

Pet Food Committee Meeting Minutes Web-Ex 3/17/2016

The meeting was called to order at 11:00 am ET

- Roll call of Pet Food Voting Members – Stan Cook (MO)

Voting members on call: Liz Beckman (WA), Liz Higgins (NM), Jo Lynn Otero (NM), Kristin Green (KY), Stan Cook (MO), Charlotte Conway (FDA), Jan Jarman (MN), Eric Nelson (FDA), Christie Shee (IN), William Burkholder (FDA)

There is a quorum so this issue can be voted on

- Roll call of Advisors – Stan Cook (MO):

Advisors on call: James Emerson (US Poultry & Egg Association), Jean Hofve (Pet Welfare Alliance), Susan Thixton (Association for Truth in Pet Food), Angele Thompson (Pet Food Institute), Pat Tovey (Pet Food Institute)

There were approximately 50 additional individuals present on the call.

- Review of “Human Grade” Definition – Stan Cook (MO)

Stan Cook presented an overview of why the “Human Grade” claim was brought to AAFCO to develop a feed-term for “human grade” and associated guidance. Charlotte Conway (FDA) gave an historic overview of how “human grade” claims were previously reviewed by the Food and Drug Administration’s Center for Veterinary Medicine (CVM) for the last decade because of the complexity of reviewing the claim. Now that guidance has been established, CVM felt that continuing to review these claims is not consistent with the other types of claims that they review on a pre-market basis. State regulatory agencies will now be reviewing “human grade” claims creating a need for guidance so that there is consistency in review by states.

The Pet Food Committee established a workgroup in conjunction with Ingredient Definitions Committee (IDC) to establish human/feed grade definitions. This larger workgroup developed “feed grade” and “human grade” feed terms which were voted on at the AAFCO mid-year meeting in South Carolina. The “human grade guidance” came to the Pet Food Committee at midyear 2016 where there was a significant amount of discussion and changes needed to clarify the guidance. The workgroup continued their work after the meeting to address comments received during the meeting. The product of that workgroup was posted to the AAFCO Feed Bin for consideration in March 2016.

- MOTION

Stan Cook (MO) moved that the report of the workgroup be accepted by the Pet Food Committee. Seconded by Charlotte Conway (FDA). Motion passed.

- DISCUSSION

Nathan Price (ID) asked for clarification on why CFR 117 was listed in the newly developed Human grade Guidance document, as it currently is in CFR 110. Charlotte Conway (FDA) indicated that CFR 110 will be moved into CFR 117 due to the Food Safety Modernization Act (FSMA). Since the “Human Grade” claim will not be published until later, the workgroup felt that CFR 117 reference makes the most sense to publish.

Angele Thompson (PFI) asked about the delayed compliance for the human food rule and whether 117 is the correct reference, Charlotte Conway (FDA) said 117 is the current up to date reference. In order to explain this indiscrepancy, a note will be placed in the front of the AAFCO Official Publication (OP) to explain this.

Note: The current CGMPs for Human Food are still 21 CFR 110, with the publication of Preventive Controls for Human foods, the rule will slide over into 21 CFR 117. Here are the established compliance dates: firms that do not qualify for Small or Very Small business status it is September 18, 2016, for Small Businesses September 19, 2017, and September 19, 2018 for Very Small Businesses. So, 110 will continue to exist until they phase out in September 2018 (depending on size).

Stan Cook (MO) and Charlotte Conway explained that the language in 4d is specific to labeling, and the reason it is being separated out.

Liz Higgins (NM) asked about section 3 and whether a company must have a food processing license. Charlotte Conway explained that depending on the jurisdiction of the area of where the company is manufacturing they will need to get a food license in order to make a “Human Grade” claim, and if they don’t qualify they will not be able to make the claim. It is up to the State Feed Control Official to ask for the documentation and make the decision.

A call in question from a firm that makes edible poultry product and manufactures under other federal regulations (USDA FSIS) and don’t fall under 21CFR 117. This company is not under compliance by FDA because they are under USDA. The response was that 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. 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.

Liz Higgins (NM) asked what type of documentation is required from the company in regard to documenting that a firm is in compliance with 21 CFR 117 in regard to transporting and holding? Charlotte answered probably an affidavit; it would be difficult to have an answer for each situation that may come up. It falls on the manufacturer to be able to provide information for the state to make the determination.

George Ferguson (NC) requested that since each state may handle differently who conducts food processing inspections, he would like each state to provide information of what agency to contact for certificate or proof of inspection of products. Stan Cook responded that this is a good idea and can be done through the AAFCO website to expedite the research. This can be worked out at a later date.

