



Final, Accepted: 9/12/14

Ingredient Definitions Committee meeting

7/26/14 Report

4pm – 6pm PST, Sacramento, CA.

Committee Recommendations to the Board and Membership:

- 1.) Delete the following Tentative definitions:
 - a. T3.2 Dehydrated Alfalfa meal, 2014 online OP rev 1 page 353
 - b. T9.40 Meat Meal, 2014 online OP rev 1 page 361
 - c. T9.41 Meat and Bone Meal, 2014 online OP rev 1 page 361

- 2.) Move the following Definitions to Official status:
 - a. TT 36.16 Dried L-Lysine Fermentation Product 2014 online OP rev 1 page 385
 - b. T60.112 (*blank – Fruit) Pomace, 2014 online OP rev 1 page 414
 - c. T73.100 Yeast for Production of Distillers Products, 2014 online OP rev 1 page 432
 - d. TT73.100 Yeast for Production of Distillers Products, place an “and/or” between the paragraphs describing each yeast, 2014 online OP rev 1 page 432
 - e. T73.105 Sodium Hydroxide Lignin Dehydrated, 2014 online OP rev 1 page 432
 - f. T73.200 Xanthan gum, 2014 online OP rev 1 page 432
 - g. T75.10 _____ Stabilized Rice Bran, 2014 online OP rev 1 page 435
 - h. T87.30 Table of Flavoring agents, 2014 online OP rev 1 page 444

- 3.) Publish the following new definitions as Tentative in the OP: (Text is in “IDC Attachment A”)
 - a. T71.30 Mustard Meal
 - b. T73.300 Sodium Salts of Fatty Acids
 - c. T73.301 Potassium Salts of Fatty Acids
 - d. T57.165 Zinc Hydroxychloride
 - e. T87.29 Yucca schidigera

- 4.) Publish the following CFR language as Official in the OP:
 - a. 87.27 Formic acid, (Text is in “IDC Attachment A”)

- 5.) Publish the new feed term “Field Wilted” in the OP. Text is in “IDC Attachment A”)

Board Recommendations:

Membership Actions:



Final, Accepted: 9/12/14

IDC Committee 7/26/2014 Minutes:

- 1) Committee Members Present: Erin Bubb; Alan Harrison; Brett Groves; Mark LeBlanc; Dave Phillips; Steve Gramlich; Richard TenEyck; Mika Alewynse; April Hunt; Ali Kashani; Don Delorme.
- 2) Industry Advisors Present: Jill Franks; Steve Traylor; Jan Campbell; Jonathan Goodson; Jessica Meisinger; David Meeker; Emily Helmes; Charles Starkey; David Ailor; Kristi Smedley; Dave Dzanis; Jon Nelson; Leah Wilkinson; Jean Hofve; Susan Thixton.
- 3) Life Member: Kent Kitade.

Actions taken on definitions.

- 4) Investigator annual recommendations to move tentative to official
 - a) T3.2 Dehydrated Alfalfa --Erin Bubb recommends **deletion**. Brett moves to ACCEPT; Steve seconds. MOTION PASSES
 - b) T9.40 Meat Meal—Richard recommends move to official. Steve moves to ACCEPT; Brett seconds. Motion Withdrawn

Discussion: Steve Traylor informed that no report had been provided by industry regarding phosphorus content on meat meal and meat and bone meal. Leah Wilkinson said that AFIA has no problems with this as a tentative definition, but not as official. Susan Thixton concurred that this is not agreed. Steve Gramlich withdrew the motion and Dave withdraws second. David Meeker supports deleting the new tentative definition.

Steve moves to delete the T9.40 definition. Dave seconds. MOTION PASSES.

- c) T9.41 Meat and Bone Meal – Richard recommends move to official. Brett moves to delete T9.41. April seconds. MOTION PASSES.
- d) T33.19 Hydrogenated Glycerides – Ken recommends move to official. Alan moves to ACCEPT. Brett seconds. MOTION PASSES.
- e) TT36.16 Dried L-Lysine Fermentation Product, Jan recommends move to official. Dave moves to ACCEPT. Steve seconds. MOTION PASSES.
- f) T54.33 Bovine Colostrum, Richard recommends move to official. Mark LeBlanc moves to leave this definition as tentative. Alan seconds. MOTION PASSES

Leah said that these should be brought forward at annual meeting and permit discussion to take place. Steve T encouraged the IDC to not set a precedent. New ingredients should be published in the paper edition as Tentative before going official.



