

MINUTES
AAFCO PET FOOD COMMITTEE
AAFCO 2010 MIDYEAR MEETING
Redondo Beach, California
Wednesday, January 20, 2010 8:00 AM – 9:30 AM

1. Introduction of Pet Food Committee Members and Advisors

Interim Chair Teresa Crenshaw (DE) called the meeting to order at 8:00 am. The following committee members and advisors were present and introduced themselves:

Committee Members

Teresa Crenshaw (DE), Interim Chair
Dr. William Burkholder (FDA-CVM)
Tony Claxton (MO)
Elizabeth Higgins (NM)
Dr. Rod Noel (IN)
Jan Jarman (MN)
Dave Syverson (MN)

Industry Advisors

Jan Campbell (NGFA)
Nancy Cook (PFI)
Dr. David Dzanis (ACVN, APPA)
Jarrod Kersey (AFIA)
Dr. Angele Thompson (PFI)
Jason Vickers AFIA
Ed Rod (APPA)

There were a total of 24 control officials, 54 industry representatives, and 10 industry association representatives who signed the attendance roster.

2. Announcements

Teresa Crenshaw welcomed two new members: Dr. Jean Bowman with FDA-CVM and Jan Jarman with the MN Department of Agriculture. She also welcomed back Dave Syverson with the MN Dept. of Agriculture as a member of the committee.

3. Modifications to the Agenda

Teresa Crenshaw asked to move the reports for the Calorie Working Group and the Small Manufacturers Working Group to the end of the agenda to allow time for discussion. Dr. William Burkholder (FDA-CVM) asked for an opportunity to explain some policy changes within FDA-CVM if time permitted.

4. Approval of Minutes from Washington, DC

Teresa Crenshaw asked if there were any changes to the minutes from the AAFCO 2009 Annual Meeting. Hearing none, Dr. Rod Noel (IN) motioned to accept the minutes, and Tony Claxton (MO) seconded the motion. With no additional discussion, the committee approved the motion to accept the minutes.

5. Reports from the AAFCO Pet Food Committee Working Groups

A. Report from the Small Pet Food/Treat Manufacturers Working Group - Lynn Sheridan, WA State Dept. of Agriculture & Elizabeth Higgins, NM Department of Agriculture

Elizabeth Higgins (NM) serves as Co-Chair of the Small Manufacturers Working Group and gave the report. She said the group had been working diligently on the educational component to provide information and links to information that could be beneficial to new companies. The working group was in agreement that this project should be accomplished. The working group had discussed an exemption from nutritional labeling for small companies, but this exemption did not have consensus and was tabled until the educational component was completed.

Tony Claxton (MO) motioned to accept the report. Dr. Rod Noel (IN) seconded the motion. With no further discussion, the committee approved the motion to accept the report of the Small Manufacturers Working Group.

B. Report from the Working Group for Weight Related Terms and Calories – Roger Hoestenbach, Feed & Fertilizer Control Services, TX A&M University

In the absence of Roger Hoestenbach, Dr. William Burkholder (FDA-CVM) presented the report on behalf of the working group. Dr. Burkholder noted that he had not imagined that calories on a pet food label would be such a contentious issue. He said regulators appear to be in favor of the proposal, and industry opposes it. He continued that consumers need calorie information on pet food labels as noted in a paper written by Drs. Deborah Linder and Lisa Freeman and published in the Journal of the American Veterinary Medical Association (JAVMA, Vol 236, No. 1, January 1, 2010.) In this report, the authors conducted a comprehensive survey on products with weight management claims, and Dr Burkholder said the article was a good, independent illustration of why calorie content statements on products with weight-related claims are necessary.

Dr. Burkholder said the report of the working group had been submitted to the committee. The report included the recommendation that calories be required on pet food labels, but he added that the report contained some recommended exemptions. He said there was a phase-in period for products that contain more than a specified number of calories. Dr. Burkholder suggested that the committee take the next six months to review the working group's report for discussion at the AAFCO annual meeting.

Dr. Rod Noel (IN) motioned to accept the report of the working group. Dave Syverson (MN) seconded the motion. Dr. Angele Thompson (PFI) commented that not all of the members saw this report, and she noted that there was not a consensus of all members of the working group. Dr. Burkholder responded that all of the Pet Food Committee members on the working group did see the report before it was submitted to the chair; however, the advisors and other work group members have not seen the report. Dr. Burkholder said the Pet Food Committee members on the working group were in favor of

the report, but some of the advisors were not. Dr. Burkholder confirmed that this report was the working group's recommendation to the Pet Food Committee.

