



Shannon Jordre
Division of Compliance
FDA/CVM, HFV-235
7519 Standish Place
Rockville, MD 20855
Telephone: 240-276-9229
Fax: 240-276-9241
E-mail: shannon.jordre@fda.hhs.gov

Ingredient Definitions Committee
Miscellaneous & Special Purpose
Products Investigator

MEMORANDUM

DATE: August 29, 2007

TO: Ingredient Definitions Committee
Other Interested Parties

RE: 2007 Annual Meeting – Report of IDC Committee Meeting

The Ingredient Definitions Committee (IDC) met Friday, August 3, 2007, from 3:30 - 5:00 PM, in the Ambassador East room at the Amway Grand Plaza Hotel in Grand Rapids, Michigan. The meeting was well-attended with 96 people signing-in. We had a busy, productive meeting. The agenda was ambitious, and for those items for which there was significant discussion the report below contains a very brief summary of those discussions (in italics, below the business item). The definitions discussed are also provided, so everyone can see exactly what was proposed, and if changes made. The following items were on the agenda for consideration:

Definitions to be moved from Tentative to Official

1) T87.15 Formaldehyde Solution [**ACCEPTED**]

T87.15 Formaldehyde solution may be safely used in the manufacture of animal feeds according to the following conditions: (a)(1) The additive is used, or intended for use, to improve the handling characteristics of animal fat in combination with certain oilseed meals by producing therefrom a dry, free-flowing product as follows: (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. (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. (a)(2) The dried mixture described in paragraph (a) of this section is used, or intended for use, as a component of dry, nonpelleted feeds for beef and nonlactating dairy cattle. (3) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug & Cosmetic Act (the Act), the label and labeling of the dried mixture described in paragraph (a) of this section shall bear: (i) The name of the additive. (ii) Adequate directions for use providing that feed as consumed is not to contain more than 25 percent of the mixture. (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). (21 CFR 573.460)

Editorial Changes/ Modifications to Existing Definitions

(Language to be deleted is lined-out, and new language is underlined)

2) 63.1 Beet Molasses **[ACCEPTED]**

Beet Molasses is a by-product of the manufacture of sucrose from sugar beets. It must contain not less than 48% total sugars expressed as invert ~~and its density determined by double dilution must not be less than 79.5 Brix.~~

3) 63.3 Citrus Molasses **[ACCEPTED]**

Citrus Molasses is the partially dehydrated juices obtained from the manufacture of dried citrus pulp. It must contain not less than 45% total sugars expressed as invert ~~and its density determined by double dilution must not be less than 17.0 Brix~~

4) 63.7 Cane Molasses **[ACCEPTED]**

Cane Molasses is a by-product of the manufacture of sucrose from sugar cane. It must contain not less than 43% total sugars expressed as invert. ~~If its moisture content exceeds 27%, its density determined by double dilution must not be less than 79.5 Brix. and not less than 73% total solids.~~

After some discussion, and a timely phone call, we determined that the last sentence fragment in the definition request above, the "and not less than 73% total solids", was not part of the existing definition, and was not intended to be part of the modified definition, so that language was struck and the proposal accepted.

5) 90.12 Vitamin E Supplement **[TABLED UNTIL NEXT MEETING]**

90.12 Vitamin E Supplement – is a feeding material used for its vitamin E activity. It must contain a minimum vitamin E activity equal to 10,000 International Units of vitamin E per pound. Ingredients used for their Vitamin E activity may be admixed with silicon dioxide at levels up to 50% to produce a vitamin E supplement for addition to animal feed. Where silicon dioxide is used as a dispersant and/or flow agent to assist with uniform and consistent distribution of the vitamin E supplements in animal feed, silicon dioxide should be declared on the ingredient list of the vitamin E supplement.

We had several minutes of discussion about the use of silicon dioxide in the definition and subsequent use of the terms "dispersant" and "flow agent". Once we determined that consensus would not be reached, the Investigator said he would work with the sponsor and FDA to clarify the language, and that he would plan to bring the proposal back to the group at the meeting in January 2008.

6) Table 87.5 Yucca Schidigera Extract **[ACCEPTED]**

Name : Yucca Schidigera Extract, FDA Regulation: 172.510, Classification: Flavoring agent in feeds of all animals; as an aid in the control of manure odor (post excretion) in the finished feeds of poultry and livestock,
Limitations: Minimum quantity necessary to produce intended effect, but not exceeding 125 ppm.

New Tentative Definitions

7) T96.8 Yeast Culture **[REMOVED FROM THE AGENDA AS REQUESTED BY THE INVESTIGATOR]**

T96.8 Yeast Culture is the dried product composed of yeast and the media on which it was grown, dried in such a manner as to preserve the fermenting activity of the yeast. The media must be stated on the label. (For label identification the source must be identified in the guarantee as either Saccharomyces cerevisiae, Kluyveromyces marxianus or as permitted by FDA.) *Note: No reference to media in main ingredient listing is required when yeast culture forms a component of a proprietary mixed feed.

Prior to the meeting the Investigator asked that this item be taken off the agenda. Yeast Culture has been on the agenda for the last several meetings, and has been deferred while discussions are held concerning whether or not the definition includes non-viable yeast. The Investigator is continuing to work on resolution of this issue and will bring the proposal back to a future meeting.

8) T90.25 25-Hydroxyvitamin D3 **[ACCEPTED]**

Recognized English Name	Article or Substance Indicated	Status Under Food Additive Amendments 21 CFR
25-Hydroxyvitamin D ₃	Source of Vit. D ₃ Activity-- 25-Hydroxyvitamin D ₃ -- Commercial Feed Grade	Reg. 584.725 (Affirmed as GRAS)

9) T48.89 Corn Protein Concentrate **[ACCEPTED AS AMENDED DURING THE MEETING]**

Corn Protein Concentrate is the dried proteinaceous fraction of the corn primarily originating from the endosperm after removal of the majority of the non-protein components by enzymatic solubilization of the protein stream obtained from the wet-mill process. This proteinaceous fraction of the corn must contain not less than 80% protein on a moisture free basis and not more than 1% starch on a moisture free basis. The product must be labeled on "as fed" basis. This fraction shall be free of fermented corn extractives, corn germ meal, and other non-protein components except in such amounts as might occur unavoidably in good manufacturing processes. Vegetable oils or other appropriate ingredients as defined in Section 87 in the Association of American Feed Control Officials Official Publication (AAFCO OP) may be added in concentrations not to exceed 3% to reduce dust during handling. The name of the ~~conditioning~~ dust control agent, if used, must be shown as an added ingredient.

We spent a significant amount of time discussing this definition. The first issue discussed was what is the definition of a "conditioning agent", and eventually the Committee replaced "conditioning" with the words "dust control". The second issue discussed was how the product should be labeled once it goes into commerce. After further discussion the Committee added the sentence requiring the product to be labeled on an "as fed" basis. The edits reflected above are the changes made during the meeting.

Addition to Table 87.5

10) Sodium Hexametaphosphate **[ACCEPTED]**

Name : Sodium Hexametaphosphate, FDA Regulation: 582.6760, Classification: Sequestrant,
Limitations: In accordance with good manufacturing or feeding practice as a tartar control agent coated on dry food products for reducing the accumulation of dental tartar in dogs or cats.

Discussion Items

The following items were not submitted for official action, but for informal discussion by the committee and interested people attending the meeting. As a result, no official action was taken on any of the following topics; however, official action could take place in the future as a result of follow-up by the Investigators or other committees.

11) Adding sulfur guarantees to certain maize product definitions

This issue, sulfur levels in co-products of ethanol production, has been discussed at IDC meetings in the past, however, it seems to have become a more common problem and there is more interest in modifying the affected definitions (most are in either maize products or distiller's products) than there has been in the past. Because this is predominantly an issue in ruminant feeds it was suggested that perhaps it would be better to have the feed labeling committee develop a labeling strategy for ruminant feeds and ingredients rather than to do this ingredient by ingredient. As it stands at this writing, the Investigators have been

charged with researching which of their ingredients this might apply to, and considering definition changes, and the Feed Labeling Committee is also exploring their options for dealing with this situation.

12) Wheat Gluten

This was discussed as a follow-up to the melamine contamination earlier this year. Wheat gluten, although not defined in the AAFCO Official Publication, it does have a feed term in the AAFCO OP. Wheat gluten has a long history of use in animal feed and is a well-understood product, and the regulatory agencies can support the use of wheat gluten in feed.

13) Rice Protein Concentrate, and other undefined vegetable protein concentrates

This was also discussed as a follow-up to the melamine contamination earlier this year. A question about rice protein concentrate had been raised by a feed control official at an IDC meeting in the past year, but without significant discussion. Ingredient suppliers and feed manufacturers were encouraged to make sure that ingredients they manufacture and/or use are approved by FDA, defined by AAFCO, or recognized in some other manner. It is difficult for regulatory agencies to explain the use of unrecognized ingredients to the public.

14) Selenium Yeast – why allow as much as 2% inorganic Se in this definition?

An industry member asked why the FDA regulation and AAFCO definition for selenium yeast allow as much as 2% inorganic selenium in the product definition, when it is possible to make selenium yeast with less inorganic selenium than that? The regulation and definition are based on the data submitted to FDA for review, and the regulation and definition reflect the date that FDA reviewed.

15) Rewriting model animal waste regulations

Eric Nelson, Recycled Animal Waste Products Investigator, will be looking at whether the recycled animal waste product definitions need to be updated, and will be working with the Model Bill and Regulations Committee to review the Model Regulations for Processed Animal Waste to see if those regulations need to be updating. The Investigator and the Model Bill Committee welcome comments and help with these efforts.

16) Write guidelines for proper use of feed terms

The IDC has briefly discussed the proper use of the AAFCO Feed Terms a couple of times in the past few years, but this issue continues to draw interest. Rod Noel, Feed Term Investigator, will be putting together a small group to begin drafting up some guidance on the appropriate use of feed terms. The Investigator would welcome comments and help with this effort.

17) GIPSA Federal Register announcement regarding the establishment of standards for ethanol production inputs and byproducts

The USDA Grain Inspection, Packers and Stockyards Administration (USDA/GIPSA) published a Federal Register announcement in July asking for comment on the prospect of their agency establishing standards for specialty grains intended for use in biofuel production, as well as the feed co-products coming out of these biofuel operations. Ricky Schroeder and Brett Groves are coordinating AAFCO's response to this announcement and would welcome comments from AAFCO members. The IDC would also encourage individual states to comment.

If you have any questions or comments regarding this report, please contact me.