



Association of American Feed Control Officials

**2016 AAFCO Annual Meeting
Agenda and Committee Reports**



**July 31 – August 3, 2016
Marriott City Center
Pittsburgh, Pennsylvania**





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Association Business Meeting Minutes

2016 AAFCO Midyear Meeting
Wild Dunes Resort
Isle of Palms, South Carolina
Monday, January 18, 2015
8:44–9:24 am

1) **Mark LeBlanc, President called to order the Business Session of the Association at 8:44 am**

2) Ken Bowers states the AAFCO Board of Directors approved the following Committee Reports: Collaborative Check Sample, Education and Training, Feed and Feed Ingredient Manufacturing, Feed Labeling, Ingredient Definitions, Inspection and Sampling, Laboratory Methods and Services, Model Bills and Regulations, Pet Food and Strategic Affairs and recommends the same to the membership. I so move. **Judy Thompson. MOTION CARRIES**

3) **Acceptance of Committee Recommendations:** Ken Bowers, President-Elect

Ingredient Definitions 1-4:

Report starts on page 18 of the Committee Report Book

1) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership

- a. 33.10 _____ Distillers Oil, Feed Grade; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership. I so move. **Bob Geiger Seconds. MOTION CARRIES**

33.10 _____ Distillers Oil, Feed Grade is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture and mechanical or solvent extraction of oil by methods employed in the ethanol production industry. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 85% total fatty acids, not more than 2.5% unsaponifiable matter, and not more than 1% insoluble impurities. Maximum free fatty acids and moisture must be guaranteed. If an antioxidant(s) is used, the common or usual name must be indicated, followed by the words "used as a preservative". If the product bears a name descriptive of its kind or origin, i.e. "corn, sorghum, barley, rye", it must correspond thereto with the predominating grain declared as the first word in the name. (Proposed 2015 402 (Proposed 2015))

- b. 54.33 Bovine Colostrum; Ken Bowers states the IDC recommends to the membership to move definition as Official. The AAFCO Board of Directors recommends to leave the definition in the Official Publication as tentative and recommends the same to the membership. I so move. **Chad Linton Seconds. MOTION CARRIES**

54.33 Bovine Colostrum is lacteal secretions obtained within 48 hours post 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)

- c. 60.111 Biodiesel-derived Glycerin; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership. I so move. **Tim Darden Seconds. MOTION CARRIES**

60.111 Biodiesel-derived glycerin is a liquid co-product of biodiesel production by a base catalyzed transesterification process. It must be derived from processes utilizing sources of fatty acids compliant with the term “feed grade” and if animal fat of ruminant origin is utilized, sources must not contain more than 0.15% insoluble impurities. It is intended as a source of energy in livestock diets. It must contain not less than 80% glycerin, not more than 15% water, not more than 0.5% methanol, and not more than 5 ppm heavy metals. It may contain up to 8% salt. It must be labeled with guarantees for minimum percentage glycerin, maximum percentage moisture, maximum percentage sulfur, maximum percentage ash, and maximum percentage methanol as well as the statement “For further mixing into livestock feed.” It is for use in an amount not to exceed 15% of the complete feed for ruminants and 10% of the complete feed for all other livestock species, including poultry. (Proposed 2015)

- d. 60.113, 114, 115, 116 Pulse Definitions including Lentil language; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership. I so move. **Judy Thompson Seconds. MOTION CARRIES**

60.113 Pulse fiber consists primarily of the outer coverings and/or hull of pulse crops derived from pulse dry milling. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The product must contain not less than 23% crude fiber on a dry matter basis. 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. (e.g., pea fiber) (Proposed 2015)

Accepted pulse crops:

Lentil (*Lens culinaris*)

IFN 05-17-726 - Pea (*Pisum sativum L.*) 436 **Judy Thompson Seconds.**

MOTION CARRIES

T60.114 Pulse flour is the fraction remaining after removal of fiber from pulse seeds. It is obtained from mechanically dehulled and dry milled pulse seeds. This flour fraction must be free of fiber and/or seed hull/pod, except in such amounts as might occur unavoidably in good manufacturing practices. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The ingredient must contain not less than 20% crude protein and not more than 3% crude fiber on a dry matter basis. 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 (e.g., pea flour). (Proposed 2015)

Accepted pulse crops:

Lentil (*Lens culinaris*)

IFN 05-17-726 – Pea (*Pisum sativum* L.) **Judy Thompson Seconds. MOTION CARRIES**

T60.115 Pulse protein is the mechanically separated protein fraction free of the fiber and/or seed hull/pod, except in such amounts as might occur unavoidably in good manufacturing practices. It is obtained from dehulled, dry milled and air-classified pulse seeds. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The product must contain not less than 53 % crude protein on a dry matter basis. 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. (e.g., pea protein) (Proposed 2015)

Accepted pulse crops:

Lentil (*Lens culinaris*)

IFN 05-17-726 – Pea (*Pisum sativum* L.) **Scott Zhier Seconds. MOTION CARRIES**

T60.116 Pulse starch is the fraction remaining after removal of protein and fiber from pulse seeds. It is obtained from mechanically dehulled, dry milled and air-classified pulse seeds. This starch fraction must be free of fiber and/or seed hull/pod, except in such amounts as might occur unavoidably in good manufacturing practices. 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% starch on a dry matter basis. 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. (e.g., pea starch) (Proposed 2015)

Accepted pulse crops:

Lentil (*Lens culinaris*)

IFN 05-17-726 – Pea (*Pisum sativum* L.) **Judy Thompson Seconds. MOTION CARRIES**

- e. 73.400 Benzoic acid; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership. I so move.

73.400 Benzoic acid. - The food additive, benzoic acid, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

- (a) 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 0.5 percent of the complete feed.
- (b) The additive consists of not less than 99.5 percent benzoic acid (CAS 65-85-0) by weight with the sum of 2-methylbiphenyl, 3-methylbiphenyl, 4-methylbiphenyl, benzyl benzoate, and isomers of dimethylbiphenyl not to exceed 0.01 percent by weight.
- (c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b) of this section, the label and labeling shall contain:
 - (1) The name of the additive.

- (2) Adequate directions for use including a statement that benzoic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing benzoic acid.
 - (3) Appropriate warnings and safety precautions concerning benzoic acid.
 - (4) A warning statement identifying benzoic acid as a possible irritant.
 - (5) Information about emergency aid in case of accidental exposure.
 - (6) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS). Show citation box.
- ii. (Proposed 2015) 21 CFR 573.210 **Judy Thompson Seconds. MOTION CARRIES**

- f. 87.36 Phaffia Yeast; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following definitions as Official in the Official Publication and recommends the same to the membership. I so move. **Judy Thompson Seconds. MOTION CARRIES**

87.36 Phaffia yeast – The color additive, phaffia yeast, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

- (d) Identity.
- i. The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast phaffia rhodozyma.
 - ii. Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.
- (e) Specifications. Phaffia yeast shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:
- i. Physical state, solid.
 - ii. Lead, not more than 5 parts per million.
 - iii. Arsenic, not more than 2 parts per million.
 - iv. Mercury, not more than 1 part per million.
 - v. Heavy metals (as lead), not more than 10 parts per million.
 - vi. Astaxanthin, not less than 0.4 percent.
- (f) Uses and restrictions. Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
- (1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in part 73 of Title 21 of the Code of Federal Regulations (21 CFR 73), shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

2) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definitions as Tentative in the Official Publication and recommends the same to the membership, with a Vote on each separately:

a. T3.2 Dehydrated Alfalfa; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **David Dressler Seconds. MOTION FAILS 6 Approve and 13 Opposed**

T3.2 Dehydrated Alfalfa is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds and mold, which has been ground and dried by thermal means under controlled conditions. Its source shall consist of either suncured alfalfa hay that has been stored in bales or stacks; or suncured alfalfa hay that has been stored in bales or stacks that has been blended with fresh cut alfalfa.

b. T3.5 Direct Dehydrated Alfalfa meal or Pellet; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **David Dressler Seconds. MOTION CARRIES 17 Approve 3 Opposed**

T3.5 Direct Dehydrated Alfalfa meal or Pellet is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds and mold, which 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.

c. T9.10 Poultry By-Product Meal; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Stan Cook Seconds. MOTION CARRIES**

T9.10 Poultry By-Product Meal consists of the ground, rendered, clean parts of the carcass of poultry, such as necks, feet, undeveloped eggs, viscera, and whole carcasses, exclusive of added feathers, except in such amounts as might occur unavoidably in good processing practices. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum calcium (Ca), and minimum phosphorus (P). The calcium (Ca) level shall not exceed the actual level of phosphorus (P) by more than 2.2 times. If the product bears a name descriptive of its kind, the name must correspond thereto. It shall be suitable for use in animal food. (Proposed 1985, Adopted 1990, Amended 2000).

d. T9.14 Poultry By-Products; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Judy Thompson Seconds. MOTION CARRIES**

T9.14 Poultry By-Products consists of non-rendered clean parts of poultry such as heads, feet, viscera, and whole carcasses, free from foreign matter except in such trace amounts as might occur unavoidably in good processing practices. If the product bears a name descriptive of its kind, the name must correspond thereto. It shall be suitable for use in animal food. (Proposed 1963, Adopted 1964, Amended 2000)

- e. T9.57 Poultry; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Judy**

Thompson Seconds. MOTION CARRIES

T9.57 Poultry is the clean combination of flesh and skin with or without accompanying bone, derived from the parts or whole carcasses of slaughtered poultry, or a combination thereof, exclusive of feathers, heads, feet and viscera. If it bears a name descriptive of its kind, it must correspond thereto. If the bone has been removed, the process may be so designated by use of the appropriate feed term. It shall be suitable for use in animal food. (Proposed 1978, Adopted 1979, Amended 1995, Amended 1997)

- f. T9.71 Poultry Meal; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Stan Cook**

Seconds. MOTION CARRIES

T9.71 Poultry Meal is the wet rendered or dry rendered product from a combination of clean flesh and skin with or without accompanying bone, derived from the parts of whole carcasses of slaughtered poultry, or a combination thereof, exclusive of feathers, heads, feet, and viscera. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum calcium (Ca), and minimum phosphorus (P). The calcium (Ca) level shall not exceed the actual level of phosphorus (P) by more than 2.2 times. If it bears a name descriptive of its kind, it must correspond thereto. It shall be suitable for use in animal food. (Proposed 1988, Adopted 1992)

- g. T60.115 (B) Pulse protein; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Judy**

Seconds. MOTION CARRIES

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.

- i. Accepted pulse crops:
- ii. IFN 05-17-726 – Pea (*Pisum sativum L.*)

iii. Lentil (*Lens culinaris*)

- h. T60.116 (B) Pulse starch; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Steve Gramlich Seconds. MOTION CARRIES**

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.

- i. Accepted pulse crops:
- ii. IFN 05-17-726 – Pea (*Pisum sativum L.*)
- iii. Lentil (*Lens culinaris*)

- i. T33.20 Fat Product, Feed Grade; Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to publish the following new definition as Tentative in the Official Publication and recommends the same to the membership. I so move. **Richard Ten Eyck Seconds. MOTION CARRIES**

T33.20 Fat Product, Feed Grade is obtained only from production methods and fat sources described in the definitions for animal fat and/or vegetable fat or oil. Provided the product is safe for use in animal food, the product may not meet specifications in the ingredient definitions for animal fat or vegetable fat or oil. It must be sold on its individual specifications which will include the minimum percentage of total fatty acids, the maximum percentage of unsaponifiable matter, the maximum percentage of insoluble impurities, the maximum percentage of free fatty acids and moisture. The above listed specifications must be guaranteed on the label. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative". This definition shall be deleted from the Official Publication 12 months after electronic publication.

- 3) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the IDC to Delete the following definition in the Official Publication: 33.5 Fat Product, Feed Grade from the OP (2015 OP page 380). and recommends the same to the membership, I so move. **Richard Ten Eyck Seconds. MOTION CARRIES**

33.5 Fat Product, Feed Grade is any fat product which does not meet the definitions for animal fat, vegetable fat or oil, hydrolyzed fat or fat ester. It must be sold on its individual specifications which will include the minimum percentage of total fatty acids, the maximum percentage of unsaponifiable matter, the maximum percentage of insoluble impurities, the maximum percentage of free fatty acids and moisture. The above listed specifications must be guaranteed on the label. If an antioxidant(s) is used, the common

name or names must be indicated, followed by the words "used as a preservative".
(Proposed 1989)
IFN 4-00-414 Animal vegetable fat product

Model Bill 1:

Report starts on page 33 of the Committee Report Book

- 4) Ken Bowers states the AAFCO Board of Directors accepted the recommendation from the Model Bills and Regulations Committee that revisions proposed by the Feed Labeling Committee to the AAFCO Swine Nutrient Profile, as indicated in (Attachment A page 35 in Committee Report Book), conforms to the Model Regulations and recommends the same to the membership. I so move. **Doug Lueders Seconds. MOTION CARRIES**

This concludes committee recommendations needing membership approval.

Mark LeBlanc adjourned meeting 9:24 am

- 5) **Credential Report – FASS**
Number of Voting Members Represented – **27**
Number of States in attendance – **42**
Number of Countries – **5**
Number of FDA Representatives – **30**
Number of Life Members – **3**
Total Meeting Attendance – **341**

Richard MOTION to approve Business Meeting minutes. Kristen Green Seconds. MOTION CARRIES

Collaborative Check Sample Committee Report/Minutes

2016 AAFCO Midyear Meeting
Isle of Palms, South Carolina
January 18, 2016
1:30 – 5:30 pm

Committee Recommendations

Committee recommendation summary or list.

- (1) None.

Board Recommendations

Board recommendation summary or list.

- (1) None.

Association Actions

Association action summary or list.

- (1) None.

Committee Participants *Note sign-in sheet misplaced. Attendance and participation were excellent!

Members Present: List here.

Advisors Present: List here.

Committee Report

Committee Activities

ACTION: None

Sub-Committee Activities

ACTION: None

Committee Minutes

- 1) Review and Approval of Agenda
- 2) Introductions—sign-in sheet sent around.
- 3) Feedback on DRW updates. Mark Budden – Upgrade review of DRW (Note: Slides will be available on Feed Bin and public website):
 - a. Dashboard updates
 - b. Shipment tracking.
 - c. Improving client experience. Dashboard NEW features.
 - d. Support for a continuous program instead of distinct programs each year.
 - e. Submitters can now view, edit, and track shipments.
 - f. Online Subscriptions are automated. All can be done on the DRW.
 - g. Shipping Options: USPS or Lab's Courier Account by:
 - i. Program-specific analyte/methods.
 - ii. Support for a continuous program.
 - iii. Support for samples crossing programs.
 - h. Dashboard – Examples: Add/Edit Data reporters, shipping address, history, and tracking information available.
 - i. DRW (Date Reporting Website) updates:
 - j. Increased automation

- k. NEW – Supports program specific method lists - Can save method as default for multiple programs.
 - l. Can change shipping method.
 - m. Supports program specific method lists.
 - n. Samples can be shared between programs; i.e. regular, pet food, mycotoxins, etc.
 - o. Finalizing transition to new website:
 - p. Disable old DRW and redirect.
 - q. Move remaining documents to new DRW.
 - r. Number of subscribers: Same amount of members for most programs – Mineral Program has approximate 3x more subscribers than last year.
 - s. Questions:
 - t. Downloads been tested? Yes – they should be fine.
 - u. Credit Card information being store? – It is stored encrypted IMIS.
- 4) Program Discussions, Materials, subscriptions, etc.
- a. Participation – Andy Crawford – Presentation will be available (Feed Bin and public website).
 - b. Regular Program Summary – 13 samples, 279 labs submitting, 210 participating, more feeds for different animals.
 - c. Pet food Program – 4 samples, 64 subscribed for 2016
 - d. Minerals Program – 18 labs – 35 for 2016 signed up.
 - e. Mycotoxin Program – 35 labs, very focused.
 - f. Vet drugs
 - i. Participation/reporting is low.
 - ii. Some of the methods have no data (Narasin, Neomycin, Salinomycin, etc.) Per Nancy T. – there is a lot of resources dedicated to adding the vet drugs. Need to assess the process and viability. Cost effective?
 - iii. Residuals (PPB) – Lasalocid and Monensin – Low data (proto types).
 - iv. Aaron – Medicated vs. Residue.
 - g. Incorporation of veterinary drugs – added to the regular program (table of 2015 samples provided for review: (Amprolium, Bacitracin, Decoquinat, Lasalocid, Monensin, OTC, CTC, Sulfamethazine, Tylosin, Neomycin, Penicillin, Nicarbazine, Narasin, Methoprene, Roxarsone, Fenbendazole).
 - i. 201525 – Equine Feed – Trace Level Monensin and Lasalocid.
 - ii. 201530 – Dairy Feed – Monensin.
 - iii. 201621, 22, 23 – all have medicated items (4-5 drugs for each sample variable)
 - iv. Problems: Finding feeds with drugs in them are difficult to find. Trying to add the medications. Carbadox and Bacitracin are desired analytes. NEEDS: trying to find premixes but not type A. Type A is a mixing nightmare. Kentucky has volunteered to assist.
- 5) Number of samples per year with drugs – drops to six. Possibility of a two-year rotation?
 - 6) Roxarsone – Banned substance (have the raw material- to add or not?)
 - 7) Vitamin and Mineral – adding mineral/vitamin mix to some feeds. How is the response?
 - 8) For sample 201521 – only one lab analyzed for biotin and folic acid. Water-soluble vitamins low participation.
 - 9) 201591 - was a vitamin mineral premix – had good participation for vitamins.
 - 10) 201621 – NPN – 6.25 is the factor. (Yes this came up and is now on the label).
 - 11) 201622- Lamb Feed – Long labels has vitamins/mineral premix added.
 - 12) 201525 – Equine Feed – Review of where the residual levels. (SIDEBAR – Question regarding enforcement on residues – Labs do not do the enforcement (Sharon - Kentucky – Regulatory

does). From Aaron – Canada does have residual specifications and enforcements. HPLC vs. LC-MSMS).

- 13) Goal to have four samples with residuals – 2 samples are just residuals, 2 samples are residual with drugs.
- 14) Review of schedule for Check Sample Programs – Samples (so far).
- 15) Regular Program – Beef Supplement, Lamb Starter, Chick Starter....
- 16) Pet food program – Tomato Pomace, Lamb Meal, Cheese Powder....
- 17) Mineral – Swine Feed, Lamb Feed (Copper), DDG, Beef Supplement, Forage Product. Maybe a pet food. (NOTE DDG- not really a concern).
- 18) Suggestion – Add a catfish food – (after break – it was noted that the fish food sent out previously and although labeled as Fish Food but was actually Catfish Food.).
- 19) Little excitement – residues in Forage Product? Group excitement about that possibility.
- 20) Notes: Few bags leftover from 2015 for QRMs. Samples are kept for 2 years. Mineral samples were not added to the sample availability list – This is available on the website.
- 21) Program Promotional Efforts.
 - a. Created a one page – AAFCO paged (on website).
 - b. Created a banner that is at the registration desk.
 - c. Banner and flyers are traveling with the AAFCO group – to the poultry show.
 - d. Developed a set of slides – Email Nancy Thiex.
 - e. Currently there are no webinars for the check samples programs.
- 22) Introduction of Bob and Amy – They make the check samples for the AAFCO program. They are located about hour north of Chattanooga, Tennessee. Archived samples are stores ambient temperature. They grind and split materials for AAFCO and several other PT organizations.

<<Refreshment Break>>

Quick Review of some Items from before the break: Catfish food, adding pet food to the minerals and concerns that the bagged forage might be wet.

- 23) Accreditation Efforts.
 - a. Trying to find a QA manager – was fruitless.
 - b. Nancy contacted Belinda Snodgrass and Louise Ogden for assistance – they volunteered to write the Quality Manual and SOPs.
 - c. Gap analysis has been performed (60–70-page document), SOPs are in draft but there has been no movement since the last meeting.
 - d. QA group for the laboratory side will need a new leader.
- 24) Financials
 - a. None to display – available on the Feed Bin.
- 25) Program Leaderships.
 - a. Adding Belinda Snodgrass and Louise Ogden – have to restructure to include them but how this will be done is still in the works. This will affect the Laboratory group.
- 26) Review of Roster
 - a. Please let Nancy know if you want to be on the committee.

- b. No review of roster from 2015.

27) Questions:

- a. What will be the cost increase on the check sample program once it has been accredited?
- b. Not much, currently there are volunteers assisting and the thought is it will be ~20%.
 - 1. If labs would volunteer to do homogeneity (some have) this could reduce overall cost.
- c. Cost will be considered later on down the road.

28) Meeting Adjourned 5:35 pm.

Action Item Table

Responsible	Item	Action	Timing / Status

Appendix

Attachments:

Budden presentation: DRW Upgrade Review Presentation – Mark Budden 20160118

Crawford presentation: AAFCO Check Sample 2015 Program Participation and AACO Check Samples 2015 Vet Drugs Program

Education and Training Committee Report/Minutes

2016 AAFCO Midyear Meeting
Wild Dunes Resort
Isle of Palms, SC
January 20, 2016
8:00 – 10:00 am

Committee recommendations to Board and membership.

- Encourage committees to identify training needs.
- State participation as SME's or other input when association is tasked for future initiatives of FSMA.

Committee Action Items

- Committee members to continue to work on National and Feed Training Curriculums.
- Coordinate Seminar in North Dakota.
- Coordinate AITS training on Tennessee.
- Coordinate Inspector Certification Workgroup with NEHA.
- Work with Feed Labeling Committee for Medicated Feed Workshop in Pittsburgh, PA (Annual Meeting).

Summary of Liaisons from ETC

Committee Participants

Members Present: Jim Fear, Judy Thompson, Darlene Krieger, Ken Bowers, Meagan Davis (Vice Chair), Tim Lyons (Chairperson), Kristen Green, Bob Geiger, Jim True, Richard TenEyck, Shannon Jordre, Jo Lynn Otero, Tim Darden, Craig Kaml, David Fairfield.

