

Laboratory Methods & Services Committee

2024 AAFCO Mid-Year Meeting January 24, 2024, 8:00am – 3:15PM (EST), Chattanooga, TN

Committee Recommendations and Board Recommendations

Recommendation to the AAFCO ETC:

The LMSC members voted and approved the attached LMSC Training Proposal. The LMSC therefore recommends approval and funding of the attached LMSC Training Proposal (and all supplemental documents) by the AAFCO Education and Training Committee in order to complete the AAFCO Strategic Plan Objective 3.2 Task 5. Training a. and b.

Committee Participants

Members Present: Joshua Arbaugh (WV), Ametra Berry (GA), H. Dorota Inerowicz (OISC), Teresa Riegel (FL), Kristi McCallum (cochair/CO), Sharon Webb (co-chair/UKY), Dancia Wu (OISC), Deepika Curole (LA), Rebecca Moseley (AL), Angela Swinford (FDA), Eli Williams (PA), Carrie Crabtree (GA), Naomi High (NC)

Advisors Present: Matt Nichols (Neogen), Lars Reimann (Eurofins), Ken Riter (PFI NPAL), Leo Schilling (Eurofins) Virtual Attendees: William Hoek (NY), Srinu Chigurupati (FDA), Lawrence Novotny (Life member), Nancy Thiex (Life member), Brenda Snodgrass (AAFCO PTP), William Hoek (NY), Andy Crawford (Consultant AAFCO PTP), Jeff Horst (Agri King), Michele Swarbrick (MN), Robin Johnson (MT), Patty Lucas (FL), Melanie Titley (CFIA)

Others Present: Buffy Meyer (LA), Chelsea Kent (Parsley Pet), Marleen VanAardt (Ankom), Andrew Komarek (Ankom), Chris Almon (Fresh Pet), Kathryn Thamann (Videka LLC), Chuck Cawley (IL)

Committee Report

Linda Morrison confirms that the AAFCO strategic plan updates will be sent out to committee chairs after the meeting. The updated information was added to the report after the meeting and Linda sent the updated plan on 2/13/2024.

Committee Activities None Subcommittee Activities None

Committee Minutes

Kristi McCallum, co-chair, called the meeting to order at 8:00 AM (EST).

• Dietary fiber & Vitamin in Feeds and Pet Foods

Andre Komarek gave a presentation on dietary fiber and vitamin analysis and on the ANKOM Flex instrument. He emphasizes the increasing relevance of dietary fiber in recent years due to improved research showing its benefits. He then introduces their product lines,

focusing on macro nutrient instrumentation.

- The presentation delves into the importance of dietary fiber analysis, particularly for mono gastric animals like dogs, and the differences between crude fiber and detergent fibers. The speaker compares dietary fiber with crude fiber, highlighting the significant differences in values and lack of correlation.
- The discussion shifts to the methods for dietary fiber analysis, including challenges with the 991.43 method and the development of new methods by McCleary. The speaker talked about automation, showing how it has simplified the process and improved accuracy.
- A video is played to illustrate the challenges of finding hidden problems in labs during analysis. The speaker mentioned the involvement of a challenging method (991.43) and how automation has streamlined the process.
- The presentation transitions to a new product, discussing the analysis of vitamins A, E, D, and cholesterol. The speaker explained the traditional methods involving saponification and separation, contrasting them with their automated method using solid-phase extraction (SPE). The instrument's capabilities, including custom methods, were highlighted.
- The presenter provided insights into the instrument's application across various food groups and matrices, emphasizing its versatility. The discussion covered the instrument's performance in comparison with manual methods and its potential in different laboratories worldwide.
- Lastly, the presentation touched on total fat analysis, mentioning challenges with sample sizes, and introduces another instrument, the HCL XT, for crude fat analysis. The speaker shared experiences with naming products and concluded by presenting the instrument's automation capabilities and the user interface.

The presentation ended and the floor was opened for questions: The first question discussed the analytical methods for testing vitamin D, specifically focusing on HPLC UV. Marlene was recommended to speak about the details. Different methods like UPLC and mass spec were mentioned for quantifying vitamin D, with flexibility in sample preparation. There was a question about the final dilution for vitamin D, and the response included information about adding internal standards and the reconstitution process.

The discussion then touched upon the maximum test portion mass for vitamin tests, with variations based on sample types like feed or liquid samples. Traceability in the instrument for recording methods was discussed, and the flexibility of the instrument's Wi-Fi connectivity for remote monitoring was highlighted.

