



FINAL 8/24/18

Pet Food Committee Minutes

AAFCO Midyear Meeting

July 31, 3:00 pm-5:00 pm EST; Fort Lauderdale, FL

Committee Recommendations

Committee recommendation summary or list.

- (1) Pet Food Committee (PFC) moved to accept the revisions to PF4 and PF9 (see APPENDIX III) and move to the Model Bill and Regulations Committee for their consideration.
- (2)

Board Recommendations

Board recommendation summary or list.

- (3)
- (4)

Association Actions

Association action summary or list.

- (1)
- (2)

Committee Participants

Members Present: Kristen Green (Chair, KY), Stan Cook (Vice-Chair, MO), Lizette Beckman (WA), Bill Burkholder (FDA-CVM), Charlotte Conway (FDA-CVM), James Embry (TX), George Ferguson (NC), Liz Higgins (NM), Tiffany Leschishin (MN – call in), Jo Lynn Otero (NM), Jason Schmidt (LA), Katie Simpson (IN), Austin Therrell (SC), Kristen Hamilton (ID – call-in); Sue Hays (AAFCO Executive Director), Caitlin Price (NC), Kathleen Close (FDA-ORA)

Advisors Present: Leah Wilkinson (AFIA), Robert King (AFIA), Dave Dzanis (APPA and ACVN), Angela Mills (NGFA), David Fairfield (NGFA), David Meeker (NRA), Angele Thompson (PFI), Pat Tovey (PFI), Bill Bookout (NASC), BC Henschen (AFTP), Cathy Alinovi (NGPFMA), Mollie Morrissette (PWA); James Emerson (US Poultry), Ken Gilmurray (NRA)

Committee Report

Committee Activities

Motion to disband the GAPFA workgroup. Moved by Charlotte Conway (FDA-CVM) and seconded by Liz Higgins (NM). Motion Passed.

Motion to accept the Large Size Dogs Feeding Protocol Workgroup report as displayed (see APPENDIX I). Moved by Liz Higgins (NM) and seconded by Charlotte Conway (FDA-CVM). Motion passed. PFC intends to vote on this item before the midyear meeting.

Motion to accept the Human Grade Workgroup report as displayed (see APPENDIX II). Moved by George Ferguson (NC) and seconded by Nathan Price (ID). Motion passed.

Motion to dissolve the exploratory Human Grade Pet Food Validation Workgroup. Moved by Charlotte Conway

(FDA-CVM) and seconded by George Ferguson (NC). Motion Passed. Note that a new workgroup was formed.

Motion to accept the proposed revisions to PF4 and PF9 (see APPENDIX III) and refer them to the Model Bill and Regulations Committee. Moved by Liz Higgins (NM) and seconded by Nathan Price (ID). Motion passed.

Committee Minutes

Meeting called to order at 3:00 pm EST

Announcements

PFC welcomed Caitlin Price from North Carolina as a new committee member. PFC also welcomed Ken Gilmurray as the alternate advisor for the National Renderer's Association. Suzanne Riddle (previously MO) has left the committee and will be pursuing other opportunities. Liz Higgins (NM) gave a tribute to Jan Jarman. Liz Higgins also announced her upcoming retirement, although she intends to stay involved with AAFCO.

Working Group Reports:

AAFCO Website Review – Lizette Beckman (WA)

The workgroup has been meeting regularly to update the AAFCO Talks Pet Food website and will soon be moving on to The Business of Pet Food website. The calorie content and human grade updates have been drafted, although the workgroup would like to talk to the web designer at FASS regarding the pending website update to consider style elements. The workgroup would welcome a new member to replace Liz Higgins. Anyone interested should contact Lizette Beckman (WA)

GAPFA Maximum Vitamin A Workgroup – Charlotte Conway (FDA-CVM)

Work is completed. Workgroup disbanded.

Reviewing AAFCO Feeding Protocols Workgroup (to account for growth of large size dogs) – Kristen Green (KY), standing in for Dr. Bill Burkholder (FDA-CVM).

The workgroup met several times over the last few months to draft a proposal that was displayed on the screen. The workgroup felt that it might be too restrictive to always require the use of large size dogs in feeding protocols to substantiate suitability for growth of large size dogs. As an alternative option, a more typical small to medium colony dog could be used for feeding trials with the added constraint of limiting calcium and phosphorous in the formula to the most restrictive maximum values in the AAFCO Dog Food Nutrient Profiles (max 1.8% Ca and 1.6% P on a dry matter basis). Language is being proposed for addition to PF7(a)(2) and PF7(b)(3) and can be found in APPENDIX 1. Language will also need to be added to the protocols to refer back to the new PF7 requirements. This language will be provided to the committee prior to a vote. The workgroup report was accepted and uploaded to the Feed Bin for broader circulation prior to a full committee vote.

