, Guidance - FSMA Proposed Rule to Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, *available at* http://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm.

4. 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, *available at* http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf.

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