

# Association of American Feed Control Officials

# 2017 AAFCO Annual Meeting Committee Reports



August 10-12, 2017

**Hyatt Regency** 

Bellevue, Washington

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# **Association Business Meeting Minutes**

2017 AAFCO Midyear Meeting
January 16, 8:56 am–9:26 am, Mobile, Alabama

- 1) Ken Bowers convened the business session of the Association at 8:56 am.
  - A) Certificates of Appreciation were presented to Liz Higgins and Kelsey Luebbe for their hard work in organizing and managing the AAFCO newsletter.
  - B) Distinguished Service Awards were present to Linda Morrison, Dan Danielson, and Jennifer Godwin for their leadership, hard work, and dedication to AAFCO.
  - C) Distinguished Service Award was presented to Dragan Momcilovic for organizing and coordinating the Medicated Feeds Labeling Workshop.
- 2) Stan Cook states the AAFCO Board of Directors approved the following committee reports: Current Issues and Outreach, Education and Training, Feed and Feed Ingredient Manufacturing, Feed Labeling, Ingredient Definitions, Ingredient Definitions Committee eMeeting Report September 30, Inspection and Sampling, Laboratory Methods and Services, Model Bill and Regulations, Pet Food, Proficiency Testing Program, and Strategic Affairs, and recommends the same to the membership. I so move. **Bob Geiger Seconds. MOTION CARRIES**
- 3) Acceptance of Committee Recommendations—Stan Cook, President-Elect **Feed Labeling Committee:**

# Report starts on page 20 of the Committee Report Book

A) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the Feed Labeling Committee to revise Table 1 found on page 23 of the Committee Report Book: Nutrient Guarantees Required by Species under the AAFCO Model Bill and Regulations to publish in the Official Publication and recommends the same to the membership. I so move.

# **Richard Seconds. MOTION CARRIES**

# **Ingredient Definitions 1-5:**

# Report starts on page 25 of the Committee Report Book

- A) First recommendation from the IDC to publish the following Tentative definitions in the *Official Publication* as Official:
  - Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
    - a) T6.17 L-Methionine is a product containing a minimum of 98.5% L-isomer of 2-amino-4-(methylthio)butanoic acid. L-Methionine is produced by Escherichia coli K12 fermentation followed by enzymatic conversion to L-methionine. The percentage of L-methionine must be guaranteed. (Proposed 2015)

and recommends the same to the membership. I so move. **Richard Seconds. MOTION CARRIES** 

- ii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) T27.9 Deoiled Corn Distillers Dried Grains With Solubles, Solvent Extracted is the product resulting from the solvent extraction of oil from corn distillers dried grains with solubles (DDGS) to result in a crude fat content of less than 3% on an as-fed basis. It is intended as a source of protein. The label shall include a guarantee for minimum crude protein and maximum sulfur. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 2015)

and recommends the same to the membership. I so move. **Steve Gramlich Seconds. MOTION CARRIES** 

- iii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) **T54.33 Bovine Colostrum** is lacteal secretions obtained within 48 hours after parturition. It contains 3% maximum lactose, 15% minimum total solids, and 60% minimum of the solids must be protein. The minimum specific gravity is 1.04 g/mL. (Proposed 2014 rev. 1)

- and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTON CARRIES, 3 opposed**
- iv) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) **T54.34 Dried Bovine Colostrum** is the product obtained by removing water from bovine colostrum. It contains 8% maximum moisture, 20% maximum lactose, and 50% minimum of the solids must be protein. (Proposed 2014 rev. 1)

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES, 3 opposed** 

- v) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) **T57.165 Zinc Hydroxychloride** is the hydrolysis product of zinc chloride having the empirical formula Zn<sub>5</sub>(OH)<sub>8</sub>Cl<sub>2</sub>·(H<sub>2</sub>O). The particle size must not exceed 100 microns. It must contain not less than 54% zinc and is intended to be a source of zinc for use in livestock and companion animal diets. It must not contain more than 20% chloride, 90 ppm lead, 15 ppm chromium, 10 ppm arsenic, 10 ppm cadmium, and 0.2 ppm mercury. (Proposed 2015 rev. 1)

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- vi) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - T71.30 Mustard Meal, Solvent Extracted is the product obtained by grinding the cake that remains after removal of some of the oil by mechanical extraction, and removing most of the remaining oil by solvent extraction. It is obtained from the seed of the cultivated mustard plants *Brassica juncea*, *Brassica nigra*, and *Sinapis alba* (formerly *Brassica alba*). Use should be restricted to cattle and sheep and at no more than 10% of the ration. It should not be fed to lactating dairy cows if milk production is for human consumption because of objectionable taste and/or odor. (Proposed 2015 rev. 1) IFN 5-12-149 Mustard seeds meal solvent extracted.

and recommends the same to the membership. I so move. **Bob Geiger Seconds. MOTION CARRIES** 

- vii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) T73.300 Sodium Salts of Fatty Acids are obtained by the neutralization of feed grade vegetable origin free fatty acids, or saponification of vegetable oil or a combination thereof. The specifications of the starting materials must meet the requirements stated in the AAFCO definition 33.3 (Hydrolyzed Vegetable Fats, or Oils, Feed Grade) and the AAFCO definition 33.2 (Vegetable Fat, or Oil), respectively. Sodium hydroxide is used in the neutralization or saponification reactions. The resulting sodium salts are used as a binder and/or lubricant in the pelleted and flaked feed. The source of the fatty acids or vegetable oil shall be indicated on the label. Sodium salts are in dry form with the maximum moisture not to exceed 8% by weight. It may be used in animal feed in amounts calculated on an "as is" basis not to exceed 5.5 lb./ton. Sodium salts of fatty acids shall be labeled with guarantees on an "as is" basis for no more than 0.5% free fatty acids, no more than 12% glycerin, not less than 67% total sodium salts of fatty acids, and no more than 1% unsaponifiable matter. (Proposed 2015 rev. 1)

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- viii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) T73.301 Potassium Salts of Fatty Acids are obtained by the neutralization of feed grade vegetable origin free fatty acids, or saponification of vegetable oil or a combination thereof. The specifications of the starting materials must meet the requirements stated in the AAFCO definition 33.3 (Hydrolyzed Vegetable Fats, or Oils, Feed Grade) and the AAFCO definition 33.2 (Vegetable Fat, or Oil),

respectively. Potassium hydroxide is used in the neutralization or saponification reactions. The resulting potassium salts are used as a binder and/or lubricant in the pelleted and flaked feed. The source of the fatty acids or vegetable oil shall be indicated on the label. Potassium salts are in liquid form with the maximum moisture not to exceed 68% by weight. It may be used in animal feed in amounts calculated on an "as is" basis not to exceed 15.5 lb./ton. Potassium salts of fatty acids shall be labeled with guarantees on an "as is" basis for no more than 0.5% free fatty acids, no more than 10% glycerin, not less than 24% total potassium salts of fatty acids, and no more than 1% unsaponifiable matter. (Proposed 2015 rev. 1)

and recommends the same to the membership. I so move. **Bob Geiger Seconds. MOTION CARRIES** 

- ix) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definitions in the *Official Publication* as Official:
  - a) **T87.29 Yucca schidigera Extract** may be used as a flavoring agent in all animal foods. It is also an aid in the control of manure odor (post-excretion) when added to finished feeds of poultry, livestock, rats, mice, hamsters, gerbils, and hedgehogs. The inclusion rate shall be the minimum quantity necessary to produce the intended effect, but not exceeding 125 ppm in the finished feed. 21 CFR 172.510. (Proposed 2015 rev. 1) IFN 8-19-700 Yucca, Mohave extract

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- x) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definitions in the *Official Publication* as Official:
  - a) T93.9 \_\_\_\_\_ Wheat Gluten (with edits presented in attachment A) is the major water-insoluble proteinaceous fraction of wheat, consisting primarily of gliadin and glutenin proteins. Wheat gluten is prepared from wheat flour that is free from other seeds and foreign matter, by washing with water to remove most of the water-soluble non-protein components. Vital Wheat Gluten is dried gluten that has retained its viscoelasticity when hydrated, whereas Devitalized Wheat Gluten has reduced viscoelasticity as a result of denaturation by heat. Moisture content shall not exceed 10%. Wheat gluten, on a moisture-free basis, must contain not less than 80% crude protein (crude protein based on N x 6.25), and not more than 1.5% crude fiber and 2.0% ash. (For identification of the viscoelastic properties on the ingredient label, "vital" or "devitalized" must be specified.) The words "vital" or "devitalized" are not required when listing as an ingredient in a manufactured feed. (Proposed 2013)

and recommends the same to the membership. I so move. **Dave Phillips Seconds. MOTION CARRIES** 

- xi) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following Tentative definition in the *Official Publication* as Official:
  - a) T96.13 Molasses Hydrolyzed Yeast is a concentrated, non-extracted, partially soluble yeast digest. Yeast cells are sourced from the fermentation of molasses for ethanol production. Solubilization is accomplished by enzymatic hydrolysis of whole Saccharomyces cerevisiae cells. Salts may be added as processing aids in accordance with good manufacturing practices. It must not contain less than 30% crude protein. (Proposed 2015)

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- B) Second IDC recommendation to publish the following new definitions as Tentative in the *Official Publication*:
  - i) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the *Official Publication*:
    - a) **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 pre-ruminant 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.

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- ii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the *Official Publication*:
  - a) 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 pre-ruminant 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.

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- iii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the *Official Publication*:
  - a) **T6.12 Taurine** is a product that contains a minimum of 97% 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in cat foods, dog foods, and fish foods. Taurine may also be added to the feed of growing chickens; when added to complete chicken feed, the total taurine content shall not exceed 0.054% of the feed (21 CFR 573.980).

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- iv) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the *Official Publication*:
  - a) 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.

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- C) Third IDC recommendation to publish the following definitions as Official in the AAFCO Official Publication:
  - Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the AAFCO Official Publication:

- a) **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.
- and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES**
- ii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the AAFCO Official Publication:
  - a) 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:
    - (1) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-(mu3-oxo) hexakis (mu2-propionato-O,O') trichromium propionate with the empirical formula, [Cr<sub>3</sub>(O)(CH<sub>3</sub>CH<sub>2</sub>CO<sub>2</sub>)<sub>6</sub>(H<sub>2</sub>O)<sub>3</sub>|CH<sub>3</sub>CH<sub>2</sub>CO<sub>2</sub>.
    - (2) It is added to feed as follows:
      - (A) 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.
      - (B) 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.
    - (3) The additive meets the following specifications:
      - (A) Total chromium content, 8 to 10%
      - (B) Hexavalent chromium content, less than 2 parts per million
      - (C) Arsenic, less than 1 part per million
      - (D) Cadmium, less than 1 part per million
      - (E) Lead, less than 0.5 part per million
      - (F) Mercury, less than 0.5 part per million
      - (G) Viscosity, not more than 2,000 centipoise
    - (4) The additive shall be incorporated into feed as follows:
      - (A) 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.
      - (B) 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.
      - (C) Chromium from all sources of supplemental chromium cannot exceed 0.2 part per million of the complete feed for broiler chickens and swine and 0.5 part per million of the complete feed for cattle.
    - (5) To ensure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:
      - (A) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.
      - (B) 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 part per million of the complete feed for broiler chickens and swine and 0.5 part per million of the complete feed for cattle.

(21 CFR 573.304) (Adopted 2017)

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTIION CARRIES** 

- iii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the AAFCO Official Publication:
  - a) 73.026 Feed Grade Sodium Formate—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:
    - (1) The additive is manufactured by the reaction of 99% formic acid and 50% sodium hydroxide in water to produce a solution made up of at least 20.5% sodium salt of formic acid and not more than 61% formic acid.
    - (2) 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% of the complete feed.
    - (3) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2% of complete feed when multiple sources of formic acid and its salts are used in combination.
    - (4) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:
      - (A) The name of the additive.
      - (B) 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.
      - (C) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2% of complete feed when multiple sources of formic acid and its salts are used in combination.
    - (5) To ensure safe use of the additive, in addition to the other information required by the act and paragraph (4) of this section, the label and labeling shall contain:
      - (A) Appropriate warnings and safety precautions concerning feed grade sodium formate.
      - (B) Statements identifying feed grade sodium formate as a corrosive and possible severe irritant.
      - (C) 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.
      - (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)

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- D) Fourth IDC recommendation to publish the new Official Feed Term in the Official Publication:
  - Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the new Official Feed Term in the *Official Publication*:
    - a) Animal food. See feed.
       and recommends the same to the membership. I so move. Richard Ten Eyck Seconds.
       MOTION CARRIES
  - ii) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the new Official Feed Term in the *Official Publication*:
    - a) Tracer. (Part) A harmless substance present at insignificant levels in an animal food to ensure the presence of and thorough mixing of a component (ingredient/premix) of that food.

and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

- E) Fifth IDC recommendation to Modify the current Official Feed Term in the *Official Publication* for:
  - i) **Feed.** 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.

Acceptance is recommended to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES** 

# Model Bill 1-3:

# Report starts on page 48 of the Committee Report Book

- A) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the Model Bill and Regulations Committee that Attachment 1 on page 51 of the Committee Report Book conforms to the Model Bill and Regulations and recommends acceptance from the membership. I so move. **Richard Ten Eyck Seconds MOTION CARRIES**
- B) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the Model Bill and Regulations Committee that Attachment 2 on page 52 of the Committee Report Book conforms to the Model Bill and Regulations and recommends acceptance from the membership. I so move. Richard Ten Eyck Seconds. MOTION CARRIES
- C) Stan Cook states the AAFCO Board of Directors accepted the recommendation from the Model Bill and Regulations Committee to delete the 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 replace the deleted information with an html reference link and a citation to the CGMP's Title 21, CFR part 507.14–507.28 and associated checklist (when developed) and recommends acceptance from the membership. I so move. Doug Lueders Seconds. MOTION CARRIES

This concludes committee recommendations needing membership approval.

4) Credential Report—FASS

Number of voting members represented: 37

Number of states in attendance: 43

Number of countries: 5

Number of FDA representatives: 38

Number of life members: 5 Total meeting attendance: 347

Ken Bowers adjourned the meeting at 9:26 am. The minutes were approved January 18, 2017.

# **Current Issues and Outreach Committee Report**

2017 AAFCO Midyear Meeting January 16, 9:30 am–10:30 am, Mobile, Alabama

**Committee Recommendations:** None

Board Recommendations: Report was accepted on May 1, 2017

#### **Association Recommendations:**

# **Committee Participants**

Members Present: Liz Higgins, Meagan Davis, Chad Linton, Tim Lyons, Eric Nelson, Kent Kitade,

Richard Ten Eyck, Kelsey Luebbe, and Ali Kashani

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

Vickers

# **Committee Report**

The meeting was called to order at 9:30 am EST by Chair Ali Kashani.

Kelsey Luebbe, the committee vice chair, gave an overview of a recent webinar held as well as the distribution of the newsletter Liz Higgins put together.

Kristen Green of University of Kentucky announced details of the pet food labeling workshop to be held from 1:00 pm August 12 through 5:00 pm August 13 in Bellevue, Washington, after the AAFCO annual meeting.

Robert Waltz, AAFCO liaison to NASDA, made a presentation on the cooperative agreement grant that NASDA received to develop a state implementation plan to implement the Preventive Controls for Animal Food. The grant is for \$300,000 per year subject to renewal for five years. AAFCO is fully participating in the development of the implementation framework with NASDA and the FDA, and they would appreciate participants from states to serve on the technical workgroups. The purpose of the grant is targeted to State Commissioners, Secretaries and Directors of Agriculture to support and strengthen the animal food regulatory programs to include pet food programs (subject to Part 507) and to assist in supporting estimates of fiscal needs in talking with state and federal legislators in determining budget needs. The target date for the completion of the project (finalizing the implementation framework) is December 2017. The implementation framework will be modeled after the successfully developed Produce Safety Implementation Framework, which was completed by NASDA under a separate FDA grant. AAFCO members did participate in this grant and contributed to the writing of the final application of the current grant. A workgroup for the current grant was initiated earlier this year, and formative meetings began as of October 2016. The first face-to-face meeting was held immediately prior to this meeting on Friday and Saturday. Twenty-two regulatory officials were present, including representatives from the FDA, NASDA, and AAFCO. Bob Ehart with NASDA, and I, representing AAFCO, are co-leads.

Although the Food Safety Implementation Framework will be modeled after the Produce Safety Implementation Framework, this project is in a very different place. Current good manufacturing practices and preventive controls are not totally new to the feed and pet food industries.

Waltz emphasized the need for AAFCO members to actively participate as technical workgroup members to provide input for the development of the document.

Joanne Givens, human and animal food director, Office of Regulatory Affairs, gave an in-depth explanation of the FDA's Program Alignment, including the challenges, opportunities, and its status. Division of work by programs versus regions was also discussed as well as the organizational chart. The meeting adjourned at 10:30 am.

# **Education and Training Committee Report**

2017 AAFCO Midyear Meeting January 18, 8:00 am–10:00 am, Mobile, Alabama

**Committee Recommendations: None** 

Board Recommendations: Report was accepted on June 14, 2017

#### **Association Recommendations:**

#### **Committee Actions**

- SME workgroup to develop 6 training modules for basic inspector training
- Additional members from AAFCO needed for peer review of training modules
- The FDA DHRD will provide a list of training courses for 2017
- DHRD/ORAU to send out info about access to courses
- Contact NEHA for more information about accessing credentialing certification exam
- Three workgroups developed to meet strategic plan initiatives (see below)

# **Committee Participants**

**Members Present:** Jim True, David Edwards, Richard Ten Eyck, Jim Fear, Lizette Beckman, Jo Lynn Otero, Shannon Jordre, Kevin Klommhaus, George Ferguson, Meagan Davis, Tim Lyons, Samantha Moran, Darlene Krieger, Bob Geiger, Jacob Fleig, Amanda Anderson, Becky Hostetler, Cat Marrier **Advisors Present:** Craig Kaml, Scott Ringer, Davis Fairfield

# **Committee Report**

Tim Lyons called the meeting to order at 8:03 am.

Update on National Feed Curriculum and National Assessment and Training Strategy (NATS)—Chris Weiss, IFPTI

Animal Feed Control Officials Curriculum Framework

- Approximately 25 content areas (Gen Eds)
- 20 will be available online in April (some of these cover AFRPS Standard 2, Training Requirements)

4 levels of Feed Framework (Basic, Intermediate, Advanced, Expert) Basic Level

- 6 out of 11 content areas are ready for development.
- The other 5 are in a development stage.
- A survey was sent out to the states to review 114 competency statements (9 content areas) and rank for appropriateness.
  - Of the 50 states that were reached out to, ~50% responded.
  - 85% of the competencies were found to be favorable.
  - The 15% of the competencies that were found unfavorable were reviewed.

In March 2017 the workgroup will meet again to write content for the courses: Labeling, Sampling, Nutrition, Laws and Regulations, Medicated Feed, and Feed and Feed Ingredients

 All of these FDA trainings will be online and available to the states (free of charge) by the next AAFCO meeting this summer.

Development of ABCs will begin July 2017.

Feed SME workgroup will work with IFPTI on 6 training modules in an attempt to deliver a final product at the AAFCO annual meeting in August.

More SMEs from ETC will be needed to help review content (~April) ACTION ITEM

# **Animal Species and Classes Training Module**—Amanda Arens, UC Davis WIFFS Education and Design

Provided the background and design process for Animal Species and Classification course Survey through the Animal Species and Classes course

- The last 2 job aids will be completed within the next ~2 weeks.
- This course will be published through DHRD upon completion.

