

### Association of American Feed Control Officials

# 2017 AAFCO Midyear Meeting Committee Reports



January 15–18, 2017
Renaissance Mobile Riverview Plaza Hotel
Mobile, Alabama



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#### **Association Business Meeting Minutes**

2016 AAFCO Annual Meeting Marriott City Center Pittsburgh, Pennsylvania Monday, August 1, 2016 8:53 am – 9:15 am Grand Ballroom

- 2.) Ken Bowers states the AAFCO Board of Directors approved the following Committee Reports: Collaborative Check Sample, Current Issues and Outreach, Education and Training, Feed and Feed Ingredient Manufacturing, Ingredient Definitions, Inspection and Sampling, Laboratory Methods and Services, Model Bills and Regulations, Pet Food and Strategic Affairs; and recommends the same to the membership. I so move. Stan Cook Seconds. MOTION CARRIES
- 3.) Acceptance of Committee Recommendations: -Ken Bowers, President-Elect

#### **Ingredient Definitions 1-13:**

#### Report starts on page 28 of the Committee Report Book

- Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following modified feed term in the Official Publication and recommends the same to the membership. Dave Phillips Seconds. MOTION CARRIES
  - a. Feed Grade; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership. I so move. Feed Grade: Material that has been determined to be safe, functional and suitable for its intended use in animal food, is handled and labeled appropriately, and conforms to the Federal Food, Drug and Cosmetic Act unless otherwise expressly permitted by the appropriate state or federal agency (Suitable for use in animal feed).
- 2.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new feed terms in the Official Publication: and recommends the same to the membership
  - a. Suitable for use in animal feed: See Feed Grade. Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new feed terms in the Official Publication: and recommends the same to the membership. I so move. Jan Jarman Seconds. MOTION CARRIES
  - b. Human Grade; Ken Bowers states the AAFCO Board of Directors accepted the
    recommendation from the IDC to publish the following new feed terms in the Official
    Publication: and recommends the same to the membership. I so move. Dan
    Danielson Seconds. MOTION CARRIES

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

#### **Pet Food Committee**

#### Report starts on page 86 of the Committee Report Book

1.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the Pet Food Committee to publish the following guideline in the AAFCO OP following the guideline for natural claims. This guideline is not to be published in the OP without the corresponding Human Grade definition first being accepted by association membership and recommends the same to the membership. I so move. Dan Danielson Seconds. MOTION CARRIES

#### **Ingredient Definitions Continued**

- 3.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definitions as Tentative in the Official Publication and recommends the same to the membership and recommends the same to the membership. I so move. Bob Geiger Seconds. MOTION CARRIES
  - a. 30.1 Add a Beta-Mannanase from Dried *Bacillus subtilis* fermentation solubles; edit enzyme table to show:

Classification/ Name	Source organism	Typical substrate	Function	Current supported use
Beta-	Bacillus	distillers dried	(no change)	reduction of digesta
mannanase	subtilis, var.	grains with solubles		viscosity with swine diets

- 4.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following revised definitions as Tentative in the Official Publication:
  - a. 33.1 Animal Fat; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following revised definitions as Tentative in the Official Publication and recommends the same to the membership. I so move. Steve Gramlich Seconds. MOTION CARRIES
    - 33.1 Animal Fat is obtained from the tissues of mammals and/or poultry in commercial processes of rendering or extracting. It consists predominately of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2.5% unsaponifiable matter, and not more than 1% insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If the product bears a name descriptive of its' kind or origin; e.g. "beef", "pork", "poultry", it must correspond thereto. Rendered animal fat derived from only pork raw materials can be labeled as white grease. Rendered animal fat derived from only cattle raw materials can be labeled as beef tallow. Tallow containing greater than 0.15% insoluble impurities must be labeled with the BSE caution statement "do not feed to cattle or other ruminants." If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative".
  - b. Add "Lactobacillus animalis" to the organism list in definition 36.14; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following revised definitions as Tentative in the Official Publication and recommends the same to the membership. I so move Jan Jarman Seconds. MOTION CARRIES
    - 36.14 Direct-Fed Microorganisms-- The following microorganisms were reviewed by the Food and Drug Administration, Center for Veterinary Medicine and found to present no safety concerns when used in direct-fed microbial products: Aspergillus niger Aspergillus oryzae Bacillus coagulans Bacillus lentus Bacillus licheniformis Bacillus pumilus Bacillus subtilis Bacteroides amylophilus Bacteroides capillosus Bacteroides ruminocola Bacteroides suis Bifidobacterium adolescentis Bifidobacterium animalis Bifidobacterium bifidum Bifidobacterium infantis Bifidobacterium Iongum Bifidobacterium thermophilum \*Enterococcus cremoris \*Enterococcus diacetylactis \*Enterococcus faecium \*Enterococcus intermedius \*Enterococcus lactis \*Enterococcus thermophilus Lactobacillus acidophilus Lactobacillus brevis Lactobacillus buchneri (cattle only) Lactobacillus bulgaricus Lactobacillus casei Lactobacillus cellobiosus Lactobacillus curvatus Lactobacillus delbruekii Lactobacillus farciminis (swine only) Lactobacillus fermentum Lactobacillus helveticus Lactobacillus lactis Lactobacillus plantarum Lactobacillus reuteri Leuconostoc mesenteroides Megasphaera elsdenii (cattle only) Pediococcus acidilactici Pediococcus cerevisiae (damnosus) Pediococcus pentosaceus

Propionibacterium acidipropionici (cattle only) Propionibacterium freudenreichii Propionibacterium shermanii Rhodopseudomonas palustris (broiler chickens only) Saccharomyces cerevisiae Yeast (as defined elsewhere) (Proposed 1991, Adopted 1993, Amended 2001, 2004, 2006, 2011) \*Formerly cataloged as Streptococcus.

- 5.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Publish the following tentative definitions in the Official Publication:
  - a. T33.24 Used Cooking Oil, Feed Grade; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Publish the following tentative definitions in the Official Publication and recommends the same to the membership. I so move.

#### **Austin Therrell Seconds MOTION CARRIES**

T33.24 Used Cooking Oil, Feed Gradeis the product of used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils, collected from commercial human food facilities then heated to reduce moisture. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 1% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative".

b. T40.100 Recovered Retail Food; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Publish the following tentative definitions in the Official Publication and recommends the same to the membership. I so move.

#### **David Dressler Seconds. MOTION CARRIES**

T40.100 Recovered Retail Food- is composed of edible human food products safe and suitable for livestock feed that are collected from retail food establishments, domestic holding facilities, and domestic packing facilities. Permitted recovered retail foods are products from overstocks, lacking consumer acceptance, or beyond their sell-by date that include items such as bruised, cut, or overly-ripe produce (fruit and vegetables), bakery goods, eggs, and dairy products. It shall be safe and appropriately labeled for its intended use and shall be free of material harmful to animals. Materials excluded from this definition include pet foods, products containing: beef, lamb, pork, poultry, fish or shellfish. It must not contain packaging materials (e.g., plastics, glass, metal, string, styrofoam, cardboard, and similar materials), flowers, potted plants, or potting soil.

The recovered foods shall be collected and intermixed in secure holding containers to exclude unauthorized addition of trash, materials harmful to animals, or infestation and adulteration by pests. Egg and dairy products (and other products ordinarily held at refrigerator temperatures) must be kept in cold storage until the scheduled pick-up. To minimize spoilage, the recovered retail food shall be collected at least weekly, or more frequently if necessary. The establishment should have a sanitation plan in place, and the containers should be cleaned and sanitized as necessary. The collected material may be further processed or delivered as-is to an animal feeding facility. The product must be handled to preserve its safety and nutritional value.

c. T60.117 Dried Black Soldier Fly Larvae; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Publish the following tentative definitions in the Official Publication and recommends the same to the membership. I so move.

#### **Bob Geiger Seconds. MOTION CARRIES**

T60.117 Dried Black Soldier Fly Larvae is the dried larvae of the Black Soldier Fly, Hermetia illucens, that has been raised on a feedstock composed exclusively of feed grade materials. The ingredient must contain not less than 34% crude protein and 32% fat on an as-fed basis. The ingredient is dried by artificial means to no

more than 10% moisture. It is for use in salmonid fish feed as a source of protein and fat consistent with good feeding practices.

d. T87.35 Glucose syrup; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Publish the following tentative definitions in the Official Publication and recommends the same to the membership. I so move. **Bob Geiger Seconds. MOTION CARRIES** 

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 percent mass/mass (m/m) and reducing sugar content (dextrose equivalent), expressed as D-glucose, not less than 20.0 percent 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)

e. T33.21 Yellow Grease, Feed Grade; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Publish the following tentative definitions in the Official Publication and recommends the same to the membership. I so move.

#### Stan Cook Seconds. MOTION CARRIES

T33.21 Yellow Grease, Feed Grade is the rendered product from the tissues of mammals and/or poultry blended with used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 1% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." If the product contains tallow (from cattle) containing greater than 0.15% insoluble impurities then it must be labeled with the BSE caution statement "do not feed to cattle or other ruminants."

- 6.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the Note to add under the header in Section 40 in the Official Publication and recommends the same to the membership. I so move. **Alan Harrison Seconds. MOTION CARRIES** 
  - a. Section 40 Human Food By Products

NOTE: All ingredients must be feed grade. Firms should perform a safety assessment of materials that may be included in the offered feed ingredient, at the maximum use level (including cocoa products and non-nutritive sweeteners), to determine safety for the intended animal species and the safety of milk, meat, or eggs from animals consuming the ingredient. The safety assessment should be archived in the firm's files and provided to State or Federal Regulators upon request.

7.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the nine prior Section 60 ingredient definitions in Section 40 in the Official Publication using new Section 40 numbering and recommends the same to the membership. I so move. Erin Bubb

#### Seconds. MOTION CARRIES

- a. 60.96 Food processing waste
- b. 60.35 Sugar Food By-Product
- c. 60.93 Pasta Product
- d. 60.14 Cereal Food Fines
- e. 60.29 Gelatin By Products
- f. 60.34 Dried Beans
- g. 60.15 Dried Bakery Product
- h. 60.97 Restaurant Food waste
- i. 60.107 Mixed feed Nuts

- 8.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the modified definition in the Official Publication and recommends the same to the membership. I so move. **Steve Gramlich Seconds. MOTION CARRIES** 
  - a. 57.163 Selenium Yeast is a dried non-viable yeast, Saccharomyces cerevisiae, cultivated in a fed-batch fermentation which provides incremental amounts of cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed 2% of the total selenium content in the final selenium yeast product. Guaranteed organic selenium content must be declared on the product label. The additive selenium yeast may be added to:
    - 1) complete feeds for chickens, turkeys, swine, beef cattle, dairy cattle, bison, sheep, goats, llamas, alpacas, and horses at a level not to exceed 0.3 part per million of selenium, and to complete dog foods at a level not to exceed 0.333 part per million of selenium on a dry matter basis;
    - 2) feed supplements for limit feeding for beef cattle, bison and horses at a level not to exceed an intake of 3 milligrams per head per day:
    - 3) feed supplements for limit feeding for goats, llamas, and alpacas at a level not to exceed an intake of 0.7 milligrams per head per day:
    - 4) salt-mineral mixtures for free-choice feeding of beef cattle, bison, and horses up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day:
    - 5) salt-mineral mixtures for free-choice feeding for goats, llamas and alpacas up to 90 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 0.7 milligrams per head per day.

Selenium yeast 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. 21 CFR 573.920. 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 2002, Amended 2003, 2004, 2007\*, 2008, 2009, Adopted 2011).

- 9.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to replace the current definition of 87.1 Algae Meal with the official definition (from the color additive definition 21 CFR 73.275) in the OP of 87.1 Dried Algae Meal and recommends the same to the membership. I so move. **Michael Blume Seconds. MOTION CARRIES** 
  - a. 87.1 Algae Meal The color additive, algae meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:
     (a) Identity.

The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) Uses and restrictions.

The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

- (2) The quantity of the color additive incorporated in the feed is such that the finished feed:
  - (i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this definition; and
  - (ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(c) Labeling.

The label of the color additives and any premixes prepared therefrom shall bear in addition to the information required by 21 CFR 70.25.

- (1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.
- (2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this definition.
- (d) Exemption from certification.

Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 FR 73.275

- 10.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish new definition in the Official Publication and recommends the same to the membership. I so move. Austin Therrell Seconds. MOTION CARRIES
  - a. 87.36 Phaffia yeast The color additive, phaffia yeast, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:
     (a) Identity.
    - (1) The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast phaffia rhodozyma.
    - (2) Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.
    - (b) Specifications.

Phaffia yeast shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.

Lead (as Pb), not more than 5 parts per million.

Arsenic (as As), not more than 2 parts per million.

Mercury (as Hg), not more than 1 part per million.

Heavy metals, not more than 10 parts per million.

Astaxanthin, not less than 0.4 percent.

(c) Uses and restrictions.

Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

- (1) The color additive is used to enhance the pink to orange-red c olor of the flesh of salmonid fish.
- (2) The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.
- (d) Labeling requirements.
  - (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this definition.

- (2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
- (3) The presence of the color additive in salmonid fish that have been fed feeds containing phaffia yeast shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 21 CFR 101.100(a)(2).
- (e) Exemption from certification.

Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

FR 73.355 (adopted xxxxx)

11.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish official definitions for the following color additives in the Official Publication (Found on page 44 of the Committee Report Book) and recommends the same to the membership. I so move.

#### **Dave Phillips Seconds. MOTION CARRIES**

- a. 87.100 FD&C Blue No 1.
- b. 87.102 FD&C Blue No 2.
- c. 87.103 FD&C Green No 3.
- d. 87.104 FD&C Red No 3.
- e. 87.105 FD&C Red No 40.
- f. 87.106 FD&C Yellow No 6.
- g. 87.107 FD&C Yellow No 5.
- h. 87.110 Annatto Extract
- i. 87.112 Astaxanthin dimethyldisuccinate
- j. 87.114 Astaxanthin
- k. 87.116 Caramel
- I. 87.118 Carmine
- m. 87.120 Carrot Oil
- n. 87.122 Cochineal Extract
- o. 87.124 Corn Endosperm Oil
- p. 87.126 Dehydrated Beets
- q. 87.128 Fruit Juice
- r. 87.130 Haematococcus algae meal
- s. 87.132 Paprika Oleoresin
- t. 87.134 Paprika
- u. 87.136 Paracoccus pigment
- v. 87.138 Riboflavin
- w. 87.140 Saffron
- x. 87.142 Synthetic Iron Oxide
- y. 87.144 Tagetes (Aztec Marigold) Extract
- z. 87.145 Tagetes (Aztec Marigold) Meal
- aa. 87.146 Titanium Dioxide
- bb. 87.148 Toasted Partially Defatted Cooked Cottonseed Flour
- cc. 87.150 Tomato Lycopene Concentrate
- dd. 87.152 Tomato Lycopene Extract
- ee. 87.154 Turmeric Oleoresin
- ff. 87.155 Turmeric
- gg. 87.156 Ultramarine Blue
- hh. 87.158 Vegetable Juice
- ii. 87.160 β-Apo-8'-carotenal
- ii. 87.164 β-Carotene
- 12.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to renumber Section 73 ingredients of the OP according to the list in attachment A page 42 of the Committee Report Book, and leave the cross-reference to the old number there for 2 years and then remove cross-reference and recommends the same to the membership, I so move. Steve Gramlich Seconds. MOTION CARRIES

#### Section 73 edits: (page 430 2015 OP revision 1)

73.001 (old 73.1) Technical Additives table

#### Acidifiers (73.020-029)

73.020 (87.26) Ammonium Formate 73.025 (87.27) Formic Acid

#### Antimicrobial Agents (73.030-039)

73.030 (old 87.15) Formaldehyde

#### Anticaking Agents (73.040-060)

73.040 (old 87.12) Bentonite

73.042 (old 87.28) Castor Oil

73.044 (old 87.17) Perlite

73.046 (old 87.3) Silicon Dioxide

73.048 (old 87.13) Sodium Bentonite

73.050 (old 87.4) Verxite (incl flake and grits)

#### Binders (73.106-130)

73.107 (old 87.2) Lignin Sulfonate

T73.109 (old T73.300) Sodium salts of Fatty Acids .... Stays in tentative section ....

T73.111 (old T73.301) Potassium Salts of Fatty Acids .... Stays in tentative section ....

#### **Biofuel Production (73.090-104)**

73.100 Yeast for Production of Distillers Products

#### Emulsifiers (73.200-220)

73.200 Xanthan gum

#### Floculants (73.221-240)

73.221 (old 87.16) Chitosan

73.223 (old 87.21) Kraft Lignin

#### Nutritional Diluents (73.241-249)

73.241 (old 87.18) Reed-Sedge Peat

#### Pelleting Aids (73.300-340)

73.305 (old 87.24) Hide Glue

73.307 (old 87.6) Rice By-Products Fractions

73.309 (old 87.19) Urea Formaldehyde Condensation Polymer

73.105 Sodium Hydroxide Lignin Dehydrated

#### **Surfactants (73.341-360)**

73.341 (old 87.10) Poloxalene

#### Thickening agents (73.370-390)

73.370 (old 87.23) Cassia Gum

- 13.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the modified definition in the Official Publication and recommends the same to the membership, I so move. Bob Geiger Seconds. MOTION CARRIES
  - a. 60.73- Salts of Volatile Fatty Acids- Is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids/isovaleric, 2-methylbutyric and n-valeric. The contained ammonium or calcium salts of volatile fatty acids shall conform to the specifications in 21 CFR 573.914. It is used as a source of energy in dairy cattle feed. The label of the product shall bear adequate

directions for use including statements expressing maximum use levels: For ammonium salts of volatile fatty acids—not to exceed 120 grams per head per day Not to exceed 160 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy; For calcium salts of volatile fatty acids—Not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy. (Proposed 1985, Adopted 1986, Amended xxxx) Reg 21 CFR 573.914

#### Model Bill 1:

#### Report starts on page 79 of the Committee Report Book

1.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from The Model Bills and Regulations Committee recommends that revisions proposed by the Pet Food Committee to Model Pet Food Regulation 9(a) as stated in Attachment B conform to the Model Bill and Regulations and recommends the same to the membership. I so move. Bob Geiger Seconds. MOTION CARRIES

#### **Strategic Affairs Committee:**

#### Report starts on page 96 of the Committee Report Book

- 1.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the Strategic Affairs Committee to change to By-Laws provisions for quorum for voting by adding: ARTICLE VI: Section 3. "Voting. For committee work, at least one-half of the members of any committee are required to be present or represented by proxy (in person or by phone) to conduct a vote. A majority of those voting must vote in the affirmative for the motion to pass. Only the Chair or Co-Chairs/Vice-Chairs may preside over a vote." and recommends the same to the membership. I so move. Wayne Nelson Seconds. MOTION CARRIES
- 2.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the Strategic Affairs Committee to change to By-Laws provisions for member voting by substituting: ARTICLE II
  - Section 2. "Voting. Each State, District or Territory engaged in regulating animal feed or livestock remedies in the United States of America and each Federal Agency primarily responsible for regulating animal feed or livestock remedies in their country, and paying annual dues as prescribed in Article II Section 4 of these By-Laws, shall designate one member as the voting representative of that State or Agency." and recommends the same to the membership. I so move. **Wayne Nelson Seconds. MOTION CARRIES**
- 3.) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the Strategic Affairs Committee to accept the new Strategic Plan for 2017-2020. and recommends the same to the membership. I so move. Ali Seconds. MOTION CARRIES

#### Strategic Plan Updated Goals 2017–2020

Strengthen organizational infrastructure

- Manage and pursue revenue generating opportunities to maintain a sound financial base
- Pursue hiring executive support
- Evaluate the effectiveness of the organization of AAFCO for continuous improvement
- To provide leadership skills enhancement to develop and support AAFCO leaders
- Optimize resource sharing opportunities
- Enhance internal communication efficiencies and documentation within the association

#### Promote and enhance membership participation (internal)

- \*\*Identify opportunities to increase member agency participation
- \*Develop and provide professional development and technical training opportunities in support of feed programs
- \*Enhance collaboration, communication and cooperation among regulatory agencies

Communicate and document AAFCO benefits and accomplishments

#### Emphasize feed and food safety

- Continue developing member feed safety programs in alignment with FSMA and IFSS
- \*Promote and support laboratory technology, methods, quality systems and collaboration

#### Vitalize partnerships with external stakeholders

- Identify key stakeholders and working partners and common goals
- Develop and maintain professional relationships with stakeholders and affiliated organizations

#### Strengthen international presence

- · Participate in relevant international meetings as resources permit
- Invite International attendees to association activities
- Provide a forum for international discussions on feed safety
- \* Top 3 priority goals

#### 4.) Nomination Committee

The Nominating Committee recommends the following slate for Board of Directors to take office January 1, 2017.

President: Ken Bowers (KS)

President-elect: Dan Danielson (TN) Secretary-Treasurer: Ali Kashani (WA)

Sr. Director: Stan Cook (MO) Sr. Director: Robert Geiger (IN) Jr. Director: Kristen Green (KY) Jr. Director: Erin Bubb (PA) Jr. Director: Bob Church (MT)

Immediate past President: Mark LeBlanc (LA)

This concludes committee recommendations needing membership approval.

#### 5.) Credential Report - FASS

Number of Voting Members Represented 37

Number of States in attendance 46

Number of Countries 6

Number of FDA Representatives 37

Number of Life Members 3 Total Meeting Attendance 386

Mark LeBlanc adjourned meeting at 9:15 am

Richard Ten Eyck MOTION to approve minutes as displayed on August 3, 2016. Ali Kashani Seconds. MOTION CARRIES

<sup>\*\*</sup> Priority goal 4 for consideration if adequate progress is made on the top 3

#### **Current Issues and Outreach Committee Report/Minutes**

2016 Annual Meeting Marriott City Center Pittsburgh, PA August 1, 2016 Grand Ballroom 9:30 am–10:30 am

#### **Committee Recommendations**

Committee recommendations summary or list None

#### **Board Recommendations**

Report was accepted on October 20, 2016

#### **Association Recommendations**

Association recommendation summary or list None

#### **Committee Participants**

**Members Present:** Liz Higgins, Meagan Davis, Jennifer Godwin, Chad Linton, Tim Lyons, Eric Nelson, Isabel Pocurull, Steve Gramlich, Kent Kitade, Richard Ten Eyck, Shaness Thomas and Ali Kashani

**Advisors Present:** Scott Ringer, Angela Mills, David Dzanis, David Fairfield, David Meeker and Jason Vickers.

Committee Report

Committee Activities ACTIONS:

The meeting was called to order at 9:34 am EST by Chair, Ali Kashani

Ali Kashani gave an update on the June 9<sup>th</sup> webinar. [This meeting was recorded and is posted on the Current Issues and Outreach BIN Team board.]

Ali Kashani welcomed Kelsey Luebbe (NE) as the new Vice-Chair of the Committee and indicated that she will be concentrating on communications aspects of the committee. Liz Higgins was welcomed as the newest committee member. He invited committee members, advisors and other interested parties to submit proposed topics for consideration for future meetings.

#### **AAFCO Newsletter, Liz Higgins (NM)**

Liz Higgins gave an update on the newsletter survey and the new AAFCO newsletter, which will be published biannually. The first issue of the newsletter will be published in November, 2016. The AAFCO newsletter survey will be sent out a week or two after the AAFCO meeting. Members are encouraged to complete the survey and to give feedback on what they want to see in a newsletter. It was also asked that proposed names be submitted for the newsletter which will be voted on and the person who submits the wining newsletter name will receive an AAFCO OP or PF&SPF Labeling Guide.

Implementation of FSMA Rules and NASDA's Perspectives, Bob Ehart, Senior Policy and Science Advisor, National Association of State Departments of Agriculture (NASDA)

Bob Waltz introduced Bob Ehart, who is the Senior Policy and Science Advisor for the National Association of State Departments of Agriculture (NASDA). Mr. Ehart gave an update on the Implementation of FSMA Rules particularly in regard to the NASDA Model Framework for Produce Safety

Rule Implementation. The focus of FSMA is on preventing foodborne illness. Education is key to prevention. Education should include (voluntary) farm visits in preparation for compliance assessments prior to enforcement programs. Preventing foodborne illness through the PSR will require finding ways to learn from inspections and assure what is learned is used in continuing education programs. Programs will need basic competencies to successfully carry out the work, and through self-assessment they can identify areas where they need to act to ensure alignment with the Produce Safety Rule. The technical working group focus is on "Educate before you Regulate". In September, educational programs at the state level will begin. NASDA has submitted for an expansion of the current cooperative agreement. In addition, NASDA, in collaboration with AAFCO, has submitted for a funding opportunity to develop a state-centric operational plan for the implementation of the Preventive Controls Animal Food Rule.

Principles of Quality Consumer Research: *Dr. Jean Collins, Vice-President of Consumer and Marketplace Insights for Nestle Purina* 

Dr. Jean Collins, who is the Vice President of Consumer and Marketplace insights for Nestle Purina, gave a presentation on Principles of Quality Consumer research. The overall purpose of this presentation was to provide a framework for assessing the quality or credibility of consumer research. Key differences between Qualitative and Quantitative Research were highlighted:

Qualitative approaches (e.g. focus groups, shop-alongs) are ideal when the goal is to better understand consumer motivations, emotions, and communication. Advantages include direct interactions with consumers and the ability to be iterative and flexible in topics/questions. Social media can also be very helpful in identifying emerging "hot topics" and potentially better anticipating future trends. The limitation is that Qualitative (including social media) is not projectable to a larger population. Insights are "directional." Quantitative research is more structured and based on survey data. The key is that the larger, representative sample sizes are projectable to a larger population and enable statistical analyses that result in more robust conclusions. The actual Framework for Quality Consumer Research focused on (1) Credible Source, (2) Representative Sample of consumers, (3) Adequate Sample Size (typically 200-400), (4) Survey Questions that DO NOT "lead" or "bias" consumer responses.

Meeting was adjourned at 10:41 am EST.

Responsible	Item	Action	Timing/Status
Kelsey Luebbe	AAFCO Newsletter survey	Will be sent out by August 26	Response due by September 2
		1st newsletter aimed to be sent out	November

#### **Education and Training Committee Report/Minutes**

2016 AAFCO Annual Meeting Pittsburgh Marriott City Center Pittsburgh, PA Grand Ballroom Wednesday, August 3, 2016 8:00–10:00 am

#### Committee Recommendations to Board and Association:

AAFCO Promotes the Feed Inspector Professional Certification coordinated through NEHA which demonstrates professional knowledge and experience that serves as a verification that the individual achieved a baseline level of competency.

#### **Board Recommendations to membership**

Report was accepted on November 9, 2016

Board sent Committee recommendation back to the Committee for clarification on what promote means

#### **Association Actions:**

#### **ET Committee Future planning recommendations:**

Continue to work with FDA and IFPTI to develop Animal Feed Curriculum developing competencies and training to meet these competencies for Basic, Advanced, Expert and Leadership levels.

- Monitor PC Alliance trainings for industry and regulators.
- Continue to promote BITS and AITS Trainings
- Work with Strategic Affairs Committee on FTSS

#### **Committee Participants**

**Members Present:** Jim Fear, Darlene Krieger, Meagan Davis, Tim Lyons (Chairperson), Bob Geiger, Jim True, Richard TenEyck, David Edwards, Jo Lynn Otero, Lizette Beckman, Tim Darden, Krisden Ingram, Amanda Anderson, Jacob Fleig, George Ferguson, Samantha Moran, Laura Scott, Amanda Anderson,

Via Telephone: None

Advisors Present: David Fairfield, Matt Frederking,

- 1. Introductions and Agenda Review
- 2. Feed Curriculum
  - Division of Human Resource Development and Office of Partnerships updated the
    workgroup on the progress of the courses and provided a live demo of the online Animal
    Species and Classes course. The courses are designed to have competency checks to
    evaluate what the student learned but can also be used to evaluate more advanced
    inspectors coming in. These courses will be available to states that have access to the FDA
    Learning Management System. There are talks to see if there is a way to make the courses
    available for industry personnel as well.
  - Preventive Controls, cGMP, and Alliance courses will be required courses for inspectors.
- 3. Preventative Controls Outreach by National Grain and Feed Association (NGFA)

 Dave Fairfield, with assistance from Matt Frederking of Ralco Nutrition provided and NGFA update. NGFA has provided 7 FSMA outreach sessions with the next one planned for March in CA. This is intended for industry and State regulatory officials that provides an overview on what is required to comply with FSMA. There are 5 more sessions planned following the CA one.

#### 4. Inspector Certification through National Environmental Health Association (NEHA)

• NEHA provided an overview of the credentialing process which included the job task analysis, DACUM Chart analysis, and an Item Writing Workshop to develop exam questions. This is a third party impartial credentialing process with an exam that can be taken at Pearson Vue Testing Centers with a passing score between 650-900. The exam will cost \$245 for NEHA members and \$390 for non-member. The credentials expire in 2 years with a \$130 renewal price. If an applicate does not pass the test they will have a 90-day waiting period in order to re take the test.

#### 5. AITS and Bits Training update

- AITS in Tennessee had 50 attendees.
- BITS in Missouri the last week in Sept. Limited number of attendees
- There is no current location for upcoming AITS trainings.

#### 6. Administrator Seminar

 Dave Philips provided an overview of the 2016 seminar in Medora, North Dakota and shared that North Dakota will again be hosting Seminar in Medora May 1-5, 2017

#### 7. Additional Discussion

- Darlene Krieger talked about the table top exercise for January 15, 2017. This will be a pet food incident that will include regulators, laboratories, and industry.
- FTSS will be sending out a survey to set up conference call times to complete action items from Strategic Affairs committee.

Meeting adjourned at 10:00 AM

#### **Action Item Table**

Responsible	Item	Action	Timing / Status
Meagan Davis	Seminar 2017	Coordinate Seminar to be held in Medora, ND May 1-5, 2017	
Tim Lyons	National curriculum development	Continue to work with FDA and IFPTI on developing competencies and training for feed inspectors	Ongoing

#### **Feed and Feed Ingredient Manufacturing Committee**

2016 AAFCO Midyear Meeting Tuesday, August 2, 2016 Marriott City Center Pittsburgh, Pennsylvania 3:30–5:00 pm

#### Committee recommendations to Board and membership:

None

#### **Board Recommendations to membership:**

Report was accepted on November 9, 2016

#### **Committee Action Items:**

- 1. Mineral Guidelines Working Group: Revise the "Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients".
- 2. Emergency Response Working Group: Plan 2017 Tabletop Exercise. Work with Education and Training Committee and Jennifer Roland if necessary.
- 3. FSMA Implementation Task Force Working Group 3

Create action plan to determine the processes of implementing the decision making and method development.

4. 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.

#### Committee Minutes 08/02/2016

#### **Committee Participants**

#### **Members Present:**

Eric Brady – TN (Co-Chair); Austin Therrell - SC (Co-Chair); Bob Church – MT; Wayne Nelson – CT; Ken Bowers – KS; Bob Geiger – IN; Dragan Momcilovic – FDA; Dan Danielson – TN; Mike Davidson – CA; Darlene Krieger – FDA; Tim Darden – NM; Laura Scott – Canada; Ali Kashani – WA

Via Telephone: None

#### **Advisors Present**

Matt Frederking – NGFA; David Ailor – NOPA; Tomas Belloso – NGFA; Lorri Chavez – PFI; Pat Tovey – PFI; David Meeker – National Renderers Association; Richard Sellers – AFIA; David Dzanis – APPA

#### **Committee Report/Minutes**

Eric Brady called the meeting to order at 3:33 PM EST. Members and advisors in the room introduced themselves.

# Introductions and Agenda Review, Eric Brady Canadian Food Inspection Agency Update - Laura Scott

See Attachment A

Nancy Cook – How close do the findings compare to AAFCO documents? To ingredient definitions? Approvals?

Continue to be aligned as they currently are and take into consideration the EU and FSMA changes.

#### **Review of Action Items**

#### Mineral Guidelines Working Group - Bill Burkholder

Working group has not yet finalized their revision of the "Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients". in the OP but is hoping to have a submission of October 2016.

#### Strategic Plan - Emergency Response - Darlene Krieger

Recommendation was made to the Board to replace the AAFCO Model Emergency Response Preparedness Guidance Document with revised language following the 2016 Mid-Year Meeting in Isle of Palms. The Board will review the document and will vote to include it in the next printed Official Publication. Tim Darden will be the new Section Editor, replacing Darlene Krieger.

The Working Group has planned an Emergency Response Tabletop Exercise to be held in conjunction with the AAFCO 2017 Mid-Year Meeting in Mobile Alabama (January 16 – 18<sup>th</sup>).

- Sunday, January 15, 2017
- Save the Date will go out shortly
- Workshop will last 6 hours
- Lunch will be provided
- Will consist of regulatory, industry and laboratory representatives
- The working group will reach out to Dave Fairfield of NGFA to ensure industry participation.
- Working Group consists of: Darlene Krieger (lead), Glo Dunnavan; Dragan Momcilovic, Tim Darden, Stan Cook, Tim Lyons and David Fairfield.

Roger Hoestenbach, section editor of the AAFCO Model Emergency Response Preparedness Guidance Document, recently retired. Tim Darden has been chosen to be the new section editor.

#### **FSMA IMPLEMENTATION TASK FORCE UPDATES**

#### Working Group #1 - Strategy for AAFCO GMPs - Ken Bowers

Working Group Charge: Develop a plan for states that have adopted AAFCO's Model GMPs to make the transition to FSMA GMPs.

3 states have adopted the AAFCO CGMPs however the current CGMPS are being deleted from the OP Ken Bowers moved to disband the working group and Bob Church seconded the motion. Motion passed to disband the working group.

No further action is necessary.

# Working Group #2 - Model Feed Safety Program Plan in the OP- Bob Waltz Working Group Charge -

Recommendation to the Board following Mid-Year Meeting in Isle of Palms was to remove the AAFCO Model Feed Safety Program Plan from the OP, where it will be archived in the Feed Bin.

**UPDATE:** This request was approved by the AAFCO Board of Directors on September 7, 2016. See Attachment: Board Minutes 09/07/2016

#### 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

The Alliance will reference the EU list and the documents will come in a series of releases, not all at once.

Linda Morrison referenced the 2017-2020 AAFCO Strategic Plan – is there a list of expected method developments? Response: At this moment, it is not clear how it will all work.

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

The curriculum for Inspectors from FSPCA can be downloaded online at <a href="https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food">https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food</a>

Linda Morrison – Has a review of this to see what's missing; a gap analysis may need to be completed? Response: At this moment, no, a review as not been completed.

#### **Industry Updates**

American Feed Industry Association (AFIA) – Richard Sellers – See attachment B

National Grain and Feed Association (NGFA) - Matt Frederking

#### Pet Food Institute (PFI) - Pat Tovey

In July 2016, PFI co-instructed in a Food Safety Preventive Controls Alliance combination training course along with staff from AFIA, NGFA and NRA. 75 lead instructors were issued certificates granting their status as lead instructors in the Animal Food Curriculum.

Pet Food Institute members developed a model Hazard Analysis for groups of ingredients typical for pet food use. This model is available on the PFI website for use by members.

In May 2016, PFI unveiled its new and updated webpage. The webpage contains material for PFI members as well as information for media or the general public.

Also, PFI recently sent an open letter to small pet food businesses as a reminder that we are approaching many of the Food Safety Modernization Act's compliance dates. The letter urges small manufacturers to reach out to the Food Safety Preventive Controls Alliance or PFI if any assistance is needed to comply with these rules under FSMA. A copy of the letter was shared with the AAFCO Board of Directors and state regulators can receive a copy by contacting PFI. During the update PFI asked AAFCO members to please pass this information along to any pet food manufacturers in their state that may benefit from this direction.

#### **National Renderers Association – David Meeker**

On behalf of the National Renderers Association, David Meeker reported that the rendering industry has been using GMPs and preventive controls for more than 10 years in their voluntary Rendering Code of Practice and thus are prepared to implement FSMA. He also complemented FDA for working cooperatively with the industry in developing the very good FSPCA training curriculum for both PCQIs and inspectors.

#### National Oilseed Processors Association (NOPA) - Dave Ailor

Reported that David Ailor was leaving NOPA effective May 31, 2017, and that he hoped his replacement, Lorraine Gershman, would be joining him at the last meeting, the 2017 Midyear Meeting.

#### Other Business

Jon Nelson had a question about FSCPA Lead Instructor Registration – processes had just started

There will be a course at Kansas State August 9. All courses are listed on Alliance website at: <a href="https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food">https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food</a>

#### **Action Item Table**

Responsible	Item	Action	Timing / Status
Mineral Guidelines Working Group	Mineral Guidelines	To review and revise the "Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients".  Working Group: Bill Burkholder (lead), Jon Nelson, Tim Costigan, Jennifer Kormos, David Syverson, Bill Hall, David Dzanis, Roger Hoestenbach (now retired)  Will Roger Hoestenbach need to be replaced?	Tentative: October 2016
Strategic Plan Emergency Response Working Group	Roundtable Exercise	Host the exercise prior to the 2017 AAFCO Mid- Year Meeting	January 2017
FSMA Implementation Task Force – Working Group 3	Hazard and Contaminant Action Levels and Enforcement Strategies	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.	Update January 2017
FSMA Implementation Task Force – Working Group 4	Inspector Training Development	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	Update January 2017

#### **Feed Labeling Committee**

2016 AAFCO Midyear Meeting Tuesday, August 2, 2016 Marriott City Center Pittsburgh, Pennsylvania 8:00–9:00 am

#### Committee recommendations to Board and membership

1. The committee recommends that the revised Table 1: Nutrient Guarantees Required by Species under the AAFCO Model Bill and Regulations is published in the OP.

#### **Board Recommendations to membership:**

Report was accepted on November 9, 2016

# Board accepted the Feed Labeling Committee recommends revision to Table 1: Nutrient Guarantees Required by Species.

#### **Committee Action Items**

- 1. Non-Pet Food Label Design and Format Guide review should be completed to remove medicated feed labels that are no longer valid due to the changes in the VFD regulations. Also, additional example labels, such as single ingredients and processing aids, should be included.
- 2. Expert Panel to be created to review the NRC's Nutrient Requirements of Beef Cattle once updated to ensure the AAFCO Model Regulations specific to beef cattle are adequate.
- 3. Working Group for the Non-Medicated Feed Labeling Workshop shall submit a proposal to the Education and Training Workshop Review Committee.
- 4. Determine if the Medicated Feed Labeling Workshop manual and information will be available at no cost.

#### Committee Minutes 08/02/2016

#### Committee Participants Members Present

Dave Dressler – PA (Chair); Dave Phillips – ND (Vice Chair); Richard TenEyck (OR); Erin Bubb – PA; Miriam Johnson – NC; Mika Alewynse – FDA; Al Harrison – KY; Heather Bartley – WI; George Ferguson – NC; Steve Gramlich – NB. Al Harrison - KY

Via Telephone: None

#### **Advisors Present**

Jan Campbell – NGFA; Angela Mils – AFIA; Sue Hayes – WBFI; Dave Dzanis – ACVN/APPA; Chris Olinger – NGFA; Megan Dicks – AFIA; Pat Tovey - PFI

#### **Committee Report/Minutes**

David Dressler called the meeting to order at 8:02 am EST. Members and advisors in the room introduced themselves.

#### Introductions and Agenda Review, Dave Dressler

#### **Table 1 - Miriam Johnson**

Richard TenEyck moved to publish the amended Table 1 in the OP, replacing the existing Table 1 in the OP once the NDF/ADF equine editorial change has been made.

Miriam Johnson seconded

Motion carried

#### Medicated Feed Labeling Workshop Recap - Jan Campbell

99 Attendees

Extended a "Thank You" to Dragan Momcilovic, Isabel Pocurell, Dave Edwards, and Dan Benz Richard TenEyck will approach the Board of Directors to determine if the workshop material will be available for a fee or for free.

Currently available on the FeedBIN under "All Users" → "Presentations"

#### Facilitating Shared Label Review - Dave Phillips/Richard TenEyck/Meagan Davis

EIC is charged with determining how to facilitate sharing of all compliance letters, etc.

#### **Beef NRC Update**

Should be available end of the year

Will need an Expert Panel – 5 industry and 5 academia – Richard Sellers and Dave Dzanis will assist in filing this panel

Al Harrison, Richard TenEyck & Miriam Johnson will lead this Expert Panel

#### Labeling of Direct Fed Microbials - Mika Alewynse

Updating bacterial nomenclature in Fermentation product definition 36.14 will affect the labeling of DFM products. Many of these products contain multiple types of bacteria. This is an agenda item at the IDC meeting.

#### Non-Pet Food Label Design and Format Guide

Mika Alewynse and Angela Mills will review the guide

Medicated feed label labels will need to be revised due to the VFD changes

Tomas Belloso wants processing aids in the guide (Definition of one, criteria for labeling of processing aids in a finished feed) – will also assist in review

Kristi Smedley mentioned single ingredient feed label examples and others that should be added to the guide.

Meagan Davis will provide the revised document to the abovementioned folks for review.

#### Non-Medicated Feed Labeling Workshop

August 2018 - Tentative date

Working Group will have to submit a proposal to Education and Training Committee

Dave Phillips, Dave Dressler, AFIA (Angela Mills), and NGFA (Chris Olinger) will lead this working group

#### **Other Business**

None

#### **Action Item Table**

Responsible	Item	Action	Timing / Status
Al Harrison, Richard TenEyck and Miriam Johnson Richard Sellers and David Dzanis	Expert Panel Formation	Form an Expert panel to review the NRC update for Beef Cattle Nutrition	January 2017
Mika Alewynse and Meagan Davis Angela Mills and Thomas Belloso	Non-Pet Food Label Design & Format Guide	Review the guide to remove any medicated feed labeling examples that contain drugs/indications for use that are affected by the new VFD regulations  Create additional labels for single ingredients, processing aids, etc.	January 2017
Dave Phillips and Dave Dressler  AFIA (Angela Mills) and NGFA (Chris Olinger)	Workshop Proposal	Submit a workshop proposal for the Non-Medicated Feed Label Workshop to the Education and Training Committee for Review	September 2016
Richard TenEyck	Medicated Feed Labeling Review Workshop Materials	Work with the Board to determine if these materials will be available at no cost following the workshop	September 2016

Table 1. Nutrient Guarantees Required by Species under the AAFCO Model Bill and Regulations<sup>1</sup>

	Complete and Supplement Feeds <sup>1</sup>						
Nutrient	Swine	Poultry	Beef	Dairy	Equine	Goat	Sheep
Crude Protein, min %	Yes	Yes	Yes	Yes	Yes	Yes	Yes
NPN, max %	No	No	a/	a/	No	a/	a/
Lysine, min %	Yes	Yes	No	No	No	No	No
Methionine, min %	No	Yes	No	No	No	No	No
Crude Fat, min %	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Crude Fiber, max %	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ADF, max % NDF, Max %	No No	No No	No No	Yes No	Yes Yes	Yes No	No No
Calcium, min and max %	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Phosphorus, min %	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Salt, min and max %	a/	a/	a/	No	No	a/	a/
Sodium, min and max %	b/	b/	b/	No	No	b/	b/
Magnesium, min %	No	No	No	No	No	No	No
Potassium, min %	No	No	Yes	No	No	No	No
Copper, min ppm (e/)	No	No	No	No	a/	f/	c/
Selenium, min ppm (e/)	Yes	No	No	Yes	Yes	Yes	Yes
Zinc, min ppm (e/)	No	No	No	No	Yes	No	No
Vitamin A, min IU/lb	No	No	a/	a/	a/	a/	a/

	Complete and Supplement Feeds <sup>1</sup>			Mineral Feeds <sup>1</sup>			
Nutrient	Duck/ Geese	Fish	Rabbit	Veal/Herd Milk Replacer	Beef	Dairy	Equine
Crude Protein, min %	Yes	Yes	Yes	Yes	No	No	No
NPN, max %	No	No	No	No	No	No	No
Lysine, min %	No	No	No	No	No	No	No
Methionine, min %	No	No	No	No	No	No	No
Crude Fat, min %	Yes	Yes	Yes	Yes	No	No	No
Crude Fiber, max %	Yes	Yes	d/	Yes	No	No	No
ADF, max %	No	No	No	No	No	No	No
Calcium, min and max %	Yes	No	Yes	Yes	a/	a/	Yes
Phosphorus, min %	Yes	Yes	Yes	Yes	a/	a/	Yes
Salt, min and max %	a/	No	a/	No	a/	a/	a/
Sodium, min and max %	b/	No	b/	No	b/	b/	Yes
Magnesium, min %	No	No	No	No	a/	a/	No
Potassium, min %	No	No	No	No	a/	a/	No
Copper, min ppm (e/)	No	No	No	No	a/	No	a/
Selenium, min ppm (e/)	No	No	No	No	a/	a/	Yes
Zinc, min ppm (e/)	No	No	No	No	a/	No	Yes
Vitamin A, min IU/lb	No	No	a/	a/	a/	a/	a/

<sup>1/</sup> All guarantees in this table are subject to the exemptions in model regulation 3 (a) 4 section XII. Typically, if the feed is not intended or represented to be a principal source of the nutrient then a guarantee is not required, but can be voluntarily provided by the guarantor.

a/ Guarantee required only when nutrient source is added.

b/ Sodium guarantee required only when total sodium exceeds that furnished by the maximum salt guarantee.

c/ Copper minimum and maximum guarantee for sheep required when added or level exceeds 20 ppm.

d/ Rabbit feeds require minimum and maximum crude fiber guarantee (range not to exceed 5.0 units)

e/ Guarantee shall be stated in ppm when less than 10,000 ppm and in percentage when concentration is 10,000 ppm (1%) or greater.

f/ Minimum and maximum in parts per million (ppm) (if added).

#### **Ingredient Definitions Committee 8/2/16 Report**

**Recommendations to the Board and Association membership:** When needed new text is presented in attachment A of this report.

- 1.) Move the following definitions from tentative to Official:
  - a. T6.17 L-Methionine
  - b. T27.9 Deoiled corn distillers dried grains with solubles, solvent extracted
  - c. T54.33 Bovine Colostrum
  - d. T54.34 Dried Bovine Colostrum
  - e. T57.165 Zinc Hydroxychloride
  - f. T71.30 Mustard Meal, Solvent Extracted
  - g. T73.300 Sodium Salts of Fatty Acids
  - h. T73.301 Potassium Salts of Fatty Acids
  - i. T87.29 Yucca schidigera extract
  - j. T93.9 \_\_\_\_\_ Wheat Gluten (with edits presented in attachment A)
  - k. T96.13 Molasses Hydrolyzed Yeast
- 2.) Publish the following new definitions as tentative in the Official Publication:
  - a. T33.25 Stearic Acid
  - b. T33.26 Palmitic Acid
- 3.) Publish the following definitions as Official in the AAFCO Official Publication:
  - c. 57.160 Zinc Propionate
  - d. 57.166 Chromium Propionate

**Note:** Other changes discussed will be completed as edits and are not being sent for membership consideration.

#### Board recommendations to membership:

Report was accepted on October 20, 2016

Board accepted recommendations 1-3 as presented by the committee.

