Non-Ruminant Session I

Tuesday, September 17, 2013

Notes

Food Safety Modernization Act: Impact on the Feed Industry

Richard Sellers, PAS

American Feed Industry Association, Arlington, VA

The Food Safety Modernization Act 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 $300 million of additional funding annually.

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 Oct.-Dec. beginning in 2012. FDA 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.

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. 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 are due within 18 months from FDA, and these will 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).

New Fees Allowed to be Collected by FDA

FDA is authorized to collect new fees (e.g. direct costs at $221/hr) 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 inspection 600 foreign facilities annually and increase inspections by 10% each year.

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. Rules are due in four months.

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. Rules are due within 24 months.

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.

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

As of late July, proposed rules for feed, foreign verification and transportation are still being review at the White House's Office of Management and Budget. A federal judge has ordered these to be released by November 30, 2013 and finalized by June 30, 2015. Once released, feed industry representatives will comment on the rules, assist FDA in making useful guidance documents for industry and FDA/state investigators and request a long phase-in time.

Published with these rules will be new feed industry good manufacturing practices rules for all feed, ingredients and pet food. On top of that will be the new FSMA hazard identification and preventive control rules.

Latest information on FSMA can be found here:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

AFIA

AMERICAN FEED INDUSTRY ASSOCIATION