Via Telephone: None

Advisors Present:

1. Introductions and Agenda Review

- There will be a BSE training course in Raleigh, NC, and another in April.
- Shannon stated the short list of VFDs were posted on the FDA website.
- If states need the tissue residue course talk to Jim Fear or Teresa Bills.

2. Intermediate Inspector Training Course (Meagan Davis and Tim Lyons):

- Discussion about working with the Inspection and Sampling Committee to determine if there is a need to develop an intermediate feed inspector course.
- Develop workgroup with Inspection and Sampling Committee to research curriculum development for this course if needed.
- This was brought back to the Inspection and Sampling Committee to work on the contents for the course.

3. Standardizing Training (Craig Kaml (IFPTI) and Jim Fear (FDA):

- Thoughts are that we should start considering standardizing AITS and any other courses that we offer. I would ask a couple of organizations such as IFPTI or NEHA to help explain this.

- IFPTI provided an overview of the current framework.
- IFPTI provided background on the general education courses that are being developed through grants with FDA.
- A discussion point was made that due to the length of time to create the general education, some states will have to working on their own training. This is due to the requirements under the standards.
- There was discussion on overlaying some of the courses with AITS and BITS.
- There was discussion on the need for learning sites to be accessible for different platforms.
- IFPTI talked about the various systems for tracking training including IFPTI's and DHRD's.
- Center of Excellence is working with labs to identify laboratories that perform specialized tests.

4. Training Cadres (Meagan Davis):

- While developing training, we should also develop a “bench” to ensure that we have people to help train these courses.
- Looking at different dates for the upcoming AITS training.
- There are Medicated Feed trainings scheduled for this year.
- Plan is for non-Medicated Feed training in 2018.
- Need budget information from the committee.

5. Animal Feed Inspector Certification Process (Judy Thompson and Rance Baker (NEHA):

- Discussion on what this is and how it will be developed.
- Judy explained that she will need assistance with this since there is a strong possibility that she will be taking a detail outside of Canada.
- Working with NEHA to develop a certification exam.
 - i. This is a three-step process, and the first meeting will be in Denver, February 2016.
 - ii. There was an overview of the exam writing process.
 - iii. Part of the process is to create a study guide for the exam.

Meeting adjourned at 10:00 am

Action Item Table

Responsible	Item	Action	Timing / Status
Lyons/Davis	NEHA Inspector Assessment	Underway. Jacob Fleig is coordinating	
Davis/Lyons	Labeling Workshop	Medicated feed workshop for Annual meeting in Pittsburg.	
Davis//Lyons	AITS Training	Hosted by Tennessee	

Feed and Feed Ingredient Manufacturing Committee Report/Minutes

2016 Midyear Meeting
Isle of Palms, South Carolina
Monday, January 18, 2016
1:30–3:00 pm

Committee Recommendations to Board and Membership:

1. The Feed and Feed Ingredient Manufacturing Committee recommends the following modifications to the 2016 Official Publication:
 - a. 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.
 - b. 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 Darlene Krieger.

Committee Participants:

Members present: Ken Bowers, Bill Burkholder, Bob Church, Stan Cook, Mike Davidson, Tim Darden, Bob Geiger, Jamey Johnson, Ben Jones, Ali Kashani, Darlene Krieger, Doug Leuders, Dragan Momcilovic, Shaness Thomas, Judy Thompson

Advisors present: David Ailor, Tomas Belloso, Lorri Chavez, David Dzanis, David Fairfield, Matt Frederking, David Meeker, Jessica Meisinger, Richard Sellers

Committee Report/Minutes:

1. Meeting called to order by Judy Thompson at 1:30 pm MT. Members and advisors in the room and introduced themselves.
2. The minutes from the 2016 Midyear Feed and Feed Ingredient Manufacturing Committee Meeting held on January 18, 2016, were voted on and approved on February 11 and 12, 2016 (February 8, 2016, Motion – Tim Darden, NM/Second – Ken Bowers, KS). These were posted to the website. No further action needed.
3. **Review of Action Items (See Attachment A for summary of updates)**
 - **Mineral Guidelines Working Group – Bill Burkholder**
Working Group has not yet finalized their revision of the Mineral Guidelines Chapter in the OP but is hoping to submit their recommendation by May 1, 2016.
 - **Emergency Response Working Group – Darlene Krieger**
The working group requested that earlier proposed revisions to the AAFCO Model Emergency Response Preparedness Guidance Document (pages 310-313 in the 2016 OP) identified in Attachment B with Darlene Krieger as the new Section Editor be made. The working group is developing a table top exercise to be held in conjunction with the 2017 Mid-Year Meeting.
 - **AAFCO FSMA Implementation**
 - Working Groups formed to address the items assigned by the FSMA Implementation Task Force. Charge to the working group and deadlines are identified in the Action Item Table in Attachment A.

1. Strategy for AAFCO GMPs – Ken Bowers
 - A survey of twelve states was conducted (eight states responded) with the following questions:
 1. Do you issue GMP certificates?
 2. Did you adopt the AAFCO GMPs and if so are you going to replace them with the new Federal (non-medicated) ones?
 3. Would guidance help states with the transition to FSMA GMPs or are states diverse enough that they will decide individually how and what to adopt regarding the Federal GMPs?
 - The survey identified two States that had adopted the AAFCO GMPs. Richard Sellers, AFIA indicated that AFIA had surveyed all the States earlier and that they would share that information with this working group.
2. Model Feed Safety Program Plan in OP – Judy Thompson
 - The working group proposes the removal of 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 will be archived in the Feed Bin for future information.
3. Contaminant and Hazard Lab Strategy – Mike Davidson
 - In preparation for FSMA implementation the California Department of Food and Agriculture has developed a number of tools for inspection staff (e.g., Hazard List, 3 Checklists for Internal Audits – FSMA GMPS, Hazard Analysis and Preventive Control) and regulated parties that are available on their web-site at <https://www.cdfa.ca.gov/is/ffldrs/safe.html>
4. Inspector Training for Ingredient Manufacturing Inspections – Judy Thompson
 - Awaiting completion of FSPCA curriculum and training materials

4. US Federal Regulatory Update – Eric Nelson

FSMA

FDA is in the process of developing guidance for regulated industries, State and Federal regulators and International stakeholders.

Program Alignment

This initiative was directed by the previous Commissioner and aligns the functions and work in the FDA within seven (7) commodity groups, including: food and animal food; and pharmaceuticals (includes veterinary drugs). The goal is to apply science and policy to field results and ensure that ORA activities are aligned with the Centre's priorities. The Agency is moving to a uniform inspection approach using a common case material template and is also working toward common and uniform application of import controls.

Risk-informed work planning will be used to collect information to support the use of qualitative public health metrics rather than quantitative delivery targets. The intent is to measure the impact of FDA's programs and presence on industry responsiveness. Educate while and before we regulate will continue to be the approach.

5. Preventive Control Alliance (David Fairfield, Sonya Lambkin, FDA)

Discussion this morning provided a good update of the work so only a limited update was required.

The importance of looking for the Alliance logo in conjunction with training for Qualified Individuals was stressed for both Lead Instructor and Participant courses. This will ensure that the training being offered is the standardized curriculum recognized by the FDA. The hope is that there will be a large network of qualified individuals available to provide the training. There are opportunities to customize the materials for a specific industry sector; however, the trainer will require permission of the Alliance to do so.

Reminder that there are options to be considered a Qualified Individual; a combination of experience and other training is an alternative to the completion of FSPCA curriculum. For those that chose the curriculum, a 2.5-day course is anticipated. In the future, there is a possibility of a blended learning approach (e.g. 1 day online to address basic information and 1.5-day face-to-face to allow for questions, discussions and exercises). There is international interest in the curriculum (especially for food) so the FDA is looking at providing foreign language translations possibly as early as 2017.

Applications for Lead Instructors to deliver courses for participants to receive FSPCA certification have been received from a wide range of individuals. So far, only 18 that are animal food specific have been received but there are a large number that have identified both food and feed. David Fairfield, NGFA is involved in the review panel. There has been a delay in responding to the animal food applications as the qualifications for animal food (experience/qualifications, instructional experience) were not requested in the applications. Applicants will receive follow-up communications so that the needed information can be provided. There is still an opportunity to submit an application to be a Lead Instructor on the FSPCA web-site for FDA, States and Industry. http://www.iit.edu/ifsh/alliance/resources/li_application_form

6. Canadian Regulatory Update – Judy Thompson

Judy provided the Membership with a regulatory update of the current and planned changes for the Canadian Food Inspection Agency (CFIA). (See Attachment C)

Please note that information on the "Consultations on Proposed Regulatory and Policy Changes" webpage has been updated:

<http://inspection.gc.ca/animals/feeds/consultations/eng/1343855817011/1343856000143>

Four (4) documents have been added:

*1. Feed Regulatory Renewal Consolidated Modernized Framework Proposal
The Closing Date for comments is March 18, 2016.*

2. Collective Terms on Feed Ingredient Labels Consultation Summary - Respondent Comments and CFIA Responses

3. Feed Ingredient Assessment and Authorization Consultation Summary - Respondent Comments and CFIA Responses

4. Feed Labelling Consultation Summary - Respondent Comments and CFIA Responses

7. ISO/TC 34/SC 17 – Management Systems for Food Safety – Working Group 9 – Feed Production (David Fairfield).

This work was initiated to develop technical specifications for prerequisite programs for animal feeds to support management systems for those companies using ISO 22000. PAS 222/2011 was used as a starting point. PAS 222/2011 can be downloaded at <http://shop.bsigroup.com/en/forms/PASs/PAS-222/>

Animal food requirements will be applicable to animal feed for food producing animals as well as pet food.

The Working Group includes representatives from 25 countries. American National Standards Institute (ANSI) is the organization representing the USA. The U.S. Technical Advisory Group includes Henry Turlington (AFIA), Pat Tovey (PFI) Dave Harlan (Cargill), Dave Fairfield (NGFA).

Three meetings were held the last being in Paris, France in October, 2015. At this meeting the working group reviewed comments received related to the draft circulated after the February 2015 meeting. The final document should be published in June 2016 as a technical specification subject to a 3-year review period and available for purchase. At that point, the document will either become a standard or remain a technical specification for a maximum of three more years at which time it would either become a standard or removed from the ISO web-site.

8. Industry Updates

- a. American Feed Industry Association (AFIA)
 - i. Richard Sellers reminded meeting participants of the upcoming 5th Global Food and Feed Conference in Ankara, Turkey (April 2016). The annual feed regulators round table will be held in conjunction with the Conference. **Confirmed with Richard after out meeting that the Conference is going to go ahead as planned.**
 - ii. Richard Sellers reminded meeting participants of the upcoming International Production and Processing Expo in Atlanta, Georgia. Sam Davis, Richard TenEyck, Ali Kashani and Kent Kitade will be attending on behalf of AAFCO.
 - iii. AFIA has contracted with the University of Minnesota to develop a HACCP model to address known hazards and those reasonably expected to occur. The report is expected to be available in late October 2016. Individual feed mills would use the model as a starting point that would be customized based on their specific ingredients and processes using scientific data.
- b. National Renderers Association (NRA) and National Oilseed Processors Association (NOPA)
 - i. David Meeker, NRA and David Ailor, NOPA, both members of the working group developing the standardized curriculum with FDA, Industry and Academia, expressed appreciation for the collaborative process being used to develop the curriculum and the model food safety plans.
- c. Meeting attendees were also advised of a proposed 1/2 day seminar on the process for hazard identification planned for the upcoming joint meeting of The American Society of Animal Science (ASAS), the American Dairy Science Association (ADSA), the Western Section of the American Society of Animal Science (WSASAS), and the Canadian Society of Animal Science (CSAS) will hold the 2016 Joint Annual Meeting (JAM) in Salt Lake City, Utah, July 19-23 <https://asas.org/meetings/jam-2016/home>

9. Other Business

- a. The Committee Chair, Judy Thompson announced her intention to step down because she was taking on a new role in the Canadian Food Inspection Agency that precluded her ongoing participation in AAFCO. Going forward, the Committee Leadership will be comprised of: Committee Chair – Alan Harrison, Feed and Milk Coordinator, Division of Regulatory Services, University of Kentucky and Vice Chair – Eric Brady, Pesticide Inspector III, Field Supervisor, Tennessee Department of Agriculture

10. Meeting adjourned at 2:45 pm.

Attachment A: Action Item Table

Responsible	Item	Action	Timing / Status
Mineral Guidelines Working Group	Review and Revise Mineral Guidelines	<p>Working group to develop plan to review and revise Mineral Guidelines in the OP for discussion by the Committee</p> <p>Workgroup Members: Bill Burkholder (lead) Jon Nelson, Tim Costigan, Jennifer Kormos David Syverson, Bill Hall, Dave Dzanis, Roger Hoestenbach</p> <p>Update Working group is progressing well and it is expected that a report will be provided to the committee by May 1, 2016.</p>	Update at August 2016 Annual Meeting
Darlene Krieger	Strategic Plan – Emergency Response	<p>Working Group to:</p> <ul style="list-style-type: none"> • review and revise the information on emergency response in the current OP (completed) • develop a folder in the Feed Bin for States to place any table top exercise materials they may have for others states to use (completed) • develop a table top exercise that could be used at an upcoming AAFCO meeting <ul style="list-style-type: none"> ○ Tabletop exercise at April 2015 Feed Administrator’s Seminar (completed) ○ Larger tabletop exercise to be held in conjunction with the 2017 Mid-Year Meeting <p>Workgroup Members: Darlene Krieger (lead), Glo Dunnavan, David Fairfield, Dragan Momcilovic, Tim Darden, Stan Cook, Tim Lyons</p>	Update at August 2016 Annual Meeting

Responsible	Item	Action	Timing / Status
Judy Thompson	FSMA Implementation Task Force	<p>Items identified at April 27, 2015 meeting</p> <ol style="list-style-type: none"> 1. By August 2016, determine the path forward for: <ol style="list-style-type: none"> a. AAFCO GMPS (in consultation with MBRC and PFC) <ol style="list-style-type: none"> i. Develop a plan for states that have adopted AAFCO's model GMPs to make the transition to FSMA GMPs <p>Working Group #1 – Ken Bowers (lead), Bob Church, Bob Geiger, Matt Frederiking, Richard Sellers</p> b. Model Feed Safety Program Plan (in consultation with Linda Morrison (OP Section) and Bob Waltz (Feed Safety Coordinator) (recommendation to the Board and Members made – completed) <p>Working Group #2 – Judy Thompson (lead), Linda Morrison, Bob Waltz</p> 2. After FSPCA/FDA conclude their work in this area, determine the contaminants, hazards, matrix and action levels and enforcement strategies to provide guidance to LMSC to inform method development priority setting. Integrate collaboratively into current LMSC priorities. (in consultation with FSPCA, EIC, ISC, IDC and LMSC) <p>Working Group #3 – Mike Davidson (lead), Srinu Chigulubadi (FDA) ++</p> 3. After FSPCA/FDA conclude their work in this area, determine whether training material for feed ingredient manufacturing from the FSPCA will meet the needs of Inspectors for training (in consultation with ETC and ISC) <p>Working Group #4 – Judy Thompson (lead), Mike Davidson, Darlene Krieger, David Ailor, Matt Frederiking</p> 	Ongoing committee updates

Attachment B: AAFCO Model Emergency Response Preparedness Guidance Document

PURPOSE

To provide for a coordinated and consistent approach to preparing for, preventing, protecting against, mitigating, responding to, and recovering from incidents involving or impacting animal food/feed safety.

Emergency is defined as unforeseen or sudden occurrence requiring immediate action to protect against substantial risk to animal and/or public health, and that involves the safety, efficacy, and security of animal food/feed supply.

SCOPE

The role of the feed control agency in an emergency is to implement activities which contribute to ensuring a safe animal food/feed supply. The agency should be prepared to provide thorough and timely inspections/investigations of food and feed related issues; provide scientific, technical, operational guidance; support internal and external working relations; and, monitor implementation of recommended remediation strategies by responsible firms.

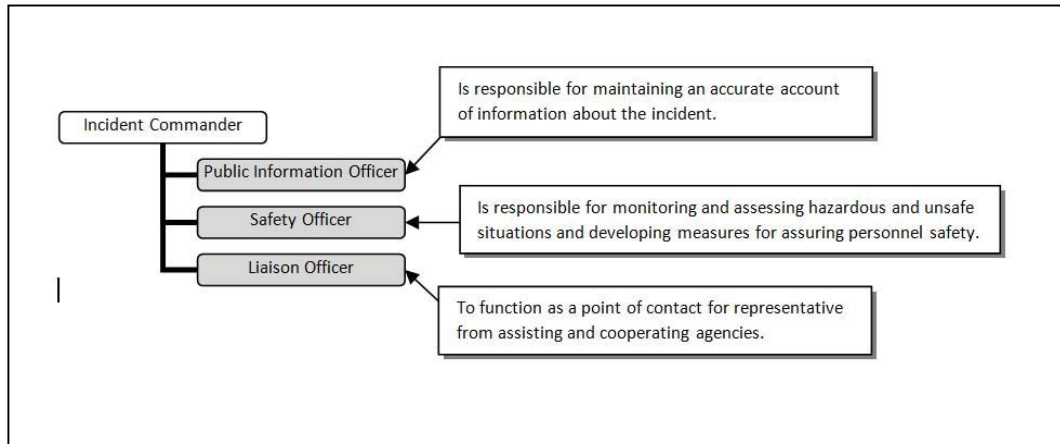
BACKGROUND

All levels of government, the private sector, and nongovernmental agencies must be prepared to prevent, protect against, respond to, and recover from a wide spectrum of major events that could exceed the capabilities of any single entity. These hazards require a unified and coordinated national approach to planning and to domestic incident management. To address this need, Homeland Security Presidential Directive 5: Management of Domestic Incidents (HSPD-5, <http://www.dhs.gov/publication/homeland-security-presidential-directive-5>) and Homeland Security Presidential Directive 8: National Preparedness (PPD-8, <http://www.dhs.gov/xlibrary/assets/presidential-policy-directive-8-national-preparedness.pdf>) establish the following national initiatives that develop a common approach to preparedness and response. HSPD-5 identifies steps for improved coordination in response to incidents. It requires the Department of Homeland Security (DHS) to coordinate with other Federal, State, tribal and local governments to establish a National Incident Management System (NIMS). NIMS provides a consistent nationwide template to enable Federal, State, tribal and local governments, the private sector, and nongovernmental organizations to work together to prepare for, respond to, recover from, and mitigate the effects of incidents regardless of cause, size, location, or complexity in order to reduce the loss of life and property and harm to the environment. One of the major components of NIMS is the Incident Command System (ICS), which establishes a standardized organizational structure and terminology utilized for the management of incidents.

PROCEDURE

The first step in any emergency response plan is the establishment of an Incident Management Team (IMT), which may include the following ICS positions:

Command Staff: encompasses the Incident Commander (IC), Public Information Officer (PIO), Safety Officer (SO), and Liaison Officer (LNO).



General Staff: encompasses the Operations Section Chief (OSC), Planning Section Chief (PSC), Logistics Section Chief (LSC), and Finance/Administration Section Chief (FSC).

ICS may be expanded easily from a very small response for routine incidents into a larger organization capable of handling a complex incident.

All team members should receive appropriate training for implementation before the plan is needed. Basic training includes ICS 100, 200, 700, 800, which are available online on the FEMA training website (<https://www.fema.gov/national-incident-management-system/training>). Additional ICS courses are available as classroom courses, including position specific courses.

IS-100.FDA [Introduction to Incident Command System \(ICS 100\) for Food and Drug Administration](#)

IS 200.b [ICS for Single Resources and Initial Action Incidents](#)

IS 700.a [National Incident Management System \(NIMS\) An Introduction](#)

IS 800.b [National Response Framework, An Introduction](#)

FEMA has an ICS Job Aids webpage (<http://training.fema.gov/EMIWeb/IS/ICSResource/JobAids.htm>) that includes the ICS forms and description of the Planning "P".

Identify team members by position and a sufficient back up to ensure someone is available in an emergency. Prepare a contact list of team members (including phone, FAX, cell phone, home phone, email, and regular mail address), alternates (as many as needed to ensure someone is available). Critical time can be lost locating key contacts/personnel during a real emergency. This contact list should be maintained and reviewed at least annually and more often when necessary.

Possible Contacts to Initiate Management Team

INTRA-AGENCY	
Laboratory	Office of Legislative Affairs
Office of General Counsel	Office Public Information
Office of Director or Administration	

FEDERAL	
United States Department of Homeland Security	United States Department of Energy
Food Safety and Inspection Service (FSIS)	United States Department of Defense
United States Food and Drug Administration (FDA)	National Security Administration
United States Department of Health and Human Services (HHS)	Federal Bureau of Investigations (FBI)
Environmental Protection Agency (EPA)	Trade Commission
United States Department of Agriculture (USDA)	Health Department
United States Customs and Border Protection (CBP)	Veterinary Medical Diagnostic Lab
United States Department of Justice	Animal and Plant Health Inspection Services (APHIS)
United States Department of Commerce	Centers for Disease Control and Prevention (CDC)
Federal Emergency Management Agency (FEMA)	Fish and Wildlife Services
Plant Protection and Quarantine (PPQ)	

STATE/PROVINCIAL/LOCAL GOVERNMENT OFFICES	
Department of Conservation, Natural Resources, or Environmental Protection Agency	Department of Commerce
Department of Agriculture, Plant Board, or Forestry	Department of Wildlife and Fisheries
Board of Pharmacy	Department of Marine Resources
Department of Public Safety	Veterinary Medical Diagnostic Laboratory
Department of Public Health Human Services, Social Services	Land Grant University/Extension Service
State Veterinarian, Animal Health, Livestock Commission	Police, Sheriff, Constable
Attorney General	Fire Department
Local Public Health Department	Hospital (local and/or regional)
	Utilities: Gas, Electric, Water, Sewage

INDUSTRY ORGANIZATION	
Producers Associations, e.g. cattle raisers, cattle feeders, pork producers, poultry producers, etc.	Grain and Feed Associations
Equipment Suppliers Association	Feed Manufacturers Association

ADDITIONAL ASSISTANCE	
Forensics Laboratory	Universities/University "Centers"
Poison Control Center	Federal, State and Local Emergency Management Agencies
Toxicology	Pathology

THE PLAN

Consider the four (4) C's of Crisis Management: Contain, Communicate, Control, and Correct

I. Contain

- Define the crisis through investigation, including but not limited to; determine site safety/risk to investigation (risk analysis), stabilize – secure the site, etc.
- Gather details of who, what, where, and when.
- Alert supervisor of crisis.
- Initiate regulatory response, as needed.
- Implement a demobilization plan for staff and resources.

