

Current Issues and Outreach Committee Report/Minutes
2017 Annual Meeting
Hyatt Regency
Bellevue, Washington
Evergreen Ballroom D-I
Thursday, August 10, 2017
9:30–10:30 am

Committee Recommendations

Committee recommendations summary or list

None

Board Recommendations

Board recommendation summary or list

None

Association Recommendations

Association recommendation summary or list

None

Committee Participants:

Members Present: Liz Higgins (Vice-Chair), Meagan Davis, Chad Linton, Tim Darden, Tim Lyons, Kent Kitade, Richard Ten Eyck, and Ali Kashani (Committee Chair)

Advisors Present: Leah Wilkinson, Angela Mills, David Dzanis, David Fairfield, David Meeker, Angele Thompson

Committee Report

Committee Activities

ACTIONS:

The meeting was called to order at 9:30 am PST by Ali Kashani (Chair) who made opening remarks. He announced that Liz Higgins agreed to serve as Vice-Chair of the committee.

Liz Higgins gave an update on the AAFCO newsletter (AAFCO News Feed). The second volume of the AAFCO News Feed was sent out to AAFCO members and posted on the AAFCO website on June 30, 2017. Feedback is appreciated to let the committee know what people are interested in and if the newsletter is providing the information that members and industry want to see.

By-Products from Human Food Processing Plants

Jamie Wiggins, Director of Food Safety and Policy for the Northwest Food Processing Association gave a presentation on Human Food By-products for Animal Food related to FSMA Animal Food Rules from a Fruit & Vegetable Processor's Perspective. Ms. Wiggins noted that

approximately 73% of human food waste (over 42 million tons) is currently recycled through animal feed. By some extrapolated estimates, approximately 16% (15,000,000 tons) of the above amount may not be recycled due to new regulations and mentioned possible alternatives. A copy of Ms. Wiggins PowerPoint presentation is attached.

Inspection Findings under cGMP/FSMA

Ms. Dianne Milazzo, Consumer Safety Officer with Office of Surveillance & Compliance, FDA/CVM, moderated a round table discussion on inspectional findings under CGMP/FSMA participated by Sean Cheney, FDA/Office of Regulatory Affairs/Dallas District, Doug Lueders, MN Department of Agriculture, and David Fairfield, National Grain and Feed Association.

Mr. Sean Cheney gave a perspective on inspections conducted by FDA. There have been 145 FSMA cGMP inspections completed to date [139 NAI (No Action Indicated), 6 VAI (Voluntary Action Indicated; FDA 483 issued)]. The top reasons for investigators issuing a 483 are pest control issues and product contamination (i.e., plastic). Investigators have, for the most part, been discussing observations rather than issuing FDA-483s (i.e., for violations that did not raise to a level of a human or animal health safety concern). The majority of inspections have been conducted in the following states: CA, IL, IA, NY and MO (in no particular order). The feedback provided from investigators is that firms have been cooperative and patient with investigators during inspections.

Mr. David Fairfield, Senior Vice President for the National Grain and Feed Association, provided an industry perspective on the initial inspections that have been performed by FDA and state feed regulatory officials to evaluate compliance with CGMP requirements established by preventive controls animal food rule.

Mr. Fairfield noted that industry's experience with the inspections generally has been positive, and commended FDA and state officials for their "educate before and while we regulate" approach. Regarding education, Fairfield also asked that FDA publish final CGMP guidance and draft preventive controls guidance as soon as possible to better inform the industry of the agency's compliance expectations associated with the new animal food rule.

Mr. Fairfield also urged FDA to continue in its efforts to ensure that investigators during inspections have expectations that are realistic for the facility, consistent with the new requirements, and uniformly applied. He also noted that investigator requests for information that are not consistent with regulatory provisions can create tension during the inspection, and ultimately hinder the exchange of information and collaboration that FDA is seeking with the regulated industry. He requested that FDA consider this issue when implementing its inspectional approach.

Mr. Doug Lueders with Minnesota Department of Agriculture gave a state perspective on conducting the new 507 CGMP inspections. Minnesota was one of five states contracted with FDA to do feed CGMP inspections in 2017. Mr. Lueders indicated that all inspectors that conduct FDA CGMP contract inspections have to go thru specific FDA 507 CGMP regulator training in order to do the inspections. Inspectors encouraged dialog with the facility's team throughout the inspection. The statement was made that some facilities that have not previously

been inspected by FDA may have some discomfort sharing information regarding their total annual dollars of sales and other business information. MDA inspectors did not get any pushback related to these business questions. One area that had quite a few questions was utensils. Industry also had a number of situational questions that would have been easier to address if a FDA guidance document had been available.

Ms. Dianne Milazzo indicated that investigators use the Investigations Operations Manual (IOM) to tell them what procedures they are to perform during inspections. The IOM does direct staff to ask the firm about customer complaint files. Inspectors have been instructed to request to view complaint files and will put this into their reports. Firms are not required to provide this information under any regulatory authority. Customer complaints are also reported to FDA. Inspectors will have reviewed that information prior to conducting an inspection and will follow up on the complaint while conducting the inspection. Ms. Milazzo noted that there is still FSPCA money available for training of the states' staff and there has been an extension to apply for this grant money until June 2018. She also indicated that Canada, Australia and New Zealand have been assessed and recognized that their systems are equivalent for human food, however, currently there are not any countries' systems recognized to meet the requirements for animal food.

The meeting adjourned at 10:30 AM.