SAFEGUARDS
CONSUMER GOODS AND RETAIL

FOOD

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US FDA cGMP, HAZARD ANALYSIS AND PREVENTIVE CONTROL FOR ANIMAL FOOD PROPOSAL

On 29 October 2013 the United States Food and Drug Administration (US FDA) published the proposed rule establishing current good manufacturing practices (cGMPs), Hazard Analysis and Preventive Controls for Animal Food[1]. The comment period for this proposed rule ends 26 February 2014.

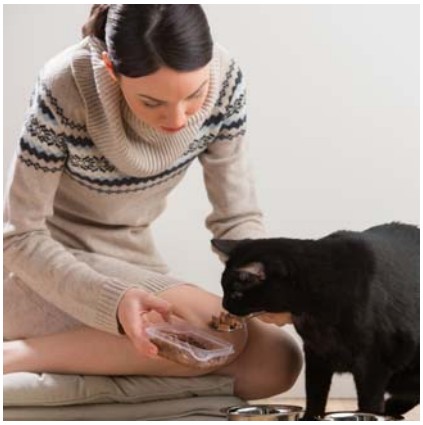
cGMPS AND PREVENTIVE CONTROLS FOR ANIMAL FOOD

This proposal rule applies to domestic and imported animal food which includes pet food, animal feed, raw materials and ingredients. Modified requirements are proposed for very small businesses, small businesses and warehouses that require refrigeration or freezing for food safety. Low acid canned foods (LACF) would be exempt from assessing microbiological hazards which is already covered on the LACF regulations. Also exempt are farms, grain elevators used for only storage, low risk manufacturing or processing such as conveying/weighing/sorting/culling, grading of grain and by-products, oil seed and by-products, forage and warehouses where products are not exposed to the environment and don't require refrigeration or freezing for food safety.

The cGMPs will be established for these operations, which will be similar to those established for human food operations with exceptions such as allergen cross-contamination which will not be part of the animal food cGMPs. The cGMP areas that will apply to animal food are hygienic personnel and training, facility operations, maintenance and sanitation, equipment and utensil design, use and maintenance, process and controls, and warehouse and distribution.

Hazard Analysis and Preventive Controls will apply to animal food operations. This once again will be similar to those proposed for human food. Each facility would require developing and documenting a food safety plan that would include:

1. Hazard Analysis,
2. Preventive controls of the hazards (such as sanitation and prevention of cross-contamination) – including a recall plan and possibly including supplier approval and verification programs,
3. Monitoring procedures,



4. Corrective actions – including reevaluation of the plan if found to be ineffective,
5. Verification Activities (such as record review or calibration) – including validation and possibly including environmental testing,
6. Record Keeping of the aforementioned activities.

[1] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Additionally the US FDA has published a Draft Qualitative Risk Assessment on the Risk of Activity/Food Combinations Activities Conducted in a Facility Co-Located on a Farm[2] to provide a risk assessment of that type of operation.

The effective date of this rule will be 60 days after the final rule is published. Compliance date will be three years after the final rule is published for very small businesses; two years for small businesses and one year for all other businesses.

For more information on FSMA and how to comment on the proposed regulations visit http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

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[2] Center for Veterinary Medicine Food and Drug Administration U.S. Department of Health and Human Services

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