Food Safety Modernization Act Update

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The Food Safety Modernization Act (FSMA) was signed into law by the President on January 4, 2011—this is an important date for rulemaking deadlines.

Note: Many of the new authorities are dependent on Congress providing $450 million of additional funding annually, especially for facility inspections.

PRIMARY SECTIONS AFFECTING THE FEED INDUSTRY:

Registration

As this law uses the term "facility," firms registered under the Bioterrorism Act are affected. Registration must be renewed every even-numbered year between October and December beginning in 2012. The U.S. Food and Drug Administration can revoke a facility's registration, which means firms may not operate. This is a new authority for FDA. Go to www.fda.gov/food/foodsafety/FSMA to view the law/proposed rules. Dairy farms selling feed must register and comply with all the FSMA rules beginning in 2016.

Hazard Identification and Written Risk Management Plan

The centerpiece of the law is the hazard identification and written risk management plan to control those hazards. It is required of all feed, pet food and ingredient facilities that process, pack, manufacture or hold feed unless the facility is a farm, as defined as those facilities feeding their own animal on their own land. This plan must be available for FDA to review and copy. It encompasses several areas and requires recordkeeping for two years. Basically, Congress requires the following (quoted from the new 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 new law were due within 18 months from FDA, and these must be separate from the food rules. FDA is authorized to hire 17,000 new employees over the next four years to carry out inspections (subject to congressional funding). Only a couple of the rules have been finalized. Under a court order, FDA must publish all the main seven rules by August 31, 2015. Implementation will be phased beginning in 2016 by one-, two- and three-year periods depending on the facilities' size.

The first round of proposed rules also added current good manufacturing practices rules (CGMPs) that are not required by FSMA, but FDA is allowed to create these under the federal Food, Drug and Cosmetic Act. These rules were very prescriptive and have been released again with new proposals to lessen the costs of the rules on the feed industry.

Basically, there are three sets of proposed rules:

1) CGMPs
2) Hazard analysis and preventive controls
3) Records required for both rules

New Fees Allowed to be Collected by FDA

FDA is authorized to collect new fees (e.g. direct costs at $217/hr. for domestic and $305/hr. for foreign) for reinspection of failed facilities, reinspection at ports of entry, participation in voluntary import programs and export certifications ($175).

Mandated Inspections Timeframes

FDA is required to create regulations for low and high risk facilities and inspect all low risk facilities within five years of the date of enactment and seven years thereafter and for high risk facilities within three years of enactment and five years thereafter. Feed industry high risk facilities are

likely to be those that have had inspection problems or have high risk products.

FDA is also required to inspect 600 foreign facilities annually and increase inspections by 10 percent each year. The criteria have not been established.

Traceability and Recordkeeping

FDA may require more records for high risk facilities and must require records for all facilities to be maintained for at least two years. Traceability for "commingled" products has been limited (e.g. corn bins).

Records Access

The Bioterrorism Act language was amended to allow FDA to obtain records for "…any other similar products…" that are related in adulteration events. This may be products of the same type (e.g. swine feed) or processed on the same line. This new authority is immediate, but it is unclear how FDA will interpret it.

Mandatory Recall Authority

This is a new authority, but FDA must request a firm to first voluntarily recall products and if it refuses or does not accomplish it within the FDA's specified timeframe, FDA can issue a recall order, but only to be issued by the commissioner. Firms may request a hearing that must be granted within two days and the recalls may only be for serious adverse health consequences or death in humans or animals.

Administrative Detention

This authority has been increased from the Bioterrorism Act. FDA is authorized to detain products that are either adulterated or misbranded (instead of serious adverse health consequences or death in humans or animals) and if it has a "reason to believe" (instead of "credible evidence"). This authority is only granted to a district director or higher and not for investigators.

Third Party Certifications

FDA is authorized to certify third parties (e.g. foreign governments or private groups) for certifying products for export.

Import Requirements

All feed and food importing firms must certify that firms exporting products must meet the same hazard ID and written risk management program requirements before exporting to the U.S. This also allows such firms expedited imports. Proposed rules have been published.

Safe Food Transportation Act

FDA is required to publish final rules in 18 months for this law that was originally passed in 1990 but never implemented. It would require records on backhauls and non-food items. Proposed rules have been published.

Performance Standards

FDA is required to develop performance standards for adulterants (e.g. mycotoxins, etc.) based on existing science and review every two years with USDA. These will likely be guidance documents or action advisory levels.

Current Status

FDA published proposed rules for feed on October 29, 2013, and the comments closed on March 31, 2014. A second round of "supplemental proposed rules" was published on September 29, 2014, and the comment period will close on December 15, 2014. Transportation safety rules are still pending. A federal judge has ordered most of the rules to be finalized by August 30, 2015.

Guidance documents are being developed jointly by industry and FDA. Published with the animal food hazard identification and preventive control rules were new feed industry good manufacturing practices rules for all feed, ingredients and pet food. FDA has proposed a very small business size of firms with less than $2.5 million in feed sales. These firms would be allowed some leeway and not required to develop a facility animal food safety plan, provided that the firms notify FDA and provide documentation regarding the firm's feed sales. The firms will need to assert that they have an adequate animal food safety plan.

The American Feed Industry Association has filed objections to the high cost (ca. $500 million) of the FSMA rules and low benefit (ca. $30 million) and lack of either empirical data or scientific basis to demonstrate the rules will result in industry or societal benefits. Such justification is required by law and Executive Order. Additional rules are expected this summer and will likely drive up the costs.

AFIA continues to work with FDA to lower the costs of the final rules and to assist in developing guidance documents and training curricula for FSMA compliance.