

# Association Business Meeting Agenda

2017 AAFCO Annual Meeting  
Hyatt Regency  
Bellevue, Washington  
Thursday, August 10, 2017  
9:05 am – 9:30 am  
Evergreen D-I Ballroom

To view meeting via WebEx register here: <http://fass.webex.com>  
And/Or to listen to meeting Conference Call Line: US TOLL 1-650-479-3207  
Access code: 663 128 336#

- 1.) **Convene Business Session of the Association.** – Ken Bowers, President
- 2.) **Acceptance of committee reports from:** Current Issues and Outreach, Education and Training, Feed and Feed Ingredient Manufacturing, Feed Labeling, Ingredient Definitions, Ingredient Definitions Committee eMeeting Report March 10, Inspection and Sampling, Laboratory Methods and Services, Model Bills and Regulations, Pet Food, Pet Food eMeeting April 24, Proficiency Testing Program and Strategic Affairs. –Stan Cook, President-Elect *(Reports are published on the AAFCO website in the Annual meeting 2017 page, Bottom Right side and in hardcopy distributed to meeting attendees)*
- 3.) **Acceptance of Committee Recommendations:** –Stan Cook, President-Elect

## **Ingredient Definitions 1-7 & eMeeting March 10, 1-12: Report starts on page 21 of the Committee Report Book**

- 1.) Publish the new Section 101 header including the introductory paragraphs and the table header row of the new GRAS notice table in the OP.

### **101. GRAS NOTIFIED SUBSTANCES INTENDED FOR ANIMAL FOOD**

#### **Section Editor: Nathan Price, ID**

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/GenerallyRecognizedasSafeGRASNotifications/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.**

AGRN	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's 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*. **Board recommends acceptance**

2.) Publish a new microorganism to the list in Definition T36.14 Direct-Fed

Microorganisms: *Bacillus amyloliquefaciens*. **Board recommends acceptance**

3.) Publish the following definitions as Official in the AAFCO Official Publication:

- a. 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 sun-cured alfalfa hay prior to being ground and dried by thermal means under controlled conditions. (Proposed 2016 rev. 1)

**Board recommends acceptance**

- b. 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) **Board recommends acceptance**

c. 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) **Board recommends acceptance**

- d. 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% 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.) **Board recommends acceptance**

- e. 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)

Accepted pulse crops:

Lentil (*Lens culinaris*)

IFN 05-17-726 Pea (*Pisum sativum* L.) **Board recommends acceptance**

- f. T33.21 Yellow Grease, Feed Grade, is the rendered product from the tissues of mammals and/or poultry blended with used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2.5% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.” If the product contains tallow (from cattle) containing greater than 0.15% insoluble impurities, then it must be labeled with the BSE caution statement “do not feed to cattle or other ruminants.” (Proposed 2017) **Board recommends acceptance**
- g. 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% total fatty acids, not more than 1% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common



<b>record)</b>							
<a href="#">6</a> (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	<a href="#">FDA has no questions.</a> (PDF, 3 pages)

c. Polysorbate 60 AGRN 7 **Board recommends acceptance**

<b>AGRN (select for detailed record)</b>	<b>Notifier</b>	<b>Substance</b>	<b>Common and Usual Name</b>	<b>Intended Use</b>	<b>Intended Species</b>	<b>Date of Filing</b>	<b>FDA's Letter (select to view letter)</b>
<a href="#">7</a> (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	<a href="#">FDA has no questions.</a> (PDF, 3 pages)

d. Phytase AGRN 14 **Board recommends acceptance**

<b>AGRN (select for detailed record)</b>	<b>Notifier</b>	<b>Substance</b>	<b>Common and Usual Name</b>	<b>Intended Use</b>	<b>Intended Species</b>	<b>Date of Filing</b>	<b>FDA's Letter (select to view letter)</b>
<a href="#">14</a> (PDF, 576 pages)	DSM Nutritional Products	Phytase enzyme produced by an <i>Aspergillus oryzae</i> strain expressing a synthetic gene coding for a 6-phytase from <i>Citrobacter braakii</i>	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	<a href="#">FDA has no questions.</a> (PDF, 3 pages)

--	--	--	--	--	--	--	--

e. Phytase AGRN 15 **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)
<a href="#">15</a> (PDF, 505 pages)	DSM Nutritional Products	Phytase enzyme produced by an <i>Aspergillus oryzae</i> strain expressing a synthetic gene coding for a 6-phytase from <i>Citrobacter braakii</i>	Phytase	To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in swine diets when fed at the rate of 500–4000 FYT/kg feed	Swine	August 8, 2013	<a href="#">FDA has no questions.</a> (PDF, 3 pages)

f. L-Methionine 85% AGRN 16

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)
<a href="#">16</a> (PDF, 87 pages)	Metabolic Explorer	L-methionine 85% produced by a bioengineered <i>Escherichia coli</i> K-12	L-methionine 85%	Nutrient at levels up to 0.3% in animal feed	All animals	January 3, 2014	<a href="#">FDA has no questions.</a> (PDF, 4 pages)

g. Canthaxanthin AGRN 17

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)
<a href="#">17</a> (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	<a href="#">FDA has no questions.</a> (PDF, 4 pages)



## **Model Bills 1-2:**

**Report starts on page 48 of the Committee Report Book**

- 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

**Board recommends acceptance**

- 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 recommends acceptance**

## **Pet Food Committee 1:**

**Report starts on page 63 of the Committee Report Book**

- 1.) The Pet Food Committee recommends acceptance of the Guidelines for Dental Related Claims intended to replace the Guidelines for Tartar Control Claims found on page 147 of the 2017 Official Publication. **Board recommends acceptance**

### **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.
- 6) 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.

**This concludes committee 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