The Flex instrument was clarified as a sample preparation tool, not for quantitation. The TDF instrument's performance on AACC PT samples was mentioned showing that it correlated well with other labs, but the methods used by those labs were not specified. The issue of sample matrix affecting vitamin concentration, especially in single ingredients like cottonseed meal, was brought up. There was also a question about LOQs (Limits of Quantitation) for different vitamins and components, with a focus on proper sample handling.

The presenters expressed their willingness to share comparative data offline and mentioned the potential publication in a peer-reviewed journal, possibly leaning towards AOAC or others suggested by the audience. Questions about pre-install checklists were asked. The presenter explained the specifies of the nitrogen line requirement and the venting system. He then described the waste products, including KOH, alcohol, and hexane. The session concluded with thanks to the speakers.

• Survey of Quantitative Methods for Feed Additives

Leo Schilling, introduces himself as a senior technical expert at Eurofins, focusing on the animal health industry. Leo emphasized his role as a conductor in the animal health symphony, bringing together minds from various fields. He is responsible for developing new business relationships and has a diverse skill set, including experience in chemistry, biotechnology, food and feed, quality testing, research and development, and regulatory compliance.

- Leo's presentation centered on a survey of quantitative methods for feed additives. He discusses the importance of feed additives in modern animal feed formulas, outlining various types such as nutritional, zoo technical, sensory, and technical additives. Leo emphasized the regulations governing medicated feeds in the United States, specifically under the FDA, and the need for accurate testing methods.
- He highlighted challenges in existing methods, especially in microbiological assays, where issues of specificity and selectivity arise. Leo highlighted the advancements in chemistry methods, such as HPLC and LC/MS/MS, as more suitable for current testing needs. He also addressed the limitations of existing methods, including gaps in concentration levels and the necessity of adapting to modern formulas.
- Leo emphasized the importance of collaboration and resource-sharing among laboratories to address challenges in medicated feed testing. He suggested the need for updated methods to ensure the accuracy and reliability of results.
- Leo mentioned having tables and an Excel file with official methods that could be filled in. The idea was to create a repository to support labs conducting animal feed testing and provide best practice guidance.

The presentation then transitions into an open discussion: There was discussion about a previous list or repository of FDA-approved methods, specifically Chapter 13 of the Feed Additive Compendium, but it was noted to be incomplete. The conversation highlighted the importance of having a list that analysts can refer to, especially focusing on category two drugs. Leo Schilling emphasized the need to bridge the gap between residue methods and medicated feed methods, particularly for validation purposes. There was a mention of a survey sent to regulatory program managers to understand their priorities and needs, which would guide the committee's work.

The discussion then touched on challenges related to method needs varying from state to state, and the impact of the Veterinary Feed Directive (VFD) on the demand for certain methods. Linda was tasked with finding information on the previous list of methods. Leo Schilling stressed the significance of obtaining a comprehensive list to identify gaps and plan accordingly. The conversation concluded with the committee discussing strategic plan objectives, including updating the hazards contaminant survey and addressing gaps through training and quality assurance updates.

A comment from the chat is shared, suggesting the creation of a list detailing methods corresponding to different drugs for analysis and a list of drugs and methods used by state labs. It was mentioned that this suggestion would be incorporated into the next survey to be sent out.

• Training Proposal Review

Kristi McCallum discussed the LMSC training proposal that was written and emphasized the need to develop a comprehensive training program and repository for resources for analysts, specifically focused on the analysis of animal feed. The presenter highlighted the lack of specific training programs for feed analysts, the challenge of turnover in laboratories, and the potential loss of valuable knowledge as experienced individuals retire. The training proposal includes an online platform with various resources and links to training materials on topics such as ethics, data integrity, method validation, lab safety, unit conversions, microbiology, chromatography, and accreditation. The speaker also mentioned the idea of forming a workgroup to monitor and update the resources regularly.

The LMSC co-chairs opened the newly written LMSC Training Proposal Draft Document then transitioned into an open discussion and detailed review of this proposal: The first question inquired about the fluidity of the training program and in what way it would be updated. The presenter clarified that the term "fluid" was used to convey the program's flexibility to adapt to changing needs, both from a regulatory perspective and based on surveys or studies conducted. The background and needs assessment section explained the importance of having a training program for animal feed testing laboratories, emphasizing the need for specialized staff, equipment, and expertise due to the complexity of feed analysis. A suggestion was made to include the word "maintain" in the statement to highlight the ongoing nature of the training program.

The discussion then moved to the objectives of the training program, focusing on ensuring analysts have necessary training, reducing the training burden on individual laboratories, offering comprehensive training, and promoting collaboration among state agriculture laboratories. A suggestion was made to include the word "maintain" again, and the change was incorporated into the document.