II. Communicate

- Notify designated Team Leader.
- Initiate notification both interdepartmentally and interagency.
- Identify the Team.
- Evaluate and control dissemination, internally, and externally, of any information received.
- Involve outside contacts as needed.
- Interact with Media, Press, and social media.

III. Control

- Establish authority and leadership early.
- Maintain on-site control.
- Trace forward to ensure containment.
- Expand size of containment, regulatory response, and team members, as necessary.

IV. Correct

- Disposition and disposal of crisis.
- Determine strategies to prevent reoccurrence of crisis or future crisis.
- Conduct post crisis review and performance evaluation.

Review

1. Review Plan at least annually.
2. Allow for the Plan to evolve to respond to the changing needs that are determined in review.
3. Test model Plan periodically.
4. Retrain all participants regularly.

*The events may not include every step and likely will not occur in any particular order.

Attachment C

<http://www.aafco.org/Regulatory/Committees/Feed-and-Feed-Ingredient-Manufacturing>

Ingredient Definitions Committee Report

First Meeting: 2016 AAFCO Midyear Meeting
South Carolina

Tuesday, January 19, 2016

1:20 – 5:00 pm EST

IDC recommendations to the Board and Association Members. Text for the OP is in Attachment A.

1. Publish the modified feed term for Feed Grade in the OP.
2. Publish the new feed term, Suitable for use in animal food in the OP.
3. Publish the new feed term for Human Grade in the OP.
4. Publish the tentative definition in the OP for β -Mannanase from *Bacillus subtilis* for Table 30.1 Enzymes and Source Organisms.
5. Publish the revised definition in the OP for 33.1 Animal Fat.
6. Publish the tentative definition in the OP for T33.24 Used Cooking Oil, Feed Grade.
7. Publish the tentative definition in the OP for T36.14 *Lactobacillus animalis*.
8. Publish the Note to add under the header in Section 40 in the OP.
9. Publish the nine prior Section 60 ingredient definitions in Section 40 in the OP using new Section 40 numbering.
10. Publish the tentative definition in the OP for T40.100 Recovered Retail Food.
11. Publish the modified definition in the OP for 57.163 Selenium Yeast.
12. Publish the tentative definition in the OP for T87.35 Glucose Syrup.
13. Publish the tentative definition in the OP for T60.117 Dried Black Soldier Fly Larvae.

Minutes of January 19, 2016 IDC Meeting:

Role:

Committee Members: Richard Ten Eyck, Alan Harrison, April Hunt, Steve Gramlich, Ali Kashani, Charlotte Conway (new member), Shannon Jordre, David Dressler, Erin Bubb, Mark LeBlanc, Brett Groves, Jacob Fleig, Kent Kitade.

Via telephone: Mika Alewynse, David Phillips.

Advisors: Dave Dzanis, Kristi Smedley, Jean Hofve, Susan Thixton, David Meeker, Leah Wilkinson, Jon Nelson, Jason Vickers, Denise Fung, James Emerson, Jessica Meisinger, Vince Sewalt, Jan Campbell, Jonathan Goodson.

Via telephone: Mollie Morrissette.

The meeting was convened at 1:21 pm by Chairperson TenEyck.

Announced at the end of the meeting: Plan to hold teleconference/webinar meeting on February 12 (Friday) to cover the topics not covered in today's session because of limited time. All Feed Bin users and General Public will be invited to attend. All interested are welcome to join.

The Committee and Advisors introduced themselves, and the chair asked the regulators if anyone would like to join the committee. Charlotte Conway volunteered to join and participated.

- 1) Definitions to move tentative to official.
 - a) None.
- 2) Work Group Reports
 - a) Feed Grade work group report-
The work group recommended new terms for Feed Grade, Suitable for use in animal feed, and Human Grade. Steve Gramlich moves, April Hunt seconds the motion to ACCEPT the report. Motion PASSES.
 - b) AAFCO GRAS Work group report.

(i) The AAFCO GRAS Work group report was posted in the Feed Bin. Motion was made to accept the report. Steve Gramlich moves. Al Harrison seconds. Motion PASSES. Discussion: Leah Wilkinson summarized the workgroup activities, specifically that they discussed GRAS as an accepted federal designation for ingredients. The initial focus was on GRAS Notifications on which FDA had issued a no-questions letter. Subsequent meetings will focus on state GRAS determinations and AAFCO GRAS determinations. As for the first topic, the work group developed Recommendation #1 which proposes an approach to include GRAS Notification ingredients in the AAFCO OP. The Work group proposed these ingredients (those that were subject of no-questions letter) be entered into the AAFCO OP in new Section 101, and that they also be listed in the relevant ingredient section, with the statement, "GRAS Notification received a No-question letter by FDA on mm/dd/yyyy". A question was raised how the ingredient definition language would be developed; the thinking of the workgroup is that the definition would come through the IDC process so would be reviewed first by FDA and then by IDC. Future GRAS Notifications would be able to include a proposed definition, to make this process more efficient. Dave Edwards commented on the Feed Bin that GRAS notices are not evaluated the same as food additives and AAFCO feed ingredients since in the former case, FDA reviews a summary of the firm's determination of GRAS for an intended use. He wondered if the submitting firm would mind their information being included in a general definition in the AAFCO OP. Industry replied that this same situation occurs for food additives and AAFCO ingredient definitions. Since the "no questions" letter issued by CVM is firm/product/process specific, who "owns" the definition? Can it be generically used? Is it okay for the definition to be expanded upon?

(ii) Motion made by Steve Gramlich to ACCEPT the GRAS Work group Recommendation #1. Al Harrison seconds. Motion TABLED to the next IDC face-to-face meeting. Discussion: Brett Groves believes that there are issues that are not resolved/addressed. Will these run through IDC? Will the company name be listed? Charlotte Conway and Mark LeBlanc agreed. Some discussion ensued around whether or not these GRAS ingredients should be double-listed. According to Dave Dzanis and Kristi Smedley, double listing makes it easier for users to find ingredients. Jason Vickers (PFI) and Jan Campbell (NGFA) asked if they can join Workgroup. Brett suggested surveying the states and Industry.

(iii) Motion was made to survey the states and industry about accepting Recommendation #1. Brett moves and Jacob Fleig seconds. Motion PASSED. The Work group will develop a survey and provide the results to the IDC.

c) Recap of Sunday Ingredient Definition workshop and any resource lists generated from it. Susan Thixton felt that the workshop was a useful exchange of wants and needs of regulatory authorities to get ingredients approved. Consumers provided their input. Jean Hofve offered that the information was somewhat confusing. Richard Ten Eyck said that the ingredient definition workshop recording and presentations will be organized and then posted to the IDC public website and in the BIN. Kristi Smedley mentioned that it would be helpful for the IDC to do a follow-up on Utility data submission since this is a complex area and was not addressed by FDA at the workshop. This will be considered by FDA. E-Submitter training will be provided again later on according to Dave Edwards.

3) New Definitions, deletions and edits:

a) New Term: Animal Food – Ali Kashani

Steve Gramlich moves to ACCEPT. Shannon Jordre seconds. MOTION to TABLE this definition to the next Meeting was PASSED.

Discussion: Ali Kashani mentioned that this term was developed from 21 CFR Part 507.3 language was altered for food for humans and to include specialty pet food. April Hunt said that Model Bill sent these definitions to the Feed Grade Workgroup and explained

that some felt there should be consistency with the Part 507.3 language – so should use “man” rather than “human”. Specialty pets are a different category in the AAFCO OP. Jenny Murphy asked why AAFCO needs to modify the FSMA definition. Erin Bubb supports including specialty pet food and asked if it is clear that finished feed and ingredients and premixes are included. Shannon offered that we could use the FSMA language, cite it, and then add a second sentence to say that this term includes specialty pet food and supplements. April Hunt suggested another option to use the FSMA term and then add the AAFCO extras parenthetically. Ali will offer a modification at the next meeting.

b) Modify term: Feed(s) – Ali Kashani

Shannon Jordre moves to ACCEPT. Mark LeBlanc seconds. MOTION to TABLE and consider modifying this definition for consideration at the next AAFCO Meeting was PASSED. FDA acknowledges that this is the definition in the AAFCO OP. Charlotte Conway said that this is not a useful definition the way it is worded and offered that someone from FDA would work with Ali Kashani on this term. Food and feed are more “what” terms and food grade and feed grade include a “processing” component. Jan Jarman thought that the definitions should align with one another. Jenny Murphy said that FDA is moving away from the term “feed” except for “medicated feed” and is using the term, “animal food”; feed and animal food need to be the same. Dave Dzanis said that we could use, “Feed – see Animal Food”.

c) Modify term: Feed Grade. Ali Kashani

Brett Groves moves to ACCEPT the definition as modified in the IDC meeting (on screen). Mark LeBlanc seconds. MOTION PASSES. Discussion: Feed Grade definition and Suitable for use in animal feed need to be the same language. Various approaches to cross-referencing were discussed and it was agreed to define the Feed Grade term followed by the parenthetical, “suitable for use in animal feed”. Then the latter term would be referenced to Feed Grade. Judy Thompson asked if Human Food grade ingredients could not be used for animals since this term is not part of the Feed Grade definition. Charlotte Conway replied that human food grade is a higher standard than animal feed grade, so it is assumed that Human Food grade may qualify for use in animal food. The caveat is that the Human Food grade ingredient must be, “safe, functional and suitable for its intended use...”

d) New Term: Suitable for use in animal feed – Ali Kashani

Shannon Jordre moves to ACCEPT the definition as modified in the IDC meeting (on screen). Steve Gramlich seconds. MOTION PASSES.

e) New Term: Human Grade – Ali Kashani

Shannon Jordre moves to ACCEPT as edited in the IDC meeting (on screen). Mark LeBlanc seconds. MOTION PASSES.

Discussion: Jenny Murphy said that not all Human Grade food meets cGMPs. Charlotte Conway said that because USDA does not cover all human food, then the FDA regulation takes over. Further processing to make the USDA-regulated food into pet food makes this food covered by FDA 21 CFR part 117 (Human GMP’s). For a meat product, it is produced in a USDA-inspected plant and then would need to travel to an FDA-inspected plant to make it into pet food. This is a high threshold and this is on purpose. It was suggested that the IDC consider adding a reference in this new definition to the draft Human Grade guideline in the model pet food regulations.

f) New Feed Term: “sprouted” -Ali Kashani

Brett Groves moves to ACCEPT. Jacob Fleig seconds. Motion FAILS. Discussion: This came from Industry and Regulators. Sharon Benz had suggested that the example seeds (flax, quinoa, corn, rice, wheat, and barley) be included in the new feed term. Charlotte

Conway asked if we should include these seeds and whether this is warrants a new feed term or rather should be new definition(s) because the nutritional value may be different for sprouted seeds. Jenny Murphy asked if preventative controls referred to the FSMA term. Mika Alewynse recalled that the original intention was to define sprouted and include the ingredient definition from the USDA human food database. This new feed term would be used predominantly in pet food as nutrients. According to Steve Gramlich, since this is a process, it would in theory need to be able to be added to any grain. Does it change the grain nutritionally? If there will be a nutritional change, then it should not be a feed term, but a definition. It was decided to find out who in industry supports this new term, and to understand what is their intention.

g) Edit 30.1 Enzymes tables – Jan Jarman discussed that she is working on modifying Table 30.1 Enzymes and Source Organisms to a text from a table format. Jan had raised this topic with the Enzyme Technical Association (ETA) and they had requested that this topic be deferred until after their Table 30.1 initiative is completed. Emily Helmes explained that ETA -- in response to the FDA request that companies need to start looking at available data to categorize ingredients as GRAS or Food Additives – has started to work on this for the ingredients in Table 30.1. She continued that in the course of discussing the table to text project, some questions have arisen regarding the Enzymes Table and that ETA would work with Jan Jarman and Mika Alewynse to investigate a way to help resolve these questions.

h) New organism editorial add to 30.1 β -mannanase from Dried Bacillus subtilis fermentation solubles – Jan Jarman
Brett Groves moves to ACCEPT. Mark LeBlanc seconds. MOTION PASSES.

i) Edit 33.1 Animal Fat – Ken Bowers
Steve Gramlich moves to ACCEPT. Erin Bubbs seconds. MOTION PASSES. Discussion: FDA is proposing this and the following fat and grease definitions in response to the deletion of Fat Product, Feed Grade (approved by the AAFCO Membership on January 18, 2016). This particular one is a technical edit to the existing definition and encompasses information provided by the NRA.

j) T33.21 Yellow Grease, Feed Grade –Ken Bowers
Steve Gramlich moves to ACCEPT. Erin Bubbs seconds. MOTION was TABLED to the next IDC Meeting. Discussion: Charlotte Conway asked if this definition needs a BSE caution statement in this definition. David Meeker said that this caution statement is not needed on this definition. Shannon said that for tallow it should be included.

k) T33.22 White Grease, Feed Grade –Ken Bowers withdrew this definition.

l) T33.23 Tallow, Feed Grade – Ken Bowers withdrew this definition

m) T33.24 Used Cooking Oil, Feed Grade – Ken Bowers
Shannon Jordre moves to ACCEPT as adjusted. David Dresslor seconds. MOTION PASSES. Discussion: Vegetable oil can come from multiple sources. Ross Hamilton, Darling Ingredients said that the level of 20% free fatty acid (FFA) maximum would exclude several products. The FFA level is generally disclosed by the producer to the buyer and may be over 20%. Charlotte said that the 20% described a typical analysis of cooking oil according to a trade publication; FDA had some concern about a higher level of FFA being problematic, with rancidity potential. Shannon would not object to changing the FFA provided that a guaranteed maximum level (not to exceed) is clearly stated. Does tallow need to be included in this definition? It was thought not because Used cooking oil is included in the FDA plate waste exemption. Concern expressed over the international (Canada) standards being met. It was agreed to amend language to strike the 20% max FFA and add, "Maximum free fatty acids must also be guaranteed."

- ~~n) T33.xx Fatty acids/esters (placeholder) – Ken~~
- ~~e) Modify 33.3 Hydrolyzed _____ Fat, or Oil, Feed Grade (placeholder) – Ken~~
- p) T36.14 *Lactobacillus animalis* –Jan Jarman
Shannon Jordre moves to ACCEPT. Alan Harrison seconds.
MOTION PASSES. Discussion: This microorganism is to be added to the Direct Fed Microorganisms list due to a nomenclature change.
- q) Add note below the Section 40 Header– Dan Danielson.
April Hunt moves to ACCEPT with original language plus an “a” to coco. Steve Gramlich seconds. MOTION PASSES.

Discussion: Who is the “firm”? The intention is that this is the company placing the ingredient on the market; this is consistent with the FFDCA. And what is meant by “safety assessment”? This same company must be responsible for conducting a safety assessment to ensure that their by-products are suitable for use in animal food. This note was added because the firms responsible for these are not necessarily focused on animal food. So there is extra language to take this into account. According to Jenny Murphy, a lot of human by product food producers may not have the capability to make these determinations. The consensus was that the company placing the ingredient in the market for feed use is responsible for proving safety for the intended use prior to such marketing.

- r) Section 40 Sort human food by products – Dan Danielson.
Erin Bubb moves to ACCEPT. David Dresslor seconds. MOTION PASSES. Discussion: Preference appears to be to use the new numbers, and not the old. Leah Wilkinson thinks that there are other definitions that will need to move to this Section. Richard Ten Eyck suggested the IDC deal with these now and others later.
- s) T40.100 Recovered Retail Food – Dan Danielson
Dave Dresslor moves to ACCEPT. April Hunt seconds. MOTION PASSES. Discussion: Considerable effort has been made on this definition. All were in favor with no discussion.
- t) T54.xx Dried Milk Permeate– Catherine Marrier.
Dr. Burkholder would like more information on the processing of this ingredient. Industry is asked to contact Catherine Marrier/Investigator.
- u) Technical correction to 57.163 Selenium Yeast – Jennifer Kormos_.
Brett Groves moves to ACCEPT. Mark LeBlanc seconds. MOTION PASSES. Discussion: This language aligns the definition with the CFR.
- ~~v) List of standard food names from USDA – Richard~~
- w) 87.1 Dried Algae Meal (out of time: deferred to Feb 12)
- x) 87.36 Phaffia yeast (out of time: deferred to Feb 12)

Colorants: (out of time: deferred to Feb 12)
Plan to take these as a group (with luck ☺)

- y) 87.100 FD&C Blue No 1.
- z) 87.102 FD&C Blue No 2.
- aa) 87.103 FD&C Green No 3.
- bb) 87.104 FD&C Red No 3.
- cc) 87.105 FD&C Red No 40.
- dd) 87.106 FD&C Yellow No 6.
- ee) 87.107 FD&C Yellow No 5.
- ff) 87.110 Annatto Extract
- gg) 87.112 Astaxanthin dimethyldisuccinate
- hh) 87.114 Astaxanthin

- ii) 87.116 Caramel
- jj) 87.118 Carmine
- kk) 87.120 Carrot Oil
- ll) 87.122 Cochineal Extract
- mm) 87.124 Corn Endosperm Oil
- nn) 87.126 Dehydrated Beets
- oo) 87.128 Fruit Juice
- pp) 87.130 Haematococcus algae meal
- qq) 87.132 Paprika Oleoresin
- rr) 87.134 Paprika
- ss) 87.136 Paracoccus pigment
- tt) 87.138 Riboflavin
- uu) 87.140 Saffron
- vv) 87.142 Synthetic Iron Oxide
- ww) 87.144 Tagetes (Aztec Marigold) Extract
- xx) 87.145 Tagetes (Aztec Marigold) Meal
- yy) 87.146 Titanium Dioxide
- zz) 87.148 Toasted Partially Defatted Cooked Cottonseed Flour
- aaa) 87.150 Tomato Lycopene Concentrate
- bbb) 87.152 Tomato Lycopene Extract
- ccc) 87.154 Turmeric Oleoresin
- ddd) 87.155 Turmeric
- eee) 87.156 Ultramarine Blue
- fff) 87.158 Vegetable Juice
- ggg) 87.160 β -apo-8'-carotenal
- hhh) 87.164 β -Carotene
- iii) Renumber section 73 transfers – Richard (out of time: deferred to Feb 12)
- jjj) T87.35 Glucose Syrup – Richard Ten Eyck/Mika Alewynse

Mark LeBlanc moves to ACCEPT. Brett Groves seconds. MOTION PASSES. Discussion: Leah Wilkinson questioned the use of “must” in the AAFCO definition versus “may” in the CFR citation. FDA said that the meaning is the same.

kkk) T60.117 Dried Black Soldier Fly Larvae– Erin Bubb
Brett Groves moves to ACCEPT. Mark LeBlanc seconds. MOTION PASSES. Discussion: Submission packet was complete. CVM has reviewed this packet and has agreed to this definition. This is only for use in salmonids. Typically CVM has not extrapolated from aqua species to terrestrial species. This is limited to larvae grown on feed grade materials. If industry is interested in non-salmonids, then they would need to submit safety and utility data on other species.

lll) Modify Dried Bovine Colostrum to 9.5% moisture – Catherine Marrier
Would like more industry support on this definition. With Bovine Colostrum still in tentative status, this one is not yet ready to become a definition.

mmm) TXX.XXX Dried Colostral Cream – Catherine Marrier.
Bill Burkholder asks Industry to provide substantiating information to these definitions and to submit this to Catherine Marrier.

- 4) Discussions: (out of time all deferred to 2/12/16)
- a) Hemp in Feed -- ~~National Hemp Growers Association~~
 - b) Values in Footer on Vitamin Table ; original source? Use human or animal bio-availabilities? – Tom
 - c) Montmorillonite update for Industry – Tom
 - d) Fabricated Meat background information. Term needed? – ATPF
 - e) ~~Gras notified section in the BIN or OP? – Mika, CVM covered by workgroup~~
 - f) Materials NOT suitable for animal feed list in the BIN or website – rt

Next Meeting will be February 12, 2016 by webinar at 11:30 am EST

IDC Meeting February 12, 2016

Join us for a webinar on Feb 12, 2016 at 8:30 AM PST.

Register now!

<https://attendee.gotowebinar.com/register/487372095351291905>

Ingredient Definitions Committee meeting.

After registering, you will receive a confirmation email containing information about joining the webinar.

Erin Moves, Mark seconds Meeting was adjourned at 5:05 pm.
Minutes and report were approved by IDC February 12, 2016.

Attachment A for the 1/19/16 IDC Meeting

New Feed Terms

Feed Grade: Material that has been determined to be safe, functional and suitable for its intended use in animal food, is handled and labeled appropriately, and conforms to the Federal Food, Drug and Cosmetic Act unless otherwise expressly permitted by the appropriate state or federal agency (Suitable for use in animal feed).

Suitable for use in animal feed: See *Feed Grade*.

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

New Definitions or Edits:

30.1 Add a Beta-Mannanase from Dried *Bacillus subtilis* fermentation solubles; edit enzyme table to show:

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

33.1 Animal Fat is obtained from the tissues of mammals and/or poultry in commercial processes of rendering or extracting. It consists predominately of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2.5% unsaponifiable matter, and not more than 1% insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If the product bears a name descriptive of its' kind or origin; e.g. "beef", "pork", "poultry", it must correspond thereto. Rendered animal fat derived from only pork raw materials can be labeled as white grease. Rendered animal fat derived from only cattle raw materials can be labeled as beef tallow. Tallow containing greater than 0.15% insoluble impurities must be labeled with the BSE caution statement "do not feed to cattle or other ruminants." If an antioxidant is used, the common name or names must be indicated, followed by the words "used as a preservative".

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 then heated to reduce moisture. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 1% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative".

Add "*Lactobacillus animalis*" to the organism list in definition 36.14.

Section 40 Human Food By Products

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

ReNUMBER and move the following to section 40:

60.96 Food processing waste
60.35 Sugar Food By-Product
60.93 Pasta Product
60.14 Cereal Food Fines
60.29 Gelatin By Products
60.34 Dried Beans
60.15 Dried Bakery Product
60.97 Restaurant Food waste
60.107 Mixed feed nuts

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

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

57.163 Selenium Yeast is a dried non-viable yeast, *Saccharomyces cerevisiae*, cultivated in a fed-batch fermentation which provides incremental amounts of cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed 2% of the total selenium content in the final selenium yeast product. Guaranteed organic selenium content must be declared on the product label. The additive selenium yeast may be added to:

- 1) complete feeds for chickens, turkeys, swine, beef cattle, dairy cattle, bison, sheep, goats, llamas, alpacas, and horses at a level not to exceed 0.3 part per million of selenium, and to complete dog foods at a level not to exceed 0.333 part per million of selenium on a dry matter basis;
- 2) feed supplements for limit feeding for beef cattle, bison and horses at a level not to exceed an intake of 3 milligrams per head per day;
- 3) feed supplements for limit feeding for goats, llamas, and alpacas at a level not to exceed an intake of 0.7 milligrams per head per day;
- 4) salt-mineral mixtures for free-choice feeding of beef cattle, bison, and horses up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day;

5) salt-mineral mixtures for free-choice feeding for goats, llamas and alpacas up to 90 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 0.7 milligrams per head per day.

Selenium yeast shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound. 21 CFR 573.920. **The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."** (Proposed 2002, Amended 2003, 2004, 2007*, 2008, 2009, Adopted 2011).

T60.117 Dried Black Soldier Fly Larvae is the dried larvae of the Black Soldier Fly, *Hermetia illucens*, that has been raised on a feedstock composed exclusively of feed grade materials. The ingredient must contain not less than 34% crude protein and 32% fat on an as-fed basis. The ingredient is dried by artificial means to no more than 10% moisture. It is for use in salmonid fish feed as a source of protein and fat consistent with good feeding practices.

T87.35 Glucose syrup is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch. It shall meet the following specifications: total solids content not less than 70.0 percent mass/mass (m/m) and reducing sugar content (dextrose equivalent), expressed as D-glucose, not less than 20.0 percent m/m calculated on a dry basis. The sulfated ash content is not more than 1.0 % m/m (calculated on a dry basis) and the sulfur dioxide content is not more than 40 mg/kg. If the product bears a name descriptive of its kind or origin, e.g., "corn syrup", "grain sorghum syrup", it must correspond thereto. (21 CFR 168.120)

Ingredient Definitions Committee Report 2

February 12, 2016

IDC recommendations to the Board and Association Members. *Text for the OP is in attachment A at the end of this document. This document is 44 pages long, please consider not printing it to review.*

- 1) Publish the tentative definition in the OP for T33.21 Yellow Grease, Feed Grade.
- 2) Replace the current definition of 87.1 Algae Meal with the official definition (from the color additive definition 21 CFR 73.275) in the OP of 87.1 Dried Algae Meal.
- 3) Add the new official definition (from the color additive definition 21 CFR 73.355) in the OP of 87.36 Phaffia Yeast.
- 4) Publish official definitions for the following color additives in the OP:
 - 87.100 FD&C Blue No 1.
 - 87.102 FD&C Blue No 2.
 - 87.103 FD&C Green No 3.
 - 87.104 FD&C Red No 3.
 - 87.105 FD&C Red No 40.
 - 87.106 FD&C Yellow No 6.
 - 87.107 FD&C Yellow No 5.
 - 87.110 Annatto Extract
 - 87.112 Astaxanthin dimethyldisuccinate
 - 87.114 Astaxanthin
 - 87.116 Caramel
 - 87.118 Carmine
 - 87.120 Carrot Oil
 - 87.122 Cochineal Extract
 - 87.124 Corn Endosperm Oil
 - 87.126 Dehydrated Beets
 - 87.128 Fruit Juice
 - 87.130 Haematococcus algae meal
 - 87.132 Paprika Oleoresin
 - 87.134 Paprika
 - 87.136 Paracoccus pigment
 - 87.138 Riboflavin
 - 87.140 Saffron
 - 87.142 Synthetic Iron Oxide
 - 87.144 Tagetes (Aztec Marigold) Extract
 - 87.145 Tagetes (Aztec Marigold) Meal
 - 87.146 Titanium Dioxide
 - 87.148 Toasted Partially Defatted Cooked Cottonseed Flour
 - 87.150 Tomato Lycopene Concentrate
 - 87.152 Tomato Lycopene Extract
 - 87.154 Turmeric Oleoresin
 - 87.155 Turmeric
 - 87.156 Ultramarine Blue
 - 87.158 Vegetable Juice
 - 87.160 β -Apo-8'-carotenal
 - 87.164 β -Carotene
- 5) Renumber Section 73 ingredients of the OP according to the list in attachment A, and leave the cross-reference to the old number there for 2 years and then remove cross-reference:
- 6) Publish the modified definition in the OP for 60.73 Salts of Volatile Fatty Acids.

Minutes of 2/12/2016 IDC Webinar Meeting

(Meeting was web-recorded and is posted in the Feed BIN.)

Role:

Committee Members: Bob Church, Jan Jarman (thinking of becoming a member), Richard Ten Eyck, Alan Harrison, April Hunt, Steve Gramlich, Charlotte Conway, David Dressler, Mark LeBlanc, Jacob Fleig, Mika Alewynse

Advisors: Leah Wilkinson, Kristi Smedley, Jean Hofve, Susan Thixton, David Meeker, Vince Sewalt, Mollie Morrissette

The meeting was convened at 8:30 am PST by Chairperson Ten Eyck.

1. Approve Minutes of last meeting
Steve Gramlich moves to ACCEPT the minutes from the January meeting. Jacob Fleig seconds. Motion PASSES.
2. Work Group Reports
 - a) AAFCO Affirmed GRAS workgroup report. Richard Ten Eyck informed the IDC that the GRAS Workgroup met this week to start drafting the survey requested at the January meeting; the Workgroup plans to complete the survey draft in the next two weeks or so. If any questions, please post these to IDC Team.
3. New Definitions, deletes & edits:
New Term: Animal Food – Ali Kashani and Charlotte Conway are working on this. Animal food is the more modern term and feed is a more historic term in FDA's vernacular. Having both terms defined is still desired. *Under consideration nothing was proposed or voted on in terms:*
 - a) **Animal food** – Food for animals other than humans and includes pet food, specialty pet food, nutritional supplements, raw materials and ingredients. No Motion
 - b) **Feed(s)** – Edible material(s) which are consumed by animals, other than humans, and contribute energy and/or nutrients to the animal's diet. (2016 OP pg 225) No Motion
 - c) T33.21 Yellow Grease, Feed Grade. Steve Gramlich moves to ACCEPT this definition. Jacob Fleig seconds. Dave Meeker said it is fine with NRA. Motion PASSES.
 - d) ~~List of standard food names from USDA – Richard need form~~
 - e) 87.1 Dried Algae Meal. Steve Gramlich moves to ACCEPT definition. Jacob Fleig seconds. Mika Alewynse explains that this is a more careful definition of this color ingredient and is the same language as is in the Color Additive definition. Motion PASSES.
 - f) 87.36 Phaffia yeast. Jacob Fleig moves to ACCEPT this color additive definition. Steve Gramlich seconds. Motion PASSES.
 - g) =====+ Accept as a group? ++++
Angel Thompson mentioned that some are misspelled, especially turmeric, and this was corrected. The purpose is to include most of the CFR-listed color additives (evaluated through the Color Additive Petition process) into the AAFCO OP; however, this is not the complete list because some of these additives are not accepted for use in animal food. Each regulation includes the CFR text so that firms will see the appropriate information. Mika Alewynse pointed out that there was a discrepancy in the regulation for canthaxanthin in that it is already defined in the OP as a special purpose ingredient. It is not included in this current list of color additives since Mika Alewynse is seeking clarification of this discrepancy.

Steve Gramlich moves to ACCEPT this group h) through qq) of official definitions. Jacob Fleig seconds. Motion PASSES.

- h) 87.100 FD&C Blue No 1.
- i) 87.102 FD&C Blue No 2.
- j) 87.103 FD&C Green No 3.
- k) 87.104 FD&C Red No 3.
- l) 87.105 FD&C Red No 40.
- m) 87.106 FD&C Yellow No 6.
- n) 87.107 FD&C Yellow No 5.
- o) 87.110 Annatto Extract
- p) 87.112 Astaxanthin dimethyldisuccinate
- q) 87.114 Astaxanthin
- r) 87.116 Caramel
- s) 87.118 Carmine
- t) 87.120 Carrot Oil
- u) 87.122 Cochineal Extract
- v) 87.124 Corn Endosperm Oil
- w) 87.126 Dehydrated Beets
- x) 87.128 Fruit Juice
- y) 87.130 Haematococcus algae meal
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- mm) 87.155 Turmeric
- nn) 87.156 Ultramarine Blue
- oo) 87.158 Vegetable Juice
- pp) 87.160 β -Apo-8'-carotenal
- qq) 87.164 β -Carotene
- rr) ++++++
- ss) Renumber section 73 transfers – Richard

Steve Gramlich moved to transfer the proposed ingredients into section 73 in the AAFCO OP, and to leave the cross-reference to the old number there for 2 years and then remove reference. Mark LeBlanc seconds. Motion passes. Many questions about these feed ingredients. Mika Alewynse thinks that the acidifiers list may be incomplete (e.g., benzoic acid is not listed).

- tt) 60.73- Salts of Volatile Fatty Acids- editorial change –Dave Dressler moves to approve this change; Mark LeBlanc seconds. Motion passes. Kristi Smedley pointed out that some definitions include the entire regulation and other definitions contain more limited text. What is the correct approach for the approved Food Additives? Charlotte Conway said that the specifications (heavy metals, etc) are missing from this definition. Richard Ten Eyck said that he will add the CFR reference and dates as now in the AAFCO OP.

4. Discussions:

- a) Hemp in Feed – Presentation on industrial hemp products, how they are made, how used, and typical product specifications was made by Timothy Bonnar of

Hemp Oil Canada. Charlotte Conway said that FDA is working on what is the appropriate regulatory path for hemp products. In Oregon, hemp is an undefined ingredient not allowed in animal food.

- a) ~~Values in Footer on Vitamin Table ; original source? Use human or animal bio-availabilities? – Tom~~
- b) ~~Montmorillonite update for Industry – Tom~~
- c) Fabricated Meat background information. Is a Feed Term needed? – Susan Thixton (TAPF) informed that this is commonly used as non-meat product in human food. Technology has progressed tremendously. They would like AAFCO to develop a definition to address that this product is used in pet foods and that consumers want to find out what is in it. Does AAFCO want to develop a definition? They need industry to provide comment. Susan Thixton will get together with Ali Kashani to discuss this matter and put together a path forward.
- d) Materials NOT suitable for animal feed list in the BIN or website. Richard Ten Eyck explained that the goal here is to assemble a list of what ingredients are not allowed. If it is not listed, does this mean that it is not allowed? Rather the point here is to include those substances that have been reviewed by the IDC and found to be not suitable for use in feed. Per Kristi Smedley, some of these ingredients are already listed in section 589 (?? Not in the OP) (Maybe this is in CFR but is not in the AAFCO). Both Kristi and Mika Alewynse pointed out that very few ingredients have been determined to be disallowed. Often ingredients are tabled pending further information requested from the Sponsor.

Richard Ten Eyck is considering holding another IDC meeting at the end of April, prior to the AAFCO Board Meeting in early May.

Needs Vice Chair.

Needs Investigators for NPN and for Collective Terms.

Meeting was adjourned 10 AM Pacific.
Minutes were accepted on 4/8/16 by evote

Attachment A for 2/12/16 IDC Meeting

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

60.73- Salts of Volatile Fatty Acids- Is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids/isovaleric, 2-methylbutyric and n-valeric. The contained ammonium or calcium salts of volatile fatty acids shall conform to the specifications in 21 CFR 573.914. It is used as a source of energy in dairy cattle feed. The label of the product shall bear adequate directions for use including statements expressing maximum use levels: For ammonium salts of volatile fatty acids—~~not to exceed 120 grams per head per day~~ *Not to exceed 160 grams per head per day* thoroughly mixed in dairy cattle feed as a source of energy; For calcium salts of volatile fatty acids—Not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy. (Proposed 1985, Adopted 1986, Amended xxxx) Reg 21 CFR 573.914

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

73.001 (old 73.1) Technical Additives table

Acidifiers (73.020- 029)

73.020 (87.26) Ammonium Formate

73.025 (87.27) Formic Acid

Antimicrobial Agents (73.030-039)

73.030 (old 87.15) Formaldehyde

Anticaking Agents (73.040-060)

73.040 (old 87.12) Bentonite

73.042 (old 87.28) Castor Oil

73.044 (old 87.17) Perlite

73.046 (old 87.3) Silicon Dioxide

73.048 (old 87.13) Sodium Bentonite

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

Binders (73.106-130)

73.107 (old 87.2) Lignin Sulfonate

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

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

Biofuel Production (73.090-104)

73.100 Yeast for Production of Distillers Products

Emulsifiers (73.200-220)

73.200 Xanthan gum

Floculants (73.221-240)

73.221 (old 87.16) Chitosan

73.223 (old 87.21) Kraft Lignin

Nutritional Diluents (73.241-249)

73.241 (old 87.18) Reed-Sedge Peat

Pelleting Aids (73.300–340)

73.305 (old 87.24) Hide Glue

73.307 (old 87.6) Rice By-Products Fractions

73.309 (old 87.19) Urea Formaldehyde Condensation Polymer

73.105 Sodium Hydroxide Lignin Dehydrated

Surfactants (73.341-360)

73.341 (old 87.10) Poloxalene

Thickening agents (73.370-390)

73.370 (old 87.23) Cassia Gum

moved 73.105,

can we double list in 2 or more use categories? –yes if the full definition is with it.

Delete the current language in 87.1 and replace it with:

87.1 Algae Meal – The color additive, algae meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) Identity.

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

(b) Uses and restrictions.

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

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

(2) The quantity of the color additive incorporated in the feed is such that the finished

feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this definition; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(c) Labeling.

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

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this definition.

(d) Exemption from certification.

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

21 CFR 73.275

Add these new Official Definitions:

87.36 Phaffia yeast – The color additive, phaffia yeast, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast *phaffia rhodozyma*.

(2) Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) Specifications.

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

Physical state, solid.

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

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

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

Heavy metals, not more than 10 parts per million.

Astaxanthin, not less than 0.4 percent.

(c) Uses and restrictions.

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

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) Labeling requirements.

(1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this definition.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing phaffia yeast shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 21 CFR 101.100(a)(2).

(e) Exemption from certification.

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

21 CFR 73.355 (adopted xxxxx)

87.100 FD&C Blue No. 1 – The color additive, FD&C Blue No. 1, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[p-[ethyl (m-sulfobenzyl) amino]- α -(o-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (m-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl [4-[p-[ethyl(p-sulfobenzyl) amino]- α -(o-sulfophenyl) benzylidene]- 2,5-cyclohexadien-1-ylidene] (p-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-

[p-[ethyl (o-sulfobenzyl) amino] - α - (o -sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (o-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for food use made with FD&C Blue No. 1 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.

FD&C Blue No. 1 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 current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of o-, m-, and p-sulfobenzaldehydes, not more than 1.5 percent.

N-Ethyl,N-(m-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.

Subsidiary colors, not more than 6.0 percent.

Chromium (as Cr), not more than 50 parts per million.

Manganese (as Mn), not more than 100 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Total color, not less than 85.0 percent.

(c) Uses and restrictions.

FD&C Blue No. 1 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(e) Certification.

All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in 21 CFR 80.21 CFR 74.101

87.102 FD&C Blue No. 2 – The color additive, FD&C Blue No. 2, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid (CAS Reg. No. 860-22-0) with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid (CAS Reg. No. 54947-75-0) and the sodium salt of 2-(1,3-dihydro-3-oxo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid (CAS Reg. No. 605-18-5). Additionally, FD&C Blue No. 2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of N-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation.

(2) Color additive mixtures for food use made with FD&C Blue No. 2 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.

The color additive FD&C Blue No. 2 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 current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid, not more than 18 percent.

Sodium salt of 2-(1,3-dihydro-3-oxo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid, not more than 2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

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

Total color, not less than 85 percent.

(c) Uses and restrictions.

The color additive FD&C Blue No. 2 may be safely used for coloring foods generally in amounts consistent with current good manufacturing practice except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(e) Certification.

All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in 21 CFR 80.21 CFR 74.102

87.103 FD&C Green No. 3 – The color additive, FD&C Green No. 3, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive FD&C Green No. 3 is principally the inner salt disodium salt of N-ethyl-N-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide (CAS Reg. No. 2353-45-9); with smaller amounts of the isomeric inner salt disodium salt of N-ethyl-N-[4-[[4-[ethyl[(3-sulfophenyl)methyl] amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; of N-ethyl-N-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide and of N-ethyl-N-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid with two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic acid, and smaller amounts of 4 [(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2'-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium 5-amino-2-formylbenzenesulfonate. This amine is diazotized and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) Color additive mixtures for food use made with FD&C Green No. 3 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 food.

(b) Specifications.

The color additive FD&C Green No. 3 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 current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.

Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.

2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.

Subsidiary colors, not more than 6 percent.

Chromium (as Cr), not more than 50 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

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

Total color, not less than 85 percent.

(c) Uses and restrictions.

The color additive FD&C Green No. 3 may be safely used for coloring foods generally in amounts consistent with current good manufacturing practice except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(e) Certification.

All batches of FD&C Green No. 3 shall be certified in accordance with regulations in 21CFR 80.21 CFR 74.203

87.104 FD&C Red No. 3 – The color additive, FD&C Red No. 3, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (o-carboxyphenyl)-6-hydroxy - 2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imidinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red No. 3 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.

FD&C Red No. 3 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:

Volatile matter (at 135 °C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

Unhalogenated intermediates, total not more than 0.1 percent.

Sodium iodide, not more than 0.4 percent.

Triiodoresorcinol, not more than 0.2 percent.

2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

Monoiodofluoresceins not more than 1.0 percent.

Other lower iodinated fluoresceins, not more than 9.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 87.0 percent.

(c) Uses and restrictions.

FD&C Red No. 3 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(e) Certification.

All batches of FD&C Red No. 3 shall be certified in accordance with regulations in 21 CFR 80.21 CFR 74.303

87.105 FD&C Red No. 40 – The color additive, FD&C Red No. 40, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 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.

(3) The listing of this color additive includes lakes prepared as described in 21 CFR 82.51, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by 21 CFR 82.51.

(b) Specifications.

FD&C Red No. 40 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:

Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than 1.0 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.

4-Amino-5-methoxy-o- toluenesulfonic acid, not more than 0.2 percent.

Disodium salt of 6,6'-oxybis (2-naphthalene-sulfonic acid), not more than 1.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85.0 percent.

(c) Uses and restrictions.

FD&C Red No. 40 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice except that 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.

(d) Labeling.

The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25

(e) Certification.

All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in 21 CFR 80.21 CFR 74.340

87.106 FD&C Yellow No. 6 – The color additive, FD&C Yellow No. 6, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

- (1) The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783-94-0). The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880-65-4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid which may be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid.
- (2) Color additive mixtures for food use made with FD&C Yellow No. 6 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.

The color additive FD&C Yellow No. 6 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 current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water insoluble matter, not more than 0.2 percent.

Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.

Disodium salt of 6,6'-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.

Disodium salt of 4,4'-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.

Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid, not more than 1 percent.

Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5 percent.

4-Aminoazobenzene, not more than 50 parts per billion.

4-Aminobiphenyl, not more than 15 parts per billion.

Aniline, not more than 250 parts per billion.

Azobenzene, not more than 200 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

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

Total color, not less than 87 percent.

(c) Uses and restrictions.

The color additive FD&C Yellow No. 6 may be safely used for coloring foods generally in amounts consistent with current good manufacturing practice, except that 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.

(d) Labeling requirements.

- (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25 of this chapter.

(e) Certification.

All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in 21 CFR 80.21 CFR 74.706

87.107 FD&C Yellow No. 5 – The color additive, FD&C Yellow No. 5, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[4-sulfophenyl-azo]-1H-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 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.

FD&C Yellow No. 5 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:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1H-pyrazol-1,3-diy]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.

4-[(4',5-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1H-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

4,4'-(1-Triazene-1,3-diy)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminobiphenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

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

Total color, not less than 87 percent.

(c) Uses and restrictions.

FD&C Yellow No. 5 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that 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.

(d) Labeling requirements.

The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(e) Certification.

All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in 21 CFR 80.21 CFR 74.705

87.110 Annatto extract – The color additive, annatto extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana L.*, using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this definition:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this definition. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only 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 in color additive mixtures for coloring foods.

(b) Specifications.

Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead (as Pb), not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this definition are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in 21 CFR 170 through 189.

(c) Uses and restrictions.

Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25. Labels shall bear information showing that the color is derived from annatto seed. The requirements of 21 CFR 70.25(a) that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this definition.

(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 73.30

87.112 Astaxanthin dimethyldisuccinate – The color additive, astaxanthin dimethyldisuccinate, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

a) Identity.

(1) The color additive astaxanthin dimethyldisuccinate is 3,3'-bis(4-methoxy-1,4-dioxobutoxy)- β,β -carotene-4,4'-dione.

(2) Astaxanthin dimethyldisuccinate may be added to the fish feed only as a component of a stabilized mixture. Color additive mixtures for fish feed use made with astaxanthin dimethyldisuccinate may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) Specifications.

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

(1) Physical state, solid.

(2) 0.05 percent solution in chloroform, complete and clear.

(3) Absorption maximum wavelength 484-493 nanometers (in chloroform).

(4) Residue on ignition, not more than 0.1 percent.

(5) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than 4 percent.

(6) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million).

(7) Arsenic, not more than 2 mg/kg (2 parts per million).

(8) Mercury, not more than 1 mg/kg (1 part per million).

(9) Heavy metals, not more than 10 mg/kg (10 parts per million).

(10) Assay including astaxanthin dimethyldisuccinate, astaxanthin monomethylsuccinate, and astaxanthin, minimum 96 percent.

(c) Uses and restrictions.

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

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin dimethyldisuccinate in the finished feed, when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 110 milligrams per kilogram (mg/kg), which is equivalent to 80 mg/kg astaxanthin (72 grams per ton).

(d) Labeling requirements.

(1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this definition.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.

87.114 Astaxanthin – The color additive, astaxanthin, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive astaxanthin is 3, 3'-dihydroxy- β,β -carotene-4, 4'-dione.

(2) Astaxanthin may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) Specifications.

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

Physical state, solid.

0.05 percent solution in chloroform, complete and clear.

Absorption maximum wavelength 484-493 nanometers (in chloroform).
Residue on ignition, not more than 0.1 percent.
Total carotenoids other than astaxanthin, not more than 4 percent.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Assay, minimum 96 percent.

(c) Uses and restrictions.

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

- (1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.
- (2) The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) Labeling requirements.

- (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this definition.
- (2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
- (3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with 21 CFR 101.22(k)(2) and 21 CFR 101.100(a)(2).

(e) Exemption from certification.

Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.
21 CFR 73.35

87.116 Caramel – The color additive, caramel, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

a) Identity.

- (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:
 - Dextrose.
 - Invert sugar.
 - Lactose.
 - Malt syrup.
 - Molasses.
 - Starch hydrolysates and fractions thereof.
 - Sucrose.
- (2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.
 - (i) Acids: acetic acid, citric acid, phosphoric acid, sulfuric acid, and sulfurous acid.
 - (ii) Alkalis: ammonium hydroxide, calcium hydroxide U.S.P., potassium hydroxide, and sodium hydroxide.
 - (iii) Salts: ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.
- (3) Polyglycerol esters of fatty acids, identified in part 172.854 of Title 21 of the Code of Federal Regulations (21 CFR 172.854), may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(b) Specifications.

Caramel shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 0.1 part per million.

(c) Uses and restrictions.

Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(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 Federal Food, Drug, and Cosmetic Act.

21 CFR 73.85

87.118 Carmine – The color additive, carmine, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)).

(2) Color additive mixtures for food use made with carmine may contain only 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 in color additive mixtures for coloring foods.

(b) Specifications.

Carmine shall conform to the following specifications:

Volatile matter (at 135 °C. for 3 hours), not more than 20.0 percent.

Ash, not more than 12.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Carminic acid, not less than 50.0 percent.

Carmine shall be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this definition, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine free of viable *Salmonella* microorganisms, which substances are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

(c) Uses and restrictions.

Carmine may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they 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.

(d) Labeling requirements.

The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(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 73.100

87.120 Carrot Oil – The color additive, carrot oil, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota L.*) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carotenoids naturally occurring in carrots. The definition of carrot oil in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or carrot oleoresin under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.

Carrot oil shall contain no more than 25 parts per million of hexane.

(c) Uses and restrictions.

Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(d) Labeling requirements.

The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(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 73.300

87.122 Cochineal extract – The color additive, cochineal extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal (*Dactylopius coccus costa (Coccus cacti L.)*). The coloring principle is chiefly carminic acid.

(2) Color additive mixtures for food use made with cochineal extract may contain only 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 in color additive mixtures for coloring foods.

(b) Specifications.

Cochineal extract shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25 °C.

Protein (N × 6.25), not more than 2.2 percent.

Total solids, not less than 5.7 and not more than 6.3 percent.

Methyl alcohol, not more than 150 parts per million.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Carminic acid, not less than 1.8 percent.

Cochineal extract shall be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of

pasteurization or other treatment used. For the purposes of this definition, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the cochineal extract free of viable *Salmonella* microorganisms, which substances are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

(c) Uses and restrictions.

Cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they 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.

(d) Labeling requirements.

The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(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 73.100

87.124 Corn Endosperm Oil – The color additive, corn endosperm oil, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of a color additive only and shall not be construed as a food standard of identity under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.

Corn endosperm oil conforms to the following specifications:

Total fatty acids, not less than 85 percent.

Iodine value, 118 to 134.

Saponification value, 165 to 185.

Unsaponifiable matter, not more than 14 percent.

Hexane, not more than 25 parts per million.

Isopropyl alcohol, not more than 100 parts per million.

(c) Uses and restrictions.

The color additive corn endosperm oil may be safely used in chicken feed in accordance with the following prescribed conditions:

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

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this definition.

(d) Labeling requirements.

The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by 21 CFR 70.25, a statement of the concentration of xanthophyll contained therein.

(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 73.315

Editing note: The existing definition for corn endosperm oil in definition 33.6 should be deleted when this definition is added to the Official Publication. The current definition in the OP refers to an outdated regulation. The current regulation for corn endosperm oil can be found in 21 CFR 73.315.

87.126 Dehydrated Beets – The color additive, dehydrated beets, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring foods.

(b) Specifications.

The color additive shall conform to the following specifications:

Volatile matter, not more than 4 percent.

Acid insoluble ash, not more than 0.5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

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

(c) Uses and restrictions.

Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements 21 CFR 70.25.

(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 73.40

87.128 Fruit Juice – The color additive, fruit juice, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the Federal Food, Drug, and Cosmetic Act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.

Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(c) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) Exemption from certification.

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

21 CFR 73.250

87.130 Haematococcus algae meal – The color additive, Haematococcus algae meal, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis*.

(2) Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) Specifications.

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

Physical state, solid.

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

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

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

Heavy metals, not more than 10 parts per million.

Astaxanthin, not less than 1.5 percent.

(c) Uses and restrictions.

Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) Labeling requirements.

(1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this definition.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing haematococcus algae meal 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 73.185

87.132 Paprika Oleoresin – The color additive, paprika oleoresin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (*Capsicum annuum L.*) by extraction, using any one or a combination of the following solvents: acetone, isopropyl alcohol, ethyl alcohol, methyl alcohol, ethylene dichloride, methylene chloride, hexane, and trichloroethylene.

The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.

Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this definition than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in 21 CFR 170 through 189.

(c) Uses and restrictions.

Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(d) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25 of this chapter.

(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 345

87.134 Paprika – The color additive, paprika, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum L.*). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.

Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(c) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25 of this chapter.

(d) Exemption from certification.

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

21 CFR 340

87.136 Paracoccus Pigment – The color additive, paracoccus pigment, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive paracoccus pigment consists of the heat-killed, dried cells of a nonpathogenic and nontoxicogenic strain of the bacterium *Paracoccus carotinifaciens* and may contain added calcium carbonate to adjust the astaxanthin level.

(2) Color additive mixtures for fish feed use made with paracoccus pigment may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) Specifications.

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

(1) Physical state, solid.

(2) Lead (as Pb), not more than 5 milligrams per kilogram (mg/kg) (5 parts per million (ppm)).

(3) Arsenic (as As), not more than 2 mg/kg (2 ppm).

(4) Mercury (as Hg), not more than 1 mg/kg (1 ppm).

(5) Heavy metals, not more than 10 mg/kg (10 ppm).

(6) Astaxanthin, not less than 1.75 percent.

(c) Uses and restrictions.

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

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from paracoccus pigment when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 mg/kg (72 grams per ton) of finished feed.

(d) Labeling requirements.

(1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this definition.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing paracoccus pigment 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 352

Editing note: The existing listing of Paracoccus pigment in Table 87.5 should be deleted when this definition is added to the Official Publication.

87.138 Riboflavin – The color additive, riboflavin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 262-263, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring foods.

(b) Specifications.

Riboflavin shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this definition.

(c) Uses and restrictions.

Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice; except that 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 the use of added color is authorized by such standards.

(d) Labeling.

The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(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 73.450

87.140 Saffron – The color additive, saffron, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive saffron is the dried stigma of *Crocus sativus L.* The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.

Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(c) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) Exemption from certification.

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

21 CFR 73.500

87.142 Synthetic Iron Oxide – The color additive, synthetic iron oxide, may be safely used in the manufacture of dog and cat foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this 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.

Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

- Arsenic (as As), not more than 5 parts per million.
- Lead (as Pb), not more than 20 parts per million.
- Mercury (as Hg), not more than 3 parts per million.

(c) Uses and restrictions.

Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) Labeling requirements.

The label 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.

(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 73.200

87.144 Tagetes (Aztec Marigold) Extract – The color additive, tagetes (Aztec marigold) extract, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) Identity.

The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (*Tagetes erecta L.*). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) Specifications.

Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals free from admixture with other plant material from *Tagetes erecta L.* or from plant material or flowers of any other species of plants and shall conform to the following additional specifications:

Melting point: 53.5 – 55.0 °C

Iodine value: 132 – 145

Saponification value: 175 – 200

Acid value: 0.60 – 1.20

Titer: 35.5 – 37.0 °C

Unsaponifiable matter: 23 percent – 27 percent

Hexane residue: not more than 25 p.p.m.

All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60 °C. for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(c) Uses and restrictions.

The color additives tagetes (Aztec marigold) extract may be safely used in chicken feed in accordance with the following prescribed conditions:

- (1) The color additive is used to enhance the yellow color of chicken skin and eggs.
- (2) The quantity of the color additive incorporated in the feed is such that the finished

feed:

- (i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this definition; and
- (ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(d) Labeling requirements.

The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required 21 CFR 70.25:

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

(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 73.295

Editing note: The existing listing of Tagetes (Aztec Marigold) Meal and Extract in Table 87.5 should be deleted when this definition is added to the Official Publication.

87.145 Tagetes (Aztec Marigold) Meal – The color additive, tagetes (Aztec marigold) meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) Identity.

The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(b) Specifications.

Tagetes (Aztec marigold) meal is free from admixture with other plant material from *Tagetes erecta* L. or from plant material or flowers of any other species of plants.

(c) Uses and restrictions.

The color additive tagetes (Aztec marigold) meal may be safely used in chicken feed in accordance with the following prescribed conditions:

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

(2) The quantity of the color additive incorporated in the feed is such that the finished

feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this definition; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(d) Labeling requirements.

The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required 21 CFR 70.25:

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this definition.

(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 73.295

Editing note: The existing listing of Tagetes (Aztec Marigold) Meal and extract in Table 87.5 should be deleted when this definition is added to the Official Publication.

87.146 Titanium Dioxide – The color additive, titanium dioxide, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive titanium dioxide is synthetically prepared TiO₂, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide 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 in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO₂ and/or aluminum oxide, Al₂O₃, as dispersing aids—not more than 2 percent total.

(b) Specifications.

Titanium dioxide shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.
Antimony (as Sb), not more than 2 parts per million.
Mercury (as Hg), not more than 1 part per million.
Loss on ignition at 800 °C. (after drying for 3 hours at 105 °C.), not more than 0.5

percent.

Water soluble substances, not more than 0.3 percent.

Acid soluble substances, not more than 0.5 percent.

TiO₂, not less than 99.0 percent after drying for 3 hours at 105 °C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(c) Uses and restrictions.

The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) 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.

(d) Labeling.

The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(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 73.575

87.148 Toasted Partially Defatted Cooked Cottonseed Flour – The color additive, toasted partially defatted cooked cottonseed flour, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable and that are listed in this part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.

Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

Arsenic (as As): It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

Lead (as Pb), not more than 10 parts per million.

Free gossypol content, not more than 450 parts per million.

(c) Uses and restrictions.

The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(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 73.140

87.150 Tomato Lycopene Concentrate – The color additive, tomato lycopene concentrate, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive tomato lycopene concentrate is a powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate and then evaporating off the solvent.

(2) Color additive mixtures made with tomato lycopene concentrate may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring food.

(b) Specifications.

Tomato lycopene concentrate shall conform to the following specifications: Lycopene, not less than 60 percent of oleoresin as determined by the method entitled "Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC)," S.O.P. number : Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

(c) Uses and restrictions.

Tomato lycopene concentrate may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) Labeling.

The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(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 73.585

87.152 Tomato Lycopene Extract – The color additive, tomato lycopene extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive tomato lycopene extract is a red to dark brown viscous oleoresin extracted with ethyl acetate from tomato pulp followed by removal of the solvent by evaporation. The pulp is produced from fresh, edible varieties of the tomato by removing the liquid. The main coloring component is lycopene.

(2) Color additive mixtures made with tomato lycopene extract may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring food.

(b) Specifications.

Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5 percent of oleoresin as determined by the method entitled "Qualitative Analysis of Lycopene, Its

Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC)," S.O.P. number : Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

(c) Uses and restrictions.

Tomato lycopene extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) Labeling.

The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(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 73.585

87.154 Turmeric Oleoresin – The color additive, turmeric oleoresin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (*Curcuma longa* L.) by extraction using any one or a combination of the following solvents: acetone, isopropyl alcohol, ethyl alcohol methyl alcohol, ethylene dichloride, methylene chloride, hexane, and trichloroethylene.

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.

Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this definition than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in 21 CFR parts 170 through 189.

(c) Uses and restrictions.

Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(d) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of 21 CFR 70.25.

(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 73.615

87.155 Turmeric – The color additive, turmeric, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

a) Identity.

(1) The color additive turmeric is the ground rhizome of *Curcuma longa* L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.

Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(c) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) Exemption from certification.

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

21 CFR 73.600

87.156 Ultramarine Blue – The color additive, ultramarine blue, may be safely used to color salt intended for animal foods in accordance with the following prescribed conditions:

(a) Identity.

The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700 °C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $\text{Na}_7\text{Al}_6\text{Si}_6\text{O}_{24} \text{S}_3$.

(b) Specifications.

Ultramarine blue shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

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

(c) Uses and restrictions.

The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) Labeling requirements.

The color additive shall be labeled in accordance with the requirements of part 70.25 of Title 21 of the Code of Federal Regulations (21 CFR 70.25).

(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 73.50

87.158 Vegetable Juice – The color additive, vegetable juice, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried

vegetable. The color additive may be concentrated or dried. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the Federal Food, Drug, and Cosmetic Act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.

Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that 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 the use of added color is authorized by such standards.

(c) Labeling.

The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) Exemption from certification.

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

21 CFR 73.260

87.160 β -apo-8'-carotenal – The color additive, β -apo-8'-carotenal, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive is β -apo-8'-carotenal.

(2) Color additive mixtures for food use made with β -apo-8'-carotenal may contain only 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 in color additive mixtures for coloring foods.

(b) Specifications.

β -Apo-8'-carotenal shall conform to the following specifications:

Physical state, solid.

1 percent solution in chloroform, clear.

Melting point (decomposition), 136 °C.-140 °C. (corrected).

Loss of weight on drying, not more than 0.2 percent.

Residue on ignition, not more than 0.2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Assay (spectrophotometric), 96-101 percent.

(c) Uses and restrictions.

The color additive β -apo-8'-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β -apo-8'-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(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 73.90

87.164 β -Carotene – The color additive, β -carotene, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive is β -carotene prepared synthetically or obtained from natural sources.

(2) Color additive mixtures for food use made with β -carotene may contain only 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 in color additive mixtures for coloring foods.

(b) Specifications.

β -carotene shall conform to the following specifications:

Physical state, solid.

1 percent solution in chloroform, clear.

Loss of weight on drying, not more than 0.2 percent.

Residue on ignition, not more than 0.2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Assay (spectrophotometric), 96-101 percent.

(c) Uses and restrictions.

The color additive β -carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those 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.

(d) Labeling.

The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(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 73.95

Inspection and Sampling Committee Report/Minutes

2016 AAFCO Midyear Meeting
Wild Dunes Resort
Isle of Palms, South Carolina
Monday, January 18, 2015
11:00 am – 12:00 pm

Committee Recommendations

(1) None

Board Recommendations

Board recommendation summary or list.

(1) None

Association Actions

Association action summary or list.

(1) None

Committee Participants

Members Present:

Bob Church (MT)
Barb Schroeder (MN)
Jim True (KY)
Stan Cook (MO)
Mark Glover (FDA)
Kevin Klommhaus (FDA)
Meagan Davis (LA)
Dan Danielson (TN)
Chad Linton (WV)
Mike Davis (CA)
Bob Geiger (IN)
Brett Groves (IN)
Judy Thompson (CFIA)
Jim Fear (FDA)
Shaness Thomas (FL)

Members on Phone:

Liz Higgins (NM) and others

Advisors Present:

Jan Campbell (NGFA)
Marty Smith (AFIA)
Pat Tovey, PFI
Chris Olinger, NGFA

Committee Report

AITs:

The AITs agenda needs to be standardized and aligned with the requirements of Animal Feed Regulatory Programs Standard 2: Training and a cadre identified.

FSMA Implementation:

Discussion on potential AAFCO Inspector Manual revisions needed
Add section regarding Bio-security – submitted to ISC Chair

Aseptic Sampling – training need identified

Risk-based Inspections

Overview of MN Risk informed inspection targeting pilot project

California has a risk ranking model as well

It is possible that the Committee can standardize the format for a model that can be used by the AAFCO Membership

Previous Action Item Table:

Need to identify what GoodSamples Concepts should be incorporated into IM.

Other Business:

Nancy Thiex requested for 3 to 5 feed program representatives to participate in the Centers of Excellence for Laboratories.

Committee Activities

ACTION: None

Sub-Committee Activities

ACTION: None

Committee Minutes

See Committee Report.

Action Item Table

Responsible	Item	Action	Timing / Status
Committee	Future Sampling Studies	Proposal	By Annual
Danielson	Defensible Sampling Concepts	Survey Committee as to priorities to address	By Annual
Krieger/ Lueders/ Areias	Questionnaire for Risk-Based Inspections	Make questionnaires available for states that wish to have it	As requested
True	Inspector Manual	Review manual to ensure it lines up with FSMA	No deadline established
Danielson	Biosecurity	Must be available for vote at Annual	30 days prior to Annual Meeting

Laboratory Methods and Services Committee Report/Minutes

AAFCO Midyear Meeting
January 19, 2016
8:00 am to 5:00 pm
Isle of Palms, SC

Committee Recommendations:

1. None

Board Recommendations:

1. None
- 2.

Association Actions:

1. None
- 2.

Committee Participants: (C *Committee members, ** Advisors)

Aaron Price*	Canadian Food Inspection Agency	aaron.price@inspection.gc.ca
Nancy Thiex*	TLS / AAFCO Consultant	nancy.thiex@gmail.com
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Srinu Chianrupah	FDA	Srinivasulu.chianrupah@fda.hhs.gov
Lisa Ruiz	Eurofins	LisaRuiz@eurofinus.com
Jennifer Turpin	Mars PetCare	Jennifer.Turpin@effem.com
Lawrence Novotny	SD Dept. of Ag. – Retired	Lawrence.Novotny@sdaglabs.com
Kyle Bennett	Neogen Corp.	kbennett@neogen.com
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Michael Prinster	Romer Labs	Michael.prinster@romerlabs.com
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Melissa Miller**	Covance Laboratories	melissa.miller@covance.com
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Robert Sheridan*	New York Dept. of Ag	Robert.sheridan@agriculture.ny.gov
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Alex MacDonald**	Pharma Science	beemac201@aol.com
Deepika Curole*	LA Dept. of Ag and Forestry	dcurole@ldaf.state.la.us
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H. Dorota Inerowicz*	Office of Indiana State Chemist	inerowic@purdue.edu
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Ivy Bevill	FDA	Ivy.bevill@fda.hhs.gov
Patty Lucas	Florida Dept. of Ag. & Consumer Serv.	patricia.lucas@freshfromflorida.com

Committee Report:

• **Committee Activities**

ACTION: Motion passes, all in favor

MOTION: “Motion to accept the Best Practices working group’s phosphorus white paper and method matrix as complete.” (L. Novotny move, M. Stenske second)

Committee Minutes:

- Committee attendees introduced themselves. Sign-up sheet was sent around and verified the Webex was working.
- The Laboratory Methods and Services Committee (LM&SC) membership roster and industry advisor list was reviewed and A. Price indicated new appointments. A. Price reminded

Committee Members that they should be active participants due to the size of the committee. People wishing to be added or eliminated from the list should contact A. Price.

- FSMA Implementation Task Force reps for our committee are Teresa Grant and Robert Sheridan. The task force will be meeting on Wednesday, January 20. They will be looking at the needs and if or what methods need to be developed.
- Working Group updates:
 - Tylosin WG – Tom Phillips was absent, no update from him. Tom has started acting as the State Chemist for Maryland and no longer has time to devote to this work. He is looking for another lab to chair this working group, but he would still like to be involved. M. Miller from Covance Laboratories said that her lab has done some work on tylosin. Getting all homologues of tylosin (A, B, C, D and urea adduct) is the challenge. Residue methods need only identify tylosin A to be effective (CFIA method).
 - CTC WG – Similar to above, Tom Phillips no longer has time to move this project forward and is looking for someone else to chair the group. Concerns were raised that laboratories don't have access to UPC² and super critical fluid systems. Also, Greg Hoffman (Zoetis) raised concerns with the limits in FDA – Guide 135 that they are too tight down at drug levels seen in type C feeds. Leo Schilling (Eurofins) volunteered to chair the CTC working group going forward. A Price to provide him with T. Phillips contact info.
 - Fat Soluble vitamins WG – Chairs (K. Riter and D. Inerowicz) reported that 9 samples were sent out to 11 labs for Vitamin A, 8 labs for Vitamin E. The reproducibility and repeatability were very high on these results and wider than typical AAFCO results. They compared the results to the sample weight used for each lab and saw some correlation, but it wasn't definitive. The working group had a conference call in November to discuss where to go next. The group decided it would be a good idea to send more homogeneous samples to the labs, such as infant formula and cheese products (processed cheese slices). The working group would welcome suggestions on where to go next. Discussion from the committee agreed that an increased sample size would probably improve reproducibility. Also, some thought it might not be realistic for one method to cover all vitamin levels in feed. The working group will go forward with a more uniform sample and sample prep and try to have the labs analyze a uniform sample size.
 - Best Practices WG – Sharon Webb and Lawrence Novotny presented to the committee a white paper on best practices guidelines for phosphorus and a method matrix for various sample types, which will be added to the LM&SC website. An article in JAOAC (50) pg 137, 1975, stated that dry ashing mineral mixes results in low recoveries, which may be why some of the higher concentration samples in the AAFCO check sample program have had issues. The information from this article will be added to the white paper and method matrix. The committee voted that the phosphorus best practices guidelines are complete and the working group should move on to another analysis. After discussion, the committee decided fiber (crude, ADF and NDF) would be next. There will be a call sent out by A. Price and S. Webb to the membership calling for experts to join the working group.
 - Sugars (mono- and disaccharide) WG – J. Horst reported that the single laboratory validation was performed by Covance. They complete a paper that has been reviewed and is about to be published on the AOAC website through their Fast Track process. The working group is looking for a sponsor (preferably affiliated) to move the method through to a full collaborative study. Some of the committee raised concerns that not enough labs have the required technology. A solution to this could be to open the collaborative study up to food matrices.

- Mycotoxin WG – Robert Sheridan reported that the working group has sent out AAFCO mycotoxin check samples (201461, 201462, 201463, and 201464) to labs, but is still waiting for results. They are considering removing aflatoxin G1 and G2 from the study, since those can't be spiked into the samples. By next meeting they will have mycotoxin results from each lab using their own individual methods. R. Sheridan also reported that the European Commission has completed a collaborative study for mycotoxin in feed. The only lab that participated from our WG was Romer Labs. The method analyzes for 18 mycotoxins, 13 in positive mode and 5 in negative mode using a single extraction. They matrix match and use isotope labelled standards and can achieve >85% recovery for all mycotoxins. This method is similar to what New York State has been working on and is close to meeting the mycotoxin method needs statement, including matrices required. The working group needs to consider whether this method is fit for the group's needs, since it has already been through a collaborative study. Should this working group join with the European group?
 - Quality Assurance WG – Brenda Snodgrass and Louise Ogden were not able to attend but sent in a brief update to Nancy. Currently, the group is working on clarifying recommendations on water conductivity testing frequency. It has been recommended that this working group be made a sub-committee under the LM&SC. The LM&SC chairs agree with this proposal, which will make the working group permanent. Both Brenda and Louise must resign as chairs of the working group since they will be taking on the quality management of the AAFCO check sample program. Srinu Chigurupati (FDA) volunteered to be a chair of the sub-committee and Teresa Grant from NC State volunteered to be a co-chair. Assisting State labs to become ISO accredited and other aspects of lab quality assurance will be the mandate of the new sub-committee.
 - Sampling WG – The group (~12 members) is revising the AAFCO Sample Preparation Guidelines for laboratories to be in line with the recently published GOODSamples document. Areas such as sample splitting, explanation of minimum mass, sample quality criteria, etc. will be a total re-write from the previous version. The group hopes to have a draft out about a year from now. An early draft without examples may be available in August. There will be a workshop of sample preparation at the 2016 Mid-West AOAC meeting in Sioux Falls, SD. There will be a hands-on portion to the workshop and vendor equipment to try. The working group will contact the Inspection Sampling Committee to try to create some linkages and start a dialogue. This will be a challenge since the two groups do not speak the same language.
 - Multi-Element Validation – R. Sheridan presented the validation data for toxic levels of minerals in pet and livestock food by ICP-MS using microwave digestion. Samples tested were wheat flour, tomato leaves, feed scratch, poultry feed, medicated sheep concentrate. The sample size was 0.25 to 0.5 grams with 2 mL of acid used. Some on the committee expressed concerns that this was quite a small sample size and could be the reason for some reproducibility values being larger than what might be expected. The lab is looking into cryogrinding 10 grams down to 0.5 grams. Sharon Webb shared with R. Sheridan her lab's digestion procedure. The next steps will be to start a working group that could work towards completing a collaborative study, and to review the method needs statement. Some other matrices that could be tested are rice flour and fish meal. Also, it was noted that a multi-element method was published as AOAC 2015.01.
- Upcoming Collaborative Studies and New Method Needs

There are several methods and method needs that are in the queue. 2012 was the last time that a survey was sent to the Ag community requesting a method needs ranking. Currently, there are more methods in the pipeline than volunteers to take them on. The FSMA task force will eventually identify priority method needs. Fructans will need to be worked on after the sugars method is complete. A vitamin D LC-MS/MS method exists and it can be compared against the method needs statement. If anyone is interested in reviewing the list of method needs, it is posted on the AAFCO website, under the Laboratory tab as follows:

<http://www.aaftco.org/Regulatory/Committees/Laboratory-Methods-and-Services#method-needs>

- **Laboratory Curriculum Framework**
Craig Kaml presented on the laboratory curriculum framework for State feed and food labs. The framework is organized into levels: entry, mid, expert, supervisor/manager, and senior manager. It can be used as a career ladder or path, identifying the competencies required to move between levels. A conceptual overview of the framework can be found at:
<http://incs.ifpti.org/frameworks/Home>. The framework will have links to courses and ways to evaluate training. More information can be found at <http://incs.ifpti.org>.
- **FDA Cooperative Agreement:**
 - Update from Teresa Bills: There are 24 openings and 20 States have applied for grant funding. The goal is to get all labs ISO accredited and to continue to expand the program.
 - Ruiqing Pamboukian (FDA) presented on the Office of Regulatory Science (ORS) and the FERN network. She outlined the benefits of accreditation as 1) reliable and defensible data, 2) provides decision makers with confidence, and 3) establishing and implementing national standards. The ORS has a State mentor/mentee program which has many benefits such as strong collaboration among partners, enhanced state to state relationships, increased number of accredited food/feed testing laboratories, and building a strong national integrated food/feed safety system. The vision for the future is to promote lab accreditation and best practices, improve MFRPS and AFRPS, maintain a National Surveillance Program, use State data for regulatory action, and faster and more effective response to food safety events.
 - Robyn Pyle presented on APHL activities. She indicated there are 31 labs working on ISO Accreditation. APHL is looking to expand to fertilizer, FIFRA and radiation labs. Currently, APHL has 12 working groups with over 70 members. They are also looking at how to sustain the program after the funding sunsets. A lot of resources on training and discussion forums can be found at www.APHL.org. There is a public site as well as a member site. The member site requires a login and has usable examples of documents from labs.
- **Promotion of Resources for Labs:**
 - Nancy Thiex informed the committee that there is a presentation that provides a good overview of AAFCO and the Check Sample Program available in the Feed Bin website. This presentation can be used to promote AAFCO and its lab relevant activities to other groups and committees.
 - Nancy Thiex reported on the completed GOODSamples document that is a free download from the AAFCO website. The objective of GOODSamples is to improve analytical data equivalency amongst laboratories by outlining a scientific and systematic approach to the sampling process. There are several outreach efforts that the

GOODSamples working group is involved in, such as webinars, training events, presentations (at AOAC, BERM, MFRPA, Southwest Nutrition conference, etc), and papers. A four day training event will take place in early April, location TBD and possibly in other States at a later time. Also, the Midwest AOAC will host a 1 day sampling seminar.

- Other Topics:
 - Laboratory Centres of Expertise: A. Price and N. Thiex informed the committee on having a network of laboratories with specific expertise in certain chemistry testing areas so that the full range of FSMA contaminants can be covered more efficiently and cost-effectively. Many private laboratories are set up this way. State labs often use this system informally, if they can find a lab to do a test that they can't. The proposal is to formalize the system with some sort of agreement. Many details need to be worked out. The committee co-chairs will be presenting a white paper outlining this concept to the AAFCO BOD on Jan. 20, 2016. The white paper will ask the board to set up a working group comprised of AAFCO members from several different committees, including the LM&SC. The working group would examine the feasibility of setting up this sort of agreement and what it might look like. Initial discussions with the BOD on Jan 17 were positive.
 - Education and Training committee liaison update: Mark Stenske reported is our committee liaison and reported on this activity. Currently, it is felt that the relationship between our committee and Education and Training is under-utilized. There will be a survey sent around to identify what are the training needs. Once some training needs have been identified, the Education and Training committee could help facilitate this.
 - CFIA Method Update on Organic Arsenicals: Lise-Anne Prescott (CFIA) presented her lab's new method to determine arsenillic acid, roxarsone and nitarsone residues in feed. There were several challenges encountered along the way, e.g. dirty extracts, co-elution of interferences, and IS linearity. Their current method uses LC-MS/MS in negative ionization mode. The mobile phase and extraction solutions have been optimized and method validation has been completed.
 - Measurement uncertainty (MU) in Protein Combustion method: Heidi Hikes presented her lab's uncertainty budget for their protein analysis method. They used AAFCO check sample data points from over a year of testing, on different instruments with different analysts to obtain the analytical MU. They also attempted to estimate the sample preparation MU by performing replicate splits and replicate weighings for each split. This gave a robust uncertainty estimate for their method and outlined a good approach to incorporate sample prep uncertainty.
 - Multi-mycotoxin LC-MS/MS method by Romer Labs: Michael Prinster from Romer Labs presented their LC-MS/MS method for analyzing mycotoxins. Their method uses isotope labelled internal standards (IS) to correct for suppression and enhancement. For compounds that don't have internal standards, they used one that closely matched. For example, use DON IS for 3-ADON and 15-ADON. This way, all compounds had >85% recovery on 18 analytes. They also showed how the use of the isotope labelled IS can be minimized, which reduces the overall cost of the method. Romer used this method to participate in the EU collaborative study mentioned above. That study had an option to use or not use internal standards.
- Roundtable Discussion:
 - FDA has formed a working group to review the Animal and Food Standards (Standard 10). Several members of the LM&SC will be working on that. Comments need to be in

ASAP and the draft will be completed by April. The current standards expire in 2017. The next version needs to be vetted prior to the current version's expiration. This document is on a 3 year review cycle.

- o G. Hoffman from Zoetis is requesting assistance from a laboratory to perform some testing on 30 to 40 samples. This will be needed near the end of the year. Please contact Greg Hoffman if you are interested.

Action Item Table:

Responsible	Item	Action	Timing / Status
All	Reviewing Committee Roster	Review the committee roster and let Aaron Price know if you would like to be removed or know someone who should be added to the committee.	Prior to next meeting
A. Price	CTC working group	Provide Leo Schilling with the contact info for Tom Phillips.	ASAP
D. Inerowicz and K. Riter	Fat-soluble vitamins working group	Decide on and send out more homogenous samples to labs for vitamin A and vitamin E analysis. These might be sliced cheese or infant formula.	Prior to next meeting
A. Price and S. Webb	Best Practices working group	Send out a call to membership looking for experts on fiber analysis methods.	Prior to next meeting
R. Sheridan and A. Price	Multi-element working group	Start a new working group to review the method needs statement and move towards a collaborative study.	Prior to next meeting
Education and training comm. liaison	Survey of training priorities	Send a survey to the committee to identify priority training needs.	Prior to next meeting
All	Analytical help to Zoetis	Contact Greg Hoffman from Zoetis if your lab is interested in helping them with some analyses.	ASAP
A. Price	LM&SC conference calls	Schedule next conference calls of the LM&SC with members and advisors.	Mid-March and Mid-May of 2016.

Model Bills and Regulations Committee Report

2016 AAFCO Midyear Meeting
January 18, 2016
Isle of Palms, South Carolina

Committee Recommendations:

1. The Model Bills and Regulations Committee recommends that revisions proposed by the Pet Food Committee to Model Pet Food Regulation 9(a) as stated in Attachment B conform to the Model Bill and Regulations and that the AAFCO Board of Directors review the proposal for future consideration of the Association membership.

Board Recommendations:

Association Actions:

Committee Report and Minutes (January 18, 2016):

Model Bills and Regulations Committee Chairman Doug Lueders called the meeting to order at 2:45 pm. on January 18, 2016. He welcomed committee members, industry advisers and guests who were present, and reviewed the agenda. He asked if there were any suggested changes to the agenda or additional topics to be brought before the committee, and none were offered.

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

There were no committee members participating by phone.

Industry advisers present were: Angela Mills and Scott Ringger (AFIA); David Dzanis (APPA/ACVN); Jan Campbell and David Fairfield (NGFA); Angele Thompson and Pat Tovey (PFI); and Sue Hayes (Wild Bird Feeding Industry).

Minutes from Previous Committee Meetings

Chairman Lueders noted that minutes from the August 4, 2015 committee meeting conducted in Denver and minutes from the supplemental e-committee meeting conducted August 27–Sept. 9, 2015 were previously approved, posted on the AAFCO website and were included in the 2015 Midyear Meeting's General Session packet.

Old Business

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

New Business

The committee proceeded to consider new business.

1. Food Safety Modernization Act (FSMA) Harmonization with AAFCO Model Bills and Regulations
 - a. FSMA Harmonization Workgroup Recommendations: Chairman Lueders noted that individuals participating within the workgroup created to review the AAFCO Model Bills and Regulations for harmonization with FSMA rules, in addition to himself, are Ms. Hunt, Mr. Ten Eyck, Mr. Fairfield, Mr. Tovey, and Ms. Wilkinson. Chairman Lueders invited a motion to accept the workgroup's recommendations for discussion. Mr. Ten Eyck moved to accept the

recommendations for discussion. The motion was seconded by Mr. Darden. Committee members approved the motion by a voice vote.

- i. Attachment A, Item 1: Ms. Hunt reviewed the workgroup's recommendation as stated in Attachment A, Item 1, noting that the intent was to provide different options of language that states could add to their feed laws to adopt federal food and drug rules.

It was moved by Mr. Ten Eyck that the committee accept the recommendation as stated in Attachment A, Item 1 and forward it to the AAFCO Board of Directors with the recommendation that the proposed language be added to the Model Bill and Regulations and that the Board of Directors review the proposal for future consideration of the Association membership. The motion was seconded by Ms. Hunt.

The committee discussed the recommendation. Some committee members expressed opinions that the parts of the Code of Federal Regulations, title 21, referenced within Option A should be changed. Other discussion questioned whether there was a need for the recommended language given that Section 10(a)(2) of the Model Bill and Regulations already provides states the opportunity to adopt any regulation promulgated pursuant to authority of the Federal Food, Drug, and Cosmetic Act.

Following discussion, committee members voted on the motion. The motion failed by a 4 to 2 vote. In response, Chairman Lueders directed the workgroup to reconsider Attachment A, Item 1 given the committee's comments.

- ii. Attachment A, Items 2 and 3: Ms. Hunt reviewed the workgroup's recommendations as stated in Attachment A, Items 2 and 3. She noted that the proposed definition for "animal food" was being recommended to provide consistency with Code of Federal Regulation, title 21, part 507.3, and was necessary since FSMA-related rules use such a definition. Ms. Hunt also noted that the proposed revision to the definition of "feed(s)" was being made so that the definition better harmonized with the recommended definition for "animal food" and to make the definition gender neutral.

The committee discussed the recommendations as stated in Attachment A, Items 2 and 3. During the discussion, some concerns were raised that the recommended definition for "animal food" was not completely consistent with the definition for "animal food" established in Code of Federal Regulation, title 21, part 507.3. Regarding the recommended revisions to the definition of "feed(s)", opinions were expressed that components of the definition were not comprehensive or completely accurate, and, that if the definition were to be revised, additional changes should be made.

Following discussion, Chairman Lueders tabled Attachment A, Items 2 and 3, and directed the workgroup to reconsider the items given the committee's comments.

- iii. Attachment A, Item 4: Ms. Hunt reviewed the recommendation as stated in Attachment A, Item 4 to add facility recall plans as Section 8 of the Model Bill and Regulations. She noted the recommended language was based upon Code of Federal Regulation, title 21, part 507.38.

The committee discussed the recommendation as stated in Attachment A, Item 4. Some views were expressed that the recommendation was not consistent with FSMA requirements since the language would apply to all commercial facilities, and not just those that fall under the requirements of Code of Federal Regulation, title 21, part 507.38. Other views were expressed that recall requirements are best established at a federal level so as to maintain consistency, since a given recall may extend into multiple states.

Following discussion, it was moved by Mr. Ten Eyck to table consideration of Attachment A, Item 4 until the committee's next meeting. The motion was seconded by Mr. Nelson. The committee approved the motion by a voice vote.

- iv. Attachment A(2). Ms. Hunt reviewed Attachment A(2), which recommended changes to Model Bill and Regulations Section 11(a) to accommodate adoption by states of FSMA rules.

Following discussion, it was moved by Mr. Burkholder to table consideration of Attachment A(2) until the committee's next meeting. The motion was seconded by Mr. Darden. The committee approved the motion by a voice vote.

2. Revisions to Model Pet Food Regulation 9(a). The committee considered the recommendation from the Pet Food Committee to revise Model Pet Food Regulation 9(a) as stated in Attachment B.

Following discussion, it was moved by Mr. Burkholder that the committee recommend that revisions proposed by the Pet Food Committee to Model Pet Food Regulation 9(a) as stated in Attachment B conform to the Model Bill and Regulations and that the AAFCO Board of Directors review the proposal for future consideration of the Association membership. The motion was seconded by Mr. Darden. The committee approved the motion by a voice vote.

3. Model Bill Discrepancies, AFIA Findings: Due to the lack of time, Chairman Lueders tabled discussion of the proposed Model Bill discrepancies identified by AFIA as stated in Attachment C until the committee's next meeting.

Assignments/Homework for Annual Meeting

Chairman Lueders directed the FSMA Harmonization Workgroup to reconsider Attachment A, Items 1, 2 and 3 given the committee's comments.

Adjournment

Mr. Lueders asked whether there was any other business to be considered by the committee. Given that none was identified, the committee meeting was adjourned at 3:50 pm.

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

Model Bills and Regulations Committee: Attachment A
AAFCO Feed PC Harmonization Work Group
FSMA Model Bill Language
11/9/15 DRAFT

1. Add as Section 10 (c) in the Model Bill

Option A. All food and drug rules

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

Option B. FSMA animal food preventive control rules

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

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

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

2. Add definitions to Section 3 of the Model Bill (From 21 CFR 507.3 Definitions)

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

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

3. Update the AAFCO Official Feed Terms – Animal food as a new term and update to existing Feed term

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

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

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

From 21 CFR 507.38

Section 8. Recall Plan

(a) Commercial feed licensees and registrants must:

- (1) Establish a written recall plan for the animal food; and
- (2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

- (1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

- (2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;
- (3) Conduct effectiveness checks to verify the recall has been carried out; and
- (4) Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

Model Bills and Regulations Committee: Attachment A(2)

Section 11(a)

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

Model Bills and Regulations Committee: Attachment B

AAFCO 2016 Midyear Meeting
Monday, January 18, 2016
Palms Ballroom
2:45 – 3:30 pm

Clarification of Regulation PF9(a)

Revision appears below in red and can be found. Revised language appears below in red and should be inserted on line 13 on page 144 of the 2015 AAFCO Print OP.

Regulation PF9. Statements of Calorie Content

(a) The label of a dog or cat food, including snacks, treats, and supplements, shall bear a statement of calorie content and meet all of the following:

Model Bills and Regulations Committee: Attachment C

2016 MBRC Midyear Meeting

AFIA proposed changes to the AAFCO Model Bill November 2015

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

Edit Requested	MB Section	Language showing edit	Rationale
		totes must document their <u>its</u> cleanout procedures.	
Add "commercial" in front of "feed" in this Certificates section	Section 12. Certificates	Opening sentence where it says ... <u>access to markets for commercial feed and ingredients...</u>	Throughout the MB it is always referred to as "commercial feed" or another qualifier (customer-formula feed, medicated) but it was not in this section
Change "an" to "any"	Section 14. Penalties	(h) In <u>any</u> action to compel performance of an order of the _____ to enforce this Act, the court must require a defendant adjudged responsible to perform the acts within the person's power that are reasonably necessary to accomplish the purposes of the order.	It should be "any" action to be consistent with the rest of the section and the use of "any"
Require rule-making to define conditions labels would be requested.	Section 4. Registration and Licensing Option B. Licensing	(d) <u>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.</u>	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) <u>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.</u>	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.

PFC Committee Report/Minutes

AAFCO Annual Meeting
Isle of Palms, South Carolina
January 19, 2016
9:30 am – 12 pm

Committee Recommendations

Committee recommendation summary or list.

- (1)
- (2)

Board Recommendations

Board recommendation summary or list.

- (3)
- (4)

Association Actions

Association action summary or list.

- (1)
- (2)

Committee Participants

Members present: Stan Cook (MO), Kristen Green (KY), Charlotte Conway (FDA-CVM), William Burkholder (FDA-CVM), Austin Therrell (SC), Natasha Hedin (MN), Lizette Beckman (WA), Jo Lynn Otero (NM), Christie Shee (IN), Jason Schmidt (LA), Eric Nelson (FDA-CVM). Present via telephone: Jan Jarman (MN).

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

PFC attendance: 160 which includes 51 Control Officials.

Committee Report

Committee Activities

ACTION: Based on the availability of an AOAC sugars method in pet food, the carbohydrate workgroup will be reformed to consider revising the Carbohydrate Guidelines previously drafted by the workgroup for inclusion of the new method and other revisions deemed necessary.

MOTION: Bill Burkholder moved to reconvene the Carbohydrate workgroup.
Seconded by Austin Therrell (SC). Motion Passed.

ACTION: The workgroup presented the result of the joint IDC/PFC work on human grade guidelines and human grade term.

MOTION: Stan Cook moved to accept the workgroup report, "Human Grade Guidelines".
Seconded by Charlotte Conway (FDA-CVM). Motion passes.

ACTION: Based on substantial comments by the PFC and audience, additional edits may be necessary to appropriately revise the "Human Grade Guidelines".

MOTION: Bill Burkholder moved to send the workgroup report, "Human Grade Guidelines" back to the workgroup for additional editing.
Seconded by Austin Therrell (SC). Motion passes.

Committee Minutes

Announcements

New committee members were introduced: Christie Shee from the Office of the Indiana State Chemist, Jason Schmidt from the Louisiana Department of Agriculture, and Jo Lynn Otero from the New Mexico Department of Agriculture.

AAFCO Dog and Cat Food Nutrient Profiles Errors in 2016 Official Publication

Stan Cook (MO) announced Dog and Cat Food Nutrient Profiles editorial changes are required to correct errors found in the printed Official Publication (OP) AAFCO Dog Food Nutrient Profiles table based on Dry Matter and the AAFCO Cat Food Nutrient Profiles based on Calorie Content. The corrections that have been identified are:

Incorrect Values Appear in the Table AAFCO Dog Food Nutrient Profiles Based on Dry Matter for Maximum Vitamin D, Maximum Vitamin E, Minimum Thiamine, and Minimum Riboflavin Concentrations. The correct values should be:

- Max Vitamin D IU/kg 3000
- Max Vitamin E IU/kg Blank – No Value Listed
- Min Thiamine mg/kg 2.25 for Both Growth and Reproduction and Adult Maintenance Profiles
- Min Riboflavin mg/kg 5.2 for Both Growth and Reproduction and Adult Maintenance Profiles

An incorrect value appears in the Table AAFCO Cat Food Nutrient Profiles Based on Calorie Content for minimum Arachidonic acid. The correct value should be:

- Min Arachidonic acid g/1000kcal ME 0.05 for Both Growth and Reproduction and Adult Maintenance Profiles

A workgroup was appointed which consists of Dr. Bill Burkholder, Charlotte Conway, Kelvin Hawkins, Angele Thompson to review the complete AAFCO Dog and Cat Food Nutrient profiles as published with errors in the 2016 OP to the correct version passed by the PFC in Denver 2015 which is the version that should appear in the OP. The charge of the workgroup is to identify all errors in the AAFCO Dog and Cat Food Nutrient Profiles tables and text and report those back to PFC by March 2016.

The PFC leadership will continue to notify AAFCO members and Feed Bin users via the Feed Bin of any errors in the AAFCO Dog and/or Cat Food Nutrient Profiles that are identified. Once the workgroup has identified all of the errors in the 2016 OP, corrected information will be provided to all purchasers of the 2016 physical OP. The online version of the 2016 AAFCO OP will be corrected as soon as possible.

Reminders and Timelines

Kristen Green (KY) provided a reminder to the membership of the enforcement dates that PFC has recommended over the past couple of years regarding the revisions to PF9 (Calorie Content Statements) and the revised AAFCO Dog and Cat Food Nutrient Profiles with revised nutritional adequacy statements. PF9: Delayed enforcement until 18 months for new products in development and three years for existing products after publication in the AAFCO OP (published 2014).

- New products (those introduced after January 1, 2014) must currently meet the new requirements of PF9.
- Existing products must meet this requirement by January 1, 2017.

Revised AAFCO Dog and Cat Food Nutrient Profiles and Nutritional Adequacy statements (published 2016):

- The Pet Food committee recommends that the revisions to the AAFCO Dog and Cat Food Nutrient Profiles not be enforced until 12 months for new products in development and 24 months for existing products after publication of the revised AAFCO Dog and Cat Food Nutrient Profiles in the print version of the AAFCO OP (2016).
- The Pet Food committee also recommends that the revisions to PF7 of the Pet Food Model Regulations for Pet and Specialty Pet Food Under the Model Bill not be enforced until enforcement commences for the revised AAFCO Dog and Cat Food Nutrient Profiles.

- Delayed enforcement and implementation of the revised PF7 language for nutritional adequacy statements would allow nutritional adequacy statements on products in the market place to be either: *verbatim* as shown in 2014 OP hard copy, *or verbatim* as shown in the OP hard copy containing the revised nutrient profiles, until 24 months after publication of the revised nutrient profiles (*Jan 1, 2016*) at which time the statement must be as verbatim in the revised PF7.

Members and audience members were reminded of the utility of the AAFCO Talks Pet Food and encouraged to continue to promote the site.

AAFCO Pet Food & Specialty Pet Food Labeling Guide Workgroup – Charlotte Conway, FDA-CVM

The revised Pet Food Labeling Guide has been voted through the PFC and is currently with FASS for formatting. The guide is still missing the ‘example labels’ that appeared in the previous Pet Food Labeling Guide. The Pet Food Labeling Workshop committee is charged with putting these label examples together and they will be added to the Pet Food Labeling Guide when available.

Pet Food Labeling Workshop Workgroup – Kristen Green, KY Div Reg Svcs

The workgroup has convened, and task specific subgroups have been created. A GAP analysis is being conducted on past slides to determine where additional slides are necessary. The entire workgroup will convene again by conference call in March to clarify next steps. The Pet Food Labeling Workshop is currently planned for 1.5 days at the 2017 annual AAFCO meeting in Bellevue, WA.

Carbohydrate Workgroup – Jan Jarman, MN Dept. of Agriculture

Jan Jarman (MN) reported that a new method for sugar detection in pet food has been electronically published by the JAOAC. Based on the availability of a suitable method, the Carbohydrate workgroup has reformed to consider revising the Carbohydrate Guidelines previously drafted by the workgroup for inclusion of the new method and other revisions deemed necessary.

Analytical Method for Sugar Profile in Pet Food and Animal Feeds by High Performance Anion Exchange Chromatography with Pulsed Amperometric Detection. **Authors:** Ellingson, David ; Anderson, Phillip; Berg, Daniel. Accessible: <http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/pre-prints/content-150258>

Tartar Control Claims Workgroup – Austin Therrell, SC Dept. of Agriculture

Austin Therrell (SC) is the new chairman of this workgroup. The workgroup has made progress since the annual 2015 meeting and anticipates having a draft for the PFC to consider at the 2016 annual meeting.

Human/Feed Grade Workgroup – Stan Cook, MO Dept. of Agriculture

The Human/Feed Grade workgroup, which is a joint effort between PFC and IDC members and advisors, has put together a proposed feed term for ‘human grade’ along with guidelines for “Human Grade” claims to be placed in Chapter 4 after the “Natural” Guidelines. PFC reviewed the human grade feed term, which is under consideration by the IDC, and no comments or modifications were provided.

The intent of the workgroup in proposing the term and guidelines was for the feed term (under control of IDC) and Guidelines (under control of PFC) to travel or fail together.

There was some concern by the audience and PFC members/advisors that the Guidelines as presented were not clear, in particular in (1). There were additional questions regarding ‘edible’ and ‘raw’ as applied to humans, whether ‘human grade’ could apply to a single ingredient in a mixed pet food. Generally agreed upon changes included ‘*current* good manufacturing practices (cGMP)’ and ‘21 CFR *part* 117’ [italicized portion indicates added language] as well as a change in (3) from “should” to “must”.

Once the document has been edited and accepted by PFC, it will not need to go to the MBRC. The workgroup will work on revised language to present to the BOD before the summer 2016 meeting so that the Guidance can still travel with the feed term.

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

The BOD has given the PFC the following charge:

“Review and consider potential changes to modernize pet food labeling that enhances transparency and expands safety, taking into account the following:

- Alignment with human food nutrition box formatting
- Use of front-of-packaging nutrition cues
- Consideration of microbial risks and safe handling instructions
- Availability of new sugar and dietary starch methods
- Use of modern fiber labeling
- Ideas put forth in the public comments received on the FDAAA public meeting.”

It is the intention of the PFC to form a workgroup to consider the above charge along with any other modernization factors that the workgroup deems important to consider. There were several comments from PFC members, advisors and the audience and some discussion items included:

- Importance of consistency
- Separate identity/nomenclature for pet food ingredients from feed ingredients
- Remove ‘crude’ from guarantees
- Lack of accuracy in provided values in the human nutrition facts box
- Consider modern technology (scan boxes, etc)
- Concern about FDAAA Pet Food labeling requirements coming out and not matching AAFCO guidelines.

Industry and associations agreed to provide input and data on consumer preferences.

Members and advisors may put in a request to be on the workgroup and the PFC leadership will appoint advisors/members to achieve a well-balanced and manageable workgroup. It is expected that this workgroup will have a long term charge. It is the intention that this workgroup provide input back to the PFC at the 2016 annual meeting.

Administrative Issues - *Kristen Green, KY Div Reg Svcs*

A few items were added to the action items table, and the completed table will appear in the official PFC meeting minutes.

New PFC policies regarding agenda submissions were outlined. All agenda submissions must follow the justification and formatting requirements found on page 91 of the 2016 AAFCO OP in Committee Guidelines. Items submitted in time for draft agenda consideration will be presented to the members of PFC for their consideration. Items presented after the draft agenda for a meeting has been prepared may be pushed for consideration at the following meeting. The PFC membership may or may not consult advisors regarding agenda item submissions.

Pet Food Committee Adjourned at 11:30 pm EST.

Action Items Table

Responsible	Item	Action	Timing/Status
Bill Burkholder	Revised Profiles Corrections Workgroup	Review the 2016 OP against the version that is known to be correct for any additional errors. Present to PFC appropriate distribution	By March 1, 2016
Stan C./ Kristen G	AAFCO Dog and Cat Food Nutrient Profile Corrections outreach to OP users	(1) Post updates (as confirmed) on FeedBin (2) Letter to OP holders (with known issues. (3) Updated tables/other information (from result of WG) (4) Update online OP (5) Make sure print OPs still in stock are 'updated' (6) Other actions deemed necessary	As soon as possible, some information will come from the revised profiles workgroup.
Kristen G.	PF/SPF Labeling Guide Formatting	Send to FASS and facilitate formatting process	1.2016 – sent to FASS but still missing label examples.
Austin T.	Revised Tartar Control Workgroup	Workgroup to provide revised AAFCO Tartar Control Guidelines to the PFC for consideration	Update due 8.2016
Jan J.	Carbohydrate WG	WG reformed to consider new AOAC Sugars method and other revisions to the Carbohydrate Guidelines.	Update due 8.2016
Stan C.	Human Grade Guidelines	Guidelines returned to WG for editing/revisions	Update to PFC due April 2016 (after PFC goes to the BOD for consideration prior to 2016 annual meeting)
Stan C.	Human Grade Term	Make sure that Guidelines and Term are approved/not approved together at the 2016 annual meeting	Confirm status of Guidelines. Term goes to membership vote in August 2016.
Kristen G.	Pet Food Labeling Workshop Work Group	Continue subgroup activities, arrange for entire WG webex to further define future responsibilities.	Mar 2016
Stan C.	Pet Food Modernization Workgroup	Gather interest and assign PFC member and advisors to this workgroup.	February 15, 2016
Stan C.	Pet Food Modernization Workgroup	Consider and report back to PFC at 2016 annual meeting the WG recommendations.	Update due 8.2016
Lizette B.	AAFCO Talks Pet Food Revisions	Manage comments/revisions provided by the public/members for inclusion in the site	Ongoing, no immediate action required.
Charlotte C.	PF/SPF Labeling Guide revisions	Finalize Labeling guide, complete revisions and move to PFC vote	Complete – passed 12.2015. Needs formatting.
Kristen G. / Liz H.	Pet Food Labeling Workshop AAFCO facilitation	Complete and submit workshop information to Education and Training Committee. Make necessary arrangements with FASS regarding general dates/times for reservation purposes.	Complete – Oct. 2015

Pet Food Committee Meeting Minutes Web-Ex 3/17/2016

The meeting was called to order at 11:00 am ET

- Roll call of Pet Food Voting Members – Stan Cook (MO)
Voting members on call: Liz Beckman (WA), Liz Higgins (NM), Jo Lynn Otero (NM), Kristin Green (KY), Stan Cook (MO), Charlotte Conway (FDA), Jan Jarman (MN), Eric Nelson (FDA), Christie Shee (IN), William Burkholder (FDA)

There is a quorum so this issue can be voted on

- Roll call of Advisors – Stan Cook (MO):
Advisors on call: James Emerson (US Poultry & Egg Association), Jean Hofve (Pet Welfare Alliance), Susan Thixton (Association for Truth in Pet Food), Angele Thompson (Pet Food Institute), Pat Tovey (Pet Food Institute)

There were approximately 50 additional individuals present on the call.

- Review of “Human Grade” Definition – Stan Cook (MO)
Stan Cook presented an overview of why the “Human Grade” claim was brought to AAFCO to develop a feed-term for “human grade” and associated guidance. Charlotte Conway (FDA) gave an historic overview of how “human grade” claims were previously reviewed by the Food and Drug Administration’s Center for Veterinary Medicine (CVM) for the last decade because of the complexity of reviewing the claim. Now that guidance has been established, CVM felt that continuing to review these claims is not consistent with the other types of claims that they review on a pre-market basis. State regulatory agencies will now be reviewing “human grade” claims creating a need for guidance so that there is consistency in review by states.

The Pet Food Committee established a workgroup in conjunction with Ingredient Definitions Committee (IDC) to establish human/feed grade definitions. This larger workgroup developed “feed grade” and “human grade” feed terms which were voted on at the AAFCO mid-year meeting in South Carolina. The “human grade guidance” came to the Pet Food Committee at midyear 2016 where there was a significant amount of discussion and changes needed to clarify the guidance. The workgroup continued their work after the meeting to address comments received during the meeting. The product of that workgroup was posted to the AAFCO Feed Bin for consideration in March 2016.

- MOTION
Stan Cook (MO) moved that the report of the workgroup be accepted by the Pet Food Committee. Seconded by Charlotte Conway (FDA). Motion passed.
- DISCUSSION
Nathan Price (ID) asked for clarification on why CFR 117 was listed in the newly developed Human grade Guidance document, as it currently is in CFR 110. Charlotte Conway (FDA) indicated that CFR 110 will be moved into CFR 117 due to the Food Safety Modernization Act (FSMA). Since the “Human Grade” claim will not be published until later, the workgroup felt that CFR 117 reference makes the most sense to publish.

Angele Thompson (PFI) asked about the delayed compliance for the human food rule and whether 117 is the correct reference, Charlotte Conway (FDA) said 117 is the current up to date reference. In

order to explain this indiscrepancy, a note will be placed in the front of the AAFCO Official Publication (OP) to explain this.

Note: The current CGMPs for Human Food are still 21 CFR 110, with the publication of Preventive Controls for Human foods, the rule will slide over into 21 CFR 117. Here are the established compliance dates: firms that do not qualify for Small or Very Small business status it is September 18, 2016, for Small Businesses September 19, 2017, and September 19, 2018 for Very Small Businesses. So, 110 will continue to exist until they phase out in September 2018 (depending on size).

Stan Cook (MO) and Charlotte Conway explained that the language in 4d is specific to labeling, and the reason it is being separated out.

Liz Higgins (NM) asked about section 3 and whether a company must have a food processing license. Charlotte Conway explained that depending on the jurisdiction of the area of where the company is manufacturing they will need to get a food license in order to make a “Human Grade” claim, and if they don’t qualify they will not be able to make the claim. It is up to the State Feed Control Official to ask for the documentation and make the decision.

A call in question from a firm that makes edible poultry product and manufactures under other federal regulations (USDA FSIS) and don’t fall under 21CFR 117. This company is not under compliance by FDA because they are under USDA. The response was that products coming directly out of this firm would not qualify for the human grade claim under the guidelines since they are not subject to 21 CFR 117. However, human edible ingredients made by this firm could potentially be incorporated into products by other firms operating under 21 CFR 117 and have the resulting end product meet the human grade guidelines.

Liz Higgins (NM) asked what type of documentation is required from the company in regard to documenting that a firm is in compliance with 21 CFR 117 in regard to transporting and holding? Charlotte answered probably an affidavit; it would be difficult to have an answer for each situation that may come up. It falls on the manufacturer to be able to provide information for the state to make the determination.

George Ferguson (NC) requested that since each state may handle differently who conducts food processing inspections, he would like each state to provide information of what agency to contact for certificate or proof of inspection of products. Stan Cook responded that this is a good idea and can be done through the AAFCO website to expedite the research. This can be worked out at a later date.

Angele Thompson (PFI) mentioned the experience of some firms trying to comply with the regulation but have experienced redundancy of documentation. It seems that 3a and 3b are redundant. If a facility is complying with cGMP’s that by definition is that every ingredient needs to be stored appropriately and there is an additional overlay for a facility to make human food. Charlotte laid out in historical context how the human edible should be handled – an affidavit for each ingredient should be provided by each ingredient supplier for all ingredients used in the products, copies of food facility licenses and affidavits that cGMPs are being followed in the production, storage, handling and transporting of the animal food.

Both Kristen Green (KY) and Stan Cook (MO) asked if there was an objection to voting now or if there should be an e-vote. Conversation around whether the motion needs to be made to send to AAFCO Model Bill and Regulation Committee can be made at this time due to the fact that the “human grade”

definition has not yet been voted on by the AAFCO Membership. Doug Lueders (MN) indicated that technically AAFCO's Model Bill and Regulations Committee could not work on the "Human Grade Guidelines" until the "Human Grade" definition is official. After some discussion, it was determined that this document would not need to go through the MBRC. The intent was that the "human grade" feed term and the associated guidance would be voted on together. The following statement was added to the document "This guideline is not to be published in the AAFCO OP without the "Human Grade" Definition first being accepted by the association membership."

- **MOTION:**

Charlotte Conway (FDA) moved that the guidelines on the webinar screen be approved and follow in the OP the "Human Grade" Claims.

Conversation around where the guidelines are placed in the AAFCO OP came up; Jan Jarman (MN) and Kristen Green (KY) both agree that whether it is in AAFCO Model Pet Food Regulations PF4 or PF5, all guidelines should be in one place.

Charlotte Conway (FDA) amended her motion to the below statement, Liz Higgins seconded, and Kristen and Stan asked for a roll call vote:

Lizette Beckman (WA) aye
Bill Burkholder (FDA) aye
Charlotte Conway (FDA) aye
Kristen Green (KY) aye
Liz Higgins (NM) aye
Jan Jarman (MN) aye
Eric Nelson (FDA) abstain
Jo Lynn Otero (NM) aye
Christie Shee (IN) nay

PFC Recommendation to board and association members: To publish the following guideline in the AAFCO OP following the guideline for natural claims. This guideline is not to be published in the OP without the corresponding Human Grade definition first being accepted by association membership. Moved by Charlotte Conway (FDA), seconded by Liz Higgins (NM). Motion passed 8 in favor, 1 abstain, 1 opposed

Motion was made to accept the minutes by Charlotte Conway (FDA) and Seconded by Austin Therrell (SC). Motion passed by PFC evote on 3/29/2016.

Pet Food Committee – Human/Feed Grade WG

Guidelines for “Human Grade” Claims, must travel with the Feed Term ‘Human Grade’

March 17, 2016

Proposed addition to Chapter 4, Model Bill and Regulations to be placed on page 150, line 34 of the 2016 print AAFCO OP (this section follows the ‘Guidelines for “Natural Claims”’ and precedes the ‘AAFCO Methods for Substantiating Nutritional Adequacy of Dog and Cat Foods’).

Guidelines for “Human Grade” Claims

AAFCO recommends and supports the following guidelines for the use of the term “human grade” in the labeling of pet foods and specialty pet foods.

- (1) In the AAFCO defined feed term “human grade”, the use of the term “human grade” is only acceptable in reference to the product as a whole. The feed term specifies that every ingredient and the resulting product must be stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods as specified in 21 CFR part 117.
- (2) In the definition, the term “human grade” is false and misleading if the product as a whole is not human edible. “Human grade” claims may not be made for individual ingredients in a finished product that does not fully adhere to the manufacturing and ingredient specifications identified above.
- (3) In order to substantiate that a “human grade” claim is truthful and not misleading, a manufacturer making one or more “human grade” claims must have documentation that:
 - a. Each of the individual ingredient suppliers has verified that the individual ingredients supplied to the manufacturer are fit for human consumption.
 - b. Every ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods as specified in 21 CFR part 117.
 - c. The manufacturing facility is licensed to produce human food by the appropriate authority (which varies by jurisdiction). Such evidence may include, but is not limited to, facility licenses or permits for operation of edible food manufacturing facilities or results of most recent inspections issued by local, county, or state public health authorities.
- (4) A pet food or specialty pet food product with “human grade” claims must be clearly labeled for its intended use as animal food, such as “dog food” or “cat treats”, and follow all other pet food or specialty pet food labeling requirements. The following also applies to labeling:
 - a. Statements of quality or grade may not appear in the ingredient statement [PF5(d)(3)].
 - b. All uses of the words “human grade” on the label can be no larger than the statement of intended use required by PF2(a)(2).

- c. A claim of “human grade ingredients” is only acceptable if the product complies with all parts of this guideline.
- d. In order to use the term “human grade” on labeling (brochures, point of sale materials, websites, etc.), the statement of intended use must also be included. All uses of the words “human grade” on labeling can be no larger than the statement of intended use.

Strategic Affairs Committee Report/Minutes

January 20, 2016
10:30 am – 12:00 pm
Isle of Palms, South Carolina

Committee Recommendations:

1. **Report acceptance.**
2. Publish the revised Manual of Procedures. Can be done by Board and does not need Association action. Manual can be found on the AAFCO website <http://www.aafco.org/Regulatory> or in the Feed BIN under All BIN Users library.
3. Accept change to By-Laws provisions for quorum for voting by adding:
ARTICLE VI
Section 3. "Voting. For committee work, at least one-half of the members of any committee are required to be present or represented by proxy (in person or by phone) to conduct a vote. A majority of those voting must vote in the affirmative for the motion to pass. Only the Chair or Co-Chairs/Vice-Chairs may preside over a vote."
4. Accept change to By-Laws provisions for member voting by substituting:
ARTICLE II
Section 2. "Voting. Each State, District or Territory engaged in regulating animal feed or livestock remedies in the United States of America and each Federal Agency primarily responsible for regulating animal feed or livestock remedies in their country, and paying annual dues as prescribed in Article II Section 4 of these By-Laws, shall designate one member as the voting representative of that State or Agency."

