

Minutes of AAFCO
CURRENT ISSUES & OUTREACH COMMITTEE MIDYEAR MEETING
Saturday, August 4th, 2012, 10:15 AM - 12:00 PM
Indianapolis Mariette Downtown
Indianapolis, Indiana

Members Present: Jennifer Godwin, Miriam Johnson, Richard Ten Eyck, Meagan Davis, Caleb Michaud, Chad, Linton, Nate Bartz, Tim Darden, Tim Lyons, Donna Dicesare, Steve Gramlich and Ali Kashani.

Members Absent: April Wilcox, Luann Wetzler, Kent Kitade, Sam Davis and Isabel Pocurull.

Advisors Present: David Dzanis, David Ailor, Randall Gordon, Wayne Bomgarden, Kristi Krafta, David Fairfield, David Meeker, Kurt Gallagher and Tami Sergent.

Advisers Absent: Ben Morgan

Dr. Daniel G. McChesney, Director, Office of Surveillance and Compliance, FDA/CVM, provided the following comments on the topic of implementing FSMA and the Future of Feed:

“The food and feed supply is a global supply system, and while the food and feed supply is very safe the current system is reactive to problems. FSMA mandates a change to a preventive based system with FDA responsible for establishing standards for safety and industry for implementing the standards and being responsible for the safety of the products they produce. To accomplish this FDA is taking numerous steps with the cornerstone of these steps being the five major rules; produce, preventive controls for human food, preventive controls for animal feed, foreign supplier verification program, and third party certification. The current food and feed safety system while good, is not sustainable with the pressures of a global supply system. Moving from a reactive to a preventive approach has an associated cost as does increasing both domestic and international coverage through additional inspections. The cost is driven by the requirements in the FSMA legislation and that associated regulations, and the number of firms covered and the level of acceptable risk. These factors are all currently being carefully considered as part of the internal review process prior to publishing the proposed rules.”

Dr. Sharon Benz and Ms. Jo Gulley of Center for Veterinary Medicine provided the following information under the topic of Veterinary Feed Directive: “On April 11, 2012, the Center for Veterinary Medicine, FDA, announced the availability of three documents supporting the judicious use initiative for veterinary drugs. The first was the final Guidance #209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals, which provides the overall policy direction. The focus is on assuring drugs are used as judiciously as possible so that antimicrobials are available for

treatment, control, and prevention of animal disease. Two key principles outlined in this guidance include limiting the use of medically important antimicrobial drugs to those uses considered necessary for animal health and the veterinary involvement in the use of antimicrobials in animal feed. The second document is draft Guidance #213 that provides more detailed guidance on the implementation of the principles outlined in Guidance 209. This guidance provides information for drug sponsors to update product labels to remove animal production claims for medically necessary antimicrobials and proposes a timeline for the implementation of the judicious use policy. The third document is a draft text for proposed veterinary feed directive regulations. The regulations propose to amend Title 21 Code of Federal Regulations Part 558.3 and 558.6. Proposed amendments will allow for the transition of all antimicrobials for use in feed with involvement of a veterinarian. Some of the proposed changes affect the requirements for information on the identity and location of the treated animals, the amount of feed for the treated animals, expiration date of the veterinary feed directive, and the valid veterinarian-client-patient relationship. After addressing the comments already received, the public will have another opportunity to comment, as CVM will publish the proposed regulation. CVM is working with USDA to hold a series of listening sessions in five locations across the US to provide the opportunity to discuss and provide critical feedback on the challenges faced by livestock producers and practicing veterinarians as FDA phases in veterinary oversight of the therapeutic use of medically important antimicrobials.”

Mr. Joe Reardon, Senior Advisor for Federal State-Relations discussed the work that has been done, and is underway to implement an Integrated Food Safety System, or IFSS. Mr. Reardon also described the impact of the Partnership for Food Protection (PFP) and the Food Safety Modernization Act, or FSMA, and the way FDA is looking to leverage existing efforts with new initiatives. He also talked about the Integration Task Force, and how it is providing the agency with a new look at the path forward, and discussed how all of these important topics will be manifested in the 2012 PFP 50-State Workshop. Mr. Reardon called the engagement of state and local partners to protect the public health a success stories. He noted that FDA is also building a robust infrastructure within DFRS to empower and support states as they implement Manufactured Food Regulatory Program Standards and ISO Accreditation Standards. He emphasized that improvements in training and certification programs are needed to result in a uniform and consistent approach to food safety. In conclusion, Mr. Reardon mentioned as a proof of his agency’s commitment to states and local partners, there has been \$34.2 million increase in funding from 2009 to 2012 to states and local partners.

Ms. Anita MacMullan, Contracts and Grants Branch Director with FDA’s Division of Federal State Relations presented an overview of the Animal Feed Regulatory Program Standards as well as an update on the status of the process to develop the standards. Major accomplishments include the completion of the standards and the initial review of the standards by FDA’s Office of Foods, Office of Regulatory Affairs, and Center for Veterinary Medicine. The feed standards will proceed through additional review by the President of AAFCO. After the feed standards are cleared by FDA, they will be available for public comment in the Federal Register. Interested parties will have 60 days to submit comments.

The benefits of implementing the standards were presented and include building uniformity and consistency within and among regulatory programs. This uniformity will serve to increase communication, cooperation, and coordination among agencies that will ultimately result in the increased ability to use inspection findings from enrolled agencies for effective, timely, and efficient regulatory actions. In addition, the standards will serve as a tool or structured mechanism for self assessment-providing the structure for programs to assess training and resource needs, improve documentation of accomplishments, and provide a framework to link inspection findings to compliance actions.

Implementing the standards will be voluntary. State feed programs that choose to implement the standards will be expected to implement all eleven standards. FDA fully intends to commit resources (as appropriate and subject to availability) to support a pilot program to assist a few states in implementing the standards. A brief overview of some of the elements of a self assessment was presented. The presentation concluded with a reminder of the collaborative process used to develop the standards and the commitment to continue that collaboration with both FDA and AAFCO playing key roles in the process.

The meeting was adjourned at about 12:00 PM.