FSMA Update

April 16, 2014

More FSMA Rules are Open for Comment and AFIA Needs Assistance in Comment Preparation
As noted in last week's update, the American Feed Industry Association is now turning our attention to several other proposed rules and documents the U.S. Food and Drug Administration has published to implement the Food Safety Modernization Act. Your assistance is needed to help prepare AFIA's positions and responses to the agency. This week we look at the advanced notice of proposed rulemaking on consumer notification of reportable foods and the proposed rule on intentional adulteration.

Please contact Paul Keppy, AFIA legislative and regulatory specialist, at (703) 650-0144 if you would like to provide comments on these issues or the proposed rule on sanitary transportation or the high risk methodology. AFIA is not forming working groups on notification of reportable foods or intentional adulteration proposed rules as the staff is likely to work with the lawyers to prepare these comments. The drafts will be circulated to affected committees to review.

How Does Consumer Notification on Reportable Foods Apply to Animal Food?
On March 26, FDA published an advanced notice of proposed rulemaking seeking comments, data and information on how the agency should implement Section 211 of FSMA which requires notification of consumers who may have purchased reportable foods. Under the early draft requirements being considered, a firm that has certain reportable food events would need to submit new consumer oriented materials to FDA which would enable a consumer to accurately identify if they are in possession of the reportable food. A grocery store that sold the reportable food that has an FDA one-page summary would need to prominently display the information within 24 hours of the page being posted on FDA's website.

In the advanced notice of proposed rulemaking, FDA asks several questions where they are seeking further guidance to meet the requirements in Section 211 of FSMA. For example, FSMA states that "grocery stores" must display the information for consumers. FSMA and the Federal Food, Drug & Cosmetic Act do not define "grocery stores." FDA is asking for comments on what types of retail establishments should be considered within the meaning of "grocery stores." How should the feed industry respond to this topic? On first review, it appears this rule is designed for human food only. AFIA could make that argument, if its members agree.

FDA also seeks information on when a firm should provide the consumer-oriented materials to FDA for posting on the agency's website. Should a firm be required to supply the information on when the product being reported on has actually reached a grocery store? Or should the information be provided with every reportable food even if there is no possibility of the product reaching the consumer?

FDA also asks several other questions regarding what type of information should be supplied and how a grocery store should display or notify consumers. AFIA will need to carefully consider these questions and provide input to FDA to guide any proposed requirements for animal food. Comments are due June 9.

Intentional Adulteration Proposed Rule Suggests Exemption for Animal Food Facilities
FDA published the proposed rule on "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" in late December. The proposal meets several requirements of FSMA. Although there are many different types of intentional adulteration (e.g., acts of disgruntled employees, economically motivated adulteration), this proposal only addresses acts of terrorism

intended to cause massive public health harm and economic disruption. This concept is often referred to as "food defense."

The proposed rule recommends that animal food facilities be exempt from the requirements of the rule as the products have a significantly reduced risk of causing intentional harm to human health. AFIA agrees with FDA's conclusion and will work with our members to provide comments in support of the exemption. Comments are due by June 30.

Contact AFIA

To keep track of FSMA updates from FDA, visit the FSMA webpage, www.fda.gov/fsma, and sign up for email updates. For questions on any aspect of FSMA, please contact Richard Sellers, AFIA senior vice president of legislative and regulatory affairs, at (703) 558-3569, Leah Wilkinson, AFIA director of ingredients, pet food and state affairs, at (703) 558-3560, Henry Turlington, AFIA director of quality and manufacturing regulatory affairs, at (703) 650-0146, or Keppy.

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 is unclear whether Congress will provide sufficient funding authorization to fully implement the law, but it is clear that FDA is proceeding with rulemaking to meet the new law's regulation deadlines.