The discussion also touched on the design and content of the training program, emphasizing that the training would be based on actual needs, and the committee would review training need forms to determine the best approach, considering factors like the number of people and the methodology involved. The idea of developing videos for training purposes was mentioned, but challenges with recording and editing were acknowledged.

The session concluded with a break before delving into the logistics of the training proposal.

• Training Proposal, Logistics, Schedule & Budget

- One-on-One Training
 - The presenter discussed the one-on-one training aspect of the proposal, where a person is identified, and a lab close to them is contacted to provide training assistance. This approach has been informally practiced for a while, with people coming from different locations, even globally, seeking help not only on feed-related matters but also quality management for accreditation. The importance of involving quality managers in the training process was highlighted, allowing them to visit other labs for insights into ISO 17025:2017 and AOAC compliance.
 - The trainee would travel to a host lab for personalized instruction. The importance of vetting the host lab's competency, demonstrated through continuous participation in a PT program, was emphasized. The proposal suggested that the host lab may need to fund its own travel expenses, or alternatively, apply for a travel scholarship from AFFCO, depending on available funding.
- Workshops & Survey Results
 - Workshops were also discussed, and a survey was sent out to gauge interest in hosting or participating in workshops. The proposal emphasized the need for funding to support the workshops, considering the potential time and monetary investment required. The idea of hosting workshops based on demand, with a threshold of six or more requests for the same training, was suggested. The document also touched on the challenges of developing training videos and the preference for hands-on workshops.
 - The logistics of workshops, including potential funding from AFFCO, were detailed, covering expenses like supplies, travel, and accommodation. The document highlighted the potential benefits of workshops, such as collaboration and sharing of expertise among labs. The discussion extended to the proposal's goal of conducting at least one workshop annually, contingent on the identified needs.
 - The proposal also outlined examples of workshops, covering topics like microbiology, chemistry, and mycotoxin analysis. The presenter sought feedback on various aspects, such as the number of participants needed to justify a

workshop, the potential inclusion of video demonstrations, and the need for workshop materials and exams to be approved by a working group or subcommittee.

• Vendor Training

- The group discussed vendor training and emphasized that links to different vendor training programs are available on their website. These trainings offer options for analysts to attend in their respective areas, sometimes without the need for extensive travel. Speaker 3 added that if any vendor is not listed on their website, it's because they haven't found it yet, and vendors are encouraged to send links for inclusion.
- It was clarified that LMSC training program does not intend to cover all staff's vendor training expenses. Instead, individuals are expected to coordinate with their state and lab managers and attend on their own. There was a suggestion by Speaker 9 that vendors often provide substantial discounts or free seats if labs agree to host the event regionally.
- The document also mentioned training resources through the APHL curriculum framework, with a note that the classes are still in development. Speaker 2 raised a question about the possibility of the committee hosting workshops during AAFCO meetings, either before or after. Speaker 1 suggested adding a section for pre-meeting workshops hosted by AFFCO, potentially inviting vendors as trainers. Speaker 9 emphasized the potential inclusion of QA-focused training, analytical and quality, software, and technology. The intention is to revise the LMSC Training Proposal and hold an electronic vote on the proposal.

o Budget

- The discussion then moved on to the LMSC Training Proposal budget and cost estimation for the training workshops. The presenter explained that the costs provided are estimates and may vary based on factors such as laboratory costs, supplies, and method dependencies. A commentor suggested adding a cost range for lab supplies to address potential concerns during board review.
- The conversation touched on the importance of host laboratories having a budget for supplies rather than using their own materials. The document also highlighted concerns about the cost being prohibitive and the need to put a range for lab supplies. It was suggested to not get too detailed on predicting airfare and lodging costs due to their unpredictability.

• Evaluation

- The discussion continued to the effectiveness evaluation section, emphasizing the need for metrics to ensure the program's success. Different evaluation methods were discussed, including knowledge assessments, performance metrics, surveys, and proficiency assessments. There was a suggestion to expand the proficiency assessment beyond the AFCO PTP. The working group updates were mentioned as the next agenda item, and Speaker 1 expressed gratitude for the positive feedback. There was a mention of potential budget proposals and justification for costs related to training, with a focus on a hands-on microbiological training session.
- Training Workgroup
 - The LMSC discussed and formed a Training Workgroup. This workgroup will monitor and evaluate the AAFCO LMSC Training webpage, obtain resources for this webpage and evaluate training proposals. Volunteers for this workgroup include Rebecca Moseley (AL), Michele Swarbrick (MN), Teresa Rygiel (FL), Robin Johnson (MT), Sharon Webb (KY) and Leo Schilling (Eurofins).

