

## **The Food Safety Modernization Act: Regulatory Impact on Feed Manufacturing**

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### **OVERVIEW**

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 and provides the U.S. Food and Drug Administration (FDA) with sweeping new authorities and requirements. The law was a bi-partisan supported bill backed by the food and feed industries. It authorizes FDA to promulgate new rules for preventive controls, develop performance standards, create new administrative detention rules, provides authority for mandatory recall of adulterated products, and provides authority for hiring more than 4,000 new field staff among other provisions. It remains unclear whether Congress will provide sufficient funding to fully implement the law, but the FDA is proceeding with rulemaking to meet the court ordered deadlines that were established. The animal food final rule must be published by August 2015.

The centerpiece of the law is the hazard identification, written food safety plan, and preventive controls. These items are required of all feed, pet food, and ingredient facilities that process, pack, manufacture, or hold feed unless they are exempt as a *farm*, (facilities that feed their own animals on their own farms) or are classified as a very small business. The food safety plan must be available for FDA to review and copy. It encompasses several areas and requires recordkeeping for 2 yr. Basically, Congress requires FDA to do the following (quoted from the law):

*“The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.”*

Regulations to implement this provision of the law were to be finalized by July 2012. FDA missed this deadline and was sued by food safety activists and is now under a court ordered mandate to finalize many of the FSMA regulations. This hazard analysis and preventive control regulation for animal food is due to be finalized by August 30, 2015.

### **IMPROVING FEED SAFETY**

The intent of FSMA is to better protect human and animal health by helping to ensure the safety and security of the food and feed supply. FDA 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. Thus, FSMA is designed to take a proactive approach by promoting continuous improvement through audits vs. compliance to regulatory requirements through inspections.

FDA states that ensuring the safety of animal food involves:

- 1) the safety of the food consumed by animals and
- 2) the safety of humans handling the food, particularly pet food.

The agency indicates the gaps in the current system to ensure the safety of animal feed include a lack of federal regulations for Current Good Manufacturing Practices (CGMP) to provide baseline requirements for non-medicated animal feed, pet food, raw materials, and ingredients. In addition, the agency feels that there is a lack of federal regulation relating to hazard analysis and preventive controls for all animal feed and ingredients. FSMA provides requirements for these areas.

Manufacturers of animal feed, pet food, raw materials, and ingredients will be responsible for ensuring the safety of their finished products. Each facility is responsible for identifying reasonably foreseeable hazards that may occur and determining the preventive controls necessary to minimize or eliminate the hazard. Manufacturers will establish CGMP to ensure the proper design, monitoring, and control of manufacturing processes are maintained. CGMP provide an environment where hazards may be controlled more effectively.

FSMA requires facilities to create an animal food safety plan, which includes hazard analysis and the development of preventive controls for reasonably foreseeable hazards. The food safety plan must include a supplier verification program, a recall plan, management of preventive controls, verification and validation activities for preventive controls,

and a corrective action program. Records will be essential to demonstrate compliance.

The greatest risks for most feed manufacturing facilities come from outside of their facilities through raw materials and ingredients. Thus, an effective supplier verification program is critical to maintaining or improving the safety of animal food. Verification activities are required to ensure materials are obtained from approved suppliers and that reasonably foreseeable hazards are controlled.

While the FSMA requirements for animal food will not be final until August 30, 2015, facilities are developing programs and processes to ensure compliance with the new federal regulations. Based on the size of the facility, a business will have 1, 2, or 3 yr to comply with the requirements from the final rule on CGMP and hazard analysis and risk-based preventive controls for food for animals.

A facility that develops an effective quality and feed safety program to drive continuous improvement will reach compliance with the new FSMA requirements more efficiently and effectively. It is anticipated that facilities within the feed industry will seek third-party certifications to drive compliance with the new FSMA regulations and help gauge their success with manufacturing safer animal food. Complete information on FSMA and its rules can be found at: [www.fda.gov/fsma](http://www.fda.gov/fsma).

The American Feed Industry Association developed feed safety programs that mirror the FSMA approach, in that they require hazard analysis and development of preventive controls. The Safe Feed/Safe Food program can be utilized for feed and feeding ingredients. Separate programs for export to the European Union (EU), pet

food, and pet food ingredients also have been developed and are based on either the EU Hazard Analysis Critical Control Point (**HACCP**) approach or the global food safety initiative approach, which is also a HACCP program. More information about these programs can be found at [www.safefeedsafefood.org](http://www.safefeedsafefood.org).