

MINUTES
AAFCO PET FOOD COMMITTEE
AAFCO 2008 ANNUAL MEETING
Nashville, Tennessee
Sunday, August 3, 2008 1:15 PM – 3:00 PM

1. INTRODUCTIONS

Teresa Crenshaw, Vice-Chair (DE), called the meeting to order at 1:18 pm and announced that she would be filling in for Chair Dave Syverson, as he was unable to attend. The following committee members and industry advisors were present:

Committee Members

Teresa Crenshaw (DE), Vice-Chair
Dr. William Burkholder (FDA-CVM)
Tony Claxton (MO)
Elizabeth Higgins (NM)
Roger Hoestenbach (TX)
Dr. Rod Noel (IN)

Industry Advisors

Jan Campbell, NGFA
Nancy Cook, PFI
Dr. David Dzanis, ACVN, APPMA
Jarrod Kersey, AFIA
Dr. Angele Thompson, PFI
Jason Vickers, AFIA

There were 28 state/federal control officials and 66 industry representatives for a total of 94 attendees who signed the committee roster.

2. ANNOUNCEMENTS

Teresa Crenshaw also announced that in addition to Dave Syverson (MN), other Pet Food Committee members who could not attend the meeting were Eric Nelson (WI), Lynn Sheridan (WA), and Dr. Cathie Marshall (FDA-CVM).

SPECIAL THANKS AND RECOGNITION

Teresa Crenshaw, on behalf AAFCO, gave special thanks and recognition to Nancy Cook, Dr. Angele Thompson, Dr. Bill Burkholder, the staff of the Pet Food Institute, the presenters, and all others who worked to make the Pet Food Labeling Workshop a success.

3. MODIFICATIONS TO THE AGENDA

Dr. Burkholder requested that the agenda be modified so that he could present both the AAFCO Profiles Update and FDAAA Update together. Additionally, the Raw Milk Working Group Report was moved as the last item so that Tony Claxton could be present. Tony had to give a presentation at another committee meeting, but he would be back to the Pet Food Committee meeting as soon as possible.

4. REVIEW OF MINUTES FROM 2008 MIDYEAR MEETING IN SAN ANTONIO, TX

Teresa Crenshaw called for any changes or modifications to the minutes. There were none. It was moved by Dr. Rod Noel and seconded by Roger Hoestenbach to accept the 2008 Midyear minutes. Motion passed.

5. REPORT FROM THE SMALL PET FOOD/TREAT MANUFACTURERS WORKING GROUP - Lynn Sheridan (WA), Working Group Chair

In Lynn Sheridan's absence, Dr. Dave Dzanis presented an update on the progress of the Small Pet Food/Treat Manufacturers Working Group. This working group compiled information that is already available to those who are interested in understanding the requirements of state and federal laws and rules. Some of these documents are:

Materials online are:

- *Pet Food: The Lowdown on Labels* (FDA Consumer magazine May-June 2001);
- *FDA CVM Information for Consumers "Interpreting Pet Food Labels"*, "*Interpreting Pet Food Labels—Special Use Foods*" by David A. Dzanis, "*Information on Marketing a Pet Food Product*", "*FDA's Regulation of Pet Food*";
- *An article on Animal Food (Feed) Product Regulation; Guideline No. 55 "Supportive Data for Cat Food labels Bearing 'Reduces Urinary PH Claims: Guideline in Protocol Development' "*;
- *FDA Talk Paper "FDA Issues Safety Guidance on the Use of Raw Meat for Pet Diets" December 18, 2002.*
- Articles on the APPMA website (only accessible to APPMA members) can be found in their Products & Law Section with a Labeling Web Page, a Pet Food Registration Chart, a Pet Food Compendia, Feed Manufacturing Process Controls page, and the publications "*Guidelines for the Manufacturing of Natural Part Treats for Pets*" and "*Pet Industry Guidelines for Product ID, Labels and Shipments (GIPD)*".
- The Minnesota Department of Agriculture has a fact sheet titled "*Information Update on Raw and Undercooked Animal Products*",
- The New Mexico Department of Agriculture has documents such as *Pet Food Facts and Registration Information Brochure, Commercial Feed Registration Fact Sheet, Pet Food and Pet Treat Labeling Guide, and links to FDA Commercial Pet Feed Fact Sheets*
- PFI has a downloadable publication titled "*Handling Salvage & Distressed Pet Food*".