#### **Association Actions:**

For consideration at mid-year 2017, Mobile AL meeting.

#### **Ingredient Definitions Committee 8/2/16 Meeting Minutes**

1:30–3:00 pm Eastern time, Pittsburgh, PA.
Pittsburgh Marriot City Center, Grand Ballroom 1–5

The meeting was convened at 1:30 pm by the chair, Ten Eyck.

#### 1) Role Call

**Committee Members:** Mika Alewynse, Ken Bowers, Erin Bubb, Bob Church, Charlotte Conway, Stan Cook, David Dressler, Jacob Fleig, Brett Groves, Steve Gramlich, Alan Harrison, April Hunt, Jan Jarman, Mark LeBlanc, Laura Scott, Richard Ten Eyck, Dave Phillips, Kent Kitade, Jennifer Kormos (on phone), Shannon Jordre (on phone). A quorum is present (20/29).

**Advisors:** Leah Wilkinson, Kristi Smedley, Jean Hofve, Susan Thixton, David Meeker, Vince Sewalt, Mollie Morrissette, David Ailor, Jan Campbell, David Dzanis, Jason Vickors, David Fairfield, Jon Nelson, Emily Helmes, James Emerson, Pat Tovey,

# 2) Investigator recommendations to move definition and common name from tentative to official in the AAFCO Official Publication:

- T6.17 L-Methionine. Brett Groves moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.
- b) T27.9 Deoiled corn distillers dried grains with solubles, solvent extracted. Steve Gramlich moves to ACCEPT. Brett Groves seconds. MOTION PASSES.
- c) T54.33 Bovine Colostrum. Steve Gramlich moves to ACCEPT. Dave Phillips seconds. MOTION PASSES. Issue raised by Jan Jarman that some companies may make a claim of immunity with the use of this ingredient. Cat Marrier said that Industry is aware that immunity claims are not permitted for this ingredient.
- d) T54.34 Dried Bovine Colostrum. Steve Gramlich moves to ACCEPT. Brett Groves seconds. MOTION PASSES. Cat Marrier indicated that one person in the industry requested a change to maximum 9.5% dry matter, and she indicated wide spread support from the colostrum industry. However, she indicated that change would need to be made at a later time.
- e) T57.165 Zinc Hydroxychloride (zinc chloride hydroxide monohydrate) Brett Groves moves to ACCEPT as amended with second name removed. Mark LeBlanc seconds. MOTION PASSES. Jennifer Kormos informed IDC that the reason that an additional ingredient name was requested was that it is a synonym and is the usual name used in Canada and the EU. Mika Alewynse said that an FDA CPG states that the AAFCO ingredient name is the Common and Usual Name of the ingredient. She highly encourages companies to use the AAFCO name. It was agreed that it would be simpler to keep a single ingredient name and Jennifer Kormos agreed that the second name could be struck.
- f) T71.30 Mustard Meal, Solvent Extracted. Bob Church moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.
- g) T73.300 Sodium Salts of Fatty Acids. Mark LeBlanc moves to ACCEPT. April Hunt seconds. MOTION PASSES.
- h) T73.301 Potassium Salts of Fatty Acids. Jacob Fleig moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.
- i) T87.29 Yucca schidigera extract. Brett Groves moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.
- j) T93.9 \_\_\_\_\_ Wheat Gluten. Dave Phillips moves to ACCEPT the edited version of this definition. Mika Alewynse seconds. MOTION PASSES.
- k) T96.13 Molasses Hydrolyzed Yeast. Alan Harrison moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.

#### 1) Work Group Reports

a) AAFCO GRAS Workgroup for IDC Report – The GRAS WG was convened last November to work on understanding how the states handle different GRAS situations, and a survey was constructed. The purpose was to look at GRAS Notification when FDA issues a No Questions Letter, GRAS recognized by State processes, and other GRAS processes. There are 28 replies to date out of @ 140. Refer to GRAS Survey interim results posted on Feed Bin Ingredient Definitions Team Board. Mika Alewynse discussed the differences between GRAS Notification and other processes. For GRAS Notifications, it is the firm's conclusion of GRAS and FDA evaluates and issues a No Questions Letter, if appropriate. In contrast, for an AAFCO Ingredient Definition, it is FDA's review and hence their opinion that the ingredient is safe for use.

Bill Burkholder said that a GRAS Notice concerns a specific Notifier's ingredient. An AAFCO Ingredient definition covers a specific petitioner's specifications for an ingredient. If GRAS Notified ingredients are listed in the AAFCO OP, then other firm's seeking to make/supply that ingredient would need to review/understand the GRAS notification.

Mark LeBlanc said that he has changed his mind. He is now thinking that the GRAS Notices would be best included in a table with the name of the ingredient, the intended use, and use level not just a common name.

Vince Sewalt pointed out that the GRAS Notified ingredients are no more proprietary than are AAFCO ingredients. There are many ingredients in the AAFCO OP that are specific to individual companies. Chromium propionate and stearic acid are examples from today's IDC agenda.

Mika Alewynse said that firms that submit a GRAS Notice and then say that they are working on an AAFCO ingredient definition are told that they must choose between the two, since FDA does not have sufficient resources to review ingredients twice. Vince Sewalt said that the AAFCO Ingredient definition review does not result in an Agency approval. Mika Alewynse replied that the FDA reply letter has changed, due to input from lawyers, but is FDA's recommendation.

Several Committee Members including Chair Ten Eyck agreed that we need more responses from the survey. Chair Ten Eyck will send out reminders to AAFCO Members.

Per Dave Edwards, in Question 1 of the survey, the intent was difficult to understand. Kristi Smedley replied that this was meant to refer to the original GRAS Notifier's ingredient, and not a follow-on company. Mark LeBlanc said that he would require that the firm provide a letter be issued from FDA to that firm.

The work group will continue.

- 4) New Definitions, deletes and edits:
  - a) New Term: Animal Food. Charlotte Conway recommends that Feed and Animal Food be used interchangeably. The issue with adopting the FSMA definition is that Specialty Pet Food is not included.
  - b) Modify Term: Feed(s). Charlotte Conway has proposed that this be discussed in a WG and then be brought back to IDC in January. Animal Food Term Working Group members: Ali, RTE, Charlotte, AFIA, NGFA, PFI,
    - TIPFL, APPA, Mollie, Cathy Alinovi (Next Gen PFMA). WG will plan to meet by web meeting in late September.
  - c) T30.xx Xylanase enzyme (placeholder ) -Jan
  - d) Edit 33.3 Hydrolyzed Fat, or Oil Feed Grade Ken

e) T33.25 Stearic Acid. Ken Bowers moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES.

Charlotte Conway explained that the specifications included in the definition are needed to ensure that the ingredient is safe. FDA has received some questions that the definition may limit the product to that made by only some companies and not all. She recommended that the IDC approve this definition and then consider modifications to the definition at a future date via an amendment to the definition. Debborah Baldwin (Vantage Oleochemicals) relayed that there are other processes besides fractional distillation that can enable meeting these specifications, and these are not represented in this definition. Her biggest concern is that stearic acid is marketed to feed customers, as it comes from a production process and very often this product will be a mixture of C16 and C18. This is because most stearic acid is from a combination of soy and tallow. Charlotte Conway replied that most of these concerns can be readily addressed through later amendments to the definition. She also felt that the mixture of roughly half C16 and half C18 would not be best defined as Stearic Acid. Doug Smith (Baker Commodities) said that the industry's use of the name Stearic Acid for a product that is roughly half C16 and C18 is not a mixture. Charlotte reiterated that for feed, the ingredient name Stearic Acid should not be used for a substance that is only half stearic acid.

- f) T33.26 Palmitic Acid. Ken Bowers moves to ACCEPT. MOTION PASSES. Mark LeBlanc seconds. These fatty acids were submitted by the same sponsor. As with Palmitic Acid, Charlotte says that FDA would entertain edits and modifications as needed.
- g) 57.160 Zinc Propionate. Edit and bring in as Official. Brett Groves moves to ACCEPT. Mark LeBlanc seconds. MOTION PASSES.
- h) 57.166 Chromium Propionate. A Food Additive regulation was approved by FDA in June 2016 and hence a new definition is proposed that uses the Federal Register language. Brett Groves moves to bring it into the OP as an official definition. Ken Bowers seconds. MOTION PASSES.
- i) Edit T93.9 \_\_\_\_ Wheat Gluten Dave P.
- j) Edit Footer on Vitamin Table Tom (DELAYED)
- k) Sort more Miscellaneous ingredients into section 40. April Hunt moves to ACCEPT as corrected. Stan Cook seconds. MOTION PASSES. Rationale: Erin Bubb explained that these five ingredients which are Food Processing Waste items are listed in Miscellaneous and it seemed more appropriate to move them to Section 40. Use new numbers and cross-reference with old numbers for two years.
  - a) Renumber and move the following to section 40:
    - 60.1 Dried Apple Pomace
    - 60.2 Dried Apple Pectin Pulp
    - 60.28 Dried Potato Products
    - 60.8 Dried Tomato Pomace
    - 60.112 (Blank-Fruit) Pomace
- I) Edits on citations of 21 CFR 582.1. Dave Edwards explained that reference to 21 CFR 582.1 is being used in the AAFCO OP when it is not adding any relevant information. Aside from the MSG definition, Dave recommends removing 21 CFR 582.1 from clay, montmorillonite, and a couple of other places. Section Editor Ten Eyck agreed to handle this as an editorial change to the AAFCO OP and he will take care of it.

#### 5) Discussions:

- a) Discussion/clarification on the following ingredient definitions: 57.150 Metal Amino Acid Complex, 57.151 Metal (specific amino acid) complex and 57.142 Metal amino acid chelate.
- b) Acceptable claims on enzymes -ETA
- c) Montmorillonite questions for Industry Tom (delay)
- d) Materials NOT suitable for animal feed list in the BİN or website AAFCO (not enough time)

- e) General discussion of materials advised to seek a FAP CVM (not enough time)
- f) List of standard food names from USDA Richard (not enough time) Industry should bring forth a list of common human food ingredients they want in the OP.
- g) Discussion of Direct-Fed Microbials Modernization Kristi/Jan/Mika.

Jan Jarman moves to form a WG to update DFM nomenclature to scientifically correct standards in Section 36.14. Mark LeBlanc seconds. MOTION PASSES. WG: Jan Jarman(lead); Mika Alewynse; Kristi Smedley; AFIA; Jean Hofve; Pat Tovey; Cathy Alinovi; NGFA; Mollie Morrisette.

According to Kristi Smedley (based on FDA discussion), about 33% (or more) of the DFMs are use incorrect nomenclature. The mistakes were included in the original list and some corrections were made in 1996 that were actually incorrect. EU is now requiring current microorganism naming conventions be used, based on genomic testing. In the past, FDA has pushed back on one-at-a-time changes. Industry understands that this list is out of date and would like it changed as efficiently as possible, and will work with AAFCO and FDA on this initiative. These are thought to be editorial changes. Pat Tovey has some concerns about the need for a scientific literature review, when it was a correction of an error. Why would a change in name necessitate a complete literature review? Mika Alewynse explained that if a strain was originally named Bacillus subtilis and the name was changed to a new Bacillus species, then it should be researched to confirm that an appropriate reclassification method was used and that the new genus species presents no safety concerns.

h) Status on several high profile ingredients – Richard / CVM (out of time) Link to FDA's marijuana and Cannabidiol (CBD) FAQ's was provided. Firms wanting to use animal feed with CBD should pursue a new animal drug approval. See <a href="http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm">http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm</a> - <a href="dietsuppsexclude">dietsuppsexclude</a>

Mark LeBlanc moved; Steve Gramlich seconds. Meeting adjourned 3:02 pm. MOTION PASSES.

Parking lot for the next meeting:

- I. Modify Term: Feed(s).
- II. Edit 33.3 Hydrolyzed Fat, or Oil Feed Grade
- III. Edit Footer on Vitamin Table Tom
- IV. Discussion/clarification on the following ingredient definitions: 57.150 Metal Amino Acid Complex, 57.151 Metal (specific amino acid) complex and 57.142 Metal amino acid chelate.
- V. Acceptable claims on enzymes –ETA
- VI. Montmorillonite questions for Industry Tom
- VII. Materials NOT suitable for animal feed list in the BIN or website AAFCO
- VIII. General discussion of materials advised to seek a FAP CVM

Minutes approved 9/6/16 by BIN vote of 16 members.

#### Attachment A

8/2/16 IDC meeting

#### Move to Official:

#### **Publish as Tentative:**

**T33.25 Stearic acid** is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats, including hydrogenated oils. It is used as an energy source in growing and adult ruminant diets up to a maximum inclusion of 3% (w/w) in the finished feed. It cannot be used in preruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly stearic acid, with lesser amounts of palmitic acid. It must contain, and be guaranteed for, minimum 92% stearic acid, maximum 5% palmitic acid, minimum 99% total free fatty acids, maximum 1% sulfated ash, and maximum 5 ppm lead. Maximum moisture must also be guaranteed.

Animal fats, vegetable oils, and hydrogenated vegetable oils used in the hydrolysis reaction to produce stearic acid must meet the specifications stated in the respective AAFCO definitions, 33.1 (for Animal Fat), 33.2 (for Vegetable Fat or Oil), and/or 33.19 (for Hydrogenated Glycerides). If tallow is used, the starting material must comply with the BSE feed regulation under 21 CFR 589.2000 and 589.2001.

T33.26 Palmitic acid is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats, including hydrogenated oils. It is used as an energy source in growing and adult ruminant diets up to a maximum inclusion of 2% (w/w) in the finished feed. It cannot be used in preruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly palmitic acid, with lesser amounts of myristic acid. It must contain, and be guaranteed for, minimum 98% palmitic acid, maximum 0.8% myristic acid, minimum 99% total free fatty acids, maximum 1% sulfated ash, and maximum 5 ppm lead. Maximum moisture must also be guaranteed.

Animal fats, vegetable oils, and hydrogenated vegetable oils used in the hydrolysis reaction to produce palmitic acid must meet the specifications stated in the respective AAFCO definitions, 33.1 (for Animal Fat), 33.2 (for Vegetable Fat or Oil), and/or 33.19 (for Hydrogenated Glycerides). If tallow is used, the starting material must comply with the BSE feed regulation under 21 CFR 589.2000 and 589.2001.

#### **Publish as Official:**

**57.160 Zinc Propionate** is the product resulting from reaction of a zinc salt with propionic acid. Zinc propionate is prepared with an excess of propionic acid, at an appropriate stoichiometric ratio. Minimum zinc content must be declared.

#### 57.166 Chromium Propionate

The food additive, chromium propionate, may be safely used in animal feed as a source of supplemental chromium in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-(mu<sub>3</sub>-oxo) hexakis (mu<sub>2</sub>-propionato-

- O,O) trichromium propionate with the empirical formula,  $[Cr_3(O)(CH_3CH_2CO_2)_6(H_2O)_3]CH_3CH_2CO_2$ .
- (b) It is added to feed as follows:
- (1) In the complete feed of broiler chickens and swine at a level not to exceed 0.2 milligrams of chromium from chromium propionate per kilogram of feed.
  - (2) In cattle diets at a level not to exceed 0.5 milligrams of chromium from chromium propionate per kilogram of the complete feed. Chromium propionate must be premixed with dry ingredients prior to adding to high moisture ingredients or forages.
    - (c) The additive meets the following specifications:
      - (1) Total chromium content, 8 to 10 percent.
      - (2) Hexavalent chromium content, less than 2 parts per million.
      - (3) Arsenic, less than 1 part per million.
      - (4) Cadmium, less than 1 part per million.
      - (5) Lead, less than 0.5 part per million.
      - (6) Mercury, less than 0.5 part per million.
      - (7) Viscosity, not more than 2,000 centipoise.
    - (d) The additive shall be incorporated into feed as follows:
      - (1) It shall be incorporated into each ton of complete feed by adding no less than one pound of a premix containing no more than 181.4 milligrams of added chromium from chromium propionate per pound.
      - (2) The premix manufacturer shall follow good manufacturing practices in the production of chromium propionate premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production.
      - (3) Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed for broiler chickens and swine and 0.5 parts per million of the complete feed for cattle.
    - (e) To assure safe use of the additive in addition to the 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.
      - 2) The label and labeling of the additive and any feed premix shall also contain:
        - (i) A guarantee for added chromium content.
        - (ii) Adequate directions for use and cautions for use including this statement: Caution: Follow label directions. Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed for broiler chickens and swine and 0.5 parts per million of the complete feed for cattle.

