



PFC Committee Report/Minutes
AAFCO Annual Meeting
August 2nd, 2016, 9:30am-12pm; Pittsburgh PA

Committee Recommendations

Committee recommendation summary or list.

- (1)
- (2)

Board Recommendations

Board recommendation summary or list.

- (3)
- (4)

Association Actions

Association action summary or list.

- (1)
- (2)

Committee Participants

Members present: Stan Cook (MO), Kristen Green (KY) Lizette Beckman (WA), George Ferguson (NC), Liz Higgins (NM), Jan Jarman (MN), Jo Lynn Otero (NM), Jason Schmidt (LA), Christie Shee (IN), Austin Therrell (SC), Bill Burkholder (FDA-CVM), Charlotte Conway (FDA-CVM), Eric Nelson (FDA-CVM)

Advisors present: Dave Dzanis (APPA/ACVN), Jean Hofve (PWA), Mollie Morrisette (PWA), Susan Thixton (ATPF), Angele Thompson (PFI), Dave Fairfield (NGFA), Pat Tovey (PFI), David Meeker (NRA), Leah Wilkinson (AFIA), Jason Vickers (AFIA).

Committee Report

Committee Activities

Motion to disband the Pet and Specialty Pet Labeling Guide working group. Moved by Charlotte Conway (FDA-CVM). Seconded by Liz Higgins (NM). Motion Passed.

Motion to accept the Carbohydrate working group report. Moved by Liz Higgins (NM). Seconded by Charlotte Conway (FDA-CVM). Motion Passed.

Motion to disband the Carbohydrate working group. Moved by Bill Burkholder. Seconded by Jan Jarman (MN). Motion Passed.

Motion to place the Carbohydrate working group work product on the Feed Bin for consideration and comments until September 30th, for committee consideration thereafter via webinar. Moved by Bill Burkholder (FDA-CVM). Seconded by Charlotte Conway (FDA-CVM). Motion Passed.

Motion to disband the Human Grade working group. Moved by Charlotte Conway (FDA-CVM). Seconded by George Ferguson (NC). Motion Passed.

Motion to accept the Dental Claims working group report. Moved by Austin Therrell (SC). Seconded by Jan Jarman (MN). Motion Passed.

Motion to place the Dental Claims working group work product on the Feed Bin for consideration and comments until September 30th, for committee consideration thereafter via webinar. Moved by Charlotte Conway (FDA-CVM). Seconded by Liz Higgins (NM). Motion Passed.



Motion to disband the Dental Claims working group. Moved by Liz Higgins (NM). Seconded by Austin Therrell (SC). Motion Passed.

Motion to form a working group to review the definitions for pet and specialty pet in the Model Bill and any other affected definitions in the Model Bill and Regulations regarding the word domesticated. Moved by Liz Higgins (NM). Seconded by Charlotte Conway (FDA-CVM). Motion Passed.

Committee Minutes

Announcements

Pet Food Committee (PFC) welcomes George Ferguson (NC) as a new member. It was noted that Roger Hoestenback (TX) has retired and Natasha Hedin (MN) has moved on to other opportunities.

Corrections to the AAFCO Dog and Cat Food Nutrient Profiles have been completed.

Working Group Reports:

Pet and Specialty Pet Food Labeling Guide – Charlotte Conway (FDA-CVM) explained that the revised guide is now finished and available for purchase and use. The working group was disbanded.

Pet Food and Specialty Pet Food Labeling Workshop – Kristen Green (KY) explained that the working group is working on the content and reminded the audience to save the dates of August 12-13, 2017 for the workshop.

Carbohydrate Working Group – Jan Jarman (MN) explained that the working group has a final product after many years of work and revision. The work product was accepted by PFC and the final language has been posted to the Feed Bin in the Pet Food Team (APPENDIX A).

The committee was asked if this work product should be referred to the Pet Food Modernization Working Group for their consideration or if it should be considered by the PFC following the normal deliberative process. There were several comments from members and advisors that they would like to see this work product move separately from the pet food modernization work to avoid delays.

The PFC is requesting that anyone who wishes to make comments on the document should open the document in the Feed Bin (it is present in the Pet Food team board) and make comments in the right hand box until September 30th, 2016. It is the intention of the PFC to consider all comments submitted before that time and vote on the work product via webinar before the mid-year meeting. There was discussion whether it is appropriate to disband the working group before comments have been received, however it was determined that PFC as a whole would consider the comments, not just the working group. The carbohydrate working group was disbanded.