A question was asked about whether there was a review of CVM guidance during the development. Shannon stated that the OP was used, but it should be an easy review prior to the course going live.

# **Inspector Training Cadre Update**—Kevin Klommhaus

- 1) FSPCA Regulator Course
  - CGMP Animal Food Regulator Course—February 2017
  - PC Animal Food Regulator Course
- 2) The Inspector Cadres courses will be available to state and the FDA in 2018.
- 3) CGMP Inspections of Large Firms will begin January 2017.
- 4) Courses moving from face to face to online
  - VM 101
  - VM 206
  - VM 213

#### Other Federal Information Provided

- The TAN for FSMA has been operational since September 9, 2015. Will be starting TAN Phase II
- FDA Form 2481 has changed and has no VFD information on it.
- DHRD put together a list of the 2017 training courses available ACTION ITEM
- Cooperative Agreement/Grant Information
  - Have Teresa Bills explain who can use/apply for grants and what trainings it can be used for
- CGMP courses will be available August 29–30, 2017, in Kansas City for regulators.
- Training survey sent out to regulators to outline training needs by DHRD in near future.

#### **ORAU Website**

Several states were having issues accessing ORAU, so Jim Fear will identify the correct path and share with the committee for dissemination. **ACTION ITEM:** DHRD/ORAU to send out info about access to courses

# **Inspector Credentialing Exam**

Tim Lyons and Jacob Fleig will get more information for the Board regarding NEHA to determine what is needed/what is wanted to promote this exam. **ACTION ITEM** 

# **Strategic Plan Charges**

Workgroups were identified to work on 3 of the outcomes from Strategic Affairs Committee found on page 8 of the OP. See Work Group Table for membership, work group charge, and deadline information. Tim Lyons will contact other chairs for assistance on any their outcome needs. In regard to the AFRPS Standard 2, it was requested that states make available their hosted trainings and post them on the AAFCO calendar.

State of Nebraska will host FSPCA course with Dave Fairfield and Matt Frederking (NGFA)

**Strategic Plan Work Group Information** 

Responsible	Action	Timing/Status
Work Group #1	Identify all available courses that will meet	Revised
Amanda Anderson (Lead)	the requirements of the AFRPS Standard 2	deadline
Jim True	2) Identify gaps between the requirements of	requested
Jolene Gordon	the AFRPS Standard 2 and available trainings	
Jon (PA)???		
Work Group #2	Develop a catalog of courses (provided by	January 2018
Jeff Scallan (Lead)	Work Group #1) and categorize as either Basic	-
Scott Ziehr	or Advanced	
Richard Ten Eyck		
Jim Fear		

Responsible	Action	Timing/Status
Work Group #3	Develop a model document for joint	January 2018
George Ferguson (Lead)	inspections that can be used for on-the-job-	-
Bob Geiger	training	
	2) Develop a model training plan	
Must include Inspection and		
Sampling Committee		

# **Action Item Table**

Responsible	Item	Action	Timing/Status
Jim Fear DHRD	ORAU access	DHRD/ORAU to send out information	
		about available F2F and online courses	
		and access to online courses	
Tim Lyons and	Inspector	Meet with AAFCO Board of Directors to	
Jacob Fleig	Credentialing Exam	discuss AAFCO support of the exam	

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

2017 AAFCO Midyear Meeting January 17, 3:30 pm–5:00 pm, Mobile, Alabama

# Committee Recommendations to Board and Membership: None

Board Recommendations: Report was accepted on June 14, 2017

#### **Association Recommendations:**

#### **Committee Action Items**

- 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 whether AAFCO needs to provide additional training for state inspectors.

# Committee Minutes, August 2, 2016

# **Committee Participants**

**Members Present:** Eric Brady – TN (co-chair); Bob Church – MT; Ken Bowers – KS; Bob Geiger – IN; Darlene Krieger – FDA; Tim Darden – NM; Laura Scott – Canada; Doug Lueders – MN; Laura Scott – CFIA

**Advisors Present:** Lorri Chavez – PFI; Pat Tovey – PFI; David Meeker – National Renderers Association; Richard Sellers – AFIA; David Dzanis – APPA; David Fairfield – NGFA

#### **Committee Report**

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 midyear 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 midvear meeting in Mobile, Alabama (January 16–18).

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.

Three 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 midyear 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 C: 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 and 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 regard to training. Working group will work in consultation with the Education and Training Committee and the Inspection and Sampling Committee.

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

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

The NGFA began conducting regional one-day seminars in March 2016 to educate industry members on the new rules being promulgated by the FDA to implement FSMA. The seminars were conducted in cooperation with state feed regulatory agencies and state and regional associations affiliated with NGFA to help industry members understand the changes, requirements, and appropriate exemptions included in the FSMA rules. More than 1,200 industry representatives attended the 16 regional seminars offered by the NGFA during 2016.

The NGFA is actively involved in delivering FSPCA preventive controls qualified individual training to the animal food industry since the roll-out of the curriculum in June 2016. The NGFA will cooperate with

Kansas State University's International Grains Program Institute to deliver four courses in 2017. In addition, the NGFA will be partnering with state feed regulatory agencies and other industry stakeholders to conduct additional PCQI training courses during the year.

The NGFA and American Feed Industry Association (AFIA) have partnered to develop a scientific database of animal food hazards that companies will be able to use when completing their own evaluation of hazards as required by the FSMA-related rule for preventive controls for animal food. With funding provided by NGFA's and AFIA's respective foundations, the University of Minnesota College of Veterinary Medicine's Center for Animal Health and Food Safety has reviewed available scientific literature and the FDA recall information and developed a database tool that summarizes the occurrence of hazards that have caused animal food safety incidents. The database tool is expected to be made available to members of the NGFA and AFIA in April.

# 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. A total of 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 the 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 have just started There will be a course at Kansas State August 9. All courses are listed on Alliance website at https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food.

#### **Action Item Table**

Responsible	Item	Action	Timing/Status
Mineral	Mineral	To review and revise the "Official	Tentative:
Guidelines	Guidelines	Guidelines for Contaminant Levels	October 2016
Working Group		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?	

Responsible	Item	Action	Timing/Status
Strategic Plan Emergency Response Working Group	Roundtable Exercise	Host the exercise prior to the 2017 AAFCO midyear 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 whether there is any missing education that should be provided to inspectors who perform feed ingredient manufacturing inspections	Update January 2017

# Attachment A: Canadian Regulatory Update—Laura Scott

Laura Scott presented an update on the continuing discussion relative to the regulatory renewal process that is currently underway in Canada as part of a larger change agenda at the Canadian Food Inspection Agency (CFIA).

The CFIA regulates feed and food in Canada under different regulatory authorities. With respect to human food, the Safe Food for Canadians Act was passed in 2012, and the Safe Food for Canadians Regulations are anticipated to be published for public comment in Canada Gazette I in the near future [note: the Regulations were published on January 21, 2017, and are available (http://www.gazette.gc.ca/rp-pr/p1/2017/2017-01-21/html/reg1-eng.php#reg) for comment until April 21, 2017].

Feed regulatory modernization is about six months behind the food modernization. The Animal Feed Division at the CFIA has been consulting on the proposed approach in preparation for publication in Canada Gazette I. A consolidated proposal was posted for comment in early 2016.

Comments from that consultation along with other feedback were incorporated and used to create drafting instructions. These were then forwarded along to drafters to create the proposed regulatory text. While the regulatory text is being drafted, the Animal Feed Division continues to consult on some technical proposals. Over the summer of 2016 CFIA consulted on proposed approaches to Weed Seeds, Required Nutrient Guarantees, Permissible Claims, and the use of Veterinary Biologics in feeds. Summaries of the comments received on these consultations are available on the CFIA website. In the fall of 2016 CFIA consulted on proposals for maximum limits for nutrients in swine and poultry feeds. These comments are still under review. The next steps include consulting on maximum nutrient limits for additional livestock species (beef and dairy cattle, fish) and maximum contaminant levels for both biological contaminants (e.g., mycotoxins and *Salmonella*) and chemical contaminants (e.g., dioxin and heavy metals). The CFIA encourages feedback on these proposals.

# Attachment B: AFIA Update—Richard Sellers

AFIA's Richard Sellers reported on a number of issues related to AFIA and the feed industry. He noted that the International Production and Processors Expo with 30,000+ expected attendees will be held later in the month and was pleased that AAFCO took advantage of the free booth. He noted that the new administration will dramatically change thinking, and AFIA is working toward reducing regulatory burdens. In FSMA-related news, AFIA announced the impending release of its University of Minnesota—developed scientific portion of the FSMA-required hazard analysis for feed and ingredient facilities. He also noted that AFIA has produced a qualified individual training video available to AFIA members and nonmembers.

# **Attachment C: AAFCO Board Minutes**

Wednesday, September 7, 2016 1:00 pm CDT

Board of Directors Present: Bob Geiger, Richard Ten Eyck, Mark LeBlanc, Stan Cook, Ken Bowers, Ali

Kashani, Erin Bubb, Kristen Green

Absent: Bob Church

Others Present: Dave Phillips, Nancy Thiex, Dave Dressler, Abe Brown, Jacob Fleig

FASS: Jennifer Roland (Recorder)

# Board Meeting Call Called to Order by Mark LeBlanc at 1:02 pm CDT

- Standing Reports
  - A) Co-Ag—Nancy
    - i) August end of funding year
    - ii) Had Sampling Training week of August 15 in Phoenix, Arizona
    - iii) Had Sampling Pilot week of August 22 in Florida
    - iv) Have Sampling Training in Washington
    - v) Full funding received for year five
  - B) Proficiency Testing Program Committee
    - Working on application for ISO 17043 accreditation for program hoping to submit application by end of September
    - ii) Developed a FAQ that is on website
    - iii) Working on a new handbook for program
  - C) Liaison report
    - i) NASDA—Bob Waltz
      - a) Not available for report
      - b) Meeting September 20 to 24 in Lincoln, Nebraska
    - ii) IFIF—Bob Waltz
      - a) Not available for report
      - b) Meeting at IPPE in January
    - iii) AFDO—Ali Kashani
      - a) Ali was invited to serve as AAFCO liaison on Board of Directors
      - b) Attended WAFDO meeting in August
      - ACTION: Need to appoint to two state representatives on PCQI joint advisory committee.
  - D) AAFCO FSMA Implementation Taskforce—Linda
    - Not available for report
  - E) Training update
    - ) FSPCA Training—Mike, Tim Lyons, Richard
      - AFIA doing FSMA webinars guiding people to Alliance website where training is listed
    - ii) IFPTI—Tim Lyons
      - a) Sending survey out regarding feed curriculum
    - iii) NEHA—Jacob Fleig

- a) October 1 brochure and website information on credential requirements for Animal Feed Inspector test
- b) November 1 testing made available
- F) AFRPS—Ali/Tim Weigner
  - i) Face-to-face meeting being held at midyear meeting in Mobile, Alabama
- 2) Speaking Engagement/Meeting Reports
  - A) WAFDO—Ali
    - i) Covered in AFDO liaison report
- 3) Old Business
  - A) Committee reports approval
    - i) FFIMC requests
      - a) Ali MOTIONED to Remove the AAFCO Model Feed Safety Program Plan—August 2007 (pages 260–261 in the 2016 OP) and the Model Feed Safety Program Development Guide (pages 262–273 in the 2016 OP) as this information is redundant to the recently published Animal Feed Regulatory Program Standards. The information should be archived separately in the Feed BIN. Stan Seconds. MOTION CARRIES
      - b) Ali MOTIONED to Replace the AAFCO Model Emergency Response Preparedness Guidance Document (pages 310–313 in the 2016 OP) with the text contained in Attachment B and assign the role of Section Editor to Tim Darden. Stan Seconds. MOTION CARRIES
- 4) New Business
  - A) Inspection and Sampling Committee structure—Bob Geiger
    - i) Propose splitting committees
    - ii) Have committees flow AFRPS?
    - iii) ACTION: Form group to discuss, report back to board in October
  - B) Appoint new board member to replace Dan Danielson—Mark
    - Kristen MOTIONED to accept Nominations Committee recommendation to move up a spot and appoint Dave Phillips as Junior Director. Bob Geiger Seconds. MOTION CARRIES
  - C) Executive support—Mark
    - i) Discuss tabled to board meeting during FDA briefing
    - ii) **ACTION:** d have executive director at FASS call in during board meeting. Start discussion with executives before meeting.
  - D) Egyptian delegation—Kristen
    - i) Going to be in Kentucky on November 2 at 10:30 am
    - ii) Presentations on AAFCO in Feed BIN under All AAFCO Members Library
    - iii) Discuss
      - a) Proficiency Testing Program
      - b) IDC Process Overview
      - c) International Membership
  - E) International members—Richard
    - i) Document for international membership information for main website
    - ii) Have available as a flyer at IPPE
  - F) 2018 annual meeting hotel selection—Jennifer
    - i) Marriott Harbor Beach
  - G) FDA briefina—Jennifer
    - ACTION: Need agenda for board meeting and briefing
    - ii) Travel on Sunday, October 16, and travel home on Friday, October 21
  - H) Review action item
    - i) Not reviewed

Kristen MOTIONED to accept minutes as displayed. Bob Geiger Seconds. MOTION CARRIES

# **Feed Labeling Committee Report**

2017 AAFCO Midyear Meeting January 17, 8:00 am–9:00 am, Mobile, Alabama

Committee Recommendations: None

Board Recommendations: Report was accepted on May 1, 2017

#### **Association Recommendations:**

# **Committee Participants**

**Members Present:** Chair: Dave Dressler (PA); Vice Chair: Dave Phillips (ND); Al Harrison (KY); Jan Jarman (MN); George Ferguson (NC); Mika Alewynse (CVM); Steve Gramlich (NE); Tim Darden (NM); Heather Bartley (WI); Miriam Johnson (NC); Erin Bubb (PA); Liz Beckman (WA); and Richard Ten Eyck

(OR); Via Telephone: Liz Higgins (NM)

Advisors Present: Pat Tovey (PFI); Angela Mills (NGFA); Meaghan Dicks (ADM); Dave Dzanis

(ACVN/APPA); Sue Hays (WBFI); and Chris Olinger (Wenger Feeds)

#### **Committee Report**

David Dressler called the meeting to order at 8:05 am CST. Members and advisors in the room introduced themselves.

# Introductions and Agenda Review—Dave Dressler

**Updates to the Non-Pet Food Labeling Guide** 

Labels for medications previously OTC that have moved to VFD status have been removed. The guide currently does not provide examples of VFD labels.

Update of Table 1 will be added.

New example labels are being created.

Expect updates to be completed by August 2017 for committee review.

There were suggestions to change the name of this document to Animal Food Labeling Guide.

# Update to Expert Panel for Nutrient Indicators Review for Beef Cattle—Al Harrison

Recommendations for the panel have been received from AFIA.

We are working to secure panel members to begin review of Nutrient Indicators.

# Non-Medicated Feed Labeling Workshop—Dave Dressler and Dave Phillips

The workshop is scheduled to occur in conjunction with the annual meeting to be held in August 2018.

#### Development of Centrally Located Database for Feed Labels—Dave Dressler

Discussion was had as to developing a database that would centrally locate feed labels for review. The intent would be to submit the label to the database and flag missing information, labeling violations, and claims

There is concern from industry that due to the database being voluntary, companies may not choose to participate or that it would be a burden to maintain due to the volume of labels and their variances. Other concerns would be that the same brand name would be for different products, distributed elsewhere in the United States, and who would store this information. Using the Feed BIN as the central location was discussed. We would need to determine what format in which to store the labels.

# Feed Label Review Software—Dave Phillips

A discussion was held to determine whether investments should be made to develop software that would review labels for accuracy to speed up the review process, as well as helping industry determine the accuracy of the labels prior to sending them into the state.

There was concern that taking the human element away would not lead to an accurate review, depending on label claims that a computer could not pick up. Thoughts were the computer software could review key points of the label; however, the human element would still be needed to review other aspects of the label.

This discussion will continue and will be brought back up at the annual meeting in August 2017.

# Other Items

Bill Burkholder suggested that review of the labels in the OP to ensure units of measure are accurate should be worked through by the Model Bill Committee versus the Feed Labeling Committee. Heather Bartley is to be the liaison to the Enforcement Issues Committee. The meeting adjourned at 8:46 am CST.

# **Action Item Table**

Responsible	Item	Action	Timing/Status
Al Harrison, Richard Ten   Expert Panel		Form an Expert panel to review the	August 2017
Eyck, Miriam Johnson,	Formation	NRC update for Beef Cattle Nutrition	
Richard Sellers, and			
David Dzanis			
Mika Alewynse, Meagan	Non-Pet Food	Expected completion of updates	August 2017
Davis, Angela Mills, and	Label Design &		
Thomas Belloso	Format Guide		
Dave Phillips and Dave	Workshop	Submit a workshop proposal for the	August 2017
Dressler	Proposal	Non-Medicated Feed Label Workshop	
		to the Education and Training	
AFIA (Angela Mills) and		Committee for Review. The workshop	
NGFA (Chris Olinger)		should be scheduled to occur August	
		2018.	

# **Ingredient Definitions Committee Report**

2017 AAFCO Midyear Meeting January 17, 1:30 pm–3:00 pm, Mobile, Alabama

#### **Committee Recommendations**

When needed, new text is presented in Attachment A of this report.

- 1) Publish the new Section 101 header including the introductory paragraphs and the table header row of the new GRAS notice table in the *Official Publication* (OP).
- 2) Publish a new microorganism in the list in definition T36.14 Direct-Fed Microorganisms: *Bacillus amyloliquefaciens*.
- 3) Publish these definitions as Official:
  - A) 3.5 Direct Dehydrated Alfalfa Meal or Pellet—Moving T3.5 to Official
  - B) 87.20 Guanidinoacetic Acid—Publish as Official (CFR listed)
  - C) 87.115 Canthaxanthin—Publish as Official (CFR listed)
- 4) Publish these as new definitions as Tentative:
  - A) T96.14 Scheffersomyces stipitis Dried Yeast
- 5) In the OP, delete Canthaxanthin from Table 87.5, if 87.115 is added.
- 6) Financial and Revenue Needs
  - IDC has no direct financial requests at this time. The scientific review of ingredients prior to marketing continues to take an excessive amount of time. It may take association resources to expedite the current process or provide suitable alternatives to establish an ingredient standard of identity acceptable to state members.
- 7) The committee approved several editorial changes not requiring further Board or Association Membership action. Among them:
  - A) Enzyme Section 30—Section introduction language and Enzyme Table 30.1 header
  - B) Definition 36.14 and T36.14, edit the opening paragraph by adding, "These microorganisms must be nontoxigenic."
  - C) 57.165 Zinc Hydroxychloride, added poultry to the intended species listed in the newly approved Official definition.
  - D) 73.026 Feed Grade Sodium Formate, added poultry to the intended species listed in the newly approved Official definition.
  - E) 93.5 Wheat Middlings, changed the crude fiber maximum to 11%.

Board Recommendations: Report was accepted on May 1, 2017.

Board accepted recommendations 1-7 as presented by the committee.

# **Association Recommendations:**

# **Committee Report**

The meeting was convened at 1:30 pm by Chairperson Ten Eyck.