The session concluded with a break before delving into the final section of the agenda which was the Working Group updates.

• Working Group Updates

- Hemp
 - Hunter Buffington of Ag Policy Solutions provided updates on the development of a preliminary method for GC-FID (Gas Chromatography with Flame Ionization Detection) for hemp seed meal. They are seeking two or three state regulatory labs to run a preliminary analysis using the method to identify and address any potential issues before sending it out to 30 labs for a larger trial.
 - Additionally, Hunter mentioned the collaboration with USDA on developing an HPLC (High-Performance Liquid Chromatography) MS/MS (Tandem Mass Spectrometry) method to understand the variability in their labs. This method will be used to qualify GC-FID results. The upcoming Interlaboratory Study (ILS) will involve 30 labs running GC-FID and 30 labs running HPLC MS/MS to validate a 10 parts per million threshold for THC on hemp seed meal.
 - Hunter discussed the recent definition with a 10 ppm THC limit and expressed concerns about being the only
 jurisdiction with a 10 ppm CBD limit for hemp seed meal. The goal is to run ILS studies to gather more data and
 eventually validate the methods through ASTM.
 - Hunter invited labs interested in participating in the preliminary trial to contact her via email at <u>hunter@agpolicysolutions.com</u>
 - She emphasized the importance of getting feedback from labs before proceeding with the larger trial. Despite
 potential challenges with FDA acceptance, Hunter expressed dedication to the project and encouraged labs to reach
 out if they have any questions.

o Metals

 The metals working group is in the process of finalizing documents related to best practices. The drafting is almost complete, with the majority of the content already written. The group is combining and editing the materials to ensure comprehensive coverage. Sharon acknowledged the contributions of individuals like Michelle Swarbrick, Melanie Titley, and others to the work.

• Fat Soluble Vitamins

There was a brief recap of the progress made in the working group that had previously published a paper in Journal of AOAC on vitamin A. The approach involved using an enzyme to break the encapsulation on a 100-gram sample, and the testing was ongoing. Robyn Johnson from Montana provided an update on the status of the instrument, mentioning that more data would be available soon to guide the working group's direction. The enzymes seemed to work adequately, but further analysis and testing were needed.

o Mycotoxins

The mycotoxin working group does not have an update at the moment. While there are enough people in the group, setting up meetings has been challenging, and there's a plan to start working on it. The group has already downloaded relevant materials from the LMSC FoodShield and will continue moving forward.

o Moisture

- No updates
- o Microbiology
 - The microbiology working group discussed the lack of new information regarding probiotics. The group engaged in conversations with regulators about the labeling of probiotics in animal feed. The discussion revolved around the difficulty in specifying individual species due to the nature of microbiological testing. The group provided detailed

explanations to regulators about the challenges labs face in analyzing probiotics at the species level and shared their approach to microbiological testing. The focus was on nutritional aspects, not pathogen reduction.

- Additionally, the group considered methods to test raw pet food for the organisms present in probiotics. The idea of labeling guarantees for different genera of bacteria was suggested, and concerns were raised about the limitations of current methods when dealing with multiple bacterial groups.
- There was a suggestion to use multiplex PCR to separate viable and non-viable organisms in probiotic analysis, but challenges were noted. The discussion also touched on the FDA LAMP method, a PCR method for detecting Salmonella, which is now available in BAM Chapter 5 for labs with an ABI 7500 instrument.
- The group mentioned the ongoing verification of the FDA LAMP method through FDA LFFM cooperative agreement
 program and expressed the benefits of using this method in terms of time savings and quicker results.
- o Toxins
 - The toxins working group discussed their limited progress and mentioned that there are methods for pentachlorophenol (PCP) and pentobarbital available on FoodShield. They acknowledged that the pentobarbital method was listed in an FDA Laboratory Information Bulletin (LIB) using LC-MS/MS. The discussion included the availability of the method in certain labs and its potential inclusion in the survey for regulators. It was noted that some labs may face challenges due to the high cost of equipment and service contracts for running certain toxin analyses.
 - The conversation also touched upon the importance of an educational component for labs, especially when considering methods that may require expensive equipment. The group expressed interest in sending out a survey to regulators to gather information on their needs and challenges related to toxin analysis. Additionally, there was a discussion about the limitations labs may face in running specific methods, such as the high cost of equipment and service contracts.

