



FDA Provides Update on Implementation of Food, Feed Safety Law



NGFA advisers to various committees of the Association of American Feed Control Officials (AAFCO) are shown with AAFCO President Robert Waltz (center). Pictured are (from left): NGFA Vice President of Feed Services David Fairfield; Matt Frederking, director of regulatory affairs and operations, Ralco Nutrition Inc., Marshall, Minn., who chairs the NGFA's Feed Manufacturing and Technology Committee; Ellen Slaymaker, feed labeling supervisor, Southern States Cooperative Inc., Richmond, Va.; Jon Goodson, technical support specialist, Evonik Degussa, Kennesaw, Ga.; Dr. Waltz, Indiana state chemist and AAFCO president; Matt Gibson, vice president, sales and technical services, Lifeline Foods LLC, St. Joseph, Mo., who chairs the NGFA's Biofuels and Co-Products Committee; Jan Campbell, manager, regulatory affairs, Land O'Lakes Purina Feed LLC, St. Louis, Mo.; Chris Olinger, nutrition coordinator, Wenger's Feed Mill Inc., Rheems, Pa.; and NGFA Acting President Randy Gordon.

A top Food and Drug Administration (FDA) official provided an update on the status of pending rulemakings to implement the massive food and feed safety law – the Food Safety Modernization Act (FSMA) – during an Aug. 4 address at the Association of American Feed Control Officials' (AAFCO) annual meeting in Indianapolis, Ind.

Dr. Daniel G. McChesney, director of the Office of Surveillance and Compliance at FDA's Center for Veterinary Medicine, dubbed the rulemakings as the "big four rules, plus one."

Signed into law on Jan. 4, 2011, FSMA requires FDA to develop and implement regulations that, among other things, will require most facilities involved in grain, feed manufacturing, feed ingredient, grain processing, milling and other sectors of the commercial food and feed system to conduct analyses for known or reasonably foreseeable food/feed safety hazards associated with their operations, and to implement effective controls to prevent such hazards from causing products to be adulterated or misbranded.

As referenced by McChesney, the "big four rules" consist of three distinct rules intended to implement the hazard analysis and preventive control regulations for: 1) produce (leafy greens, fruits and vegetables); 2) human food; and 3) animal feed and pet food. The fourth "big" rule pertains to regulations that will require importers of food/feed products intended for consumption in the United States to implement foreign supplier

verification programs to assure the safety of imported products.

The "plus-one" rule, as designated by McChesney, refers to provisions in FSMA that require FDA to establish a system for granting official recognition to accreditation bodies that will accredit third-party auditors to issue certifications for imports of food and feed products. While such certification is voluntary, FSMA provides FDA with the authority to refuse admission of imported food/feed products lacking such certification if, among other things, the agency has determined that: 1) there are known safety risks with either the product, or the country, territory or region of origin from whence the product originated; or 2) there is evidence that the safety programs where the product originated are inadequate to ensure that the product is safe.

In addition to its application to imported food/feed products, McChesney said FDA is considering whether accredited third-party audits might be used to assist the agency in meeting the number of foreign food/feed facility inspections that it is mandated to perform by FSMA. Under the law, FDA is to conduct 1,200 foreign facility inspections in fiscal year 2012, and to "at least" double that number of inspections in each of the next five years – resulting in a mandate of "at least" 19,200 foreign facility inspections in fiscal 2016. By comparison, FDA conducted 438 inspections of foreign facilities in 2011. Given its limited resources, McChesney said, FDA is evaluating the potential use of accredited third-party audits at foreign facilities to assist the agency in meeting the inspection mandate.

McChesney said rulemaking notices for the "big four rules, plus one," currently remain under review by the White House Office of Management and Budget (OMB), and that the approval timeframe for publishing the proposed regulations is unknown. However, McChesney said it is anticipated that proposed regulations for hazard analysis and preventive controls for human food and produce will be issued first, followed by proposed rules for animal feed and pet food and the foreign supplier verification program. He also indicated the proposed regulations for human food likely will span 700 pages, with a previously reported estimated economic cost of \$1 billion to \$2 billion. The proposed regulations for animal feed and pet food, he said, will cover 500 pages and have an estimated economic cost of \$100 to \$200 million.