**Committee Members:** Richard Ten Eyck, Mark Le Blanc, Mika Alewynse, Erin Bubb, Charlotte Conway, Jacob Fleig, Steve Gramlich, Brett Groves, Alan Harrison, James Embry, April Hunt, Jan Jarman, Shannon Jordre, Jennifer Kormos (phone), Laura Scott, Dave Phillips, David Dressler, Bob Church, Dan King, Ken Bowers, Kent Kitade. A quorum was present (21/25).

- 1) Investigator Recommendations to Move from Tentative to Official
  - A) T3.5 Direct Dehydrated Alfalfa Meal or Pellet—Erin
    Erin Bubb moves to ACCEPT. Brett Groves seconds. MOTION PASSES.
    Ken Vaupel (Alfagreen Supreme, by phone) asked after the motion passed if he could comment on the definition. He thanked the committee and reminded them that in
    Charleston there was discussion that the Direct Dehydrated Alfalfa cannot come from sun-dried alfalfa. He believes that there is still work to be done on this definition.

# 2) Work Group Reports

A) AAFCO affirmed GRAS workgroup report

Leah Wilkinson—Most state laws need the feed ingredient to be published in the OP or have a 21 CFR regulation. The FDA has now published the final rule on the GRAS Notification. This AAFCO IDC WG was formed over a year ago and was tasked to discuss the inclusion of GRAS substances into the *Official Publication*. The WG's first project has been to develop a proposed new OP section that would include GRAS-notified substances that have received a No Questions letter from the FDA. As part of this project, the WG organized a survey of feed control officials to understand their views on GRAS-notified substances and on GRAS substances more broadly. The WG is now proposing the states consider Section 101 be added to the OP. This section would have introductory paragraphs and a table with links to the FDA Animal GRAS Inventory site. The table would contain only the GRAS substances that have received a No Questions letter from the FDA.

In response to a question raised by Brett Groves, Richard Ten Eyck said that the section editor will bring the updated list of animal food GRAS Notices that have been evaluated by the FDA and received a No Questions letter through the IDC. The Committee asked for clarification on the table. David Dressler asked if an animal species is not listed in the GRAS substances table, does that mean that the substance is not GRAS for that species. Kristi Smedley replied that the GRAS substance is GRAS for a very specific intended use. In the case of notifications, if a species is not listed in the table, then that use of the substance was not a part of the notification. Gary Yingling, counsel for the Enzyme Technical Association (on phone), provided a prepared statement in support of proposed Section 101.

Mark LeBlanc moves to ACCEPT the WG report. Shannon Jordre seconds. MOTION PASSES.

Steve Gramlich moves to ACCEPT the header including the introductory paragraphs and the header row of the table. David Dressler seconds. MOTION PASSES. *Text is in Attachment A.* 

DFM Reclassification Workgroup—Jan Jarman B) Jan Jarman explained that the WG formed last August because several of the organisms have been reclassified and, as a result, some of the microbe names used in the 36.14 definition may be out of date. Kristi Smedley and Leah Wilkinson along with others put together a table with the list of organisms and indicated the necessary changes. There are six organisms that need renaming to a species not currently listed in 36.14. and a literature-based safety review has been requested by the FDA. Some changes will not require a safety review as it is either an editorial change or the change is to currently listed organisms. Potential name changes have implications for labels. Jan Jarman would like to broadly distribute the table only after agreement has been reached in the WG with Mika Alewynse (timeframe for alignment = 2–3 weeks). Kristi Smedley noted that there are changes in microbial nomenclature because of scientific changes and also mistakes that were entered in 1996. There is a spelling mistake as well. Some reclassified organisms will be changed to ones that are already listed—in such cases, the original organism that changed would no longer be listed. Jan just wanted to introduce the topic. Mika Alewynse said that in all probability there will need to be safety assessments (literature review only) to list the new name (if not already on the list).

#### 3) New Definitions, Deletes and Edits

- A) Enzyme Table header edits—Jan Jarman. *Text is in Attachment A.*Brett Groves moves to ACCEPT. David Dressler seconds. MOTION PASSES.
- B) T36.14 *Bacillus amyloliquefaciens*—Jan Jarman/Mika Alewynse. Add organism to the list in definition T36.14.
  - Jan Jarman moves to ACCEPT. Mika Alewnse seconds. MOTION PASSES.
- C) 36.14 and T36.14 header edit to read: (added language is bolded and underlined)
  36.14 Direct-Fed Microorganisms—The microorganisms listed below were reviewed by the US Food and Drug Administration, Center for Veterinary Medicine, and found to

present no safety concerns when used in direct-fed microbial products. <u>These microorganisms must be nontoxigenic.</u>

Mark Le Blanc moves to ACCEPT. Mika Alewynse seconds. MOTION PASSES. This is an editorial change. Mika Alewynse stated that the change is being driven by the change in nomenclature and genomic analysis. As science has progressed these species have been moving closer, and it is necessary to assess the safety of the organism. This statement was lifted from the enzyme table (Table 30.1—"…nonpathogenic and nontoxigenic").

Leah Wilkinson stated that the AFIA membership does not think that this sentence is necessary; it is redundant. This is part of the responsibility of the manufacture to ensure the safety of the product. In addition, there is a concern in regard to trade (export)—foreign governments might have concerns in regard to this addition. The AFIA membership proposes "These microorganisms must be safe" as an alternative clarifying statement.

Jan Jarman asked if there are any issue with this (trade/export) in regard to the enzymes. Emily Helmes stated that there is no issue with enzymes or the enzyme table. Mika Alewynse stated if we say "safe," it could bring in other issues—most organisms on the list are safe but if they are fed to the wrong species, there could be issues. She said that we need to be careful how we define "safe." Kristi Smedley stated that safety should be specific to the intended use.

- 57.165 Zinc Hydroxychloride edit—Jennifer. Text is in Attachment A.
   Jennifer Kormos moves to ACCEPT. April Hunt seconds. MOTION PASSES.
   This is an editorial change to add poultry to the newly approved Official definition.
- E) 57.29 Metal polysaccharide complex Edit (placeholder) Jennifer
- F) 73.026 Expansion of the newly accepted Feed Grade Sodium Formate approval as an acidifier in complete poultry feed. *Text is in Attachment A.*Mika Alewynse moves to ACCEPT as an editorial change. April Hunt seconds. MOTION PASSES.
- G) 71.XXX Brassica carinata (placeholder)
- H) 87.20 Guanidinoacetic Acid—Richard Ten Eyck. *Text is in Attachment A.*Brett Groves moves to ACCEPT. Mark Le Blanc seconds. MOTION PASSES.
  At the end of the definition, change "Proposed" to "Adopted" and add definition number 87.20
- 87.115 Canthaxanthin—color additive—Richard Ten Eyck. Text is in Attachment A. Mark Le Blanc moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES. Need to delete Canthaxanthin from Table 87.5.
  Dave Philips moves. Steve Gramlich seconds. MOTION PASSES.
- J) 93.5 Wheat Middlings—edit—Dave Phillips. Editorial change of crude fiber specification. Committee discussed if this needed an association vote. Agreed interested parties were represented here with no opposition to the change. *Text is in Attachment A.* 
  - Dave Phillips moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.
- K) Add section 101 GRAS Notifications to the OP—Addressed above. *Text is in Attachment A.*
- T96.14 Scheffersomyces stipitis Dried Yeast—Mika Alewynse. Publish a new Tentative definition. Text is in Attachment A.
   Need to correct the spelling (stipitis not stipites).
   Alan Harrison moves to ACCEPT. Jan Jarman seconds. MOTION PASSES.

# 4) Discussions

A) Materials NOT suitable for animal feed list in the Feed BIN or website—AAFCO A "Reading Room" has been set up on the Feed BIN. We are ready to start working on this and forming a WG to flesh out how this information should be shared with industry. David Dressler thinks that this is a good idea—if something has been reviewed and not accepted, the information should be public. Leah Wilkinson suggested that a discussion should be had—there are pluses and minuses—how do we get things off the list once they are put on it. Jan Jarman stated that this should not be in the OP.

Richard Ten Eyck agrees. Leah Wilkinson also stated that there may be some companies that have done GRAS self-determinations. Jason Vickers said there are several mechanisms for new ingredients—GRAS Notification, GRAS self-determination, FAP, new ingredient definition. Is this work of great value? Richard Ten Eyck stated that it may be easy to have a listing of ingredients that have not been approved.

Leah Wilkinson, Richard Ten Eyck, Dave Dressler, Cathy Alinovi, Dave Phillips, Steve Gramlich, Susan Thixton, someone from FDA/CVM, PFI and Jan Campbell to form a WG to discuss this topic.

- B) Status on high profile ingredients (if needed)—Richard Ten Eyck/CVM Richard Ten Eyck also brought up hemp seed oil and hemp seed meal—might need a policy on the proper use of hemp. It was also mentioned that "hemp heart" (dehulled hemp seed) is also being sold in food and feed. Bob Church stated that Montana has policy that no hemp products will be allowed in animal feed. Leah Wilkinson tries to notify state regulators if there is something to watch out for. She will continue to look out for these instances and will help notify the states. Richard will develop hemp guidelines and circulate them to the Committee and the Board in attempt to build a consensus position to support states.
- C) Discussion of common human foods in pet food
  Human foods as they move to animal food—when does the common name no longer
  work? Charlotte Conway brought up peas/pea protein as an example. Peas are food
  that we eat, but when it gets processed, it is no longer the same food. The processing
  can concentrate (make a change in the food), so it is no longer the same food.
  Blueberries are food and okay for animals, but blueberry pomace needs to be defined
  and is now different than the traditional food.

Susan Thixton brought up cricket meal as another thing that is being used in pet food. What are Regulators going to do—let it go? Jan Jarman stated that no, regulators will not approve cricket meal. Charlotte Conway talked with "cricket ranchers" to help them understand that cricket meal needs to be defined. Hopefully, companies/people will do the right thing.

Leah Wilkinson stated that she is also trying to help people understand that a definition is needed. Some people do not want to go through the process and deal with FSMA. Charlotte Conway said different safety evaluations may be needed for different things. People should talk with the FDA.

- D) We will be establishing standing quarterly meeting dates for the committee. In addition to our two face-to-face meetings during the AAFCO meetings, we will meet by webinar on Friday, March 10, 2017, and Friday, October 13, 2017.
  - Richard Ten Eyck said that GRAS items to be included in the Section 101 table will be on the March agenda. They need a section editor and investigator for this section. Leah Wilkinson asked if these meetings will be timed before the next Board meeting. Richard Ten Eyck confirmed that they will.

Leah Wilkinson asked what kind of deadline to get things posted to the Feed BIN for the investigators. Richard Ten Eyck stated that he would like things to be posted one month ahead but can be flexible with placeholders.

Kristi Smedley stated that there should be an update from the DFM WG by the March meeting.

- E) Stale definition requests: We will remove material from definition consideration if the investigator is not contacted by the January 17, 2017, meeting.
  - i) Camelina Meal—additional use,
  - ii) HEA Rapeseed meal,
  - iii) Soy Fiber Isolate,
  - iv) Chorella Algae Meal as source of omega 3,
  - v) Calcium Chloride—new source,
  - vi) Chromium Tripicolinate—additional uses,
  - vii) Copper Urea Sulfate,
  - viii) Kaolin-additional uses.

Jennifer Kormos stated that Chromium Tripicolinate should be removed from AAFCO consideration. The submitter did not want to pursue.

Bob Church stated that HEA Rapeseed Meal is still active.

There has been no communication back from the industry on the others.

The meeting adjourned at 3:02 pm.

Follow up Discussion items: Investigators may want to have a meeting with CVM on how to provide a better request review.

The minutes were approved by the committee during the webinar on March 10, 2017.

# **Attachment A: Ingredient Definitions Committee Report**

**3.5 Direct Dehydrated Alfalfa Meal or Pellet** is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, that has not been stored in bales or in stacks as suncured alfalfa hay prior to being ground and dried by thermal means under controlled conditions. (Proposed 2016, Adopted 2017 rev. 1)

# Edit OP Section 30 enzymes by adding the bolded and underlined text

\*See the "Enzyme Marketing Coordination" document that appears under chapter 5. page 348. The immediate following pages contain Table 30.1, Enzymes/Source Organisms Acceptable for Use in Animal Feeds. The purpose statement of a product label shall include a statement of enzyme functionality ("Function" and/or "Supported Use" as stated in Table 30.1) if enzymatic activity is represented in any manner.

30.1 Enzymes/Source Organisms Acceptable for Use in Animal Feeds
In the case of microbial enzymes, it is understood that they are produced from nonpathogenic and nontoxigenic strains.

Classification/	Source	Typical		Current
Name	Organism	Substrate <sup>1</sup>	Function	Supported Use <sup>2</sup>

<sup>2</sup>The Supported Use column references additional enzyme functionality beyond that in the Function column, and does not limit the enzyme functionality statement to specific animal species.

36.14 header and T36.14 header edit to read:

**36.14 Direct-Fed Microorganisms**—The microorganisms listed below were reviewed by the US Food and Drug Administration, Center for Veterinary Medicine, and found to present no safety concerns when used in direct-fed microbial products. **These microorganisms must be nontoxigenic.** 

**57.165 Zinc Hydroxychloride** is the hydrolysis product of zinc chloride having the empirical formula  $Zn_5(OH)_8Cl_2\cdot(H_2O)$ . The particle size must not exceed 100 microns. It must contain not less than 54% zinc and is intended to be a source of zinc for use in livestock, **poultry**, and companion animal diets. It must not contain more than 20% chloride, 90 ppm lead, 15 ppm chromium, 10 ppm arsenic, 10 ppm cadmium, and 0.2 ppm mercury. (Proposed 2015 rev. 1, Adopted 2017 rev. 1, Revised 2017 rev. 1)

**73.026 Feed Grade Sodium Formate**—The food additive feed grade sodium formate may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions:

- (a) The additive is manufactured by the reaction of 99% formic acid and 50% sodium hydroxide in water to produce a solution made up of at least 20.5% sodium salt of formic acid and not more than 61% formic acid.
- (b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine **and poultry** feeds at levels not to exceed 1.2% 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% 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% 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.
  - 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.
    - (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, Edited 2017 rev. 1)

**87.20 Guanidinoacetic Acid**—The food additive guanidinoacetic acid may be safely used in broiler chicken and turkey feeds in accordance with the following prescribed conditions:

- (a) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.
- (b) The additive is used or intended for use to spare arginine and as a precursor of creatine in broiler chicken and turkey feeds at levels not to exceed 0.12% of the complete feed.
- (c) The additive consists of not less than 97% guanidinoacetic acid [N-(aminoiminomethyl)-glycine] (CAS 352-97-6) by weight.
- (d) The additive meets the following specifications:
  - (1) Dicyandiamide not to exceed 0.5%;
  - (2) Cyanamide not to exceed 0.01%;
  - (3) Melamine not to exceed 15 parts per million (ppm);
  - (4) Sum of ammeline, ammelide, and cyanuric acid not to exceed 35 ppm; and
  - (5) Water not to exceed 1%.
- (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 statement to indicate that the maximum use level of guanidinoacetic acid must not exceed 0.12% of the complete feed for broiler chickens and turkeys; and
    - (ii) Adequate directions for use.

21 CFR 573.496 (Adopted 2017 rev. 1)

**87.115 Canthaxanthin**—The color additive canthaxanthin may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

- (a) Identity.
  - (1) The color additive canthaxanthin is  $\beta$ -carotene-4,4'-dione.
  - (2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that 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.

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

Physical state, solid.

1% solution in chloroform, complete and clear.

Melting range (decomposition), 207 to 212°C (corrected).

Loss on drying, not more than 0.2%.

Residue on ignition, not more than 0.2%.

Total carotenoids other than trans-canthaxanthin, not more than 5%.

Lead, not more than 10 parts per million. Arsenic, not more than 3 parts per million. Mercury, not more than 1 part per million. Assay, 96 to 101%.

- (c) Use and restrictions.
  - (1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:
    - (i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and
    - (ii) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.
  - (2) Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogram (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.
  - (3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
    - (i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;
    - (ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and
    - (iii) The quantity of color additive in feed 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 mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.
  - (2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c)(3) of this definition.
  - (3) The presence of the color additive in feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
  - (4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2), and 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.
- 21 CFR 73.75 (Adopted 2017 rev. 1)
- **93.5 Wheat Middlings** consists of fine particles of wheat bran, wheat shorts, wheat germ, wheat flour, and some of the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than **9.5%** 11% crude fiber. (Proposed 1959, Adopted 1960, Revised 2017 rev. 1)
- **T96.14** *Scheffersomyces stipitis* **Dried Yeast** is the dried, non-viable yeast of the botanical classification *Scheffersomyces stipitis* that has been grown on thin stillage from the ethanol production process from the fermentation of a grain or grain mixture, and is separated by centrifugation from the media on which it was propagated. The product is produced in accordance with good manufacturing practices to control the potential for mycotoxin and other contaminants. The product is intended as a source of protein in cattle, sheep, goat, and swine feeds at levels up to 15%. It must contain not less than 40% crude protein. The label shall include guarantees from

minimum crude protein and crude fat and maximum sulfur contents. Non-protein nitrogen content must be guaranteed when added. (Proposed 2017 rev. 1)

# New OP section:

# 101. GRAS NOTIFIED SUBSTANCES INTENDED FOR ANIMAL FOOD Section Editor: xxxxx

The following is a list of GRAS Notices filed voluntarily by the notifiers pursuant to 21 CFR 570.205 which the FDA has evaluated (21 CFR 570.265) and determined that it had no questions regarding the conclusion that the notified animal food substance is generally recognized as safe (GRAS) under the intended conditions of use. The filed notice and the FDA response letter provide information (identity, manufacture, specifications, intended effect, and safety) on the substance under the intended use conditions, and the most up to date version is posted at the following website:

[http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeG RASNotifications/ucm243845.htm]. This section is provided as a convenience for the State Feed Control Officials.

While the information on the substance and the intended use is specific to that provided by the notifier, other firms may use information within the notice along with other data specific to their substance to support the GRAS conclusion (see 21 CFR 570.3-570.280). Such other firms who conclude that an animal food substance is GRAS under the conditions of its intended use by relying on a posted GRAS notice submitted by another person shall carefully evaluate whether their production process, product specifications, and intended conditions of use fall within the parameters addressed by the referenced GRAS notice. GRAS conclusions are not legally required to be submitted to the FDA but may be voluntarily submitted in accordance with the GRAS Notice regulation (21 CFR Part 570. 205). Nevertheless, firms that elect to make use of the GRAS provision must document their GRAS conclusions prior to marketing a substance for a particular intended use. State Feed Control Officials may request the GRAS Conclusion to support their registration or inspection duties.

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

Table 101.1 GRAS Notified Substances with no questions letters from the FDA.