Final, Accepted: 9/12/14

- g) T54.34 Dried Bovine Colostrum, Richard recommends move to official. Mark LeBlanc moves to leave it as tentative. Steve seconds. MOTION PASSES.

Brett Groves questioned whether there is a test method for colostrum and hence how do we know it is not milk.

- ~~h) TT60.111 Biodiesel derived Glycerin, Item removed from IDC agenda. membership already deleted it on 7/25/14~~
- i) T60.112 (*blank - fruit) Pomace, page 414 Erin recommends move to official. Brett moves to ACCEPT. Mark seconds. MOTION PASSES.
- j) T73.100 Yeast for Production of Distillers Products, Richard recommends move to official. Steve moves to ACCEPT. Dave seconds. MOTION PASSES.

What is the difference between T and TT designation? It indicates there was already a tentative definition in the OP when the next one was proposed. Richard TenEyck said that the TT definition was added by membership in January, and that it has only been published in the online OP and not in the paper OP. Mika explained that this ingredient will only be seen on the yeast label going to the ethanol producer.

The yeast would be a component of the DDGS, as such the yeast would not be listed as an ingredient in any feedstuff.

- k) TT73.100 Yeast for Production of Distillers Products, Richard recommends move to official. Steve moves to ACCEPT. Ali seconds. MOTION PASSES. Steve Traylor suggested that there should be an “or” separating these 2 definitions, otherwise it will be very confusing.
- l) T73.105 Sodium Hydroxide Lignin Dehydrated, Richard recommends move to official. Steve moves to ACCEPT. April seconds. MOTION PASSES.
- m) T73.200 Xanthan gum, Richard recommends move to official. Mark moves to ACCEPT. Brett seconds. MOTION PASSES.
- n) T75.10 ____ Stabilized Rice Bran, page 435, IDC recommends move to official. Ali moves to ACCEPT. Mark seconds. MOTION PASSES.
- o) T87.30 table of flavoring agents on page 444, Richard recommends move to official. Mark moves to ACCEPT. Brett seconds. MOTION PASSES.

Mika said that these are the natural flavors that CVM has used enforcement discretion for a long time. Kristi said that they are currently listed as Food Additives for human use.

- p) T93.9 ____ Wheat Gluten , page 453, IDC recommends move to official. Mika so moved; Steve seconds. Mark mentioned that it is not in the hard copy of the AAFCO OP. Mika removed her motion. Steve seconds. Mark moved that this remain tentative. Dave seconds. MOTION PASSES.

5) New Definitions

- a) T71.30 Mustard Meal -Modification - Bob Church. Mark moves to ACCEPT. Brett seconds. MOTION PASSES.
Bob Church said that he has taken several questions on this definition and believes that the definition should be tightened. Steve (Agrisoma), a Canadian company that supplies mustard meal and they believe that the definition should remain as is or that this variety should be added to the new tentative definition. He presented information on Brassica carinata, Ethiopian mustard. They have conducted animal feeding trials and have gotten Canadian approval and are working with the US FDA currently. It is essentially identical to other mustard meals on the market. Mika Alewynse clarified that the Agrisoma information is still under review and that FDA cannot support this addition to the definition at this time. Leah questioned whether we are going to review every species and every crop and this creates a large burden for industry. Susan Thixton commented that she would like to see the animal species specified. Judy Thompson pointed out that the company could market based on the current official definition. Mika said that the company can market the mustard meal if they have self-determined as GRAS based on scientific procedures using a qualified expert panel. Kristi Smedley said that if an ingredient is safe and meets an AAFCO definition, then it can be marketed.
Dave Dzanis reminded that we have always in the past added a new Tentative definition and then automatically removed the old definition.

Mika moves to REMOVE the original definition, 71.30 Mustard Meal, Solvent-extracted. Brett seconds. MOTION FAILS.

Judy Thompson asked how you can delete a definition without any notification. Leah agreed that this change cannot be made without notification as this would indeed have market ramifications.
- b) T73.300 & T73.301 Sodium Salts of Fatty Acids and Potassium Salts of Fatty Acids – Richard (**One request split into two definitions**). Steve moves that T73.300 become a new tentative definition. Brett seconds. MOTION PASSES. Steve moves that T73.301 be made a tentative. Erin seconds. MOTION PASSES.
- c) T3.5 Direct Dehydrated Alfalfa Meal or Pellets --- NO MOTION MADE.