Board Recommendations:

1. Report accepted – *add date*
2. Manual of Procedures
3. By-Laws add Article VI, Section 3
4. By-Laws substitute Article II, Section 2

Association Actions:

1. Report accepted – *add date*
2. By-Laws add Article VI, Section 3
3. By-Laws substitute Article II, Section 2

Full Committee Members:

Linda Morrison	Ken Bowers	Richard TenEyck	
Andy Gray	Roger Hoestenbach	April Hunt	Jamey Johnson
Shannon Jordre	Ali Kashani	Chad Linton	Mark LeBlanc (Board Liaison)
Dragan Momcilovic	Jenny Murphy	Aaron Price	Kent Kitade
Nancy Thiex	Judy Thompson	Robert Waltz, Vice Chairperson	

Finance Sub-Committee:

Ali Kashani (Chair), Ken Bowers, Jamey Johnson, Mark LeBlanc, Chad Linton, Richard TenEyck, Judy Thompson

By-Laws Sub-Committee:

Ken Bowers (Chair), April Hunt

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. Working Group (Bob/Shannon/Ali/Roger/Ken):
 - o Procedures Manual Review – Committee coordination processes
 1. Update/review draft Phase 2 work:
 - Final Revisions were made and shared with the Committee prior to the meeting (separate attachment from Committee report).

Motion to accept and publish the revised Manual of Procedures: Bob; second - Shannon; Motion carries.

Motion March 23–25, 2016 to replace the January version with the March version regarding the Procedures Manual edits: Ken; second – Nancy; Motion carries.

2. Sub-Committee Activities:
 - o By-Laws: Ken
 1. Quorum provisions for Committees:

ARTICLE VI

Section 3. "Voting. For committee work, at least one-half of the members of any committee are required to be present or represented by proxy (in person or by phone) to conduct a vote. A majority of those voting must vote in the affirmative for the motion to pass. Only the Chair or Co-Chairs/Vice-Chairs may preside over a vote."

 - Discussion:
 - Need for better attendance and voting records at Committee meetings.
 - Language is consistent with Roberts Rules of Order.
 - Committee Meetings can proceed but voting will not be possible if quorum voting requirements are not met and would require follow up such as electronic voting.

Motion to accept change to By-Laws, Article VI, Section 3. Voting.: Shannon; second - Judy; Motion carries.
 2. International Membership (Appendix 2)
 - Report shared with Committee for integration into Procedures Manual
 - Change recommended to the By-Laws as follows:

ARTICLE II

Section 2. "Voting. Each State, District or Territory engaged in regulating animal feed or livestock remedies in the United States of America and each Federal Agency primarily responsible for regulating animal feed or livestock remedies in their country, and paying annual dues as prescribed in Article II Section 4 of these By-Laws, shall designate one member as the voting representative of that State or Agency."

Motion to accept report: Richard; second – Judy; Motion carries.

Motion to accept recommendation to change By-Laws, Article, Section 2. Voting.: Richard; second – Judy; Motion carries.
 - o Finance: Ali
 - Sub-Committee report for SAC approval (Appendix 1)
 - Recommendations have been actioned

Motion to accept Sub-Committee report: Shannon; second - Bob; Motion carries.

 - Board (October meeting) has decided that the Finance Sub-Committee will now report directly to the Board as a Committee.

3. Strategic Plan (SP) Priority Activities 2013-16 - update
 - o Working group (Bob, Jenny, Richard, Linda) report on Integrated Tracking System implementation in FeedBin
 - Project tab is being used. There are currently 3 tabs (Pet Food, FSMA TF, Model Bill harmonization). Strategic Plan information is dated
 - Need updates loaded so we have current information for strategic planning in May.

Action: Linda will send update request to Strategic Plan leads
 - o Work plan status reviewed and updates provided for priority activities:
 2. Sound financial planning / More cost effective operations: Ali

- Last meeting: Quantitative aspects in order but need to examine qualitative aspects.
 - Haven't seen a need for changes inasmuch as association finances are sound
3. Process for new members: Ali
 - Continues on hold due to Committee member changes.
 4. Build leaders with AAFCO background who support AAFCO: Linda/Tim L.
 - Jenny and Tim were to seek suggestions and return with recommendations. Obtained information from Fertilizer, but no further progress. Jenny will follow up in FDA to see if there is an AAFCO appropriate off the shelf product to use by Annual 2016
 5. Emergency Preparedness Exercise: Judy
 - FFIMC contains report; large exercise planned for Midyear January 2017
 6. Partnership establishment: Ali – complete
 - More actively following up with USDA (October)
 7. Support APHL Grant: Nancy
 - On target with deliverables, monthly reporting to APHL and regular Board reports, annual report completed (posted in the FeedBin/web site)
 8. Enhanced Communications (6 sub-elements): Ali
 - Ongoing
- SP leads continue to be challenged

4. Strategic Planning 2017+

- Will use current Strategic Plan framework, update it, review status of current priorities, integrate FSMA TF priorities and identify limited priorities to manage work load and expectations from implicated committees.
- Will include Committee Chairs and Board for process to identify priorities for 2017-20 Strategic Plan.
- Have allocated a full day pre-Seminar, and will try to engage the TF facilitator for consistency

Action: Linda will begin organization of planning session and identify budget needs to Board.

5. AAFCO FSMA Implementation Task Force (Appendix 3)

- Update and Next Steps from Midyear meeting:
 1. Model Bill: task force report presented and discussed. Next step: WG reconvene to consider feedback. Will post proceedings in the FeedBin and return for final consideration at Annual 2017. IDC will be working on related feed terms.
 - 2.a. FFIMC: GMPs small survey will be complemented with AFIA survey information for consideration in August
 - 2.b. Model guide to be archive
 - 3./4. Waiting on Alliance work product
 5. ISC: Inspector Manual review; have biosecurity work product; considering whether risk based inspection program positioning; next step is more fulsome review of Manual (using AFRPS audit experience) to address conflicts before August Annual
 6. Working to produce newsletter biannually. Also reached out to FDA to help with Communications Plan

6. Other Business

- Industry suggestion that guidelines/manuals be made available at a cost (e.g. Inspector Manual).

Action: Nancy Cook to identify potential items not already listed on web site.

- Committee work in progress is supposed to be limited to the relevant group until the group has a product ready to share more broadly. It is felt that information under discussion is being shared prematurely (Pet Food). Comments have been shared with the Board for follow up as appropriate.

Confirm Committee financial needs from the 2016-17 budget:

- Travel for Strategic Planning for 2016-17.
- Need to consider leadership training costs likely for 2018.
- Emergency planning costs expected to come from FFIMC.

Motion: To accept the Strategic Affairs Committee report, subject to minor edits/formatting: Chad; second - Andy; Motion carries.

Action Item Table

Responsible	Item	Action	Timing / Status
Working Group: Bob, Roger, Shannon, Ali and Ken	Phase 2: general review of the Procedures Manual to ensure timely work flow between Committees	Final draft shared with SAC prior to January Midyear 2016.	Complete: Committee accepted and forwarded to Board.
By-Laws Sub-Committee	By-Laws issues	Quorum provision suggestions finalized and shared for consideration at January Midyear 2016.	Complete: Committee accepted and forwarded to Board.
Working Group: Bob W. (lead), Jenny and Richard	Strategic Plan and Priority Action Item tracking and progress updates	Integrated Tracking system drafted in FeedBin with FASS support for detail input. Updates have not been made by SP priority leads.	Linda will send update request to Strategic Plan leads to inform strategic planning in May 2016.
Strategic Plan 2017-20 (Linda)	Organize planning session pre-Seminar 2016.	Board/Committee Chairs to identify SP priorities for 2017-20.	Linda will begin organization of May 2016 planning session and identify budget needs to Board.
Other business	Industry suggestion that guidelines/ manuals be made available at a cost (e.g. Inspector Manual)	Nancy Cook to identify potential items not already listed on web site.	

Appendix 1: Finance Subcommittee Report/Minutes

Tuesday, August 4, 2015

12:15 – 1:30 PM

Denver, Colorado

Committee Recommendations:

1. No need to invest further in the market at this time.
2. Purchase certificate of deposit for the amount that is above the FDIC limit in bank account.
3. Arrange for external audit with the firm conducted the last, one three years ago.

Board Recommendations:

None

Association Actions: Previous Board Recommendation of Posting Association's financial statements were completed

Committee Participants:

Members present: Richard Ten Eyck, Judy Thompson, Bob Waltz, Mark LeBlanc, Ken Bowers, Jamey Johnson, Doug Lueders and Ali Kashani.

Member absent: Chad Linton.

Guests Present: Randy Treadwell, Feed & RRT Program Manager, Washington State Department of Agriculture

Committee Report/Minutes:

1. Meeting called to order by Ali Kashani at 12:15 pm CT.
2. Update on investment of AAFCO funds – The sub-committee discussed the investment portfolio and recommended moving additional funds from savings account to a certificate of deposit. Ali will work with FASS to bring the account below the FDIC limit.
3. Official publication (OP) sales and total net income were discussed. Both electronic and paper OP sales have increased during the last two years (by about 25% and 53%, respectively). This information was to be presented at the Strategic Affairs committee meeting on Wednesday, August 5th, as had been requested at their last meeting.
4. A question was asked about the association's budget and investment level related to the status as not-for-profit organization. There appears to be no concern at this point.
5. Discussion of Budget Generating Plan – Discussion of options related to check sample program, meetings, training as potential sources of ongoing/new revenue were briefly discussed in addition to OP sales.
6. AAFCO budget in general (monthly financial statements, invoices, etc.)
 - Discussion of Association's budget and development of documents to track the Association's financial status and activities were discussed. No required changes to fiscal reports were identified.
 - It was recommended that committee chairs be encouraged to submit plans for their committee activities as funds are available to conduct needed activities. This can be done during chair meetings and by emails when secretary treasurer sends budget generation plans during the month of December.
7. Meeting adjourned at 1:30 pm.

Appendix 2: By-Laws: International Membership

Summary

The Board created a Task Force (Judy Thompson, Bob Gieger, Ellen Buchanan and Ken Bowers) were given an assignment regarding International Membership and possible ways to engage other countries in AAFCO. The following is a summary of discussions and recommended path forward.

AAFCO was founded to encourage uniformity between the States and this remains a key AAFCO mandate. With Canada and Costa Rico as members, AAFCO is already an international organization though membership is currently limited to the Americas. If we want China to actively participate in AAFCO, the Task Force felt we need to offer them the opportunity to be members. The current AAFCO definition of membership is very broad and the Task Force feels that feed control officials from any country could join now. In over a hundred years, we haven't had a line knocking on our door to become members so the risk is considered minimal.

We discussed the possibility of removing Canada and Costa Rico from the membership, drafting language like NASDA for non-voting members or just inviting others to come and get involved in discussions from the floor but we didn't see any of these options as the right approach. In order to determine the best strategy, we need to think a bit more about why we are inviting others (e.g., China) to participate and how much involvement we want from other countries and what influence they should have on how the US is going to regulate feed.

The Task Force agreed that AAFCO should continue to allow international participation. This would do nothing but help AAFCO and the feed industry. Feed moves globally now so this could be an incentive to invite other countries. We discussed limiting geographic catchment and limiting AAFCO membership to only feed control officials from the Americas. We could also add language for non-voting members from other jurisdictions (e.g, Europe and Asia) that allow them to be on committees in a similar capacity to industry advisors, e.g., no voting privilege. These feed control officials would be international associate members with restrictions on their participation in AAFCO.

The Task Force did not believe that we should have two AAFCO organizations. There are not enough volunteers available to support the management and leadership of two organizations.

The Canadian perspective on participation is to understand what is happening with US feed regulation and contribute so as to not have conflicting systems. Assuming China would be participating for the same reason, there is no risk in letting them vote (e.g.: Canada does not vote on pet food and other issues that are not relevant to them).

Recommendations

1. The Task Force felt that if AAFCO wants to promote international participation, feed control officials from other countries should join as members but we might want to change the By-Laws so that countries, other than the US, would only have one vote in the membership vote (e.g.: Federal only for countries other than US). This would not limit committee participation as often times there are two or more representatives from the same State or FDA on a Committee and they can all participate and vote individually.

- For Committee work, the Task Force didn't see broader participation in committee work as a huge issue because committee work is approved and vetted by the Board and then the entire membership.
- For eligibility to serve on the Board of Directors, The Task Force does not foresee a problem with this but maybe in the future limit number of board members to 1 or 2 that are not US.
- For the By-Laws, a change would be needed. To facilitate this change, *Article II, Section 2. Voting* of the By-Laws would need to be amended as follows:

Each State, District or Territory engaged in regulating animal feed or livestock remedies in the United States of America and each Federal Agency primarily responsible for regulating animal feed or livestock remedies in their country, and paying annual dues as prescribed in Article II Section 4 of these By-Laws, shall designate one member as the voting representative of that State or Agency.

**Appendix 3: FSMA Implementation Task Force
AAFCO Specific Priority Activities 2015–17**

Rev. Item No.	Responsible Committee and Deliverable Description: April 27, 2015	Timing	Status January 20, 2016
1	MBRC – When FSM rules come out in summer of 2015, make recommendations to align Model Bill with needed authorities to implement FSMA.	Fall 2015	Draft language presented and discussed at Midyear. Feedback will be used for additional review by WG. WG will post proceedings in the FeedBin and return for final consideration at Annual 2017. IDC will be working on related feed terms.
2	FFIMC – Livestock feed, pet food and feed ingredients to be included to determine the path forward for: a. AAFCO GMPs; Develop a plan for states that have adopted AAFCO's model GMPs to make the transition to FSMA GMPs – include MBRC and PFC b. Model Feed Safety Program Plan – include Linda (OP Section) and Bob Waltz (Feed Safety Coord.)	NOW	a. 12 states surveyed, 8 replied and 2 have adopted. Remaining states will be surveyed and AFIA survey information be used to determine action on AAFCO GMPs. b. Remove from OP and archive for historical use. Use AFRPS instead.
3	FFIMC - include Alliance (FSPCA), Enforcement Issues Committee, ISC, IDC and LMSC - To determine the contaminants, hazards, matrix and action levels and enforcement strategies to provide guidance to LMSC to inform method development and priority setting. Integrate collaboratively into current LMSC priorities	NOW	Waiting on Alliance work product
4	FFIMC & ISC - supported by ETC – To verify if training material for feed ingredient manufacturing from the Alliance meets the needs of Inspectors and revise as needed	Fall 2015 pending Alliance	Waiting on Alliance work product
5	ISC - supported by LMSC & ETC – Review and revise the Feed Inspector's Manual to make sure it supports the implementation of FSMA (notably aseptic sample)	NOW	Have biosecurity work product; considering risk based inspection program position; next step is more fulsome review of Manual (using AFRPS audit experience) to address conflicts before Annual 2016
6	Current Issues and Outreach Committee-supported by SAC a. Develop an AAFCO communication plan to better inform. b. Develop a model communication plan for states to use for outreach to regulated parties.	NOW	Working to produce newsletter biannually. Also reached out to FDA to help with Communications Plan

Appendix 3

Reference information

The Task Force (TF) was formed, with representatives from key Committees, to assess the federal *Food Safety Modernization Act* (FSMA) changes being proposed and to develop an implementation plan for AAFCO affected activities.

The representatives from the key AAFCO Committees are:

Laboratory Methods and Services - Robert Sheridan, Jennifer Mirabile and Teresa Grant

Education and Training - Tim Lyons

Feed and Feed Ingredient Manufacturing - Judy Thompson

Feed Labelling - Jenna Areias

Ingredient Definitions - Richard TenEyck

Inspection and Sampling - Jim True

Model Bill - Doug Lueders

Pet Food - Stan Cook

Current Issues and Outreach - Ali Kashani

The charge for the Task Force is:

Review FDA FSMA and regulations, new CGMP rule and FDAAA to identify the changes and develop a prioritized implementation strategy for activities relevant to AAFCO to:

1. Facilitate and coordinate change within AAFCO.
2. Identify, develop and deliver materials needed by members for implementation.
3. Facilitate policy discussions around new FDA rules. e.g. adopt by reference or rewrite models.
4. Coordinate the implementation process with NASDA.

Time Frame: 2 years

Strategic Planning 2017–2020 Report

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	✓	✓	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

Strategic Plan Draft Updated Goals 2017–2020

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

* Top 3 priority goals

** Priority goal 4 for consideration if adequate progress is made on the top 3

Goals that were deleted or integrated

Enhance communications	
5	Expedite the feed ingredient definition approval process (part of 3)
7	Enhance committee performance and support (part of 2, 3 and 8)
13	Identify a deliver system information needs for membership and stakeholders
14	Identify and utilize new technologies for efficient sharing of information with stakeholders
15	Improve internal communications within the Association
16	Increase public awareness of AAFCO programs
18	Participate in Rapid Response Team efforts
20	Continue participation in FDA Integrated Food Protection Plan to 17
21	Focus on Association priorities relevant to regulatory issues
22	Identify common goals of stakeholders

**Outcomes Brainstorming and Activity Identification
Top 3 Priority Goals with FSMA TF activities integrated**

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

* participated in follow up call June 9 to finalize table activities

Outcome	Activity	Resources Needed	Timeline	Responsibility
Strategy: Emphasize feed and food safety				
Goal: Promote and support laboratory technology, methods, quality systems and collaboration				
**Fund AOAC method development and validation	Identify resources to clear out analytical method needs backlog. Use existing strategy to identify method needs and prioritize them to continuously identify new needs (includes sample preparation)	Funds People	6 months (January 2017) to identify resources to address backlog. 3-5 years to address backlog	LSMC
	Identify resources to perform additional (field) sample collection studies	Funds Equipment People	6 months to identify resources 1 year to develop adequate protocols 3 years to perform additional sample collection studies	1. ISC 2. LSMC
***FSMA TF item 3: priority setting and method development for contaminants/hazards	Determine the contaminants, hazards, matrix and action levels to provide guidance to LMSC to inform method development. Integrate collaboratively into current LMSC priorities	Subject matter experts Funds Equipment	Waiting on Alliance work product @ January 2018 (complete method needs statement for LMSC) Up to 3 years for subsequent method development and validation (dependent on whether there is existing method)	FFIMC lead, include Alliance (FSPCA), EIC, ISC, IDC and LMSC
**Validation of sampling methods	Establish sampling methods needs statement. Perform field sampling method validation including sampling equipment and sample type.	Funds Equipment People Time	6 months to establish sampling method needs statement. 5 years to perform sampling method validation.	ISC with LMSC support

Outcome	Activity	Resources Needed	Timeline	Responsibility
** Collaboration between feed 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/email) in AAFCO.	Time People	June 2016 - initial letter to state Directors/Commissioners. August 2016 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. January 2018 develop initiatives to increase collaboration.	AAFCO Board (President) LMSC EIC

** Top 3 outcomes identified at May 2nd 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* Bub

* participated in follow up call June 3 to finalize table activities

Outcome	Activity	Resources Needed	Timeline	Responsibility
Strategy: Promote and enhance membership participation (internal)				
Goal: Enhance collaboration, communication and cooperation among regulatory agencies				
**Share compliance letters/enforcement actions. Coordination of enforcement action.	Categorize Listserv topics to Feed BIN	Administrative support Feed Bin	January 2017	EIC to designate lead with FASS support - Jennifer
	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 FDA) (frequency to be determined)	Listserv EIC IDC Any committee	January 2017	EIC to designate lead with FASS support
***FSMA TF part of item 3: Enforcement strategy for contaminants/hazards	Determine the contaminants, hazards, matrix, action levels and enforcement strategy to provide guidance to LMSC to inform method development and priority setting.		Waiting on Alliance work product	FFIMC lead, include Alliance (FSPCA), EIC, ISC, IDC and LMSC
**Enhanced use of Feed BIN	Identify activities to enhance use	Financial support	August 2017	CIOC
**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	NASDA-AAFCO-FDA FSMA Steering Committee (AAFCO reps: Linda, Ali, Bob W., Richard)
***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		Fall 2015 (was commitment)	MBRC

Outcome	Activity	Resources Needed	Timeline	Responsibility
***FSMA TF item 2 - transition AAFCO GMPs to FSMA GMPs and convert AAFCO Model Feed Safety Program Plan to AFRPS	<ul style="list-style-type: none"> 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 		<p>Now looking to have language finalized for August 2017</p> <p>August 2016</p>	<ul style="list-style-type: none"> a. FFIMC with MBRC and PFC b. FFIMC with OP section editor and Feed Safety Coordinator
FSMA TF item 6 – develop communication plan for AAFCO specific FSMA implementation activities	<ul style="list-style-type: none"> 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	<p>CIOC</p> <p>Working to produce biannual newsletter.</p> <p>Reached out to FDA to help with Communications Plan</p>

** Top 3 outcomes identified at May 2nd planning session

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

Group 3: Dan Danielson, Ali Kashani, Tim Weigner

* participated in follow up call June 8 to finalize table activities

Outcome	Activity	Resources Needed	Timeline	Responsibility
Strategy: Promote and enhance membership participation (internal)				
Goal: Develop and provide professional development and technical training opportunities in support of feed programs				
**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 universities	Subject matter experts. Potential travel for non-Co-Ag contract states	August 2017	ETC together with ISC
**Directory/listing of trainings available	Once training needs and model training plan are done (above), catalogue courses and categorize as basic and advanced	FASS support	August 2017	ETC
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	ETC and ISC
***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	Waiting on Alliance work product January 2018	FFIMC & ISC supported by ETC
***FSMA TF item 5 – review and revise the Feed Inspector’s Manual to support FSMA implementation	Review and review 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/FeedBIN costs.	Have biosecurity work product; considering risk based inspection program position; next step is more fulsome review of Manual (using AFRPS audit experience) to address conflicts before Annual in August 2016. Now to August 2018	ISC supported by LMSC and ETC

** Top 3 outcomes identified at May 2 planning session

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