Association of American Feed Control Officials

2019 AAFCO Annual Meeting
Committee Reports

University of Kentucky
Regulatory Services
College of Agriculture, Food and Environment

August 5–7, 2019
Louisville Marriott Downtown
Louisville, Kentucky
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Association Business Meeting Minutes
2019 AAFCO Midyear Meeting
January 21, 9:44–10:20 am, Savannah, Georgia

Agenda
1) Bob Geiger convened business session of the Association at 9:44am EST.
   1) Presentation of Awards
      a) Dave Phillips: For outstanding vision and dedication in developing the ODI project
      b) Steven Stewart: For outstanding vision and dedication in developing the ODI project
      c) Nathan Price: For outstanding vision and dedication in developing the ODI project
      d) Charlotte Conway: For outstanding vision and dedication in developing the ODI project
      e) Laura Earhart: For outstanding vision and dedication in developing the ODI project
      f) Kristen Green: For Dedicated Professional Teamwork Developing the Spotlight On Presentations
      g) George Ferguson: For Dedicated Professional Teamwork Developing the Spotlight On Presentations
      h) Dave Dressler: For Dedicated Professional Teamwork Developing the Spotlight On Presentations
      i) Erin Bubb: For Dedicated Professional Teamwork Developing the Spotlight On Presentations
      j) Dr. Robert Waltz: For Dedicated Professional Teamwork Developing the Spotlight On Presentations
      k) Dr. Steven Hooser: For Dedicated Professional Teamwork Developing the Spotlight On Presentations
      l) Britney Fraley: For Dedicated Professional Teamwork Developing the Spotlight On Presentations

   *Not present to receive the award

2) Kristen Green states the AAFCO Board of Directors approved the following Committee Reports:
   Current Issues and Outreach, Education and Training, Feed and Feed Ingredient Manufacturing,
   Feed Labeling, Ingredient Definitions Committee 7/31, Ingredient Definitions eMeetings: 4/19/18,
   10/5/18, 10/19/18; Inspection and Sampling, Lab Methods & Services, Model Bills and Regulations,
   Pet Food, Proficiency Testing, Strategic Affairs and recommends the same to the membership. I so move.
   George Ferguson Seconds. MOTION CARRIES

3) Acceptance of Committee Recommendations:
   –Kristen Green, President-Elect
   Ingredient Definitions 7/31/18, 1-3; eMeeting April 19, 1-6; eMeeting October 5, 1-4; eMeeting October 19, 1-2:
   Report is in the Committee Report Book
   1) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Move the Enzyme Marketing Coordination document from chapter 5 to chapter 6 and place after Table 30.1 in the AAFCO Official Publication and recommends the same to the membership. I so move. Richard Ten Eyck Seconds. MOTION CARRIES
   2) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Add 2 Carbohydrases to Table 30.1 in the AAFCO Official Publication and recommends the same to the membership. I so move. Richard Ten Eyck Seconds. MOTION CARRIES
   Beta-Glucanase  Talaromyces versatilis overexpressing glucanase
   Xylanase  Talaromyces versatilis overexpressing xylanase

3) Publish the following tentative definitions as Official and remove the existing Official Definition, if any.
   a) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T6.12 Taurine in the AAFCO Official Publication as an Official definition and remove the existing Official definition, if any and recommends the same to the membership. I so move. Shaness Thomas Seconds. MOTION CARRIES
   i. T6.12 Taurine:
      is a product that contains a minimum of 97% 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in cat foods, dog foods, and fish foods. Taurine may also be added to the feed of growing chickens; when added to complete chicken feed, the total taurine content shall not exceed 0.054% of the feed (21 CFR 573.980). (Proposed 2017 rev. 1)
b) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T60.117(B) Dried Black Soldier Fly Larvae in the AAFCO Official Publication as an Official definition and remove the existing Official Definition, if any and recommends the same to the membership. I so move. Jacob Fleig Seconds. MOTION CARRIES
i. T60.117(B) Dried Black Soldier Fly Larvae: is the dried larvae of the Black Soldier Fly, Hermetia illucens, with or without mechanical extraction of part of the oil, that has been raised on a feedstock composed exclusively of feed grade materials. The ingredient must be labeled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is dried by artificial means to no more than 10% moisture. It is for use in salmonid and poultry feed as a source of protein and fat consistent with good feeding practices. (Proposed 2018 rev. 1)

c) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T71.35 Brassica carinata Meal, Solvent Extracted in the AAFCO Official Publication as an Official definition and remove the existing Official Definition, if any and recommends the same to the membership. I so move. Bob Church Seconds. MOTION CARRIES
i. T71.35 Brassica carinata Meal, Solvent Extracted,** **The words “Solvent Extracted” are not required when listing as an ingredient in a manufactured feed: is the meal obtained after the removal of most of the oil by solvent extraction of Brassica carinata seeds. The meal shall contain less than 2.0% erucic acid and less than 30 micromoles of total glucosinolates per gram. It is a source of protein for beef cattle in an amount not to exceed 10% of the total diet. The maximum sulfur content must be guaranteed. (Proposed 2017 rev. 1)

d) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T73.051 Iron Tartrates in the AAFCO Official Publication as an Official definition and remove the existing Official Definition, if any and recommends the same to the membership. I so move. Richard Ten Eyck Seconds. MOTION CARRIES
i. T73.051 Iron Tartrates: is the reaction product of sodium tartrates [D-, L-, and meso-tartrates] and iron(III) chloride for use as an anticaking agent in salt. The molar ratio of iron(III) to meso-tartrate must be 1:1. It must contain no less than 8% iron(III) on a dry weight basis. It must contain no more than 1.5% oxalic acid, 3 ppm arsenic, 2 ppm lead, and 1 ppm mercury on a dry weight basis. The maximum iron tartrates inclusion rate (calculated as iron) is not more than 12 ppm. (Proposed 2018 rev. 1)

e) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T73.400 Iron Nickel Tracer in the AAFCO Official Publication as an Official definition and remove the existing Official Definition, if any and recommends the same to the membership. I so move. Shaness Thomas Seconds. MOTION CARRIES
i. T73.400 Iron Nickel Tracer: are the particles resulting from water atomization of high purity iron and nickel. The nickel content of the particles is between 35% and 51% with the remainder being iron. The particle size of the iron nickel alloy must range between 150 and 300 microns. This ingredient may be used in animal foods as a tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the ingredient must not exceed 10 ppm in the finished food. The label shall include a maximum nickel guarantee and a caution statement indicating the maximum permitted inclusion level. (Proposed 2017 rev. 1)

f) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T87.35 Glucose Syrup in the AAFCO Official Publication as an Official definition and remove the existing Official Definition, if any and recommends the same to the membership. I so move. Richard Ten Eyck Seconds. MOTION CARRIES
i. T87.35 Glucose Syrup:
is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch. It shall meet the following specifications: total solids content not less than 70.0% mass/mass (m/m) and reducing sugar content (dextrose equivalent), expressed as D-glucose, not less than 20.0% m/m calculated on a dry basis. The sulfated ash content is not more than 1.0% m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 40 mg/kg. If the product bears a name descriptive of its kind or origin, e.g., “corn syrup,” “grain sorghum syrup,” it must correspond thereto. (21 CFR 168.120) (Proposed 2017)

g) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish T96.14 Scheffersomyces stipitis Dried Yeast in the AAFCO Official Publication as an Official definition and remove the existing Official Definition, if any and recommends the same to the membership. I so move. Shaness Thomas Seconds. MOTION CARRIES

i. T96.14 Scheffersomyces stipitis Dried Yeast:
is the dried, non-viable yeast of the botanical classification Scheffersomyces stipitis that has been grown on thin stillage from the ethanol production process from the fermentation of a grain or grain mixture, and is separated by centrifugation from the media on which it was propagated. The product is produced in accordance with good manufacturing practices to control the potential for mycotoxin and other contaminants. The product is intended as a source of protein in cattle, sheep, goat, and swine feeds at levels up to 15%. It must contain not less than 40% crude protein. The label shall include guarantees from minimum crude protein and crude fat and maximum sulfur contents. Non-protein nitrogen content must be guaranteed when added. (Proposed 2018)

4) Establish and publish in the Official Publication a new tentative definition(s) for:

a) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to establish and publish T57.167 Manganese Hydroxychloride in the AAFCO Official Publication as a new tentative definition and recommends the same to the membership. I so move. Shaness Thomas Seconds. MOTION CARRIES

i. T57.167 Manganese Hydroxychloride:
is the reaction product of manganese oxide and hydrochloric acid at the appropriate stoichiometric ratio, having the empirical formula Mn2(OH)3Cl. Particle size must not exceed 100 microns. It must contain not less than 44% manganese and is intended to be a source of manganese for use in livestock, poultry, and companion animal diets. It must not contain more than 20% chloride, 50 ppm lead, 50 ppm arsenic, 10 ppm cadmium, and 0.5 ppm mercury.

b) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to establish and publish T73.311 (A) Hydrogenated Glycerides in the AAFCO Official Publication as a new tentative definition and recommends the same to the membership. I so move. Austin Therrell Seconds. MOTION CARRIES

i. T73.311 (A) Hydrogenated Glycerides:
are obtained by hydrogenation of animal fats or vegetable oils and are used as a coating agent for ingredients or a binder and lubricant in pelleting of feed (pelleting aid) of all animal species. The maximum use rate of hydrogenated glycerides is 4 lb per ton of complete feed. Specifications of animal fats or vegetable oils used to produce the hydrogenated glycerides must meet the requirements stated in AAFCO definition 33.1 (for Animal Fat) and AAFCO definition 33.2 (for Vegetable Fat, or oil), respectively. The specification for tallow must specify insoluble impurities not more than 0.15% to be consistent with BSE feed regulation 21 CFR 589.2000 and 589.2001, and a guaranteed titer above 40° C. The source of the hydrogenated glycerides must be indicated on the label. The hydrogenated glycerides must contain, and be guaranteed for, not less than 90% total ester content, not more than 0.8 % unsaponifiable matter, not more than 0.001% heavy metals, and not more than 5 of iodine value. The maximum moisture, maximum insoluble matter, maximum free fatty acids, saponification value and melting range must also be guaranteed on the label. If an antioxidant is used, the common name or names must be indicated on the label, followed by the words “used as a preservative.”
c) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to establish and publish **T73.401 Colored Graphite Tracer** in the AAFCO Official Publication as a new tentative definition and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES**

i. **T73.401 Colored Graphite Tracer:**
   
   are the particles resulting from the milling of naturally occurring graphite coated with a color additive(s) approved for use in animal food. The graphite must be of feed grade material and may be used in animal food as a colored tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the tracer must not exceed 50 ppm in the finished food. The label shall include a caution statement indicating the maximum permitted inclusion level.

5) Publish the following definitions as Official in the Official Publication:

a) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish **73.046 Silicon dioxide** as Official in the AAFCO Official Publication and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES**

i. **73.046 Silicon dioxide:**

   The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:
   
   (a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.
   
   (b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:

<table>
<thead>
<tr>
<th>Feed component</th>
<th>Limitations (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BHT (butylated hydroxytoluene)</td>
<td>2</td>
</tr>
<tr>
<td>Methionine hydroxy analog and its calcium salts</td>
<td>1</td>
</tr>
<tr>
<td>Piperazine, piperazine salts</td>
<td>0.8</td>
</tr>
<tr>
<td>Sodium propionate</td>
<td>1</td>
</tr>
<tr>
<td>Urea</td>
<td>1</td>
</tr>
<tr>
<td>Vitaminsa</td>
<td>3</td>
</tr>
</tbody>
</table>

   (c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

   (d) It is used or intended for use in feed components, as a carrier as follows:

<table>
<thead>
<tr>
<th>Feed component</th>
<th>Limitations (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavors</td>
<td>50</td>
</tr>
</tbody>
</table>

   (e) To assure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.


   a Silicon dioxide may be mixed with Vitamin E at levels up to 50%, to produce Vitamin E Supplement for addition to animal feed. Where silicon dioxide is used as a dispersant and/or flow agent to assist with uniform and consistent distribution of the vitamin E supplements in animal feed, silicon dioxide should be declared on the ingredient list of the vitamin E supplement.

b) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the New feed term **Common or usual name** in the AAFCO Official Publication and recommends the same to the membership. I so move. **Ali Kashani Seconds.**

**Doug Lueders MOTION to table. Dave Phillips Seconds. MOTION CARRIES**

i. **Common or usual name.** The common or usual name of a feed ingredient shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the ingredient or its characterizing properties. The name shall be uniform among all identical or similar ingredients and may not be confusingly similar to the name of any other ingredient that is not reasonably encompassed within the same
name. Each ingredient shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from other ingredients. An ingredient which has had a constituent removed, such that the ingredient is no longer identical or similar to the original ingredient, shall be identified with a different name. Common or usual names of many ingredients used in animal feed are found in the Association of American Feed Control Officials' Official Publication, Chapter 6 – Official Feed Terms and Ingredient Definitions.

c) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish 33.27 Marine Microalgae as Official in the AAFCO Official Publication and recommends the same to the membership. I so move. **Ali Kashani Seconds.**

**MOTION CARRIES**

1. **33.27 Marine Microalgae:**
   The food additive, marine microalgae, may be safely used as a source of docosahexaenoic acid (DHA) and other omega-3 fatty acids in accordance with the following prescribed conditions:
   
   (a) The additive is dried whole cells of nonviable, nontoxicenic, nonpathogenic Schizochytrium sp. algae grown as a pure culture.
   
   (b) The additive is used in complete, dry adult maintenance food for dogs in accordance with good manufacturing and feeding practices not to exceed 16.5 pounds per ton (7.5 kilograms (kg) per 1000 kg) of complete, dry, adult maintenance dog food.
   
   (c) The additive consists of not less than 17.0 percent (4Z,7Z,10Z,13Z,16Z,19Z)-docosahexaenoic acid (docosahexaenoic acid or DHA).
   
   (d) The additive meets the following specifications:

   1. Not less than 40 percent crude fat;
   2. Not more than 12 percent ash;
   3. Not more than 8 percent unsaponifiable matter;
   4. Not more than 5 percent insoluble impurities;
   5. Not more than 5 percent free fatty acids; and
   6. Not more than 6 percent water.
   
   (e) To ensure the safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

   1. The label and labeling of the additive, any feed premix, and complete feed, shall contain the name of the additive, marine microalgae.
   2. The label and labeling of the additive and any feed premix shall also contain:

      (i) A statement to indicate that the maximum use level of the additive shall not exceed 16.5 pounds per ton (7.5 kg per 1000 kg) of complete, dry, adult maintenance dog food.
      
      (ii) Adequate directions for use.

21 CFR 573.615

d) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Update Table 36.14 with both the new and the old microorganism names, with a compliance date of January 2022 until which date it is acceptable to use either name, in the AAFCO Official Publication and recommends the same to the membership. I so move. **Shaness Thomas Seconds.**

**MOTION CARRIES**

i) Lactobacillus bulgaricus, renamed to Lactobacillus delbrueckii**

ii) Lactobacillus cellobiosus, renamed to Lactobacillus fermentum**

iii) Lactobacillus lactis, renamed to Lactobacillus delbrueckii**

iv) Propionibacterium shermanii, renamed to Propionibacterium freudenreichii**

**Date of compliance January 2022**

e) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to publish **90.9 25-hydroxyvitamin D3** as Official in the AAFCO Official Publication and recommends the same to the membership. I so move. **Ali Kashani Seconds.**

**MOTION CARRIES**

i) **90.9 25-hydroxyvitamin D3:**
The food additive, 25-hydroxyvitamin D3, may be safely used in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a source of vitamin D3 activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:
   (1) In feed or drinking water of chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.
   (2) In feed or drinking water of turkeys not to exceed:
      (i) 92 ppb in feed; or
      (ii) in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94 percent 25-hydroxyvitamin D3 (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(c) The additive meets the following specifications:
   (1) Not more than 1 percent of any individual sterol.
   (2) Not more than 5 percent water.
   (3) Not more than 20 parts per million (ppm) lead.
   (4) Not more than 5 ppm aluminum.
   (5) Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.
   (6) Not more than 1 ppb 1,25-dihydroxycholecalciferol.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:
   (1) The name of the additive.
   (2) A statement to indicate the maximum use level of 25-hydroxyvitamin D3 must not exceed 69 ppb in feed or 34.5 ppb in drinking water for chickens.
   (3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D3 must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.
   (4) Adequate use directions to ensure that 25-hydroxyvitamin D3 (and all premixes) is uniformly blended throughout the feed or drinking water.
   (5) An expiration date on all premix labeling.
   (6) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D3 cannot be used simultaneously in both feed and water.

21 CFR 573.550, 584.725 (Adopted 2019 ver 1)

6) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Add AAFCO Definitions 84.62, 84.16, 84.63, 84.64, & 84.71 to the collective term Plant Protein in the Official Publication and recommends the same to the membership. I so move.

Bob Church Seconds. MOTION CARRIES

7) Add to GRAS Notification table in Section 101.
   a) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Add L-Glutamine the subject of AGRN 19 to GRAS Notification table in section 101 in the Official Publication and recommends the same to the membership. I so move.

Bob Church Seconds. MOTION CARRIES
8) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Delete Definition T73.311 Hydrogenated Glycerides if T73.311 (A) is accepted by Association membership from the Official Publication and recommends the same to the membership. I so move.  **Shaness Thomas Seconds.  MOTION CARRIES**

9) Edit tables with results to be reflected as official
   a) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to edit Table 101.1 AGRN 24 L-Methionine 90% with results to be reflected as official in the Official Publication and recommends the same to the membership. I so move.  **Ali Kashani Seconds.  MOTION CARRIES**

10) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the IDC to Delete Definition 33.19 Hydrogenated Glycerides as an energy source. See page 383 of the 2018 online OP revision 1 from the Official Publication and recommends the same to the membership. I so move.  **Ali Kashani Seconds.  MOTION CARRIES**
1) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the Education and Training Committee’s recommendation that the “Model Training Manual” for Animal Feed Inspectors, (Version: Final Draft, July 30, 2018) be accepted as the official AAFCO “Model Training Manual” to be utilized by Animal Feed Inspection Programs for development of their Training Plan as well as On The Job Training (OJT) and recommends the same to the membership. I so move. Amanda Anderson Seconds. MOTION CARRIES

Model Bills 1:
1) Kristen Green states the AAFCO Board of Directors accepted the recommendation from the Education and Training Committee that the following language be added to the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as PF2(a)(8) and current PF2(a)(8) be changed to PF2(a)(9), PF2(a)(8): A statement of calorie content if required under PF9; and …. and recommends the same to membership. I so move. Doug Lueders Seconds. MOTION CARRIES.

Board Recommendations:
1) Kristen Green states the AAFCO Board of Directors recommends a new Association Vision Statement and recommends the same to the membership. I so move. Ali Kashani Seconds. MOTION CARRIES
   To be the trusted leader, building collaboration and regulatory uniformity, to safeguard animal feed.
2) Kristen Green states the AAFCO Board of Directors recommends a new Mission Statement and recommends the same to the membership. I so move. Amanda Anderson Seconds. MOTION CARRIES
   AAFCO provides science-based resources as the cornerstone to continuously advance animal feed regulatory programs.

This concludes committee and board recommendations needing membership approval.

5) Credential Report – FASS
   Number of Voting Members Represented - 29
   Number of States in attendance - 45
   Number of Countries - 6
   Number of FDA Representatives - 0
   Number of Life Members - 5
   Total Meeting Attendance - 344

Bob Geiger adjourned meeting at 10:20am

February 20, 2019 - Kristen Green MOTION to approve Midyear Business Meeting. Hollis Glenn Seconds. MOTION CARRIES
Current Issues and Outreach Committee Report  
2019 AAFCO Midyear Meeting  
January 21, 10:00–10:30 am, Savannah, Georgia

Committee Recommendations: None

Board Recommendations: Report accepted May 6, 2019

Association Recommendations: None

Committee Participants
Members Present: Jennifer Combs (KY), Tim Lyons (MI), Caitlin Price (NC), Richard Ten Eyck (OR), Shaness Thomas (FL), Kent Kitade (Life Member), Wendy Powell (MI) Ali Kashani (WA-Chair)
Advisors Present: Leah Wilkinson (AFIA), David Dzanis (APPA), David Fairfield (NGFA), David Meeker (NRA), Tomas Bellos (NGFA), Angela Mills (AFIA), Pat Tovey (PFI), Louise Calderwood (AFIA), Steve Younker (AFIA)

Committee Report
The meeting was called to order at 10:00 am EST by Chair, Ali Kashani

Modifications to Agenda:
Due to federal government shutdown no one represented from FDA at the meeting and no presentation on behalf of the agency was made.

