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Ingredient Definitions Committee 8/2/16 Report

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

1.) Move the following definitions from tentative to Official:

- a. T6.17 L-Methionine
- b. T27.9 Deoiled corn distillers dried grains with solubles, solvent extracted
- c. T54.33 Bovine Colostrum
- d. T54.34 Dried Bovine Colostrum
- e. T57.165 Zinc Hydroxychloride
- f. T71.30 Mustard Meal, Solvent Extracted
- g. T73.300 Sodium Salts of Fatty Acids
- h. T73.301 Potassium Salts of Fatty Acids
- i. T87.29 *Yucca schidigera* extract
- j. T93.9 ____ Wheat Gluten (with edits presented in attachment A)
- k. T96.13 Molasses Hydrolyzed Yeast

2.) Publish the following new definitions as tentative in the Official Publication:

- a. T33.25 Stearic Acid
- b. T33.26 Palmitic Acid

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

- a. 57.160 Zinc Propionate
- b. 57.166 Chromium Propionate

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

Board recommendations to membership:

To be added in October 2016.

Association Actions:

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

8/2/16 Meeting draft minutes

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

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

1) Role Call

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

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

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

- a) T6.17 L-Methionine. Brett Groves moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.
- b) T27.9 Deoiled corn distillers dried grains with solubles, solvent extracted. Steve Gramlich moves to ACCEPT. Brett Groves seconds. MOTION PASSES.
- c) T54.33 Bovine Colostrum. Steve Gramlich moves to ACCEPT. Dave Phillips seconds. MOTION PASSES. Issue raised by Jan Jarman that some companies may make a claim of immunity with the use of this ingredient. Cat Marrier said that Industry is aware that immunity claims are not permitted for this ingredient.
- d) T54.34 Dried Bovine Colostrum. Steve Gramlich moves to ACCEPT. Brett Groves seconds. MOTION PASSES. Cat Marrier indicated that one person in the industry requested a change to maximum 9.5% dry matter, and she indicated wide spread support from the colostrum industry. However she indicated that change would need to be made at a later time.
- e) T57.165 Zinc Hydroxychloride (~~zinc chloride hydroxide monohydrate~~) Brett Groves moves to ACCEPT as amended with second name removed. Mark LeBlanc seconds. MOTION PASSES. Jennifer Kormos informed IDC that the reason that an additional ingredient name was requested was that it is a synonym and is the usual name used in Canada and the EU. Mika Alewynse said that an FDA CPG states that the



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AAFCO ingredient name is the Common and Usual Name of the ingredient. She highly encourages companies to use the AAFCO name. It was agreed that it would be simpler to keep a single ingredient name and Jennifer Kormos agreed that the second name could be struck.

- f) T71.30 Mustard Meal, Solvent Extracted. Bob Church moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.
- g) T73.300 Sodium Salts of Fatty Acids. Mark LeBlanc moves to ACCEPT. April Hunt seconds. MOTION PASSES.
- h) T73.301 Potassium Salts of Fatty Acids. Jacob Fleig moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.
- i) T87.29 *Yucca schidigera* extract. Brett Groves moves to ACCEPT. Ken Bowers seconds. MOTION PASSES.
- j) T93.9 _____ Wheat Gluten. Dave Phillips moves to ACCEPT the edited version of this definition. Mika Alewynse seconds. MOTION PASSES.
- k) T96.13 Molasses Hydrolyzed Yeast. Alan Harrison moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.

3) Work Group Reports

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

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

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

Vince Sewalt pointed out that the GRAS Notified ingredients are no more proprietary than are AAFCO ingredients. There are many ingredients in the



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AAFCO OP that are specific to individual companies. Chromium propionate and stearic acid are examples from today's IDC agenda.

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

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

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

The work group will continue.

- 4) New Definitions, deletes & edits:
 - a) New Term: Animal Food. Charlotte Conway recommends that Feed and Animal Food be used interchangeably. The issue with adopting the FSMA definition is that Specialty Pet Food is not included.
 - b) Modify Term: Feed(s). Charlotte Conway has proposed that this be discussed in a WG and then be brought back to IDC in January.
Animal Food Term Working Group members: Ali, RTE, Charlotte, AFIA, NGFA, PFI, TIPFL, APPA, Mollie, Cathy Alinovi (Next Gen PFMA). WG will plan to meet by web meeting in late September.
 - c) T30.xx Xylanase enzyme (placeholder) — Jan
 - d) Edit 33.3 Hydrolyzed _____ Fat, or Oil Feed Grade — Ken
 - e) T33.25 Stearic Acid. Ken Bowers moves to ACCEPT. Jacob Fleig seconds.
MOTION PASSES.

