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Ingredient Definitions Committee Minutes

Final

DATE: August 21, 2012

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

RE: 2012 Annual Meeting IDC Minutes (draft)

Minutes taken by April Hunt; edited by Richard Ten Eyck; Reviewed by Aaron Elam, Leah Wilkinson, Vince Sewalt

134 Attendees on Role sheet

The Ingredient Definitions Committee (IDC) met Sunday August 5, 2012 4:05 PM – 6:10 PM Marriot, Indianapolis, IN.

Conference call Line and webex site were provided for the meeting.

Roll call with introductions:

Members: (16) Richard Ten Eyck, Aaron Elam, Deb Hargrave (for Don Delorme), Brett Groves, Ali Kashani, Roger Hoestenbach, Ricky Schroeder, Linda Morrison, Steve Gramlich, Mark Leblanc, Erin Bubb, April Hunt, Neil Lanning (conference line) Shannon Jordre

Non-voting members: Mika Alewynse, Becky Muir (conference call)

Committee Advisors: (12) David Ailor, Dave Dzanis, Jill Franks, Pat Tovey, Jan Campbell, Jonathan Goodson, Leah Wilkinson, David Meeker, Vince Sewalt, Jon Nelson, Jean Hofve

Guests: Jenna Stoia, Susan Thixton

BOARD ACTION ITEMS: The committee recommends the board passes to the membership the following changes to the official publication: A, B, C, D, E (Text of the action items is in attachment A).

A.) Move the following definitions from tentative to official:

- 1. Definitions to be moved from Tentative to Official (Kashani/Gramlich motion carried) <u>1.1.T60.12</u> Quinoa Seed –Roger approved in January
 - 1.2. T60.98 L-Carnitine -Roger
 - 1.3. T87.18 Reed-Sedge Peat Roger approved in January

Roger received no comments on 1.4 – 1.6 (Hostenbach/Bubb- motion carried)

- 1.4. T87.26 Ammonium Formate Roger
- 1.5. T87.27 Formic Acid -Roger
- 1.6. T87.28 Castor Oil -Roger

B.) Accept the following new definitions and place them in the OP as tentative:

- 2. New Definitions:
 - 2.1. T73.100 Yeast for Production of Distillers Co-Products Mika (Kashani/Groves motion carried)
 - 2.2. T73.105 Sodium Hydroxide Lignin Dehydrated Richard (Gramlich/Groves motion carried)
 - 2.3. moved to discussion section
 - 2.4. moved to discussion section
 - 2.5. moved to discussion section
 - 2.6. moved to discussion section
 - 2.7. moved to discussion section

C.) Edit the following tables and listings and place in the OP as Official

2.8, 2.9, 2.10 - Motion to accept the table as shown (Jordre/Elam – motion carries)

- 2.8. Phytase enzyme Definition number 30.1 *Trichoderma reesei* Enzyme table, Phosphatase section. Mika
- 2.9. Pytase enzyme- move Penicillum f. into it's own box for poultry only. Mika
- 2.10. Listing of S. pombe derived phytase in 2012 OP page 380
- 2.11. section 73 Header for new processing aid section Ten Eyck Motion to form working group of: Vince Sewalt, Leah Wilkinson, Jill Franks and Linda Morrison will review document and edit for the January meeting. The header is

to clarify what goes in the section since it is not populated yet (TenEyck/Gramlich – motion carried)

2.13. Correct list in 36.14, ADD R. palustris – Mika

2.13.1. (Gramlich/Jordre – motion carried) Direct-fed are accepted in a viable state. Direct fed products, organism should appear on this list, should respect species limitations, these are live organisms and so at this time, we are only able to assess these species. There is an improper list circulating with the DirectFed list that does not include the species limitations.

2.14 Correct page 368 remove 87.1 algae meal from list (Jordre/Gramlich – motion carried) Currently algae meal in the OP and CFR is only defined as a coloring agent. The collective terms are not meant to provide new uses that go beyond how the ingredient is defined.

2.14a add kelp and seaweed in collective term plant protein –Aaron (Jordre/Gramlich – motion carried)

2.12 section 66 NPN notes section – Aaron (moved from 2.12) Add the following to the non-protein nitrogen section notes:

Condensed, Extracted Glutamic Acid Fermentation Product

See Definition 36.1 in Fermentation Products Section; Condensed, Extracted Glutamic Acid Fermentation Product as a source of Non-Protein Nitrogen.

Condensed_____ Fermentation Solubles See Definition 36.10 in Fermentation Products Section; Condensed _____ Fermentation Solubles as a source of Non-Protein Nitrogen. (Hostenbach/Groves – motion carried)

6.13 Edit Header for Mineral section for clarity – Mel Bryant (Groves/Jordre – motion carried)

3. Modifications:

D.) Add these modified definitions as tentative to the OP

3.1. T3.2 Dehydrated Alfalfa Meal – Erin Bubb (Gramlich/Jordre – motion carried)

3.2. T36.1 Condensed, extracted Glutamic Acid Fermentation Product (Gramlich/Elam – motion carried with the word "maximum" added to read: "(4) Maximum non-protein nitrogen content must be guaranteed when present."

3.3. T36.10 Condensed molasses fermentation solubles Discussion that maximum would be appropriate due to the safety concerns. (Gramlich/Groves – motion carried with the Investigator's recommendation to add the word "maximum")

- 3.4.84.4 Soybean Feed, Solvent Extracted Geiger (placeholder) discuss only Did not cover during the meeting, place in parking lot for January.
- 3.5. T75.10 Stabilized Rice Bran Jamey Johnson (pg 426) (Gramlich/Groves motion passes) Hofve will look into working with Johnson and Gramlich on possible language regarding effects on cats.

3.6. T 60.111 Bio Diesel Derived glycerine – Roger, need FDA review (parking lot) E) Move to Model Bill Committee with recommendation to adopt and place in uniform policy section: MSP

Live Plants and Animals Distributed as Food for Pets and Specialty Pets Policy Statement

Live plants and animals typically distributed as food for pets and specialty pets, such as but not necessarily limited to rodents, insects, fish, and grasses, shall be exempt from registration and labeling as commercial feed products, unless the manufacturer or distributor, in its product labeling or advertising, makes any claim that the product contains added nutrients or otherwise implies increased nutritional value.

This exemption does not apply to direct-fed microorganisms and other products or ingredients defined in the AAFCO Official Publication, or plants and animals that are not live at the time of purchase.

4.) Withdrawn Definitions:

-none-

The following agenda sections 5 through 9 are provided as information for the committee and advisors. They may prompt development of future definitions:

- 5.) Food Additive Petitions received by FDA (contact CVM for more information)
 - 5.1 CLA in dairy cattle
 - 5.2 Bioengineered (GLA) Safflower seed meal in cattle and poultry
 - 5.3 Calcium Formate in poultry and Swine Feed

5.4 Erthromycin Thiocyanate as an antimicrobial processing aid in distillers. (2 filings)

- 5.5 Penicillin G Procaine as an antimicrobial processing aid in distillers.
- 6.) Discussion Items:

6.1 workgroup report on whole live animals excluded from definitions policy statement. – Aaron. Workgroup: Aaron Elam (lead), Roger Hostenbach, Dave Dzanis, Shannon Jordre

Workgroup presented a 7/13/2012 draft AAFCO Policy Statement on the issue. The draft exempts these animals from regulation with a few exceptions. Motion to send the draft to Model Bills and Regulations Committee for review for future inclusion in the OP (Hostenbach/Jordre – motion carried)

6.2 MOU expiration, extention and cleaning up the pipeline. –Sharon Benz (tabled to next meeting)

6.3 **5:00PM** History of beverage and fuel distillers grains. -Brett Groves (tabled to next meeting)

6.7 **5:05 PM** What feed co-products should we expect from isobutanol production? - speaker: Harold Tilstra, D.V.M. Land O'Lakes Purina Feed (by Phone) Dr. Tilstra gave a PowerPoint presentation to the group by phone. Isobutanol is a distillation with an alcohol that is the direct result of fermentation.

6.12 **5:10 PM** T33.10 ______ Distillers Oil, Feed Grade, - Kim Young, Marla Luther, Discussion of how to label ingredient in the market place until industry finishes AAFCO definition request. Should it be in the market in the interim? Young & Luther: FDA looked at the ingredient section and put together a tentative draft definition they presented to the group. The definition still needs some values and additional information to support or modify as needed. FDA welcomes input from industry on the draft definition so it can be ready to present to the IDC at the January meeting. Industry is preparing the needed data package to support a new definition. In the mean time the material should be marketed as "Fat Product, Feed Grade".

6.4 Page 334 Workgroup report – Richard Workgroup: Richard Ten Eyck*, Kristi Smedley*, Gary Yingling*, John Machado, Glo Dunnavan, Dave Fairfield, Aaron Elam, Sharon Benz, Kent Kitade, Nancy Cook, Shannon Jordre, Linda Morrison, Emily Helmes, Vince Sewalt, *denotes draft edit team Ten Eyck reported. Progress has been made, but draft not ready for presentation yet.

Ten Lyck reported. Progress has been made, but drait not ready for presentation yet.

6.5 Work Group report: Need for lamb meal, rabbit meal, or venison meal. –Neil Neil Lanning (lead) Jill Franks, Steve Traylor, Leah Wilkinson, Jean Hofve, Susan Thixton, Dave Meeker

Lanning reported group has not met, only had a couple 1:1 phone exchanges. Has been in contact with work group, waiting for a consensus definition to come forward.

6.6 Flavor approvals in Animal Feed. What are the rules? How to add them to the OP? - Leah Wilkenson, AFIA, Mika Alewynse, CVM Alewynse suggested that these flavors and their uses can be added in the OP.

Hostenbach has a flavor agent list that's almost ready for inclusion. He and Alewynse will work with Ten Eyck to put them into proper form for introduction to the IDC for

inclusion in the OP at the January meeting. Others interested in contributing to the list can contact Hostenbach before the January meeting deadlines.

Most of the remaining topics were tabled due to time constraints.

6.8 Krill vs. Shrimp meal – (mika) parking lot

6.9 GRAS ingredients with no-question letters. We have 3 now, how does IDC want to proceed? (need speaker) parking lot

6.10 How to use the new IDC web forum for discussions and voting. –Jenna Will do by webinar this fall with the committee and advisors.

6.11 Pulses – discussion of definition request modifications – Roger parking lot

6.13 moved up to section 2

6.14 Roger H. would like input on grocery waste nomenclature and concerns.

6.15 Spent Bleaching Clay – Dave Ailor Addressing with request to modify unified policy #28

6.16 Wheat Gluten will be on the January agenda. Contact is Steve Gramlich. parking lot

6.17 Header for Feed Terms Section. Ali and Meagan are editing for clarity. parking lot

- 7.) GRAS Notifications to FDA: (as of 5/15/12 does not include no basis items)
 7.1 Hydrophobic Silica as a component of a defoamer used as a processing aid up to 20 ppm in distillers grains with solubles. (*FDA has no Questions*)
 7.2 Polyethylene glycol (400) dioleate as a component of a defoamer used as a processing aid up to 64 ppm in distillers grains with solubles. (*FDA has no Questions*)
 - 7.3Polysorbate 60 as a component of a defoamer used as a processing aid up to 20 ppm in distillers grains with solubles. (*FDA has no Questions*)
 - 7.4 Inactivated modified Saccharomyces cerevisiae as a component in animal feed when used in corn fermentation and distillation to produce isobutanol. (*Pending*)

7.5 Isobutanol Distillers grain as a component of animal feed. (Pending)

- 8) Topics Left from past meetings including 8/5/12: (parking lot for future action items)
 - a) Edits in Chemical Preservatives Section, antioxidant vs. preservative Richard
 - b) T 60.111 Bio Diesel Derived glycerine Roger
 - c) Other Definitions with Chromium levels Mika
 - d) 60.115 pumice Roger
 - e) section 73 Header for new processing aid section Ten Eyck
 - *f*) 84.4 Soybean Feed, Solvent Extracted Geiger
 - g) MOU expiration, extention and cleaning up the pipeline. –Sharon Benz
 - h) Page 334 Workgroup report Richard Workgroup: Richard Ten Eyck*, Kristi Smedley*, Gary Yingling*, John Machado, Glo Dunnavan, Dave Fairfield, Aaron Elam, Sharon Benz, Kent Kitade, Nancy Cook, Shannon Jordre, Linda Morrison, Emily Helmes, Vince Sewalt, *denotes draft edit team
 - *i*) T33.10 _____ Distillers Oil, Feed Grade, Kim Young,
 - j) History of beverage and fuel distillers grains. -Brett Groves
 - k) Work Group report: Need for lamb meal, rabbit meal, or venison meal. Neil; Neil Lanning (lead) Jill Franks, Steve Traylor, Leah Wilkinson, Jean Hofve, Susan Thixton, Dave Meeker
 - *I)* Flavor approvals in Animal Feed. What are the rules? How to add them to the OP? Leah Wilkenson, AFIA, Mika Alewynse, CVM
 - m) Krill vs. Shrimp meal (mika)
 - n) GRAS ingredients with no-question letters. We have 3 now, how does IDC want to proceed
 - *o*) Pulses discussion of definition request modifications Roger
 - p) _____ Wheat Gluten Steve Gramlich
 - *q)* Header for Feed Terms Section. Ali and Meagan are editing for clarity.
- 9) FDA Presentation on electronic portal for document submission. –Tim Schell, FDA, gave a PowerPoint presentation to the group regarding the upcoming Electronic Document Submission and Review (EDSR) process FDA is moving towards in the next year. Esubmitter is a program that will need to be downloaded on the submitter's computer.

We'll use new web page to vote on minutes after we get home.

MEETING ADJOURNED Approximately 6:10 PM

Attachment A. Ingredient Definitions Committee recommendations 8/5/12

A.) IDC recommends the definitions 60.98,87.26, 87.27 and 87.28 be made Official:

IDC committee Recommendation	Voted to accept and forward to board on 8/5/12.
Board Recommendation	
Membership Vote	

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. L-Carnitine is also for use for dog foods at levels not to exceed 0.075% (750 mg/kg) on a dry matter basis, and for use in cat foods (intended for adult maintenance only) at levels not to exceed 0.10% (1000 mg/kg) 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, Amended 2011)

87.26 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 Safey Data Sheet (MSDS). (Proposed 2011)

87.27 Formic Acid is manufactured by heating carbon monoxide and NaOH under pressure and decomposing the resulting sodium formate with H2SO4, the resulting acid, CH2O2 has a molecular weight of 46.02. Formic acid may be safely included in swine feed as a pH control agent at levels not to exceed 1.2% in the finished feed. (Proposed 2011)

B.) IDC recommends the new definitions T73.100 and T73.105 be published as tentative:

IDC committee Recommendation	Voted to accept and forward to board on 8/5/12.
Board Recommendation	
Membership Vote	

T73.100 The ingredients list of the yeast marketed to the ethanol manufacturer should declare the genus species of the yeast and the enzyme that is expressed.

Saccharomyces cerevisiae expressing glucoamylase from Saccharomycopsis fibuligera for use in dry grind corn fuel ethanol production of distillers coproducts for animal feed. Distillers products for use in animal feed contain no live bioengineered yeast.

T73.105 Sodium Hydroxide Lignin Dehydrated is obtained from the acid precipitation of lignin from spent black liquor produced in the sodium hydroxide and steam digestion of wheat straw without a bleaching process. The final product is dried to a powder with less than 4% moisture by weight. It must contain, and be guaranteed for, not less than 83% total lignin (including acid insoluble and acid soluble lignins) and not more than 3.5% of ash. It is used as a pelleting aid in livestock and poultry feeds in an amount calculated on a dry weight basis not to exceed 4% of the finished pellets.

C.) IDC recommends publishing as official: the edits to phosphatases in table 30.1; the edits to the organism list in 36.14: edits to the plant protein collective term; edits to the header of the mineral section; edits to section 66 NPN notes.

IDC committee Recommendation	Voted to accept and forward to board on 8/5/12.
Board Recommendation	
Membership Vote	

Table 30.1

Table 30.1	r			
Classification/N	Source Organism	Typical	Function	Current
ame		Substrate ¹		Supported Use
Phosphatases				
Phytase	Aspergillus niger, var Aspergillus oryzae, var Phytase canola (Brassica napus expressing the Aspergillus niger phytase gene) Aspergillus oryzae expressing the Peniophora lycii phytase gene Schizosaccharomyces pombe expressing an Escherichia coli strain B phytase gene Pichia pastoris expressing a phytase gene from a Risk Group 1 Escherichia coli Trichoderma reesei expressing an altered phytase gene from a Risk Group 1 Escherichia coli Trichoderma reesei expressing an altered phytase gene from a Buttiauxella sp. Penicillum funiculosum*	corn, soybean meal, sunflower meal, hominy, tapioca, plant byproducts	hydrolyzes phytate	Increases the digestibility of phytin-bound phosphorus in swine and poultry diets *Increases the digestibility of phytin-bound phosphorus only in poultry diets

Definition 36.14 organisms:

Aspergillus niger Aspergillus oryzae Bacillus coagulans **Bacillus** lentus **Bacillus** licheniformis Bacillus pumilus **Bacillus** subtilis Bacteroides amylophilus Bacteroides capillosus Bacteroides ruminocola Bacteroides suis Bifidobacterium adolescentis Bifidobacterium animalis Bifidobacterium bifidum Bifidobacterium infantis Bifidobacterium longum Bifidobacterium thermophilum Lactobacillus acidolphilus Lactobacillus brevis Lactobacillus buchneri (cattle only) Lactobacillus bulgaricus Lactobacillus casei Lactobacillus cellobiosus Lactobacillus curvatus Lactobacillus delbruekii Lactobacillus farciminis (swine only) Lactobacillus fermentum Lactobacillus helveticus Lactobacillus lactis Lactobacillus plantarum Lactobacillus reuteri Leuconostoc mesenteroides Megasphaera elsdenii (cattle only) Pediococcus acidilacticii Pediococcus cerevisiae (damnosus) Pediococcus pentosaceus Propionibacterium acidipropionici (cattle only) Propionibacterium freudenreichii Propionibacterium shermanii Rhodopseudomonas palustris (broiler chickens only) Saccharomyces cerevisiae *Enterococcus cremoris

*Enterococcus diacetylactis *Enterococcus faecium *Enterococcus intermedius *Enterococcus lactis *Enterococcus thermophilus Yeast (as defined elsewhere)

(Proposed 1991, Adopted 1993, Amended 2001, 2004, 2006, 2011) * formerly cataloged as Streptococcus

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Preface for minerals section:

The mineral products section includes ingredients that come from mined and processed rock and ore deposits, chemically manufactured salts, recovered natural salts, residue or remains of living organisms, and organic salts or organically bound elements as well as other similar ingredients.

Minerals from animal and plant sources can be found in other sections of the Official Publication.

(See Official Guidelines for Contaminant Levels Permitted in Mineral feed ingredients located on page 287.)

*Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following statement: "Do not feed to cattle or other ruminants."

66. NPN Add the following to the non-protein nitrogen section notes: Condensed, Extracted Glutamic Acid Fermentation Product See Definition 36.1 in Fermentation Products Section; Condensed, Extracted Glutamic Acid Fermentation Product as a source of Non-Protein Nitrogen.

Condensed Fermentation Solubles

See Definition 36.10 in Fermentation Products Section; Condensed _____ Fermentation Solubles as a source of Non-Protein Nitrogen.

22.4 Plant Protein Products

Delete 87.1 algae meal from the plant protein products (22.4) collective terms list Add **60.19 Dried Kelp** and **60.76 Dried Seaweed Meal** to the plant protein products (22.4) collective terms list

D.) IDC recommends publishing as tentative the modifications of definitions 3.2, 36.1, 36.10 and 75.10.

IDC committee Recommendation	Voted to accept and forward to board on 8/5/12.
Board Recommendation	
Membership Vote	

T 3.2 Dehydrated Alfalfa Meal or Pellets is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, which has not been stored as bales or stacks prior to being finely ground and dried by thermal means under controlled conditions.

T 36.1 Condensed, Extracted Glutamic Acid Fermentation Product is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of Corynebacterium lilium or Corynebacterium glutamicum used to produce the glutamic acid. It is used or intended for use as follows: in poultry feed as a source of protein in an amount not to exceed 5 percent of the total ration; and in cattle feed as a source of protein in an amount not to exceed 10 percent of the feed. In order to assure safe use, the label and labeling of the additive shall bear the following:

- (1) The name of the additive.
- (2) A statement of the concentration of the additive contained in any mixture.
- (3) Adequate directions for use.
- (4) Non-protein nitrogen content must be guaranteed when present.

T 36.10 Condensed Fermentation Solubles is the product resulting from the removal of a considerable portion of the liquid by product resulting from the action of the ferment on the basic medium of grain, molasses, whey, or other media. Non-protein nitrogen content (when present) must be guaranteed. (For label identification, the source must be indicated as "Condensed (Whey, Grain, or Molasses) Fermentation Solubles."

T 75.10 Stabilized Rice Bran is rice bran that has been treated soon after milling by heat or other means that will substantially reduce the lipase activity. Free fatty acid content of the crude fat extracted shall not exceed four percent. (AOAC 940.28) Stabilization process must be specified i.e. Heat Stabilized Rice Bran.

E.) IDC recommends the Model Bills and Regulations committee publish the following uniform policy on live animal labeling:

IDC committee Recommendation	Voted to accept and forward to model bill	
	committee on 8/5/12.	
Model Bills & Regulations		
Committee recommendation		
Board Recommendation		
Membership Vote		

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