			Common and Usual	Intended	Intended	Date of	FDA's
AGRN	Notifier	Substance	Name	Use	Species	Filing	Letter

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

# Ingredient Definitions Committee Report Webinar Meeting

March 10, 2017

#### **Committee Recommendations**

- 1) Move Tentative definition T60.115 (B) Pulse Protein to Official in the OP.
- 2) Move Tentative definition T60.116 (B) Pulse Starch to Official in the OP.
- 3) Move Tentative definition T33.21 Yellow Grease to Official in the OP.
- 4) Move Tentative definition T33.24 Used Cooking Oil, Feed Grade, to Official in the OP.
- 5) Publish the Tentative definition in the OP for T71.35 *Brassica carinata*.
- 6) Publish Hydrophobic silica AGRN 5 in Table 101.1 in the new section 101 GRAS Notices.
- 7) Publish Polyethylene glycol (400) dioleate AGRN 6 in Table 101.1 in the new section 101 GRAS Notices in the OP.
- 8) Publish Polysorbate 60 AGRN 7 in Table 101.1 in the new section 101 GRAS Notices in the OP
- 9) Publish Phytase AGRN 14 in Table 101.1 in the new section 101 GRAS Notices in the OP.
- 10) Publish Phytase AGRN 15 in Table 101.1 in the new section 101 GRAS Notices in the OP.
- 11) Publish L-Methionine 85% AGRN 16 in Table 101.1 in the new section 101 GRAS Notices in the OP.
- 12) Publish Canthaxanthin AGRN 17 in Table 101.1 in the new section 101 GRAS Notices in the OP.

**Board Recommendations:** Report was accepted on May 1, 2017. Board accepted recommendations 1-12 as presented by the committee.

#### **Association Recommendations:**

#### **Committee Report**

(Meeting was web recorded and is posted in the Feed BIN, Ingredient Definitions library.) The meeting was convened at 8:30 am PDT by Chairperson Ten Eyck.

**Committee Members:** Mika Alewynse, Ken Bowers, Erin Bubb, Bob Church, Stan Cook, Charlotte Conway, David Dressler, James Embry, George Ferguson, Jacob Fleig, Steve Gramlich, Brett Groves, Al Harrison, Jan Jarman, Ali Kashani, Dan King, Jennifer Kormos, Kent Kitade, Mark LeBlanc, Laura Scott, Richard Ten Eyck, Tom Phillips. 21 members present; this is a quorum (≥50%).

Minutes of the January 17, 2017, IDC meeting were approved during the role call.

- 1) New Definitions, deletes and edits
  - A) Move Tentative definition T60.115 (B) Pulse Protein to Official. Erin Bubb moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.

**T60.115 (B) Pulse Protein** is the protein fraction of pulse seeds. It is obtained from mechanically dehulled, dry milled pulse seeds that are further separated through air classification or the addition of water, acid, and alkali. The ingredient may be obtained from pulse seed separated by dry separation, wet separation, or both. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The ingredient must contain not less than 53.0% crude protein on a dry matter basis, and a label shall include a guarantee for minimum crude protein. If a conditioning agent is used, the name of the conditioning agent must be shown as an added ingredient. If the ingredient bears a name descriptive of its kind or origin, it must correspond thereto. (Proposed 2016 rev. 1)

Accepted pulse crops:

Lentil (Lens culinaris)

IFN 05-17-726 Pea (Pisum sativum L.)

B) Move Tentative definition T60.116 (B) Pulse Starch to Official. Erin Bubb moves to ACCEPT. Ali Kashani seconds. MOTION PASSES.

**T60.116 (B) Pulse Starch** is the fraction remaining after removal of protein and fiber from pulse seeds. It is obtained from mechanically dehulled, dry milled pulse seeds that are further separated through air classification or through the addition of water. The ingredient may be obtained from pulse seed separated by dry separation, wet separation, or both. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The product must contain not less than 65% dietary starch on a dry matter basis, and the label shall include a guarantee for minimum dietary starch. If a conditioning agent is used, the name of the conditioning agent must be shown on the product label as an added ingredient. If the ingredient bears a name descriptive of its kind or origin, it must correspond thereto. (Proposed 2016 rev. 1)

Lentil (Lens culinaris)

Lenui (Lens Cuimans)

IFN 05-17-726 Pea (Pisum sativum L.)

C) Move Tentative definition T33.21 Yellow Grease to Official. Ken Bowers moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES.

Discussed that T33.20 Fat Product, Feed Grade, will be deleted from the Official

Discussed that T33.20 Fat Product, Feed Grade, will be deleted from the *Official Publication* as of May 1, 2017. T33.21 will go in front of the membership for vote in August. There will be a few months of no official definition for these type of products.

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 90.0% total fatty acids, not more than 2.5% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1.0% 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." (Proposed 2017)

D) Move Tentative definition T33.24 Used Cooking Oil, Feed Grade, to Official. Ken Bowers moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES.

T33.24 Used Cooking Oil, Feed Grade, is 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 and then heated to reduce moisture. It must contain, and be guaranteed for, not less than 90.0% total fatty acids, not more than 1.0% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1.0% 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." (Proposed 2017)

E) Publish new Tentative definition T71.35 *Brassica carinata*. Bob Church moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.

**T71.35** *Brassica carinata* meal, solvent extracted, is the meal obtained after the removal of most of the oil by solvent extraction of *Brassica carinata* seeds. The meal shall contain less than 2.0% erucic acid and less than 30 micromoles of total glucosinolates per gram. It is a source of protein for beef cattle in an amount not to exceed 10% of the total diet. The maximum sulfur content must be guaranteed.

F) Publish Polysorbate 60 AGRN 7 in Table 101.1 in the new section 101 GRAS Notices. Nathan Price moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES, with 1 opposed.

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
7 (PDF, 101 pages)	Emerald Carolina Chemicals LLC	Polyoxyethylene (20) sorbitan monostearate (polysorbate 60)	Polysorbate 60	As an emulsifier component of a defoamer used in the removal of oil from condensed distillers solubles, at levels up to 20 ppm	Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine	May 12, 2011	FDA has no questions. (PDF, 3 pages)

G) Publish Hydrophobic silica AGRN 5 in Table 101.1 in the new section 101 GRAS Notices.

Nathan Price moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES, with 1 opposed.

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
5 (PDF, 67 pages)	Emerald Carolina Chemicals LLC	Hydrophobic silica	Hydrophobic silica	As a defoaming component of a defoamer used in the removal of oil from condensed distillers solubles, at levels up to 20 ppm	Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine	May 12, 2011	FDA has no questions. (PDF, 3 pages)

 Publish Polyethylene glycol (400) dioleate AGRN 6 in Table 101.1 in the new section 101 GRAS Notices. Nathan Price moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES,

with 1 opposed.

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
6 (PDF, 57 pages)	Emerald Carolina Chemicals LLC	Polyethylene glycol (400) dioleate	Polyethylene glycol (400) dioleate	As an emulsifier component of a defoamer used in the removal of oil from condensed distillers, at levels up to 64 ppm	Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine	May 12, 2011	FDA has no questions. (PDF, 3 pages)

Publish Phytase AGRN 14 in Table 101.1 in the new section 101 GRAS Notices. Nathan Price moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES, with 1 opposed. Richard Ten Eyck asked question why the common name is Phytase, when listing other Enzymes the organism name is listed. Emily Helmes with ETA (Enzyme Technical Association) explained that Phytase is the common and usual name and the microorganism name is listed under substance. Jan Jarman explained that there is a slight difference in the column headers on this table versus the 30.1 Enzyme table in the *Official Publication* and that this table reflects the information from the FDA GRAS Notice website. She added that the

enzyme ingredient name used on the label will be the same as used for all enzymes.

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
14 (PDF, 576 pages)	DSM Nutritional Products	Phytase enzyme produced by an Aspergillus oryzae strain expressing a synthetic gene coding for a 6-phytase from Citrobacter braakii	Phytase	To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in poultry diets when fed at the rate of 250–4000 FYT/kg feed	Poultry (turkey, broiler chickens, and egg laying hens)	November 14, 2012	FDA has no questions. (PDF, 3 pages)

J) Publish Phytase AGRN 15 in Table 101.1 in the new section 101 GRAS Notices. Nathan Price moves to ACCEPT, Jan Jarman seconds, MOTION PASSES, with 2 opposed. Jan Jarman explained that Table 30.1 Enzyme table is not a list of ingredient names but a list of enzymes allowed to be produced by specific organisms; the ingredient names are listed in Fermentation products in section 36. The name listed here is not the ingredient name: it is the common and usual name for the substance/enzyme. Phytase would be listed under the Guarantee Analysis on the enzyme product label. Mika Alewynse explained that Phytase is the active material in a Fermentation product. In the ingredient list they would have to check with the supplier to describe whether this is an enzyme that has been highly purified that would qualify for use of the term Phytase from the Ingredient list. The vast majority of enzyme products used in Animal Feed are relatively unpurified, which is why they are identified as

dried or liquid	d blank fermentation p	product.

	arica or rigar	J DIATIK TETTTETILAL	ion product.				
AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
15 (PDF,	DSM Nutritional	Phytase enzyme	Phytase	To increase the	Swine	August 8,	FDA has no questions.
505	Products	produced by		digestibility of		2013	(PDF, 3
pages)		an Aspergillus oryzae strain		phytin-bound phosphorous			pages)
		expressing a		or to increase			
		synthetic gene coding		phosphorous availability			
		for a 6-		from phytate			
		phytase from		in swine diets			
		Citrobacter braakii		when fed at the rate of			
				500–4000			
				FYT/kg feed			

Publish L-Methionine 85% AGRN 16 in Table 101.1 in the new section 101 GRAS Notices. Nathan Price moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES, with 1 opposed.

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
<u>16</u>	Metabolic	L-methionine	L-methionine	Nutrient	All	January	FDA has
(PDF,	Explorer	85% produced	85%	at levels	animals	3, 2014	no
87		by a		up to			questions.
pages)		bioengineered		0.3% in			(PDF, 4
		Escherichia		animal			pages)
		coli K-12		feed			F~3~~/

L) Publish 101.1 Canthaxanthin AGRN 17 in Table 101.1 in the new section 101 GRAS Notices. Nathan Price moves to ACCEPT. Jacob Fleig seconds. MOTION PASSES, with 1 opposed.

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
17 (PDF, 170 pages)	DSM Nutritional Products	Canthaxanthin	Canthaxanthin	To be used in breeder hen diets at the rate of 6 mg/kg of feed as a nutritive antioxidant to support the development of chicks	Breeder hens used for hatching egg production	July 22, 2014	PDA has no questions. (PDF, 4 pages)

- 2) Work Group Reports
  - A) DFM reclassification workgroup

Jan Jarman gave an update on working group progress. They met for a strategic planning session. Mika is reviewing the spreadsheet document figuring out which organisms will need to be renamed or reclassified and which ones would need a safety review. After her review the group will meet again. Put time on next IDC meeting.

- B) GRAS workgroup update—Members: Richard Ten Eyck (lead), Leah Wilkinson, Jan Jarman, Jan Campbell, Stephanie Adams, Kristi Smedley, Kent Kitade, Emily Helmes, Tom Phillips, Gary Lynch, Jennifer Roland (admin support), Nathan Price, Mollie Morrissette, Cathy Alinovi, Chris Cowell.
  - Workgroup will schedule a meeting and give a report at the annual meeting.
- C) Materials NOT suitable workgroup—Members: Leah Wilkinson, Richard Ten Eyck, Dave Dressler, Cathy Alinovi, Dave Phillips, Steve Gramlich, Susan Thixton, Brett Boswell, someone from Dave Edwards, FDA/CVM, someone from PFI, and Jan Campbell (workgroup documents are in the Feed BIN projects)

Workgroup will schedule a meeting and give a report at the annual meeting.

- 3) Discussions
  - A) Status on high profile ingredients (if needed)—Richard/CVM
    - None at this time
  - B) Discussion of common foods [21 CFR 582.1(a)] in wild bird food—BSFL—Erin
    - Erin Bubb presented a discussion on adding Black Soldier Fly Larvae to wild bird food. Would like to introduce an SUIP into the Model Bill since it would be listed under common food for Wild Birds. Erin Bubb will take SUIP language to Model Bill; work with Sue Havs with WBFI.
  - C) Hemp Guidelines
    - i) Committee discussed proposed guidelines on hemp. Questions were asked from the hemp industry on the process for submitting new ingredient definitions. The process was walked through by Richard Ten Eyck and Bob Church, the Other Oil Seed Investigator. Jan Jarman motion to pass Hemp Guidelines on to the AAFCO Board of Directors for approval to be distributed on aafco.org website. Stan Cook seconds. MOTION PASSES. A copy of the final version of the guidelines is included at the end of these minutes.
  - D) Next meeting of the committee will be at the AAFCO annual meeting in Bellevue, Washington, August 10–12.

The meeting adjourned at 10:25 am PST.

The minutes were approved April 27, 2017, 16-1-0.

#### AAFCO Guidelines on Hemp in Animal Food, March 5, 2017

#### For more information, visit the aafco.org website.

Ingredients used in animal food (pet, livestock, and poultry) in the United States undergo a scientific review prior to being allowed for sale or distribution. The most comprehensive list of ingredients defined for animal food use is found in the Association of American Feed Control Officials *Official Publication* (AAFCO OP). Ingredient definitions and their common name come into the OP through one of three routes. They can be the subject of a Food Additive Petition to the FDA (FAP); receive a letter of no questions from the FDA to a generally recognized as safe (GRAS) notification (new—subject to membership approval); or the most popular route, be requested of AAFCO. Each of these routes has some level of a safety and utility review done by the FDA/CVM. States and others then rely on the AAFCO OP to allow feeds to be made with defined ingredients. The common ingredient name established by AAFCO is reflected in the feed's ingredient statement. The FDA and a few states also recognize self-conclusions by firms of GRAS for an intended use.

Hemp production is increasing in the United States. In 2015 AAFCO asked the hemp industry to come forward and present information for the scientific review to establish definitions for animal foods made from the hemp plant. We expected information on hemp seed oil, hemp seed meal, and whole hemp seeds. To date, the industry has not provided any data showing that ingredients derived from the hemp plant are safe and useful in animal food. AAFCO is encouraging the industry to submit their data promptly. Regulatory members continue to ask for the information prior to distribution of hemp seed products in their state. To allow an entire industry to enter the market without the appropriate safety data is unfair to other ingredient manufacturers that are doing their due diligence. There are some potential safety concerns related to the presence of certain compounds, including THC (tetrahydrocannabinol) and CBD (cannabidiol), in parts of the hemp plant that must be addressed.

One thing has become clear as we have had discussions with the hemp industry, materials and products that are CBD infused need to be treated as drugs. There is no nutritional intended use for this compound. This means that several parts of the hemp plant will not be appropriate for animal feeding.

Quoting from the FDA and Marijuana website: "FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which cannabidiol has been added."

#### For further information:

AAFCO Ingredient Definition Process: http://www.aafco.org/Regulatory/Committees/Ingredient-Definitions

AAFCO Hemp Seed Oil Investigator: brett.boswell@state.mn.us

AAFCO Hemp Seed Meal, Whole Hemp Seed Investigator: bchurch@mt.gov

#### FDA Food Additive Petitions:

http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm056809.htm

#### FDA GRAS Notification:

http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/default.htm

FDA and Marijuana: Questions and Answers:

http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietsuppsexclude

DEA Announces Actions Related to Marijuana and Industrial Hemp:

http://www.oisc.purdue.edu/seed/hemp/dea\_cannabis.pdf

DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol:

http://www.oisc.purdue.edu/seed/hemp/dea\_cbd\_research.pdf

# **Inspection and Sampling Committee Report**

2017 AAFCO Midyear Meeting January 16, 2017, 11:00 am–12:00 pm, Mobile, Alabama

Committee Recommendations: None

Board Recommendations: Report was accepted on May 1, 2017.

#### **Association Recommendations:**

#### **Committee Action Items**

1) Include the Biosecurity Procedures Document in the AAFCO Inspectors Manual

- 2) Bulk Aseptic Sampling Work Group Charge: to included protocol for bulk aseptic sampling. The group includes the following members: Tim Lyons MI; Miriam Johnson NC; Kevin Klommhaus FDA; Jacob Fleig MO. AFIA and NGFA will provide members following the meeting.
- 3) AAFCO Inspectors Manual FSMA Alignment Work Group Charge: to review the AAFCO Inspectors Manual to ensure it aligns with FSMA requirements. The group includes the following members: Kevin Klommhaus (lead) FDA; Brett Groves IN; Jim True KY.

#### **Committee Participants**

**Members Present:** Chad Linton – WV (incoming chair/current vice-chair); Stan Cook – MO; Bob Church – MT; Bob Geiger – IN; Tim Lyons – MI; Kevin Klommhaus – FDA; Brett Groves – IN; Meagan Davis – LA: David Dressler – PA: Laura Scott – CAN: Jim True – KY: Miriam Johnson – NC

Advisors Present: Megan Dicks – AFIA; Preston Buff – AFIA; Jan Campbell – NGFA; Chris Olinger –

NGFA

Others Present: Mark LeBlanc - LA; Kelsey Luebbe - NE; Jacob Fleig - MO

#### **Committee Report**

Chad Linton called the meeting to order at 11:05 am CST. Members and advisors in the room introduced themselves.

#### Inspector Credentialing Exam—Jacob Fleig

The Credentialing Exam is available for registration for feed inspectors via the NEHA website.

The total expense and information can be found on the following website: neha.org/professional-development/credentials.

#### Biosecurity Procedures—Chad Linton and Brett Groves

See Attachment A.

Jim True made a motion to accept the Biosecurity Procedures as written in order to include them in the AAFCO Inspectors Manual. Stan Cook seconded the motion. MOTION CARRIES. Biosecurity Procedures have been updated to the AAFCO website in Chapter 2, and all necessary editing is complete.

## Aseptic Sampling—Bob Geiger

Discussion regarding the detail required to cover this topic determined that the document should not be included in the AAFCO Inspectors Manual. However, the document is missing procedures for bulk aseptic sampling. A work group was formed to address this identified gap in the procedures.

Tim Lyons (MI) asked if any state was performing environmental sampling, a beneficial procedure for those states with certain types of manufacturing facilities. Kevin Klommhaus stated that the FDA was already discussing this and suggested that this committee be brought into the discussion.

#### **AAFCO Sampling Study—Kelsey Luebbe and Mark LeBlanc**

Kelsey Luebbe provided a background on the historical work performed regarding our current sampling procedure and stated a literature review was being performed.

The group requested direction from the committee to prioritize the study. The group decided that revalidating the sampling methods for crude protein, crude fat, and crude fiber analysis was unnecessary, so the priority would be sampling for other analytes. Aaron Price, co-chair of the Laboratory Methods and Services Committee, requested that sample study work group coordinate with his committee to ensure valid analytical methods are available. The sample study work group was not provided a deadline or action item, leaving the decisions to pursue future sampling studies to the work group. Further work will be reported to the committee at the 2017 annual meeting.

#### **AAFCO Feed Inspector's Manual and FSMA Alignment**

A review of the AAFCO Feed Inspector's Manual must be performed to ensure it is aligned with the requirements of FSMA. A workgroup was formed and provided a deadline of August 2018 to complete this task. The taskforce will be Brett Groves and Stan Cook.

#### **Action Item Table**

Responsible	Item	Action	Timing/Status
Chad Linton	Biosecurity	Include in the AAFCO Feed Inspector's	Completed
	Document	Manual	
Work Group	Bulk Aseptic	Develop protocol for bulk aseptic sampling	January 2018
	Sampling		·
Work Group	Feed Inspector's	Ensure the manual aligns with FSMA	August 2018
	Manual	requirements	

# **Attachment A: 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.
  - Check to see if the farm has biosecurity procedures. If so, ensure that you comply with the farm or facility's 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. Floor mats will need to be cleaned and disinfected between visits.
  - 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 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
  - Disposable rubber boot covers without deep cleats
  - Rubber gloves
  - Dusk mask
  - Safety goggles
- A micro/virucidal disinfectant can be used 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, park the vehicle in a clean or designated parking 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, which might require you to park on the road in front of the farm.
  - At a minimum, avoid driving through manure, puddles, or wasted water.
- Ensure farm personnel are aware of your arrival before exiting the vehicle to avoid contamination or breach of the farm's biosecurity plan.
- Put on clean coveralls and boots in an area that avoids potential contamination, such as 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 with the disinfectant 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 in a protected area to avoid contact with livestock, children, and pets when necessary.