o Drug Residues

- The Drug Residues working group discussed the survey results on quantitative methods for drug residues in feed. The focus is on providing appropriate methods for regulatory labs to analyze residues in feed. The group aims to ensure that the selected methods are official and suitable for the analysis of various drug residues.
- The survey results indicated a critical need for methods related to monensin and lasalocid. The discussion
 highlighted the challenges with total residues methods, emphasizing the importance of using methods optimized for
 specific drug classes. The group plans to compile a list of appropriate methods and address gaps in available
 methodologies.
- There was also a mention of the potential use of high-resolution mass spectrometry (Q-TOF) for screening drug
 residues, but it was acknowledged that such methods might have limitations and would require careful interpretation
 of results.
- The working group plans to develop best practice recommendations, including considerations for test portion size and the use of appropriate LOQs. The presentation of survey results showed that respondents identified drug residues as a critical need without specifying particular drugs, prompting a need for more specific survey questions.
- The discussion concluded with considerations for posting methods on accessible platforms, with potential challenges
 related to copyrights, and the mention of FDA LIBs (Laboratory Information Bulletins) not being outward-facing but
 sharable with labs under a 2088 agreement. There was also a suggestion to explore the transition to a new
 SharePoint format for better sharing of information.
- o Dietary Fiber

- The discussion on dietary fiber focused on the work group's efforts in comparing methods and making recommendations. The 991.43 method was highlighted as the most affordable for laboratories, meeting regulatory needs. Other HPLC methods, such as AOAC methods, were acknowledged as good but more expensive options.
- The work group's recommendation is in the process of being finalized and will be presented to the committee for acceptance.
- There was a sidebar discussion within the work group involving Charlotte Conway (FDA), who provided insights into why crude fiber is still used in regulations. The need for more comparisons and a potential proposal for graduate student work to study differences in calorie values using current and newer methods were mentioned.
- The discussion also touched on the use of crude fiber in calculating metabolizable energy for pet food and the potential need for a study to modify the equation for dietary fiber. However, it was emphasized that this falls outside the scope of the current committee's work.
- A suggestion was made to consider this as a potential AFFCO project, but concerns were raised about the challenges and costs associated with such studies
- The survey results on dietary fiber indicated that the majority of labs that responded stated that suitable methods already exist, suggesting that it might not be a critical need at the moment. However, it was acknowledged that the landscape might change over time.

o QA/QC

- The QA/QC subcommittee provided an update on their recent meeting, where they discussed taking over the work initiated by the LMSC co-chairs regarding the QAQC guidelines for feed lab analysis. The subcommittee aims to update the 2007 version of the guidelines, which was based on the 2005 version of ISO 1725, to align with the 2017 version of ISO 1725.
- David Snow, who agreed to lead the subcommittee, mentioned that they are in the process of updating the content and structure of the guidelines. The task involves significant changes due to the major revisions in ISO17025 in 2017, including rearranged sections and renumbering.
- Kristi McCallum emphasized the complexity of the task, especially dealing with track changes, and mentioned the
 progress made on updating the content list. The subcommittee plans to continue working on the guidelines and aims
 to have a draft ready by March 1st.
- The subcommittee also discussed the importance of ongoing education and suggested that the meetings could include presentations on various QA/QC topics, such as validations, internal auditing, and corrective action reports. The subcommittee encouraged members to express their interests in specific topics for future presentations. Additionally, there was a brief discussion on the challenges some labs face in choosing between following the guidelines or pursuing accreditation, and the need for timely updates in this regard.

Other Business

During the "Other Business" segment of the meeting, participants discussed various topics related to feed lab analysis

- Lars Reiman (Eurofins) raised concerns about the particle size of certain analytes, such as manganese oxide, vitamin A, and vitamin D, making it challenging to achieve homogeneity in the vial. The discussion revolved around the need to grind samples to a finer particle size, ideally below 0.2 millimeters, to ensure better representation in sub-samples.
- Lars Reiman (Eurofins) expressed difficulties in finding suitable grinding mechanisms and sought suggestions from the group for effective methods. Some participants, including Macy (CEM), mentioned using specific grinders, and Nancy Thiex recommended a grinder that allows grinding up to 100 grams.

- The conversation then shifted to an open forum where participants discussed the challenges associated with different ashrelated terms, such as air ash, sulfated ash, and acid-insoluble ash. Sharon Webb (KY) mentioned that there's a need to define these terms as feed terms, and a working group was formed, including Josh Arbaugh (WV), David Snow, and a representative from CEM, to address this.
- The meeting concluded with an update from Marla Keller (FDA) about the Laboratory Accreditation for the Analysis of Foods (LAAF) program, a voluntary accreditation program for laboratories. The program focuses on import tests, commodities on import alert, and certain circumstances related to food safety. The benefits for laboratories include being listed on a data dashboard. Participants were encouraged to check the FDA website for more information.

• Adjournment

The Laboratory Methods & Services Committee Adjourned at 3:05pm (EST)