FSMA Weekly Update

Feb. 26, 2014

FSMA Court Ordered Timeline - Extensions Granted
A consent decree between the U.S. Food and Drug Administration and consumer groups has pushed back the previous court-ordered deadlines for when FDA is required to issue final rules on the Food Safety Modernization Act. The decree also says the comment period deadlines previously set by the court "are no longer operative." FDA has the ability, therefore, to extend the comment periods (or to reopen comment periods that have closed), as long as they meet the new deadlines for issuing the final rules. The court just approved the following new deadlines for issuing final rules:

Preventive controls for human food	Aug. 30, 2015
Preventive controls for animal food	Aug. 30, 2015
Produce safety standards	Oct. 31, 2015
Foreign Supplier Verification Program	Oct. 31, 2015
Accreditation of third-party auditors	Oct. 31, 2015
Sanitary transportation of food	March 31, 2016
Intentional adulteration/food defense	May 31, 2016

The American Feed Industry Association is working with our legal counsel to determine the most effective way to proceed. Tentatively, AFIA is planning to ask for a 90-day extension of the comment period.

Overview of Select Topics in AFIA's Comments
As noted in last week's update, we intend to cover different topics in the updates for the next few weeks to better educate members on issues in the rule and how AFIA will be commenting. In this update, we will provide a brief overview of our concerns with the Current Good Manufacturing Practices proposal, finished product testing, environmental monitoring and supplier verification-which were not proposed in the rule, but FDA is seeking comments for potential inclusion in the final rule.

As a reminder, AFIA will distribute our draft comments on March 10. Please be prepared to review them quickly as timeframes will be short. AFIA hopes to accept comments for one week after the draft is distributed. All AFIA members are free to utilize any parts of AFIA's comments in their own submissions.

Current Good Manufacturing Practices (CGMPs)
Unfortunately FDA used human food CGMPs as a starting point for animal food CGMPS. AFIA would have preferred any number of other references as a starting point, such as PAS 222 (Publicly Available Standard 222 from the British Standards Institute), medicated feed CGMPs, Association of American Feed Control Officials' CGMPs or even the Codex Alimentarius Code of Good Animal Feeding Practice manual. AFIA believes FDA erred in

jumping from limited animal food manufacturers following medicated feed CGMPs to all animal food manufacturers following CGMPs based on human food CGMPs.

While AFIA strongly encourages FDA to consider our suggested alternatives, it is prudent to comment on what has FDA proposed. Therefore, AFIA drafted revisions to the codified language, so as to make the proposed CGMPs appropriate for animal food, instead of human food.

AFIA stressed the fact there are different potential risks among different animal food manufacturers. Including phrases such as "as appropriate" or "as necessary" allow for differences among the manufacturing of animal food that has different levels of risk. For example, "sanitizing" is not always the correct control for a potential hazard-it therefore should be removed from the codified language. AFIA also believes that "for intended use" should be included in many CGMPs because it allows the animal food safety to be risk-based and risk-appropriate.

AFIA would also like to see FDA focus on the "adulteration of animal food" rather than the "contamination of animal food, animal food contact surfaces or animal food packaging materials," as "adulteration" has legal definitions in both state and federal law.

Overall, FDA's CGMPs have a prescriptive nature, which in many cases would create overly detailed requirements, and would not allow for a risk-based assessment and would restrict innovative approaches to addressing site-specific food safety concerns. AFIA worked with industry stakeholders to significantly revise the proposed CGMPs. Now AFIA is working with allied industry to make our recommendations as strong as possible.

If you or your firm has questions or comments on the CGMP portion of the proposed rules, please contact Paul Keppy, AFIA's legislative and regulatory specialist, at (703) 605-0144.

Finished Product Testing and Environmental Monitoring
FDA did not address a requirement to test products or for environmental monitoring in the proposed rule but asked many questions whether the testing should be required, and if so, how much detail should FDA require via regulation? AFIA will address those questions and urge that prior to FDA issuing a final regulation that requires testing, FDA provide an opportunity to comment on specific codified language via a proposed rule.