# Leaving the premises:

- Follow biosecurity procedures for farm, if applicable.
- 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 a 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.
  - 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 it.
- 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**

2017 AAFCO Midyear Meeting January 17, 8:00am–5:00 pm, Mobile, Alabama

Committee Recommendations: None

Board Recommendations: Report was accepted on May 1, 2017.

**Association Actions:** 

# **Committee Participants**

**Members Present:** 

First Name	Last Name	Affiliation	E-mail	Role
Aaron	Price	CFIA	Aaron.Price@inspection.gc.ca	Chair
Nancy	Thiex	AAFCO	Nancy.thiex@gmail.com	Vice Chair
Josh	Arbaugh	WV Dept. of Ag	jarbaugh@wvda.us	Member
Andy	Crawford	AAFCO	andy@crawford.org	Member
Deepika	Curole	LSU Dept. of Ag Chemistry	dcurole@ldaf.state.la.us	Member
Ted	Gatesy	MI Dept. of Ag and Rural Dev	gatesyt@michigan.gov	Member
Manisha	Das	FDA	manisha.das@fda.hhs.gov	Member
Teresa	Grant	NC Dept. of Ag	teresa.grant@ncagr.gov	Member
Heidi	Hickes	MT Dept. of Ag	hhickes@mt.gov	Member
H. Dorota	Inerowicz	OISC	inerowic@purdue.edu	Member
Mary	Koestner	MO Dept. of Ag	Mary.koestner@mda.mo.gov	Member
Patty	Lucas	FL Dept. of Ag and CS	partricia.lucas@freshfromflorida.com	Member
Kristi	McCallum	CO Dept. of Agriculture	kristina.mccallum@state.co.us	Member
Lawrence	Novotny	SD—retired	lawrence.novotny@sdaglabs.com	Member
Louise	Ogden	AAFCO	pt@aafco.org	Member
Bob	Sheridan	NY Ag	robert.sheridan@agriculture.ny.gov	Member
Brenda	Snodgrass	OK Dept. of Ag	Brenda.Snodgrass@ag.ok.gov	Member
Michele	Swarbrick	MN Dept. of Ag	Michele.swarbrick@state.mn.us	Member
Lei	Tang	FDA CVM	lei.tang@fda.hhs.gov	Member
Sharon	Webb	UK Reg. Services	sharon.webb@uky.edu	Member
Sara	Williams	OTSC	smw@otcs.tamu.edu	Member

#### **Advisors Present:**

First Name	Last Name	Affiliation	E-mail	Role
Dan	Berg	Covance	Dan.berg@covance.com	Advisor
Lars	Reimann	Eurofins	larsreimann@eurofins.com	Advisor
Jeff	Rich	Romer Lab	jeff.rich@romerlabs.com	Advisor
Ken	Riter	Nestle-Purina Analytical Labs	ken.riter@purina.nestle.com	Advisor
Leo	Schilling	Eurofins	leoschilling@eurofins.com	Advisor
John	Szpylka	Merieux Nutrisciences	john.szpylka@mxms.com	Advisor

#### **Committee Report**

- 1) The meeting was called to order at 8:00 am.
- 2) Review and approval of agenda
- 3) Introductions—sign-up sheet sent around
- Committee roster reviewed. Anyone wishing to be added to the Committee should contact Aaron Price or Nancy Thiex.
- 5) Working Group Updates
  - A) Tylosin—Leo Schilling gave an overview of the method needs statement for tylosin and shared preliminary data obtained by a LC-MS/MS-based method, *PowerPoint presentation*, "Development of an LC-MS/MS Method for the Determination of Tylosin in Feed at Medicated Levels." Issue with high CVs for the 4 components of interest and less than optimal recoveries. It was suggested to consider cryogrinding if finer particles were needed, to inject samples in duplicate to differentiate between instrument and extraction sources of error, and to check the availability of isotopically labeled standards. Louise Ogden offered to have PTP Round 201629 sent to Leo for additional analysis.
  - B) CTC—by HPLC—Fluorescence. Tom Phillips reported that the SLV had been completed and that he had almost completed the collaborative study protocol. He was looking for samples that had been tested by the micro method for further equivalency verification. Need to get additional funding to Tom to continue the study. Sharon Webb has samples frozen that could be sent to him since they have done the micro testing on these.
  - C) Fat Soluble Vitamins. H. Dorota Ineroicz and Ken Riter reported on further studies that still indicated that the methods used were not very reproducible within most labs and definitely not reproducible between labs. There is focus on improving method precision. AAFCO can make ring test samples if needed. Requested that Able Labs prepare the samples and fortify with a premix of vitamins A and E. Ken will contact PT Program with needs.
  - D) Best Practices Working Group—Lawrence Novotny reviewed the first draft "Critical Factors in Determining Fiber in Feeds and Forages" from the Fiber working group. The working group was praised for the quality of the document and promised constructive criticism that could be considered for incorporation into the final version. It was specifically suggested to include a table listing preferred methods for specific matrices. Sharon Webb has a checklist for the final review of the document before publication. Once completed the document can be posted; no motion is needed. PTP will send out an alert to participating labs about this new Best Practices document.
    - It was agreed that the next analyte would be "moisture" and the next step is to establish a "Moisture Working Group." Andy Crawford will run the 2016 data for moisture.
  - E) Sugars—Dan Berg's PowerPoint presentation "Sugar Analysis by HPAEC-PAD" reported that the method is based on ion-chromatography with electrochemical detection, published in JAOAC **99**(2), 2016, and can be downloaded for free. Dan Berg has since improved the method including adding arabinose as an internal standard and a post-column pump flushing the electrode with NaOH.

It was suggested to seek AOAC status for the method. This would require going through the AOAC process (Stakeholder Panel, ERP, Collaborative study with labs, etc.) and require paying AOAC around \$60,000 as a "project management fee." The scope of the method would include both foods and feeds. AAFCO has offered to provide \$20K. Other potential contributors include IDF, PFI, and AFIA. The goal is getting funding commitments prior to the AOAC midyear meeting in early April. Thermo may be willing to loan labs the appropriate instrumentation. Also, anyone interested in collaborating on a third-party verification of the method should contact Dan Berg.

- F) Dietary Starch—The method authored by Mary Beth Hall received AOAC First Action status in 2014 and was scheduled to be evaluated for Final Action Status at the 2016 AOAC annual meeting. However, due to administrative issues this review did not take place as scheduled and has been rescheduled for the 2017 annual AOAC meeting in Atlanta. Lars Reimann repeated his request that anyone using the method send him their feedback, including performance parameters and suggestions for improvements.
- G) Mycotoxins—Robert Sheridan summarized a round-robin study in which 8 labs participated (7 LC-MS/MS and 1 ELISA test kit). The data indicated very high variability between labs. A ring test managed by the EU followed a much more controlled approach (specified method) and provided significantly tighter results. There is also an FDA method that has been validated through the FDA-sponsored validation process. It was agreed that we should try to get copies of the methods and validation reports for the EU and FDA method.
- H) Multi-Element Validation—Robert Sheridan has validated a method in house. The method is focused on validating label claims as well as identifying contaminants present at toxic (relatively high) levels. Michele Swarbrick, Sharon Webb, and Robert will form a working group and recommend the next step at the annual AAFCO meeting. In the meantime Robert would greatly appreciate if 2 labs would try his method and share their experiences. Contact the team if you want to participate.
- I) Lab Sample Preparation Guideline Group—Michele Swarbrick—The group met in Saint Paul in November 2016 and this past Sunday. The group hopes to have a rough draft by the AAFCO annual meeting in August.
- 6) Vitamin A Splits
  - Heidi Hickes reported that she struggled with the poor reproducibility of vitamin A assays even within her own lab. Based on the initial feedback, Heidi believed the State of Indiana method may perform better, and she will work further with this method to see if better results can be obtained. One key factor for improving performance is the use of Vit A2 as internal standard. Nancy Thiex will examine data from the 1990s that in detail dealt with vitamin A testing issues and see how much can be recovered and summarized for use with this project. Nancy has a paper, "Sources of Error in Vitamin A Analysis," from 25 years ago and will send the paper out again.
- 7) Methods and Method Needs Statements (MNS)—Aaron Price reported that we had a relatively large amount of completed MNS and that the AAFCO Board of Directors was pushing to clear the backlog. It was agreed to survey the states for a priority ranking for methods as well as a commitment to participate in collaborative studies. Sharon Webb and Louise Ogden volunteered to prepare and distribute the survey. The FDA suggested that focus be put on getting an updated thiamine method because the current AOAC method is old and results in variable data, especially when applied on canned cat food.
- 8) Accreditation to the ISO/IEC 17025 Standard—Robyn Randolph reported that APHL as part of the FDA Collaborative Agreement had done the following:
  - A) Implemented a Discussion Board
  - B) Made training courses available
  - C) Would be holding a filth testing workshop
  - D) Had prepared a "Laboratory Best Practices" manual that currently was under FDA review. It is hoped that it will be available by August 2017.
  - E) Data Acceptance White Paper: "Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Labs"—FDA added comment and changes, added importance of accreditation and working with customers. It was published in October on the

- APHL website. Working on a position statement as to the FDA's use of state and other NFP labs to support FDA's analytical needs.
- F) Current Major Lab Initiatives—Partnership—to be published later this year
- G) APHL Position Paper "FDA and the Use of Governmental Food and Feed Testing Laboratories"—to be presented to Board at the end of January 2017
- H) Sustainability for ISO continued funding
- A listing of proficiency samples commercially was also being updated. Kristi McCallum asked for people to provide her with any sources she had overlooked. The list is found on the APHL website and AAFCO Lab website.
- 9) Quality Assurance Subcommittee
  - A) John Szpylka gave a PowerPoint presentation "Big Picture of Becoming Accredited to ISO 17025" outlining the many good reasons for seeking ISO 17025 Accreditation.
  - B) Patty Lucas gave a PowerPoint presentation "A State's First Year Experience with FDA Grant to Gain ISO 17025" describing the challenges her lab faced when seeking accreditation with focus on the challenges associated with document control.
  - C) Transfer of Methods for New Ingredient Approvals from FDA to State Labs—Lei Tang discussed how the FDA could share methods submitted to the FDA as part of new ingredient applications with state and private labs, minimizing the need for labs to go through the FOI process. She said that she was working with FDA legal staff that currently had to approve such distribution.
- 10) IFPTI Curriculum Framework—Chris Weiss from International Food Protection Training Institute (IFPTI) gave an overview of the status of their 5-year project with the FDA creating a competency-based framework for state lab professionals, including sharing the current draft. Currently, the curriculum framework is being worked on and not publicly available.

  Patty Lucas mentioned how she felt such a program would assist state labs dealing with high employee turnover while retaining institutional knowledge.
- 11) FDA Cooperative Agreement—Nancy Thiex reported that the status of the individual projects covered by the agreement had already been discussed earlier in the meeting. In addition two 4-day sample prep training sessions for inspectors and lab personnel have been scheduled (March 6–9 in Dallas, April 3–6 in New York). Nancy is also looking for states interested in being part of a pilot feasibility project.
- 12) Lab Centers of Expertise—Nancy Thiex and Aaron Price—It was mentioned that at the request of the lab committee the AAFCO Board of Directors has formed a working group headed by Bob Geiger examining the possibility of states forming Centers of Excellence for tests with marginal volume in each state similar to the programs sponsored by the EPA and industry. The goal is for the group to prepare a white paper on this issue for submission to the AAFCO Board of Directors. It was mentioned that the laws in some states would make it difficult to implement such a program and that the Pesticide Residue Working Group is examining a similar approach.
- 13) FSMA Implementation Task Force—Robert Sheridan reported that not a lot was happening as the rules for FSMA were still being written and the impact of the Trump presidency was yet to be assessed.
- 14) Roundtable discussion
  - A) Lawrence Novotny—Mid-West AOAC—Scheduled for May 23–25, 2017, in Minneapolis.
  - B) Salmonella in Feeds—Ted Gatesy presented the successful identification of the pet food origin of a nationwide pathogen infection in humans identified through a routine sampling and analysis program. It was suggested that more microbiologists should be part of and active in the AAFCO Lab Methods and Services Committee.
  - C) PTP Stability—Nancy Thiex discussed the need for analyte stability data for the samples prepared and distributed as part of the AAFCO Proficiency Testing Program. Louise Ogden will send out a request to members and advisors on the PTP Advisory Committee.
  - D) FDA Table-top—held on Sunday, January 15—poor lab presence because it was not advertised clearly to labs—need to improve the communications.
  - E) Asked Kristy and Ted to do a micro method validation and instrumentation, best practices in micro at an upcoming meeting.
- 15) The meeting adjourned at 4:50 pm.

# **Action Item Table**

Responsible	Item	Action	Timing/Status
L. Ogden	Tylosin working group	Send L. Schilling PT round 201629 for additional analysis.	ASAP
S. Webb	CTC working group	Coordinate with T. Phillips to get samples to him that have been analyzed by plate assay.	Before August meeting
K. Riter	Fat soluble vitamins working group	Contact PT program with needs for some vitamin-fortified samples.	ASAP
A. Crawford	Best Practices working group	Run the 2016 PT data for moisture.	ASAP
S. Webb, R. Sheridan, and M. Swarbrick	Multi-Element working group	Form a working group and recommend next step at the annual AAFCO meeting.	Before August meeting
N. Thiex	Vitamin A work	Send out to the committee paper from 1990s on vitamin A sources of error.	ASAP
S. Webb and L. Ogden	Method Needs statements	Send out a survey to state labs to prioritize needs and gauge commitment to collaborative studies. Resources can be obtained from A. Price. Present survey results to committee.	Before August meeting

## **Attendance List**

First	Last			
Name	Name	Affiliation	E-mail	Role
Josh	Arbaugh	WV Dept. of Ag	jarbaugh@wvda.us	Member
Dan	Berg	Covance	Dan.berg@covance.com	Advisor
Ametra	Berry	GA Dept. of Ag	ametra.berry@agri.georgia.gov	
Raynette	Cason	LA Dept. of Ag and Forestry	rcason@ldaf.state.la.us	
Gina	Clapper	Merieux Nutrisciences	gina.clapper@mxns.com	
Andy	Crawford	AAFCO	andy@crawford.org	Member
Deepika	Curole	LSU Dept. of Ag Chemistry	dcurole@ldaf.state.la.us	Member
Manisha	Das	FDA	manisha.das@fda.hhs.gov	Member
Ted	Gatesy	MI Dept. of Ag and Rural Dev.	gatesyt@michigan.gov	Member
Teresa	Grant	NC Dept. of Ag.	teresa.grant@ncagr.gov	Member
Nadia	Guagliardo	CF Industries Nitrogen	nguagliardo@cfindustries.com	
Casey	Guccione	KS Dept. in Ag	casey.guccione@ks.gov	
Leslie	Hancock	JMS Smuckers	leslie.hancock@jmsmucker.com	
Heidi	Hickes	MT Dept. of Ag	hhickes@mt.gov	Member
H. Dorota	Inerowicz	OISC	inerowic@purdue.edu	Member
Isiah (John Smith)	Isakson	FDA/ORA/OP	Isiah.isakson@fda.hhs.gov	

First Name	Last Name	Affiliation	E-mail	Role
Solmon	Kariuki	UK Reg. Services	s.kariuki@uky.edu	
Brenda	Keavey	WV Dept. of Ag	bkeavey@wvda.us	
Mary	Koestner	MO Dept. of Ag	Mary.koestner@mda.mo.gov	Member
Dominika	Kondratko	CO Dept. of Ag	dominika@kondratko@state.co.us	
Joyce	Lewis	LA Dept. of Ag and Forestry	jlewis@ladf.state.la.us	
Patty	Lucas	FL Dept. of Ag and CS	partricia.lucas@freshfromflorida.com	Member
Kristi	McCallum	CO Dept. of Ag	kristina.mccallum@state.co.us	Member
Dragan	Momcilovic	FDA	Dragan.Momcilovic@fda.hhs.gov	
Quintin	Muenks	MO Dept. of Ag	quitin.muenks@mda.mo.gov	
Lawrence	Novotny	SD - retired	lawrence.novotny@sdaglabs.com	Member
Louise	Ogden	AAFCO	pt@aafco.org	Member
Aaron	Price	CFIA	Aaron.Price@inspection.gc.ca	Co- Chair
Robyn	Randolph	APHL	robyn.randolph@aphl.org	
Lars	Reimann	Eurofins	larsreimann@eurofins.com	Advisor
Jeff	Rich	Romer Lab	jeff.rich@romerlabs.com	Advisor
Ken	Riter	Nestle-Purina Analytical Labs	ken.riter@purina.nestle.com	Advisor
Teresa	Rygiel	FL Dept. of Ag	Teresa.rygiel@fresh.from.florida.com	
Leo	Schilling	Eurofins	leoschilling@eurofins.com	Advisor
Bob	Sheridan	NY Ag	robert.sheridan@agriculture.ny.gov	Member
Brenda	Snodgrass	OK Dept. of Ag	Brenda.Snodgrass@ag.ok.gov	Member
Mike	Stage	Arkansas Dept. of Ag	Mike.stage@aspb.ar.gov	
Jason	Swancer	PA Dept. of Ag	jswancer@pa.gov	
Michele	Swarbrick	MN Dept. of Ag	Michele.swarbrick@state.mn.us	Member
John	Szpylka	Merieux Nutrisciences	john.szpylka@mxms.com	Advisor
Lei	Tang	FDA CVM	lei.tang@fda.hhs.gov	Member
Nancy	Thiex	AAFCO	Nancy.thiex@gmail.com	Co- Chair
Sharon	Webb	UK Reg. Services	sharon.webb@uky.edu	Member
Sara	Williams	OTSC	smw@otcs.tamu.edu	Member
Ron	Winter	FDA/ORA/OP	Ronald.winter@fda.hhs.gov	
Dancia	Wu	OISC	scharfd@purdue.edu	

# **Model Bill and Regulations Committee Report**

2017 AAFCO Midyear Meeting January 16, Mobile, Alabama

#### **Committee Recommendations**

1) The Model Bill and Regulations Committee recommends that the following Veterinary Feed Directive language be included into the Model Regulations Under the Model Bill and that the AAFCO Board of Directors review the proposed language for future consideration by the Association membership pending review by Dragan Momcilovic, FDA (Attachment D).

#### Regulation 13. Veterinary Feed Directive

- (a) For the purposes of enforcement of Section 10(a)(2) of the Act the \_\_\_\_\_ adopts the definitions of Title 21, Code of Federal Regulations, Section 558.3(b)
- (b) For the purposes of enforcement of Section 10(a)(2) of the Act the \_\_\_\_\_ adopts the requirements of Title 21, Code of Federal Regulations, Section 558.6
- 2) The Model Bill and Regulations Committee recommends that the term "feed" be revised within the AAFCO Non-Commercial Feed Model Bill [Section 3. Definitions of Words and Terms. (e)] to conform with modifications adopted to the Official Feed Term by the AAFCO membership on January 16, 2017, and that the AAFCO Board of Directors review the proposed revision for future consideration by the Association membership. The modified language for the Official Feed Term adopted by the AAFCO membership is as follows:

**Feed.** 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.

**Board Recommendations:** Report was accepted on May 1, 2017. Board accepted recommendations 1-2 as presented by the committee.