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Feed Facts

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According to McChesney, the proposed regulations for human food, animal feed and pet food are expected to include requirements that covered facilities adopt and implement prerequisite current good manufacturing practices (CGMPs) patterned after existing regulations that apply to facilities involved with manufacturing, packing or storing human food (*Title 21 Code of Federal Regulations Part 110*). These CGMPs cover such topics as training of personnel; upkeep and sanitation of facilities and grounds, including good housekeeping practices; access to and maintenance of equipment; storage; and manufacturing operations. Importantly, McChesney said the proposed regulations for animal feed and pet food likely will have modified sanitation requirements versus those required of human food facilities, and no requirements associated with the control of allergens.

The proposed regulations also are expected to seek stakeholder input on how FDA should apply the hazard analysis and preventive control provisions of FSMA to various types of food and feed facilities. **Importantly in that regard, McChesney previously has stated the proposed regulations likely will pose questions as to whether and how the hazard analysis and preventive-control requirements should be applied to grain elevators and other warehouses that are engaged solely in storing, handling and shipping raw grains and oilseeds.** Pertaining to this issue, he said the proposed rules will ask whether hazards, such as mycotoxins, that could pose a human or animal health risk, are controlled adequately by upstream buyers, such as feed manufacturers, corn and flour millers, and grain processors.

McChesney said that once proposed regulations are published, there likely will be a 120-day comment period for stakeholder review. Given the administrative rulemaking process, FDA then will review and consider comments received – likely hundreds in number – and then subsequently issue final regulations. **Importantly, McChesney also noted the final regulations will provide a phase-in time period for facilities to implement practices to comply with the regulations, which likely will range between one to two years for most facilities, depending upon company size.**

Facility Registration Renewal Process On Track: Importantly, in response to a question posed by the NGFA, McChesney said FDA is on track later this year to begin receiving renewed facility registrations from domestic and foreign facilities that are required to be registered with the agency under the Bioterrorism Act. Among the types of facilities covered by the facility-registration requirement that took effect on Dec. 12, 2003 are grain elevators, feed mills, flour mills, corn and oilseed processors, pet food manufacturers, renderers and others. FSMA mandates that such facilities, which already are required to be registered with FDA, renew and update those registrations every two years. This requirement is designed to rectify the problem that FDA has experienced with facilities not

correcting or updating their registration information, despite already being required to do so under the Bioterrorism Act. Under FSMA, the registration renewals are required between Oct. 1 and Dec. 31 of even-numbered years, starting in 2012.

AAFCO is the professional organization of federal and state feed regulatory officials, with which the NGFA interacts extensively. Among other things, NGFA feed industry members and staff serve as non-voting advisers to AAFCO committees, and participated actively in the meeting.

Other Issues: Other significant issues addressed during the AAFCO meeting included the following:

► **Civil Penalties:** AAFCO's Enforcement Issues Committee proposed draft language to be added to the AAFCO Model Bill to grant authority to subject violators of feed and feed ingredient regulations to civil penalties. Currently, the AAFCO Model Bill includes a variety of enforcement mechanisms, including legal administrative actions, misdemeanor charges, temporary and permanent injunctions, and withdrawal from sale orders that halts product distribution. During the discussion, the NGFA and other industry representatives expressed strong reservations about the concept, including the potential for misuse given shortfalls in state budget resources and the lack of protections afforded the industry in the draft language. In response, the committee took no action on the issue, but does intend to further discuss civil penalty language at its next meeting in January.

► **Feed Labeling:** AAFCO's Feed Labeling Committee reviewed a recommendation provided by members of a working group established to evaluate whether to require maximum sulfur guarantees on labels of all feeds containing greater than 0.5 percent sulfur. The working group's recommendation was that AAFCO should **not** require such a label guarantee within its model regulations, and, after considerable discussion, the committee agreed.

The Feed Labeling Committee also received an update from a working group established to: 1) evaluate whether to require minimum and maximum selenium guarantees on all feeds containing greater than 0.5 parts per million (p.p.m.) and less than 25 p.p.m. selenium; and 2) deem swine gestation and lactation complete diets to be adulterated if such diets contain more than 1 p.p.m. selenium. The working group reported that it is awaiting input from the National Pork Board before finalizing a recommendation.

► **Mineral Contaminant Guidelines:** The Feed and Feed Ingredient Manufacturing Committee currently has a working group established to review AAFCO's guidelines for contaminant levels permitted in mineral feed ingredients and complete feeds. The working group likely will make recommendations to the committee at the next AAFCO meeting in January.

