# **Association Business Meeting Agenda**

2019 AAFCO Midyear Meeting Hyatt Regency Savannah, GA Monday, January 21, 2019 9:25–10:00 am Regency Ballroom

To view meeting via WebEx register here: https://zoom.us/j/987527717 and/or to listen to meeting Conference Call Line: US TOLL 1- 646-876-9923, access code: 987 527 717#

## Agenda

- Convene Business Session of the Association. Bob Geiger, President
   Presentation of Awards
- 2) Acceptance of committee reports from: Current Issues and Outreach, Education and Training, Feed and Feed Ingredient Manufacturing, Feed Labeling, Ingredient Definitions Committee 7/31, Ingredient Definitions eMeetings: 4/19/18, 10/5/18, 10/19/18; Inspection and Sampling, Lab Methods & Services, Model Bills and Regulations, Pet Food, Proficiency Testing, Strategic Affairs. –Kristen Green, President-Elect (Reports are published on the AAFCO website in the Midyear meeting 2019 page, Bottom Right side and in hardcopy distributed to meeting attendees)
- 3) Acceptance of Committee Recommendations: –Kristen Green, President-Elect Ingredient Definitions 7/31/18, 1-3; eMeeting April 19, 1-6; eMeeting October 5, 1-4; eMeeting October 19, 1-2:

Report starts on page 19 of the Committee Report Book

- Move the Enzyme Marketing Coordination document from chapter 5 to chapter 6 and place after Table 30.1 Board recommends acceptance
- Add 2 Carbohydrases to Table 30.1 Board recommends acceptance

Beta-Glucanase	Talaromyces versatilis overexpressing glucanase
Xylanase	Talaromyces versatilis overexpressing xylanase

- 3) Publish the following tentative definitions as Official and remove the existing Official definition, if any.
  - a) T6.12 Taurine:
    - is a product that contains a minimum of 97% 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in cat foods, dog foods, and fish foods. Taurine may also be added to the feed of growing chickens; when added to complete chicken feed, the total taurine content shall not exceed 0.054% of the feed (21 CFR 573.980). (Proposed 2017 rev. 1) **Board recommends acceptance**
  - b) T60.117(B) Dried Black Soldier Fly Larvae:
    - is the dried larvae of the Black Soldier Fly, Hermetia illucens, with or without mechanical extraction of part of the oil, that has been raised on a feedstock composed exclusively of feed grade materials. The ingredient must be labeled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is dried by artificial means to no more than 10% moisture. It is for use in salmonid and poultry feed as a source of protein and fat consistent with good feeding practices. (Proposed 2018 rev. 1) **Board recommends acceptance**
  - c) T71.35 Brassica carinata Meal, Solvent Extracted,\*\* \*\*The words "Solvent Extracted" are not required when listing as an ingredient in a manufactured feed: is the meal obtained after the removal of most of the oil by solvent extraction of Brassica carinata seeds. The meal shall contain less than 2.0% erucic acid and less than 30 micromoles of total glucosinolates per gram. It is a source of protein for beef cattle in an amount not to exceed 10% of the total diet. The maximum sulfur content must be guaranteed. (Proposed 2017 rev. 1) Board recommends acceptance

#### d) T73.051 Iron Tartrates:

is the reaction product of sodium tartrates [D-, L-, and meso-tartrates] and iron(III) chloride for use as an anticaking agent in salt. The molar ratio of iron(III) to meso-tartrate must be 1:1. It must contain no less than 8% iron(III) on a dry weight basis. It must contain no more than 1.5% oxalic acid, 3 ppm arsenic, 2 ppm lead, and 1 ppm mercury on a dry weight basis. The maximum iron tartrates inclusion rate (calculated as iron) is not more than 12 ppm. (Proposed 2018 rev. 1) **Board recommends acceptance** 

#### e) T73.400 Iron Nickel Tracer:

are the particles resulting from water atomization of high purity iron and nickel. The nickel content of the particles is between 35% and 51% with the remainder being iron. The particle size of the iron nickel alloy must range between 150 and 300 microns. This ingredient may be used in animal foods as a tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the ingredient must not exceed 10 ppm in the finished food. The label shall include a maximum nickel guarantee and a caution statement indicating the maximum permitted inclusion level. (Proposed 2017 rev.

## 1) Board recommends acceptance

#### f) T87.35 Glucose Syrup:

is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch. It shall meet the following specifications: total solids content not less than 70.0% mass/mass (m/m) and reducing sugar content (dextrose equivalent), expressed as D-glucose, not less than 20.0% m/m calculated on a dry basis. The sulfated ash content is not more than 1.0% m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 40 mg/kg. If the product bears a name descriptive of its kind or origin, e.g., "corn syrup," "grain sorghum syrup," it must correspond thereto. (21 CFR 168.120) (Proposed 2017) **Board recommends acceptance** 

## h) T96.14 Scheffersomyces stipitis Dried Yeast:

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

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

## a) T57.167 Manganese Hydroxychloride:

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

# b) T73.311 (A) Hydrogenated Glycerides:

are obtained by hydrogenation of animal fats or vegetable oils and are used as a coating agent for ingredients or a binder and lubricant in pelleting of feed (pelleting aid) of all animal species. The maximum use rate of hydrogenated glycerides is 4 lb per ton of complete feed. Specifications of animal fats or vegetable oils used to produce the hydrogenated glycerides must meet the requirements stated in AAFCO definition 33.1 (for Animal Fat) and AAFCO definition 33.2 (for Vegetable Fat, or oil), respectively. The specification for tallow must specify insoluble impurities not more than 0.15% to be consistent with BSE feed regulation 21 CFR 589.2000 and 589.2001, and a guaranteed titer above 40° C. The source of the hydrogenated glycerides must be indicated on the label. The hydrogenated glycerides must contain, and be guaranteed for, not less than 90% total ester content, not more than 0.8 % unsaponifiable matter, not more than

0.001% heavy metals, and not more than 5 of iodine value. The maximum moisture, maximum insoluble matter, maximum free fatty acids, saponification value and melting range must also be guaranteed on the label. If an antioxidant is used, the common name or names must be indicated on the label, followed by the words "used as a preservative." **Board recommends acceptance** 

# c) T73.401 Colored Graphite Tracer:

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

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

#### a) 73.046 Silicon dioxide:

The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:

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

Feed component	Limitations (percent)		
BHT (butylated hydroxytoluene)	2		
Methionine hydroxy analog and its calcium salts	1		
Piperazine, piperazine salts	0.8		
Sodium propionate	1		
Urea	1		
Vitamins <sup>a</sup>	3		

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

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

Feed component	<u>Limitations</u> (percent)
Flavors	50

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

21 CFR 573.940 (Proposed 1964, Adopted 1965, Amended 2008, Adopted 2010,)

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

## b) New feed term:

**Common or usual name.** The common or usual name of a feed ingredient shall accurately identify or describe, in as simple and direct terms as possible, the basic nature

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

## c) 33.27 Marine Microalgae:

The food additive, marine microalgae, may be safely used as a source of docosahexaenoic acid (DHA) and other omega-3 fatty acids in accordance with the following prescribed conditions:

- (a) The additive is dried whole cells of nonviable, nontoxigenic, nonpathogenic Schizochytrium sp. algae grown as a pure culture.
- (b) The additive is used in complete, dry adult maintenance food for dogs in accordance with good manufacturing and feeding practices not to exceed 16.5 pounds per ton (7.5 kilograms (kg) per 1000 kg) of complete, dry, adult maintenance dog food.
- (c) The additive consists of not less than 17.0 percent (4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoic acid (docosahexaenoic acid or DHA).
- (d) The additive meets the following specifications:
  - (1) Not less than 40 percent crude fat:
  - (2) Not more than 12 percent ash;
  - (3) Not more than 8 percent unsaponifiable matter;
  - (4) Not more than 5 percent insoluble impurities;
  - (5) Not more than 5 percent free fatty acids; and
  - (6) Not more than 6 percent water.
- (e) To ensure the safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:
  - (1) The label and labeling of the additive, any feed premix, and complete feed, shall contain the name of the additive, marine microalgae.
  - (2) The label and labeling of the additive and any feed premix shall also contain:
    - (i) A statement to indicate that the maximum use level of the additive shall not exceed 16.5 pounds per ton (7.5 kg per 1000 kg) of complete, dry, adult maintenance dog food.
    - (ii) Adequate directions for use.