Final, Accepted: 9/12/14

Erin recommended that this needs more work. IDC agreed to defer. Erin proposes a Work Group be formed to include members of states where alfalfa is produced together with stakeholders. Richard asked Erin to come back in January with a consensus solution

d) T57.165 Zinc Hydroxychloride – Jennifer Kormos.

Mark moves that the definition be approved as Tentative. Dave seconds. MOTION PASSES.

Susan Thixton is concerned about the amount of heavy metals allowed in this ingredient particularly lead. Kristi Smedley indicated that the established metal contaminate levels were below the AAFCO prescribed limits for mineral products and below the tolerable levels set by NRC. Mika explained that the level used would be extremely low in the diets and the metals content were reviewed and the use level restriction was imposed. Jean Hofve explained that pet foods include 300% of NRC and hence this is a concern. Jon Nelson informed that the levels are quite low. Dr. Oscar Chavez, DVM & Dr. Cathy Alinovi, DVM from the audience spoke and presented concern of bioaccumulation of the lead in the human food. Mika said that they looked at margin of safety in their evaluation and FDA toxicologists reviewed this ingredient dossier. In this case, there was no concern however specifications were put in place to ensure that use would be safe. Susan Thixton of Association for Truth in Pet Food asked Mika Alewynse of FDA if consideration was given to the effects of heat for this ingredient such as with extrusion and Dr. Alewynse couldn't recall.

e) T3.2A Dehydrated Suncured Alfalfa – NO MOTION MADE.

Erin recommended that this needs more work. IDC agreed to defer. Erin proposes a Work Group be formed to include members of states where alfalfa is produced together with stakeholders. Richard asked Erin to come back in January with a consensus solution.

~~f) T27.xxx deoiled distillers grains. (placeholder) — Steve removed from agenda~~

~~g) Xx.xxx Glucose Syrup (late add) (need form) — Mika removed from agenda~~

~~h) xx.xxx Hydrolyzed Wheat Protein (late add) (need form) — Mika, removed from agenda~~

i) T87.29 Yucca schidigera, –Richard.

Mika moves to ACCEPT this new tentative definition. Steve seconds. MOTION PASSES. The plan is to leave the current definition in the table until this new tentative definition becomes official.

6) Modifications to tables etc.

- a) 87.27 Formic Acid, page 431-Sharon. This is an editorial change to add the CFR language for this Food Additive into the OP. Steve moves to ACCEPT. Mika



Final, Accepted: 9/12/14

seconds. MOTION PASSES.

- b) **New Feed Term:** Field Wilted (process)-Material partially dried by exposure in open air and to the direct rays of the sun before further processing. – Ali. Steve moves to ACCEPT. Mark seconds. MOTION PASSES.

Ali said that the alfalfa investigator felt this was needed. Jon Goodson advised that the current terms work fine. Erin Bubb added that this feed term would be useful in that it is being used by alfalfa processors.

7) Discussion Topics:

- a) Meat Meal Work Group Report – (need new leader) Jan Jarman, Meagan Davis, Susan Thixton, Dave Meeker, Jill Franks, Leah Wilkinson. No report was given. Discussion was held to determine if the group was needed. Industry said no, consumers said yes. Susan Thixton of Association for Truth in Pet Food objected to tentative ingredients being deleted and then the meat meal working group being disbanded. No regulators were willing to lead the group. Chair instructed that the Work Group be disbanded. The chair will pursue other means to accomplish the revisions needed in the animal products section.
- b) Report on Ingredient Monograph Pilot - Kent Kitade. Kent reported the results of the monograph pilot project. For Food Additives and GRAS definitions, the FDA looks at information from one firm, according to Dan McChesney. Therefore by having monographs on ingredients, then it would provide standards for the ingredients no matter who proposed the ingredient. Dan McChesney, FDA voiced support of the concept. It was agreed to take this topic up in a Webinar in the future to enable discussion on this topic.
- c) Environmental information on definition requests – Mika Alewynse , CVM. Mika informed the committee that there has been some confusion about the information needed to support an AAFCO definition. Because of FDA's interest in having definitions become food additive regulations (21 CFR 573), FDA is asking for an environmental statement specific to the regulations as provided in 21 CFR 25. As the vast number of ingredients occur naturally in the environment and are sources of proteins, minerals, and hence this is a substitution of the use of other ingredients. New ingredients will typically not have a material impact on the environment. Mika indicated that most AAFCO definition could likely refer to the categorical exclusion for natural product ((21 CFR 25.32(r)). Submitters should consider what happens to the ingredient in the environment, and whether any extraordinary circumstances take place with the ingredient. Exemptions from the need for environmental assessments need to be correctly articulated in definition request packages. Examples of this type of exclusion language can be found at 21 CFR 25.32. Kristi Smedley noted that ingredient definitions, as they are handled under enforcement discretion, were not under the jurisdiction of the National Environmental Policy Act (NEPA) as such are not required to provide an