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- ▶ **AAFCO Ingredient Definition Process:** AAFCO officials announced during the meeting that the organization and FDA have signed an agreement to extend by 12 months the current Memorandum of Understanding (MOU) between the two parties that clarifies and outlines FDA's participatory role within the current, existing AAFCO ingredient definition process. The current MOU was set to expire on Sept. 1, unless mutually extended by AAFCO and FDA. Acceptance of the industry-requested extension of the MOU by AAFCO and FDA allows the current ingredient-definition process to proceed until Sept. 1, 2013. The extension particularly is relevant because of FDA's policy decision to end its long-standing practice of issuing regulatory discretion letters ("letters-of-no objection") routinely to individual companies or establishments for FDA-regulated products. Historically, AAFCO has relied upon the issuance of such regulatory discretion letters as a primary means of determining and communicating whether a feed ingredient is safe for its intended purpose. The extension of the MOU provides additional time for all affected parties to further consider appropriate pathways for authorizing feed ingredients in the future.
- ▶ **Distillers Oil, Feed Grade:** During the AAFCO Ingredient Definition Committee meeting, FDA officials presented for discussion purposes a draft definition for "Distillers Oil, Feed Grade." FDA envisions that such a definition would apply to oils, such as corn oils, that are obtained by mechanical or solvent extraction after the fermentation and distillation of a grain or a grain mixture during the production of fuel ethanol. FDA presented the draft definition for discussion purposes only, and suggested that industry should formally develop and submit a definition and supporting information for such oils that could be reviewed through the AAFCO ingredient-definition process.
- ▶ **Feed Inspector Training:** The Inspection and Sampling Committee continued its work to revise the *AAFCO Feed Inspector's Manual*. The manual is designed to provide inspectors with a comprehensive explanation of the regulatory and enforcement functions of a feed inspection program. The manual also serves as an excellent resource for feed industry representatives. Members receiving the *NGFA Newsletter* electronically may access and download the current manual free of charge by [clicking here](#).
- ▶ **Pet Food Calorie Statements on Labels:** AAFCO's Model Bill and Regulations Committee approved modifications to AAFCO's Model Pet Food Regulations that, among other things, would require calorie-content statements on dog and cat food labels. The committee also approved an affidavit to be used to substantiate such calorie-content statements. The approvals will be presented to the AAFCO Board of Directors for review and referral to the AAFCO membership for final vote, likely in January.
- ▶ **AAFCO Dog and Cat Food Nutrient Profiles:** The AAFCO Pet Food Committee accepted a report offered by an expert working group that contained recommended updates to the AAFCO Dog and Cat Food Nutrient Profiles. The committee will discuss the working group's recommendations at its next meeting. The Pet Food Committee also disbanded a working group previously established to evaluate appropriate labeling requirements for pet food claims for low dietary starch and sugar content. In doing so, it was the working group's view that evaluating such claims is not possible, since no analytical methods currently exist to detect the carbohydrate fractions of interest.

NGFA members having questions on these or other feed-related issues are encouraged to contact NGFA Vice President of Feed Services David Fairfield at dfairfield@ngfa.org, or by phone at 712-243-4035.

FDA Reports Decline in Salmonella Detected in Feed, Pet Food Samples

The Food and Drug Administration's Center for Veterinary Medicine reported on Aug. 3 the findings of a new study that indicates a significant decline in the presence of *Salmonella* in animal feed, pet food and pet treats.

The study's results were contained in a manuscript published recently in the publication *Foodborne Pathogens and Disease*, which presented the results of *Salmonella* sampling data collected by FDA as part of a feed contaminants surveillance program from 2002-09 and a special *Salmonella* sampling assignment conducted from 2007-09.

FDA reported that a total of 2,058 samples were collected from complete animal feeds, feed ingredients, pet foods, pet

treats and pet supplements. Of the total number of samples, 257 (12 percent) tested positive for *Salmonella*. When *Salmonella* isolates were recovered, they underwent serotyping and testing for antimicrobial susceptibility.

FDA's testing results indicate what the agency called a "significant overall *Salmonella* reduction in animal feeds" during the time span subject to the sampling initiative – despite the increasing number of samples tested. Specifically, the number samples testing positive for *Salmonella* declined from 18.2 percent in 2002 (187 samples tested) to 8 percent in 2009 (584 samples tested). Among these samples, feed ingredients and

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