PF(3)e – James Embry (TX)

No report as the workgroup has not yet met.

Human Grade – George Ferguson (NC)

The workgroups comments and suggestions were posted publically in the Feed Bin this spring. This workgroup included representatives from USDA-FSIS and USDA-AMS as well as committee members and advisors. The Workgroup has completed its charge and will not be amending the AAFCO human grade guidelines or definition at this time. The Workgroup provided 5 recommendations as well as additional comments to the PFC, see APPENDIX II. A copy of the workgroup report will be provided to Ali Kashani, AAFCO Feed Terms investigator. The recommendations include establishing a new workgroup to implement the recommendations. The Chair of

PFC will be determining the makeup of the new Human Grade workgroup and electing a Member to chair this committee. Anyone interested in serving on this new workgroup should contact Kristen Green with your qualifications.

Discussion Items:

PF4 Guaranteed Analysis Header and PF9 and ME requirements – Liz Higgins, NM

Liz Higgins provided proposed revised language to PF4 and PF9 as found in APPENDIX III. The proposed revision for PF4 specifies that the heading “Guaranteed Analysis” be required with that specific language. The proposed revision for PF9 was to specify that the words “Metabolizable energy” or abbreviation “ME” must appear as part of the calorie content statement. Both recommendations were accepted by the committee for referral to MBRC.

Discussion of a suggested implementation period for rabbit labeling – Kristen Green (KY)

PFC was asked whether a suggested implementation period for the change in pet rabbit labeling would be appropriate. It was discussed that because most state laws don’t change as quickly as the AAFCO Model Regulations, States often utilize discretion. The PFC would like to encourage states to consider using their discretion when considering the labeling changes required for pet rabbit labeling. No other committee action to be taken.

Discussion of ‘95% claims’ vs. ‘95% Product name rule’ – James Embry (TX)

States have been seeing an increasing trend to include specific meat/ingredient percentage claims on labeling. For example, the front of a package may claim ‘95% chicken’, but a check of the formula indicates that that percentage is exclusive of water content, similar to the exemption allowed in PF3(b)(1). Some states consider this claim to be misleading since the claim is not truthful or qualified. In addition, there is also precedent in PF3(a) allowing for the exclusion of water in 100% claims. A workgroup will be formed, to be chaired by James Embry (TX) to explore this issue. Anyone interested in serving on this new workgroup should contact James Embry.

Discussion of non-GMO in meat/animal products

This item was not discussed due to time restriction. The PFC committee will consider whether to include it on the January 2019 agenda at a later date.

Pet Food Label Modernization Discussion – Sue Hays

Sue Hays is the new project manager for the Label Modernization Workgroup. The label modernization remains a major focus for PFC. The ongoing goal for the workgroup is to reach consensus in the four subgroups for their work products. Sample labels continue to be developed that contain elements from the subgroups that have been working. The four subgroups are Nutrition Facts Box (Jason Schmidt, Chair), Ingredient List (Richard Ten Eyck, Chair), Nutritional Adequacy Statement (Jo Lynn Otero, Chair) and Safety Statement (Lizette Beckman, Chair). Each subgroup chair reviewed their group’s progress and explained the elements on the mock up labels as well as discussing areas of on-going work and any specific questions that the subgroups have. The presentation can be found in the Feed Bin. The floor was opened for comments.

Some of the general comments or concerns regarding the safe handling group included: how to include all required information on smaller packages and packages with multiple languages, following ready to eat approach for human foods for safe handling instructions as well as Guidance for Industry #122, and cautionary statements on raw foods compared to kibbled foods. Comments were raised regarding the possibility of confusing pet and human products since the formatting of the labels is being aligned. There was considerable

discussion of the nutritional adequacy graphic or 'bug' on the front of the label and what it should say as well as the necessity of it appearing on treats/supplement. A comment was made regarding the economic burden or reworking labels to comply with the ultimate outcome of this project. It would certainly be PFC's intention to suggest discretion and implementation periods to reduce this burden.

The subgroups are to the point that they need validation of their work and want structured consumer input. Sue Hays presented bids from two independent firms that have submitted proposals for a qualitative approach to do the consumer market research. The PFC will be meeting prior to the January meeting to choose a provider with the hope to have a report back to the PFC.

Pet Food Committee Adjourned at 5:00 pm EST.