Final, Accepted: 9/12/14

environmental assessment. This is similar to GRAS notifications as no rule-making is promulgated., no environmental assessment is required.

- d) Update on the number of food additive petitions and number of ingredient definitions that are submitted for review. – Mika, CVM. 12 Active food additive petitions. 5 Inactive food additive petitions. 18 Ingredient definitions are being worked on. This is the largest number the CVM has ever had.

- e) The following Definition Requests are stale. The submitting firm needs to respond to the indicated investigator by 7/26/14 or the request will be removed without prejudice from investigator consideration. Typically CVM has asked the firm for more information 2 years ago or more, and has not received a response. The firm will need to send a new request package with all information if they want to pursue the listing after 7/26/14. For communication only. NO MOTION WAS MADE.
 - i. Oilseed Protein Modified - Bob Church
 - ii. Agave Syrup — Erin Bubb
 - iii. Artemia Frozen Biomass - Richard Ten Eyck
 - iv. Artificially Dried Deer Antler Velvet - Richard
 - v. Borage Oil - Ken Bowers
 - vi. Brewers Condensed Yeast – Jenna Areias
 - vii. Choline Stabilized Orthosilic Acid – Erin
 - viii. Cooked Bone Meal (modify Definition to incl steamed)- Jennifer
 - ix. CoQ10 – Erin
 - x. Gelatin By Products (modify 60.29) – Richard
 - xi. Hydrolyzed Whole Cassava Meal - Erin
 - xii. Kiwi Fruit Extract – Erin
 - xiii. Kombo Nut - Erin
 - xiv. Meadowfoam Seed Meal – Bob
 - xv. Milk Protein Concentrate - Richard
 - xvi. Noni Fruit – Richard
 - xvii. Stevia Rebaudiana (flavor) - Richard
 - xviii. Sunflower Hull Ash - Bob (needs to go to Jennifer)
 - xix. Whey Minerals - Richard
 - xx. Whey Permeate Dried Yeast - Richard

IDC Attachment A for 7/26/14 meeting

Recommendation #3: Publish the following new definitions as Tentative in the OP:

- 1.) **T71.30 Mustard Meal, Solvent Extracted** is the product obtained by grinding the cake which remains after removal of some of the oil by mechanical extraction, and removing most of the remaining oil by solvent extraction. It is obtained from the seed of the cultivated mustard plants *Brassica juncea*, *Brassica nigra*, and *Sinapis alba* (formerly *Brassica alba*). Use should be restricted to cattle and sheep and at no more than 10% of the ration. It should not be fed to lactating dairy cows if milk production is for human consumption because of objectionable taste and/or odor. (Proposed 1972, Adopted 1973,)

IFN 5-12-149 Mustard seeds meal solvent extracted

- 2.) **Binders**

T73.300 Sodium Salts of Fatty acids are obtained by the neutralization of feed grade vegetable origin free fatty acids, or saponification of vegetable oil or a combination thereof. The specifications of the starting materials must meet the requirements stated in the AAFCO definition 33.3 (Hydrolyzed Vegetable Fats, or Oils, Feed Grade) and the AAFCO definition 33.2 (Vegetable Fat, or Oil), respectively. Sodium hydroxide is used in the neutralization or saponification reactions. The resulting sodium salts are used as a binder and/or lubricant in the pelleted and flaked feed. The source of the fatty acids or vegetable oil shall be indicated on the label.