(21 CFR 573.304) (adopted 2017)

#### **Ingredient Definitions Committee Report**

9/30/2016 Webinar Meeting

#### **IDC** recommendations to the Board and Association Members:

- 1. Publish the new Official Feed Term in the OP for Animal Food.
- 2. Modify the current Official Feed Term in the OP for Feed(s).
- 3. Publish the new Official Feed Term in the OP for Tracer.
- 4. Publish the tentative definition in the OP for T6.12 Taurine.
- 5. Publish the new tentative definition in the OP for T73.400 Iron Nickel Tracer.
- 6. Publish the new official definition in the OP for: 73.026 Feed Grade Sodium Formate.

#### **Board recommendations to membership:**

Report was accepted on October 20, 2016

Board accepted recommendations 1-6 as presented by the committee.

#### Minutes of 9/30/2016 IDC Webinar Meeting

(Meeting was web recorded and is posted in the Feed BIN/Ingredient Definitions library.)

#### Meeting convened at 8:30 am PDT by Chairperson Ten Eyck.

1) Role Call – 15 Members present; this is a Quorum (≥50%)

**Committee Members:** Ken Bowers, Bob Church, Charlotte Conway, David Dressler, Erin Bubb, Steve Gramlich, Alan Harrison, Tim Lyons (for April Hunt), Jan Jarman, Ali Kashani, Dan King, Dave Phillips, Mark LeBlanc, Mika Alewynse, Richard Ten Eyck, Shannon Jordre,

**Advisors:** Jan Campbell, Pat Tovey, Leah Wilkinson, Kristi Smedley, Jean Hofve, Susan Thixton, Emily Helmes, Mollie Morrissette

#### 1). Work Group Reports

a) AAFCO IDC GRAS workgroup report. Leah Wilkinson summarized the efforts made by the Workgroup to develop the proposed new Section 101 for Animal GRAS Notices on which FDA had issued a no questions letter. As part of the Workgroup efforts, a survey had been sent out to the AAFCO Membership to get insights from the states on how they regulate and handle GRAS substances. Excluded from this Section 101 list are the GRAS Notices that do not have a no questions letter from FDA, such as those that are pending or have been withdrawn. Richard Ten Eyck informed IDC that the online OP would link to the GRAS Notices and the FDA Letters. Emily Helmes pointed out ETA's editorial comments (on Feed Bin) including that the statements referred to as Alternative 1 and 2 were not needed in that the preceding paragraph should be sufficient. Jen Henderson (Cargill) and Tony Pavel (Cargill) agreed with the ETA edits and viewpoint and Tony Pavel continued that there was no need for these GRAS substances to undergo any additional FDA or AAFCO consultation in that they were already evaluated by the Agency. With the publication of the GRAS Notice Final Rule, these substances are now accepted under Federal law. The FDA NQ letter means that the Agency has no questions about the firms conclusions at this time. Therefore these substances are acceptable for use at this time. Jen Henderson said that if there was going to be a re-review, then she does not understand why we are discussing this Section at all. Kristi Smedley said that her view is that this would be a pro forma type of review by the AAFCO IDC in that the FDA had already conducted an evaluation.

Mika Alewynse explained that the GRAS Notice reflects the firm's conclusion and not that of the FDA, that the substance is GRAS. In contrast, for an FAP or an AAFCO Ingredient Definition, FDA actually reviews the data and information quite carefully, and FDA is making a conclusion of safety.

Kristi Smedley explained that any updates to the AAFCO OP in this section would be "covered" by the statement in Alternative 2. This would satisfy the needs of some states.

Richard Ten Eyck asked the IDC how they felt about the statements Alternative 1 and 2. Mark LeBlanc asked if it was the intent for the substances to be reviewed again. He felt that it would be a formality, and that IDC would give it an official stamp. Another state official agreed. Mika Alewynse recommended that the Notifier should be invited to attend the AAFCO Meeting, in the event that there would be any further questions. Jen Henderson asked if this would be more of an acknowledgement, and some state officials agreed. Jan Jarman (MN) said that the ingredient name and definition would need to be established by AAFCO IDC and so they would need to be acknowledged. She further asked if this table information would satisfy the needs of whether or not there are any limitations to the use of the ingredients. Mika Alewynse said that the specifications and limitations would be addressed in the notices and/or in the FDA

response letters. One idea was to add language to the Section 101 text that the feed control officials need to review the GRAS Notices and the FDA Letters for information on any use limitations. Tom Phillips (MD) said that his regulations incorporate ingredients by reference, and that he would need to update the state Feed Regulations every year in order to include these new GRAS ingredients; his plan is to review and update regulations every 3 years. Al Harrison (KY) said that this will not change what they can and cannot do in his state. Ali Kashani (WA) felt that it would be a good idea to have a discussion at the AAFCO IDC before new GRAS Notice substances are added to the list. It was agreed to send this Section 101 draft back to the Workgroup to address the comments raised during this webinar.

- b) "Feed" Definition Workgroup completed their work and submitted a modified definition for Feed and a new definition for Animal Food. Ken Bowers moves to ACCEPT the work group report. Ali Kashani seconds. MOTION PASSES.
- 3) New Definitions, deletes & edits:
  - a) New Official Feed Term: Animal Food. Ken Bowers moves to ACCEPT. Ali Kashani seconds. MOTION PASSES.

(new term) Animal Food, see "feed"

b) Modify Official Feed Term: Feed. Ken Bowers moves to ACCEPT. Dave Phillips seconds. MOTION PASSES. Charlotte Conway explained that technical effect includes preservatives, binding agents, etc, that have an effect on the feed, and not on the animal. Other examples are in Section 73. This definition for Feed does not replace the definition for Commercial Feed in the AAFCO Model Bill. Tony Pavel (Cargill) noted that the courts case in 1983 (Nutralab v. Schweiker) resulted in the court upholding that food is primarily used for nutrition, taste, aroma, and that structure /function claims are more of a secondary effect.

(revise existing term) <u>Feed</u>. Material consumed or intended to be consumed by animals other than humans that contributes nutrition, taste, aroma, or has a technical effect on the consumed material. This includes raw materials, ingredients, and finished product.

c) New Term: Tracer. Dave Dressler moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.

<u>Tracer</u>. (Part) A harmless substance present at insignificant levels in an animal food to assure the presence of and thorough mixing of a component (ingredient/premix) of that food.

d) Publish Tentative Definition for T6.12 Taurine – add new intended use (fish). Ken Bowers moves to ACCEPT. Ali Kashani seconds. MOTION PASSES. A question was raised about whether the term, fish, would include other aqua species such as shrimp. Charlotte Conway, CVM replied that shrimp and other aqua species are excluded from the category of fish, and a separate application would be needed.

<u>T6.12 Taurine</u> is a product which 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).

- e) Make editorial change to the tentative definition, T33.21 Yellow Grease, by changing 1.0% unsaponifiable matter to 2.5% unsaponifiable matter, so that this is the same as for animal fat, since in many cases YG will be composed mostly of animal fat. Jan Jarman moves to ACCEPT. Bob Church seconds. MOTION PASSES. Committee discussed how extensive the edit was and if it needed membership approval. The edit will be placed directly into the OP without an association vote.
  - T33.21 Yellow Grease, Feed Grade is the rendered product from the tissues of mammals and/or poultry blended with used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2.5% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." If the product contains tallow (from cattle) containing greater than 0.15% insoluble impurities then it must be labeled with the BSE caution statement "do no feed to cattle or other ruminants."
- f) Publish new tentative definition for T73.400 Iron Nickel Tracer. **Ken Bowers moves. Steve Gramlich seconds. MOTION PASSES.** 
  - 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 parts per million in the finished food. The label shall include a maximum nickel guarantee and a caution statement indicating the maximum permitted inclusion level.
- g) Add new official definition for 73.026 Feed Grade Sodium Formate. Ken Bowers moves. Charlotte Conway seconds. MOTION PASSES.
  - <u>73.026 Feed Grade Sodium Formate.</u> The food additive, feed grade sodium formate, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:
  - (a) The additive is manufactured by the reaction of 99 percent formic acid and 50 percent sodium hydroxide in water to produce a solution made up of at least 20.5 percent sodium salt of formic acid and not more than 61 percent formic acid.
  - (b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.
  - (c) To assure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.
  - (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) Adequate directions for use, including a statement that feed grade sodium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing feed grade sodium formate.
    - (3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

- (e) To assure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain:
  - (1) Appropriate warnings and safety precautions concerning feed grade sodium formate.
  - (2) Statements identifying feed grade sodium formate as a corrosive and possible severe irritant.
  - (3) Information about emergency aid in case of accidental exposure as follows:
  - (i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration (OSHA) human safety guidance regulations. 8
    - (ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

21 CFR § 573.696 (adopted 2017 rev 1)

#### 4) Discussions:

- a) Montmorillonite questions for Industry Tom
  - a. Lab methods question. Drug manufacturers take into account the interference impact and formulate to yield the correct bioavalibility. **Drug manufacturers should email Tom** with how they compensate for the interference.
  - b. Firms can add drugs to the list on page 452 by sending a request to the section editor.
- b) Edit Footer on Vitamin Table Tom
  - a. Wants to find source of the original numbers on vitamin bioactivity. Is the wt to wt ratio appropriate? Jan Jarman, is willing to help with table edits to make it more understandable. **Industry should get information on the source of numbers asap.**
- c) Acceptable functionality statements on enzymes -ETA
  - a. Modification to header for the enzyme table needs to be done. **Jan will bring to next meeting.**
- d) Materials NOT suitable for animal feed list in the BIN or website AAFCO
  - a. Document is in the ingredient definitions library. Discuss further at next IDC meeting
- e) General discussion of materials advised to seek a FAP CVM
  - a. Bring up again at next meeting.

Meeting adjourned 10:05AM PST

Minutes accepted by the committee 10/xx/2016

# **Inspection and Sampling Committee**

2016 AAFCO Midyear Meeting Monday, August 1, 2016 Marriott City Center Pittsburgh, Pennsylvania 11:00 am – 12:00 pm

#### Committee recommendations to Board and membership

None at this time.

#### Board recommendations to membership:

Report was accepted on October 20, 2016

#### **Committee Action Items**

1. Review Biosecurity document

#### Committee Minutes 08/01/2016

# **Committee Participants**

#### **Members Present**

Dan Danielson – TN (Outgoing Chair); Chad Linton – WV (Incoming Chair/Current Vice-Chair); Jacob Fleig – MO; Stan Cook – MO; Bob Church – MT; Mike Davidson – CA; Bob Geiger – IN; Tim Lyons – MI; Kevin Klommhaus – FDA; Brett Groves – IN; Meagan Davis – LA; David Dressler – PA; Laura Scott – CAN; Jim True – KY; Wayne Nelson - CT

Via Telephone: None

#### **Advisors Present**

Jan Campbell – NGFA; Chris Olinger – AFIA; Tomas Belloso – AFIA;

#### **Committee Report/Minutes**

Dan Danielson called the meeting to order at 11:03 AM EST. Members and advisors in the room introduced themselves.

# Introductions and Agenda Review, Dan Danielson

#### Presentation from FDA/CVM - Dianne Milazzo and Kevin Klommhaus

See Attachment A

#### Questions stemming from presentation:

Are TAN questions being published? Response: NO. At this time, maybe a FAQ sheet will be developed but not a priority to do so

What part of ingredient process does the GMP start? On the ground? On the truck? Response: This question should be submitted to TAN.

Will there be a FSMA Facility Inventory Listing? States would like to know this information. Response: FDA does not collect information on business. They pulled data from DUNS to select inventory for "other" businesses. CVM will work with the states to share this information.

Would a private brand (co-packer) have to follow FSMA provisions if they have multiply suppliers?

Response: Only if the private brand owns the supplier, or is affiliated with the supplier or the supplier is a subsidiary of the private brand. If not, the suppliers will have to handle everything on their own.

Request for 2 more state instructors for the training cadre.

## Aseptic Sampling - Bob Geiger

See Attachment B

Aseptic sampling techniques should be added to the AITS course

# **Biosecurity - Chad Linton and Brett Groves**

See Attachment C

Committee will need to review document in order to vote on acceptance of the document and its subsequent addition to the AAFCO Inspectors Manual.

#### **Other Business**

None

#### **Action Item Table**

Respons	ble	Item	Action	Timing / Status
Committe	ee	Biosecurity Document	Review for acceptance	September 2016

# Aseptic Sampling—Attachment B

- 4.3.6 ASEPTIC SAMPLE Aseptic sampling is a technique used to prevent contamination by your sampling method. Aseptic sampling involves the use of sterile sampling implements and containers. Your sampling technique is where the lot or sample is contacted only by the sampling implements or the container. Samples collected using aseptic technique, will permit testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment. Whenever possible collect intact, unopened containers. Aseptic sampling is often used in the collection of in-line samples, environmental samples, product samples from bulk containers and collection of unpack-aged product that is being collected for microbial analysis. Note: Products in 55 gallon drums, or similar large containers, either aseptically filled or heat processed, should not be sampled while the shipment is enroute unless the owner accepts responsibility for the portion remaining after sampling. Try to arrange sampling of these products at the consignee (user) so the opened containers can be immediately used or stored under refrigerated conditions. Use ASEPTIC TECHNIQUE when sampling these products. For more guidance on aseptic technique, you may consult the course Food Microbiological Control 10: Aseptic Sampling, which is available to FDA employees through the ORA U intranet site.
- <u>4.3.6.1 General Procedures</u> If it is necessary to open containers, draw the sample and submit it under conditions, which will prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling technique. Take steps to minimize exposure of product, sampling equipment, and the interior of sampling containers to the environment.
- 4.3.6.1.1 Sterilized Equipment Use only sterilized equipment and containers. These should be obtained from the servicing laboratory or in an emergency, at local cooperating health agencies. Presterilized plastic or metal tools should be used. However, if unavailable, the metal tools can be sterilized immediately before use with a propane torch. Permit the tool to cool in the air or inside a sterile container before using. Soaking with 70% alcohol and flaming off is an acceptable method of field sterilization, and may be used as a last resort. If it is necessary to drill, saw, or cut the item being sampled (such as large frozen fish, cheese wheels, frozen fruit, etc.), if at all possible, use stainless steel bits, blades, knives, etc. Wooden handled sampling instruments are particularly susceptible to bacterial contamination, are difficult to sterilize, and should be avoided.
- 4.3.6.1.2 CAUTIONS Be extremely careful when using a propane torch or other flame when sterilizing tools and equipment. Evaluate the conditions pertaining to explosive vapors, dusty air, flame restricted areas, firm's policy or management's wishes. The use of supportive devices should be considered when torch is not being hand held. Also be sure all flammable liquids, such as alcohol, in your filth kit are in metal safety cans and not in breakable containers. If it is necessary to handle the items being sampled, use sterile disposable type gloves (rubber, vinyl, plastic, etc. surgeon's gloves are good). Use a fresh glove for each sub and submit an unopened pair of gloves as a control. See IOM 4.3.6.5. 4
- <u>4.3.6.1.3 Opening Sterile Sampling Containers</u> When opening sterile sampling containers, work rapidly. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid. (See IOM 4.3.5)
- <u>4.3.6.1.4 Dusty Areas</u> Do not collect samples in areas where dust or atmospheric conditions may cause contamination of the sample, unless such contamination may be considered a part of the sample.
- <u>4.3.6.2 Sampling Dried Powders</u> Cautions The proper aseptic sampling of dried milk powder, dried eggs, dried yeast, and similar types of products is difficult because they are generally packed in multilayer poly-lined paper bags. These may be stitched across the entire top, may have filler spouts, or the top of the poly-liner may be closed or sealed with some type of "twists". The practice of cutting an "X" or "V" or slitting the bag and folding the cut part back to expose the contents for sampling should not be used because it creates a resealing problem; the opening cannot be properly repaired. The following

procedures have been approved by the scientific units in Headquarters and should be used when sampling this type product. 4

## 4.3.6.2.1 - Bag And Poly-Liner Stitched Together Across Top Seam

- 1. Remove as much dust as possible from the seam end by brushing and then wiping with a cloth dampened with alcohol. Note: This does not sterilize the bag as porous paper cannot be sterilized.
- 2. Remove the seam stitching carefully (and dust cover, if any) and spread the walls of the bag and the poly-liner open enough to permit sampling being careful that no extraneous material such as dust, bits of twine, paper, etc., drops into the product.
- 3. Carefully scrape off the surface of the product with a sterile device and aseptically draw the sample from the material below.
- 4. Carefully reclose the bag and re-stitch by hand, or by machine if firm or FDA portable sewing machine is available.

# <u>4.3.6.2.2 - Bag Stitched Across Top And Poly-Liner Twist-Closed And Sealed With "Twist" Device - Wire, Plastic, Etc.</u>

- 1. Brush, alcohol wipe, and remove stitching as described.
- 2. Remove "twist" seal and carefully open poly-liner using caution that no extraneous material drops into the product.
- 3. Draw aseptic sample in same manner as in step 3 above.
- 4. Carefully close the poly-liner with a twisting motion and reseal with "twist" seal arranging it so it will not puncture the poly-liner, and re-sew bag as in step 4 above.

# <u>CHAPTER 4 INVESTIGATIONS OPERATIONS MANUAL 2016 128 4.3.6.2.3 - Bags With Filling Spouts</u> The filling spout will be located at one side of the top stitching and will either pull out to form a top or side spout.

- 1. Brush and alcohol wipe the area around the spout and carefully pull it out to reveal the opening. It is better to have the bag on its side while pulling the spout so any dust in the opening falls outside the bag.
- 2. Carefully spread the sides of the spout apart and aseptically draw the sample. A trier or long handled device is usually better for this type opening because of the limited opening.
- 3. Carefully close the spout with a firm twisting motion and be sure the opening is closed prior to pushing back into the bag.
- <u>4.3.6.4 Sample Handling</u> For frozen samples, pre-chill sterile containers before use and keep frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration. See IOM 4.5.3.5, 4.5.3.6 and 8.3.3.3. Under normal circumstances dried products may be shipped unrefrigerated except in cases where they would be exposed to high temperatures, i.e., above 37.80 C (1000 F). Submit samples subject to rapid spoilage (specimens of foods involved in poisoning cases, etc.) by immediate personal delivery to the bacteriologist where feasible.



# **AAFCO Minimum Biosecurity Procedures**

The farm biosecurity procedures identified in this manual are a minimum standard; if your Agency's are more stringent, use them. These procedures described may appear to be simple and tedious but, persistence and attention to detail is vital for the successful elimination of disease agents. You do not want to be the reason the disease spread to another farm.

Preparation for inspection is very critical; you need to keep your visits to the infected area at a minimum. If you have more than one area to visit, the highest risk area should be your last.

#### Before you leave:

- Obtain as much information as possible from your supervisor, the veterinarian, the farm manager to insure you will be prepared for your visit.
  - o Check to see if the farm has biosecurity procedures.
- Designate a clean and dirty area in your vehicle.
  - Dirty area means items that may come in contact with animal secretions and excretions including blood, saliva, milk, semen, manure, urine, mucus or other discharges. The plastic lined trunk of your car would be a good example.
  - Clean area means items free from any visible dirt, mud, manure, etc. At the beginning of the day, your entire vehicle including tools and clothing should be clean.
- Rubber floor mats in your car should be used for the driver and each passenger. If that is not
  possible, your floor mats will need cleaned and disinfected.
  - Heavy plastic can be used to lay over your floor mats and trunk but make sure the plastic will not interfere with the safe operation of your vehicle.
- Items that can be stored in a plastic sealable container or garbage bag in your trunk in case of an emergency. When possible, you should leave all of your disposable items at the farm before you leave.
  - Disposable coveralls
  - o Disposable rubber boot covers without deep cleats
  - Rubber gloves
  - Dusk mask
  - Safety goggles
- A micro/virucidal disinfectant for onsite disinfecting
  - A pail and brush will be necessary to clean your boots if disposable covers are not available.
  - Rubber boots should have a pattern of the indentations on the soles that allows easy cleaning
  - Also bring an equipment pail for cleaning and disinfection of your tools.
    - There are wipes that can also be used in place of the pail of disinfectant.

#### At the farm:

- On arrival at the farm, always park the vehicle in a clean area with no obvious manure
  accumulation. Avoid exhaust fans from livestock areas. Close all windows to prevent insects
  from entering the car. It is best to park on an impermeable surface and might require you to park
  on the road in front of the farm.
  - o At a minimum, avoid driving through manure, puddles or wasted water.
- Put on clean coveralls and boots beside the vehicle.
- Prepare the approved disinfectant solution in the boot pail using the amounts of water indicated on the manufacturer's label.
- Make sure you have all the equipment you will need for your inspection but try not to
  overcompensate and take too much. Anything brought back will need to be disinfected or
  disposed of.

- Rinse your boots before entering the farm. Even when the risk is negligible, producers may perceive a risk from inspection staff who have visited other sites.
- Leave the boot pail, brush, and disinfectant beside the vehicle (protected from access by livestock, children and pets when necessary).

#### Leaving the premises:

- Before leaving the barn, remove manure and debris from your boots.
- Remove your rubber gloves and wash your hands and the exposed portion of your arms with hand disinfectant and scrub under the nails. Wipe your hands with damp paper towel.
- Do the preliminary cleaning of equipment and then prepare a disinfectant solution in the
  equipment pail or use your disposable wipes. If a pail is used, equipment should soak for a few
  minutes.
- At the vehicle, wipe down equipment that has been soaking. Open equipment box and clean any extraneous material from taggers, blood samples, etc., used for livestock activities.
- Clean and disinfect exterior of equipment box.
- Brush and rinse your boots in the boot pail or remove your disposable boot covers and place in the garbage bag.
- Using brush, wipe sides and bottom of equipment pail. Place in trunk and put cleaning and disinfecting equipment back in equipment pail.
- Remove (inside out) soiled coveralls without contaminating street clothing and place in dirty compartment, preferably in a heavy duty polyethylene bag or plastic carrier.
  - o If these are disposable coveralls, put in your trash bag with boot covers, rubber gloves, dusk mask or any other disposable item to be left at the farm.
- If you cannot dispose of clothing, consider the interior of the vehicle contaminated and it will be necessary to clean and disinfect.
- Do not travel to another farm or feed mill until all is clean and disinfected.

#### Return to the office:

- On your way to the office, a commercial carwash or a power washer should be used to facilitate clean-up.
  - Pay special attention to tires and wheel wells.
- All plastic equipment, carriers, etc. should be replaced regularly to avoid deep scratches which cannot be readily cleaned and disinfected.
- When necessary, do a more in-depth cleaning of the interior of the vehicle.
  - Clean and soak the floor mats.
- Taking a shower at the office or at home will also help remove any infectious particles.

# **Laboratory Methods and Services Committee Report/Minutes**

AAFCO Annual Year Meeting August 2, 2016, 8:00 am- 4:00 pm, Pittsburgh, PA

#### **Committee Recommendations**

Committee recommendation summary or list.

1) None

#### **Board Recommendations**

Report was accepted on October 20, 2016

#### **Association Actions**

Association action summary or list.

1) None.

# Committee Participants - Full listing of attendees can be found at end of report

#### **Members Present**

chibers Freschi				
e-mail	Organization			
inerowic@purdue.edu	Office of Indiana State			
	Chemist			
hhickes@mt.gov	MT Dept of Ag			
aaron.price@inspection.gc.ca	CFIA			
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	Services			
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#### **Advisors Present**

Name	e-mail	Organization
Lars Reimann	LarsReimann@EurofinsUS.com	Eurofins Scientific
Andy Crawford	andy@crawford.org	Consultant
Ken Riter	Ken.Riter@purina.nestle.com	NPAL
Jeff Horst	Jeff.Horst@agriking.com	Agriking
Bill Hall	Bill.Hall@mosaicco.com	Mosaic

# **Committee Report Committee Activities**

**ACTION: None** 

**Sub-Committee Activities** 

**ACTION: None** 

#### **Committee Minutes**

1) Review and Approval of Agenda – Agenda was approved with the addition of a discussion about Starch Method (AOAC 2014.10). Sign-up sheet sent around.

- Committee Roster and Appointments the list was sent out for review and update. People interested in joining the committee either as Members or as liaisons should contact Nancy Thiex or Aaron Price.
- 3) FSMA Implementation Task Force Update Looking for potential new analytes and associated method needs. The Taskforce will report its needs to the Lab Committee.
- 4) Working Group (WG) Updates:
  - a. Tylosin

Tom Phillips is progressing slowly and with new duties is unlikely to be able to continue chairing this working group. Leo Schilling (Eurofins) offered to help out this working group as they have an LC method for tylosin.

b. CTC

Tom Phillips looking to finalize method draft, prepare and distribute collaborative samples. Leo Schilling to assist. The collaborative study will start soon. Sharon Webb promised to assist with providing results based on the official microbial method.

c. Fat soluble vitamins

Ken Riter reported that the group is looking into alternative organizational approaches in light of current slow progress. Next step is a ring trial using NIST Infant Formula material with each lab analyzing the sample once on two days. Results are expected at the January meeting.

d. Best Practices - Fiber

Lawrence Novotny reviewed method details obtained from a survey by 50 labs. Committee will generate a report based on the info received. It was suggested to ask the respondents for the uncertainty they associate with their method.

e. Sugar method:

Jeff Horst reported that Covance had not had time to work a lot on the method, that Thermo Fisher had donated Covance a system enabling them to fine-tune the method. The method will be validated for food, pet food, feed and their ingredients. Goal is to present at AOAC's March EPR meeting.

f. Mycotoxin analysis:

No report. An EU group has completed a collaborative study focused on feed and is planning to take it to AOAC. The WG will be maintained in a "dormant" state pending the issuance of the method. One task is to get hold of the EU method and study. Nancy Thiex will contact Robert Sheridan to obtain this.

g. Multi-element metal determination:

NY Dept of Ag presented a SLV for a multi metal analysis at the January meeting, and is in the process of preparing a manuscript of their SLV. The CV's were higher than what some labs are able to achieve. Sharon Webb plans to do a SLV of her method using the same materials.

h. AAFCO Lab Sample Preparation Guidelines:

Michelle Swarbrick reported that the WG would meet for a 1 week off-site session to rewrite the 2000 document covering feed sample preparation.

- 5) Sample Splitting Results Heidi Hickes presented her study on sample preparation and splitting procedures. This presentation will be made available with the meeting minutes.
- 6) Sample Prep and ISO 17025 compliance Heidi Hickes outlined her understanding of the ISO requirements covering grinding and associated activities. Discussion followed as to what would be the minimum requirements of the standard. This presentation will be made available with the meeting minutes.
- 7) Starch method Lars Reimann discussed the need for user feedback as part of the process of moving the starch method put together by Mary Beth Hall (AOAC 2014.10) from "First Action" to "Final Action" status with AOAC. Anyone with comments as to the ease of use and other constructive criticism should contact Lars Reimann.
- 8) LM&SC Funding Proposals and Opportunities Nancy Thiex reported that AAFCO had funded several projects last year, that 2 projects had received funding this year and that additional funding might be available this year. The funding cycle is July 1-June 30.
- 9) APHL Web Resources Yvonne Salfinger presented the tools incorporated into the APHL website. It is open to the public and contains a lot of material of value when seeking 17025 accreditation.
- 10) AAFCO website and resources many resources are available. Updated verbiage for the program formerly known as the "AAFCO Check Sample Program", now the "AAFCO Proficiency Testing

- Program". FDA may provide a repository of the methods submitted to them by industry including validation data summaries as this is one of their deliverables under FSMA. Short term States can contact Lei Tang (lei.tang@fda.hhs.gov).
- 11) AAFCO's "Feed Bin": Louise Ogden summarized the capabilities of "Feed Bin" and how it could be of help to AAFCO committees and work groups. Comparisons were made with "Food Shield".
- 12) New Methods Needs and New Needs Statements Aaron Price discussed the status of the identified methods needs and associated Needs Statements. Last survey asking for and ranking needs was completed in 2012. In a couple of years it is expected that the AAFCO FSMA Task Force will provide additional method needs. Until then this project will remain "dormant".
- 13) International Food Protection Teaching Institute (IFPTI) WG update Yvonne Salfinger reported that the WG was working on a supplement for labs. Working in 18 areas building teaching programs meeting specific standards (identifies the competences expected of a person having completed a specified training program). An overview to be distributed with the meeting minutes.
- 14) Laboratory Centers of Expertise the committee submitted a "white paper" on the subject to the AAFCO BoD at the last meeting. A working group will be formed at the BoD level and volunteers from the committee will be requested to participate.
- 15) Strategic plan for the Lab Committee AAFCO BoD had specific "wishes" in their strategic plan most of which we are already working on.
- 16) AgLabs accessibility currently AgLabs can only be accessed by members of the regulatory community. The option of opening it to industry as well was not popular it would likely put a damper on the exchanges. Another was to have a second listserv that industry could join the challenge is finding someone willing to manage the exchange.
- 17) Identification of "Subject Matter Experts" Question if (and where) we could list people willing to offer assistance in specific areas. Supposedly one venue is already available on the AFDO website. No action taken on this issue.
- 18) AAFCO's cooperative agreement with FDA Nancy Thiex reported that the agreement was about to begin the 5<sup>th</sup> year of a 5 year contract. See Nancy Thiex if interested in any of the deliverables. Nancy is looking for suggestions for needs suitable for use as the basis for a new contract.
- 19) QC/QA sub-committee This is a newly formed sub-committee under the Lab Methods committee and replaces the QA/QC working group. S. Chigurupati is the Chair, Teresa Grant & Kristi McCallum are Vice-Chairs. Committee activities include sharing best practices, promote lab accreditation, build list of PT Providers, facilitate equivalency of data, etc. The chairs of the LM&SC have outlined the scope of the sub-committee.
- 20) Animal Feed Program Regulatory Standards (AFRPS). Theresa Bills, Program Officer, outlined the funding mechanism and funding availability. Currently 19 states are participating although the program likely will likely end up with 22 state labs. Standard 10 outlines FDA's performance standard expectations for labs receiving FDA grants.

# The meeting was adjourned at 4:00PM

#### **Action Item Table**

Responsible	Item	Action	Timing / Status
CTC working	Method draft and	See item 4b above	January meeting
group	Collab study		
Fat-soluble	Distribute NIST	See item 4c above	January meeting
vitamin WG	samples to labs		
Best practices	Laboratory survey	L. Novotny to collect information on method	January meeting
working group		uncertainties from responding labs.	
Sugars	Validation results	Covance to present these at the AOAC ERP	March 2017
working group		meeting in March, 2017.	
Mycotoxin WG	EU collaborative study	Nancy to obtain the collaborative study from	September 2016
		R. Sheridan	(complete)
Multi-element	Single lab validation	S. Webb to perform a SLV with their method	Next annual meeting
method WG		using the same materials as used by NY.	in August 2017.

Full List of Attendees at the Meeting

Name	e-mail	Organization

Lava Daimanu	Lara Daimana @ Functional IC ages	Function Colombia
Lars Reimann	LarsReimann@EurofinsUS.com	Eurofins Scientific
Dorota Inerowicz	inerowic@purdue.edu	Office of Indiana State Chemist
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Kristi McCallum	Kristina.McCallum@state.co.us	CO Dept of Ag.
Yvonne Salfinger	<u>yhale@aol.com</u>	APHL/AFDO
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# **Model Bills and Regulations Committee Report**

2016 AAFCO Annual Meeting August 1, 2016 Pittsburgh, Pennsylvania

#### **Committee Recommendations:**

- 1) The Model Bills and Regulation Committee (MBRC) recommends that the AAFCO Board of Directors review Attachment 1 for consideration by the Association membership.
- 2) The MBRC recommends that the AAFCO Board of Directors review Attachment 2 for consideration by the Association membership.
- 3) The MBRC recommends that the Board of Directors considers the deletion of AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients and associated checklist from the AAFCO Official Publication (pages 230-239 of the 2016 hardcopy OP) and replacing the deleted information with a html reference link and a citation to the CGMP's Title 21, CFR part 507.14 – 507.28 and associated checklist (when developed) and forward to the Association membership for consideration.

#### **Board Recommendations:**

Report was accepted on October 20, 2016

Board accepted recommendations 1-3 as presented by the committee.

#### **Association Actions:**

## **Committee Report and Minutes**

April Hunt called the meeting to order at 1:35pm. She graciously filled in for MBRC Chairman Doug Lueders at his request as he was unable to attend. Committee members and industry advisors provided introductions.

In addition to April Hunt (Michigan), committee members in attendance were: Tim Darden (New Mexico), Mike Davidson (California), Ken Bowers (Kansas), Eric Nelson (FDA), Bill Burkholder (FDA), and Richard Ten Eyck (Oregon).

Industry advisors present were: Jan Campbell, David Dzanis, David Fairfield, Susan Hays, Angela Mills, Scott Ringger, Angele Thompson, Pat Tovey, and Emily Helmes.

There were no committee members or industry advisors participating by phone.

#### **Minutes from Previous Committee Meetings**

The minutes from January 18, 2016 meeting in the Isle of Palms, South Carolina were approved as written on April 5. The minutes are published in the Feed BIN and also in this meeting's packet.

#### Preventive Controls (PC) Harmonization Work Group Report, Attachment C

April Hunt, chair of the PC Harmonization Working Group gave a report of the Working Group's activities since the January Midyear meeting. Attachment C is new take on the feedback the Working Group received at the Midyear meeting. The Working Group was tasked in August 2015 to review the AAFCO Model Bills and Regulations for harmonization with the Food Safety Modernization Act (FSMA) preventive control rules for animal food.

Motion to accept the report was made by Mr. Bowers. Second by Mr. Darden. Discussion followed. The motion was carried.

A motion to accept Items 1 and 2 in the working group report was made by Mr. Bowers. Second by Mr. Darden. The motion was carried.

Ms. Hunt explained that Item 3 in Attachment C is a proposal to delete the AAFCO Model GMPs if 1 and 2 are adopted and replace with FSMA animal food rules. The AAFCO Model GMPs are on pages 230 to 239 of the 2016 Official Publication.

A motion to approve Attachment C, Item 3 by Mr. Burkholder. The motion was seconded by Mr. Ten Eyck.

There was a question about how states, like Kansas and Michigan, which have adopted the AAFCO GMP's, would be impacted. The year of adoption of the language is the year the state uses in its law, so states will use the adoption year version until replacing it with updated state legislation. Ms. Cook asked if AAFCO hold GMP's in place for 1 more year to give states time to adjust their legislation. Mr. TenEyck clarified that the MBRC voted to accept the FSMA Animal Food Rule GMP's to avoid having 2 sets of GMP's in the US. There will be no gap in having GMP's. Mr. Sellers commented that coordination will be also be needed on export certificate requirements. There was a question whether the GMP checklist will be tied to AAFCO GMP's or the FSMA GMPs? Mr. TenEyck clarified that the checklist will evolve to be the FSMA GMP checklist and replace the AAFCO checklist.

The motion to approve Attachment C, Item 3 was passed on a voice vote.

Item 4 in Attachment C was discussed. It would modify the language in section 11(a) of Model Bill to accommodate the change from AAFCO's GMPs to the FSMA Animal Food Rule GMPs (507 rules). After discussion, the MBRC's consensus was that the language in #4 was clearer than the alternate language.

Mr. Ten Eyck moved to strike the alternate language sentence from the Attachment C, Item 4. Mr. Bowers seconded the motion. The MBRC approved the motion in a voice vote. with one dissenting vote.

The Feed PC Harmonization Working Group will continue with harmonization activities by reviewing the entire Model Bill and Regulations for consistency and uniformity.

#### **Old Business**

Attachment B was not addressed in South Carolina due to time constraints. Mr. Sellers explained that some of the items are purely editorial and do not need a vote, like "commercial feed" compared to "feed." Mr. Ten Eyck and Mr. Burkholder asked Mr. Sellers to discuss the Section 4 Registration language that specifies rules when labels could be requested. The proposed language in Attachment B suggests a state has to have a rule in place in order for a state to demand all of a company's labels. Requiring label submission is a product registration requirement vs. licensing which does not have a product registration component. Every state had product registration at one time but several have now gone to licensing only or licensing and small package registration for pet food.

The term "domesticated" from the 4<sup>th</sup> item on the first page was discussed and that it excludes zoos. Mr. Dzanis was concerned about use of "domesticated" in specialty pet section (such as tortoises and fish that are captive bred). Mr. Sellers explained that this came out of the lack of definition of dog and cat at the federal level in 2000.

Mr. Ten Eyck moved to approve the editorial corrections to the Model Bill in the Official Publication with the exception of the 4<sup>th</sup> section including "domesticated" and the last 2 sections on product registration and licensing. Mr. Darden seconded. Motion passed.

Richard Ten Eyck moved to place the removed items on Attachment B on the January 2017 agenda so we don't lose them. Mr. Darden seconded. Motion passed.

#### **New Business**

Ms. Hunt noted that the Feed PC Working Group identified other areas in the Model Bill and Regulations could be reviewed for consistency. There is interest in having the working group develop a plan to go

through entire Model Bill and Regulations to review and harmonize them. Mr. Davidson commented that California is interested in having Veterinary Feed Directive (VFD) language added to the Model Bill. Ms. Hunt commented that Michigan included VFD language in its law last year.

Ms. Hunt, as acting MBRC chair, appointed the Feed PC Harmonization Working Group to this project. Others are welcome to volunteer. Ms. Hayes volunteered to help. The working group will look into holding a full day face to face meeting right before or after the AAFCO Board meeting in Washington DC in October.

Mr. Burkholder asked about the items in Attachment A. Attachment A, item 1 was addressed previously in Preventive Controls (PC) Harmonization Work Group Report (Attachment C). Mr. Ten Eyck stated that the feed and food definitions and terms (Attachment A, Items 2 and 3) are on the Ingredient Definitions Committee agenda on August 2. The Attachment A Item 4, recall plan action item was not addressed and Attachment A(2) was previously addressed in Preventive Controls (PC) Harmonization Work Group Report (Attachment C).

The meeting was adjourned at 2:45 pm.

On behalf of the Model Bills and Regulations Committee, I respectfully submit this semi-annual report and request acceptance of the report and recommendations by the AAFCO Board of Directors and the Association Membership.

# Model Bills and Regulations Committee—Attachment 1

Pittsburgh MBRC Minutes

#### Section 3. Definitions of Words and Terms

When used in this Act:

- (a) The term "brand name" means any word, name, symbol, or device, or any combination thereof, identifying the commercial feed of a distributor or registrant/licensee and distinguishing it from that of others.
- (g) The term "drug" means any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man and articles other than commercial feed intended to affect the structure or any function of the animal body.
- (m) The term "official sample" means a sample of commercial feed taken by the \_\_\_\_\_ or their agent in accordance with the provisions of Section 11(c), (e), or (f) of this Act.

## Section 5. Labeling

A commercial feed shall be labeled as follows:

effective use.

- a) In case of a commercial feed, except a customer-formula feed, it shall be accompanied by a label bearing the following information.
  (3) The guaranteed analysis, expressed on an "as is" basis, stated in such terms as the \_\_\_\_\_ by regulation determines is required to advise the user of the composition of the commercial feed or to support claims made in the labeling. In all cases the substances or elements must be determinable by laboratory methods such as the methods published by the AOAC International.
  (6) Adequate directions for use for all commercial feeds containing drugs and for such other commercial feeds as the \_\_\_\_\_ may require by regulation as necessary for their safe and
- Section 8. Prohibited Acts

The following acts and the causing thereof within the State of \_\_\_\_\_ are hereby prohibited.

(h) Bags or totes used for commercial feeds (including customer-formula feed) shall not be reused unless appropriately cleaned. A firm that intends to re-use bags or totes must document its cleanout procedures.

#### Section 12. Certificates

To facilitate continued access to markets for commercial feed and feed ingredients, the \_\_\_\_\_ may:

#### Section 14. Penalties

(h) In any action to compel performance of an order of the \_\_\_\_\_ to enforce this Act, the court must require a defendant adjudged responsible to perform the acts within the person's power that are reasonably necessary to accomplish the purposes of the order.

# 2016 Pittsburgh MBRC Minutes—Attachment 2

**Section 10 (c) Food and drug rules.** Federal regulations contained in Title 21, Code of Federal Regulations, part 507, not otherwise adopted herein, also are adopted as feed rules of this state.

#### Section 11

(a)(2) to inspect at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. The inspection may include the verification of records, and production and control procedures related to the manufacture, distribution, storage, handling, use or disposal of commercial feed as may be necessary to determine compliance with this Act.

# Regulation 11 Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls (b) Pursuant to Section 10 of the Act, the \_\_\_\_\_ adopts the requirements of Title 21, Code of Federal Regulations, part 507.

# 2016 MBRC Annual Meeting—Attachment A

AAFCO Feed PC Harmonization Work Group FSMA Model Bill Language 6/6/16 DRAFT

#### 1. Add as Section 10 (c) in the Model Bill-Returned to workgroup

#### Option A. All food and drug rules

**Food and drug rules.** Applicable federal regulations including recodification contained in Code of Federal Regulations, title 21, parts 1 to 1299, not otherwise adopted herein, also are adopted as feed rules of this state.

#### Option B. FSMA animal food preventive control rules

**Food and drug rules.** Applicable federal regulations including recodification contained in Code of Federal Regulations, title 21, part 507, not otherwise adopted herein, also are adopted as feed rules of this state.

#### Option C. FSMA animal food preventive control rules, GMPs only

**Food and drug rules.** Applicable federal regulations including recodification contained in Code of Federal Regulations, title 21, part 507.1 to 507.28, not otherwise adopted herein, also are adopted as feed rules of this state.

#### 2. Add definitions to Section 3 of the Model Bill (From 21 CFR 507.3 Definitions)—Tabled in January

Animal food – means food for animals other than humans and includes pet food, specialty pet food, animal feed, and raw materials and ingredients.

Feed(s) – Edible materials(s) which are consumed by animals, other than humans, and contribute energy and/or nutrients to the animal's diet.

# 3. Update the AAFCO Official Feed Terms – Animal food as a new term and update to existing Feed term—Tabled in January

Animal food – means food for animals other than humans and includes pet food, specialty pet food, animal feed, and raw materials and ingredients.

Feed(s) – Edible materials(s) which are consumed by animals, other than humans, and contribute energy and/or nutrients to the animal's diet.

**4. Add Facility recall plans as Section 8 in the Model Bill.** (The current Section 8 and the remaining sections will need to be renumbered)—**Tabled in January** 

From 21 CFR 507.38

Section 8. Recall Plan

(a) Commercial feed licensees and registrants must:

- (1) Establish a written recall plan for the animal food; and
- (2) Assign responsibility for performing all procedures in the recall plan.
- (b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:
  - (1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;
  - (2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;
  - (3) Conduct effectiveness checks to verify the recall has been carried out; and
  - (4) Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

# Attachment A(2) Tabled in January

## Section 11(a)

(2) to inspect at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. The inspection may include the verification of only such records, and production and control procedures related to the manufacture, distribution, storage, handling or disposal of commercial feed as may be necessary to determine compliance with as may be necessary to determine compliance with the Good Manufacturing Practice Regulations established under Section 7(d) of this Act.

**2016 MBRC Annual Meeting—Attachment B**AFIA proposed changes to the AAFCO Model Bill November, 2015

Edit Requested	MB Section	Language showing edit	Rationale
Should say "registrant/licensee" in the definition for "brand name"	Section 3. Definitions	(a) The term "brand name" means any word, name, symbol, or device, or any combination thereof, identifying the commercial feed of a distributor or registrant/licensee and distinguishing it from that of others.	The MB allows for states to decide between registration or licensing therefore this option should be stated here to get it correctly stated in state law.
Add "commercial" in front of "feed" in the definition for "official sample"	Section 3. Definitions	(m) The term "official sample" means a sample of commercial feed taken by the or their agent in accordance with the provisions of Section 11(c), (e), or (f) of this Act.	Throughout the MB it is always referred to as "commercial feed" or another qualifier (customer-formula feed, medicated) but it was not in this definition.
Add "commercial" in front of "feed" in the definition for "drug"	Section 3. Definitions	(g)articles other than <u>commercial</u> feed intended to affect	Throughout the MB it is always referred to as "commercial feed" or another qualifier (customer-formula feed, medicated) but it was not in this definition.
Add "domesticated" in front of "dog or cat" in the definition of "pet"	Section 3. Definitions	(q) The term "pet" means domesticated dog or cat.	In (u) specialty pet – it states "domesticated animal" and we think the intent of AAFCO is to cover domesticated dogs and cats only and this clarifies that.
Add "commercial" in front of "feed" in this Labeling section	Section 5. Labeling	(a)(3)advise the user as to the composition of the commercial feed or to support	Throughout the MB it is always referred to as "commercial feed" or another qualifier (customer-formula feed, medicated) but it was not in this section
Add "commercial" in front of "feed" in this Labeling section	Section 5. Labeling	(a)(6)and for such other commercial feeds as the may require	Throughout the MB it is always referred to as "commercial feed" or another qualifier (customer-formula feed, medicated) but it was not in this section
Change "their" to "its" when referring to the firm	Section 8. Prohibited Acts	(h) Bags or totes used for commercial feeds (including customerformula feed) shall not be re-used unless appropriately cleaned. A firm that intends to re-use bags or totes must document their its cleanout procedures.	"Its" is appropriate when talking about the "firm"
Add "commercial" in front of "feed" in this Certificates section	Section 12. Certificates	Opening sentence where it saysaccess to	Throughout the MB it is always referred to as "commercial feed" or another

Edit Requested	MB Section	Language showing edit	Rationale
		markets for <u>commercial</u> feed and ingredients	qualifier (customer-formula feed, medicated) but it was not in this section
Change "an" to "any"	Section 14. Penalties	(h) In any action to compel performance of an order of the to enforce this Act, the court must require a defendant adjudged responsible to perform the acts within the person's power that are reasonably necessary to accomplish the purposes of the order.	It should be "any" action to be consistent with the rest of the section and the use of "any"
Require rule-making to define conditions labels would be requested.	Section 4. Registration and Licensing Option B. Licensing	(d) The is authorized to promulgate a rule defining under what conditions the may request labels and/or labeling from a license applicant or licensee. The may request from, at any time, a license applicant or licensee copies of labels and labeling in order to determine compliance with the previsions of the Act.	The state should need to detail out under rule-making the conditions for which they may request labels. The rule-making process would allow transparency in the thought process and rationale between the state official and the industry.
Require rule-making to define conditions labels would be requested.	Section 4. Registration and Licensing Option C. Registration and Licensing	(d) The is authorized to promulgate a rule defining under what conditions the may request labels and/or labeling from a license applicant or licensee. The may request from, at any time, a license applicant or licensee copies of labels and labeling in order to determine compliance with the provisions of the Act.	The state should need to detail out under rule-making the conditions for which they may request labels. The rule-making process would allow transparency in the thought process and rationale between the state official and the industry.

#### **Pet Food Committee Report/Minutes**

AAFCO Annual Meeting August 2, 2016, 9:30 am–12 pm; Pittsburgh PA

#### **Committee Recommendations**

Committee recommendation summary or list.

#### **Board Recommendations**

Report accepted on October 20, 2016

#### **Association Actions**

Association action summary or list.

#### **Committee Participants**

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

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

#### **Committee Report**

#### **Committee Activities**

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

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

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

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

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

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

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

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

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

#### **Committee Minutes**

#### **Announcements**

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

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

#### **Working Group Reports:**

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

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

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

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

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

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

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

Question 2 Discussion - No additional discussion.

Question 3 Discussion – George Ferguson (NC) has been addressing some of these issues in his state. He proposes to require as substantiation for the human grade claim would be a certificate (whether a license or certificate of free sale) with the date of last inspection from the agency authorized in the

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

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

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

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

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

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

#### **New Business -**

<u>Discrepancy in 'pet' and 'specialty pet' definitions</u> - The Model Bill and Regulations Committee (MBRC) has directed the PFC to consider modifications to the 'pet' and 'specialty pet' definitions on page 108 in the 2016 Official Publication as there is some discrepancy as noted by AFIA regarding the use of the word 'domesticated' to describe specialty pets but not pets. There was discussion involving how current

and possible new definitions would affect certain species such as rabbits and zoo animals, as well as the non-domesticated status of many species considered to be 'specialty pets'. A working group was formed to review the definitions for pet and specialty pet in the model bill, and any other affected definitions in the model bill or regulations regarding the word domesticated. Bill Burkholder will chair the committee consisting of Leah Wilkinson (AFIA), Angele Thompson (PFI), Dave Dzanis (APPA), Liz Higgins (NM), Jean Hofve (PWA), Jason Schmidt (LA), Austin Therrell (SC) and Lizette Beckman (WA).

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

Pet Food Committee Adjourned at 11:50 pm EST.

# **Proficiency Testing Program Committee Report/Minutes**

AAFCO Annual Year Meeting August 1, 2016, 1:30–5:30 pm, Pittsburgh, PA

#### **Committee Recommendations**

Committee recommendation summary or list.

(1) Committee name change to "Proficiency Testing Program Committee"

#### **Board Recommendations**

Report accepted on October 20, 2016

#### **Association Actions**

Association action summary or list.

(1) None.

# Committee Participants – Full listing can be found at end of report. Members Present:

## **Position**

Brenda	Snodgrass	brenda.snodgrass@ag.ok.gov	Chair - AAFCO PM
Louise	Ogden	louweeziann@gmail.com	Vice-Chair - AAFCO QM
Nancy	Thiex	nancy.thiex@gmail.com	AAFCO manager
Andy	Crawford	andy@crawford.org	AAFCO Statistician
Bob	Kieffer	kiefferbob@gmail.com	AAFCO Prep Lab
Amy	Kieffer	amy@ablelaborotory.com	AAFCO Prep Lab
Mark	LaBlanc	mark_I@ldaf.state.la.us	Board Liaison
Teresa	Grant	teresa.grant@ncagr.gov	APHL Liaison
Mary	Koestner	mary.koestner@mda.mo.gov	Member
Aaron	Price	aaron.price@inspection.gc.ca	Member
Sharon	Webb, Ph.D.	sharon.webb@uky.edu	Member

#### **Advisors Present:**

#### **Position**

Lars	Reimann	larsreimann@eurofinsus.com	Advisor
Ken L.	Riter	ken.riter@purina.nestle.com	Advisor

**Committee Report Committee Activities** 

ACTION: None

#### **Sub-Committee Activities**

**ACTION: None** 

#### **Committee Minutes**

- 1.) Review and Approval of Agenda
- 2.) Introductions sign-up sheet sent around.
- 3.) Program Leadership and Administrative Update
  - a. Chair:b. Vice-Chair;c. StatisticianBrenda SnodgrassLouise OgdenAndy Crawford
  - d. Administration Jennifer Roland and Mark Budden

e. Programing Consultant/CoAg Principal Investigator Nancy Thiex

#### 4.) Accreditation update

a. As part of the efforts to get the program accredited, Louise Ogden is writing and Brenda Snodgrass is reviewing the documents needed for accreditation to ISO 17043 by ANAB (formerly ACLASS). Application is likely to be submitted to ANAB before the end of September. The program has made a name change to the "AAFCO Proficiency Testing Program" and will have 4 schemes: animal feed, minerals, pet food, and mycotoxins.

#### 5.) Subscription renewal

a. 2017 renewal opens up October 1, 2016. Early sign-up is requested to assist program management in assessing how many samples to produce. Need approx. 3 months lead time. While no price increase is anticipated for 2017, an increase is expected for 2018 to provide the additional funds needed to cover the fees associated with maintenance of the ISO accreditation.

#### 6.) Program summary:

a. Program participation

Feed program approx. 220 active participants each month
Pet food program -approx. 60 active participants each quarter
Mycotoxin program -approx. 35 active participants each quarter
Minerals -approx. 25 active participants each quarter.

- There was discussion on how frequently samples should come to labs with quarterly shipments being suggested. Nancy and Able Labs said this would not increase efficiencies for the program.
- Lots of new feed types are being added to the program (fish, equine, llama, rabbit, goat, etc.).
- Overall, the 4 schemes are working well and the new ones are growing.

#### b. Medicated feeds

Homogeneity – no indications that the program has homogeneity issues. The CFIA's Ottawa Laboratory (Carling) has performed analyses on the program's medicated feeds to yield homogeneity statistics.

Method code changes – Aaron Price and Heidi Hickes to work with Andy Crawford to see if it makes sense to "merge" the medicated feed and the feed residue codes and standardizing reporting unit to mg/kg.

#### c. Reference material:

Bob Kiefer reported that during every sample production cycle extra samples are made that are stored at ambient temperature and sold upon request. Holding time is around 2 years unless sold out earlier. The amount of samples sold has been stable for the past several years. Some feed types appear more popular, e.g. poultry and swine feed. Able labs will look into

making additional feed samples expected to have a larger demand as a reference material. The PT Program will survey participants and other feed labs to determine potential demand.

d. Range of analytes and matrices:

Several people requested that a full fat dairy powder (around 25% fat) be included.

#### 7.) Promotional efforts

- a. The area on the AAFCO Laboratory webpage where labs order proficiency test samples and quality reference materials isn't intuitive. The PT Program staff thinks a link right on the AAFCO Home webpage would be good and will propose some additional enhancements to promote the PT program to FASS on the website.
- b. A FAQ section will be added to the Proficiency Testing Program page.
- c. People with other suggestions for improving the web site including volunteering to be on a WG should contact Louise Ogden.
- d. The brochure is being updated to reflect the name changes in the program.
- 8.) "Feed bin" Louise Ogden discussed the benefits associated with the use of the AAFCO "Feed bin" portal. The PT Program uses Feed BIN as a virtual office. The PTP Committee members/advisors are encouraged to acquire a Feed BIN account for future committee work. The cost for Feed Bin Annual access is \$50.00 for Feed Bin Access only, Official Publication (OP) access member is \$70.00 and OP access for industry and commercial is \$125.00.
- 9.) Customer survey as part of the accreditation activities a survey will soon be sent out asking for suggestions for program improvements.
- 10.) Mission statement Mission statement and Scope will be updated and a draft presented at the January meeting.
- 11.) Acknowledgments Committee members and visitors applauded Louise Ogden and Brenda Snodgrass for all their efforts toward getting the program ISO accredited.
- 12.) Meeting Adjourned

#### **Action Item Table**

Responsible	Item	Action	Timing / Status
A Price and	Method Codes	Look at combining method codes for drug	30 days
A Crawford		guarantees and drug residues.	

#### **Attendees**

FIRST	LAST	EMAIL	
Louise	Ogden	louweeziann@gmail.com	<u>Vice Chair – QM</u>
Brenda	Snodgrass	brenda.snodgrass@ag.ok.gov	<u>Chair – PM</u>
Nancy	Thiex	nancy.thiex@gmail.com	<u>Manager</u>
Andy	Crawford	andy@crawford.org	<u>Statistician</u>
Bob	Kieffer	kiefferbob@gmail.com	Prep Lab
Amy	Kieffer	amy@ablelaborotory.com	Prep Lab
Mark	LaBlanc	mark_I@ldaf.state.la.us	<u>Member</u>
Teresa	Grant	teresa.grant@ncagr.gov	<u>Member</u>
Mary	Koestner	mary.koestner@mda.mo.gov	<u>Member</u>
Aaron	Price	aaron.price@inspection.gc.ca	<u>Member</u>
Tai	На	tai.ha@nebraska.gov	New Member 8/2016
Sharon	Webb, Ph.D.	sharon.webb@uky.edu	<u>Member</u>
Frank	Sikora, Ph.D.	fsikora@uky.edu	New Member 8/2016
Josh	Arbaugh	jarbauch@wvda.us	New Member 8/2016

FIRST	LAST	EMAIL	
Patty	Lucas	patricia.lucas@freshfromflorida.com	New Member 8/2016
Deepika	Curole	dcurole@ldaf.state.la.us	New Member 8/2016
Lars	Reimann	larsreimann@eurofinsus.com	<u>Advisor</u>
Ken L.	Riter	ken.riter@purina.nestle.com	<u>Advisor</u>
Sara	Williams	smw@otsc.tamu.edu	
Teresa	Rygiel	teresa.rygeil@freshfromflorida.com	
Jim	Zhang	jianzhang@agri.nv.gov	
Jenny	Bailie	jbailie@milkspecialties.com	
Kyle	Burton	kyle.burton@covance.com	
Susan	Wiegert	susan.wiegert@pahc.com	
Milea	Alswynse	milea.alswynse@fda.hhs.gov	
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# **Strategic Affairs Committee Report/Minutes**

August 3, 2016 10:15 am–12:00 pm Pittsburgh, Pennsylvania

#### **Committee Recommendations**

1. Report acceptance.

#### **Board Recommendations**

1. Report accepted - October 20, 2016

#### **Association Actions**

1. Report accepted - add date

#### **Full Committee Members**

Andy Gray Roger Hoestenbach \*April Hunt \*Jamey Johnson

Shannon Jordre \*Ali Kashani \*Chad Linton \*Mark LeBlanc (Board Liaison)

\*Dragan Momcilovic Jenny Murphy Aaron Price \*Kent Kitade

\*Nancy Thiex \*Judy Thompson \*Robert Waltz, Vice Chairperson

\* Present at meeting

#### **By-Laws Sub-Committee**

Ken Bowers April Hunt Richard TenEyck

#### **Committee Advisors**

\*Dave Ailor \*Nancy Cook Dave Dzanis Bob Ehart \*Dave Fairfield Pat Tovey Kristi Krafka Ed Rod

\*Richard Sellers
\* Present at meeting

#### **Committee Report**

- 1. Sub-Committee: By-Laws (Ken)
  - Update

Clarification of Article 5, Section 1 needed.

Action: Complete by October and share with Committee

Add Richard T. to Sub-Committee:

2. Strategic Plan (SP) Priority Activities 2013-16 - update

Working group (Bob, Jenny, Richard, Linda) report on Integrated Tracking system implementation in FeedBin

Further work is not required given the 2017–20 priorities will replace it and will be tracked in the FeedBin

Motion to dissolve WG - Chad L.; second - Bob W.; motion carries

3. Last update on Strategic Plan 2013-16 work plan progress with responsible Committee Chairs Process for new members: Ali/Vice Chair CIOC

New Vice Chair - Kelsey Luebbe

New approach implemented for first time attendees

Work group is expanding program to include mentoring program

Build leaders with AAFCO background who support AAFCO: Linda/Tim L./Jenny

Course selected but not service provider. No further action.

Partnership establishment: Kelsey/Ali

Liaison to AFDO has strengthened relationship

NASDA relationship expanded and doing well via technical working groups, FSMA grant application, etc

IFPTI through ETC have expanded relationship significantly

USDA remains a challenge; Board have continued to use opportunities to meet with individually them

Support APHL Grant: Nancy

Cooperative Agreement entering 5th and final year

Extensive reporting process has enabled synergistic relationship development with AFDO and APHL

Discussions underway and will continue in coming months regarding need for next grant round Request for lab corner in AAFCO newsletter

Action: Ali will forward request to Kelsey and Liz

Enhanced Communications (6 sub-elements): Kelsey/Ali

Kelsey Luebbe, Vice Chair, has drafted a survey

Liz Higgins is working establish a newsletter (twice yearly, hope to start in November)

Work will transition over to the 2017-20 Strategic Plan priorities under AAFCOs FSMA communication activities

Board direction, July 13, 2016, to remove leftover priorities from 2013-16 Strategic Plan and move forward with the 2017-20 priority activities.

#### 4. Strategic Planning 2017-20

Update: planning session held May 2 with Board of Directors and Committee Chairs and follow up calls early June to finalize the plan. The Board of Directors accepted the plan and it was approved by the membership August 1, 2016 at the Annual meeting. Committee Chairs were made aware of the need to begin moving the items forward during their respective Committee meetings. Richard has entered the basics into the FeedBin which will be used to track progress.

AAFCO FSMA Implementation Task Force priorities have been integrated into the 2017-20 Strategic Plan.

Action: Linda will work to add details to the tracking system in the Bin and will ask responsible Committee Chairs to review it. They will also be asked to develop action plans with milestones and deliverables.

#### 5. Other Business

Suggestion that AAFCO review resource material costing with a view to reducing prices to promote more widespread use.

Action: refer to Board for Finance Committee consideration.

Consider increasing meeting pricing to make it a substantive source of revenue.

Action: refer to Board for Finance Committee consideration.

Suggestion that AAFCO again consider the need for an Executive Director.

Action: refer to Board for consideration.

Confirm Committee membership for the 2017 year

Committee financial needs from the 2016–17 budget:

None at this time

The meeting report was accepted by the Chair without exception. Draft report will be circulated to the Committee prior to finalization.

Motion: To adjourn the meeting: Bob W.; second – Richard T; Motion carries.

# **Action Item Table**

Responsible	Item	Action	Timing / Status
Working	Strategic Plan and	Integrated Tracking system drafted in FeedBin	Dissolved.
Group: Bob W.	Priority Action	with FASS support for detail input.	2017–20 Strategic Plan will
(lead), Jenny	Item tracking and		be tracked in the bin using
and Richard	progress updates		the project management tools
Other business	Industry	Nancy Cook to identify potential items not	Complete. Reviewed a
	suggestion that	already listed on web site.	number of training sites but
	guidelines/		found they aren't quite ready
	manuals be made		to suggest adding.
	available at a cost		
	(e.g. Inspector		
	Manual)		
By-Laws	Clarification of	Complete by October and share with	
	Article 5, Section 1	Committee	
	needed		
Linda	Strategic Plan	Work to add details to the tracking system in	August 2016
	priorities 2017-20	the Bin and ask responsible Committee Chairs	
		to review it. They will also be asked to develop	
<u> </u>		action plans with milestones and deliverables.	
Board		Suggestion that AAFCO review resource	
		material costing with a view to reducing prices	
		to promote more widespread use. Refer to	
Daniel		Board for Finance Committee consideration.	
Board		Consider increasing meeting pricing to make it	
		a substantive source of revenue. Refer to	
Doord		Board for Finance Committee consideration.	
Board		Suggestion that AAFCO again consider the	
		need for an Executive Director.	
		Refer to Board for consideration.	