The charge of this working group is:

- To consider strategies for outreach and technical assistance regarding feed law compliance for pet and specialty pet food products manufactured/distributed/guaranteed by small businesses;
- To consider strategies for supporting AAFCO members who are charged with regulating such businesses;
- To consider a plan of action that would help to inform pet food small business of the feed program requirements for each state;
- To make recommendations for actions, strategies and development of AAFCO products/outreach to address the outcomes of these considerations to the AAFCO Pet Food Committee.

So far, the only exemption for fee or registration reductions for small businesses is contained within FDA's *Small Business Nutrition Labeling Exemption* and with USDA's *National Organic Program*. Simply stated, these exemptions are based on annual gross sales and number of employees that are employed on a full-time basis.

The consumer survey done by the group Defend our Pets indicated that consumers did not want to see a lessening of regulations for small pet food companies and did want to see tougher regulations for all segments of the pet food industry.

There are good materials to help the businesses get started with knowledge so that they are cognizant of the regulations governing their activities in the production of pet foods and treats. These documents could be combined somehow in an inclusive way to help small businesses find information in one spot if AAFCO deemed it necessary. Discussion on the exemption aspect of registration and the actual outreach to the small business community may be the more pressing aspects of the working group's research.

Dr. Rod Noel moved to accept the working group report. Roger Hoestenbach seconded the motion. Motion passed.

DISCUSSION:

Dr. Angele Thompson stated that the need for educating these small businesses falls within the recommendations of the National Pet Food Commission (NPFC). Another tool that can be utilized is the PowerPoint presentation from the Pet Food Labeling Workshop that was just completed. The intent is to put the workshop slides (read only) on the AAFCO website to give these small businesses another resource for labeling guidelines. PFI also looks forward to contributing to this workgroup.

6. REPORT FROM THE AAFCO PROFILES AND PROTOCOLS EXPERT COMMITTEE - Dr. Bill Burkholder (FDA-CVM), Working Group Chair

Dr. Burkholder presented an update on the AAFCO Profiles and Protocols Expert Committee. There are no formal documents at this time; however, there is work ongoing, and a small amount of progress has been made. Dr. Burkholder stated that he needs help moving things forward, and **Sharon Senesac** has agreed to help him. Dr. Burkholder stated that between now and the 2009 Midyear Meeting, there will be a significant amount of work accomplished.

It was moved by Roger Hoestenbach and seconded by Dr. Rod Noel to accept the report. Motion passed.

7. FDAAA UPDATE – Dr. Bill Burkholder (FDA-CVM), Working Group Chair

Dr. Burkholder presented an update on FDAAA. He said there has not been a significant amount of progress since the Midyear Meeting report, but FDA-CVM is working on implementing the information from the Pet Food Labeling and Nutrition public meeting held in May 2008. The comment period closed June 13, 2008. The comments have been read and considered. A first draft of the codified regulations has been formulated and is moving through evaluation at the agency. Even though there is draft language, Dr. Burkholder noted that he could not comment on any specifics.

Work is progressing towards the federally mandated requirement. FDA-CVM is working on a preamble to the regulations, but a draft is not yet available. Paperwork reduction and economic impact evaluations must still be performed. Dr. Burkholder suggested that individuals interested should watch the federal register for a notice of proposed rulemaking that will provide the next opportunity to submit comments.

Dr. Neal Bataller, Director, FDA-CVM Division of Compliance, discussed Section 1002B that deals with the early warning reporting system. Congress had concerns about an early warning reporting system, but the only such system currently in place is FDA's consumer database. The Division of Compliance will be hiring two experts to deal with consumer complaints and emergency situations. The Division will be analyzing consumer complaints and soliciting information for input into the complaint database. The database will be revised to provide better information. Dr. Bataller stated that any information on improving the system would be welcomed. In the fall, more attention to soliciting complaints regarding pet food and human food will be put in place. FDA-CVM is also working on collaborating with veterinary diagnostic laboratories. As compared to human food, the companion animal side does not have a food outbreak investigation section, and FDA-CVM plans to make improvements in this area.

It was moved by Dr. Rod Noel and seconded by Roger Hoestenbach to accept the report. Motion passed.

DISCUSSION:

Nancy Cook (PFI) asked if the agency had given any thought to sharing early information with industry so they can look at their databases to begin evaluating a potential problem. She asked if the agency would provide opportunities to share information with the public. Dr. Bataller responded that FDA-CVM has an area for adverse drug information that is an example of how information can be shared. FDA-CVM has not worked out the specifics on sharing information with a specific firm. During the melamine recall, it appeared that the more the more quickly FDA can get information to a company, the more quickly a response can be generated from that company. On the melamine issue last year, it took three to four weeks for FDA to identify and notify the company of the suspect ingredient; however, on the rice protein concentrate issue, it took only three days. Nancy Cook stated that this was not a criticism of FDA but a thought process to get the information back to companies as soon as possible. Dr. Bataller stated that with the two new staff members, the notification should be better. He said that FDA would contact the FDA District office that would then contact the firm by the next day.

Dr. Angele Thompson (PFI) stated that when FDA solicits complaints of adverse events from the public, this should include comments from the veterinary community. From the standpoint of the National Pet Food Commission (NPFC), it is imperative that the veterinary community be educated since they are the front-line responders. NPFC and industry share concerns about the criteria that would be used to determine what is a legitimate complaint. FDA should solicit information from veterinary associations to determine if the complaint is valid. Dr. Bataller agreed that this would be a collaborative effort.

Larry Hawley, Del Monte Pet Foods, stated that companies have built robust consumer complaint databases on their own. If a consumer generates a complaint to FDA, either directly or through their veterinarian, they may feel that it has been adequately handled and may never notify the company. It is crucial that the company be made aware of any complaints as soon as possible. Dr. Bataller responded that FDA suggests to consumers that they should also report the adverse event to the pet food company, but this is for non-drug reports that may not otherwise be reported. He noted that there are mandatory reporting requirements for drugs.

Dr. Dan Little, DairyNet, Inc., stated that he was concerned that all decisions must be based on sound science, not emotion.

Frank Jaramillo, University of KY, stated that it is difficult to evaluate complaints when consumers do not save the feed that they believe made their animal sick, or they bury their pet without a necropsy. There should be official protocols so that consumers and veterinarians will know what they need to do.

Larry Hawley, Del Monte Pet Foods, stated that when a pet food company receives a complaint, the company would search for other complaints on the same lot or lots made in the same factory. He noted FDA would not have access to this type of data. These investigations that a pet food company can do is different than what FDA can do.

Teresa Crenshaw thanked Dr. Burkholder and Dr. Bataller for their comments and said that she looked forward to additional information at the midyear meeting.

8. REPORT FROM THE RAW MILK WORKING GROUP – Liz Higgins (NM), Working Group Chair

Liz Higgins presented the recommendations from the Raw Milk Working Group to the committee. She discussed the changes that the working group made to the recommendations of the Feed Labeling Committee.

The charge of this working group is:

- To review the proposed model regulations forwarded to the Pet Food Committee by the BOD for any previously unforeseen issues/conflicts or appropriateness of the proposal which may be identified by the PFC; and
- To review the proposed model regulations forwarded to the Pet Food Committee by the Board of Directors (BOD) to assure that the language has no conflicts with the AAFCO Model Pet Food and Specialty Pet Food Regulations. The Raw Milk Working Group is not limited to consider only the subjects of the initial request by the BOD and is free to consider additional issues that may better serve the AAFCO membership.

RECOMMENDATIONS OF THE RAW MILK WORKING GROUP:

The distribution of raw milk is not limited to those individuals intending to use it as pet food; therefore, the Pet Food Committee concurs with the Feed Labeling Committee that new legislation should be part of the AAFCO Model Bill, the

AAFCO Model Regulations and the AAFCO Model Regulations for Pet Food and Specialty Pet Food. Please note that changes to the original proposal made by the working group are presented in red print, and additional changes approved at the Annual Meeting are presented in blue print. Deletions are presented as strikeouts. Discussion is presented at the end of the proposal.

1. Amend Section 3 of the Model Bill as follows:

Section 3. Definitions of Words and Terms

(w) The term, “raw milk” means any milk or milk product, **exclusive of USDA licensed veterinary biologics**, from any species other than humans, that has not been pasteurized in accordance with processes recognized by the U.S. Food and Drug Administration.

~~(x) **Decharacterize: A process using approved dyes which make a substance milk or milk products, clearly distinguishable from the same substance milk or milk products for human consumption.**~~

2. Amend Section 8 of the Model Bill as follows:

Section 8. Prohibited Acts

- (i) The distribution of raw milk for use as commercial feed for any species:
- (1) if it has not been decharacterized using a sufficient quantity of food coloring as designated by (director, commissioner, etc.);
 - (2) if it has been decharacterized using food coloring unless the food coloring has been approved by the U.S. Food and Drug Administration, or in the case of raw milk labeled as organic, approved by the U.S. Department of Agriculture;
 - (3) if it has been decharacterized and the nutritive value of the milk has been adversely affected by the decharacterization;
 - (4) that is packaged in containers that are or resemble those used for the packaging of milk for human consumption;
 - (5) that is stored at retail with, or in the vicinity of, milk or milk products intended for human consumption;:
 - (6) if it does not comply with Section 8 (a) through (h) of this act.**

3. Amend Model Regulation 3 as follows:

Regulation 3. Label Information

- (a) Commercial feed, other than customer-formula feed, shall be labeled with the information prescribed in this regulation.
- (1) Product name and brand name if any. ...
 - X. If the commercial feed consists of raw milk, the words, “Raw (blank) Milk” shall appear conspicuously on the principal display panel. (Blank is to be completed by using the species of animal from which the raw milk is collected.)

4. Amend Model Regulation 7 as follows:

Regulation 7. Directions for Use and Precautionary Statements

(d) Raw milk distributed as commercial feed shall bear the following statement: “WARNING: NOT FOR HUMAN CONSUMPTION - THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA.” This statement shall be displayed in a conspicuous manner and shall not be smaller than **twice** the height of the minimum font required by the Federal Fair Packaging and Labeling Act for the quantity statement as shown in the following table:

Panel Size	Minimum Warning Statement Type Size
<5 sq. in.	<u>1/8”</u> <u>1/16”</u>
5-25 sq. in	<u>1/4”</u> <u>1/8”</u>
25-100 sq. in.	<u>3/8”</u> <u>3/16”</u>
100-400 sq. in.	<u>1/2”</u> <u>1/4”</u>
400 sq. in. +	<u>1”</u> <u>1/2”</u>

5. Amend Model Pet Food and Specialty Pet Food Regulation PF3 as follows:

Regulation PF3. Brand and Product Names

(g) When pet food **and or** specialty pet food consists of raw milk, the words, “Raw (blank) Milk” shall appear conspicuously on the principal display panel. (Blank is to be completed by using the species of animal from which the raw milk is collected.)

6. Add new Model Pet Food and Specialty Pet Food Regulation PF2(i) as follows:

Regulation PF2. Label Format and Labeling

(i) Raw milk distributed as pet food or specialty pet food shall bear the following statement “WARNING: NOT FOR HUMAN CONSUMPTION - THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA.” This statement shall be displayed in a conspicuous manner and shall not be smaller than **twice** the height of the minimum font required by the Federal Fair Packaging and Labeling Act for the quantity statement as shown in the following table:

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<5 sq. in.	<u>1/8”</u> <u>1/16”</u>
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25-100 sq. in.	3/8" 3/16"
100-400 sq. in.	1/2" 1/4"
400 sq. in. +	1" 1/2"

DISCUSSION:

Liz Higgins and Dr. Dave Dzanis discussed the working group’s rationale for recommending a reduced font size that is specified in the tables. Dr. Dzanis displayed examples of how the warning statement would appear using the font size specified in the original proposal. The warning statement was much too large as compared to the rest of the label information.

Nancy Cook noted a concern with the language for the definition of “decharacterized”. She stated that it should be more generic and apply to a process that is not just for milk or milk products but also rather for any feed ingredient. This way, the definition would not have to be redone if the term were needed for something else. Dr. Bill Burkholder stated that it might be more appropriate for “*decharacterize*” to be approved as a feed term, not as a definition in the Model Bill, since it is a process.

Dr. Rod Noel made a motion to accept the working group report, but later amended his motion to accept the working group report with the removal of the definition for “decharacterize”. Dr. Burkholder seconded the motion. Motion passed.

Dr. Noel then made a motion to send the proposal of the Raw Milk Working Group to the Board of Directors with the recommendation that the proposed language be sent to the Model Bill & Regulations Committee for consideration. Liz Higgins seconded the motion. Motion passed.

Dr. Noel also made a motion that the Pet Food Committee send a recommendation to the Board of Directors to charge the Feed Terms Investigator to define the word “*decharacterize*” as a feed term. Roger Hoestenbach seconded the motion. Motion passed.

Roger Hoestenbach moved that the meeting be adjourned. Dr. Bill Burkholder seconded the motion. Motion passed. The meeting was adjourned at 2:32 pm.

Note:

In lieu of giving a report, Roger Hoestenbach conducted an open session immediately after the Pet Food Committee meeting for the Working Group for Weight Related Terms and Calories. All were welcomed to stay, but comments were limited to working group members only.