Sodium salts are in dry form with the maximum moisture not to exceed 8 percent by weight. It may be used in animal feed in amounts calculated on an "as is" basis not to exceed 5.5 lb/ton. Sodium salts of Fatty Acids shall be labeled with guarantees on an "as is" basis for no more than 0.5% free fatty acids, no more than 12% glycerin, not less than 67% total sodium salts of fatty acids, and no more than 1% unsaponifiable matter.

- 3) **Binders**

T73.301 Potassium Salts of Fatty acids are obtained by the neutralization of feed grade vegetable origin free fatty acids, or saponification of vegetable oil or a combination thereof. The specifications of the starting materials must meet the requirements stated in the AAFCO definition 33.3 (Hydrolyzed Vegetable Fats, or Oils, Feed Grade) and the AAFCO definition 33.2 (Vegetable Fat, or Oil), respectively. Potassium hydroxide is used in the neutralization or saponification reactions. The resulting potassium salts are used as a binder and/or lubricant in the pelleted and flaked feed. The source of the fatty acids or vegetable oil shall be indicated on the label.



Final, Accepted: 9/12/14

Potassium salts are in liquid form with the maximum moisture not to exceed 68 percent by weight. It may be used in animal feed in amounts calculated on an “as is” basis not to exceed 15.5 lb/ton. Potassium salts of Fatty Acids shall be labeled with guarantees on an “as is” basis for no more than 0.5% free fatty acids, no more than 10% glycerin, not less than 24% total potassium salts of fatty acids, and no more than 1% unsaponifiable matter.

- 4) **T57.165 Zinc hydroxychloride** is the hydrolysis product of zinc chloride having the empirical formula $Zn_5(OH)_8Cl_2(H_2O)$. The particle size must not exceed 100 microns. It must contain not less than 54% zinc and is intended to be a source of zinc for use in livestock and companion animal diets. It must not contain more than 20% chloride, 90 ppm lead, 15 ppm chromium, 10 ppm arsenic, 10 ppm cadmium, and 0.2 ppm mercury. (Proposed 2014 rev 2)
- 5) **T87.29 Yucca schidigera Extract** may be used as a flavoring agent in all animal foods. It is also an aid in the control of manure odor (post-excretion) when added to finished feeds of poultry, livestock, rats, mice, hamsters, gerbils and hedgehogs. The inclusion rate shall be the minimum quantity necessary to produce the intended effect, but not exceeding 125 ppm in the finished feed. 21 CFR 172.510.IFN 8-19-700 Yucca, Mohave extract.

Recommendation #4 Publish the following CFR language as Official in the OP:

- 6) **87.27 Formic Acid** is manufactured by heating carbon dioxide and NaOH under pressure and decomposing the resulting sodium formate with H_2SO_4 , the resulting formic acid, CH_2O_2 , has a molecular weight of 46.02 Formic acid may be safely used in accordance with the following conditions:
 - (a) The additive is used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of the silage on a dry weight basis or 0.45 percent when direct cut, as follows:
 - (1) The top foot of silage stored should not contain formic acid and
 - (2) Silage should not be fed to livestock within 4 weeks of treatment.
 - (b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.
 - (1) The additive consists of not less than 85 percent formic acid (CAS 64-18-6).
 - (2) The additive meets the following specifications:
 - (i) Free methyl alcohol not to exceed 1,000 parts per million (ppm);
 - (ii) Methyl formate not to exceed 1,000 ppm; and
 - (iii) Moisture not to exceed 15 percent.
 - (3) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug and Cosmetic Act, the label and labeling shall contain:



Final, Accepted: 9/12/14

- (i) The name of the additive.
- (ii) Adequate directions for use including a statement that formic 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 formic acid.
- (4) 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)(3) of this section, the label and labeling shall contain:
 - (i) Appropriate warnings and safety precautions concerning formic acid (85 percent formic acid).
 - (ii) Statements identifying formic acid (85 percent formic acid) as a corrosive and possible severe irritant.
 - (iii) Information about emergency aid in case of accidental exposure.
 - (A) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.
 - (B) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS). (21 CFR 573.480) (Proposed 2011, Adopted 2012, 2013, edited xxxx)

Recommendation #5 Publish the new feed term

- 7) “**Field Wilted (process)**-Material partially dried by exposure in open air and to the direct rays of the sun before further processing.”