Human/Feed Grade Working Group – Stan Cook (MO) reminded attendees that the Human Grade feed term and Human Grade Guidelines were passed by the membership Monday, August 1, 2016. To address some questions that may remain about the Guidelines, a Frequently Asked Questions (FAQ) document was displayed (APPENDIX B).

Question 1 Discussion – The working group acknowledges that the fact that the example of human grade noncompliance for USDA products produced in a USDA facility not subject to 21 CFR 117 was discussed by the working group as a concern, but no solution after significant discussion was found. It is suggested that affected industry consider this issue and come up with a solution to present to PFC as a new agenda item if this issue is of concern to the industry. It was also suggested to get USDA involved.

Question 2 Discussion – No additional discussion.



Question 3 Discussion – George Ferguson (NC) has been addressing some of these issues in his state. He proposes to require as substantiation for the human grade claim would be a certificate (whether a license or certificate of free sale) with the date of last inspection from the agency authorized in the manufacturers state to conduct the 117 GMP inspections in lieu of additional paperwork. He requested that the states contribute to a list of which agency in each state is authorized to conduct the 117 inspections. Kristen Green (KY) stated that she has not yet approved a human grade claim under the guidelines but is considering the use of notarized affidavits and licenses, but this thinking may change. Liz Higgins (NM) agreed. Jan Jarman (MN) suggested that states share the requirements in their state for producing human food. Minnesota will be developing a policy based on the AAFCO guideline but will also include MN's requires for human food manufacturing. It was noted that if each state has separate processes and requirements for substantiating the claim that it will be a burden to the industry. It was also noted that industry is finding it to be a challenge to identify the right person to conduct 117 GMP inspections in each state and that having a shared list would be helpful. There was interest in development of a list of human food regulatory authorities in each state, but how or where to share such a list was not clear. This question will be discussed further at the mid-year meeting.

In addition it was noted that products intended for pets and specialty pets making the human grade claim must also meet all of the AAFCO requirements to be pet foods. The working group was disbanded.

Tartar Control Working Group – Austin Therrell (SC) noted that the working group has completed work on the Dental Claims Guidelines. PFC accepted the work product (APPENDIX C). The guidelines have been posted to the Pet Food team on the Feed Bin. The PFC is requesting that anyone who wishes to make comments on the document should view it in the Feed Bin and make comments in the right hand box until September 30th, 2016. It is the intention of the PFC to consider all comments submitted before that time and vote on the work product via webinar before the mid-year meeting. The working group was disbanded.

Pet Food Modernization Working Group – Stan Cook (MO) stated that this working group had meetings on 6/24 and 7/7 and reminded the working group of a meeting immediately following the PFC meeting. Given the size of the task, it is the intention of the working group chair to begin meeting more regularly.

Presentation regarding use of the word 'Meaty' on labeling – Jeannie Perron (Big Heart Pet Brands) provided a presentation regarding use of this word on products that do not contain the AAFCO-defined ingredient meat. It was indicated that only one state has denied approval for distribution based on use of the word 'meaty' in this situation. Definitions, industry use, and consumer perceptions of the word 'meaty' were provided. Similar examples such as milky/oily/grainy were provided and discussed. The request was made that PFC become aligned on this issue.

There was discussion about whether or not this is an actionable item for PFC. Also discussed was whether the word 'meaty' would be should be submitted as a feed term to IDC. There was discussion involving other instances of accepted words similar to 'meaty' on labeling that do not have feed terms, and it was also noted that the Official Publication is not a complete listing of accepted or unaccepted feed terms, that is would be impossible to define all such acceptable or unacceptable terms. It was suggested that part of the solution may be to add additional clarification to adequately qualify the term (i.e. meaty *texture*). A note was made that historically the committee would meet with individual companies and provide written comments on labeling, but that work was discontinued due to the volume of work and due to undermining state authority. Also noted was that AAFCO or PFC could serve as an arbitrator between a state and a company on a particular labelling issue. Finally it was noted that there is another state that objects to unqualified use of 'meaty' on products that do not contain AAFCO defined 'meat', however registration was not denied, the labeling must be revised at the next printing to either remove the term or use a qualifier such as texture.

New Business -

Discrepancy in 'pet' and 'specialty pet' definitions - The Model Bill and Regulations Committee (MBRC)



has directed the PFC to consider modifications to the 'pet' and 'specialty pet' definitions on page 108 in the 2016 Official Publication as there is some discrepancy as noted by AFIA regarding the use of the word 'domesticated' to describe specialty pets but not pets. There was discussion involving how current and possible new definitions would affect certain species such as rabbits and zoo animals, as well as the non-domesticated status of many species considered to be 'specialty pets'. A working group was formed to review the definitions for pet and specialty pet in the model bill, and any other affected definitions in the model bill or regulations regarding the word domesticated. Bill Burkholder will chair the committee consisting of Leah Wilkinson (AFIA), Angele Thompson (PFI), Dave Dzanis (APPA), Liz Higgins (NM), Jean Hofve (PWA), Jason Schmidt (LA), Austin Therrell (SC) and Lizette Beckman (WA).

Cannabinoid update – Attention was drawn to the FDA and Marijuana Q&A which includes information concerning the inclusion of cannabidiol (CBD) in animal food, which is not allowed, on FDA's website. A copy of the link is available in the Feed BIN on the Ingredient Definitions team Board as well as the Pet Food team board.

Pet Food Committee Adjourned at 11:50 pm EST.



APPENDIX A - Carbohydrate Working Group Report

Recommendations

- (1) The Working Group recommends that the Pet Food Committee (PFC) accept the revision to PF4(a) of the AAFCO Model Regulations for Pet Food and Specialty Pet Food, as shown in Appendix A. This revision addresses guarantees for dietary starch and sugars, and should follow PF4(a)(2) on p. 141 of the 2016 Official Publication (OP).
- (2) The Working Group also recommends that the Pet Food Committee (PFC) accept the revision to PF10 of the AAFCO Model Regulations for Pet Food and Specialty Pet Food, also as shown in Appendix A.1. This revision addresses claims about dietary starch, sugars and carbohydrates, and should be placed at the end of PF10 on p. 149 of the 2016 OP.

Working Group Participants

Jan Jarman, Chair (MN), William Burkholder (FDA-CVM), Richard Ten Eyck (OR), Angele Thompson (PFI), David Dzanis (ACVN), Preston Buff (AFIA), Leah Wilkinson (AFIA)

Introduction

This Working Group was formed by the Pet Food Committee to recommend requirements for guaranteeing certain non-structural carbohydrate fractions and for making claims regarding these substances on the labeling of pet foods. There are three non-structural carbohydrate fractions that are important in animals' diets and that have AAFCO Official Feed Term definitions: dietary starch, sugars and fructans. For pet food, the Working Group recognized that fructans are not of dietary importance because they are typically not present in any significant quantity in dog and cat diets.

The Pet Food Committee Carbohydrate Working Group (PFC WG) examined three issues:

- The relevance of information about dietary starch and sugar content on pet food labels,
- The placement and formatting of guarantees for dietary starch and sugars, and
- Whether a level for 'low' dietary starch and sugars could be defined, and what the physiological benefit might be for pets consuming a 'low' dietary starch and sugars diet.

Discussion

(1) Guarantees for Dietary Starch and Sugars

- a) The Working Group recommends that guarantees for dietary starch and sugars should be voluntary, unless otherwise required by the Model Bill and Regulations.

The AAFCO Criteria for Labeling Nutritional Indicators do not support requiring guarantees for dietary starch and sugars (see Item I, Nutritional Considerations, on p. 137 of the 2016 AAFCO Official Publication). The Working Group believes that voluntary guarantees for dietary starch and sugars should be allowed, because they do provide nutritional information about foods. Provision for voluntary guarantees for dietary starch and sugars does meet Criteria II (Enforceability) and III (Economics), and does not conflict with AAFCO Statement for Uniform Interpretation and Policy Number 1, regarding guarantees for nitrogen-free extract and carbohydrates.

- b) Placement and units of guarantees

If guarantees for dietary starch and sugars are voluntary, they should follow the guarantees required on all pet food labels by PF4(a)(1), i.e. crude protein, crude fat, crude fiber and moisture. They would also have to follow an ash guarantee (if given) rather than moisture, because PF4(a)(2) requires that an ash guarantee (if given) must follow the moisture guarantee.

PF4(a)(3) states that pet food labels must list "other required or voluntary guarantees in the same order and units of the nutrients in the AAFCO Dog (or Cat) Food Nutrient Profiles."



