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# **Ingredient Definition Committee Minutes** (approved 8/1/10).

Chair, Ingredient Definitions Committee

DATE: August 1, 2010

TO: AAFCO Ingredient Definition Committee: members, advisors and investigators and all other interested parties.

RE: 2010 Annual Meeting IDC Minutes

The Ingredient Definitions Committee (IDC) met Sunday, August 1, 2010, from 3:30 – 4:54 PM, The Nines Hotel, Portland Oregon.

A conference call number was available during the meeting and was used by 1 participant. Role sheets were circulated with 149 participants including committee members and advisors. Committee members present were: Aaron Elam (vice chair), Ann Brueck (by phone), Brett Groves, Ken Jackson, Ricky Schroeder, Shannon Jordre, Kent Kitade (present not-voting), Ali Kashani, Linda Morrison (for Paul Loeven), Sharon Benz (for John Machado), and Richard Ten Eyck (chair). Committee advisors present were: David Dzanis, ACVN; Richard Sellers, AFIA; Jan Campbell, NGFA; Dave Ailor NOPA; David Meeker, NRA; Jill Franks, PFI; Nancy Cook, PFI; Jon Nelson AFIA; Dave Fairfield, NGFA.

Sharon Benz, FDA, gave a brief overview of the pathways available for the FDA to approve new feed ingredients. The FDA wants to move away from using enforcement discretion letters, which are used by AAFCO to begin the definition process. This will leave GRAS affirmation and the Food Additive Petition processes available to firms wanting to bring a new ingredient into the U.S. market. As of the Portland Meeting, no timeline was given by the FDA as to when they will eliminate the use of enforcement discretion letters.

The ingredient definition committee leadership formed a workgroup to edit and modify the "new and modified ingredient definitions" guide listed in the 2010 official publication on pages 310 and 311. The workgroup goal is to reflect and explain the current ingredient definition process clearly to all audiences. This should include state and federal



regulators, petitioners, AAFCO investigators, and consumers. Membership on the working group is still being established.

Neil Lanning, Animal Products Investigator, discussed the need to form a workgroup for animal protein products. Details are listed in the discussion items.

A brief explanation of how to make and amend a motion was given to the committee. Members were encouraged to move agenda items to be accepted, have the investigator explain them, and then vote to accept or reject the investigators recommendation.

An offer was extended to the audience members to join the ingredient definitions committee. No one accepted the invitation, and no changes to the published agenda were requested.

**Agenda items with committee action indicated:** (accepted definitions with approved edits are in attachment A.)

### 1. Definitions to be moved from Tentative to Official

- 1.1. 60.110 Ground Pecan Shell Shannon Jordre moved to accept, motion passed.
- 1.2. 60.98 L-Carnitine Shannon Jordre moved to accept, motion passed.
- 1.3. 60.108 Salvage Pet Food Shannon Jordre moved to accept, motion passed. One dissenting vote by Canada. They do not believe a mixed feed should be an ingredient. Same concern with distressed pet food.
- 1.4. 60.109 Distressed Pet Food Shannon Jordre moved to accept, motion passed.
- 1.5. 57.163 Selenium Yeast Mel (I have Shannon moved to accept) moved to accept, motion passed. One question was asked. It was pointed out the definition reflects the CFR.

#### 2. New Definitions to place in OP as tentative:

- 2.1. T 60.111 Biodiesel-derived Glycerin Shannon Jordre moved to accept, motion passed. There was some discussion regarding the limited scope of the proposed definition, which only includes glycerin derived from vegetable oils. Linda Benjamin, FDA, and David Meeker, NRA, will pursue amending the newly accepted definition to include glycerin derived from animal fat.
- 2.2. T 93.9 Vital Wheat Gluten Ann Brueck *This item was removed from the agenda to be discussed at the next meeting. To be brought back with a companion definition for wheat gluten.*



2.3. T 87.26 Ammonium Formate – Shannon Jordre moved to accept, motion passed. The definition will reflect the CFR when printed in the OP.

## 3. Editorial Changes or Modifications to Existing Definitions

- 3.1. 36.14 Megasphaera elsdenii (cattle only) Shannon Jordre moved to accept, motion passed. (This item was in the tentative definition portion of the agenda but should have been in modifications, reflects CFR regulation)
- 3.2. 87.15 Formaldehyde Solution Shannon Jordre *moved to accept, motion passed.*
- 3.3. Charcoal –withdraw Feed Term Shannon moved to accept, motion passed. Charcoal (term withdrawn 2010) to be placed in withdrawn section of the OP.
- 3.4. Rapeseed meal -withdraw –Bob Church. No motion made to accept. Bob asked for comment regarding the withdrawal of this definition at the next meeting.

#### 4. Discussion Items:

Flow agents in Soybean Meal – Richard Ten Eyck reported on the conference call with industry following the mid-year meeting in Redondo Beach. Some soybean crushers are not declaring added flow agents (limestone) in their ingredient statements. The conference call confirmed that this is a federal requirement. The soybean meal definitions in the OP correctly reflect the federal regulations. (discussions after the IDC meeting revealed industries concern is that this may cause them to be taxed as a mixed feed.) Dave Ailor will set up a conference call with Bob Giegor to further clarify this issue. Labeling of flow agents in other protein meals also needs to be addressed.

Lysine Sulfate – Bill Burkholder (for Mika Alewynse) Discussed species allowed in the fermentation products used to provide lysine sulfate. He presented a powerpoint prepared by Mika Alewynse. Lysine products with 50% lysine should be labeled as \_\_\_\_\_\_ fermentation products. There is one strain of micro organisms on the market that is not approved for feed in the US, but it is approved in some other countries.

Flax Seed Meal – Richard Ten Eyck / Bob Church Discussed terminology in stabilizing this material. If a material states that it is stabilized it must declare the manner in which it was stabilized. e.g. heat stabilized flax seed meal. Some of the omega acid marketers are getting slack with their ingredient names and might call this ingredient flax meal -- which would be the entire plant ground up.





Diatomaceous Earth (food grade) – Richard Ten Eyck / Ann Brueck. Addressed an industry complaint regarding the use of "food grade" on diatomaceous earth labels. When reviewing other companies labeling they claimed (wrongly) their ingredient was silicon dioxide. Silicon dioxide does have a human food additive approval, but it is not a mined product according to the AAFCO definition. States that this is coming from need to pursue misbranding investigations.

Meat and Bone Meal (calcium/phosphorus ratio) – Neil Lanning gave an overview of animal protein product issues at the start of the IDC meeting. A literature review revealed that 55% of meat and bone meal nutrient profiles do not meet the current definition specifications for calcium and phosphorus ratios. A workgroup was formed to address needed changes in the definitions. Workgroup to propose definition changes by January 2011 meeting. Neil Lanning (chair); Nancy Cook, PFI (will appoint a representative); Richard Sellers, AFIA (will appoint a representative); David Meeker, NRA; Ricky Schroeder, TX; and Richard Ten Eyck, OR. volunteered to help.

Colostrum labeling, Richard Uncles was designated as the point of contact to discuss solutions regarding this issue, which may include a definition.

Corn Gluten, Ken Jackson was designated as the point of contact to discuss corn gluten not containing gluten. Topic came from vital wheat gluten discussion

# The following items were not discussed and need to be rolled forward to the next meeting:

Yeast species used in animal feed –Mika Alewynse Citric acid locations in the GRAS lists –Mika Aleweynse Review all contents of GRAS lists -Mika Alewynse Other Definitions with Chromium levels –Mika Alewynse

### Topics Left from past meetings: (to be rolled to next meeting)

- 1.) Edits in Chemical Preservatives Section Linda Benjamin
- 2.) Unrefined salt –Mel Bryant
- 3.) Menadione Ali Kashani (seminar item)

Meeting adjourned at 4:54 PM.

Committee held in place while Aaron Elam read the minutes aloud to the committee.

Minutes accepted as read 8/1/10 by all members present.



### Attachment A.) to 8/1/10 IDC minutes

# Move following definitions from Tentative to final:

- 60.110 **Ground Pecan Shell** is obtained by grinding the hard outer shell. It must be reasonably free of the nut meat and other foreign material. It is to be used as a source of dietary fiber. A minimum crude fiber level must be guaranteed on the label. (Proposed 2009)
- 60.98 **L-Carnitine** is a nutritional supplement with a minimum content of 97.0% L-carnitine and a maximum of 0.5% D-isomer. L-carnitine is for use in swine feeds at levels not to exceed 0.1% (1000 ppm) of complete feed, for use in chicken and turkey feeds at levels not to exceed 0.02% (200 ppm) of complete feed, for use in fish feed at levels not to exceed 0.25% (2500 ppm) of complete feed, for use in milk replacers for ruminant animals at levels not to exceed 0.075% (750 ppm) of milk replacer powder, for use in dog feeds at levels not to exceed 0.075% (750 ppm) of complete feed on a dry matter basis, and for use in cat foods (intended for adult maintenance only) at levels not to exceed 0.10% (1000 ppm) of complete feed on a dry matter basis. L-Carnitine is a fatty acid carrier that plays a role in fat oxidation in the body. (Proposed 1997, Amended 1999, Amended 2002, Adopted 2004, Amended 2009)
- \*60.108 **Salvage pet food** is a product resulting from pet food manufacturing. This product may consist of, but is not limited to, start-up and over-run product, unfinished pet food, pet food fines and other product not suitable for packaging for retail sale. If it contains, or may contain, any material identified by 21 CFR 589.2000 as prohibited from use in the feed of ruminant animals, or if it is no longer accompanied by a detailed label listing all of the ingredients in the salvage pet food, the label must contain the precautionary statement "Do not feed to cattle or other ruminants". It shall be free of foreign materials harmful to animals, suitable for the purpose for which it is being marketed, and properly labeled for its intended use. (\* The asterisk indicates that this ingredient may be subject to 21 CFR 589.2000.) (Proposed 2004, Amended 2006)
- \*60.109 **Distressed pet food** is a product resulting from pet food distribution, but which is no longer available for retail sale. This product may be pet food in, but not limited to, dented cans, torn bags, product past its sell-by date, or returned product that is suitable for use in feed. It may consist of a single formula, still in the original packaging, or a variety of formulas commingled into one bulk container and containing none of the original packaging or labeling. If it contains, or may contain, any material identified by 21 CFR 589.2000 as prohibited from use in the feed of



ruminant animals, or if it is no longer accompanied by a detailed label listing all of the ingredients in the distressed product, the label must contain the precautionary statement "Do not feed to cattle or other ruminants". It shall be free of foreign materials harmful to animals, suitable for the purpose for which it is being marketed, and properly labeled for its intended use. (\* The asterisk indicates that this ingredient may be subject to 21 CFR 589.2000.) (Proposed 2004, Amended 2006)

- 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. (Proposed 2002, Amended 2003, 2004, 2007\*, 2008, 2009)



# New definitions to be placed in the OP as tentative:

**T60.111 Biodiesel-derived glycerin** is a liquid co-product of biodiesel production derived from refined vegetable oils by a base catalyzed transesterification process. 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 0.15% methanol and not more than 5 ppm of heavy metals. It may contain up to 8% salt and 0.1% sulfur.

It is for use in an amount not to exceed that necessary to accomplish its intended effect and is not to exceed 15% of the complete feed for ruminants and 10% of the complete feed for all other livestock species.

The label shall include guarantees for minimum glycerin, maximum water, and maximum methanol as well as the statement "For further mixing into livestock feed."

- **T87.26 Ammonium Formate** The food additive, partially ammonium formate, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:
- (a) The additive is manufactured by the reaction of 99.5 percent ammonia gas and 99 percent formic acid in a continuous loop reactor to produce a solution made up of 37 percent ammonium salt of formic acid and 62 percent formic acid.
- (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.
- (c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:
- (1) The name of the additive.
- (2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate.
- (d) To assure safe use of the additive, in addition to the other information required by the act and paragraph (c) of this section, the label and labeling shall contain:
- (1) Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid).
- (2) Statements identifying ammonium formate in formic acid (37 percent ammonium





salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.

- (3) Information about emergency aid in case of accidental exposure as follows:
- (i) 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.
- (ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).



# **Editorial or modifications of existing definitions:**

<b>36.14</b> Insert into the organism list in definition No36.14	
Name:_ Direct-fed microorganisms:	

<u>Megasphaera elsdenii (cattle only)</u> (During the meeting this was presented and accepted as a new tentative definition. It reflects a CFR change and should not come into the book as tentative.)

- **87.15 Formaldehyde** -- the food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:
- (a) The additive is used, or intended for use, to improve the handling characteristics of fat by producing a dry, free-flowing product, as follows:
- (1) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelletted feeds for beef and non-lactating dairy cattle.
- (i) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 303, 308, and 309, which is incorporated by reference. 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 copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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.
- (ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.



- (iii) To assure the safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling of the dried mixture shall bear:
- (A) The name of the additive.
- (B) Adequate directions for use providing that the feed as consumed does not contain more than 25 percent of the mixture.
- (2) For soybean and canola seeds and/or meals to which there may be added vegetable oil as a component of dry, nonpelleted feeds for beef and dairy cattle, including lactating dairy cattle.
- (i) An aqueous blend of oilseed and/or meals, with or without added vegetable oil, in a ratio such that, on a dry matter basis, the final protein level will be 25 to 35 percent and the fat content will be 20 to 45 percent. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 301, 307, 308, and 309, which is incorporated by reference. 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 copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers lane, rm. 1061, Rockville, MD 20852, 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.

- (ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 2.7 percent of the dry matter weight basis of the oilseeds and/or meals and the vegetable oil. This mixture, upon drying, contains not more than 0.5 percent formaldehyde and not more than 12 percent moisture.
- (iii) To assure the safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture shall bear:
- (A) The name of the additive.
- (B) The statement, "This supplement is not to exceed 12.5% of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat."



- (C) The minimum and maximum levels of crude fat must be guaranteed and must be between -5 percent and +5 percent of the analyzed fat content for each batch.
- (b)(1) The food additive is formaldehyde (CAS No. 50-00-0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients *Salmonella* negative for up to 21 days.
- (2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:
- (i) The name of the additive.
- (ii) A statement that formaldehyde solution which has been stored below 40 deg. F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.
- (iii) Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."
- (iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."
- (3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:
- (i) Appropriate warnings and safety precautions concerning formaldehyde.
- (ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.
- (iii) Information about emergency aid in case of accidental inhalation.
- (iv) 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.
- (v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).





Delete feed term "Charcoal" from page 315 of OP (2010). Insert in withdrawn section : Charcoal (feed term, withdrawn 2010).