Charlotte Conway explained that the specifications included in the definition are needed to ensure that the ingredient is safe. FDA has received some questions that the definition may limit the product to that made by only some companies and not all. She recommended that the IDC approve this definition and then consider modifications to the definition at a future date via an amendment to the definition. Debborah Baldwin (Vantage Oleochemicals) relayed that there are other processes besides fractional distillation that can enable meeting these specifications, and these

are not represented in this definition. Her biggest concern is that stearic acid is marketed to feed customers, as it comes from a production process and very often this product will be a mixture of C16 and C18. This is because most stearic acid is from a combination of soy and tallow. Charlotte Conway replied that most of these concerns can be readily addressed through later amendments to the definition. She also felt that the mixture of roughly half C16 and half C18 would not be best defined as Stearic Acid. Doug Smith (Baker Commodities) said that the industry's use of the name Stearic Acid for a product that is roughly half C16 and C18 is not a mixture. Charlotte reiterated that for feed, the ingredient name Stearic Acid should not be used for a substance that is only half stearic acid.

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

- 5) Discussions:
- a) ~~Discussion/clarification on the following ingredient definitions: 57.150 Metal Amino Acid Complex, 57.151 Metal (specific amino acid) complex and 57.142 Metal amino acid chelate.~~
 - b) ~~Acceptable claims on enzymes—ETA~~
 - c) ~~Montmorillonite questions for Industry—Tom (delay)~~
 - d) ~~Materials NOT suitable for animal feed list in the BIN or website—AAFCO (not enough time)~~
 - e) ~~General discussion of materials advised to seek a FAP—CVM (not enough time)~~
 - f) List of standard food names from USDA – Richard (not enough time)
Industry should bring forth a list of common human food ingredients they want in the OP.
 - g) Discussion of Direct-Fed Microbials Modernization – Kristi/Jan/Mika.

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

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

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

Mark LeBlanc moved; Steve Gramlich seconds. Meeting adjourned 3:02PM.



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MOTION PASSES.

Parking lot for the next meeting:

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

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

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Attachment A 8/2/16 IDC meeting

Move to Official:

93.9 _____ **Wheat Gluten** is the major water-insoluble proteinaceous fraction of wheat, consisting primarily of gliadin and glutenin proteins. Wheat gluten is prepared from wheat flour that is free from other seeds and foreign matter, by washing with water to remove most of the water-soluble non-protein components. Vital Wheat Gluten is dried gluten that has retained its viscoelasticity when hydrated, whereas Devitalized Wheat Gluten has reduced viscoelasticity as a result of denaturation by heat. Moisture content shall not exceed 10%. Wheat gluten, on a moisture free basis, must contain not less than 80% crude protein (crude protein based on N x 6.25), and not more than 1.5% crude fiber and 2.0% ash. For identification of the viscoelastic properties on the ingredient label, “vital” or “devitalized” must be specified. The words “vital” or “devitalized” are not required when listing as an ingredient in a manufactured feed. (proposed 2013, adopted 2017)

Publish as Tentative:

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

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

T33.26 Palmitic acid is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats, including hydrogenated oils. It is used as an energy source in growing and adult ruminant diets up to a maximum inclusion of 2% (w/w) in the

finished feed. It cannot be used in pre-ruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly palmitic acid, with lesser amounts of myristic acid. It must contain, and be guaranteed for, minimum 98% palmitic acid, maximum 0.8% myristic acid, minimum 99% total free fatty acids, maximum 1% sulfated ash, and maximum 5 ppm lead. Maximum moisture must also be guaranteed.

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

Publish as Official:

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

57.166 Chromium Propionate

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

(a) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-(μ_3 -oxo) hexakis (μ_2 -propionato-*O,O'*) trichromium propionate with the empirical formula, $[\text{Cr}_3(\text{O})(\text{CH}_3\text{CH}_2\text{CO}_2)_6(\text{H}_2\text{O})_3]\text{CH}_3\text{CH}_2\text{CO}_2$.

(b) It is added to feed as follows:

(1) In the complete feed of broiler chickens and swine at a level not to exceed 0.2 milligrams of chromium from chromium propionate per kilogram of feed.

(2) In cattle diets at a level not to exceed 0.5 milligrams of chromium from chromium propionate per kilogram of the complete feed. Chromium propionate must be premixed with dry ingredients prior to adding to high moisture ingredients or forages.

(c) The additive meets the following specifications:

(1) Total chromium content, 8 to 10 percent.

(2) Hexavalent chromium content, less than 2 parts per million.

(3) Arsenic, less than 1 part per million.

(4) Cadmium, less than 1 part per million.

(5) Lead, less than 0.5 part per million.

(6) Mercury, less than 0.5 part per million.



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- (7) Viscosity, not more than 2,000 centipoise.
 - (d) The additive shall be incorporated into feed as follows:
 - (1) It shall be incorporated into each ton of complete feed by adding no less than one pound of a premix containing no more than 181.4 milligrams of added chromium from chromium propionate per pound.
 - (2) The premix manufacturer shall follow good manufacturing practices in the production of chromium propionate premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production.
 - (3) Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed for broiler chickens and swine and 0.5 parts per million of the complete feed for cattle.
 - (e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:
 - (1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.
 - 2) The label and labeling of the additive and any feed premix shall also contain:
 - (i) A guarantee for added chromium content.
 - (ii) Adequate directions for use and cautions for use including this statement: Caution: Follow label directions. Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed for broiler chickens and swine and 0.5 parts per million of the complete feed for cattle.
- (21 CFR 573.304) (adopted 2017)

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