APPENDIX I –

Revising requirements to the Feeding Protocols to account for the special nutritional requirements for growth of large size dogs. DRAFT language.

I. Regulation PF7. Nutritional Adequacy

- (a) The label of a pet food or specialty pet food which is intended for all life stages and sizes of the pet or specialty pet may include an unqualified claim, directly or indirectly, such as “complete and balanced,” “perfect,” “scientific,” or “100% nutritious” if at least one of the following apply:
 - (1) The product meets the nutrient requirements for all life stages and sizes established by an AAFCO-recognized nutrient profile; or
 - (2) The product meets the criteria for all life stages as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s);
 - A. Unqualified claims of nutritional adequacy that include large size dogs can be substantiated by: completing the appropriate protocols with large size dogs or
 - B. Can be substantiated by completion of appropriate protocols with dogs less than 70 lbs adult weight while complying with the calcium and phosphorus maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles; or
 - (3) The product is a member of a product family which is nutritionally similar to a lead product which contains a combination of ingredients that has been fed to a normal animal as the sole source of nourishment in accordance with the testing procedures established by AAFCO for all life stages, provided that:
 - A. The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO; and
 - B. The family product meets the criteria for all life stages; and
 - C. Under circumstances of reasonable doubt, the (State Control Official) may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.
- (b) The label of a pet food or specialty pet food which is intended for a limited purpose (such as size of dog) or a specific life stage, but not for all life stages and sizes, may include a qualified claim such as “complete and balanced,” “perfect,” “scientific,” or “100% nutritious” when the product and claim meet all of the following:
 - (1) The claim is qualified with a statement of the limited purpose or specific life stage for which the product is intended or suitable, for example, “complete and balanced for puppies (or kittens).” The claim and the required qualification shall be juxtaposed on the same label panel and in the same size, style and color print; and
 - (2) The product meets at least one of the following:
 - A. The nutrient requirements for the limited purpose or specific life stage established by an AAFCO-recognized nutrient profile; or
 - (3) The criteria for a limited purpose or a specific life stage as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s);
 - A. Qualified claims of nutritional adequacy that include large size dogs can be substantiated by: completing the appropriate protocols with large size dogs or
 - B. Can be substantiated by completion of appropriate protocols with dogs less than 70 lbs adult weight while complying with the calcium and phosphorus maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles;

- A. or
- B. The requirements of a product family which is nutritionally similar to a lead product which contains a combination of ingredients which, when fed for such limited purpose, will satisfy the nutrient requirements for such limited purpose and has had its capabilities in this regard demonstrated by adequate testing, and provided that:
 - i. The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO; and
 - ii. The family product meets the criteria for such limited purpose; and
 - iii. Under circumstances of reasonable doubt, the (State Control Official) may require the manufacturer to perform additional testing for the family product to substantiate the claim of nutritional adequacy.
- (c) Dog and cat food labels shall include a statement of nutritional adequacy or purpose of the product except when the dog or cat food is clearly and

APPENDIX II –

While Utilizing AAFCO’s Terms, Definitions and Guidance for Human Grade Pet Food Claims; Identify options whereby FDA and USDA may partner together for the purpose of validating Human Grade Pet Food Claims, in products that span both agencies jurisdiction.

Regarding opportunities for validation of voluntary “human grade pet food” claims on products that are manufactured, processed, blended and/or packaged under rules and in facilities that span multiple regulatory agency jurisdictions (e.g., USDA-FSIS, EPA, FDA), the Human Grade Pet Food Validation Workgroup makes the following recommendations;

1. That AAFCO, under the direction of the AAFCO Pet Food Committee, establish a partnership with USDA’s Agriculture Marketing Service (AMS) for the purpose of validating a firm’s ability to make “human grade pet food” claims.
2. That AAFCO and AMS utilize AMS’s Process Verified Program (PVP) as the mechanism by which claim validation is verified.
3. That AAFCO’s Pet Food Committee establish a “Human Grade Pet Food Standards” working group to:
 - a. Develop PVP Standards for the “Human Grade Pet Food” claims, utilizing AAFCO’s current Terms, Definitions and Guidance for “Human Grade Pet Food” claims as their starting point.
 - b. Modify, only as needed for the inclusiveness of non-traditional FDA jurisdiction human food products such as meats, the current AAFCO Terms, Definitions and Guidance for Human Grade Pet Food Claims.
4. That upon completion of development and delivery of all requirements, the working group will prepare and submit to the AAFCO Pet Food Committee a written document, similar to a preamble in format and purpose, that explains the thinking, intent and expectations of the Definition, Guidance, Standards and Partnership.
5. Give significant consideration to the comments, thoughts and guidance as offered to the Committee’s working group, by the Human Grade Pet Food Validation Workgroup.