#### **Association Actions:**

#### **Committee Report**

Model Bill and Regulations Committee Chair Doug Lueders called the meeting to order at 1:30 pm on January 16, 2017. He welcomed committee members, industry advisers, and guests who were present and reviewed the agenda.

# **Committee Participants**

Members Present: Ken Bowers (Kansas), Bill Burkholder (FDA), Tim Darden (New Mexico), April Hunt (Michigan), Sherryl Stoltenow (Washington), Richard Ten Eyck (Oregon), and Scott Ziehr (Colorado) Advisers Present: Angela Mills, Richard Sellers, and Steve Younker (AFIA); David Dzanis (APPA/ACVN); Emily Helmes (Enzyme Technical Association); Jan Campbell and David Fairfield (NGFA); Angele Thompson and Pat Tovey (PFI); and Sue Hayes (Wild Bird Feeding Industry) Minutes from Previous Committee Meetings

Chair Lueders noted that minutes from the August 1, 2016, committee meeting conducted in Pittsburgh were previously approved, posted on the AAFCO website, and included in the 2017 midyear meeting's general session packet.

#### **Öld Business**

Chair Lueders noted the committee had no old business to consider.

#### **New Business**

The committee proceeded to consider new business.

- Food Safety Modernization Act (FSMA) Harmonization with AAFCO Model Bill and Regulations Workgroup Report: Hunt reviewed the agenda and outcomes from the workgroup's face-to-face meeting held October 16, 2016, in Gaithersburg, Maryland (Attachment A).
  - A) Veterinary Feed Directive: Hunt provided the following language recommended by the workgroup to incorporate Veterinary Feed Directive requirements into the AAFCO Model Bill and Regulations:

#### **Regulation 13. Veterinary Feed Directive**

- (a) For the purposes of enforcement of Section 10(a)(2) of the Act the \_\_\_\_\_ adopts the definitions of Title 21, Code of Federal Regulations, Section 558.3(b)
- (b) For the purposes of enforcement of Section 10(a)(2) of the Act the \_\_\_\_\_ adopts the requirements of Title 21, Code of Federal Regulations, Section 558.6

Ten Eyck moved that the Model Bill and Regulations Committee approve the Veterinary Feed Directive language for inclusion into the Model Bill and Regulations and that the AAFCO Board of Directors review the proposed language for future consideration by the Association membership pending review by Dragan Momcilovic, FDA. The motion was seconded by Darden. The committee approved the motion by a voice vote.

- B) Other Issues: Hunt informed the committee that the workgroup will further consider issues related to including language into the AAFCO Model Bill and Regulations pertaining to recall provisions, sanitary transportation, and adulteration and provide the committee with recommendations at a later time.
- 2) Official Feed Term: Ten Eyck moved that the Model Bill and Regulations Committee recommend that the term "feed" be revised within the AAFCO Non-Commercial Feed Model Bill [Section 3. Definitions of Words and Terms. (e)] to conform with the modifications adopted to the Official Feed Term by the AAFCO membership on January 16, 2017, and that the AAFCO Board of Directors review the proposed revision for future consideration by the Association membership. The modified language for the Official Feed Term adopted by the AAFCO membership is as follows:

**Feed.** 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.

The motion was seconded by Ziehr. The committee approved the motion by a voice vote.

3) AFIA Official Publication Requested Changes: The committee discussed requested changes to the Official Publication as recommended by AFIA that were left over from Pittsburg (Attachment B). No action was taken by the committee on the AFIA recommendations for lack of a motion.

#### Assignments/Homework

Labeling of Mineral and Vitamin Units: Chair Lueders informed the committee that Ben Jones (Texas) had brought to his attention possible discrepancies concerning requirements within the Model Bill and Regulations pertaining to the labeling of mineral and vitamin units as established in Regulation 4 and Regulation PF4 (Attachment C). Lueders requested that the committee consider the issue and be prepared to discuss during the committee's next meeting

Lueders asked whether there was any other business to be considered by the committee. Given that none was identified, the committee meeting was adjourned at 2:35 pm.

On behalf of the Model Bill 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.

# Attachment A: AAFCO Feed PC Harmonization Working Group Report

2017 AAFCO Midyear Meeting January 16

#### **Objective**

Review Commercial Feed Model Bill and Regulations. Identify updates and changes needed to harmonize them. This includes the Model Regulations for Pet Food and Specialty Pet Food.

- FSMA Animal Food Rules Harmonization—Membership approved these items on January 16, 2017.
  - A) 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.

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.

#### 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.
- B) Consider the deletion of the AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients and associated checklist from the AAFCO Official Publication (pages 228–237 of the 2017 OP) and replace the deleted information with an html reference link and a citation to the CGMP's Title 21, Code of Federal Regulations, 507.14-507.28.
- 2) **OP Editorial Edits**—incorporated into the 2017 AAFCO OP
  - A) Summer 2016 meeting (Attachment 1)
  - B) October 2016 meeting (Attachment 3)
- 3) Working Group Face-to-Face Meeting—October 17, 2016

The AAFCO Feed Preventive Controls Harmonization Working Group held a face-to-face meeting in Gaithersburg, Maryland, on October 17 to review the entire Model Bill and Regulations for consistency and uniformity. The working group, composed of state, industry, and consumer group members, was assembled in August 2015 to develop FSMA Harmonization language for the Model Bill and Regulations. During this project, the group also identified inconsistencies with citations, definitions, and other language in the Model Bill and Regulations.

The Model Bill and Regulations Committee (MBRC) approved the working group's FSMA harmonization language in August 2016 and tasked the working group to continue with the harmonization/inconsistencies project. Editorial changes the working group made at the October 17 meeting will be included in the 2017 *Official Publication*. Best practices for formatting and listing citations in the Model Bill and Regulations were developed by the working group. The working group agreed that it will move high priority updates forward quickly for implementation and prioritized its recommendations in the list as follows:

# **High Priority Recommendations**

- Editorial updates to the Model Bill and Regulations. See Attachment 3 for a summary of changes.
   submitted October 30 and incorporated into 2017 OP
- VFD language—Create a new Regulation 13. Committee approved, pending CVM review, to the Board of Directors
  - Regulation 13. Veterinary Feed Directive
  - (a) For the purposes of enforcement of Section 10(a)(2) of the Act the \_\_\_\_ adopts the definitions of Title 21, Code of Federal Regulations, 558.3(b).

(b) For the purposes of enforcement of Section 10(a)(2) of the Act the \_\_\_\_ adopts the requirements of Title 21, Code of Federal Regulations, 558.6.

# **Citation Format and Style Recommendations**

To help maintain consistency between the Model Bill and Regulations.

#### **Statutes**

Referencing the entire act: the Federal "xx" Act

Referencing a specific section: Section "x" of the Federal "xx" Act

# Regulations

Referencing the entire part: Title 21, Code of Federal Regulations, part 225
Referencing a specific section: Title 21, Code of Federal Regulations, 225.1-225.202

#### **Remaining Recommendations**

- Definition of "feed" needs to be changed in the Non-Commercial Model Bill to harmonize with the updated feed term IDC approved on September 30, 2016. MBRC approved January 16, 2017, moves to Board of Directors
- Consider AAFCO Model Recall Program Plan Review the FDA Guidance Document on preventive controls when it comes out and see if there is a need for a specific AAFCO Recall Plan Guidance Document. Feed and Feed Ingredients Committee?
- Develop a table in Chapter 5 to reference applicable (topical) FDA Compliance Policy Guides (CPG), Guidance for Industry (GFI), and other related documents. Board of Directors to determine the working group.
- Consider reorganizing the animal classes in the Model Regulations. The animal classes are not very well organized, making it difficult to find certain species. It was originally by the amount of feed produced in United States.
- Labeling—consider revising the definition to include electronic formats. States are starting to include websites and social media as part of labeling and advertising. AAPFCO added electronic to its labeling definition.
- FSMA GMP Checklist Development—The FDA is working on a new checklist. Consider adding a link to the GMP draft guidance in the OP in the meantime.

# Attachment B: From 2016 Pittsburg Model Bill and Regulations Committee to Mobile

AFIA proposed changes to the AAFCO Model Bill November 2015

Edit Requested	MB Section	Language Showing	Rationale
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 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.
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.

# **Attachment C: Model Bill and Regulations Committee Minutes**

Mobile, Alabama

From: Ben L. Jones [mailto:blj@otsc.tamu.edu]
Sent: Wednesday, August 17, 2016 4:19 PM

To: Lueders, Doug (MDA) <doug.lueders@state.mn.us>

Subject: RE: MB Inconsistency

Doug,

I'm not sure to which preference you refer. How to move forward in the AAFCO process or which way to fix the inconsistency? I would be in favor of changing Model Regulation 4(c) to mirror the intent of 4(b)(3). Something like:

#### (c) Vitamin Guarantees

- (1) Guarantees for minimum vitamin content of commercial feed shall be listed in the order specified and are stated in mg/lb unless otherwise specified.
  - (I) Vitamin A, other than precursors of vitamin A, in International Units per pound.
  - (II) Vitamin D-3 in products offered for poultry feeding, in International Chick Units per

pound.

- (III) Vitamin D for other uses, International Units per pound.
- (IV) Vitamin E, in International Units per pound.
- (V) Concentrated oils and feed additive premixes containing vitamins A, D, and/or E may, at the option of the distributor be stated in units per gram instead of units per pound.
  - (VI) Vitamin B-12, in milligrams or micrograms per pound.
- (VII) All other vitamin guarantees shall express the vitamin activity in milligrams per pound in therms of the following: menadione; riboflavin; d-pantothenic acid; thiamine; niacin; vitamin B-6; folic acid; choline; biotin; inositol; p-amino benzoic acid; ascorbic acid; and carotene.
- (2) Products labeled with a quantity statement (e.g., tablets, capsules, granules, or liquid) may state vitamin guarantees in milligrams per unit (e.g., tablets, capsules, granules, or liquids) consistent with the quantity statement and directions for use.

Just an example of a possibility.

Thanks, BLJ

From: Lueders, Doug (MDA) [mailto:doug.lueders@state.mn.us]

Sent: August 15, 2016 12:30 PM
To: Ben L. Jones < bli@otsc.tamu.edu >
Subject: RE: MB Inconsistency

Ben,

I do not disagree. What would your preference be? I'm actually surprised that AFIA didn't pick up on that. I wish that I knew what the rationale was back in the day.

Regards,

Doug Lueders, Manager
Minnesota Department of Agriculture
Commercial Feed Regulatory Program
Phone 651-248-4450
Fax 651-565-5488
E-mail doug.lueders@state.mn.us
Web Site http://www.mda.state.mn.us/feed

From: Ben L. Jones [blj@otsc.tamu.edu] Sent: Monday, August 15, 2016 11:42 AM

To: Lueders, Doug (MDA) Subject: MB Inconsistency

Doug,

Recently discovered what I see as an inconsistency in a section of the model regulations under the model bill and the model pet food regulations. At least may deserve consideration and discussion.

#### Regulation 4. Expression of Guarantees

4(b)(3) Mineral Guarantees allows for the expression of mineral guarantees in mg/unit (e.g., tablets, capsules, granules, or liquids) consistent with the quantity statement and directions for use.

4(c) Vitamin Guarantees allows for the expression of vitamins in mg/lb or units consistent with those employed for the quantity statement unless otherwise specified......and then lists some specific expressions for certain vitamins, implying that those specific expressions cannot be guaranteed in mg/unit.

Regulation PF4. Expression of Guarantees PF4(c)(3) allows for expression of minerals in mg/unit. PF4(d)(3) allows for expression of vitamins in mg/unit.

You may ask..."so what?" So, if a companion animal, say horse, product is in a tablet, capsule, granule, or liquid form, they can guarantee minerals in a mg/unit form, can guarantee some vitamins in mg/unit, but cannot guarantee all the vitamins in a mg/unit form. Makes it difficult to convey information to the consumer in a consistent manner.

Your thoughts?

Thanks,

Ben Jones, Associate Director Office of the Texas State Chemist P.O. Box 3160 College Station, TX 77841 (979) 845.1121 phone (979) 845.1389 fax blj@otsc.tamu.edu

# **Attachment D: Model Bill and Regulations Committee Minutes**

Mobile, Alabama

From: Momcilovic, Dragan [mailto:Dragan.Momcilovic@fda.hhs.gov]

Sent: Friday, March 17, 2017 6:41 AM

To: Lueders, Doug (MDA) <doug.lueders@state.mn.us>

Cc: Edwards, David <David.Edwards@fda.hhs.gov>; 'Bowers, Ken' <Ken.Bowers@ks.gov>

Subject: RE: Final MBRC Minutes for Mobile

#### Hi Doug,

Assuming that I am not missing something in your request, I concur that the wording of "Regulation 13" is correct and references the appropriate sections in 21 CFR 558.

Please let me know if you need anything else.

#### Dragan

From: Lueders, Doug (MDA) [mailto:doug.lueders@state.mn.us]

Sent: Thursday, March 16, 2017 4:18 PM

To: Momcilovic, Dragan

Cc: Edwards, David; 'Bowers, Ken'

Subject: FW: Final MBRC Minutes for Mobile

#### Dragan,

You were identified in a motion at the MBRC meeting in Mobile as having the final word on two additions to the Model Bill concerning VFDs. Please see the original wording in attachment A, and the final motion in the attached MBRC Minutes. Your stamp of approval or requested changes to this wording is appreciated. Please advise.

#### Regards,

Doug Lueders Commercial Feed Program Manager Food and Feed Safety Division Phone 651-248-4450 doug.lueders@state.mn.us http://www.mda.state.mn.us/feed

# **Pet Food Committee Report**

2017 AAFCO Midyear Meeting January 17, 9:30 am-12 pm, Mobile, Alabama

#### **Committee Recommendations**

- 1) Pet Food Committee (PFC) moved to accept and recommend the Pet and Specialty Pet definitions as displayed (see Appendix A) to the Model Bill and Regulations Committee for their consideration.
- 2) PFC moved to accept and recommend the Proposed Regulations for Dietary Starch and Sugars Guarantees and Descriptive Terms (see Appendix B) and move to the Model Bill and Regulations Committee for their consideration.

**Board Recommendations:** Report was accepted on May 1, 2017.

#### **Association Actions:**

#### **Committee Participants**

Members Present: Stan Cook (chair, MO), Kristen Green (vice-chair, KY), Jan Jarman (MN), Jo Lynn Otero (NM), Lizette Beckman (WA), Christie Shee (IN), Jason Schmidt (LA), George Ferguson (NC), James Embry (TX), Suzanne Riddle (MO), William Burkholder (FDA-CVM), Charlotte Conway (FDA-CVM), Eric Nelson (FDA-CVM), Liz Higgins (NM, via call), Austin Therrell (SC, via call)

Advisors Present: Leah Wilkinson (AFIA), Jason Vickers (AFIA), Dave Dzanis (APPA and ACVN), Susan Thixton (AFTP), Angela Mills (NGFA), David Fairfield (NGFA), David Meeker (NRA), Angele Thompson (PFI), Pat Tovey (PFI), Mollie Morrissette (PWA, via call)

#### **Committee Report**

Motion to accept the Pet and Specialty Pet working group report. Moved by Bill Burkholder (FDA-CVM). Seconded by Jan Jarman (MN). MOTION PASSED.

Motion to accept and recommend the Pet and Specialty Pet language as displayed (see Appendix A) to the Model Bill and Regulations Committee for their consideration. Moved by Bill Burkholder (FDA-CVM). Seconded by Jan Jarman (MN). MOTION PASSED.

Motion to accept and recommend the Proposed Regulations for Dietary Starch and Sugars Guarantees and Descriptive Terms (see Appendix B) and move to the Model Bill and Regulations Committee for their consideration. Moved by Jan Jarman (FDA-CVM). Seconded by Bill Burkholder (MN). MOTION PASSED.

#### **Committee Minutes**

#### **Announcements**

PFC welcomes James Embry from the Texas Office of the State Chemist as a new member. Bill Burkholder (FDA-CVM) requested an agenda addition to discuss hairball products.

#### **Working Group Reports**

## Pet Food Labeling Workshop—Charlotte Conway, FDA-CVM

The updated and expanded draft slides for the 2017 annual meeting Pet Food Labeling Workshop have been completed by the workshop workgroup and will be provided to FASS for formatting after acceptance by the workgroup. The breakout session subgroups should have their breakout materials completed by March. Additional information regarding workshop registration and agendas will be made available soon on the AAFCO website.

#### Definitions of Pet and Specialty Pet Working Group—William Burkholder, FDA-CVM

The PFC accepted the revised definitions available in Appendix A and recommended them to the Model Bill and Regulations Committee. The initial definitions provided by the workgroup were discussed and revisions made for clarification before being passed by the PFC. The specialty pet definition does not include zoo or laboratory animals, or pet chickens, horses, or pigs.

#### **Discussion Items**

# Discussion of Label Applications of New Profiles and Substantiation Claims—Kristen Green, Univ. of KY

Based on the passage of the updated AAFCO Nutrient Profiles and associated PF Model Regulation changes, states are now seeing labeling changes related to the updated 2017 AAFCO Nutrient Profiles (i.e., new nutritional adequacy statements, certain guarantees are now listed as essential). Questions have arisen regarding how states are going to manage labels featuring the elements from the newest version of the Nutrient Profiles and PF Model Regulations if their state law/regulations reference the earlier version of the Profiles and/or the Nutritional Adequacy statements. A roll call of several regulators on the phone and at the table indicated that states were mostly planning to utilize regulatory discretion to allow use of either set of Profiles and the related PF Model Regulations until the state updates their state law/regulations if current laws/regulations reference specific versions. In many cases, state laws may include specific nutritional adequacy statements but not reference a particular version of the Nutrient Profiles. If a firm is choosing to reference the 2017 AAFCO Nutrient Profiles, however, all of the firm's labeling elements must correspond to the associated 2017 AAFCO PF Model Regulations. Most states do not plan to allow a mix of new/older Profiles and associated new/older PF Model Regulations on different elements of labeling.

Example: For dog products only

Acceptable use:

Old Profiles and Model Regulations: DHA listed in the guaranteed analysis at the bottom of the list with "\*" referencing the "\*Not recognized..." statement on a product with an unmodified "growth" or "all life stages" nutritional adequacy statement.

Revised Profiles and Model Regulations: DHA listed in the guaranteed analysis in the upper part of the list with no "\*" referencing the "\*Not recognized..." statement on a product with a modified nutritional adequacy statement referencing the size of the dog [excluding/including growth of large size dogs (70 lb. or more as an adult)].

Unacceptable use:

Mixed old and new Profiles and Model Regulations: DHA listed in the guaranteed analysis in the upper part of the list with no "\*" referencing the "\*Not recognized..." statement on a product with an unmodified "growth" or "all life stages" nutritional adequacy statement.

#### Dental Claims—Austin Therrell, SC Dept. of Agriculture

The Dental Control Guidelines as previously provided to the PFC were presented along with comments that had been received in between meetings concerning issues with Guidelines (5) and (6). A comment was raised regarding the new language in Guideline (5), which appeared to not allow odor control claims on products utilizing a breath freshening flavor. Some draft proposed language was displayed and other language was proposed during the meeting. The wordsmithing issues were not resolved during the meeting, and the guidelines were tabled to be discussed during an upcoming PFC webinar. Any examples for Guideline (6) will also be discussed during the webinar.

Carbohydrate (Sugars and Dietary Starch) Guidelines—Jan Jarman, MN Dept. of Agriculture
The revisions to the PF Model Regulations to address voluntary carbohydrate claims (previously
presented to the PFC committee—see Appendix B) were discussed. An example of how the guaranteed
analysis would look, along with an alternative suggested by PFI, were displayed and are available in
Appendix B.1. The regulators at the table and on the call were polled to see if there were preferences
regarding the formatting of the Dietary Starch and Sugars guarantees. The committee preferred the
guarantee order originally proposed by the workgroup. An issue was raised that the Sugars method that
supports this work may not be complete and additional money needed in order to make this method an
official method. The PFC leadership will address this issue with the Laboratory Services Committee and
the Board of Directors to make sure that AAFCO continues to support this endeavor. The PFC accepted
the workgroup recommendations.

#### Pet Food Label Modernization Discussion—Stan Cook, MO Dept. of Agriculture

The label modernization is a major focus for PFC, and the work will increase over the coming year. Subgroups of this workgroup have been meeting and making progress. This workgroup had a face-to-face meeting directly following the PFC meeting.

# Declaration of Metabolizable Energy in Calorie Content Statements—Jo Lynn Otero, NM Dept. of Agriculture

This discussion involved the requirement of the inclusion of "ME" or "Metabolizable Energy" and the use of "as fed" in place of "fed" in calorie content statements based on PF9. There appears to be some

confusion over the requirement to specifically state ME in the calorie statement when calories are calculated since it does not specifically state this in PF9. A summary of the discussion points is available in Appendix C.

#### Modification to the Agenda, Hairball Products—William Burkholder, FDA-CVM

William Burkholder had a brief explanation of issues involving cat foods making hairball control claims. All hairball control claims are subject to premarket approval by the FDA-CVM, and the review includes submission by the firm of formulations and labeling to substantiate the claim. The FDA-CVM has noticed that, across several firms, guarantees on labeling in the marketplace are being found that do not correspond to the nutrient content of the formulas even accounting for AAFCO analytical variation allowances. The FDA-CVM would like to remind the industry that the guaranteed analysis should correspond to the actual content of the formulas. Firms are not allowed to alter the formula or labeling without first notifying and receiving acceptance by the FDA-CVM.

#### **Additional Discussion, Human Grade**

Despite the acceptance by the membership of the Human Grade Guidelines, there continue to be questions regarding the acceptability of certain materials. The PFC would like to remind industry that the human grade working group has been dissolved, and no work is being done to expand or further clarify the guidelines. The workgroup spent a long time trying to resolve some of the outstanding issues (i.e., no route to acceptability for products produced in a USDA facility) but was unable to resolve those issues. However, we would encourage industry to come up with a solution and provide a detailed argument to support their solution to the PFC for consideration.

The Pet Food Committee meeting adjourned at 11:55 pm CST.

# Appendix A: Pet, Specialty Pet, Pet Food, and Specialty Pet Food Definitions

#### Recommendations

The PFC recommends and moves the revised "Pet" and "Specialty Pet" definitions as displayed below to the Model Bill and Regulations Committee for their consideration.

The following definitions appear on page 106 of the 2017 AAFCO OP in the Model Bill and Regulations.

- (q) The term "pet food" means any commercial feed prepared and distributed for consumption by pets.
- (r) The term "pet" means dog (Canis familiaris) or cat (Felis catus).
- (v) The term "specialty pet" means any animal normally maintained in a household, such as, but not limited to, rodents, ornamental birds, ornamental fish, reptiles and amphibians, ferrets, hedgehogs, marsupials, and rabbits (non-production, non-livestock).
- (w) The term "specialty pet food" means any commercial feed prepared and distributed for consumption by specialty pets.

# Appendix B: Proposed Regulations for Dietary Starch and Sugars Guarantees and Descriptive Terms

**Recommendation 1:** The PFC recommends and moves the following addition and revisions to AAFCO Model Regulation PF4(a) on p. 139 of the 2017 *Official Publication* (OP) to the Model Bill and Regulations Committee for their consideration.

#### Regulation PF4. Expression of Guarantees

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

**Recommendation 2:** The PFC recommends and moves the following additions to AAFCO Model Regulation PF10 on p. 147 of the 2017 OP to the Model Bill and Regulations Committee for their consideration.

# **Regulation PF10. Descriptive Terms**

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

# **Appendix B.1: Sugar and Dietary Starch Guarantee Examples**

Guarantees order specified by the Carbohydrate work product (for example)—Note, this version accepted by PFC with the acceptance of the Sugar and Dietary Starch Guidelines in Appendix B.

Crude protein

Crude fat

Crude fiber

Moisture

Ash

Dietary starch

Sugars

Calcium

Vitamin A

Glucosamine\*

\*not recognized as essential...

Suggested alternative (for example)

Crude protein

Crude fat

Crude fiber

Moisture

Ash

Calcium

Vitamin A

Dietary starch\*

Sugars\*

Glucosamine\*

\*not recognized as essential...

# **Appendix C: PF9 Calorie Content Clarification Discussion**

Regulation PF9: Statements of Calorie Content

- States are seeing ME or metabolizable energy not stated as part of the calorie content statement on the product label.
- States are seeing (as fed) in the calorie content statement on product labels.

PF9 states that the calorie content "...shall be measured in terms of metabolizable energy (ME) on an "as fed" basis..."

- There seems to be some confusion as to whether or not the letters or words "ME" or "Metabolizable Energy" need to be included in the calorie content statement. YES, they do.
- The two different uses of the words "as fed" and "fed" in PF9 are leading to confusion. One ("fed") refers to the method of determination and the second ("as fed") refers to the moisture basis for the values in the statement. If the method of determination is "fed," then that needs to be stated.
  - (5) The calorie content statement shall appear as one of the following:
    - A. The heading "Calorie Content" on the label or other labeling shall be followed parenthetically by the word "calculated" when the calorie content is determined in accordance with Regulation PF9(a)(3)A; or
    - B. The heading "Calorie Content" on the label or other labeling shall be followed parenthetically by the word "fed" when the calorie content is determined in accordance with Regulation PF9(a)(3)B.

#### **Pet Food Committee Report**

Webinar April 24, 2017, 3:00 pm-4:00 pm EST

#### **Committee Recommendations**

PFC moved to accept and moves to the Board of Directors for their consideration the Guidelines for Dental Related Claims in Appendix A intended to replace the Guidelines for Tartar Control Claims found on page 147 of the 2017 OP.

Board Recommendations: Report was accepted on June 14, 2017.

Board accepted recommendation from the committee.

#### **Association Actions:**

#### **Committee Participants**

Members Present: Austin Therrell (SC), Liz Beckman (WA), Christie Shee (IN), Liz Higgins (NM), JoLynn Otero (NM), Suzanne Riddle (MO), Charlotte Conway (FDA-CVM), Kristen Green (KY), William Burkholder (FDA-CVM), Jan Jarman (MN), George Ferguson (NC). Also present was Nathan Price (ID). Advisors Present: Leah Wilkinson (AFIA), Dave Dzanis (APPA and ACVN), Angele Thompson (PFI)

#### **Committee Report**

Motion to recommend to the Board of Directors for their consideration that the Guidelines for Dental Control Claims as displayed (see Appendix A) replace the current Guidelines for Tartar Control Claims in the AAFCO OP. Moved by Jan Jarman (MN). Seconded by Austin Therrell (SC). MOTION PASSED.

#### **Discussion Items**

#### Discussion of the Guidelines for Dental Related Claims

The Dental Control Guidelines as previously provided to the PFC were presented along with comments that had been received in between meetings concerning issues and sample language for Guidelines (2) (5) and (6). Language for Guidelines (2) and (5) was amended to allow claims for control of bad breath odor through use of appropriate masking flavors. The previous language appeared to limit such claims to mechanical action. This change will need to be noted in the next version of the Pet and Specialty Pet Food Labeling Guide.

The other Dental discussion item was the addition of examples to Guideline (6). There was considerable discussion as to whether or not examples should be added. Some were concerned that the inclusion of examples would limit firms to use of only those examples. It was noted that the language "such as, but not limited to" should help mitigate this confusion. It was discussed that the examples provided in the Guidelines are not meant to represent the only acceptable examples. It was suggested to add an appropriate breath control through masking flavor example.

#### Voluntary USDA-AMS Process Verified Audit System for Human Grade Claims

There is interest in gauging regulator support for (and acceptability of) a voluntary USDA-AMS process verified audit system for human grade claims. USDA-AMS can use a common AAFCO standard and audit to a central AAFCO standard. This does not have to be written into regulation. This process would not be required, but would be a good way for firms to gather human grade documentation and be listed as process verified on the USDA-AMS website. There has been initial interest among polled regulators for support of the proposed program. This program will only likely be of benefit if states accept a successful USDA-AMS audit as adequate substantiation for human grade claims.

There was strong support on the call by regulators. This item will be added to the annual meeting agenda to further gauge regulator support in a public forum. Available information regarding the proposal will be supplied via Feed BIN to regulators in advance of the meeting.

#### Possible Agenda Items for the Annual Meeting in Bellevue

- Voluntary USDA-AMS Process Verified Audit System for human grade claims
- Updating the Business of Pet Food and AAFCO Talks Pet Food website: It has been suggested that
  the PFC look again at these websites for required updates (e.g., human grade, calorie content
  statements, etc.). The topic will be raised at the annual meeting in Bellevue with the intention of
  forming a working group.

- Discussion of history and confusion surrounding PF3e: This item in the Model Bill has elicited some confusion and requests for clarity. While not urgent, the issue may be raised at the annual meeting (time permitting).
- Updating the GLG series in the feeding trial section based on "all life stages" claims dependent on dog size. It was discussed that this item should be discussed in detail and will likely require the formation of a working group.

The call was concluded 4:00 pm EST.

# **Appendix A: Guidelines for Dental Related Claims**

The Pet Food Committee recommends for consideration to the Board of Directors that the guidelines displayed below replace the Guidelines for Tartar Control Claims found on page 147 in the 2017 OP. Guidelines for Dental Related Claims

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

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

# **Proficiency Testing Program Committee Report**

2017 AAFCO Midyear Meeting January 16, 1:30–5:30 pm, Mobile, Alabama

Committee Recommendations: None

Board Recommendations: Report was accepted on May 1, 2017.

**Association Actions:** 

# **Committee Participants**

#### **Members Present:**

First	Last	E-mail	Position
Brenda	Snodgrass	pt@aafco.org	Chair, AAFCO PM
Louise	Ogden	pt@aafco.org	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
Teresa	Grant	teresa.grant@ncagr.gov	APHL Liaison
Josh	Arbaugh	jarbauch@wvda.us	Member
Mary	Koestner	mary.koestner@mda.mo.gov	Member
Aaron	Price	aaron.price@inspection.gc.ca	Member
Sharon	Webb	sharon.webb@uky.edu	Member

#### Advisors Present:

First	Last	E-mail	Position
Lars	Reimann	larsreimann@eurofinsus.com	Advisor
Ken L.	Riter	ken.riter@purina.nestle.com	Advisor

## **Committee Report**

- 1) Call to order
- 2) Review of the agenda. Approved.
- 3) Introductions—sign-up sheet sent around.
- 4) Program leadership and administrative update
  - A) Participant Guidebook—and FAQ—Described both items.
  - B) Update committee description in AAFCO Procedures Manual
    - Update description of PTP Advisory Committee to reflect the name change from Check Sample Program (CSP) to Proficiency Testing Program (PTP) as well as other editorial changes.
  - C) There will be a price increase after the FDA cooperative agreement ends. It is the intent to keep the program "affordable." Max increase expected to be 25%. Homogeneity testing costs are currently kept low by volunteers. This helps keep the costs affordable.

- D) Program Committee leadership:
  - i) Chair/Program Manager—Brenda Snodgrass
  - ii) Vice-Chair/Quality Manager—Louise Ogden
  - iii) Statistician—Andy Crawford
  - v) Technical Advisor—Nancy Thiex
- E) The new test round approval letter that is provided with each round test results was reviewed.
- F) Accreditation update—The PT Program Managers started working on getting the program accredited in early June 2016. ANAB (formerly ACLASS) was selected to be the accrediting body, and the site visit took place January 3–5, 2017. AAFCO has 6 months to address the audit findings. Initially, the scope will cover the animal feed and pet food schemes, with the mycotoxin and the mineral schemes being incorporated later. The goal is to have all completed prior to the expiration of the FDA grant.
- G) A survey was sent to all feed subscribers and will soon be sent to the pet food subscribers. It was sent to 246 subscribers—138 US. A total of 71 were completed. It was stressed that subscribers should notify AAFCO if a package has been damaged during shipment. A FAQ section and a Participants Guidebook are both available on the AAFCO website. Questions or comments regarding these docs are GREATLY appreciated (e-mail pt@AAFCO.org).
- H) A mycotoxin survey is planned to gauge interest in additional bags of material for mycotoxin testing. Upon the completion of the survey, the PT Program managers will consider the subscribers' needs and update the PT Program purchasing website (FASS Dashboard) to reflect the number of additional packets a lab can purchase, if appropriate.
- 5) Program Summary
  - A) Program Participation Report—current enrollment
    - i) AAFCO PTP 2016 Participation (PowerPoint file attached)—Andy Crawford reported that there were approximately 160 to 200+ labs submitting results in the feed scheme.
    - ii) Discussion on change of drugs reporting units, specifically hygromycin B units to mg/kg (ppm). A motion to change the hygromycin reporting units to mg/kg (ppm) failed. Issue was tabled pending the collection of more data.
    - iii) There are approximately 35 active participants in the mycotoxin scheme. Trilogy prepares the materials by mixing feed material with incurred mycotoxins with uncontaminated feed material. Discussion followed splitting up the reporting of Total Aflatoxins based on whether the result was summarization of individual aflatoxin components (e.g., by LC-MS/MS) or a total as reported based on various rapid test kit methods. A question will be included in the Mycotoxin Contaminant survey (noted in minutes item 4.h) to determine interest of all scheme participants.
    - iv) Mineral scheme now has around 30 participants.
    - v) Requests from participants discussion
      - a) Add theobromine/caffeine as an adulterant to pet food; not feasible at this time
      - b) Add MP-AES to the method code list; technology is not widespread use at this time, continue to use Miscellaneous Method reporting code.
- 6) Promotional efforts—AAFCO Check Sample Programs
  - A) Opportunities
    - i) Midwest AOAC meeting—Nancy and Louise will be presenting at the May 2017 meeting in Minneapolis, MN.
    - ii) Update the AAFCO Resources for Laboratories slide set and make available to committee members to present at meetings.
    - iii) Provide handouts for committee members to hand out at meetings.
    - iv) Gina Clapper suggested getting ad space and facilities sometimes extended to not-forprofit companies as well as setting up a cross distribution system for brochures between AAFCO and AOCS. Future Program Improvements—B. Snodgrass and L. Ogden
  - B) Suggested that PTP trend past years' data for enrollment.
- 7) Roundtable
  - A) The issue of program improvements was discussed. Currently, feed medications are sourced commercially and their availability is difficult to predict. The VFD process may further negatively affect our ability to source material. It was agreed to ask the FDA for an exemption as well as prepare a 6-month plan of the medications to be included in round.

- B) One lab having issues with separating certain drugs—some methods are not good for certain mixes of drugs. John Szpylka suggested that this is a method committee discussion, not an issue for the PTP, and should be referred.
- C) Some participants do not understand that the label guarantees provided with a round are only estimates, not exact concentrations.
- D) Asked for industry volunteers: John Szpylka, Gina Clapper, Dan Berg, and Jeff Rich volunteered.

## 8) Adjournment

# **Attendance List**

First	Last	Affiliation	E-mail	Position
Louise	Ogden	AAFCO PTP	pt@aafco.org	Vice Chair, QM
Brenda	Snodgrass	OK Dept. of Ag, AAFCO PTP	brenda.snodgrass@ag.ok.gov	Chair, PM
Nancy	Thiex	AAFCO PTP	nancy.thiex@gmail.com	Technical Manager
Andy	Crawford	AAFCO PTP	andy@crawford.org	Statistician
Bob	Kieffer	AAFCO PTP	kiefferbob@gmail.com	Prep Lab
Amy	Kieffer	AAFCO PTP	amy@ablelaborotory.com	Prep Lab
Teresa	Grant	NC Dept. of Ag	teresa.grant@ncagr.gov	Member
Mary	Koestner	MO Dept. of Ag	mary.koestner@mda.mo.gov	Member
Aaron	Price	CFIA	aaron.price@inspection.gc.ca	Member
Sharon	Webb	UK Div. of Reg. Serv.	sharon.webb@uky.edu	Member
Josh	Arbaugh	WV Dept. of Ag	jarbauch@wvda.us	Member
Patty	Lucas	FL Dept. of Ag and Cons. Serv.	patricia.lucas@freshfromflorida.com	Member
Deepika	Curole	LSU Dept. of Ag Chem.	dcurole@ldaf.state.la.us	Member
Lars	Reimann	Eurofins	larsreimann@eurofinsus.com	Advisor
Ken L.	Riter	Nestle Purina Analytical Labs	ken.riter@purina.nestle.com	Advisor
Teresa	Rygiel	FL Dept. of Ag	teresa.rygeil@freshfromflorida.com	
Raynette	Cason	LA Dept. of Ag and Forestry	rcason@ldaf.state.la.us	
Kristi	McCallum	CO Dept. of Ag	kristina.mccallum@state.co.us	
Michele	Swarbrick	MN Dept. of Ag	michele.swarbrick@state.mn.us	
Dancia	Wu	OISC	scharfd@purdue.edu	
Dorota	Inerowicz	OISC	inerowic@purdue.edu	
Heidi	Hickes	MT Dept. of Ag	hhickes@mt.gov	
John	Szpylka	Merieux NutriSciences	john.szpylka@mxus.com	New Advisor 1/17
Solomon	Kariuki	UKY Reg. Serv.	s.kariuki@uky.edu	
Lei	Tang	FDA/CVM	lei.tang@fda.hhs.gov	

First	Last	Affiliation	E-mail	Position
Mike	Stage	AR Dept. of Ag	mike.stage@aspb.ar.gov	
Quintin	Muenks	MO Dept. of Ag	quitin.muenks@mda.mo.gov	
Dan	Berg	Covance Labs	dan.berg@convance.com	New Advisor 1/17
Casey	Guccione	KS Dept. of Ag	Casey.Guccione@ks.gov	
Dominika	Kondratko	CO Dept. of Ag	dominika.kondratko@state.co.us	
Jiri	Kratochvil	Westway Feed Program	jiri.kratochvil@westwayfeed.com	
Brenda	Keavey	WV Dept. of Ag	bkeavey@wvda.us	
Ted	Gatesby	MI Dept. of Ag	gatesbyt@michigan.gov	
Linda	Benjamin	FDA/CVM	linda.benjamin@fda.hhs.gov	
Barbara	James	Potash Corp	bjames@pcsphosphate.com	
Robyn	Randolph	APHL	robyn.randolph@aphl.org	
Jason	Swancer	PN Dept. of Ag	jswancer@pa.gov	
Jenice	Butler	FDA/ORA	jenice.butler@fda.hhs.gov	
Brenda	Walker	FDA/ORA	brenda.walker@fda.hhs.gov	
Joyce	Lewis	LA Dept. of Ag an Forestry	jlewis@ldaf.state.la.us	
Gina	Clapper	Merieux NutriSciences	gina.clapper@mxns.com	New Advisor 1/17
Jeff	Rich	Romer Labs	jeff.rich@romerlabs.com	New Advisor 1/17

# **Strategic Affairs Committee Report**

2017 AAFCO Midyear Meeting
January 18, 10:15 am–12:00 pm, Mobile, Alabama

Committee Recommendations: Report acceptance.