Teresa Crenshaw (DE) stated that the report was dated December 18, 2009, but she did not receive it until Friday, January 8, 2010. She sent the report to the Pet Food Committee members and advisors on the following Monday, January 11, 2010, which was just about a week before this meeting. Since there was not sufficient time for discussion at this meeting, she would insure that there was adequate time at the annual meeting for all comments to be heard.

Nancy Cook (PFI) stated although Dr. Burkholder said that industry did not support the proposal, she clarified that industry did support calorie content statements on products bearing weight-related claims. Elizabeth Higgins (NM) added that some state regulators also did not support calorie statements on all pet food labels, but most supported calorie content statements on the labels of weight loss products. Dr. Burkholder said he agreed with these comments.

Note: The report of the Working Group for Weight Related Terms and Calories is included with these minutes as a separate document.

C. Nutrient Profiles and Feeding Protocols Expert Committee - Dr. William Burkholder, FDA-CVM

Dr. Burkholder (FDA-CVM) reported that he was in the process of creating justification documents for the proposed changes by the subcommittees. The justification was similar to the information currently listed in the AAFCO Official Publication to explain why the changes were made. He noted that the justification for the dog food protocols was almost completed. Dr. Burkholder hoped that the committee and advisors would have the final reports to the Pet Food Committee by the annual meeting in August.

6. FDAAA Update – Dr. William Burkholder, FDA-CVM

Dr. Burkholder (FDA-CVM) reported that the draft proposed rule for labeling standards were in internal clearance review. The Economic Staff contracted the economic analysis to a private organization for input. The contract gave firms until the end of February to submit their report to FDA. The Office of Chief Counsel was also reviewing the document. There would be a three-tier review within this office. The reviews for the first two tiers have been completed. Dr. Burkholder said his best estimate of a date for a proposed rule to publish in the Federal Register was late spring or early summer, but he asked that he not be held to that timeframe.

Dr. Burkholder said the ingredient standards and processing standards would follow the labeling standards, but they were not at the same point as the labeling standards. The labeling standards were expected to publish first, followed by the ingredient standards and then processing standards.

Dr. Burkholder gave an update on the Pet Food Early Warning Surveillance System (PFEWSS) that was in place within CVM. CVM was attempting to add one more component to the system that would be the voluntary reports through the MedWatch Plus portal. This portal also contained the reportable food registry, but these were two separate categories. The dates for this portal release keep changing but may be released at the end of March or the first of April. Dr. Burkholder added that there are electronic components and systems that must talk to each other. He said that a number of private firms were contracted to do this work, but the electronic information transfer was the most difficult.

Nancy Cook (PFI) asked if the comment period for PFEWSS closed on January 29, 2010. She said FDA was asking for public comment for the data points that they were proposing to collect. Dr. Burkholder agreed.

7. AAFCO Feed Term “Natural” – APPA’s Proposal to Include Irradiation and Freeze Drying

Teresa Crenshaw (DE) explained that this proposal from APPA was requested to amend the AAFCO Feed Term “Natural” to include irradiation and freeze-drying. Dr. David Dzanis (APPA) explained that this proposal came from concerns from APPA members. He referred to a letter from FDA to AAFCO’s Feed Term Investigator that concluded that irradiated products could not be labeled as natural under the current definition. Dr. Dzanis provided two rawhide bones, one that had been irradiated and one that had not, and he noted that one could not tell the difference except that one label had to bear the radura symbol to indicate the rawhide bone was irradiated. Even though a company took extra steps to ensure the safety of the product, the irradiated bone could not be called natural. Dr. Dzanis said companies would still have to place the radura symbol on the label, and he said the product should be able to claim that it was natural.

Teresa Crenshaw stated that this committee would not take action as this was a feed term, and any action would be requested by Dr. Rod Noel, AAFCO’s Feed Term Investigator. She added that this committee meeting would be a venue for discussion for a proposed change to the feed term. She then asked for comments. Jarrod Kersey (AFIA) stated there was a consumer expectation for which we have responsibility. Irradiation was not a natural step, and it was not one of the processes associated with natural. Natural was not a safety term – all products should be safe for consumption. Mr. Kersey noted that AFIA supported adding freeze-drying to the definition of natural, but they did not support adding irradiation.

Dr. Angele Thompson (PFI) said their members knew that consumers did not think irradiation was natural. She said we understood the science, and natural was not a safety issue. She continued that all products for pet food should be safe, and irradiation did not belong in the definition of natural, but freeze-drying should be added to the definition.

Jan Campbell (NGFA) also commented that their members supported adding freeze-drying to the definition of natural, but they did not support irradiation.

Dr. Rod Noel (IN) said he wanted to hear the opinions of the committee members. Dave Syverson (MN) said the definition of natural was a feed term that included a lot of processes. He added that neither irradiation nor freeze-drying were chemical or synthetic processes.

Dr. William Burkholder commented that irradiation was regulated by FDA-CVM as a food additive, and the definition for natural stated that a natural feed or ingredient contained no additives. He continued that the irradiation process formed compounds called URC's or URP's (unidentified radiation compounds or products), and these compounds could arguably be called chemically synthetic.

Teresa Crenshaw noted that comments should be sent to Dr. Noel. She said this issue had been on the agenda for several meetings and would not be discussed again unless there was new information to present.

8. Proposal to Revise AAFCO Regulation PF4(a)(4) - Format for Guarantees on Specialty Pet Food Labels

Teresa Crenshaw (DE) explained that there were two proposals under consideration for the order of guarantees for specialty pet food labels. The current AAFCO regulations refer the order of the guarantees for specialty pet food to the Model Regulations for feed. Some time ago, there was a proposal to require guarantees for specialty pet food labels to follow the order of the nutrients as listed in the AAFCO Cat Food Nutrient Profiles, but this proposal was dropped. There was interest in bringing back this reference, and the proposal was presented at the last meeting; however, APPA presented another proposal for the committee to consider. Dr. David Dzanis representing APPA said there was concern from their members that Regulation PF4(a)(3) for dog and cat food labels disrupts the order of the guaranteed analysis by requiring guarantees for non-essential substances to be listed after all essential nutrient guarantees. APPA proposed to change the regulations to allow similar guarantees to be grouped together regardless of whether the guaranteed substances were essential or non-essential. Dr. Dzanis said they would ask for an extensive time period to allow the changes to be made to all pet food labels.

Dr. Angele Thompson (PFI) stated that the original revision to regulation PF4(a)(4) was for minimum and maximum guarantees. The guarantees for specialty pet food should follow the order and units of the AAFCO Cat Food Nutrient Profile, but this proposed regulation was dropped. PFI had not heard any complaints about the order of guarantees being a concern. To change the labels according to the APPA proposal would be a significant burden on the industry.

Nancy Cook (PFI) asked what was the cost and for what benefit? Jan Campbell (NGFA) agreed that she did not see the value for this change. Jarrod Kersey (AFIA) said FDAAA was on the cusp and labeling would be a part of the new federal regulation. He said it would not be prudent to change labeling now for dog and cat food. Elizabeth Higgins (NM) said there was confusion about the order of guarantees for specialty pet food labels and that was why she raised the question.

Dr. Dzanis said that APPA would not pursue this proposal and would agree that the committee should vote on the original change to Regulation PF4(a)(4).

Dr. Rod Noel (IN) made a motion to change Regulation PF4(a)(4) and send the proposal to the AAFCO Board of Directors for further consideration by the Model Bill Committee. Dave Syverson seconded the motion. Teresa Crenshaw asked for discussion. Tony Claxton (MO) said he was concerned from a regulator's standpoint to lose the order if essential nutrients were not grouped together. Teresa Crenshaw replied specialty pet food guarantees would follow the format of the AAFCO Cat Food Nutrient Profiles because this profile listed more nutrients than the AAFCO Dog Food Nutrient Profile. She said we were changing only the order of guarantees and not suggesting that the AAFCO Cat Food Profile was the essential nutrients for specialty pets. She said the AAFCO Cat Food Profile was used only to indicate the order of the guarantees for specialty pet food. Jan Jarman (MN) asked about APPA's proposal for Regulation PF4(a)(3). She said that it appeared that if the committee approved the modifications to Regulation PF4(a)(4), we would not be able to address Regulation PF4(a)(3). She said the original change to Regulation PF4(a)(4) affected only specialty pet food, whereas Regulation PF4(a)(3) affected both specialty pet food and dog and cat food. Dr. Bill Burkholder called for the question. The committee voted to approve the motion to accept the change to Regulation PF4(a)(4). Dr. Thompson ask to clarify that the motion to change Regulation PF4(a)(4) would first go to the Board of Directors and then go to the Model Bill & Regulations Committee for further review and discussion. The committee agreed.

9. APPA's Proposal to Revise AAFCO Regulation PF4(a)(3) & (4) - Labeling of Recognized & Non-Essential Guarantees on Pet Food and Specialty Pet Food Labels

Tony Claxton (MO) made a motion to table the APPA proposal to change Regulations PF4(a)(3) and (4). Jan Jarman (MN) seconded the motion. The committee approved the motion.

10. Incidental Additives in Pet Food Ingredients

Teresa Crenshaw (DE) explained that this item was on the agenda because of a pet owner's E-mail to AAFCO complaining about rosemary oil being added to pet food, and the pet food company told them that rosemary oil did not have to be listed in the ingredient statement. The pet owner's dog was having seizures, and the veterinarian said some dogs were sensitive to rosemary and that rosemary in the dog's food could be causing the seizures. Teresa noted that there was no allowance for incidental additives in the AAFCO model regulations, and this was a federal regulation. She wanted the issue of incidental additives discussed to ensure that companies correctly understood this regulation.

Dr. Bill Burkholder (FDA-CVM) explained that 21 CFR 501.100(a)(3) was not based on the amount of a substance in a product but whether the substance had a technical or functional effect on the product. He also indicated that if a manufacturer added an ingredient to a product, that ingredient regardless of its amount or technical or functional effect, needed to be listed in its descending order of predominance by weight on the ingredient statement of the label on the product. He said the amount of a substance to provide a flavor was quite small, but that did not exempt the flavoring substance from being listed on the label. There are exemptions for substances added to a multi-component ingredient or a feed that is subsequently incorporated into another feed to be considered incidental additives if the substance has no technical or

functional effect in the finished product and was added not by the final manufacturer but the manufacturer of the multi-component ingredient or incorporated feed. For an incidental ingredient, it was not the amount of the ingredient but the technical or functional effect it had on the finished product.

Dr. Burkholder continued that if anyone added ethoxyquin to animal feed or pet food, ethoxyquin must be listed in the ingredient statement regardless of the amount as required by the food additive regulation for ethoxyquin. Nancy Cook (PFI) asked if this information was on the AAFCO website. She said this brought up a bigger question about getting this information out to the industry.

11. AAFCO Pet Food Labeling Workshop Update

Elizabeth Higgins (NM) announced that the workshop would be held a few days before the AAFCO 2011 MidYear Meeting. She would be forming a working group to plan the workshop.

12. Other Discussion

Dr. Bill Burkholder (FDA-CVM) announced two policy changes for FDA-CVM that would affect how CVM would be doing business. First, FDA-CVM would no longer issue a letter of no objection about the use of an ingredient to an individual firm without some sort of general publication available to all stakeholders, such as a feed ingredient definition, a food additive approval, or a GRAS notification that the ingredient was acceptable for use in animal feed. FDA-CVM would no longer issue a letter to an individual firm so they could use an ingredient. He cautioned that a company should not ask unless they were willing to go through one of the existing ingredient approval processes.

Secondly, in the past FDA-CVM had issued information letters to firms regarding products that were already in the channels of trade. FDA-CVM would no longer issue these types of letters. If a firm sent a request for a label review for a marketed product, and FDA-CVM found the label to be out of compliance, the likely result would be issuance of an Untitled Letter that would be posted on the FDA website. The agency would still provide informational letters to state feed control officials. If a firm wanted a response from FDA, then it should submit questions and labeling materials to FDA prior to the product being marketed under the labeling in question. This applied to all feed products.

Jarrold Kersey (AFIA) asked if this change was because of a time management decision. Dr. Burkholder indicated that the first issue could be viewed as a time management decision because it takes CVM just as much time to review safety and utility information concerning an ingredient for issuance of a letter of no objection as it does for establishment of a feed ingredient definition. Dr. Burkholder indicated that the issuance of an Untitled Letter was a legal issue. If FDA did not agree with the label of a product in the marketplace, the agency would place an untitled letter on the website. Mr. Kersey asked if this held true for requests from state feed control officials. And, would these letters be posted on the AAFCO website? Dr. Burkholder stated that if the request was from a state feed control official about a marketed product, the response would remain one of an informational letter that was not posted on the FDA website. Whether the letter

was made available for posting on the AAFCO secure website was the state feed control official's decision.

13. Adjourn Pet Food Committee Meeting

Tony Claxton (MO) motioned to adjourn. Dr. Rod Noel (IN) seconded the motion. Hearing no further discussion, the meeting was adjourned at 9:52 am.

TAC/