Comments, Thoughts and Guidance

1. Ensure that the Standards working group includes AAFCO members and advisors as well as representatives from impacted Federal agencies (e.g., FDA, USDA, AMS, FSIS).
2. Obtain a commitment from all working group members are willing to participate by providing original ideas and thought.
3. Those who seek only to scrutinize the work of others without also providing alternatives and/or original solutions, should be removed from the working group. There will be ample opportunity for individuals to comment on the working groups submissions during committee review as well as member vote.
4. Prior to the working group addressing the concerns of their charge, members should attend an in detail PVP workshop, delivered by AMS, in order to fully understand how the PVP works, is delivered, is audited and what it includes above and beyond the standards that they will develop. This initial step will help to ensure that unnecessary duplication is created as well as

help to narrow the focus of the group to just those issues needed to be addressed by the Standard.

5. Consider AMS recommendations when determining the best way to document/allow/formalize the partnership.
6. 3rd party inspection audits/reports/findings, i.e. those from either non-regulatory agencies or agencies without jurisdictional enforcement authority, shall not be allowable as evidence/documentation of required regulatory compliance/inspections. It shall be the manufacturing firm's responsibility to ensure it is able to manufacture and be inspected by the authorized agency to conduct such inspections, in a human food facility. Human Grade Pet Food claims are voluntary, and as such, no feed control official, neither state nor federal, can mandate that a human food authority license a facility that is only manufacturing a pet food product.

The comments below are to address the blending and/or packaging of products in a non-USDA facility, that contain meat. These comments may also prove beneficial when addressing other products requiring a kill-step, such as milk.

7. Allow "human grade pet food" claims on products that are/contain ingredients that typically fall under regulatory jurisdictions other than FDA, to be blended, packaged, repackaged and/or labeled in;
 - a. A registered FDA Human Food subject to CFR 21 Part 117 as long as,
 - i. Those included ingredients that traditionally fall under the regulatory authority of an agency other than FDA, were processed, packed, held and shipped under a human food processing code in a manner applicable to their federal regulations up to and through the kill step (if applicable) and in a facility that is registered/authorized by the applicable regulatory authority.
 - b. A registered/authorized USDA, or other federally allowable human food facility as determined by federal law;
 - i. That is subject to enforcement action under federal law and,
 - ii. That produces human food requiring no further kill step.
8. In order to avoid future conflict as new pathways for human grade pet food products and ingredients are being developed, when possible, we suggest that you avoid the use of agency specific language as well as specific CFR and Part numbers, and instead consider phrases such as;
 - a. "all finished products and its included ingredients must be manufactured, inspected and in compliance with its applicable human food law."
 - b. "inspected by the agency authorized to conduct such enforcement inspections at your facility type."

The following is a list of questions submitted by individuals within the Human Grade Validation Workgroup. The answers provided represent the thoughts of a single state agency, and are in no way meant to be inclusive nor representative of all of AAFCO. They are merely provided as a prompt and intended to elicit further discussion as well as the sharing of ideas.

*It was mentioned that a PVP audit/verification (audit option allowing a seal on packaging) requires constant USDA inspection. What about a company that processes meats at a USDA facility, those meats leave the facility in a ready-to-eat state, enter a separate human food only facility that doesn't cook meat (but does process other human foods), and the meat is mixed and packaged in that second facility?

The audit would verify that the meat came from a USDA human food facility, was under constant USDA inspection through the kill/cooking step and was then moved under a USDA human food code. As for the final steps of packaging and/or blending at a Human food facility under FDA jurisdiction, the audit would verify that the facility was registered, had received a compliant inspection and then whatever additional requirements the Human Grade Guidance workgroup saw fit to include. Please keep in mind that our group is not the Guidance group. That group will likely be formed in August.

*Will manufacturer *and* packager have to be audited?

The audit will have to verify that the meat being used in the "FDA" facility came from a USDA facility and was processed and inspected through the kill step under a human food code.

*The biggest concern last week seemed to surround PVP audits being more marketing claims based and less food safety based. Mr. Ferguson mentioned that both a thorough claims/marketing audit *and* a quality audit would be required. Will all companies be required to meet the exact same quality standards?