Board Recommendations: Report was accepted on May 1, 2017.

#### **Association Actions:**

#### **Committee Participants**

**Full Committee Members:** Linda Morrison,\* Ken Bowers,\* Richard Ten Eyck,\* Andy Gray, April Hunt,\* Jamey Johnson,\* Shannon Jordre,\* Ali Kashani,\* Chad Linton,\* Mark LeBlanc\* (Board Liaison), Dragan Momcilovic,\* Jenny Murphy,\* Aaron Price, Kent Kitade,\* Nancy Thiex,\* Robert Waltz,\* Vice Chairperson

By-Laws Subcommittee: Ken Bowers, April Hunt, Richard Ten Eyck

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) Subcommittee: By-Laws—Ken
  - A) Update
    - Clarification of Article 5, Section 1. The group has reviewed and obtained legal advice.
       The draft was shared with the Committee for consideration.
       ACTION: Comments due from Committee by end of February, electronic vote by end of
      - March, to Board for May meeting, and membership in August.
- 2) Strategic Planning 2017–2020
  - A) The detailed activities, timelines, and responsible committee chairs have been entered into the Feed BIN to track progress.
  - B) Committee chairs were prompted to provide written updates prior to the meeting. Responses were received from CIOC (detailed update reflecting progress), ETC, and LSMC. ETC and LSMC indicated activities would be addressed during the midvear meeting.
  - C) The Strategic Plan 2017–2020 report was updated based on Committee proceedings and chair comments (attached).
- 3) Other Business
  - A) Procedures Manual—Retention Policy updates received pursuant to Lab ISO process requirements (e.g., records for proficiency testing). Submitted to Board and approved October 2016 (attached).
    - ACTION: Update Procedures Manual on the website/Feed BIN.
- 4) Committee financial needs from the 2017–2018 budget: None at this time.

The draft report will be circulated to the committee for comment and acceptance prior to finalization. Ali motions to accept the meeting minutes/report. Richard second. MOTION CARRIES.

Attachments

- 1. By-Laws edits
- 2. Strategic Plan 2017–2020 updates from midyear 2017
- 3. Procedures Manual Retention Policy update

# **Action Item Table**

Responsible	Item	Action	Timing/Status
By-Laws	Clarification of	Shared with the Committee for	Comments due from Committee
	Article 5,	consideration at midyear meeting	by end of February, electronic
	Section 1	2017	vote by end of March, to Board
	needed		for May meeting, and
			membership in August
Linda/commit	Strategic Plan	Add details to the tracking system	Goals, outcomes, activities,
tee chairs	priorities	in the Feed BIN. Committee chairs	timelines, and responsible
	2017–2020	asked to keep it updated.	committees input into Feed BIN.
Linda	Procedures	Retention Policy update	February 2017
	Manual		

# Attachment 1: By-Laws of the Association of American Feed Control Officials Inc.

January 18, 2017, Draft

# ARTICLE IV Officers

Section 1. Officers. The following officers shall be elected by the membership at each annual meeting by a majority vote of those present and voting, and shall serve for the year beginning January 1 of the next calendar year, and ending December 31:

President, who shall become immediate Past President of the Association on January 1 of the next calendar year following elections.

President-Elect, who shall become President of the Association on January 1 of the next calendar year following elections.

Secretary-Treasurer.

Section 1. Officers. The President, President-Elect, and Secretary-Treasurer shall be elected by the membership at each annual meeting by a majority of those present and voting, and shall serve for the year beginning January 1 of the next calendar year, and ending December 31.

Section 2. Vacancies. If any office other than that of President or President-Elect shall become vacant, a person shall be appointed by the Board of Directors for the remainder of the term. In the event that the office of the President-Elect becomes vacant, the Board of Directors shall fill the office of President-Elect for the remainder of the term. If the office of President shall become vacant, the President-Elect shall thereupon become President of the Association for the unexpired term-provided that such service shall not affect such person becoming President of the Association on January 1 of the next calendar year following elections. In the event that the office of President becomes vacant at a time when the office of President-Elect is also vacant, the Board of Directors shall fill the office of President for the remainder of the term.

# ARTICLE V Board of Directors

Section 1. Constitution **and Election** of the Board. The Board of Directors shall consist of nine positions including the President, President-Elect, Secretary-Treasurer, Immediate Past-President representing the Executive and five (5) other elected Directors. Each of the elected Directors shall be a member designated under Article II, Section 1 and elected at the annual meeting. The five (5) elected Directors shall be nominated to one of two tiers. Tier 1 shall include two (2) Senior Director positions and Tier 2 shall include three (3) Junior Director positions. Tier 1 Senior Directors may serve successive one year terms and progress into the Executive positions. Tier 2 elected Junior Directors may serve a maximum of two (2) successive one year terms and do not progress into the Executive positions unless voted into a Tier 1 Senior Director position. The President shall serve as Chairman of the Board. No two (2) members of the Board of Directors shall represent the same State, Province, Dominion, District, Territory, Republic, Commonwealth or Federal Agency, except that a Board member may be elected from the same State, Province, Dominion, District, Territory, Republic, Commonwealth or Federal Agency as the Secretary-Treasurer.

Section 1. Constitution and Election of the Board. (i) The Board of Directors shall consist of eight (8) elected individuals: the President, the President-Elect, the Secretary-Treasurer, and five (5) Directors. The Immediate Past President shall serve as a voting, ex-officio member of the Board. Officers and Directors shall be elected at the annual meeting of the voting members for one (1) year terms. In addition to the slate of candidates proposed by the Nominating Committee, any Association member may make additional nominations by submitting them in writing to the Secretary-Treasurer prior to the vote at the annual meeting. (ii) Each of the elected officers and Directors shall be a member designated under Article II, Section 1. No two (2) members of the Board of Directors shall represent the same State, Province, Dominion, District, Territory, Republic, Commonwealth or Federal Agency, except that a Board member may be elected from the same State, Province, Dominion, District, Territory, Republic, Commonwealth or Federal Agency as the Secretary-Treasurer. (iii) The President shall serve as the Chairman of the Board.

#### ARTICLE VI

Committees and Investigators

Section 1. Nominating Committee. The Board of Directors shall establish the membership of a Nominating Committee and the conditions and timeframes under which the Nominating Committee shall operate to nominate a slate of candidates for officers and directors for the ensuing year for consideration by the voting members at the annual meeting. After the nominations have been slated and announced, any Association member may make additional nominations by submitting them in writing to the Secretary-Treasurer or make a nomination from the floor prior to the vote at the annual meeting.

Section 1. Nominating Committee. (i) [The Nominating Committee shall consist of the three most immediate past Presidents. If any of the three most immediate past Presidents are unwilling or unable to serve, the remaining members of the Nominating Committee shall select one or more individuals so that the Nominating Committee consists of three individuals.] (ii) The Board of Directors shall establish the timeframes under which the Nominating Committee shall operate to nominate a slate of candidates for officers and Directors for the ensuing year for consideration by the voting members at the annual meeting. (iii) In nominating a slate of candidates for officers and Directors, the Nominating Committee should take into account the following guiding principles, to the maximum extent reasonably possible:

- The President should ordinarily serve for a single one (1) year term.
- The candidate for President-Elect should be selected with the assumption that he or she will be nominated for and elected President the following year.
- An individual should have served on the Board of Directors for a minimum of two (2) full calendar years (although not necessarily consecutively) before becoming President-Elect.
- In general, the Directors advance to the officer positions of President-Elect and the following year, to President, in order of tenure.
- An individual's general willingness and ability to serve as a future officer is a relevant, but not a necessary, factor for consideration in selecting nominees for Directors.

# Attachment 2: Strategic Planning 2017–2020 Report

Feed BIN reference numbers added and Midyear Committee Updates: January 18, 2017

# Strategic Plan Goals 2017–2020

Updat	Updated Goals 2017–2020				
Streng	Strengthen organizational infrastructure				
1	Manage and pursue revenue generating opportunities to maintain a sound financial base				
2	Pursue hiring executive support				
3	Evaluate the effectiveness of the organization of AAFCO for continuous improvement				
4	Provide leadership skills enhancement to develop and support AAFCO leaders				
5	Optimize resource sharing opportunities				
6	Enhance internal communication efficiencies and documentation within the association				
Promo	ote and enhance membership participation (internal)				
7**	Identify opportunities to increase member agency participation				
8*	Develop and provide professional development and technical training opportunities in support of feed programs				
9*	Enhance collaboration, communication, and cooperation among regulatory agencies				
10	Communicate and document AAFCO benefits and accomplishments				
Emph	asize feed and food safety				
11	Continue developing member feed safety programs in alignment with FSMA and IFSS				
12*	Promote and support laboratory technology, methods, quality systems, and collaboration				
Vitaliz	e partnerships with external stakeholders				
13	Identify key stakeholders and working partners and common goals				
14	Develop and maintain professional relationships with stakeholders and affiliated organizations				
Streng	gthen international presence				
15	Participate in relevant international meetings as resources permit				
16	Invite international attendees to association activities				
17	Provide a forum for international discussions on feed safety				

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

Top 3 Priority Goals (FSMA TF activities integrated) Updated text: italics/bold

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

Git	Group 1: Mark Lebianc, Nancy Thiex, Ken Bowers, Meagan Davis, Dave Dressier				
Outcomo	Activity	Resources	Timeline	Posnonsibility	
Outcome Strategy: Empl	Activity nasize feed and food safety	Needed	Timeline	Responsibility	
	te and support laboratory to		thode quality eyetome a	nd	
collaboration	te and support laboratory to	eciniology, ine	tillous, quality systems, a	inu	
1.1 ** Fund	Review list, remove	Funds	6 months (August	LMSC	
AOAC method	those that are not	People	2017) to update the list	LIVIOC	
development	relevant, and prioritize	i copie	and identify resources		
and validation	the remainders. Identify		to address backlog,		
and validation	resources to clear out		3–5 years to address		
	analytical method needs		backlog		
	backlog. Use existing				
	strategy to identify method				
	needs and prioritize them				
	to continuously identify				
	new needs (includes				
	sample preparation).				
Combined	Identify resources to	<del>Funds</del>	6 months to identify	1. ISC	
with 1.3	perform additional (field)	Equipment	resources	2. LMSC	
(below)	sample collection studies	<del>People</del>	1 year to develop		
			adequate protocols		
			3 years to perform		
			additional sample		
1.2 *** FSMA	Determine the	Subject	collection studies  Alliance decided not	FFIMC lead,	
TF Item 3:	contaminants, hazards,	matter	to develop specific	EIC, ISC, IDC,	
priority	matrix, and action levels	experts	hazard guidance	and LMSC	
setting and	to provide guidance to	Funds	information. The FDA	and Livioc	
method	LMSC to inform method	Equipment	has assumed the		
development	development. Integrate	q	activity; work product		
for	collaboratively into		expected late in year		
contaminants	current LMSC priorities		2017. Complete		
/hazards	-		method needs		
Hold:			statement for LMSC.		
pending			Up to 3 years for		
hazard			subsequent method		
specific			development and		
guidance			validation (dependent		
information			on whether there is		
from the			existing method).		
FDA.					

Outcome 1.3 ** Validation of sampling methods	Activity  Establish sampling methods needs statement (complete). Identify resources and develop adequate protocols to perform additional (field) sample collection studies. Perform field sampling method validation including sampling equipment and sample type.	Resources Needed Funds Equipment People Time	Timeline 6 months to establish sampling method needs statement, 6 months to identify resources, 1 year to develop adequate protocols, 5 years to perform sampling method validation	Responsibility ISC with LMSC support
1.4 ** Collaboration between feed programs and laboratories that perform feed sample analysis and laboratory participation in AAFCO	Encourage participation and attendance by state labs by programs and encourage communication between labs/programs. Reach out to states to encourage laboratory participation (letter/e-mail) in AAFCO.	Time People	March 2017 initial letter to state Directors/Commissioner s. August 2017 LMSC discussion to identify ways to increase participation by state labs not collaborating (especially AFRPS). January 2017 Follow up to identify why state labs are not participating. The FDA (Jenny M.) offered to help. January 2018 develop initiatives to increase collaboration.	AAFCO Board (President) LMSC EIC

<sup>\*\*</sup>Top 3 outcomes identified at May 2 planning session
\*\*\*FSMA TF outcomes integrated into 2017–2020 Strategic Plan

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

	Zaosso, Baro	Bassaras, Erin	BUDD	<del>                                     </del>	
Outcomo	Activity	Resources Needed	Timeline	Posponsibility	
Outcome Strategy: Promote and	Activity			Responsibility	
Strategy: Promote and enhance membership participation (internal) Goal 2: Enhance collaboration, communication, and cooperation among regulatory agencies					
2.1 ** Share compliance letters/enforcement actions. Coordination of enforcement action.  Hold: pending identification of additional EIC members to help.	Categorize Listserv topics to Feed BIN	Administrative support Feed BIN	January 2017	EIC to designate lead with FASS support—Jennifer	
members to neigh	Share compliance letters and enforcement actions	Guidance from subject matter experts	January 2017	EIC to designate lead with FASS support	
	Share Division of Animal Feed letters		January 2017	EIC to designate lead, and coordinate with FDA as necessary; FASS to support	
	Enforcement Issues Committee can pick up topics— coordinate and enhance committee action		January 2017	EIC to designate lead with FASS support— Members	
	Consider development of core report (similar to that of the FDA) (frequency to be determined)	Listserv EIC IDC Any committee	January 2017	EIC to designate lead with FASS support	
2.2 *** FSMA TF part of Item 3: Enforcement strategy for contaminants/hazards Hold: pending hazard specific guidance information from the FDA.	Determine the contaminants, hazards, matrix, action levels, and enforcement strategy to provide guidance to LMSC to inform method development and priority setting.		Alliance decided not to develop specific hazard guidance information. The FDA has assumed the activity; work product expected late in year 2017.	FFIMC lead, EIC, ISC, IDC, and LMSC	
2.3 ** Enhanced use of Feed BIN	Identify activities to enhance use	Financial support	August 2017 Complete January 2017 (activities detailed in Feed BIN)	CIOC	

		Resources		
Outcome	Activity	Needed	Timeline	Responsibility
2.4 ** Coordinate with NASDA to develop a framework for state feed programs to deliver FSMA implementation	Provide data and information for NASDA grant application (AAFCO is subcontractor) and subject matter experts to support framework development.	AAFCO subject matter experts	5 years Complete: Grant application successful and SME identified. Framework development will be tracked via grant reporting obligations.	NASDA-AAFCO- FDA FSMA Steering Committee (AAFCO reps: Linda, Ali, Bob W., Richard)
2.5 *** FSMA TF Item 1—align Model Bill with needed authorities to Implement FSMA	Make recommendations to align the Model Bill with needed authorities to implement FSMA		Language finalized August 2017. Complete: January 2017 membership vote	MBRC
2.6 *** FSMA TF Item 2—transition AAFCO GMPs to FSMA GMPs and convert AAFCO Model Feed Safety Program Plan to AFRPS	a. Develop a plan for states that have adopted AAFCO's model GMPs to transition to FSMA GMPs. b. Remove Model Feed Safety Plan from OP (archive for historical reference) and use AFRPS instead		Complete: August 2016	a. FFIMC with MBRC and PFC b. FFIMC with OP section editor and Feed Safety Coordinator
2.7 FSMA TF Item 6— develop communication plan for AAFCO specific FSMA implementation activities	a. Develop an AAFCO Communication Plan to better inform b. Develop a model communication plan for states to use for outreach to regulated parties		August 2017: framework development (activities detailed in Feed BIN); content development will be ongoing thereafter	CIOC Working to produce biannual newsletter. Reached out to FDA to help with Communications Plan

<sup>\*\*</sup>Top 3 outcomes identified at May 2 planning session
\*\*\*FSMA TF outcomes integrated into 2017–2020 Strategic Plan

Group 3: Dan Danielson, Ali Kashani, Tim Weigner

Outcome	Activity	Resources Needed	Timeline	Responsibility
	and enhance membersh		nal)	
	nd provide professional c			pportunities in
support of feed pro	ograms	-		
3.1 ** AFRPS— draft curriculum for examples. Available training needs to meet standards	Extract all resource (training) needed to meet Standard 2  Crosswalk to IFPTI; AITS/BITS; ORAU; CVM, FEMA  Identify gaps and approach land grant	Subject matter experts. Potential travel for non-Co-Ag contract states	August 2017 Work group formed.	ETC together with ISC
3.2 ** Directory/ listing of trainings available	universities Once training needs and model training plan are done (above), catalogue courses and categorize as basic and advanced	FASS support	January 2018 Work group formed	ETC
3.3 Model training framework	Develop model document for joint inspection (OJT—on the job training) for feed. Develop model training plan	Subject matter experts. Potential travel for non-Co-Ag contract states	January 2018 Work group formed	ETC and ISC
3.4 *** FSMA TF Item 4—develop training material not covered through Alliance work product	Verify if training material for feed ingredient manufacturing from the (FSPCA) Alliance meets the needs of inspectors and revise as needed and include in directory of training material	Subject matter experts. Potential travel for non-Co-Ag contract states	May 2017	FFIMC and ISC supported by ETC
3.5 *** FSMA TF Item 5—review and revise the Feed Inspector's Manual to support FSMA implementation	Review and revise the Feed Inspector's Manual to make sure it supports FSMA implementation	Subject matter experts. Potential travel for non-Co-Ag contract states. FASS support for publication, including printing/Feed BIN costs.	August 2017	ISC supported by LMSC and ETC

<sup>\*\*</sup>Top 3 outcomes identified at May 2 planning session
\*\*\*FSMA TF outcomes integrated into 2017–2020 Strategic Plan

Participants:

Name	Priority Voting Pre-meeting	Attended May 2	AAFCO Role
Mark LeBlanc	✓	✓	Board
Ken Bowers	✓	✓	Board/Chair Subc.
Richard Ten Eyck		✓	Board/Chair
Ali Kashani	✓	✓	Board/Chair
Dan Danielson	✓	✓	Board/Co-Chair
Stan Cook	✓	✓	Board/Chair
Erin Bubb	✓	✓	Board
Robert Geiger			Board
Kristen Green	✓	✓	Board
Eric Nelson			FDA advisor
Dave Edwards		✓	FDA advisor
Abe Brown		✓	FDA advisor
Tim Weigner		✓	FDA advisor
Tim Lyons			Chair
Meagan Davis	✓	<b>√</b>	Chair
Dave Dressler		✓	Co-Chair
Chad Linton			Co-Chair
Nancy Thiex	✓	✓	Co-Chair
Aaron Price	✓		Co-Chair
Doug Lueders	✓	✓	Chair
Linda Morrison	✓	✓	Chair
Bob Waltz	✓		Feed Safety Coord.
Kelsey Luebbe		✓	Co-Chair