Introduction of the Topic, GRAS:
The topic of Generally Recognized as Safe (GRAS) ingredients in animal feed to include pet food is one that AAFCO takes very seriously. Countless person-hours from states and industry have been devoted to discussions on an AAFCO process that results in state acceptance of an Independent Conclusion (ICG) of GRAS.

This morning, we are using this short time to present to you the AAFCO and industry viewpoints. Our intention is to introduce the audience to the perspectives AAFCO is working with. On Wednesday morning at 8:00 am, during the second IDC meeting, the discussion of the GOAL for the AAFCO GRAS Process will take place.

Discussion:
Mr. Doug Lueders, Commercial Feed Program Manager, Minnesota Department of Agriculture and the Chair of Model Bill and Regulations committee presented the following brief review:

Current and past terminology related to “Independent Conclusion of Generally Recognized as Safe (ICG), “GRAS Self-Conclusion”, “Self-Affirmed GRAS”, “Self-Determined GRAS” and “Self-GRAS”. It was noted that there might be other future terminologies that obviously we do not know presently. There are concerns about lack of regulator confidence that products made with ICG as ingredients are safe and effective for the intended use. IGC is an honor system without checks and balances, without any regulatory review of safety and efficacy data. State Feed control officials have expressed that there is a lack of transparency when distribution occurs without prior notification. Coupled with proprietary manufacturing processes without a required expert panel review have made states uncomfortable with the IGC. ICG is much less desirable than ingredient submissions via a Food Additive Petition, AAFCO Ingredient Definition or GRAS Notification.

Lueders noted that GRAS notification receives the least rigorous regulatory review by FDA. About 44% of GRAS notifications filed received FDA’s “no questions” letters, leaving 56% that are either withdrawn by submitter or declined by the FDA. The GRAS Notification success ratio for ingredients submitted for review is not good and states have no confidence that IGC ingredients would fare as well in a regulatory review process. The only possible conclusion is that there are IGC products in distribution that would not meet regulatory safety and efficacy review criteria. States are in precarious position, as they lack authority to require a safety and efficacy dossier or to deny ICG distribution. Most states, if not all, lack the required budget resources and technical expertise to review data, even if it were provided. ICG creates a state-by-state regulatory system that is contrary to the initial reasons for formation of AAFCO – to provide a regulatory framework for uniformity among states and jurisdictions. One resolution that would satisfy industry and state regulators is that FDA speeds up review and turn-around time on new ingredient petitions the agency receives in
order to satisfy industry’s need to get an ingredient into distribution channels. To meet the needs of regulators, a centralized regulatory body is needed to review safety and efficacy data. Whether the above needs may be met within the current system or a new system that is built from the ground up, remains to be determined.

Mr. Richard TenEyck, Feed Safety Specialist, Oregon Department of Agriculture, and Chair of AAFCO Ingredient Definition Committee gave a brief history of IDC GRAS areas of agreements and challenges:

• Our newest acronym, ICG, stands for Independent Conclusion of Generally Recognized as Safe for an intended use. A firm making an ingredient gathers a data package demonstrating the same level of safety and utility as an FDA Food Additive Regulation. Data must be in the public domain.

• Standard of identity Monographs conceived at Bass Lake, CA in 2008?

• FDA had to push back on informal review process and ask CVM to establish GRAS status of OP defined materials

• AAFCO developed GRAS process whitepaper in 2016

• AAFCO formed GRAS Verification workgroup in 2017

• CVM review of AAFCO Definitions slow as firms file GRAS notices or FAP’s

• In 2018 GRAS Verification workgroup refining acceptable process goal

• Consensus among states is that ICG does not provide the level of animal food safety we want.

• Board is ready to write a policy or SUIP that states should not accept un-reviewed self-conclusions.

• MBRC is ready to discuss removing the acceptance pathway from the model bill.

• IDC has an “AAFCO GRAS” pay to review system at an initial step as a white paper.

• Best Solution: CVM needs about 6-8 additional technical reviewers to process current workload volume within desired timelines.

Ms. Emily Bulian Helmes, Advisor, Global Regulatory Nutritional Health, Elanco Animal Health, and Co-Chair of the Enzyme Technical Association Feed Committee, provided the following industry perspectives on independent conclusions of GRAS (ICG):

• GRAS is defined as a substance Generally Recognized As Safe, among experts qualified by scientific training and experience, as having been adequately shown to be safe under the conditions of its intended use in animals.

• Marketing a GRAS substance without FDA premarket review and approval is acceptable according to federal law (21 U.S.C. 321, 341, 342, 346a, 348, 371) and according to state feed laws in nearly every US state.

• All GRAS conclusions are based on independently developed scientific dossiers, comprised of scientific data and information documenting all of the major components required by the FDA regulations (21 CFR 570.30 -570.280) including publicly available information on the safety of the GRAS substance.

• Stakeholders (States, Industry, Public) need more education on what it means for a substance to be GRAS for an intended use. The requirements of the law are not well understood.

• Industry would use the FDA CVM GRAS notification process more if the FDA expectations did not exceed federal law (e.g., requirements for utility and pre-manufacturing data), and if the timing of the reviews were more predictable and shorter.

• Many firms would consider supporting an AAFCO GRAS review process if it would: (a) adhere to federal law, (b) result in acceptance of a GRAS substance in all US states, and (c) be an efficient process (timely and not too costly).

• All feed ingredients placed on the market must be safe for their intended use in animal feed.
Education and Training Committee Report
2019 AAFCO Midyear Meeting
January 23, 9:00–10:00 am, Savannah, Georgia

Committee Recommendations: None

Board Recommendations: Report accepted May 6, 2019

Association Recommendations: None

Committee Participants
Members via Phone: Rick Manthei – MN
Advisors Present: Shaun Anderson – AFIA, Felicity Mejeris – NASDA, David Fairfield – NGFA, Pat Tovey – PFI, Lorri Chavez - PFI
Others Present: Sue Hays - AAFCO

Committee Report
• Training Calendar: Jeff Scallan, LA, updated workgroup progress. Available trainings have been added but the workgroup would like to see more industry trainings made available in the calendar. Jeffrey Scallan will continue to be the primary contact to add trainings to the calendar.
• State Training Needs: Marissa Kost, NC, updated workgroup progress. The final version of the survey was distributed via email on January 16, 2019 by AAFCO. The survey will remain open for a total of 30 days. An electronic vote will be conducted to accept the workgroup’s work after the 30-day window is over.
• AFRPS OTED Training Update: Amanda Anderson, KS. The most up to date version of the curriculum has been posted on the Feed BIN. Any future updated versions of the AFRPS curriculum will continue to be posted on the BIN.
• Feed Administrator’s Seminar: Erin Bubb, PA. The FAS will be held in Poconos, PA near Lake Harmony this year. The agenda is still in rough draft form but will include topics related to: Emergency Preparedness (AFRPS Std. 5) held as a workshop; LMS pitfalls and lessons learned; FDA work planning; and a motivational speaker will also be present.
• BITS and AITS: Miriam Johnson, NC, Inspection and Sampling Committee Chair, updated the committee on upcoming BITS and AITS training. BITS 2019 will be hosted by Georgia in Athens. Upcoming AITS 2019 training will be hosted by Alabama in Montgomery (June 18-20) at the Renaissance Montgomery Hotel & Spa at the Convention Center. The new AITS curriculum will be utilized for the first time at this training.
• Pet Food Labeling Workshop: Kristen Green, KY. This one-day workshop will take place on May 2 (the day after the Pet Food Forum has concluded). Details and registration can be found on the AAFCO website. Amanda Anderson – KS, will assist as needed.
• Industry Training:
  o AFIA to offer FSMA PCQI Training – Nashville, TN (July 30-August 01)
  o David Fairfield, NGFA: NGFA to offer PCQI/HACCP Training – Manhattan KS (January 29-31) and PCQI Training – Manhattan, KS (August 20-22)
  o FSPCA to offer PCQI Lead Instructor Training – Chicago, IL (May 21-23) and Arlington, VA (August 13-15)

George Ferguson, NC – recommendation to reach out to FDA for a summary of the courses cancelled, what the schedule is going forward, and details regarding rescheduled trainings that AAFCO can communicate to the membership.
Leah Wilkinson, AFIA – mentioned that there are some discounted rates for AFIA member for some of these industry trainings.
• **Training Endorsement Policy**: George Ferguson, NC – There is a task list for submitting online workshop requests on the Feed BIN. The committee must identify what training they want to do. ETC is not responsible for developing or delivering the training; they will assist with planning, logistics, scheduling, and promoting training. There must also be a sponsor from ETC for the training (can be your own advocate).

• **Workshop Calendar Request**: Amanda Anderson, KS – FASS would like an ongoing list of available trainings for the future (several years, would prefer 3-5 years in advance). At the Annual Meeting 2019 (Louisville, KY), there is currently there is no date available for training on front or back end of meeting
  ○ George Ferguson, NC - Request: Face-to-Face workshop for states and industry to meet and discuss registration. First half of the day would be a speed-dating style with the second half of the day dedicated to open group discussion (e.g., what can we do better, what went wrong?). It would provide an opportunity for industry and registration/licensing states to develop efficiencies for the process.
  ○ Amanda Anderson, KS – Will reach out to committees (given 60 days) for feedback on training with the goal of having all these training tentatively planned for the foreseeable future.

Meeting Adjourned.
Feed and Feed Ingredient Manufacturing Committee Report
2019 AAFCO Midyear Meeting
January 22, 9:00–10:00 am, Savannah, Georgia

Committee Recommendations: None

Board Recommendations: Report accepted May 6, 2019

Association Recommendations: None

Committee Action Items
2) FSMA Implementation Task Force – Working Group 3
   Create action plan to determine the processes of implementing the decision making and method development.
3) Working Group #4 – Inspector Training for Ingredient Manufacturing Inspections:
   Perform gap analysis of FSPCA training for inspectors to determine if AAFCO needs to provide additional training for state inspectors.
4) Committee Charge Workgroup – Review and assess the charge of the Feed and Feed Ingredient Manufacturing Committee

Committee Participants
Members Present: Austin Therrell – SC (Co-Chair); Eric Brady – TN (Co-Chair); Bob Church – MT; Ken Bowers – KS; Bob Geiger – IN; Shaness Thomas - FL; Ali Kashani – WA; Doug Lueders – MN; Laura Scott – CFIA; Jamey Johnson – AR
Via Telephone: None
Advisors Present: Pat Tovey – PFI; David Meeker – National Renderers Association; Louise Calderwood – AFIA; Dan Frank – AFIA; David Dzanis – APPA; David Fairfield – NGFA; James Emerson – US Poultry; Cathy Alinovi – Next Generation PFMA

Committee Report
Austin Therrell called the meeting to order at 9:10 AM EST. Members and advisors in the room introduced themselves.

Introductions and Agenda Review, Eric Brady – Austin Therrell
Modified Agenda noted.

Canadian Food Inspection Agency Update - Laura Scott

Review of Action Items
Mineral Guidelines Working Group – Bill Burkholder
[Minute report from meeting. Current Tables in current Official Publication. Apparent from the review information must be more clearly stated in text. Years ago Dr. Benz (retired) reviewed both individual amount and total amounts from other groups. These amounts must be combined due to tables being used for individual elements. The 1978 official publication had the original tables. The tables must be recreated to be usable. The 1978 OP had a table and it was 5 years until the first guideline – 1983-84 OP. Then two drafts were completed. The guidelines have remained the same from the 1986 OP.]
Above is continuation of discussion from Annual Meeting. FDA not present at Midyear Meeting for update. Conference call will be scheduled once the Federal Government resumes operation. Laura Scott can assign assistance.

FSMA IMPLEMENTATION TASK FORCE UPDATES
Working Group #3 – Contaminant and Hazard Lab Strategy - Bob Waltz/Mike Davidson
Working Group Charge: Following the identification of contaminants and hazards by FSPCA/FDA, the group will determine action levels and enforcement strategies to provide guidance to the Lab Methods and Services Committee (LMSC) in order to develop a priority list of method development. This Working Group will work in consultation with the FSPCA, Enforcement Issues Committee, Inspection & Sampling Committee, Ingredient Definition Committee and the LMSC.
LMSC now has new chairs in Dr. Sharon Webb and Christie McCallum. There has been improved communication at the meeting. We expect to have progress made throughout the meeting. We intend to review some contaminants – NASDA framework document has some listed – to determine action levels that FDA took action on. Communication with LMSC to determine if they have existing methods or will need to develop methods.

**Working Group #4 – Inspector Training for Ingredient Manufacturing Inspections - Mike Davidson**

*Working Group Charge: Review materials developed by FSPCA and FDA to determine whether training material for feed ingredient manufacturing from the FSPCA will meet the needs of Inspectors in regards to training. Working group will work in consultation with the Education & Training Committee and the Inspection & Sampling Committee*

Coordination with Miriam Johnson – Inspection and Sampling – Eric Brady volunteered to join the standardized AITS cadre for Feed and Feed Manufacturing training, in Alabama. Intent was to flash test the new curriculum for inspector needs. Communication with Linda pointed out draft document was going to be addressed with Jenny Murphy and Eric Brady. Expected deliverable at annual meeting with report from Advanced Inspector Training.

**Other Business:**

**Review Charge of committee**-
Members on work group: Bob Church, Ken Bowers, Laura Scott, Cathy Alinovi, Eric Brady, Austin Therrell.
Call held to review charge of committee. Review held with some ideas for updates for the purpose statement.

**Ingredient Traceback**-
Creation of workgroup to develop a concise and usable checklist to review ingredients from finished label to bills of laden.
BG- inspectors need access to ODI.
Workgroup members include Bob Church, Ken Bowers, Doug Lueders, Austin Therrell, Eric Brady, Shaness Thomas, Dave Fairfield and Pat Tovey
Call to be scheduled – Report at Annual

**Industry Compliance Assistance**
Eric Brady explained compliance assistance with respect to 507 inspections in Tennessee.
Requested by management and simple walkthroughs of facilities and records. Highlighted successes and concerns.

Austin/Eric
- Motion to adjourn
  Eric makes motion to adjourn and Austin seconds the motion
10:00 am – Meeting Adjourned

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### Action Item Table

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<thead>
<tr>
<th>Responsible</th>
<th>Item</th>
<th>Action</th>
<th>Timing / Status</th>
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<tbody>
<tr>
<td>Mineral Guidelines Working Group</td>
<td>Mineral Guidelines</td>
<td>To review and revise the “Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients”</td>
<td>Tentative: August 2019</td>
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<tr>
<td>FSMA Implementation Task Force – Working Group 3</td>
<td>Hazard &amp; Contaminant Action Levels and Enforcement Strategies</td>
<td>Work with FSPCA, EIC, ISC, IDC and LMSC to develop a prioritized list of method development once list of contaminants and hazards has been identified by the FSPCA and FDA. A plan of action should be created by the working group to determine the processes of implementing the decision making and method development.</td>
<td>Update: August 2019</td>
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<tr>
<td>Responsible</td>
<td>Item</td>
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<tr>
<td>FSMA Implementation Task Force – Working Group 4</td>
<td>Inspector Training Development</td>
<td>Gap Analysis performed on FSCPA training to determine if there is any missing education that should be provided to inspectors whom perform feed ingredient manufacturing inspections</td>
<td>Update: August 2019</td>
</tr>
</tbody>
</table>

**INDUSTRY UPDATES TO BE INCLUDED:**

**PFI – Pat Tovey**
Recap of AAFCO and PFI involvement in the National Council of Weights and Measures winter meeting. Sue Hays led discussion at NCWM to harmonize treats and chews regulation between their associations. PFI thanks AAFCO for devoting resources to this noting that AAFCO’s mission to harmonize regulations sometimes goes beyond AAFCO committee work.
PFI Scientific Symposium held in Washington, D.C. in early December for information sharing to foster continuous improvement in food safety and to set research priorities.
FDA engaged in investigation looking at the relationship between animal diets and DCM in dogs. PFI’s expert nutrition subcommittee is engaged in analyzing the issue and forming hypothesis. PFI plans on sharing any conclusions upon completion of this work.
Joint Conference and annual meeting to be held first week of October 2019. Run jointly with NGDA.
See Pat Tovey or Dave Fairfield with any questions.

**NRA – Dave Meeker**
The National Renderers Association (NRA) has had some staffing changes since Dr. Jessica Meisinger took a new job about a year ago. NRA now has a new Communications Director with revised job duties. Dr. Meeker will now handle all science, regulatory, research, and training duties for NRA and the Fats and Proteins Research Foundation (FPRF).
NRA has committed significant resources to Food Safety Modernization Act (FSMA) implementation and training over the last 5 years. We are proud to have helped develop the Food Safety Preventive Controls Alliance (FSPCA) curriculum for Preventive Controls Qualified Individual (PCQI) training. We hold a PCQI training every year and have certified more than 300 people in our industry. Several rendering companies also have certified lead instructors and have trained even more individuals internally. We appreciate the helpful way FDA and state regulators have helped in the transition to FSMA and the change to a prevention culture for inspections.
FPRF research has contributed greatly to this transition with thermal validation, salmonella control, and other food safety research. We also research new uses for rendered products in addition to animal food use, and have many projects on odor control, environmental management, and more efficient processes to extract valuable products from meat by-products. A major effort FPRF has funded is a 5-year commitment at Colorado State University named the Pet Food Alliance. This is an effort involving researchers from across the country along with rendering companies, pet food manufacturers, and allied suppliers to find solutions to shared challenges. The Alliance has identified four areas of emphasis:
- Oxidation and product quality
- Salmonella control and food safety
- Consumer perceptions
- Sustainability

This new approach to cooperative research and enhanced relationships will help the rendering industry become the best suppliers of pet food ingredients we can be.
Rendering makes a huge contribution to the sustainability of animal agriculture and the meat we eat by ensuring the highest best use for all meat by-products. Rendered products also enhance the sustainability of animal feed and pet food. NRA has identified this issue as the most important as the rendering industry communicates with customers, policy makers, and communities close to plants. NRA will be embarking on a large data collection project over the next year to characterize and monitor our sustainability as well as the sustainability of customers and suppliers.

**NGFA – Dave Fairfield**
The NGFA continues to conduct educational activities to enhance compliance with FSMA by partnering with other organizations to conduct FSPCA PCQI training. The NGFA and Kansas State University will deliver three courses in Manhattan, Kan. during 2019: Jan. 29-31; Aug. 20-22; and Nov. 5-7. The NGFA will look for opportunities to partner with other organizations during 2019 to deliver additional PCQI
training in a cost-effective manner. The NGFA also will be involved in delivering lead instructor training for
the PCQI course to build additional instructor capacity. Two FSPCA animal food lead instructor courses
2018, 569 animal food PCQI courses have been conducted and 7,455 PCQI certificates have been
issued.
The NGFA continues to be actively involved with and support the activities associated with the FSPCA.
FSPCA animal food projects for 2019 include: 1) “blended” animal food PCQI course (12-hours of on-line
content, 8-hours of instructor-led training; 2) on-line CGMP course; and 3) Spanish translation of the
PCQI manual.

**CFIA – Laura Scott**
The Canadian Food Inspection Agency (CFIA) continues to work on feed regulatory modernization in
Canada. Consultations on technical proposals are complete. All of the consultation documents and their
associated summary reports are available on the CFIA website. The CFIA is working on finalizing the
proposed rules which will be published in Canada Gazette I for public (and international) consultation.
The Gazette process in Canada is similar to the Federal Register in the US.
At the 2018 Annual meeting an update was provided on Canada’s Federal Regulatory Review on
Agriculture and Agri-food. The review process has been completed and recommendations will be
published.
CFIA has recently updated the list of approved feed ingredients, which is available upon request. CFIA
has also been working with Health Canada on further classification of Feed vs Drug products. The policy
for Viable Microbial Products has been finalized following consultation. A new consultation on Mycotoxin
Detoxification Agents will be available in February.

**Final Minutes:**
**Austin Therrell - Motion to Approve**  
**Bob Church – Second**
In Favor: Eric Brady, Wayne Nelson, Bob Geiger, Ken Bowers, Doug Lueders
Submitted to Jennifer – 3/4/2019
Committee Recommendations: None

Board Recommendations: Report accepted May 6, 2019

Association Recommendations: None

Committee Participants
Members Present: David Dressler (PA), Dave Phillips (ND), Al Harrison (KY), Erin Bubb (PA), Miriam Johnson (NC), Jason Schmidt (LA), Heather Bartley (WI), George Ferguson (NC), Richard Ten Eyck (OR), Lizette Beckman (WA), and Stevie Glaspie (MI).
Advisors Present: Dave Dzanis (ACVN/APPA), Jan Campbell (NGFA), Chris Olinger (NGFA), Meghan Dicks (AFIA), Pat Tovey (PFI), and James Emerson (UPA).
Guest Present: Laura Scott (CFIA)
Absent: Mika Alewynse (FDA), Michelle Boyd (IA), Tim Darden (NM), Steve Gramlich (NE), Ed Rod (APPA), and Angela Mills (AFIA),

Committee Report
Introductions and Agenda Review
David Dressler called the meeting to order at 1:30 PM EST. Roll call of members and advisors was taken and a quorum was established (11 out of 15). During roll call, James Emerson stated that Charles Starkey will no longer be serving as an advisor to the Feed Labeling Committee.