AFIA will address the proper role of finished product testing or environmental monitoring in the animal food industry. Testing, in Section 418(f) of the Federal Food Drug and Cosmetic Act, is discussed as a means to verify implementation of preventive controls. Testing programs can identify failures or adverse trends in CGMPs or preventive controls; however, testing cannot prevent, reduce or eliminate microbial or chemical hazards from animal foods. Thus, testing is ineffective as a preventive control measure.

Testing is only reflective of the sample or sample location evaluated at the time the sample was collected. Any reliance on testing as the sole means of controlling a hazard would be irresponsible and must be paired with proper effective and validated process, environmental and sanitation controls.

Testing better functions as a verification tool, when necessary and appropriate, rather than a measure that directly controls hazards. AFIA believes that environmental monitoring can be an appropriate means to verify the effectiveness of specific environmental controls, such as cleaning and sanitation, facility maintenance, zoning and personnel practices. Environmental monitoring programs play an important role in an animal food safety plan for a facility that has determined an environmental pathogen is a hazard that needs to be controlled in their facility. Effective environmental monitoring programs are designed to find and address likely issues before they could potentially lead to product adulteration.

In finished animal food products, if adulteration is present, it is often not possible for testing programs to detect it due to statistical sampling limitations. Thus, finished product testing results can provide a false sense of reassurance. The proposed rule covers all types of animal foods, and there are a variety of potential hazards. Thus, finished product testing may not always be the most appropriate way to verify the preventive control. Therefore, finished product testing, even as a verification tool, has limited applications in animal food.

If you or your firm has questions or comments on the testing portions of the rule, please contact Henry Turlington, AFIA's director of quality and manufacturing regulatory affairs, at (703) 650-0146, or Leah Wilkinson, AFIA director of ingredients, pet food and state affairs at (704) 558-3560.

Supplier Verification

Although FDA launched a proposed rule for Foreign Supplier Verification Program with FSMA, it did not include requirements for a domestic supplier verification program in the proposed rule for animal food. FDA discussed supplier verification in the preamble for animal food and requested comments from the industry on a mandatory supplier verification program. Thus, requirements for supplier verification are expected to be included within the final rule for animal food. Since the proposed rule did not include requirements, there is uncertainty what the final rule will contain. Information within the preamble and the FSVP provides some insight into what FDA may require for a domestic supplier verification program.

In comments to the animal food rule, AFIA will urge FDA to consider the following guiding principles for any regulation on this topic:

- Supplier verification does not control hazards. Rather, when applied as a required program, a manufacturer *verifies* that suppliers are following effective animal food safety programs.
- Supplier verification should be based on an assessment of risk for both ingredients and suppliers. Supplier verification programs should identify and evaluate the risks presented by the animal food ingredient and the supplier.
- Audits are an important verification tool, but they only offer a "snapshot" of a supplier's performance at a given time. An effective audit evaluates the level of risk controlled by a supplier and the effectiveness of its animal food safety system as a whole, and occurs at a frequency tailored to the risks presented by a supplier and/or an ingredient.
- Audits need to assure confidentiality to promote animal food safety. Confidentiality protections also are necessary for supplier audits to be effective and to

encourage robust scrutiny and an open dialog without creating fears about consequences from FDA.

AFIA's comments will emphasize that FDA's supplier verification regulations should be built on successful practices in place today. A responsible manufacturer will engage in some level of due diligence with their suppliers as deemed appropriate based on the perceived risk or hazard analysis. The regulations should be sufficiently flexible to allow facilities to tailor their programs based on the animal food safety risk and evolve their programs for continuous improvement. Companies should be allowed sufficient time to implement the new regulations, as the promulgation of CGMP rules for the animal food industry will require changes to current practices. FDA acknowledges that the lack of CGMP's for non-medicated feed facilities has been a major gap for animal food, and it will require ample time to complete their due diligence.

If you or your firm has questions or comments on the supplier verification portion of the rule, please contact Turlington.

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 senior vice president for legislative and regulatory affairs Richard Sellers, Wilkinson, Turlington, 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.