Angele Thompson (PFI) mentioned the experience of some firms trying to comply with the regulation but have experienced redundancy of documentation. It seems that 3a and 3b are redundant. If a facility is complying with cGMP's that by definition is that every ingredient needs to be stored appropriately and there is an additional overlay for a facility to make human food. Charlotte laid out in historical context how the human edible should be handled – an affidavit for each ingredient should be provided by each ingredient supplier for all ingredients used in the products, copies of food facility licenses and affidavits that cGMPs are being followed in the production, storage, handling and transporting of the animal food.

Both Kristen Green (KY) and Stan Cook (MO) asked if there was an objection to voting now or if there should be an e-vote. Conversation around whether the motion needs to be made to send to AAFCO Model Bill and Regulation Committee can be made at this time due to the fact that the "human grade" definition has not yet been voted on by the AAFCO Membership. Doug Lueders (MN) indicated that technically AAFCO's Model Bill and Regulations Committee could not work on the "Human Grade Guidelines" until the "Human Grade" definition is official. After some discussion, it was determined that this document would not need to go through the MBRC. The intent was that the "human grade" feed term and the associated guidance would be voted on together. The following statement was added to the document "This guideline is not to be published in the AAFCO OP without the "Human Grade" Definition first being accepted by the association membership."

- **MOTION:**

Charlotte Conway (FDA) moved that the guidelines on the webinar screen be approved and follow in the OP the “Human Grade” Claims.

Conversation around where the guidelines are placed in the AAFCO OP came up; Jan Jarman (MN) and Kristen Green (KY) both agree that whether it is in AAFCO Model Pet Food Regulations PF4 or PF5, all guidelines should be in one place.

Charlotte Conway (FDA) amended her motion to the below statement, Liz Higgins seconded, and Kristen and Stan asked for a roll call vote:

Lizette Beckman (WA) aye
Bill Burkholder (FDA) aye
Charlotte Conway (FDA) aye
Kristen Green (KY) aye
Liz Higgins (NM) aye
Jan Jarman (MN) aye
Eric Nelson (FDA) abstain
Jo Lynn Otero (NM) aye
Christie Shee (IN) nay

PFC Recommendation to board and association members: To publish the following guideline in the AAFCO OP following the guideline for natural claims. This guideline is not to be published in the OP without the corresponding Human Grade definition first being accepted by association membership. Moved by Charlotte Conway (FDA), seconded by Liz Higgins (NM). Motion passed 8 in favor, 1 abstain, 1 opposed

Motion was made to accept the minutes by Charlotte Conway (FDA) and Seconded by Austin Therrell (SC). Motion passed by PFC evote on 3/29/2016.

Pet Food Committee – Human/Feed Grade WG

Guidelines for “Human Grade” Claims, must travel with the Feed Term ‘Human Grade’
March 17, 2016

Proposed addition to Chapter 4, Model Bill and Regulations to be placed on page 150, line 34 of the 2016 print AAFCO OP (this section follows the ‘Guidelines for “Natural Claims”’ and precedes the ‘AAFCO Methods for Substantiating Nutritional Adequacy of Dog and Cat Foods’).

Guidelines for “Human Grade” Claims

AAFCO recommends and supports the following guidelines for the use of the term “human grade” in the labeling of pet foods and specialty pet foods.

- (1) In the AAFCO defined feed term “human grade”, the use of the term “human grade” is only acceptable in reference to the product as a whole. The feed term specifies that every ingredient and the resulting product must be 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.
- (2) In the definition, the term “human grade” is false and misleading if the product as a whole is not human edible. “Human grade” claims may not be made for individual ingredients in a finished product that does not fully adhere to the manufacturing and ingredient specifications identified above.
- (3) In order to substantiate that a “human grade” claim is truthful and not misleading, a manufacturer making one or more “human grade” claims must have documentation that:
 - a. Each of the individual ingredient suppliers has verified that the individual ingredients supplied to the manufacturer are fit for human consumption.
 - b. 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.
 - c. 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.
- (4) A pet food or specialty pet food product with “human grade” claims must be clearly labeled for its intended use as animal food, such as “dog food” or “cat

treats”, and follow all other pet food or specialty pet food labeling requirements. The following also applies to labeling:

- a. Statements of quality or grade may not appear in the ingredient statement [PF5(d)(3)].
- b. All uses of the words “human grade” on the label can be no larger than the statement of intended use required by PF2(a)(2).
- c. A claim of “human grade ingredients” is only acceptable if the product complies with all parts of this guideline.
- d. In order to use the term “human grade” on labeling (brochures, point of sale materials, websites, etc.), the statement of intended use must also be included. All uses of the words “human grade” on labeling can be no larger than the statement of intended use.