Livestock Treats
The livestock treats working group provided a brief update. Work still needs to be done, so the workgroup was not prepared to introduce anything to the group. The workgroup did state the definition of Treat from IDC may impact on the decisions of the group. Pending the IDC definition, the group is in a good place with what ingredients would be required and they are preparing a draft version of the label. More from this work group will be discussed during the 2019 annual meeting in Louisville, KY.

Maximum Levels for Nutrients with Toxicity Levels
Continuing the discussion on requiring maximum guarantees for certain elements, the committee invited Laura Scott from the Canadian Food Inspection Agency (CFIA) to provide a presentation on Canada’s research into nutrient maximums and their proposed regulatory changes. The information presented is only a proposal and is not final in Canada.
In 2016, CFIA has been consulting on proposed nutrient maximums for livestock species. Current requirements require pre-market registration for some, but not all feeds. Complete feeds and supplements are exempt if the nutrient levels fall within Table 4 (standard min and max levels), however the nutrient values in Table 4 are outdated. As a part of the proposed regulation change, CFIA is proposing to change their approach to registration by removing Table 4. In doing so, new nutrient maximums will be established for calcium, phosphorus, magnesium, sodium, potassium, sulfur, cobalt, copper, iron, manganese, selenium, zinc, Vitamin A, Vitamin E, Vitamin C and Vitamin D.
In consideration for establishing maximum nutrient levels, it is important to evaluate animal tolerances, food safety, therapeutic use, and environmental & worker safety. Obtaining stakeholder input is also important when setting these maximum levels. Some of the issues identified with establishing maximum limits are reduction in animal performance, calcium to phosphorus ratios, and species-specific requirements, such as zinc in swine feed and Vitamin D in poultry feed, for example. To accommodate nutrient maximus for all species and life stages, it would fill 9 pages of tables.

After Laura Scott’s presentation, the committee chair requested a motion to look into requiring maximum levels for nutrients with known toxicity. MOTION: Erin Bubb moves to form a workgroup to look into maximum guarantees related to the table on Page 299 of the 2019 Official Publication (Table 2. Official Guidelines Suggested for Contaminates in Individual Mineral Feed Ingredients). Miriam Johnson seconds. MOTION PASSES.
Dave Dzanis, Jan Campbell, Al Harrison, Richard Ten Eyck and Erin Bubb volunteered to be on this workgroup. It was also suggested having a representative from FDA present on this workgroup.
**Blue Bird Labels in the OP**
The blue bird labels listed in the Feed Labeling Guide sections of the official publication on Pages 238 through 244 do not currently reflect the changes in the model bill. The committee felt this work has already been done when the Feed Labeling Guide was updated for the 2018 Feed Labeling Workshop.

**MOTION:** Richard Ten Eyck motions to update the Feed Labeling Guide sections in the OP with the one that was edited for the Feed Labeling Workshop. Miriam Johnson sections. **MOTION PASSES.**
It is the committee chair’s responsibility to update the blue bird labels in the Official Publication. **ACTION:** David Dressler will see this gets completed for the 2020 official publication.

**Responsible labeling of DFMs.**
This topic was tabled until the 2019 annual meeting when FDA can be present.

**Other Topics for Discussion**
There were no other topics brought to the committee.

**Meeting adjourned at 2:30 PM EST**
Feed Labeling Committee Special Meeting Minutes
February 19, 2019, 12:00–12:30 pm Eastern

This meeting was held via conference call.

Committee Participants

Members Present: David Dressler (PA), Dave Phillips (ND), Heather Bartley (WI), Liz Beckman (WA), Al Harrison (KY), Jason Schmidt (LA), Tim Darden (NM), Miriam Johnson (NC), George Ferguson (NC), Erin Bubb (PDA), Steve Gramlich (NE), and Mika Alewynse (FDA).

Advisors Present: Dave Dzanis (ACVN/APPA), Meghan Dicks (AFIA), Jan Campbell (NGFA), Chris Olinger (NGFA), and Pat Tovey (PFI).

Guest Present: Sue Hayes (AAFCO)

Absent: Michelle Boyd (IA), Stevie Glaspie (MI), Richard Ten Eyck (OR), Angela Mills (AFIA), Ed Rod (APPA), and James Emerson (US Poultry).

Introductions and Agenda Review

David Dressler called the meeting to order at 12:02 PM EDT. Roll call of members and advisors was taken and a quorum was established (12 out of 15).

Online Database of Ingredients

David Dressler explained the sole purpose of this special meeting was to determine the future of the Online Database of Ingredients (ODI), which is currently a workgroup within the feed labeling committee. The goal of the meeting is to determine if the ODI project should remain within feed labeling, or if it should be moved to the board for reassignment.

Jan Campbell stated she thinks it is too big for the feed labeling committee and that workgroup members could change.

Heather Bartley questioned who operates the Feed BIN, because perhaps that group could manage ODI.

Sue Hayes stated the feed BIN is completely managed by Richard Ten Eyck.

Dave Phillips mentioned the AAFCO Board of Directors is in the process of forming a technology committee, which could be an option for the future place of ODI.

Mike Alewynse stated that ODI could be expanded into other label aspects.

MOTION: Heather Bartley moves to disband the ODI work group in feed labeling and move this project to the board to determine where this will reside. Jason Schmidt seconds.

DISCUSSION:

Al Harrison stated he would vote against the motion, because the ODI project is a feed labeling issue. Dave Phillips stated that this is more than one committee.

Since ODI only addresses ingredients, it would make sense to have ODI in the ingredient definitions committee. Would claims and guarantees be addressed? The upgrades can be discussed in feed labeling (or other committees) and then passed on the group that manages ODI. Dave Phillips stated that various committees could move suggestions up to the board or we could have a liaison from the committee to the group that houses ODI in the future.

George Ferguson stated that the IT committee would not put anything in place on their own. They would just aid feed labeling committee or any other committee with changes they want. The IT committee only helps facilitate the tasks assigned to them. The IT committee was not formed to make decisions.

Hearing no further discussion, David Dressler called for a vote on the motion made by Heather Bartley.

MOTION PASSED 11-1.

Meeting adjourned at 12:30 PM
Ingredient Definitions Committee Report
2019 AAFCO Midyear Meeting
January 22, 10:30 am–12:00 pm
January 23, 8:00–9:00 am, Savannah, GA

Committee Recommendations
When needed, new text is presented in the committee minutes, Appendix A.
1) Replace the guidelines on 2019 OP page 335 to 339 with the new language in Appendix A.
2) Revise Feed Term “Canned” to read: Canned (Process) a term applied to animal feed which has been processed, commercially sterilized, and sealed according to 21 CFR part 113 in hermetically sealed containers such as but not limited to cans, pouches, tubs and trays.
3) Publish the following tentative definition as Official: T71.40 Low Glucosinolate High Erucic Acid Rapeseed Meal Solvent Extracted,**


Association Recommendations: To be considered in August 2019
Committee actions not requiring Association votes:
a.) Place the graphic of the definition process on the AAFCO website (goes to BOD)
b.) Edit the feed term “Carrier”
c.) Next meeting is April 4 2019 at 8:30AM PST via webinar

Topics moved to the next meeting:
i. Revise Feed Term “stabilize”
ii. New Feed term Bison
iii. New Feed term ___(workgroup output here)_____ Buffalo
iv. New Feed term “treat”
v. Vitamin Common Names A, C, E, (concept is in the BIN Library)
vi. “Is this Animal Food” Flowchart for website
vii. Feed term slaughter or an update from new workgroup
viii. Establish Limestone workgroup
ix. GRAS verification workgroup to provide an update
x. Non-Defined workgroup to provide update in August.

Meeting Minutes
1) Roll call of Committee members
Richard Ten Eyck, Kristen Green, Erin Bubb, David Beard, Brett Boswell, Ken Bowers, Bob Church, Stan Cook, Dave Dressler, James Embry, Maggie Faba, George Ferguson, Jacob Fleig, Steve Gramlich, Brett Groves, Ali Kashani, Dan King, Mark LeBlanc, Dave Phillips, Tom Phillips, Nathan Price, Laura Scott, Kent Kitade, Jennifer Kormos, Melanie Marquez
A quorum was present (23/25). The meeting was recorded.
2) A Guide to Submitting New or Modified Ingredient Definitions to AAFCO
Work group Q/A and committee document acceptance vote – Sue Hays
Stan Cook moves to accept the workgroup report. Ali Kashani seconds. MOTION PASSES.
Sue Hays provided background on the proposed changes on how Tentative definitions would become Official. Based on a survey of Feed Bin members regarding Tentative Status (7% response rate), the majority favored that ingredients remain in Tentative Status for 6 months starting the day that the membership votes to accept the Tentative definition. After this six-month period, the definition would automatically move to official with no further action from the IDC or the Board. During the tentative status period, the investigator can stop the definition from going to official if there are any changes that are needed or if there are concerns. Once the definition is official, revisions can still be made, as there are now. It was clarified that this will not be retroactive.
Dave Phillips moves to accept the proposed revisions shown during the IDC meeting. Jacob Fleig seconds. MOTION PASSES
Erin Bubb moves to amend the language by modifying the sentence (“Once published…”) on p. 6 to: “Once accepted by membership for publication as a tentative definition, the definition will move to
Official status six months later without further action by the IDC, the Board, or membership”. Dave Phillips seconds. MOTION PASSES
Mark LeBlanc moves to strike on page 2, (2) (a) iii. Dave Phillips seconds. MOTION PASSES. Stan moves to accept the addition on page 2, as (2) (a) iii: “Be in alignment with common or usual name conventions in 21 CFR 502.5(a).” Ali Kashani seconds. MOTION PASSES.
There was discussion on the proposed document. Committee members discussed the following: tentative status moving to official automatically; how long the tentative definition will be available publicly; removing the text regarding common and usual names; the need for a tracking system to remind investigators on when definitions will move to official; and removal of commas from ingredient names. It was clarified that the last sentence in the document is a placeholder for the addition of FDA color additive process; such text will be reviewed and agreed to by the IDC before being added to this document.

3) Review IDC process flowchart. Vote to publish on the web - Sue Hays
The committee agreed to post this to the web after the membership approves the revised Guide to submitting new or modified ingredient definitions to AAFCO. No vote needed as this was not going into the AAFCO OP. There is a version of the graphic that follows the current process. This first version will be posted now and changed out when the new process is approved by membership.

4) Revise Feed Term “Carriers” to incorporate SUIP #17 including possible elimination of 1% language - Ali Kashani/ Cathy Alinovi
Carriers. An edible material to which ingredients (such as but not limited to vitamins and minerals) are added to facilitate uniform incorporation of the latter into feeds. The active substances are absorbed, impregnated or coated into or onto the edible materials in such a way as to physically carry the active ingredient.
Ali Kashani moves to accept the editorial change. Brett Groves seconds. MOTION PASSES.
It was mentioned that “edible” is a human food term and that the IDC may consider a future additional change to this Feed Term.

5) Revise Feed Term “stabilize” to incorporate SUIP #14 - Ali Kashani/ Cathy Alinovi
Ali Kashani stated that this revised feed term is not ready. No action was taken by the committee.

6) Revise Feed Term “Canned” – Ali Kashani
Ali Kashani moves to accept the revised feed term change. Jacob Fleig seconds. MOTION PASSES.
Brett Boswell moves to amend the language to align with the regulation. Canned (Process) a term applied to animal feed which has been processed, commercially sterilized, and sealed according to 21 CFR part 113 in hermetically sealed containers such as but not limited to cans, pouches, tubs and trays. Dave Phillips seconds. MOTION PASSES.
Chris Cowell (PFI) thinks that this can be the feed term should be made consistent with the FDA regulation for low-acid canned food and proposed language for the revision.
Dave Phillips moves to accept the editorial change and to include that processing includes sterilization in the revision. Brett Boswell seconds. MOTION PASSES.

7) New Feed term Bison – Brett Boswell
Brett Boswell discussed the issue regarding bison and buffalo. Considering that there are a couple of possible paths forward, he said that he wanted input from the committee.
The National Bison Association thanks the IDC and asks that AAFCO consider the need for more clarity, for the benefit of the customers.
Chris Cowell (PFI) asked if the confusion also occurs in human food as well? Dave Dzanis stated that it can be confusing in human food as well and believes that it needs to be clarified.
No action was taken by the committee.

8) New Feed term __(workgroup output here)____ Buffalo – Brett Boswell
This was discussed with bison.

9) New Feed term “treat” - Ali Kashani
Moved to April webinar.

10) Vitamin Common Names A, C, E placeholder - Tom Phillips
Moved to April webinar.

11) T71.35 Brassica carinata meal, Solvent extracted — move to Official - Church

12) T71.40 Low Glucosinolate High Erucic Acid Rapeseed Meal Solvent Extracted (placeholder) – Move to Official - Church
Bob Church moves to accept the move from tentative to official. George Ferguson seconds. 

MOTION PASSES.

13) Set IDC 3 hour meeting by webinar date in early April (4,9,10) 11:30 EST?- Richard
14) Volunteers to review “Is this Animal Food” Flowchart (for web) – Richard
   Moved to April webinar or earlier. Does not need committee review.
15) CVM item one (placeholder) (may move up agenda)
16) CVM item two (placeholder) (may move up agenda)

**At 12:05PM Meeting was recessed until 8AM Wednesday.**

Discussion session on **Wednesday Morning** 1/23 - One hour, no votes. Topics may get moved to the 
April Webinar if we run out of time.

17) Non-Defined workgroup report (10 Min) Kent Kitade
   a) Report is in the Investigator recommendations library in the BIN
   b) Workgroup to report on progress in August IDC meeting
18) GRAS Verification workgroup report (20 min) Sue Hays
   a) Report is in the Investigator recommendations library in the BIN,
   b) Workgroup to provide another update on progress at the April IDC meeting.
19) Limestone Specifications (10 min) Jon Nelson
   a) Report is in the Investigator recommendations library in the BIN
   b) Need to form a limestone workgroup to evaluate recommendations in slide set.
20) Hydrogenated Fat - update (5 min) Leah Wilkinson
   a) Leah stated that data was submitted to CVM in October 2018 to support the safe use of the
      ingredient as an energy source. No response has been received yet from the agency. Please
      contact Leah if you use or manufacture this ingredient to ensure all information is considered.
21) New Feed Term “Slaughter” (10 min) Ali Kashani
   a) Ali formed a workgroup and will have a recommendation in April.
22) Hemp Update (5 min) Bob Church & Bill Bookout
   a) Still no approved animal uses formally requested. – Waiting on data..
23) Confusing pet food name workgroup report (5 min) Brett Boswell
24) Status on high profile ingredients (placeholder) – Richard / CVM
25) Discussion of common human foods in pet food (placeholder)– George Ferguson
26) Any activities needing 19 - 20 Association funding? – Richard

Meeting was adjourned at 9:04 AM EST
Minutes approved 3/25/19 15 voting in the affirmative
Appendix A: Ingredient Definitions Committee Meeting 1/22/19

1) IDC Recommendation is to strike current language in 2019 OP on page 335 to 339 and insert this language.

Chapter Six

Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions
Editor—Richard Ten Eyck, OR

A Guide to Submitting New or Modified Ingredient Definitions to AAFCO
Section Editor – Jennifer Roland, FASS

The following guide is offered to assist in development of new or modified feed ingredient definitions. The roles of each party are described below.

The definitions should be non-proprietary as not to favor one ingredient producer over another.

Materials to be used as feed ingredients should have the following attributes:

They should be consistent batch to batch. The material should not be a combination of other ingredients. The intended use should not be to mitigate, treat, or diagnose a disease, but rather to provide nutrition, flavor, aroma for the animal or provide a technical effect in the feed. It is the manufacturer's responsibility to produce a safe ingredient for its intended purpose.

The Requester

Prior to submitting a request for a new or modified definition, the requester (industry, public, regulatory official, etc.) should consider the current ingredient definitions and develop a draft definition that includes the intended use. The requester should then contact the appropriate investigator (see the AAFCO Official Publication or website for current listing) by email to definitions@aafco.org to discuss the draft definition. Following the initial discussion, a requester should then make a request to the investigator in writing that contains the information described below, if pertinent, so there is sufficient information for the decision process:

(1) Firm and contact person.

(2) Summary of the request, including name of the ingredient, intended use, and rationale for the request.

a. The proposed name shall:

i. Not contain commas.

ii. Begin with the base material and then list any needed qualifiers (Beet Pulp plain dried).

iii. Be in alignment with common or usual name conventions in 21 CFR 502.5(a).

iv. Alternate names to be used on labeling shall be clearly stated at the end of the definition. “Plain Dried Beet Pulp” shall be used on all labeling.

v. Not include a trade name or be proprietary in nature.

(3) Proposed definition.

(4) Description of the ingredient (e.g., source, physical characteristics, any marketed formulation(s)).

(5) Proposed labeling (can be generic).

(6) Historical regulation of the ingredient, if any.

(7) Description of the manufacturing processes to support identity, composition, and consistent manufacturing of the ingredient. Data to include:

a. A description of the manufacturing process,

b. A list and regulatory citation for all substances used in its preparation,

c. Stability data (including packaging),

d. Homogeneity data when ingredient is used at low inclusion rate, and

e. Validation information of analytical methods to support testing and/or citation of official methods.

(8) Use limitations, if any.

(9) Intended use of the ingredient, including target animal species, use rate, purpose, etc.

a. Data and observations (e.g., published literature, animal feeding trials, in vitro studies, empirical data showing technical effect, etc.) to support intended use.

(10) Safety Assessment. The safety assessment should include a narrative specific to the target animal and, in the case of use in food producing animals, a human food safety assessment.
should also be provided. Intended uses specific to companion animals will only need to address target animal safety specific to the use description. The safety narrative(s) should assess all the available data. The supporting data which serves as the basis of the safety narrative and conclusion should include:

a. Assessment of the ingredient for known and/or potential contaminants and impurities.

b. Available safety information from published articles and/or unpublished studies.
   i. Target animal safety information should demonstrate the margin of safety for the intended use.
   ii. For microbial products (source of DFM, enzymes, fermentation products) information to demonstrate that they are produced from nonpathogenic and nontoxicogenic strains.

(11) List of Cited Literature.
(12) Copies of all cited analytical reports, studies, and referenced articles. These may be provided in hard copy on a CD in PDF Optical Character Recognition (OCR) format.

More specific description of information listed above may be found in FDA Guidance for Industry 221 Recommendations for Preparation and Submission of Animal Food Additive Petitions.

It is imperative that the requester provides all information that is available to support their request. Confidential business information should be clearly identified in the request. Only manufacturing information can be marked confidential business information. Safety and utility data are not considered confidential business information. It may be advisable to put confidential business information in a separate document that can be sent, if needed, only to the FDA during the scientific review. Confidential business information should not be disseminated by an investigator without requester’s knowledge; also see Section 14(f) of the AAFCO Model Bill or applicable governing state laws.

If not enough information is available in the published literature a feeding trial may be needed. Please contact FDA CVM Division of Animal Feeds (DAF) for consultation on study design & requirements. Protocols should be submitted to DAF for review prior to conducting the studies.

Once a request has been submitted, the firm should wait to market the ingredient until the definition has been voted on by the AAFCO Ingredient Definition Committee, AAFCO Board, and AAFCO members.

The requester may contact the investigator to determine if the request has been submitted to FDA for their review at the 30-day mark and every 30 days after that time.

The requester may get questions from the investigator or DAF. Questions should be addressed in a timely manner. Pending questions not addressed within 24 months will result in the investigator removing the request from AAFCO consideration.

Some ingredients are fed to intentionally alter the composition of human food (as when making human health benefit claims); these ingredients are not appropriate for review by AAFCO and need to be submitted through the Food Additive Petition (FAP) process to FDA. Additional unanswered safety questions for the ingredient may necessitate an FAP as well. FAP issues will be addressed to the Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration. Check the Official Publication for further contact information.

A requester wanting approval pursuant to the Canadian Feeds Act and Regulations is required to file a formal application with the Canadian Food Inspection Agency. Inquiries should be addressed to Director, Animal Feed Division, Canadian Food Inspection Agency. Check the Official Publication for further contact information.