All firms will be required to meet both the "Human Grade Pet Food Marketing Claim" as well as their applicable CFR's. The one area of exception will be where we must work around the 3% meat rule requiring USDA constant inspection. We will address this issue as a group and I believe that we can show the product meets the Human Grade standard as FDA is responsible for non-amenable meats as well as several areas of meat such as sandwiches, thus there are standards and cGMP's in place in the 117's to help ensure safe practices are utilized.

*An AAFCO committee would create the industry standards for audits. What sort of base standards can be expected (very basic ideas)?

The AMS PVP Quality Management System (QMS) is the base requirement for everyone, from there the committee would add steps to meet the "Human Grade Pet Food Definition, such as every product meet its applicable CFR rules up to and through their kill step (if applicable) and that it be processed in a Human Grade Facility that is registered with FDA, (or under USDA) inspected and compliant with FDA/USDA and then basic Pet Food labeling.

*How will potential new AMS claims work with the current, allowable AAFCO claims?

The current allowable AAFCO claim will be modified to include this new ingredient area (meat) that was and will remain under another agencies jurisdiction.

*Will AMS re-inspect if a new ingredient is brought in (ex: rabbit) like APHIS export audit?

That is a good question for AMS. We will get with them to work through scenarios once we have a better understanding of what our standard will be.

*PVP audited companies are required to develop a Quality Manual and AMS verifies the company's adherence to those processes through routine audits. For "distributor" companies that strictly use a co-packer, would the "distributor" need a separate QC manual from the co-packer? Would each co-packer need to submit a QC manual?

Distribution channels would have to show compliance with human food standards already in place, applicable to their product. Each co-packer would be required to develop a QC manual and be subject to audit/verification.

*Would PVP audited companies' labels require additional approval before marketing (realizing AMS does not review labels)?

Registration and labeling/label approval would be up to each state just as it is today. This means you would follow the same path. What the PVP allows for, is that when you submit a product with a HG claim and the PVP seal, the state will be able to go to the AMS website, look up your firm and product and see that yes, it is allowed to make the claim. This means that you will not have to submit any additional paperwork to the state to verify and validate your ability to make the claim. Please understand that no state is required to follow the process that AAFCO develops, yet it is rare that one does not.

*If we move forward with AMS, what would be the AAFCO-based compliance period for companies? Would we give current HG companies six months for compliance? One year?

We would look to industry as well as AMS for guidance on an acceptable transition.

APPENDIX III –

Proposed Revision to PF4 – Expression of Guarantees

There has been some confusion about use of a heading in the Guaranteed Analysis. While most labels do use the words “Guaranteed Analysis” as the heading, some companies have expressed that the regulations do not clearly state the requirement for the heading. In order to clarify the need for the use of the heading, the following change to PF4(a) is being proposed:

Regulation PF4. Expression of Guarantees

- (a) The “Guaranteed Analysis” shall be listed **under the heading “Guaranteed Analysis”** in the following order and format unless otherwise specified in these Regulations:
 - (1) A pet food or specialty pet food label shall list the following required guarantees;
 - A. Minimum percentage of crude protein;
 - B. Minimum percentage of crude fat;
 - C. Maximum percentage of crude fat, if required by Regulation PF10;
 - D. Maximum percentage of crude fiber;
 - E. Maximum percentage of moisture; and
 - F. Additional guarantees shall follow moisture.....

Proposed Revision to PF9 – Statements of Calorie Content

There has been some confusion on the part of both regulators and industry about the requirement of “...in terms of metabolizable energy (ME)...” to be included in the calorie content statement. The energy of a food can be expressed in several ways: gross energy, digestible energy and metabolizable energy. The Model Pet Food & Specialty Pet Food Regulations state in PF9(a)(2) that the calorie content statement on pet food labels must be in terms of metabolizable energy. However, the wording in the regulation is not a clear enough communication of the requirement. The proposed language change is intended to clarify the regulation and lessen the confusion on the part of both the regulator and the regulated industry.

Regulation PF9. Statements of Calorie Content

- (a) The label of a dog or cat food, including snacks, treats, and supplements, shall bear a statement of calorie content and meet all of the following:
 - (1) The statement shall be separate and distinct from the “Guaranteed Analysis” and appear under the heading “Calorie Content”;
 - (2) The statement shall be measured in terms of metabolizable energy (ME) on an “as fed” basis and must be expressed, **including either the words ‘metabolizable energy’ or the abbreviation ‘ME,’** both as “kilocalories per kilogram” (“kcal/kg”) of product, and as kilocalories per familiar household measure (e.g., cans or cups) or unit of product (e.g., treats or pieces); and
 - (3) The calorie content is determined by one of the following methods: