

AAFCO Ingredient Definitions Committee Meeting

Mid Year January 13, 2015, San Antonio, TX

Committee Report & Minutes

IDC Recommendations to Board and Membership (text is in minutes):

- 1.)** Publish the tentative definition in the OP for T6.17 L-Methionine.
- 2.)** Publish the tentative definition in the OP for T27.9 Deoiled corn distillers dried grains with solubles, solvent extracted.
- 3.)** Edit the OP to Add Paenibacillus lentus to each of the carbohydrase enzyme categories of alpha-Amylase, beta-Glucanase, Hemicellulase, beta-Mannanase, and Xylanase in table 30.1 in the OP. (2015 OP page 374)
- 4.)** Delete 71.39 Mustard Meal, Solvent Extracted from the OP, (2015 OP page 422)
- 5.)** Publish the tentative definition in the OP for T93.9 Hydrolyzed Wheat Protein.
- 6.)** Publish the tentative definition in the OP for T96.13 Molasses Hydrolyzed Yeast.
- 7.)** Edit the tentative definitions by adding Lentil as an accepted pulse crop to T60.113 Pulse fiber, T60.114 Pulse flour, T60.115 Pulse protein and T60.116 Pulse starch. (2015 OP Page 215-216)
- 8.)** Publish the tentative definition for **T33.19 Hydrogenated Glycerides** as Official. (2015 OP page 381) *(item is from the 7/26/14 IDC meeting)*

Secretary-Treasurer please note funding request placeholder at the end of the minutes.

Board Recommendations: (will consider in April 2015)

Membership Action: (will consider in August 2015)



IDC Midyear 2015 amended; Final 3/30/15

IDC Minutes 1/13/15 Face to Face at Midyear

Attending:

Committee Members: Richard TenEyck; Al Harrison; Steve Gramlich; Mika Alewynse; Ali Kashani; Dave Phillips; Bob Church; Ken Bowers; Brett Groves; Mark LeBlanc. On-Phone: Erin Bubb; Jan Jarman; Tim Darden; Marla Luther.

Industry Advisors: Charles Starkey; Jonathan Goodman; Jessica Meisinger; David Meeker; Vincent Sewalt; Steve Traylor; David Ailor; Betty McPhee; Leah Wilkinson; Jan Campbell; Dave Dzanis; Kristi Smedley; Susan Thixton; On-Phone: Jean Hofve.

Gallery: Approx. 200 industry and 50 regulatory.

New definitions or deletes or edits

T6.17 L-Methionine: Move to publish the tentative definition in the OP for: T6.17 L-Methionine is a product containing a minimum of 98.5% L-isomer of 2-amino-4-(methylthio)butanoic acid. L-Methionine is produced by Escherichia coli K12 fermentation followed by enzymatic conversion to L-methionine. The percentage of L-methionine must be guaranteed.(proposed 2015)

Ali Kashani moves to ACCEPT; Brett Groves seconds. **MOTION PASSES.**

T27.9 Deoiled Corn Distillers: Move to publish the tentative definition in the OP for: T 27.9 Deoiled corn distillers dried grains with solubles, solvent extracted is the product resulting from the solvent extraction of oil from corn distillers dried grains with solubles (DDGS) to result in a crude fat content of less than 3% on an as fed basis. It is intended as a source of protein. The label shall include a guarantee for minimum crude protein and maximum sulfur. The words “solvent extracted” are not required when listing as an ingredient in a manufactured feed. (Proposed 2015) Steve Gramlich moves to ACCEPT; Brett seconds. **MOTION PASSES.**

30.1 Paenibacillus lentus as enzyme source: Move to Add Paenibacillus lentus to each of the carbohydrase enzyme categories of alpha-Amylase, beta-Glucanase, Hemicellulase, beta-Mannanase, and Xylanase in table 30.1 in the OP.

Ali moves to ACCEPT; Brett seconds. **MOTION PASSES.**

W33.5 Delete fat product feed grade existing definition. Ken Bowers moves to delete definition 33.5 from the OP; Al Harrison seconds. Brett moves and Ken seconds a motion to table the present motion until August. **MOTION PASSES TO TABLE THIS ITEM UNTIL AUGUST 2015.**



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Discussion: Richard asked Industry to contact Ken on this topic. Mika Alewynse informed the Committee that this definition is being used inappropriately and that unsafe products have been placed on the market. She noted a number of the products marketed were not feed grade as specified by the definition. Susan Thixton asked how fat currently described by this definition would be used? Kristi Smedley relayed that all products marketed to the feed industry must be safe according to the law. Instead of removing this definition, which safe products are being marketed under, she recommended that either product specifications should be added to the existing definition and/or that the Agency and States should take action against the offending companies. David Meeker indicated that he surveyed the industry and a number of safe (and intended) products were being marketed based on this definition, removal of the definition would negatively impact these products.

71.39 Delete mustard meal existing definition; Bob moves to delete 71.39 from the OP; Steve G seconds. **MOTION PASSES.**

Discussion: Mika pointed out that she has concerns about this definition due to glucosinolate content. Kristi mentioned concern that if this definition were deleted that any products on the market would need to stop being marketed.

T87.35 Glucose Syrup: Move to publish the tentative definition in the OP for: 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. When derived from corn, wheat, rice, sorghum or tapioca, the name of the starch will replace the word, glucose. (21 CFR 168.120) (proposed 2015)

Ali moves to ACCEPT; Steve G seconds.

Brett moves to TABLE the motion; Mark LeBlanc seconds. **MOTION PASSES TO TABLE THIS ITEM UNTIL AUGUST 2015.**

Discussion: Dave Dzanis asked why a new definition is needed as this is already a common and usual term and is a standardized food, and includes “_____ syrup” (rice syrup, corn syrup, barley syrup, or any other starch). This definition appears to conflict with the standards of identity for the already standardized food. Mika explained that she developed this language analogous to other AAFCO definitions. Kristi suggested adding a reference to the relevant 21 CFR section, and that this might be a useful approach for many new ingredient definitions in light of the FDA’s often publishing lengthy regulations. Mark LeBlanc suggested changing “will” to “may” in the final sentence of the definition.

T93.10 Hydrolyzed wheat protein. Move to publish the tentative definition in the OP for: T93.9 Hydrolyzed Wheat Protein is the product resulting from complete enzymatic hydrolysis of isolated vital wheat gluten and must contain not less than 80% crude protein and not more than



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1.5% ash and 6.0% crude fat. (Proposed 2015)

Dave Phillips made a motion to accept. Brett seconds. **MOTION PASSES.**

Discussion: Leah Wilkinson asked why this definition is limited to enzyme hydrolysis only. Dave said that this product can be produced also by acid hydrolysis but that product produced by that process may be associated with human allergy issues. It was pointed out that CVM does not consider allergens (either animal or human) an issue of concern for animal feed. Mika said that this submission was abandoned by the firm but then brought forward by CVM with some new information (label) and that this enzyme hydrolysis method of production was the only one described in the original submission.

T96.13 Molasses hydrolyzed yeast. Move to publish the tentative definition in the OP for:

T96.13 Molasses Hydrolyzed Yeast is a concentrated, non-extracted, partially soluble yeast digest. Yeast cells are sourced from the fermentation of molasses for ethanol production. Solubilization is accomplished by enzymatic hydrolysis of whole *Saccharomyces cerevisiae* cells. Salts may be added as processing aids in accordance with good manufacturing practices. It must not contain less than 30% crude protein. (proposed 2015)

Alan made a motion to accept; Brett seconds. **MOTION PASSES.**

Pulses: Erin Bubb moves to Edit the tentative definitions by adding Lentil as an accepted pulse crop to T60.113 Pulse fiber, T60.114 Pulse flour, T60.115 Pulse protein and T60.116 Pulse starch. Edit to show:

Accepted pulse crops:

IFN 05-17-726 – Pea (*Pisum sativum* L.)

Lentil (*Lens culinaris*)

Erin Bubb moves; Brett seconds. **MOTION PASSES.**

Discussions

BioFuels Industry generation of undefined feed ingredients & Spent Filter cake use. Mika

Alewynse explained that she understands that companies conduct self-determination of GRAS on ingredients for intended uses, she recommends that the companies submit these as GRAS Notifications to the FDA. Alternatively companies may submit a new ingredient dossier to the AAFCO Investigator to be submitted according to the Ingredient Definition Request process, or they may send a Food Additive Petition dossier to the CVM. Mika added that companies must consider whether their GRAS self-determination has considered contaminants associated with the process might be unaccounted for. Is there the possibility of undesired levels as animal tissue residue? One firm mentioned they would like to see “crude” added to the biodiesel definition name. Mika mentioned that she had heard that some companies are seeking to market products such as spent filter-cakes. Such products may contain dioxins and hence would present food safety concerns. Companies must assess the safety in use of their prospective



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ingredients in a holistic way. FDA encourages firms to submit animal feed dossiers to the Agency prior to marketing them.

Add Deoiled DDG to collective terms. Richard advised interested companies/parties to send any comments to Aaron Elam (OK) prior to June 2015.

Extension of MOU between CVM and AAFCO. In October 2014, FDA offered to extend the MOU from September 2015 to September 2017. Richard convened an MOU Working Group to discuss this topic and review the language to determine whether any changes needed to be made. The main change being requested by IDC is to have a commitment to a timeline of 60 days for a completeness check and 180 days for a review. Doug Lueders opined that these changes present a difficult expectation for FDA to agree to in a limited time, and that we should instead focus on having the MOU extension signed. Sharon Benz relayed that the timelines suggested by the Working Group are simply not doable given the DAF resources. Leah Wilkinson said that while it would be helpful to have a timeline for IDC submissions since the FDA reviews currently take quite a long time. However, the most pressing concern for industry is to have the MOU extension to 2017 signed. The MOU Working Group agreed to take all of the comments under advisement.

A general discussion ensued about the long time dossiers spend in the “queue” waiting to have a completeness check and be reviewed. In addition, Kristi mentioned that the data requirements for dossiers have grown considerably, and this contributes to a longer review period. It was mentioned that FDA ONADE has resolved the lengthy review time problem by enacting the ADUFA (Animal Drug User Fee Act). One suggestion was made that perhaps an external group could be hired by AAFCO, and this group would conduct triage on all IDC dossiers. Sharon concurred that this might help improve the Quality Assurance to help dossier submissions be more complete, and that this might help make the process more efficient. Kristi Smedley mentioned that the feed ingredient industry is so frustrated by the long queue and review times that they are considering other options for ingredient approvals.

Nancy Cook mentioned that companies are being asked for items that are not covered in the AAFCO IDC process. Mika mentioned that FDA Staff gave a series of presentations (available on the aafco.org site) at the 2004 AAFCO Meeting and that sponsors should review and refer this information. Kristi said that she felt that the slides may be out of date; however, there is a draft guidance document for FAPs that FDA has in development. This document provides minimum guidance. Perhaps the final version of the guidance could provide the guide to all the data FDA needs for an FAP or AAFCO defined term. Another idea suggested by Leah would be to hold an ingredient definition submission workshop at a future meeting.

On another topic related to the AAFCO OP, Sharon commented that her team is charged with finding legal homes for all of the ingredients in the AAFCO OP, taking the book section by section. They are trying to GRAS Affirm as many ingredients as they can. For the recently



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reviewed ingredients, FDA is studying whether they can write a food additive regulation for the substances. They want to be sure that they have sufficient data to show that the ingredients meet the FDA standards of safety, delivering on its intended use, and can be produced to meet standards. That is why it may appear that the requirements for AAFCO defined substances have increased. The next step would be that they would reach out to ingredient manufacturers to ask them to publish data to support a GRAS affirmation or submit a FAP.

Removing temporary clearance to use High Erucic Acid Rapeseed. FDA issued a letter allowing industry to use this ingredient temporarily while a new definition request is being compiled for submission. To FDA's knowledge no progress has been made on the definition request. The FDA is urging companies to submit the new definition request, alone or as a group of companies, to substantiate a new definition. The letter will expire if substantive progress is not made on the topic.

Increase the fiber in 93.5 Wheat Middlings from 9.5% to 12.5%. Dave Phillips. Ben Burrows from NA Milling Association informed the group that this definition was accepted in the 1960s and changes have been made from the production mills. He recommended that interested parties contact Dave Phillips outside the meeting.

Strategic Affairs survey questions. Richard asked the Committee Members to respond to the survey questions via the Feed Bin in the next month.

5. Work Group Reports

- a) Monograph pilot report. Kent Kitade. Kent moved to accept the report. Mark seconded. **MOTION PASSES.** The report will be on file in the BIN in the ingredient definitions library. Richard will skim the report for action items and bring them to the appropriate committee or the board. The Chair thanks the pilot workgroup for their efforts in developing and vetting the monograph template.
- b) MOU Workgroup. Richard displayed the draft MOU document. Kristi pointed out and Sharon concurred that the word "efficacy" should be changed to "utility". Steve G asked how long it would take for FDA to review and respond, to which Sharon replied 180 days is their typical response time. Richard will pass the revised language to the board in the next week.
- c) Dehydrated Alfalfa. Alfalfa Workgroup report – Erin Bubb delivered a Dehydrated Alfalfa slide presentation from the workgroup. In 2004, Ann Bruick (ID), (past) Investigator, worked through modifications to the dehydrated alfalfa definition. Suncured alfalfa was included in the definition for alfalfa dehydrated. This inclusion of suncured alfalfa was never included in the original definition. Erin will bring the alfalfa definitions to the annual meeting. Brett moves to disband the Workgroup; Al seconded. **MOTION PASSES.** Ken Vaupel commented from the floor that the way Erin has written the T 3.2 dehydrated definition it allows mixing with sun-cured but it isn't called out in the name and he thinks it should be.



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6) The following Definition Requests are stale. The submitting firm needs to respond to the indicated investigator by 1/13/15 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 1/13/15.

- a) __ Protein Modified – Bob
- b) Low Molecular Weight Feathers Hydrolysate - Richard

IDC Parking Lot: (actions for future meetings)

Responsible	Item	Action	Timing / Status
Richard	Preservative Section	Sort out antioxidants vs. preservatives	
Mika	Chromium Levels	Identify and edit other definitions containing chromium	
Ken	Fat Product	Take up motion to delete 33.5 Fat Product Feed Grade at August 2015 meeting	August 2015
Richard	Glucose Syrup	Take up motion to add T87.35 Glucose Syrup at August 2015 meeting	August 2015
Richard	Standards of Identity	Review Monograph Pilot Report for needed actions	January 2016

Financial needs 2015-16: Expect we need to hold a 4 hour briefing on how to submit a definition request. Set aside \$2000 for AV and Travel.

Minutes approved 2/18/15 by vote in feed BIN.