The Investigator

The AAFCO Investigator is a one-person committee that will evaluate and manage the request for a new definition or modified definition. One of the goals of the investigator is to develop official feed definitions that are just and equitable in cooperation with the members of the industry producing the ingredient. A second goal is to assure that the production, sale, and use of ingredients will result in safe and effective feeds. The ingredient definitions should be non-proprietary, meaning they do not include a trade name that would favor one producer over another.

Upon receipt of the request for a new AAFCO ingredient definition or request for modification of an existing ingredient definition, the investigator will:

1) Determine if the proposed ingredient definition fits in the requested section of the AAFCO OP. If not, the request will be referred to the appropriate investigator or to the chair of the Ingredient Definitions Committee with the requesting party notified of the referral.
2) Confirm that the proposed ingredient does not fall within the scope of an existing ingredient definition.
3) Confirm that a proposed revision to an existing ingredient definition will not cause it to be moved to a different section of the OP or fall within the scope of another existing ingredient definition.
4) Conduct an initial evaluation to determine whether any unanswered safety questions exist. If so, the requester will be referred directly to Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration to pursue a food additive approval. If FDA issues a food additive regulation for the ingredient, the investigator will lead the process of bringing the recommendation before the IDC.
5) Confirm that the ingredient definition request is complete and contains all the information needed from the requester listed in the requester section above.

Upon receiving a request for a new or modified AAFCO ingredient definition, the expected administrative review time for the AAFCO investigator is 30 calendar days. If the investigator expects their review to take longer than 30 days, he/she may request an extension from the chair of the Ingredient Definitions Committee or request the chair of the Ingredient Definitions Committee assign the definition to another investigator. Once the administrative review is complete, the investigator will forward one copy (electronic copy is preferred, but if sent as PDF, use Optical Character Recognition (OCR) format) of the request to Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration. If the requestor prefers to send any manufacturing information that is confidential business information directly to FDA, that is acceptable. FDA acts in a consulting role to evaluate the safety and utility of the ingredient.

Confidential business information should not be disseminated by an investigator without knowledge of the requester (also see Section 14(f), AAFCO Model Bill or applicable governing state laws).

The expected time for FDA to complete their safety and utility review is 180 calendar days. The investigator will provide an update to the requester on the status of the submission when the requests for updates are reasonably timed. After a request has been at FDA for 180 days, the investigator may contact the FDA reviewer to determine the status. It may be necessary for additional data and information to be submitted, which may lead to multiple iterations to completely review a request. If the FDA determines that additional data and information is necessary, they will notify the requester and copy the investigator.

When FDA has completed their review and recommended publication of the ingredient definition, the investigator will prepare and forward an "Investigators Report" form to the Chair of the Ingredient Definitions Committee. These reports will be added to the agenda of the next committee meeting and are open for viewing and comments. The investigator may initiate a modification of an ingredient definition based upon their knowledge of the affected industry and not on a specific request from an external requester. It is the responsibility of the investigator to acquire sufficient documentation to support their actions, just as it is industry's responsibility to provide sufficient documentation to support their request.

Once a new ingredient definition is approved by the Ingredient Definitions Committee they forward a recommendation to the AAFCO Board to place the definition in the Official Publication in tentative status. The Board will vote for or against this recommendation before the next membership meeting so members can vote on the recommendation during the Annual or Midyear meetings. Once approved by the membership, the tentative ingredient definition will be published in the Official Publication. Once accepted by membership for publication as a tentative definition the definition will move to Official status six months later without further action by the IDC, Board or Membership. This action can be stopped or modified by the IDC in consultation with the investigator.

The AAFCO bylaws require that each OP published tentative definition must be reviewed by the responsible investigator 30 business days prior to the IDC meeting at the annual meeting. The investigator shall recommend the definition be deleted, modified, moved to official or remain at tentative.

The FDA

The Division of Animal Feeds in FDA’s Center for Veterinary Medicine performs scientific reviews of AAFCO ingredient definition requests and provides recommendations to the IDC investigators for new and amended ingredient definitions.
It typically takes at least 180 days to review a request for a new ingredient definition, depending on complexity of the request and FDA’s current workload. The AAFCO investigator can contact the FDA reviewer after that time to inquire about the status.

If FDA considers the request incomplete, FDA may contact the requester directly for that information but must copy the investigator on all communications. It may be necessary for additional data and information to be submitted, which may lead to multiple iterations to completely review a request. If needed to support their scientific review, FDA may directly request confidential business information from the requester.

FDA will provide a written response to the investigator with the conclusions of their review with the recommended ingredient definition. The requester should receive a copy of this response.

**The Association**

Once reviewed by the investigator and FDA, the proposed ingredient definition is submitted by the investigator to the chair of the Ingredient Definitions Committee. The IDC is the clearinghouse for all new or modified definitions by acting as a review panel for the investigator to assure that definitions are acceptable and consistent with AAFCO policies and existing definitions. Membership of the committee is drawn from the ranks of AAFCO members. The deadline for submission to the chair is 30 business days before the next IDC meeting and is necessary to allow ample time for committee review and corresponding with the investigator.

Once a new or modified ingredient definition is approved by the Ingredient Definitions Committee the chair will forward a recommendation to the AAFCO Board to place the definition in the Official Publication in tentative status. The Board will vote for or against this recommendation before the next membership meeting so members can vote on the recommendation during the Annual or Midyear meetings. Once approved by the membership, the tentative ingredient definition will be published in the Official Publication. Once accepted by membership for publication as Tentative, the definition will move to Official status six months later without further action by the IDC, Board or Membership. This action can be stopped or modified by the IDC in consultation with the investigator.

The AAFCO bylaws require that each OP published tentative definition must be reviewed by the responsible investigator 30 business days prior to the IDC meeting at the Annual meeting. The investigator shall recommend the definition be deleted, modified, moved to official or remain at tentative.

Firms may use the ingredient definition once the AAFCO membership vote has occurred affirming the recommended definition to appear in the Official Publication. Prior to publication in the Official Publication firms wanting to manufacture feed with the ingredient may use committee minutes and general session minutes to document the completion of the process. These are typically posted on the AAFCO website.

If deletion of an ingredient definition from the Official Publication is proposed, the investigator will follow the same dateline as if proposing any other ingredient definition change. This will allow the IDC the opportunity to review and discuss the proposed deletion.

**Canadian Food Inspection Agency**

The Chair of the IDC will share all completed definition recommendations with Canadian officials for their information once the forms have been forwarded to the Ingredient Definitions Committee.

A requester wanting approval pursuant to the Canadian Feeds Act and Regulations is required to file a formal application with the Canadian Food Inspection Agency. Inquiries should be addressed to Director, Animal Feed Division, Canadian Food Inspection Agency. Check the Official Publication for further contact information.

**Additional Pathways to AAFCO Published Ingredient Definitions**

Section Editor – Jennifer Roland, FASS
Animal Food Additives Approved by FDA

Animal food additives approved by FDA are listed in 21 CFR 573. The food additive regulation specifies the requirements for safe use of the food additive and establishes the common or usual name for the new ingredient. To ensure that the AAFCO Official Publication listing of defined feed ingredients is complete, the approved food additive, as specified in the published final rule, will be incorporated in the AAFCO Official Publication’s Official Common or Usual Names and Definition of Feed Ingredients chapter.
The designated FDA representative to the IDC will provide the appropriate investigator with the food additive regulation and will prepare a recommendation form and forward it to the Chair of the Ingredient Definitions Committee for consideration at the next committee meeting.

Since the ingredient has gone through the formal FDA approval process, once the AAFCO Ingredient Definitions Committee, the AAFCO Board, and AAFCO Membership have approved the definition, the entry will be incorporated in the AAFCO Official Publication as official.

**GRAS Notified Substances with ‘No Questions’ Letters from FDA**

A list of GRAS Notices filed voluntarily by the notifiers pursuant to 21 CFR 570.205 which FDA has evaluated (21 CFR 570.265) and determined that it had no questions regarding the conclusion that the notified animal food substance is generally recognized as safe (GRAS) under the intended conditions of use is provided in Section 101 of Chapter 6 of the AAFCO OP the filed notice and the FDA response letter provide information (identity, manufacture, specifications, intended effect, and safety) on the substance under the intended use conditions, and the most up to date version is posted at the following website: [http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm](http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm) This section is provided as a convenience for the State Feed Control Officials. The Investigator of section 101 will adapt the information as provided on the FDA website and consult with FDA on an appropriate common or usual name.

While the information on the substance and the intended use is specific to that provided by the notifier, other firms may use information within the notice along with other data specific to their substance to support the GRAS conclusion (see 21 CFR 570.3-570.280). Such other firms who conclude that an animal food substance is GRAS under the conditions of its intended use by relying on a posted GRAS notice submitted by another person shall carefully evaluate whether their production process, product specifications and intended conditions of use, fall within the parameters addressed by the referenced GRAS notice. GRAS conclusions are not legally required to be submitted to FDA, but may be voluntarily submitted in accordance with the GRAS Notice regulation (21 CFR Part 570.205). Nevertheless, firms that elect to make use of the independent GRAS provision must document their Independent Conclusions of GRAS prior to marketing a substance for a particular intended use. State Feed Control Officials may request the Independent Conclusion of GRAS documentation to support their registration or inspection duties.

The table in Section 101 is adapted from the FDA Animal GRAS Notification website and includes ingredient definition information (substance, common or usual name (from the FDA response letter), and intended use (including use limitations, if any)). For other information, see the FDA response letter for the GRAS Notice (available at link provided above).

At each AAFCO IDC meeting, the section editor will provide an updated list of animal food GRAS Notices that have been evaluated by the FDA and have received a no questions letter from the Agency. Firms making GRAS conclusions should be prepared to answer questions from the Ingredient Definitions Committee or Association if needed. The notices are voted on by the Ingredient Definitions Committee, the AAFCO board, and accepted by the Association membership for publication in the AAFCO Official Publication.

*Space reserved for future addition of FDA color additive process.*
Appendix B: Ingredient Definitions Committee e-Meeting 4/4/19

Recommendations to the Board and Association Membership
When needed, new text is presented in the committee minutes, Appendix B.1.

1) Publish the New Feed Term “Slaughter, a process of killing an animal for food or feed.”
2) Publish T3.1 Suncured Alfalfa Meal, or Pellets, or Ground Alfalfa Hay as a Tentative definition. Leave 3.1 in place.
3) Modify 33.17 Gamma-linolenic acid safflower oil and publish as Official.
4) New Definition T60.118 Ground Juniper publish as Tentative
5) New Definition 57.168 Selenomethionine hydroxy analogue publish as Official.
6) Modify 73.046 Silicon dioxide and publish as Official

Board Action

Association Action
To be considered in August 2019

Committee actions not requiring association votes:

a) Proceed with proposing edits to vitamin table adding non-chemical names.

b) Established True Limestone workgroup

Topics moved to the next meeting:

i. New Feed term Bison
  ii. New Feed term __(workgroup output here)____ Buffalo
  iii. GRAS verification workgroup to provide an update
  iv. Non-Defined workgroup to provide update in August.

Committee Report
Meeting called to Order 8:31 AM PDT
1) Roll call of Committee members, present:
   Richard Ten Eyck, Kristen Green, Mika Alewynse, Erin Bubb, David Beard, Brett Boswell, Ken Bowers, Michelle Boyd (joined late), Bob Church, Stan Cook (joined late), Dave Dressler, James Embry(left early), Maggie Faba, George Ferguson, Jacob Fleig, Steve Gramlich, Brett Groves, Ali Kashani, Dan King, Mark LeBlanc, Rick Manthei, Melanie Marquez, Dave Phillips, Tom Phillips, Nathan Price, Laura Scott, Shannon Jordre, Charlotte Conway, Kent Kitade (joined late), Jennifer Kormos,
   A quorum was present (27/27 voting members). The meeting was recorded. There were 188 people logged into the webinar including the committee members.

2) CFR Modification 33.17 Gamma-Linolenic Acid Safflower Oil--cats

3) Official Definition to publish in OP 57.168 Selenomethionine Hydroxy Analogue Jennifer Kormos moved to add 57.168 as an Official Definition. Tom Phillips seconded, Motion PASSED

4) Official Definition to publish in OP 73.046 Silicon Dioxide, CFR update
   Richard Ten Eyck moved to publish modifications to 73.046 as Official. Jacob Fleig Seconded. Motion PASSED

5) T60.118 Ground Juniper Erin Bubb moved to Publish as Tentative. George Ferguson seconded.
   – Motion PASSED
   Discussion included the evaluation of terpenes and the length of time the recommendation has been in front of the committee.

6) (placeholder) 3.1 Suncured Alfalfa Meal, or Pellets or Ground Alfalfa Hay is the aerial portion of the alfalfa plant reasonably free of other crop plants, weeds, and mold, which has been dried by solar means, stored as bales or stacks and finely or coarsely ground. If it is chopped instead of
ground it must be designated as “Suncured Chopped Alfalfa” or “Chopped Alfalfa Hay”. If it is
ground and dehydrated by thermal means it must be designated as “Dehydrated Suncured Alfalfa”.

Erin Bubb moves to publish T3.1 adding to the current 3.1 definition: “If the ingredient is further
dehydrated by thermal means after being ground, it must be designated as ‘Dehydrated
Suncured Alfalfa Meal, or Pellets’” George Ferguson seconds. Motion PASSED after a lot of
discussion and presentations from the alfalfa industry. J.P. Ray a Nebraska alfalfa producer
provided a rebuttal to the proposed change. Ken Vaupel spoke in favor of the proposal.
Presentations are in the Feed BIN Library / Ingredient Definitions/Investigator Recommendations
and on the team board.

7) Vitamin common names A, C, E – Tom, concept is in the BIN, need text. Tom Phillips moved to
pursue edits to table 90.25. Richard Ten Eyck seconded, Motion Passed
Extensive discussion on label format for vitamins, not all states allowing parenthetical add-ons to the
common or usual name. Proposal should only address vitamins used in pet and specialty pet.
Committee was most comfortable with a common name followed by a parenthetical of the source.
E.g. “Vitamin B2(Riboflavin)”
PFI, Richard Ten Eyck, Consumer group TBD, will help with edits.

8) Revise feed term Stabilized (process) – Ali Ali moved to revise the feed term “Stabilized” Jacob
Fleig Seconds, Came from the SUIP workgroup. Committee had several questions and would like to
see it go back to the SUIP workgroup for fine tuning. motion FAILED
Charlotte will help Ali to fine tune language.

9) New feed term Bison – Brett NOT Considered in this session. Workgroup will be hearing from Brett.
Should be ready in August.

10) New feed term ______(work group output here)_____ Buffalo -Brett NOT Considered in this
session. Workgroup will be hearing from Brett. Should be ready in August.

seconded. Fair amount of discussion. Occasional feeding may be preferred language. Some debate
on species covered as well as inclusion of complete and balanced wording. Motion FAILED

12) Feed term slaughter or workgroup update – Ali Ali moved to publish a new feed term “Slaughter,
a process of killing an animal for food or feed.” Jacob Fleig seconded. Requested a year ago to help
clarify its use in several animal products definitions. Good deal of discussion. Bob Church proposed
removing the word “humanely” as too subjective. Motion and second revised to remove “humanely.”
Would this require inspection? No. Brett Groves called for the question. Vote by Roll call was 13
AYE, 10 NAY motion PASSED

13) Hemp Update (5 min) Bob Church Not much new, still waiting on industry to provide safety and
efficacy data. Sue Hays will be updating the AAFCO white paper on hemp. Generally information is
current. Leah suggested adding what the Farm Bill did and did not do to animal food hemp status.
CVM is talking to people assembling Data to support a definition. FDA holding a public meeting on
5/31/19 on cannabis.

14) Limestone workgroup update – Jennifer Kormos Proposal received from industry for additional
limestone definition and some modifications. Need BIN project set up. “True Limestone” Workgroup
formed, Jennifer Kormos, Lead; AFIA; Diego Paiva (CVM);

15) GRAS verification workgroup update - Richard
a) Goal is established, workgroup needs to meet in next 6 weeks.

16) Volunteers to review “Is this Animal Food” Flowchart (for web) – Richard Volunteers: Cathy Allinovi,
AFIA, Dave Edwards, Angele Thompson

17) CVM item one (placeholder) (may move up agenda) (Juniper)

18) Confusing pet food name workgroup report (placeholder) Brett Boswell Workgroup is being re-
energized. Brett is looking for others to join.

19) Status on high profile ingredients (placeholder) – Richard / CVM NONE to discuss

20) Discussion of common human foods in pet food (placeholder)- George Ferguson. Melanie Marquez
(incoming Human Food By-Products investigator) discussed Vegetable Pomace (not defined)
seeking a definition. Industry may be using Food Processing Waste in the interim, but need to
satisfy the safety assessment requirements.
Milk Products investigator was seeking clarification on human food and Discussion of GRAS notices
being separated between Animal Food and Human Food. Each would need a separate Independent
Conclusion of GRAS because they are different intended use.
21) Topic from Gallery: When will Oat Fiber be Official? Discussed process modify vs. new definition. Investigator and CVM are getting questions on the current definition and not clear on what resolution will be. This clouds when the investigator may recommend a change to Official.
Meeting Adjourned 11:12AM PDT
Minutes accepted 5/2/19 with 17/26 members voting affirmative. These committee members did not vote: Kristen Green, Michelle Boyd, Stan Cook, James Embry, Ali Kashani, Mark Leblanc, Melanie Marquez and Laura Scott.
Appendix B.1: Ingredient Definitions Committee e-Meeting 4/4/19

T3.1 Suncured Alfalfa Meal, or Pellets, or Ground Alfalfa Hay is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, which has been dried by solar means, stored as bales or stacks, and finely or coarsely ground. If it is chopped instead of ground, it must be designated as “Suncured Chopped Alfalfa” or “Chopped Alfalfa Hay”. **If the ingredient is further dehydrated by thermal means after being ground, it must be designated as “Dehydrated Suncured Alfalfa Meal, or Pellets”** (proposed xxxx)

33.17 Gamma-linolenic acid safflower oil- The food additive, gamma-linolenic acid safflower oil, may be safely used in animal food as a source of gamma-linolenic acid and other omega-6 fatty acids in accordance with the following conditions:

(a) The additive is the oil obtained from whole seeds and/or partially dehulled seeds of a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid (all-cis-6,9,12-octadecatrienoic acid) during seed development.

(1) The additive obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in paragraph (a)(2) of this section.

(2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

   (i) Crude fat content of the additive or the safflower oil blend is not less than 99.5 percent.

   (ii) Gamma-linolenic acid content is between 350 and 450 milligrams (mg) gamma-linolenic acid per gram of the additive or the safflower oil blend.

   (iii) Total content of stearidonic acid and cis, cis-6,9-octadecadienoic acid in the additive or the safflower oil blend must not exceed a total of 0.3 percent.

(b) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance dog food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 36 mg gamma-linolenic acid per kilogram body weight of the dog per day in more than 86 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.3 percent of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.

(c) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance cat food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 33 mg gamma-linolenic acid per kilogram body weight of the cat per day in more than 79 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.5 percent of a complete dry adult maintenance cat food containing 4,000 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for cat food formulas of different caloric density and/or that are fed to specific weights, breeds, or cats of different activity levels to meet the requirements of this paragraph.

(d) To assure safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive shall bear the following:

(1) The name of the additive, gamma-linolenic acid safflower oil, or GLA safflower oil;

(2) A guarantee for the minimum content of gamma-linolenic acid; and

(3) Adequate directions for use such that the finished animal food complies with the provisions of paragraphs (b) and (c) of this section.

(Proposed XXXXX) 21 CFR 573.492
57.168 Selenomethionine hydroxy analogue
Selenomethionine hydroxy analogue [R,S-2-hydroxy-4-methylselenobutanoic acid (CAS 873660-49-2)] is manufactured by the reaction of elemental selenium with methylithium to form a methylseleno salt, which is then reacted with R,S-2-hydroxybutyrolactone to form a salt of 2-hydroxy-4-methylselenobutanoic acid. After acidification and purification, the additive consists of not less than 39.5 percent total selenium by weight with a selenomethionine hydroxy analogue content of not less than 98 percent of total selenium. The total organic selenium content of the additive is not less than 99 percent of total selenium.

(1) The selenomethionine hydroxy analogue meets the following specifications:
(i) Arsenic, not more than 2 parts per million (ppm);
(ii) Cadmium, not more than 1 ppm;
(iii) Lead, not more than 1 ppm; and
(iv) Mercury, not more than 1 ppm.

(2) Selenium, as selenomethionine hydroxy analogue, is added to complete feed for chickens, turkeys, and swine at a level not to exceed 0.3 ppm.

(3) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of selenomethionine hydroxy analogue in its packaged form shall contain:
(i) The name, selenomethionine hydroxy analogue;
(ii) Minimum and maximum guarantees for a total selenium content of not less than 2.08 percent (weight/weight) and not more than 2.24 percent;
(iii) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2 percent;
(iv) The following statement, "Storage Conditions: Selenomethionine hydroxy analogue must be stored in a closed package at temperatures not higher than 20°C (68°F)."; and
(v) An expiration date not to exceed 1 year from the date of manufacture.

(4) Selenomethionine hydroxy analogue, shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(5) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production. Production controls must assure products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(6) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

(Proposed XXXX) 21 CFR 573.920

T60.118 Ground Juniper is a roughage consisting of the entire aerial portion of the juniper plant (trunk, bark, branches, leaves, and berries), obtained only from Juniperus pinchotii and/or Juniperus ashei. Any plant part below ground level is excluded to avoid contamination with soil and/or rocks. It is ground to pass a screen no larger than 5/8 inches (15.875 mm). The ingredient must be guaranteed for crude protein and acid detergent fiber. Ground juniper is to be fed as a dietary roughage for cattle, sheep, or goats in accordance with good feeding practices. (proposed xxxx)

73.046 Silicon dioxide
The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:
(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.
(b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:
(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.  

(d) It is used or intended for use in feed components, as a carrier as follows:

<table>
<thead>
<tr>
<th>Feed component</th>
<th>Limitations (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavors</td>
<td>50</td>
</tr>
<tr>
<td>Selenomethionine hydroxy analogue</td>
<td>95</td>
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</tbody>
</table>

(e) To assure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.


*Silicon dioxide may be mixed with Vitamin E at levels up to 50%, to produce Vitamin E Supplement for addition to animal feed. Where silicon dioxide is used as a dispersant and/or flow agent to assist with uniform and consistent distribution of the vitamin E supplements in animal feed, silicon dioxide should be declared on the ingredient list of the vitamin E supplement.*
Committee Recommendations
The Request for Proposal for the Sampling Method Study has been completed and accepted by majority by the committee. The committee recommends the distribution of the submission information move forward with the timeframe to receive proposals being 90 days.

Board Recommendations: Report accepted May 6, 2019

Association Recommendations: None

Committee Action Items
1) Aseptic Sampling Work Group Charge: to evaluate current protocols for aseptic sampling. The group includes the following members: Miriam Johnson (Lead) – NC; Tim Lyons – MI; Stevie Glaspie – MI; Ethan Willis – MO; Jacob Fleig – MO; Kevin Kломmhaus – FDA; Jan Campbell – NGFA; Stephanie Adams – AFIA
2) AAFCO Inspectors Manual FSMA Alignment Work Group Charge – to review the AAFCO Feed Inspector’s Manual to ensure it aligns with FSMA requirements. The group includes the following members: Kevin Klommhaus (Lead) – FDA; Brett Groves – IN; Jim True – KY.
3) Sampling Study RFP Work Group Charge: Write a Request for Proposal in which current sampling methods will be re-validated through independent peer reviewed research. Once the RFP is approved by the Inspection and Sampling Committee it will be sent out to the appropriate venues for proposal to conduct the study. The group includes the following members: Miriam Johnson (Lead) – NC; Bob Geiger – IN; Jenny Combs – KY; Samantha Moran-Defty – CA;
4) AITS & BITS Alignment Work Group Charge: Review current guidance document for hosting AITS & BITS and establish a consistent curriculum for future AITS seminars. The group includes the following members: Miriam Johnson (Lead) – NC; Jessica Gore – NC (POC for AITS); Chad Linton – WV; Brett Groves – IN; David Dressler – PA; Amanda Anderson – KS; Eric Brady – TN; Barb Schroeder – MN; Kevin Klommhaus – FDA; Stephanie Adams – AFIA.
   • 2019 AITS Cadre: Jessica Gore – NC (POC for AITS); George Ferguson – NC; Eric Brady – TN; Stevie Glaspie – MI; Jamie Spencer – KS; Jordan Mancini – MI;

Committee Participants
Members Present: Miriam Johnson – NC (Committee Chair); Bob Church – MT; Brett Groves – IN; David Dressler – PA; Laura Scott – CAN; Jim True – KY; Jacob Fleig – MO; Tim Lyons- MI; Jenny Combs – KY; Ethan Willis – MO; Stevie Glaspie – MI; Samantha Moran-Defty – CA
Members Present Via Telephone: None
Advisors Present: Meghan Dicks – AFIA; Jan Campbell – NGFA; Chris Olinger – NGFA; Stephanie Adams – AFIA
Others Present: Sue Hays – AAFCO Executive Director

Committee Report
Miriam Johnson (Committee Chair) called the meeting to order at 11:20 AM EST. Members and advisors in the room introduced themselves.

Aseptic Sampling Work Group – Stevie Glaspie, MI and Ethan Willis, MO
A work group was formed during the 2017 Midyear Meeting in Mobile, AL to address missing procedures for bulk aseptic sampling in the sampling procedures section of the AAFCO Feed Inspector’s Manual.

Work Group Update:
The work group has been reviewing the Aseptic Sampling sections of both the AAFCO Feed Inspector’s Manual and the FDA IOM, along with other aseptic sampling SOP’s gathered from industry and regulatory groups. An update of the progress achieved by the group was given by Stevie Glaspie and Ethan Willis. Updates include the addition of a graphic depicting a method for How to Don Sterile Gloves. Permission to utilize the image has been requested. The workgroup is working with B. Braun Medical to ensure we do not impose on copyrights. General Procedures and Technique guidances have been added to the
section. The workgroup continues to determine additional updates and revisions needed. The inclusion of Environmental Sampling was discussed with the consensus that yes this would be a great topic, but with some caution, to touch on both the Feed Inspector’s Manual and during AITS (consideration of the topic will be passed on to the 2019 AITS Cadre). The work group feels that they will have a draft for the committee by the next annual meeting.

**Work Group Members:** Miriam Johnson (Lead) – NC; Jacob Fleig – MO; Tim Lyons – MI; Stevie Glaspie – MI, Ethan Willis – MO; Kevin Klommhaus – FDA Advisor; Jan Campbell – NGFA; Stephanie Adams – AFIA

**AAFCO Feed Inspector’s Manual and FSMA Alignment – Kevin Klommhaus, FDA**

*Work Group Update:*  
A review of the AAFCO Feed Inspector’s Manual is continuing to be performed to ensure it is aligned with the requirements of FSMA. The work group has completed their official review. FASS is currently updating suggested edits to the document. A final review will be given once these have been made. At this time, key representatives, were unable to attend the meeting to update and further discuss the Manual’s progression. This topic will be tabled and further addressed and discussed at the Annual meeting in 2019.

**Work Group Members:** Kevin Klommhaus (Lead) – FDA; Brett Groves – IN; Jim True – KY

**AAFCO Sampling Study – Miriam Johnson, NC**

*Work Group Update:*  
During the Annual Meeting held in Bellevue, WA in August of 2017 a work group was formed to create a Report for Proposal to conduct a sampling study. The charge of the work group is to write a Request for Proposal in which current sampling methods will be re-validated through independent peer reviewed research. Discussion from the work group revealed the RFP is completed. The study request is to re-evaluate the current bagged feed sampling technique, utilizing various feed types (ex. Crumbles, textured, pellet, mash product, etc.) with sample collection completed using the AOAC ¾” single tube trier sampling probe. The RFP has been approved by the Inspection and Sampling Committee and has been sent to the Board of Directors for approval. Once approved, the link to the RFP will be distributed to appropriate venues that could conduct the study. Proposals will be received for 90 days, close of the receipt of proposals will be June 30, 2019.

**Work Group Members:** Bob Geiger – IN; Jenny Combs – KY; Samantha Moran-Defty – CA

**AITS Seminar Review – Miriam Johnson, NC**

The Alabama Department of Agriculture will be hosting the 2019 AITS seminar June 18-20, 2019 in Montgomery, AL. Once registration is made available with the information to do so, it will be distributed to the states to register participants to attend. The AITS cadre will be using the newly updated curriculum (which includes participation from CLEAR) at this seminar.

**BITS Seminar Review – Brett Groves, IN**

The 2018 BITS seminar was hosted by the Pennsylvania Department of Agriculture on September 25-27, 2018. Thank you to FASS, Erin Bubb and Dave Dressler for their efforts in hosting and organizing the logistics. This was considered to be a very successful meeting with 52 attendees present, and representing 22 states. The facilities visited were extremely accommodating and great to work with during field activity exercises.

The Georgia Department of Agriculture has offered to host the 2019 BITS seminar in Athens, GA in mid-September 2019. As additional information is received, it will be made available to the membership.

**AITS & BITS Alignment Workgroup – Miriam Johnson, NC**

*Workgroup Update:*  
A workgroup was formed prior to the Midyear Meeting in Anaheim, CA in 2018. The charge of the work group is to review current guidance documents for hosting AITS and BITS and establish a consistent curriculum for future AITS seminars. An update presentation was given by Miriam Johnson which described to the membership and committee members the structure of AITS moving forward. From the updates presented the members learned the workgroup is currently working with CLEAR to create a customized portion of the curriculum specific to feed investigators and has agreed the following topics will be presented: Aseptic Sampling, Feed Manufacturing, GMP/Record Review, Trace Back/Trace Forward, Label Review including Medicated Labels, Feed Stuffs, and CLEAR directed modules. Work on creating the presentations and course materials is currently underway. A Cadre has been established for the 2019 AITS to include: Eric Brady (TN), Jessica Gore (NC), George Ferguson (NC), Jordan Mancini (MN), Jamie Spencer (KS), Stevie Glaspie (MI).
Workgroup Members: Miriam Johnson (Lead) – NC; Chad Linton – WV; Brett Groves – IN; Eric Brady – TN; Amanda Anderson – KS; Barb Schroeder – MN; Dave Dressler – PA; Stephanie Adams – AFIA

Other Business:
None

No further discussion or topics were brought to the attention of the committee and the meeting was adjourned at 11:50 AM EST.

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<td>Ensure the manual aligns with FSMA requirements</td>
<td>August 2019</td>
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<td>Work Group</td>
<td>Sampling Study RFP</td>
<td>RFP is out for Distribution; Proposals ready for review</td>
<td>July 2019</td>
</tr>
<tr>
<td>Work Group</td>
<td>AITS Guidelines &amp; Curriculum</td>
<td>Update and Standardize AITS Guidelines &amp; Curriculum; Establish Teaching Cadre</td>
<td>June 2019</td>
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Laboratory Methods and Services Committee Report
2019 AAFCO Midyear Meeting
January 22, 9:00 am–5:00 pm, Savannah, Georgia

Committee Recommendations: None

Board Recommendations: Report accepted May 6, 2019

Association Actions: None

Committee Participants
Members Present: Ametra Berry, Georgia Dept. of Agriculture; Sally Flowers, Nebraska Dept. of Agriculture; Teresa Grant, North Carolina Dept. of Agriculture; Casey Guccione, Kansas Dept. of Agriculture; Tai Ha, Nebraska Dept. of Agriculture; Gale Hagood, Mississippi Dept. of Agriculture; H. Dorota Inerowicz, Office of the Indiana State Chemist; Robin Johnson, Montana Dept. of Agriculture; Mary Koestner, Missouri Dept. of Agriculture; Mark LeBlanc, Louisiana Dept. of Agriculture; Patty Lucas, Florida Dept. of Ag and Consumer Services; Kristi McCallum, Colorado Dept. of Agriculture; Rebecca Moseley, Alabama Dept. of Agriculture; Lise-Anne Prescott, Canadian Food Inspection Agency; Aaron Price, Canadian Food inspection Agency; Robert Sheridan, New York Dept. of Agriculture; Brenda Snodgrass, Oklahoma Department of Agriculture; Michele Swarbrick, Minnesota Dept. of Agriculture; Nancy Thiex, Life Member; Sharon Webb, University of Kentucky Regulatory Services
Advisors Present: Kyle Bennett, Neogen; Dan Berg, Eurofins; Andy Crawford, Consultant; Jeff Horst, Agri-King; Paul Mostyn, Westway Feed; Lars Reimann, Eurofins; Ken Riter, Nestle-Purina Analytical Labs; Lisa Ruiz, Eurofins NAC; Leo Schilling, Eurofins; Liberty Sibanda, Randox Food Diagnostics; John Szpylka, Mérieux NutriSciences

Committee Report
1) Call to Order
The Agenda was approved with minor changes due to the federal government shut-down.
Introductions – sign-up sheet circulated to participants
2) Committee roster was reviewed and updated. Kristi McCallum added new members and advisors.
The updated roster was sent to Jennifer Roland on February 4, 2019.
3) FDA Cooperative Agreement – Robin Randolph of APHL gave a presentation, highlighting the following.
   • APHL is continuing work started under the Association cooperative agreements through a 2-year bridge agreement with FDA.
   • Continue to offer support and resources for laboratories seeking ISO17025:2017 accreditation.
   • A newly revised white paper is coming soon. The revised white paper will comply with the new ISO17025:2017 standard.
   • PFP Lab Best Practices Checklist, which is a companion to the white paper, is coming soon.
   • Lessons learned from first labs transitioning over to 2017 standard are being captured to assist other labs facing the transition.
   • Consultant (Yvonne Salfinger) is working with 10 laboratories towards ISO17025 accreditation.
   • Continuing the Bioinformatics Training to help with the FDA Genome Trakr program.
   • Working with FDA and the eLEXNET group on the possibility of a new data entry portal.
   • Continuing work on Laboratory Curriculum Framework development, competency development, and beginning developing courses. A survey was sent to SME and laboratory contacts to assist in evaluation/validation in order to rate the appropriateness of the content for each entry level competency.
   • Laboratories interested in hosting a GOOD Test Portions training should contact Nancy Thiex or Robyn Randolph. There is funding available for some training.
4) State Laboratory LC/MS Capability Survey – Dr. Scott Teeter, Elanco Animal Health
   • In 2011, there was a survey of State lab LC/MS capabilities. Several labs were developing LC/MS methods for drugs in feed; FDA/CVM requires assurance that state labs have, have access to, or a way to conduct LC/MS or LC/MS/MS methods before approving those methods, to ensure drug methods could be conducted by state labs if they are approved by
CVM. In the 2011 survey, 27 US labs, plus Canada, responded. Since the meeting, a new survey was developed and was posted on AGLabs List Serv on February 28, 2019. The survey will support and guide the development of new methods.

5) Moisture Best Practices Workgroup - Teresa Grant, Michael Richardson, Lawrence Novotny, Bozena Draczynska-Lusiak

Two studies were presented at this meeting by Michel Richardson and Bozena Lusiak. Each looking at comparing AOAC Karl Fisher (KF) (991.02) and AOAC Loss on Drying (LOD) methods for pet food and pet food treat samples in the 70-80% moisture range. The Karl Fisher (KF) method (991.02) is intended for samples in the 20-30% moisture range. One study showed that if you decreased the sample weight, the KF moisture values increased. The other study presented showed that extraction time and type of shaker makes a difference in moisture recovery with the overnight extraction and shaker giving the best results. It is recommended that the workgroup come up with an optimized KF method for wet pet food. Laboratory participation is needed to optimize the Karl Fisher method. Some questions remain about volume of sample and type of oven (i.e. convection). The objective is to find optimized conditions to present as best practices.

6) Working Group updates

a. Tylosin – Leo Shilling proposed that Tylosin should be removed from the methods needs list and the working group be dissolved. This would allow members to focus on new method needs. A discussion regarding this proposal led to laboratories reporting a sharp decline in requests for Tylosin analysis in each of their state labs. Colorado has seen a sharp decline in Tylosin samples – 0 last year, 1 in 2017; Kansas 2 in 2017 and 2018, Kentucky in 2017 and 2018. Sharon Webb said there had been a dramatic drop in Tylosin samples since the Veterinary Feed Directive (VFD) rules came into effect and that we may want to keep this in mind with the PT program as well. The members voted to disband the Tylosin WG which passed unanimously.

b. CTC – Leo Shilling gave an update that this workgroup is close to forming a collaborative study group for the HPLC method with fluorescence detection.

c. Fat soluble vitamins – Dorota Inerowicz, Michele Swarbrick and Ken Riter presented an update on this workgroup. Minnesota laboratory performed a study to measure particle size for guidance on the theoretical sample weight needed for analysis. Seven samples were received and they could visually see a difference. Michele presented that their lab removed cross-sections to view under the microscope. The range of particle sizes varied from <0.1mm to 1mm. The pre-mixes that were examined came from two different manufacturers. Microtrac Particle Analysis Lab performed particle size testing as well, but the results still need to be interpreted. Once the data is received from Microtrac, the minimum sample weight needed could be estimated and a single lab validation performed. Equations from Good Test Portions will be used to make these estimations, taking into account particle size, shape, density, etc.

d. Multi-element metals – Robert Sheridan, Sharon Webb, Michele Swarbrick and LiseAnn Prescott reported that the Metals Working Group is currently working on a “Metals in Feed Guidelines”. The metals WG is meeting every 4-6 weeks and they are making good progress on the Good Practices for Elemental Analysis in Feed. The next chapter to work on is “Standards.” These best practices guidelines will be for ICP/OES and ICP/MS.

e. Mycotoxins – Robert Sheridan, Sharon Webb, Kyle Bennett and Lei Tang

i. Dr. Liberty Sibanda from Randox Food Diagnostics gave a presentation on a multiplex mycotoxin assay using Biochip Array technology. This method has been validated using FAPAS Proficiency Tests samples and is published in the Journal of AOAC International Vol. 99, No. 4, 2016. Each test can analyze up to 10 mycotoxins in a single run, single sample preparation. One test kit will contain 54 biochips for 9 calibration standards and 45 samples. Calibrations are good for 90 days. There is no sample clean-up and it takes ~30-minutes for sample preparation, the total time of analysis 2.5 hour including incubation and assay. In some instances, it has lower LOD than LC/MS/MS. The Z scores on FAPAS PT samples tested were in the -1 to -1.7 range. Each test costs much less than a sample ran using LC/MS. This method may be a good alternative for laboratories to test for mycotoxins in feeds and feed ingredients that may not have access to an LC/MS or cannot afford to run mycotoxins by LC/MS. Dr. Sibanda asked for laboratories that would be willing to test this biochip array technology in a structured study. Randox would provide the instrument, 1 test kit and training free of charge to
participating laboratories. Several laboratories were interested in participating in the study. Kristi McCallum and Dr. Sibanda are coordinating the study to take place March-June. Samples for this study will be previously analyzed AAFCO PT mycotoxin samples. Results of the study will be given at the 2019 AAFCO Annual Meeting.

f. Robert Sheridan reported that Romer/UK did a 31 lab validation for the LC/MS method that was published in 2015. It is on the AAFCO Feed Bin for download by laboratories interested. Robert Sheridan reported that he is looking in to the use of internal standards to improve the method. The mycotoxin WG is working on Best Practices for Mycotoxins by LC/MS.

g. Best practices for fiber and protein – Larry Novotny gave an update that the best practices guidance documents are available on the AAFCO website.

h. Laboratory Sampling – Nancy Thiex

Nancy Thiex reported that a small pilot study would be taking place on a sample preparation PT. Twelve laboratories are needed for this study. Please contact Nancy Thiex or Kristi McCallum if your laboratory is interested in participating.

7) Quality Assurance Subcommittee – Srinu Chigurupati, Sharon Webb, Teresa Grant, John Szpylka and Kristi McCallum

John Szpylka gave a very informative presentation on the New Structure and Components of ISO/IEC 17025:2017 Standard. Dr. Szpylka presented the major difference between the 2005 versus the new 2017 standard. The broad picture is the same (reliable, defensible data), but the approach is different. In the 2005 standard, laboratories had to have fully documented, clearly defined procedures. The new 2017 standard is more flexible, less focused on the process outcome. If you were accredited to 2005, then 80% of the system elements comply with the new standard.

8) Report on the AOAC Expert Review Panel on Sugars & Fructans – Nancy Thiex and John Szpylka

Nancy Thiex reported that a method was accepted as Official First Action (AOAC Method 2018.07) and the paper was published in JAOC with supporting validation data. The method is based on 999.03 for Fructans Assay. Labs need to volunteer for the multi-lab two-year study validation. For the sugar profile, 3 methods were submitted to the call for methods, one of which was accepted as Official First Action. The sugar method was submitted with 130 pages of validation data (very thorough!) for a wide range of feed/food materials. The sugar method should appear soon in the OMA.

9) Laboratory Needs Survey Results – Nancy Thiex

The Laboratory Needs Survey was vetted and edited by the AAFCO Board of directors and Executive director. It was sent to the Feed Program with 36 responding and to the laboratory programs with 43 responding. It captured current capabilities, testing contracted and future testing needs as a result of FSMA and PCAF. Commonalities between the labs and feed program for method needs were the following:

- Multi-analyte mycotoxins, vet drug residues, microbiological pathogens, vet drug formulation levels, multi-analyte pesticides and fat-soluble vitamins. Discrepancies between the Feed Program and the laboratory were reported as the Feed Program reporting the following:
  - Prohibited materials, low level selenium, water soluble vitamins, amino acid profiles, dioxins and speciated metals.

10) Method Needs Discussion – All Members and Advisors

Several members suggested that we need to review and update the current method needs statements posted on the AAFCO website. Method Needs Revisions/Ideas Discussed:

- Need to update the website to include method reference on completed methods
- Archive Carbadox, Bacintracinc, MGA and Pyrantel tartrate from the website.
- Need to look at toxicity levels, not just LODs for some methods, like residue drugs. It may be helpful to look at the levels that Canada uses.
- Survey VFD Rules – Before and After (Aaron Price can resend the old survey and also look at the survey sent by the PT program) to get an idea of what laboratories are running or asked to run.
- Laboratories are not just seeing a dramatic decrease of VFD drug samples but they are seeing an increase in non-VFD drugs such as Lasalocid, Monensin and Decoquinate.
- Dramatic decrease in CTC, OTC and Tylosin (VFD) across all state laboratories.
- APHL is drafting a survey of the feed laboratories to find out what their capabilities are.
- Consider getting some methods through other means than AOAC because of expense and time.
11) Needs for Best Practices Guidelines – Lawrence Novotny
   Moisture is being worked on. Nitrogen Factors, Fat, Fiber and Phosphorus Best Practice Guidances
   are finished and posted. Work on Minerals is underway by the Multi-element Metals Working Group.

12) Update 2014 Quality Assurance/Quality Control Guidelines for Feed Laboratories to Comply with
    ISO17025:2017 Standard
   A working group was formed to review and update the 2014 Quality Assurance/Quality Control
   Guidelines for Feed Laboratories. This new working group will review and update these guidelines
   to ensure the AAFCO QA/QC guidelines are in line with the new ISO17025:2017 standard to
   provide consistent, relevant guidelines to feed testing laboratories. The working group members are:
   Kristi McCallum, Sharon Webb, Gale Hagood, Sarah Dedonder, John Szpylka and Sally Flowers.

13) Adjournment

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<tr>
<td>K McCallum</td>
<td>2</td>
<td>Update committee roster based on recent changes and submit to</td>
<td>Submitted February 4,</td>
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<tr>
<td>S Webb</td>
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<td>AAFCO BOD</td>
<td>2019</td>
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<tr>
<td>K McCallum</td>
<td>11</td>
<td>Initiate contact with and organize working group objectives, priorities</td>
<td>Late Spring 2019</td>
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<tr>
<td>S Webb</td>
<td></td>
<td>and deadlines with members</td>
<td></td>
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<tr>
<td>Dorota Inerowicz</td>
<td>10</td>
<td>Get updated list of Methods Needs &amp; Fitness for Purpose Statements to</td>
<td>End of 2019</td>
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<td>K McCallum</td>
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<td>Jennifer Roland for AAFCO Website</td>
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<tr>
<td>A Price</td>
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Appendix

Attachments:
For a list of presentations given during this meeting, please see the AAFCO Laboratory Methods and Services committee website at the following link:
https://www.aafco.org/Regulatory/Committees/Laboratory-Methods-and-Services#minutes

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<td>Jenny</td>
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<td><a href="mailto:jbailie@milkspecialties.com">jbailie@milkspecialties.com</a></td>
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<td>Kristen</td>
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<td><a href="mailto:kristen.gilbert@agriculture.ny.gov">kristen.gilbert@agriculture.ny.gov</a></td>
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Model Bills and Regulations Committee Report
2019 AAFCO Midyear Meeting
January 21, Savannah, Georgia

Committee Recommendations

1) The Model Bills and Regulations Committee recommends that the following revisions be made to the Statements for Uniform Interpretation and Policy (SUIP) of Chapter 5 in the AAFCO Official Publication, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
   a. Add the following preamble to the SUIP section of the AAFCO Official Publication:
      This section includes Statements for Uniform Interpretation and Policy (SUIP) of the AAFCO Model Bills and Regulations. In general, AAFCO SUIPs do not establish legally enforceable responsibilities. Instead, these SUIPs describe AAFCO’s current thinking on a topic and should be viewed only as recommendations, in the absence of specific regulatory or statutory requirements. There are many pathways for statements to be published in Chapter 5, one of which is by recommendation from the AAFCO Model Bills and Regulations Committee to the AAFCO Board of Directors as a means of further clarification and interpretation. These statements should be reviewed every two years on odd number years at the AAFCO Mid-Year Meeting by a subgroup of the Model Bills and Regulations Committee to determine relevancy and applicability, then deleted or moved to the appropriate section of the Official Publication when such actions are warranted.
   b. Delete SUIP 10 – Brand Names
   c. Move SUIP 15 – Raw Leather Residue to Regulation 10 – Adulterant of the Model Regulations under the Model Bill by adding the following language:
      10(a)(6) Raw leather residue from tanning or leather manufacturing.
      Delete SUIP 15 if Regulation 10(a)(6) is approved by the AAFCO membership.
   d. The Model Bill and Regulations Committee accepts the SUIP Workgroup recommendation to add Regulation 8(b) language to the Model Regulations under the Model Bill (as indicated below) based on SUIP 19 regarding Feeding or Use Directions for Feeds Containing High Levels of Non-Protein Sources of Nitrogen and moving current Regulation 8(b) and (c) items to Regulation 8(c) and (d) respectively.
      8(b) Feeding or use directions for those feeds in which more than 50% of the protein content is derived from non-protein nitrogen sources should include recommendations as to providing adequate supplies of drinking water, sources of energy, forages being fed, minerals, adaptation (“warm-up”) periods and stress conditions when necessary.
      Delete SUIP 19 if new Regulation 8(b) is approved by the AAFCO membership.

2) The Model Bills and Regulations Committee recommends Regulation 4 – Expression of Guarantees of the Model Regulations Under the Model Bill be revised as indicated in Attachment B, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

3) The Model Bills and Regulations Committee recommends Regulation PF4 – Expression of Guarantees of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill be revised as indicated in Attachment C, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

4) The Model Bills and Regulations Committee recommends Regulation PF9 – Statements of Calorie Content of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill be revised as indicated in Attachment C, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Association Actions: None

Committee Report
Model Bills and Regulations Committee Chairman Doug Lueders called the meeting to order at 1:30 p.m. on Jan. 21, 2019. He welcomed committee members, industry advisers and guests who were present, and reviewed the agenda.
In addition to Chairman Lueders, committee members participating in the meeting were: Ken Bowers (Kansas), George Ferguson (North Carolina), Robert Geiger (Indiana), Kristen Green (Kentucky), Richard Ten Eyck (Oregon), and Scott Ziehr (Colorado).
Industry advisers participating were: Meghan Dicks and Steve Younker (AFIA), David Dzanis (APPA/ACVN), Emily Helmes (ETA), Catherine Alinovi (Next Generation Pet Food Manufacturers Association), Jan Campbell and David Fairfield (NGFA), and Angele Thompson and Pat Tovey (PFI).
AAFCO Executive Director Sue Hayes also participated in the meeting.

Minutes from Previous Committee Meeting
Chairman Lueders noted that minutes from the July 30, 2018 committee meeting conducted in Fort Lauderdale were previously approved, posted on the AAFCO website and Feed BIN, and were included in the 2019 AAFCO Midyear Meeting Committee Reports.

SUIP Working Group Report
The committee considered recommendations made by the Statements for Uniform Interpretation and Policy (SUIP) Work Group that had been established during the 2018 AAFCO Midyear Meeting to evaluate whether SUIPs listed on pages 233-235 of Chapter 5 in the 2019 AAFCO Official Publication should have a defined path to incorporation into the Model Bills or Regulations or eventually be deleted. Members of the SUIP Work Group are Catherine Alinovi, chair (NGPFMA), Lizette Beckman (Feed Labeling Committee), Emily Bulian Helmes (ETA), Padma Pillai (FDA), Austin Therrell (Feed and Feed Ingredient Manufacturing Committee), Angele Thompson (PFI) and Steve Younker (AFIA).
The SUIP Working Group recommendations and committee actions are indicated in Attachment A.

Old Business
1) Proposed Revisions to Regulation 4 – Expression of Guarantees
   The committee considered proposed revisions to Regulation 4 – Expression of Guarantees of the Model Regulations Under the Model Bill as indicated in Attachment B.
   Ken Bowers moved that the proposed revisions to Regulation 4 be accepted and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
   Scott Ziehr seconded the motion. The committee approved the motion.

New Business
The committee proceeded to consider new business.
1) Proposed Revisions to PF4 – Expression of Guarantees
   The committee considered proposed revisions to Regulation PF4 of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as indicated in Attachment C.
   Kristen Green moved that the proposed revisions to Regulation PF4 be accepted and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
   Robert Geiger seconded the motion. The committee approved the motion.
2) Proposed Revisions to PF9 – Statements of Calorie Content
   The committee considered proposed revisions to Regulation PF9 of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as indicated in Attachment C.
   Kristen Green moved that the proposed revisions to Regulation PF9 be accepted and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
   Robert Geiger seconded the motion. The committee approved the motion.
3) Proposed Revisions to Section 7. Adulteration.
   The committee considered the proposed revisions to Section 7 – Adulteration of the Model Bill as indicated in Attachment D. The committee tabled action on the proposed revisions in order to get input from FDA. The MBRC will consider the language again at the committee’s next meeting.

Adjournment
Mr. Lueders asked whether there was any other business to be considered by the committee. Given that none was identified, the committee meeting was adjourned at 2:30 p.m. On behalf of the Model Bills and Regulations Committee, I respectfully submit this report and request acceptance of the report and recommendations by the AAFCO Board of Directors and the Association membership.
Attachment A: Model Bills and Regulations Committee
Attachment for January 21, 2019, Meeting
Statements for Uniform Interpretation and Policy (SUIP) Working Group Report to the Model Bill and Regulations Committee

The SUIP Working Group makes the following recommendations to the MBRC:

1) Recommends adding the following preamble – giving purpose and process to the SUIP section, as well as a timeline for periodic review of these policy statements.

   **Introduction/Preamble**
   This section includes Statements for Uniform Interpretation and Policy (SUIP) of the AAFCO Model Bills and Regulations. In general, AAFCO SUIPs do not establish legally enforceable responsibilities. Instead, these SUIPs describe AAFCO’s current thinking on a topic and should be viewed only as recommendations, in the absence of specific regulatory or statutory requirements. There are many pathways for statements to be published in Chapter 5, one of which is by recommendation from the AAFCO Model Bills and Regulations Committee to the AAFCO Board of Directors as a means of further clarification and interpretation. These statements should be reviewed every two years on odd number years at the AAFCO Mid-Year Meeting by a subgroup of the Model Bills and Regulations Committee to determine relevancy and applicability, then deleted or moved to the appropriate section of the Official Publication when such actions are warranted.

   **Committee Action:**
   Moved to Accept: Ken Bowers
   Seconded: Robert Geiger
   Motion: Passed

2) Recommends separating active statements from deleted statements, keeping each part in chronological sequence. This provides for historical information while making the section easier to read.

   **Committee Action:**
   Moved to Accept: Kristen Green
   Seconded: Ken Bowers
   Motion: Passed (editorial change)

3) Recommends moving SUIP 3 - Trade or Proprietary names - to the deleted list. The rationale is that AAFCO Ingredient Definitions Committee (IDC) has already incorporated this language into the update to the Guide for New Ingredient Submissions.

   **Committee Action:** Recommendation tabled until the IDC acts upon update to the Guide for New Ingredient Submissions.

4) Recommends moving SUIP 10 – Brand names – to deleted list. From a legal perspective, a feed control officer is neither in a position to determine nor manage this issue.

   **Committee Action:**
   Moved to Accept: Ken Bowers
   Seconded: Kristen Green
   Motion: Passed

5) Recommends adding language to the _____________ Stabilized feed term (as below) ensuring that the intent of SUIP 14 is included. Move SUIP 14 – Improved stability – to the deleted list if/when the new _____________ Stabilized feed term is approved by the AAFCO membership. This item to be submitted to the Feed Terms Investigator.

   _____________ Stabilized. When an ingredient which may deteriorate has been treated to improve stability, the expression “stabilized”, “stability improved” or “with improved stability” may appear following the ingredient in the statement of ingredients. (The process used is to be specified on the ingredient label.)

   **Committee Action:**
   Moved to Accept: Richard Ten Eyck
   Seconded: Kristen Green
   Motion: Passed

6) Recommends moving SUIP 15 – Raw leather residue from tanning or leather manufacturing – to the Adulterants [Model Bill, Regulation 10(a)(6)] list. Move SUIP 15 to the deleted SUIP list if/when Regulation 10(a)(6) is approved by the AAFCO membership.
10(a)(6) Raw leather residue from tanning or leather manufacturing.

Committee Action:
Moved to Accept: Ken Bowers
Seconded: Kristen Green
Motion: Passed

7) Recommends adding Regulation 6(h) language regarding Carriers (as below) to Regulation 6 of the Model Bill. Move SUIP 17 – Carriers – to the deleted SUIP list if/when 6(h) is approved by the AAFCO membership.

6(h) Each carrier shall be listed in the ingredient statement on the label unless it meets the criteria for an incidental ingredient [21 CFR 501.100(a)(3)].

Committee Action: Recommendation tabled and to be considered during subsequent Model Bill and Regulations Committee meeting.

8) Recommends the Model Bill and Regulations Committee consider adding Regulation 8(b) language (as below) regarding Feeding or Use Directions for Feeds Containing High Levels of Non-Protein Sources of Nitrogen and moving current Regulation 8(b) and (c) items to Regulation 8(c) and (d) respectively.

Move SUIP 19 – Feeding or Use Directions for Feeds Containing High Levels of Non-Protein Sources of Nitrogen – to the deleted SUIP list if/when the new 8(b) is approved by the AAFCO membership.

8(b) Feeding or use directions for those feeds in which more than 50% of the protein content is derived from non-protein nitrogen sources should include recommendations as to providing adequate supplies of drinking water, sources of energy, forages being fed, minerals, adaptation ("warm-up") periods and stress conditions when necessary.

Committee Action:
Moved to Accept: George Ferguson
Seconded: Ken Bowers
Motion: Passed

9) Recommends adding the adoption date for SUIP 23 – Registration and Labeling of Silage Additive Products – to the language: (Adopted 1979). Additionally, in the first sentence of SUIP 23, where a reference to "Commercial Feed" wrongly cited as Section 3(d) of the Model Bill, and therefore the WG recommends this should be corrected to state Section 3(b).

Committee Action:
Moved to Accept: Kristen Green
Seconded: George Ferguson
Motion: Passed (editorial change)

10) Recommends moving SUIP 27 to the AAFCO Pet Food Committee for their consideration for inclusion in the Pet Food Regulation as a new PF12 (as below). Move SUIP 27 – Chews, Bones, and Toys for Pets and Specialty Pets – to the deleted list if/when PF12 is approved by the AAFCO membership.

Regulation PF12. Chews, Bones and Toys for Pets or Specialty Pets
Chews, bones and toys for pets or specialty pets are exempt from the requirements of state registration or licensing as long as the following are met:

(a) Product labeling or advertising may not:

(1) Make claims that:
The product is intended for use as an animal food (such as any nutritional value ("digestible" or "high protein") or structure/function (? Provide example here);

(2) Provide a:
   (i) Guaranteed analysis; or
   (ii) Calorie Statement

(3) Contain the word ‘treat’ or ‘snack’.

(b) Product labeling or advertising may:

(1) Make dental claims by mechanical action;
(2) Contain animal food-acceptable flavors or color additives;
(3) Contain animal food-acceptable binders as long as the purpose is to hold the product together and at a "low inclusion rate" (to be defined).

Committee Action:
Moved to Accept: Robert Geiger
Seconded: Ken Bowers
Motion: Passed

11) Recommends to the MBRC that the working group be disbanded as the 2018-2019 mission has been completed.

Chairman Lueders did not disband workgroup due to pending actions required on recommendations. (SUIP #3 and SUIP #17)
Recommended edits

1) Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees
Add: (c) (8) Products labeled with a quantity statement (e.g. tablets, capsules, granules, or liquid) may state vitamin guarantees in milligrams per unit (e.g. tablets, capsules, granules, or liquids) consistent with the quantity statement and directions for use.

2) Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees
Revise (g) as follows:
(g) Guarantees for microorganisms shall be stated in colony forming units per gram (CFU/g) when directions are for using the product in grams, or in colony forming units per pound (CFU/lb.) when directions are for using the product in pounds. A parenthetical statement following the guarantee shall list each species in order of predominance.
(g) Guarantees for microorganisms shall list each genus and species in order of predominance, and shall be stated and conform to the following:
(1) Colony forming units per gram (CFU/g) or per pound (CFU/lb.) consistent with the directions for use; or
(2) Colony forming units per pound (CFU/lb.) consistent with the directions for use; or
(23) CFU per unit (e.g., tablets, capsules, granules or liquids) consistent with directions for use and the quantity statement or weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.

3) Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees
Revise (h) as follows:
(h) Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for each type of enzymatic activity shall be specified, such as: Protease (Bacillus subtilis) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.
(h) Guarantees for enzymes shall be stated and conform to the following:
(1) Units of enzymatic activity per unit weight or volume consistent with the directions for use; or
(2) Enzymatic activity per unit (e.g., tablets, capsules, granules, or liquids) consistent with the directions for use and the quantity statement or weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.
(3) The source organism for each type of enzymatic activity shall be specified, such as: protease (Bacillus subtilis) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.
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:
Section 7. Adulteration
A commercial feed shall be deemed to be adulterated:

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to human or animal health; but in case the substance is not an added substance, such commercial feed shall not be considered adulterated under this subsection if the quantity of such substance in such commercial feed does not ordinarily render it injurious to human or animal health; or
Committee Recommendations
1) FASS proposal for the website update referred to the AAFCO board
2) PF4(g) revisions referred to Model Bill and Regulations Committee
3) Recommendation to strike PF3(e) referred to the Model Bill and Regulations Committee

Board Recommendations: Report accepted May 6, 2019.

Association Actions: None

Committee Participants
Members Present: Kristen Green (Chair, KY), Stan Cook (Vice-Chair, MO), Lizette Beckman (WA), James Embry (TX), George Ferguson (NC), Tiffany Leschishin (MN – call in), Jo Lynn Otero (NM), Jason Schmidt (LA), Katie Simpson (IN), Austin Therrell (SC), Sue Hays (AAFCO Executive Director), Caitlin Price (NC), Richard Ten Eyck (OR)
Advisors Present: Leah Wilkinson (AFIA), Pam Kaufman (AFIA), Louise Calderwood (AFIA), David Fairfield (NGFA), Dave Dzanis (APPA and ACVN), David Meeker (NRA), Angele Thompson (PFI), Pat Tovey (PFI), Bill Bookout (NASC), BC Henschen (AFTP), Cathy Alinovi (NGPFMA), Mollie Morrissette (PWA – call in); James Emerson (US Poultry), Ken Gilmurray (NRA), Jean Hofve (PWA – call in)

Committee Report
Meeting called to order at 3:00 pm EST
Announcements
Due to the government shutdown, FDA was not present at this meeting.
Kristen Green and Stan Cook are stepping down as PFC Chair and Vice-Chair following the meeting but will remain on the committee. Liz Beckman (WA) and Jason Schmidt (LA) have agreed to co-chair the committee moving forward.
AAFCO will be conducting a Pet Food Label Workshop at Pet Food Forum. This 1 day workshop will be held immediately after the forum ends on May 2.

Committee Activities
Motion to form a workgroup to organize and develop content for the Pet Food Labeling Workshop. Moved by Jason Schmidt (LA) and seconded by Austin Therrell (SC). Motion passed. Note: Katie Simpson will chair and Angele Thompson (PFI), Bill Bookout (NASC), BC Henschen (AFTP), Cathy Alinovi (NGPFMA), Austin Therrell (SC), Kristin Green (KY) and Stan Cook (MO) volunteered for the workgroup.
Motion to accept the FASS proposal for the website update as displayed. Moved by George Ferguson (NC) and seconded by Stan Cook (MO). Motion passed.
Motion to refer the FASS proposal and recommendation to the AAFCO board. Moved by Stan Cook (MO) and seconded by Austin Therrell (SC). Motion passed.
Motion to accept the PF3(e) workgroup report (Appendix II) and disband the workgroup. Moved by Austin Therrell (SC) and seconded by Stan Cook (MO). Motion passed.
Motion to refer recommendations to strike PF3(e) to the Model Bill and Regulations Committee. Moved by Austin Therrell (SC) and seconded by Stan Cook (MO). Motion passed.
Motion to accept the proposed revisions to PF4(g) (see Appendix IV) and refer them to the Model Bill and Regulations Committee. Moved by Austin Therrell (SC) and seconded by Stan Cook (MO). Motion passed.
Motion to form a workgroup to examine transforming SUIP 27 into PF12. Moved by Austin Therrell (SC) and seconded by Stan Cook (MO). Motion passed

Working Group Reports:
AAFCO Website Review – Lizette Beckman (WA).
The workgroup has been meeting regularly to update the AAFCO Talks Pet Food website and The Business of Pet Food website. The website is out-of-date and requires updated coding. FASS submitted
a proposal for this work that was displayed on the screen. The workgroup report was accepted and referred on to the board for their consideration.

Reviewing AAFCO Feeding Protocols Workgroup (to account for growth of large size dogs) – Angele Thompson (PFI), 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 I. Language will also need to be added to the protocols to refer back to the new PF7 requirements. The workgroup report was accepted and a full committee vote will be held in a couple of months.

PF(3)e – James Embry (TX)

The workgroup recommends removing PF3(e) from the AAFCO Model Bill (Appendix II). The workgroup report was accepted by the committee and will be referred to the Model Bill and Regulations Committee for their consideration.

PF3 ‘95% claims’ vs. ‘95% Product name rule’ – James Embry (TX)

The workgroup report and revised language was accepted by the committee. It will be referred to the Model Bill and Regulations Committee for their consideration.

Human Grade – Caitlin Price (NC)

The workgroup should be completed by the annual meeting and will present a report then.

PF4(g) Clarification – Bill Bookout (NASC), standing in for Dr. Bill Burkholder (FDA-CVM).

Bill Bookout provided some background on the topic. The recommendation and proposed language was displayed on the screen for the committee (Appendix II). It will be referred to the Model Bill and Regulations Committee for their consideration.

Discussion Items:

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. The workgroup has developed revised language (Appendix III) for consideration by the committee.

Pet Food Label Modernization Discussion – Sue Hays

The label modernization work 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).

This past December, PFC approved a proposal from Jan Johnson (Millennium Research Inc.) to conduct consumer market research on the concepts under development by the four PFLM teams. Teams worked closely with Jan to develop a screener, discussion guide and mock labels for this research. On the day of testing, 4 cohorts were assembled and a guided discussion of the label elements was held.

The results of the consumer market research were presented by each team lead during this meeting. The entire presentation is available to AAFCO members in the AAFCO Feed BIN. The floor was then opened for comments. Comments were generally positive in support of the consumer research and the workgroups efforts to date. One of the audience members recommended that AAFCO reach out to veterinarians. Sue Hays will follow up with a conference call with the team leads shortly after the meeting.

SUIP 27 Chews, Bones and Toys for Pets and Specialty Pets – Liz Beckman

Model Bill and Regulations Committee has requested that Pet Food Committee consider the inclusion of SUIP 27 into the model bill as PF12. A workgroup was formed, to be chaired by Liz Beckman (WA). George Ferguson (NC), Jason Schmidt (LA), Dave Dzanis (APPA & ACVN), Cathy Alinovi (NGPFMA) and Angele Thompson (PFI) have volunteered to participate in this workgroup. Anyone else interested in serving on this new workgroup should contact Liz Beckman.

Discussion of Veterinary Directed Therapeutic Pet Foods – Leah Wilkinson
This topic was not addressed during this session due to time restrictions. The PFC committee will consider whether to include it on the 2019 annual meeting agenda at a later date.
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 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

Proposed Revision to PF3(e)

**Background:**
PF3(e) has been in the AAFCO OP since the 70s or 80s. Subsequently, many changes have been made to PF(3), including the addition of the “with” regulation and further refinement of the flavor and other regulations in this section. In the 90’s there was a complete rework of the regulations although the working group was told not to change the intent of the regulations. The workgroup at that time was not sure of the intent of PF3(e), so they left it in the PF Regulations.

It appears that PF3(e) was meant as a catch all but has outlived its usefulness. Regulators and industry have yet to identify a situation under which it might be valid to use today.

**Workgroup Recommendations:**
1) Completely remove PF3(e)
2) Form a workgroup to:
   a. Recommend an appropriate title change for PF3, “Brand and Product Names”
      i. The inclusion rate requirements in this section extend beyond the Product Name to other parts of the label. For example, the “with” and “flavor” rules extend to the entire product label.
   b. Recommend named ingredient inclusion rate requirements not currently addressed in PF3.
Appendix III

Proposed Revision to PF3

Background

Methods used to calculate the ingredient inclusion rates for percentage claims on pet food labels has become inconsistent and possibly misleading to the consumer. This workgroup was formed to review current regulations and provide recommendations to the committee.

Workgroup Recommendations:

Regulation PF3. Brand and Product Names

(a) The names of the ingredient(s) used in the brand or product name shall appear in order of predominance by weight in the product.

(b) The words “100%,” or “All,” or words of similar designation shall not be used in the brand or product name of a pet food or specialty pet food if the product contains more than one ingredient, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments.

(c) An ingredient or combination of ingredients may form part of a brand or product name of a pet food or specialty pet food:

(1) When the named ingredient(s) constitutes at least 95% of the total weight of the product. Water sufficient for processing may be excluded when calculating the percentage; however, the named ingredients shall constitute at least 70% of the total product weight.

(2) When any named ingredient(s) constitutes at least 25% of the total weight of the product, provided that:

A. Water sufficient for processing may be excluded when calculating the percentage, however, the named ingredients shall constitute at least 10% of the total product weight; and

B. A descriptor is used with the ingredient name(s). This descriptor shall imply other ingredients are included in the product formula. Examples of descriptors include "dinner," "platter," "entree," "formula," and "recipe"; and

C. The descriptor shall be in the same size, style and color print as the ingredient name(s)

(3) When a combination of ingredients which are included in the brand or product name in accordance with Regulation PF3(c) provided that: meets all of the following:

A. Each named ingredient constitutes at least 3% of the total weight of the product the product weight, excluding water sufficient for processing; and

B. The names of the ingredients appear in the order of their respective predominance by weight in the product; and

B. All such ingredient names appear on the label in the same print size, font style and color print.

(d) When the name of any ingredient appears in the brand or product name of a pet food or specialty pet food or elsewhere on the product label and includes a descriptor such as "with" or similar designation, the named ingredient(s) must each constitute at least 3% of the product weight exclusive of water sufficient for processing. If the names of more than one ingredient are shown, they shall appear in their respective order of predominance by weight in the product. The 3% minimum level shall not apply to claims for nutrients, such as, but not limited to, vitamins, minerals, and fatty acids, as well as condiments. The word "with," or similar designation, and named ingredients shall be in the same size, style, color and case print and be of no greater size than:

Regulation PF5. Ingredients

(a) Each ingredient of a pet food or specialty pet food shall be listed in the ingredient statement as follows:

(1) The names of all ingredients in the ingredient statement shall be shown in letters or type of the same size, style and color;

(2) The ingredients shall be listed in descending order by their predominance by weight in non-quantitative terms;

(3) Ingredients shall be listed and identified by the name and definition established by AAFCO; and

(4) Any ingredient for which no name and definition have been so established shall be identified by the common or usual name of the ingredient.

(b) The ingredients "meat" or "meat by-products" shall be qualified to designate the animal from which the meat or meat by-products are derived unless the meat or meat by-products are derived from
cattle, swine, sheep, goats, or any combination thereof. For example, ingredients derived from
horses shall be listed as "horsemeat" or "horsemeat by-products."

(c) Brand or trade names shall not be used in the ingredient statement.
(d) A reference to the quality, nature, form, or other attribute of an ingredient shall be allowed when the
reference meets all of the following:
   (1) The designation is not false or misleading;
   (2) The ingredient imparts a distinctive characteristic to the pet food or specialty pet food because
       it possesses that attribute; and
   (3) A reference to quality or grade of the ingredient does not appear in the ingredient statement.

(e) Any reference to the percentage of an ingredient or combination of ingredients, by symbol or
word, in the brand or product name or elsewhere on a pet food or specialty food label, shall
be based in relation to the total weight of all ingredients in the product. The names of the
ingredient(s) shall appear in order of predominance by weight in the product. Where water
sufficient for processing is excluded from the declared percentage, the exclusion of water
shall be indicated in words juxtaposed to, the same style and color print and at least one-half
the print size of the stated percentage (e.g., "95% beef exclusive of water" or "95 percent
chicken and liver exclusive of water").
Appendix IV

Proposed Revision to PF4(g)

Background:

"Guarantees for crude protein, crude fat, and [emphasis added] crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish these substances or they are of minor significance relative to the primary purpose of the product, such as a mineral or vitamin supplement."

There is an opinion that PF4(g) should not be interpreted as an all or none requirement for an exclusion for the three guarantees. Rather PF4(g) should allow for exclusion of one, two, or all three of the guarantees according to whether the product is not intended to, and in fact does not, provide significant amounts of one or more of the three nutrients. Examples, a fat/fatty acid supplement composed of triglycerides for dogs does not provide much, if any, protein of crude fiber, so guarantees for fat and crude fiber should be allowed to be excluded from the guaranteed analysis on that product's label. Another example would be a fiber supplement for, say, specialty pets like rabbits or guinea pigs that is made from wheat stalks. The product would not be intended to, and would not, provide much crude fat or crude protein, and in my opinion should not be required to make guarantees for anything other than crude fiber and moisture.

So there are two possibilities here:

1. The regulation was poorly written and needs to be amended if my interpretation of its intent is correct; or,
2. The regulation was intended to be an all or none exemption from the requirement for crude protein, crude fat AND crude fiber guarantees.

A proposal in typical AFFCO editing format (strike through for deleting, underline for new words to be added) for clarifying PF4(g) is:

Recommendation:

PF4(g) CLARIFICATION - Regulation PF4 (g) Guarantees for crude protein, crude fat, and or crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish one or more of these substances or they one or more are of minor significance relative to the primary purpose of the product, such as a mineral or vitamin supplement.”
Committee Recommendations: None

Board Recommendations: Report accepted May 6, 2019

Association Actions: None

Committee Participants

Members Present: Brenda Snodgrass – OK (Committee Chair), Louise Ogden – Life Member (Vice Chair), Ametra Berry – GA, Teresa Grant – NC, Tai Ha – NE, Kristi McCallum – CO, Patty Lucas – FL, Michele Swarbrick – MN, Victoria Watkins – KS, Sharon Webb, Ph.D. – KY

Members Present by Phone: Nancy Thiex - Life Member

Advisors Present: Andy Crawford, PhD, Lars Reimann – AFIA, Ken Riter – PFI


Committee Report

B. Snodgrass (Chair) called the meeting to order at 1:32 pm January 21, 2019. Members, Advisors and audience members introduced themselves.

1) Program Leadership and Administrative Update

   a) Accreditation Update
      i) Our site visit has been delayed to mid-February, L. Ogden, PT Quality Manager, will travel to Able Labs for the site visit. The other team members will participate by phone and web session.

   b) Survey(s)
      i) Planned Survey for 2019 - Minerals Program
      ii) Unplanned surveys will be sent out if needed.
      iii) Please make sure your information is up-to-date in the DRW. If your state or company has SPAM filters blocking Survey Monkey, please let L. Ogden know and the survey can be sent by PDF or by a different route into Survey Monkey.

   c) Continuity of Operations
      i) Standing agenda item
      ii) Discussed the loss of a key person, Victoria Siegel former PT Program Manager & Committee Chair, in 2014. Program operations continued by N. Thiex (Acting Program Manager), A. Crawford (Statistician) B. Kieffer (Able Labs) and FASS Exec. Assistant to AAFCO & FASS IT Services.
      iii) L. Ogden is backing up N. Thiex for ordering (sourcing materials & procurement). Knowledge transfer is on-going and expected to continue for the next several months due to the complex nature of the process.

   d) Official Publication
      i) Analytical Variances (AVs)
(1) Discussion regarding limitations of currently published AVs which have not been revised or updated since at least 1990.

(2) Updated the OP with a new definition and corrected the method numbers

(3) AV paper to introduce the concept to the BOD. The work group formed at the Fort Lauderdale meeting will develop a paper to present to the BOD at the Annual Meeting in Louisville in August 2019.

(4) Office of the Texas State Chemist (OTSC) – plans to publish a paper with AV recommendations as presented by former grad student K. Fischer at the 2017 Annual AAFCO Meeting in Bellevue, WA (presentation slides posted with PTP Committee Minutes. OTSC requested data from the Program in CSV format because Fischer had finished graduate internship and OTSC did not have a copy of the data or statistical models used. Request was denied due to client confidentiality requirements. OTSC did eventually reach Fischer and obtained the data & statistical model(s).

(a) L. Reimann commented that OTSC’s recommended AV for Moisture/Loss on Drying relied on merged analyte data from methods that are known to produce statistically different results. Stakeholders should be aware that recommendations based on data merged in this fashion may not estimate analyte variance well.

(5) Working group: volunteers were determined at August meeting

(6) L. Reimann – Comment: Working Group needs to address with the sampling, standardize for industry and deal with the other steps, total error is not taken into account.

(7) K. Riter – Comment: Permissible Analytical Variation was the original intent of the AVs, however this original intent has been lost since many stakeholders (regulators & industry) are not applying the AVs as they were originally intended. Ex. Variance applied to label Guarantees to determine acceptance criteria for product (incorrect use), rather than Variance applied to test result to quantify measurement uncertainty to determine product compliance with label Guarantee (more correct use). In either case, the AVs do not include field and laboratory sampling errors.

(8) B. Snodgrass – Published AVs do not account for the matrix and should not be extrapolated to methods other than those listed in the tables. Laboratory Measurement Uncertainty does take matrices into account and are specific to the lab performing the testing and the analytical method used.

(9) Action Item: Program Manager and AV Working Group to develop internal report to AAFCO BOD on misuse of current AV tables, reasons to archive AV tables, and proposed replacement or guidance going forward.

2) Scheme Discussion – A. Crawford, L. Ogden and B. Snodgrass

a) Program Participation Report
 i) A. Crawford – Presented demographics and enrollments of participants for each scheme. Presentations “PTP 2018 Demographics” and “PT 2018 Participation”

b) Animal Feed Scheme
 i) L. Ogden led the discussion about Canned Pet Food Add-on Survey – Pet Food Ingredient – An email will be sent to those labs that expressed interest in receiving the add-on. PT Program Managers will work with A. Huyghues-Despointes, L. Reimann, and K. Riter to produce a canned dog food. Presentation “Survey for Canned Pet Food Add-On”. Action Item: Schedule coordinating conference call to explore options for acquisition of product in time for inclusion in 2020 Program Year.

c) Pet Food Scheme
 i) L. Ogden - Reviewed the Purpose of Scheme – Discussion of name change to Pet Food Ingredient Scheme to match scheme description. Committee approved change by unanimous vote. Presentation “Pet Food Scheme Purpose”. Action Item: Identify use of term system-wide and revise.

d) Minerals Scheme
 i) L. Ogden - Review the Purpose of Scheme – Discussion: Concentration of minerals added are based on concentrations of health/toxicological concern. – Attendees’ consensus that Mercury be no more than 2 parts per million (ppm). Since its inception,
the Minerals scheme has not exceeded this Mercury concentration. Mercury concentrations typically seen in regulatory programs are in parts per billion (ppb) rather than ppm. Presentation “Minerals Scheme Purpose”

3) Roundtable
   a) QRM purchases – Discussed the issues with purchasers of QRMs selecting participant price when their lab is not subscribing to any PT Program Scheme. **Action Item: Add program code to purchasing portal to authenticate whether a lab is a PT participant.**
   b) Question on knowing what to analyze for from commercial lab (i.e. amino acids) – Labs are able to choose which analyses to run. The Program has no requirements. Always a good idea to look for non-guaranteed analytes noted at the bottom of the PT Sample package label. Some labs run their entire testing suite, while others run just one or two analytes.
   c) Brief discussion on reissuing PT Reports for past Mycotoxin Contaminant rounds using the new AAFCO ffp Sigma (standard deviation); previous round reports will not be issued.
   d) Vitamin D – Four (4) state program officials have requested Vitamin D testing from their labs. Discussion on existing AOAC methods (one is a chicken bioassay, other uses an elaborate cleanup followed by LC determination.) Referred to LM&S and “Method Needs and Fitness for Purpose” criteria for Vitamin D methodology.

4) Adjournment
The meeting was adjourned at 4:04 P.M.

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<tr>
<th>Responsible</th>
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<tbody>
<tr>
<td>Committee Chair (Program Manager) &amp; AV WG Volunteers</td>
<td>Analytical Variations from Official Publication</td>
<td>Internal Report on AV misuse, obsolescence, and proposed replacement/guidance.</td>
<td>August 2019 / Pending</td>
</tr>
<tr>
<td>Committee Chair (Program Manager) and Vice-Chair (Program Quality Manager) &amp; Pet Food Industry Volunteers</td>
<td>Canned Pet Food Add-on</td>
<td>Source canned pet food material (dog) for inclusion in 2020 Program Year.</td>
<td>Coordinating call scheduled for April 10, 2019 / Pending</td>
</tr>
<tr>
<td>Committee Vice-chair (Program Quality Manager)</td>
<td>Scheme name change</td>
<td>Pet Food Scheme now named Pet Food Ingredient Scheme; identify locations for revising.</td>
<td>By May 1, 2019 / In progress</td>
</tr>
<tr>
<td>Committee Chair (Program Manager) &amp; FASS IT</td>
<td>QRM purchase price</td>
<td>Add program code to authenticate whether buyer’s lab is a participant for costs.</td>
<td>By May 1, 2019 / In progress</td>
</tr>
</tbody>
</table>
Committee Recommendations

- Report acceptance.
- Recommend:
  - Edits to Committee Advisors (2019 OP page 20) to read:
    It is the general practice of AAFCO to invite representatives of industry/trade associations and consumer groups to serve as advisors to the various AAFCO committees (including subcommittees), task forces or work groups during their open meetings. AAFCO invites these groups to nominate individuals to serve as committee advisors to be available to answer questions relevant to animal nutrition, analytical expertise, industry practices or other pertinent questions. Committee advisors do not serve as members of an AAFCO committee, task force or work group, nor do they have a vote in committee level any AAFCO deliberations. Committee advisors serve as a voting member of work groups and task forces supporting the respective committee. Any advisor who behaves in a manner disruptive to committee business is subject to removal as an advisor to the committee by the AAFCO President. The following committee advisors are currently available as a resource to the specified committee(s) or task force(s):
  - Edits to 2019 OP Page 102 and Procedures Manual page 14 to read:
    Advisors – May be requested by the President to represent industry/trade and consumers groups on AAFCO committees (including subcommittees), task forces, or working groups. Following all nominations, the President, with the advice of the Board, may accept representatives. The President may also choose to appoint other individuals. Generally, the President and Board take into consideration the individual’s demonstrated expertise on a given subject matter, their willingness to work with others in AAFCO, and their ability to facilitate the goals of the organization. These advisors will be called upon to answer questions relevant to animal nutrition, analytical expertise, industry practices, or other pertinent question. The number of advisors is usually limited by the size of the committee. In accordance with the By-Laws, advisors cannot vote at the committee level or above. Committee advisors do not serve as members of an AAFCO committee, nor do they have a vote in committee level deliberations. Committee advisors serve as a voting member of work groups and task forces supporting the respective committee. Any advisor who behaves in a manner disruptive to committee business is subject to removal as an advisor to the committee by the AAFCO President.
  - Edits to 2019 OP page 102 and Procedures manual page 14 to read:
    Subcommittees – Are made up of committee members and are "task/topic specific" (e.g., By-Laws Subcommittee of Strategic Affairs), used to divide responsibilities, or focus work, into more manageable groups of interest or expertise. Subcommittees do not generally have time restrictions imposed on their existence, and work tends to by a subset of the standing committee charge(s). Subcommittees may be created by a committee chair, as needed, to address the needs on the committee function. Advisors may be asked to provide input into the subcommittee makeup.

Board Recommendations: Report accepted May 6, 2019. Board accepted recommendations.