Substances other than those listed in the Dog/Cat Food Nutrient Profiles are considered non-essential and must be placed below those that are listed in the Profiles.

Dietary starch and sugars are not listed in the Nutrient Profiles, so according to PF4(a)(3), guarantees for them should not be included with guarantees for the nutrients listed in the Nutrient Profiles. Dietary starch and sugars are no less 'essential' than crude fiber, though, so their guarantees should not be placed among the non-essential nutrient guarantees.

Therefore, the Working Group recommends that guarantees for dietary starch and sugars (in that order) follow the moisture guarantee if ash is not guaranteed, and should follow the ash guarantee if it is given.

Guarantees should be given in terms of maximum percentage, as this is more meaningful to consumers than minimums or g/1000 kcal ME. Section 5(a)(3) of the AAFCO Model Bill (p. 111 of the 2016 OP) states that guaranteed substances "must be determinable by laboratory methods such as the methods published by the AOAC International." There are AOAC Official Methods of Analysis for dietary starch and sugars in animal feeds, with the results given as percentage.

If a guarantee for one of the substances is given, a guarantee for the other must also be given. The value of information on one substance is questionable without information on the other, and reasonable comparisons between products can only be made if both substances are guaranteed on the labels of the products being compared.

c) Use of asterisks following guarantees

AAFCO Model Regulation PF4 (a)(3) states that guarantees for substances not listed in the AAFCO Dog (or Cat) Food Nutrient Profiles shall be followed by asterisks referencing the disclaimer "Not recognized as an essential nutrient by the AAFCO Dog (or Cat) Food Nutrient Profiles." Dietary starch and sugars are not listed in the Nutrient Profiles, but again, are no less 'essential' than crude fiber, which though also not listed in the Nutrient Profiles, is not required to be asterisked. The Working Group recommends that the asterisk referencing the disclaimer not be required to follow guarantees for dietary starch and sugars. Nutrient Profile values for dietary starch and sugars do not need to be developed, because although non-structural carbohydrates may be essential in a diet for supplying energy, minimum amounts cannot be determined because this depends on amounts of other nutrients present and other factors.

(2) Descriptive Terms

The Working Group recommends that a claim of "low carbohydrates", "low dietary starch" or "low sugars" not be allowed, because there is a lack of scientific data to support a physiological benefit to pets from diets 'low' in dietary starch and sugars, or to define a meaningful 'low' level of these components.

The primary relevance of information on dietary starch and sugars content is for owners of pre-diabetic and diabetic animals. However, there are a number of issues related to interpretation of this information. First, although glycemic response to varying levels of non-structural carbohydrates can be determined, scientific data are lacking to accurately specify a 'low' level of these substances in a food at which there would be clear physiological benefit to these animals. A 'low' level set either too low or too high may have significant adverse consequences.

Second, pet foods intended for moderating glycemic response in animals may be defined as drugs, in that they are intended to diagnose, cure, mitigate, treat or prevent diabetes, which is a disease.



Third, there is the potential for misuse of this information, in that foods with ‘low’ dietary starch and sugars might be fed to pets that would get no physiological benefit from them. They could also be used for purposes (such as weight control) for which scientific data are also lacking to justify such uses.

- (3) The Working Group recommends that a claim of “less _____” or “reduced _____” (blank is to be completed by using “carbohydrate”, “dietary starch” or “sugars”) be allowed. Such claims allow consumers to make meaningful comparisons between products.

Appendix A.1

Proposed Regulations for Dietary Starch and Sugars Guarantees and Descriptive Terms

Recommendation 1: The Working Group recommends the following addition and revisions to AAFCO Model Regulation PF4(a) on p. 141 of the 2016 Official Publication (OP):

Regulation PF4. Expression of Guarantees

- (a) The “Guaranteed Analysis” shall be listed in the following order and format unless otherwise specified in these Regulations:
- (1) ...
 - (2) ...
 - (3) When listed on the label of a dog or cat food product, guarantees for dietary starch and sugars shall be stated as maximum percentages. Neither guarantee shall be listed without the other. The guarantee for dietary starch shall follow ash, if also listed; or moisture, if ash is not listed. The guarantee for sugars shall follow dietary starch.
 - ~~(3)~~(4) A dog or cat food label shall list other required or voluntary guarantees...
 - ~~(4)~~(5) A specialty pet food label shall list other required or voluntary guarantees...

Recommendation 2: The Working Group recommends adding the following to the end of AAFCO Model Regulation PF10 on p. 149 of the 2016 OP:

Regulation PF10. Descriptive Terms

- (a) Calorie Terms...
- (b) Fat Terms...
- (c) Carbohydrate Terms
 - (1) “Low” Carbohydrate, Dietary Starch and Sugars Claims
A claim of “low carbohydrates”, “low dietary starch”, “low sugars” or a combination thereof) is not allowed.
 - (2) “Less” or “Reduced” Carbohydrates, Dietary Starch and Sugars claims.
 - A. A dog or cat food product which bears on its label a claim of “less _____” or “reduced _____” (blank is to be completed by using “carbohydrates”, “dietary starch” or “sugars”) or words of similar designation, shall include on the label:
 - i. The name of the product of comparison and the percentage of reduction in total dietary starch plus sugars (expressed on an equal weight basis) explicitly stated and juxtaposed with the largest or most prominent use of the claim on each panel of the label on which the term appears; and
 - ii. The comparative statement printed in type of the same color and style and not less than one-half the size used in the claim; and
 - iii. Maximum guarantees for dietary starch and sugars as stated in Model Regulation PF4(a)(3).
 - B. A comparison between products in different categories of moisture content (i.e., less than 20%, 20% or more but less than 65%, 65% or more) is misleading.



APPENDIX B - Human Grade Guidelines FAQ

Q - I make an edible poultry product and manufacture under other federal regulations (USDA FSIS) and don't fall under 21CFR 117. Can I make human grade claims?

A - No. Products coming directly out of this firm would not qualify for the human grade claim under the guidelines since they are not subject to 21 CFR 117 (currently 21 CFR 110). For example, a USDA inspected facility producing meat jerky products and under inspection by USDA but not FDA may not make human grade claims on that jerky produced in that USDA facility. However, human edible ingredients made by this firm could potentially be incorporated into products by other firms operating under 21 CFR 117 and have the resulting end product meet the human grade guidelines.

Q – I make a product that includes some human grade ingredients, but does not fully meet the guidelines. Can I make limited human grade claims on my labeling?

A – No. Human grade claims are limited to final products that completely meet the requirements set forth in the guidelines. Stating 'made with human grade ingredient x' on a product that does not completely meet the human grade guidelines (all ingredients, manufacture, packing, holding, etc.) is not acceptable.

Q – What will state regulators require as proof that products meet the human grade guidelines?

A - Each of the individual ingredient suppliers has verified that the individual ingredients supplied to the manufacturer are fit for human consumption.

A - Every ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods as specified in 21 CFR part 117.

A - The manufacturing facility is licensed to produce human food by the appropriate authority (which varies by jurisdiction). Such evidence may include, but is not limited to, facility licenses or permits for operation of edible food manufacturing facilities or results of most recent inspections issued by local, county, or state public health authorities.



APPENDIX C – Tartar Control Working Group Report

The Tartar Control Work Group recommends to the Pet Food Committee that this guideline replace the Guidelines for Tartar Control Claims found on page 149 in the 2016 OP.

Guidelines for Dental Related Claims

The AAFCO Pet Food Committee supports and recommends the following guidelines for tartar and plaque control with respect to pet food products (including snacks and treats), rawhides, and other chews.

- (1) Foods bearing dental related claims (claims to cleanse or whiten teeth or freshen breath) by virtue of their abrasive or mechanical actions are not objectionable.
- (2) Foods bearing dental related claims for plaque or tartar reduction or prevention, or control of bad breath odor may be misbranded. However, if these claims are made only with respect to the products' abrasive action, enforcement would be a low priority.
- (3) Foods bearing expressed or implied drug claims to prevent or treat dental diseases (e.g. gingivitis, gum problems, tooth loss) are not permissible unless they are the subject of approved New Animal Drug Applications.
- (4) Food ingredients that are not GRAS (generally recognized as safe) for the intended purpose of affecting the teeth or gums may be unapproved food additives or unapproved drugs, depending on the nature of the claim.
- (5) Foods bearing claims for plaque or tartar reduction, prevention, or control of bad breath odor that achieve their effect, in part or in total, by means other than mechanical action must have an approved New Animal Drug Application or a letter of favorable review from the FDA prior to being marketed.
- (6) The labels of foods bearing dental related claims must state the method(s) or mechanism(s) by which the intended effects are achieved.