## 21 CFR 573.615 Board recommends acceptance

- d) Update Table 36.14 with both the new and the old microorganism names, and the compliance date of January 2022. OK to use either name in the interim.
  - i) Lactobacillus bulgaricus, renamed to Lactobacillus delbrueckii\*\*
  - ii) Lactobacillus cellobiosus, renamed to Lactobacillus fermentum\*\*
  - iii) Lactobacillus lactis, renamed to Lactobacillus delbrueckii\*\*
  - iv) Propionibacterium shermanii, renamed to Propionibacterium freudenreichii\*\*
    \*\*Date of compliance January 2022

## **Board recommends acceptance**

#### e) 90.9 25-hydroxyvitamin D3:

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

(a) The additive is used or intended for use as a source of vitamin D3 activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

- (1) In feed or drinking water of chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.
- (2) In feed or drinking water of turkeys not to exceed:
  - (i) 92 ppb in feed; or
  - (ii) in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.
- (b) The additive consists of not less than 94 percent 25-hydroxyvitamin D3 (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).
- (c) The additive meets the following specifications:
  - (1) Not more than 1 percent of any individual sterol.
  - (2) Not more than 5 percent water.
  - (3) Not more than 20 parts per million (ppm) lead.
  - (4) Not more than 20 ppm aluminum.
  - (5) Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.
  - (6) Not more than 1 ppb 1,25-dihydroxycholecalciferol.
- (d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:
  - (1) The name of the additive.
  - (2) A statement to indicate the maximum use level of 25-hydroxyvitamin D3 must not exceed 69 ppb in feed or 34.5 ppb in drinking water for chickens.
  - (3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D3 must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.
  - (4) Adequate use directions to ensure that 25-hydroxyvitamin D3 (and all premixes) is uniformly blended throughout the feed or drinking water.
  - (5) An expiration date on all premix labeling.
  - (6) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D3 cannot be used simultaneously in both feed and water.

#### 21 CFR 573.550, 584.725 (Adopted 2019 ver 1) Board recommends acceptance

- 6) Add AAFCO Definitions 84.62, 84.16, 84.63, 84.64, & 84.71 to the collective term Plant Protein in the Official Publication **Board recommends acceptance**
- 7) Add to GRAS Notification table in Section 101.
  - a) Add L-Glutamine the subject of AGRN 19 to GRAS Notification table in section 101
     Board recommends acceptance

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)
19 (PDF - 123 pages)	Freedom Health L.L.C.	L- Glutamine	L-Glutamine	Utility information not evaluated for GRAS, see FDA's letter for more information.	Post- weaning horses.	3/22/2016	FDA has no questions. (PDF - 3 pages)

b) Add phytase the subject of AGRN 21 to GRAS Notification table in section 101 **Board recommends acceptance** 

AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Filing	FDA's Letter (select to view letter)
2 <u>1</u> (PDF – 598 pages)	Agrivida, Inc.	Ground grain obtained from a corn (Zea mays) variety that expresses an altered appA 6- phytase gene obtained from Escherichia coli strain K12	Phytase	To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in poultry feeds when used at a rate of 75 g to 1.7 kg per ton of complete feed and providing 250-6000 phytase units (FTU)/kg complete feed.	Poultry	7/28/2016	FDA has no questions. (PDF - 4 pages)

- 8) Delete Definition T73.311 Hydrogenated Glycerides if T73.311 (A) is accepted by Association membership Board recommends acceptance
- 9) Edit tables with results to be reflected as official a) Table 101.1 AGRN 24 **L-Methionine 90%**

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)
24 (PDF - 194 pages)	CJ CheilJedang Corporation	L-methionine 90% produced by a bioengineered Escherichia coli K- 12	L- methionine 90%	To be used as a nutrient in animal food.	All animals	8/17/2017	FDA has no questions. (PDF - 4 pages)

# **Board recommends acceptance**

10) Delete Definition 33.19 Hydrogenated Glycerides as an energy source. See page 383 of the 2018 online OP revision 1 **Board recommends acceptance** 

#### Model Bills 1:

## Report starts on page 45 of the Committee Report Book

1) The Model Bills and Regulations Committee recommends the following language be added to the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as PF2(a)(8) and current PF2(a)(8) be changed to PF2(a)(9),

PF2(a)(8): A statement of calorie content if required under PF9; and .... **Board recommends acceptance.** 

#### **Board Recommendations:**

- Board recommends a new Association Vision Statement:

  To be the trusted leader, building collaboration and recommends.
  - To be the trusted leader, building collaboration and regulatory uniformity, to safeguard animal feed.
- 2) Board recommends a new Mission Statement:

AAFCO provides science-based resources as the cornerstone to continuously advance animal feed regulatory programs.

This concludes committee and board recommendations needing membership approval.

# 5) Credential Report - FASS

Number of Voting Members Represented Number of States in attendance Number of Countries Number of FDA Representatives Number of Life Members Total Meeting Attendance