Association Actions: None

Committee Participants

Full Committee Members (Bold denotes those participating in the meeting.)
Linda Morrison, Stan Cook, Nancy Thiex, Dragan Momcilovic, Dan Danielson, Erin Bubb, Jamey Johnson, Doug Lueders, Shannon Jordre, Ken Bowers, Chad Linton, Mark LeBlanc, Jenny Murphy, Kent Kitade, Andy Gray, Ali Kashani (Board Liaison), Brenda Snodgrass, Richard Ten Eyck (BIN Coach), Robert Waltz, Vice Chairperson
By-Laws Sub-Committee
Committee Report

1) Sub-Committee: By-Laws Update (Ken)
   - Clarify member versus advisor participation on committees, task forces or work groups (OP, page 20)

   **Motion** - Bob, second - Erin, **passes**: to accept sub-Committee report

   **Motion** - Richard, second - Erin, **passes**: to accept recommended edits (Attachment A, Agenda, excluding *including subcommittees*) which was added in a subsequent motion) to Committee Advisors (2019 OP page 20) to read:

   It is the general practice of AAFCO to invite representatives of industry/trade associations and consumer groups to serve as advisors to the various AAFCO committees (*including subcommittees*), task forces or work groups during their open meetings. AAFCO invites these groups to nominate individuals to serve as committee advisors to be available to answer questions relevant to animal nutrition, analytical expertise, industry practices or other pertinent questions. Committee advisors do not serve as members of an AAFCO committee, task force or work group, nor do they have a vote in committee level any AAFCO deliberations. Committee advisors serve as a voting member of work groups and task forces supporting the respective committee. Any advisor who behaves in a manner disruptive to committee business is subject to removal as an advisor to the committee by the AAFCO President. The following committee advisors are currently available as a resource to the specified committee(s) or task force(s):

   **Motion** - Richard, second - Erin, **passes**: to accept recommended edits (Attachment B, Agenda, excluding *including subcommittees*) which was added in a subsequent motion) to 2019 OP Page 102 and Procedures Manual page 14 to read:

   **Advisors** – May be requested by the President to represent industry/trade and consumers groups on AAFCO committees (*including subcommittees*), task forces, or working groups. Following all nominations, the President, with the advice of the Board, may accept representatives. The President may also choose to appoint other individuals. Generally, the President and Board take into consideration the individual's demonstrated expertise on a given subject matter, their willingness to work with others in AAFCO, and their ability to facilitate the goals of the organization. These advisors will be called upon to answer questions relevant to animal nutrition, analytical expertise, industry practices, or other pertinent question. The number of advisors is usually limited by the size of the committee. In accordance with the By-Laws, advisors cannot vote at the committee level or above. Committee advisors do not serve as members of an AAFCO committee, nor do they have a vote in committee level deliberations. Committee advisors serve as a voting member of work groups and task forces supporting the respective committee. Any advisor who behaves in a manner disruptive to committee business is subject to removal as an advisor to the committee by the AAFCO President.

   **Motion** - Ken, second - Stan, **passes**: to accept recommended edits within Attachments A and B, above to insert: *(including subcommittees)*

   **Motion** - Bob, second - Erin, **passes**: to accept recommended edits (Attachment C, Agenda) to 2019 OP page 102 and Procedures manual page 14 to read:

   **Subcommittees** – Are made up of committee members and are “task/topic specific” (e.g., By-Laws Subcommittee of Strategic Affairs), used to divide responsibilities, or focus work, into more manageable groups of interest or expertise. Subcommittees do not generally have time restrictions imposed on their existence, and work tends to by a subset of the standing committee charge(s). Subcommittees may be created by a committee chair, as needed, to address the needs on the committee function. Advisors may be asked to provide input into the subcommittee makeup.

   **AAFDCO Conflict of Interest (COI) sign off for Chairs and Investigators**

   **Motion** - Bob, second - Erin, **motion withdrawn**: to accept recommended edits (Attachment D, Agenda) to Procedures manual page 8 to read:

   Conflict of Interest
The members of the Board and all AAFCO members/volunteers have an obligation to conduct business within guidelines that prohibit actual or potential conflicts of interest. AAFCO Board members, employees, Committee Chairs, and AAFCO Investigators will sign the Association of American Feed Control Officials Conflict of Interest Disclosure Statement annually that affirms such person

- Has received a copy of the conflict of interest policy,
- Has read and understands the policy, and
- Has agreed to comply with the policy.

- Understands the organization is charitable and in order to maintain its federal tax exemption it must engage primarily in activities that accomplish one or more of its tax-exempt purposes.

The Subcommittee feels it would be prudent for Committee leadership (chairs, co-chairs and vice-chairs) and Investigators to sign the COI in addition to the Board. Suggestion that individual states that adjust their COE to include AAFCO could be used in lieu of the AAFCO COI. Committee commented that COI is different when acting on behalf of AAFCO versus conducting regulatory activities for a state. As well, this places additional work on AAFCO, including legal review.

**Action:** By-Laws will continue deliberation to finalize COI recommendation.

**Motion** to add “contractors” to those who have to sign COI - Stan, Richard **seconds, motion tabled** until next meeting.

- Attachment D, also needs to consider how contractors and contractual employees should be covered with COI provisions. AAFCO currently has a number of contractual agreements. The alternative discussed was to ensure a uniform disclosure statement in contracts in lieu. Group to include Susan.

- The By-Laws currently contains provisions that a quorum for Board deliberations is 3, which was based on 7 Board members. Given there are 9 now, the suggestion is to change from 3 to 5. Could also use at least 50% for quorum and majority for voting purposes. Similarly, quorum and voting provisions should be considered for the Board Executive. Instead of majority, also consider “simple majority”.

**Action:** Subcommittee to review and return with language for committee consideration.

- There was an additional suggestion that By-Laws consider using “appointed” advisors instead of “committee” advisor in procedures manual references and in OP.

2) Strategic Planning 2017-20

- Key progress has been recorded in Attachment 1: Strategic Plan 2017-2020, updates from Midyear 2019. Edits are in italic–bold text.
- The Board decided to begin to action the fourth priority goal from the table. Additionally a fifth priority goal was selected. Key activities for both were drafted by the Board and Chairs at the beginning of Midyear and are expected to finalized within the next month or so for distribution to relevant chairs to incorporate in committee activities.

3) Strategic Planning 2021-24

- The Board will begin revising the Strategic Plan Goals for 2021-24, at the fall meeting October 2019. Priority goals will also be identified.
- Activities, deliverables and responsibilities will be developed by the Board/Chairs at Midyear 2020.
- Priority goals and activities will be finalized for presentation for member acceptance at Annual 2020 so implementation can begin in 2021.

4) Vision/Mission Discussion update: Stan

- Completed at Fall 2018 Board meeting and accepted by the membership Midyear 2019.

Committee financial needs from the 2019 budget:

- Legal costs associated with By-Laws work will be forwarded to the Board to be covered under their targeted funds.

Additional:

- Committee discussions identified the need for training on how to do Outreach planning which was forwarded to the Board for consideration (will likely part of Education and Training). The Committee report was circulated for a 2 week comment period prior to voting, finalization and submission to FASS for posting.
Motion: To accept the meeting minutes/report, subject to editorial revisions - Chad; Second - Richard; Motion carries.
## Action Item Table

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<tr>
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<tbody>
<tr>
<td>Linda/ Committee Chairs</td>
<td>Strategic Plan priorities 2017-2020</td>
<td>Update Feed BIN. Committee chairs asked to update as they make progress.</td>
<td>Update Feed BIN per Midyear 2019 meeting reporting.</td>
</tr>
<tr>
<td>Board</td>
<td>Vision/mission statement review</td>
<td>Recommendation to the Board to consider holding a session to review and update the vision/mission statement as appropriate, with a facilitator experienced in this area. The Board met the same afternoon and supported holding a Board session at Seminar.</td>
<td>Finalized at October 2018 Board session and members accepted January 2019. Complete</td>
</tr>
<tr>
<td>By-Laws (Ken)</td>
<td>OP, page 20 Committee advisors language</td>
<td>Review &quot;Committee advisors do not serve as members of an AAFCO committee, task force or work group, nor do they have a vote in any AAFCO deliberations.&quot; to better clarify member versus participation on committees, task forces or work groups.</td>
<td>January 2019 Complete</td>
</tr>
<tr>
<td>By-Laws (Ken)</td>
<td>AAFCO Conflict of Interest (COI) sign off for Chairs and Investigators</td>
<td>Follow up: 1. Suggestion that individual states that adjust their COE to include AAFCO could be used in lieu of the AAFCO COI. Committee commented that COI is different when acting on behalf of AAFCO versus conducting regulatory activities for a state. As well, this places additional work on AAFCO, including legal review. By-Laws will continue deliberation. 2. Consider how contractors and contractual employees should be covered with COI provisions. AAFCO currently has a number of contractual agreements. Alternative is to ensure uniform disclosure statement in contracts in lieu. Group to include Susan.</td>
<td>August 2019</td>
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<tr>
<td>By-Laws (Ken)</td>
<td>Evaluate adjusting Board and Board Executive quorum/voting provisions</td>
<td>Review and return with language for committee consideration. Instead of majority, also consider &quot;simple majority&quot;.</td>
<td>August 2019</td>
</tr>
<tr>
<td>By-Laws (Ken)</td>
<td>Advisor language</td>
<td>Consider using &quot;appointed&quot; advisors instead of “committee” advisor in procedures manual references and in OP.</td>
<td>August 2019</td>
</tr>
<tr>
<td>Chair (Linda)</td>
<td>Committee discussions identified the need for training on how to do Outreach planning which was forwarded to the Board for consideration (will likely part of Education and Training).</td>
<td></td>
<td>Complete Board meeting January 23 and via Committee report.</td>
</tr>
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</table>
Appendix 1: Strategic Planning 2017–2020

Updated Goals 2017-2020

Strengthen organizational infrastructure
1. Manage and pursue revenue generating opportunities to maintain a sound financial base
2*** Pursue hiring executive support
3. Evaluate the effectiveness of the organization of AAFCO for continuous improvement
4. Provide leadership skills enhancement to develop and support AAFCO leaders
5. Optimize resource sharing opportunities
6. Enhance internal communication efficiencies and documentation within the association

Promote and enhance membership participation (internal)
7** Identify opportunities to increase member agency participation
8* Develop and provide professional development and technical training opportunities in support of feed programs
9* Enhance collaboration, communication and cooperation among regulatory agencies
10** Communicate and document AAFCO benefits and accomplishments

Emphasize feed and food safety
11. Continue developing member feed safety programs in alignment with FSMA and IFSS
12* Promote and support laboratory technology, methods, quality systems and collaboration

Vitalize partnerships with external stakeholders
13. Identify key stakeholders and working partners and common goals
14. Develop and maintain professional relationships with stakeholders and affiliated organizations

Strengthen international presence
15. Participate in relevant international meetings as resources permit
16. Invite International attendees to association activities
17. Provide a forum for international discussions on feed safety

*Top 3 priority goals
**Adequate progress was made on the first three, Goal 7 was initially identified as a fourth goal. The Board/Chairs subsequently added goal 10 October 2018–January 2019.
***Board priority action completed February 2018

Top 3 Priority Goals [FSMA TF activities integrated]

Updated text: italics/bold

Group 1: Mark Leblanc, Nancy Thiex, Ken Bowers, Meagan Davis, Dave Dressler

<table>
<thead>
<tr>
<th>Outcome</th>
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<th>Resources Needed</th>
<th>Timeline</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategy: Emphasize feed and food safety</td>
<td>Goal 12: Promote and support laboratory technology, methods, quality systems and collaboration</td>
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<tr>
<td>12.1 ** Fund AOAC method development and validation</td>
<td>Review list, remove those that aren’t relevant and prioritize the remainders. Identify resources to clear out analytical method needs backlog. Use existing strategy to identify method needs and prioritize them to continuously identify new needs (includes sample preparation)</td>
<td>Funds People</td>
<td>Methods needs survey completed (vitamins top). General priority list established. Vitamin and mineral workgroup in progress. Will require review of the methods list together with the hazard list to reprioritize. Need to identify resources to address backlog thereafter. 3-5 years to address backlog. August 2018: Sugars and fructans methods submitted for ERP at AOAC Aug. 2018. Vitamin and Mineral group still in progress and have some funding requests. FDA hazard guidance published January 23, 2018 that was insufficient for use. Hold pending hazard identification priority needs from 12.2.</td>
<td>LMSC with ISC support</td>
</tr>
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</table>

January 2019 Update:
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<tr>
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<tbody>
<tr>
<td>Combined with 12.3 (below)</td>
<td>Identify resources to perform additional (field) sample collection studies</td>
<td>Funds Equipment People</td>
<td>6 months to identify resources, 1 year to develop adequate protocols, 3 years to perform additional sample collection studies</td>
<td>1. ISC 2. LMSC</td>
</tr>
<tr>
<td>12.2 *** FSMA TF Item 3: priority setting and method development for contaminants/hazards (Combined with activity 9.2 in FFIMC WG)</td>
<td>Determine the contaminants, hazards, matrix and action levels to provide guidance to LMSC to inform method development. Integrate collaboratively into current LMSC priorities</td>
<td>Subject matter experts Funds Equipment</td>
<td>Alliance decided not to develop specific hazard guidance information. FDA assumed the work and published hazard guidance January 23, 2018. Next steps: complete method needs statement for LMSC. Up to 3 years for subsequent method development and validation (dependent on whether there is existing method). Bob Waltz is lead (including LMSC representation). August 2018: WG report - FDA guidance doesn’t contain a hazard specific list or action levels. Levels are critical to inform method development. Group will deliberate refocusing to identify what can be done (e.g. identify hazards from those suggested that are higher risk (toxicity/likelihood/impact) for which levels were used for regulatory action in prior incidents. Once guiding principles established, WG could transition to Sub-Committee to formally interface with LMSC to guide ongoing method needs (new or improved). January 2019 Update: Reinvigorating efforts.</td>
<td>FFIMC lead, EIC, ISC, IDC and LMSC</td>
</tr>
<tr>
<td>12.3 ** Validation of sampling methods</td>
<td>a) Perform field sampling method validation including sampling equipment and sample type. b) Establish sampling methods needs statement (Complete). Identify resources and develop adequate protocols to perform additional (field) sample collection studies.</td>
<td>Funds Equipment People Time</td>
<td>a) Activities: needs statement, RFP, contract, evaluation. Expect it will take 2 years. b) 6 months to establish sampling method needs statement. 6 months to identify resources 1 year to develop adequate protocols. 5 years to perform sampling method validation. Will flow from 1.1 Complete June 2018: Laboratory sampling guideline. Work group established (ISC and LMSC reps) to develop RFP. August 2018: RFP development in progress Starting with bag/probe sampling and several types of feed (particle sizes), analytes (e.g. protein, fat, fiber, Ca, P, Zn) under consideration need to include high, middle and low concentration as well as residue levels; will be consulting with Andy to address statistical validity. January 2019 Update: RFP approved by Board December 2018 and will be issued immediately after meeting with 60 day submission time.</td>
<td>ISC with LMSC support</td>
</tr>
<tr>
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<td>12.4 ** Collaboration between feed programs and laboratories that perform feed sample analysis and laboratory participation in AAFCO</td>
<td>Encourage participation and attendance by state labs by programs and encourage communication between labs/programs. Reach out to states to encourage laboratory participation (letter/email) in AAFCO.</td>
<td>Time People</td>
<td>November 2017: Letter from President (Ken) to state Directors/Commissioners. LMSC WG for outreach to states and federal laboratories that are not attending to work on increasing participation (especially AFRPS). August 2018: Ongoing effort by LMSC to develop initiatives to increase collaboration. Complete</td>
<td>AAFCO Board (President) LMSC EIC</td>
</tr>
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</table>

Group 2: Kristen* Green, Doug Lueders, Richard* Ten Eyck, Abe Brown, Stan Cook, Kelsey* Luebbe, Dave* Edwards, Erin* Bubb

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<tbody>
<tr>
<td><strong>9.1 Share compliance letters/ enforcement actions</strong></td>
<td><strong>Categorize Listserv topics to Feed BIN</strong> Being done as part of Food Shield (next item)</td>
<td>Administrative support Feed Bin</td>
<td>Archive Listserv is searchable. Categorization of active Listserv North Carolina also has a “mini” Listserv. It is informal but has national data. Membership for regulators is vetted in order to control access. Made a component of item below.</td>
<td>EIC to designate lead with FASS support - Jennifer</td>
</tr>
<tr>
<td><strong>9.1 Share compliance letters and enforcement actions (State and Federal)</strong></td>
<td></td>
<td>Guidance from subject matter experts</td>
<td>Call January 2018: Need searchable and secure IT solution; can be done fairly easily and quickly according to Food Shield IT expert. Confidential company info release could be an issue for states. August 2018: WG, Surveyed 700 members, 44 responded (6%) regarding needs. RFP developed and sent to 4 companies. Three responded with proposals. WG turnover necessitated change in members. George Ferguson, Erin Bubb and Richard Ten Eyck were to review the 3 proposals to make recommendation to EIC. January 2019 Update: Decided not to proceed with proposals. Board approved proceeding with Food Shield. Search features are being adjusted. Expect to be functional within 6 months.</td>
<td>EIC to designate lead with FASS support</td>
</tr>
<tr>
<td><strong>Share Division of Animal Feed letters Being done as part of Food Shield (item above)</strong></td>
<td></td>
<td></td>
<td>Made a component of item above.</td>
<td>EIC to designate lead and coordinate with FDA as necessary; FASS to support</td>
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<tr>
<td>Outcome</td>
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|         | Enforcement Issues Committee can pick up topics – coordinate and enhance committee action |                                                                 | No action due to lack of members willing to lead.  
*January 2019 Update: New leadership will be seeking ideas/suggestions for coordinated enforcement activities* | EIC to designate lead with FASS support – Members |
|         | Consider development of core report (similar to that of FDA) (frequency to be determined) | Listserv EIC IDC Any committee                       | *January 2019 Update: Action pending*        | EIC to designate lead with FASS support          |
| 9.2 *** | FSMA TF part of Item 3: Enforcement strategy for contaminants/hazards (Combined with activity 12.2 in FFIMC WG) | Determine the contaminants, hazards, matrix, action levels and enforcement strategy to provide guidance to LMSC to inform method development and priority setting. | Alliance decided not to develop specific hazard guidance information. FDA has assumed the activity: work product published January 23, 2018. | FFIMC lead, EIC, ISC, IDC and LMSC |
| 9.3 **  | Enhanced use of Feed Bin                                               | Identify activities to enhance use                    | Financial support                             | CIOC                                             |
| 9.4 **  | Coordinate with NASDA to develop a framework for state feed programs to deliver FSMA implementation | Provide data and information for NASDA grant application (AAFCO is subcontractor) and subject matter experts to support framework development. | AAFCO subject matter experts                  | NASDA-AAFCO-FDA FSMA Steering Committee (AAFCO reps: Linda, Ali, Bob W., Richard) |
| 9.5 *** | FSMA TF Item 1: Align Model Bill with needed authorities to implement FSMA | Make recommendations to align the Model Bill with needed authorities to implement FSMA | Complete January 2017                         | MBRC                                             |
| 9.6 *** | FSMA TF Item 2: Transition AAFCO GMPs to FSMA GMPs and convert AAFCO Model Feed Safety Program Plan to AFRPS | a. Develop a plan for states that have adopted AAFCO’s model GMPs to transition to FSMA GMPs.  
b. Remove Model Feed Safety Plan from OP (archive for historical reference) and use AFRPS instead | Complete August 2016                            | a. FFIMC with MBRC and PFC  
b. FFIMC with OP section editor and Feed Safety Coordinator |
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<tr>
<td>9.7 *** FSMA TF Item 6: Develop communication plan for AAFCO specific FSMA implementation activities</td>
<td>a. Develop an AAFCO Communication Plan to better inform</td>
<td>Framework developed (activities detailed in Feed BIN). 2017 initiated biannual newsletter. Draft plan developed February 2017 included both generic and ongoing activities. August 2018: Revising to make generic. Ongoing activities will be part of CIOC regular work. Expect to finalize for Board/member approval January 2019.</td>
<td></td>
<td>CIOC</td>
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<td>b. Develop a model communication plan for states to use for outreach to regulated parties</td>
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**January 2019 Update:**

<table>
<thead>
<tr>
<th>Group 3: Dan Danielson, Ali Kashani, Tim Weigner</th>
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<tbody>
<tr>
<td><strong>Outcome</strong></td>
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<tr>
<td>Strategy: Promote and enhance membership participation (internal) Goal 8: Develop and provide professional development and technical training opportunities in support of feed program**</td>
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<tr>
<td>Outcome</td>
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<tr>
<td><strong>Model training framework</strong></td>
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<tr>
<td><strong>FSMA TF Item 4:</strong> Develop training material not covered through Alliance work product</td>
</tr>
<tr>
<td><strong>FSMA TF Item 5:</strong> Review and revise the Feed Inspector’s Manual to support FSMA implementation</td>
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**Top 3 outcomes identified at May 2, 2016, planning session**

***FSMA TF outcomes integrated into 2017-2020 Strategic Plan***

**Participants:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Priority voting pre-meeting</th>
<th>Attended May 2, 2016</th>
<th>AAFCO role</th>
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<td>Mark LeBlanc</td>
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<td>Ken Bowers</td>
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<td>Board/Co-Chair</td>
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