FSMA Final Rule Released Today; AFIA Prepped and Ready

THE RULE
This morning, the U.S. Food and Drug Administration released the long-awaited final rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals." The rule takes effect in November with compliance dates varying based on size starting a year from publication; however, implementation periods range several years for different facilities. The pre-publication version of the final rule is available online [here](#). The final rule is set to publish in the Federal Register on Sept. 17.

GET EDUCATED
The American Feed Industry Association planned diligently for the rule's release for many months and staff is already reviewing the rule. Currently, there are two one-day FSMA Phase III trainings scheduled. Both trainings will cover identical material. The first training is Dec. 8, in Arlington, Va., following the AFIA Regulatory Training Seminar Dec. 9-10, at the same venue. Registration for both will open soon (updates will be posted to [www.afia.org](http://www.afia.org)).

The second all-day seminar is slated for Wednesday, Jan. 27, 2016, at the International Production & Processing Expo in Atlanta, Ga. Richard Sellers, AFIA senior vice president of legislative and regulatory affairs, Leah Wilkinson, AFIA director of pet food, ingredients and state affairs, and Henry Turlington, AFIA director of quality and manufacturing regulatory affairs, will present at both seminars. AFIA has invited FDA speakers to participate as well. [Click here](#) to register for the January seminar.

AFIA plans to host several webinars during the next six to nine months. The first webinar will be held jointly with Feedstuffs and is scheduled for Oct. 7, from 2 to 4 p.m. EDT, where AFIA staff will provide an overview identifying the changes made by FDA and indicate what AFIA suggested changes were adopted and others that were not. Details will be released in the coming days. Full and partial sponsorships are available for one or more of the webinars. Please contact Sarah Novak, AFIA vice president of membership and public relations, if interested at (703) 558-3574.

STAY IN TOUCH
The FSMA weekly newsletter will be resurrected and work groups reactivated to assist in developing clarification questions and discussion groups with FDA and other organizations. The work groups were critical in developing the industry comments. AFIA intends to partner with other organizations to reach the maximum number of firms about the final rule.

AFIA expects the major issue of Current Good Manufacturing Practices (CGMPs) versus preventive controls will govern AFIA's training and AFIA will focus on explaining to members how to comply with the FSMA final rules.
MOVING FORWARD
Next summer, AFIA plans to provide the industry with a generic hazard analysis that contains nearly all the known or reasonably foreseeable hazards in the feed manufacturing industry and most of the ingredient industry. This document will need to be reviewed by each facility's qualified individual--the person the proposed rule says is such by training and/or experience--and adopted as appropriate to the facility and incorporated into the facility's animal food safety plan.

Assistant Professor and Co-director of the Veterinary Public Health and Preventive Medicine Residency Program, Dr. Tim Goldsmith, of the College of Veterinary Medicine at the University of Minnesota, is the principal investigator developing the hazard analysis, which will include hazards, CGMP controls, and will be published and peer-reviewed over time.

AFIA believes known or reasonably foreseeable hazards as well as significant hazards can be controlled by CGMPs in commercial feed facilities and additional preventive controls are unnecessary. This one action could save the industry approximately $600 million dollars annually.

CONTINUING RELATIONSHIPS
Finally, AFIA will continue its work with the Food Safety Preventive Controls Alliance to produce examples, qualified individual training and workshops to fully incorporate the FSMA rules into the industry's practices. This group provides an excellent interface with industry and FDA on the task of training both industry and FDA investigators, soon to be called auditors. FDA and AFIA believe full training of the FDA auditors will take five to 10 years or more.

The major focus of FSMA is to develop a "proactive" process for hazard analysis and implementation of preventive controls. Such a process requires the industry to develop a facility animal food safety plan(s), implement, document and keep records for two years--all subject to FDA review. This is a daunting task and one AFIA stands ready to assist the members. It is "our industry, our passion and our voice."

For more information on FSMA, visit www.fda.gov/fsma or contact Sellers, Wilkinson, Turlington, Paul Keppy, AFIA government affairs specialist, or Gary Huddleston, AFIA manager of feed manufacturing safety and environmental affairs.

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.

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