

Ingredient Definitions Committee Meeting Report and Minutes

Tuesday, 8/6/19 3:00PM—5:30PM EDT Marriott Ballroom 5-6, second floor, Louisville Marriot Downtown, Louisville, KY

Recommendations to the Board and Association membership:

When needed, new text is presented in the committee minutes, appendix A.

- 1) Publish the **New Feed Term "Bison",** includes language to allow "North American buffalo". Required Roll Call Vote: AYE 14, NAYS 6, Abstain 2, MOTION PASSED
- 2) Revise the Feed Term "Carrier".
- 3) Revise the **Feed Term** " Stabilized".
- 4) Publish **New Feed Term "Treat".**
- 5) Publish the **New Feed Term "Water Buffalo"**. Required Roll Call Vote: AYE 17, NAYS 4, Abstain 1, MOTION PASSED
- 6) Move to Official w/minor edits T33.25 Stearic Acid
- 7) Move to Official w/minor edits T33.26 Palmitic Acid
- 8) Move to Official T**69.8 Oat Fiber**
- 9) Move to Official T73.311(A) Hydrogenated Glycerides
- 10) Move to Official T73.401 Colored Graphite Tracer
- 11) Move to Official T73.450 Cashew Nut Shell Liquid
- 12) Move to Official T87.50 Cashew Nut Shell Extract
- 13) Edit Table 101 to add: Dried Methylobacterium extorquens biomass AGRN 26

Board Action:

To be considered Fall 2019.

Association Action:

To be considered Midyear 2020 meeting.

Committee actions not requiring Association votes:

- a) Continue investigation/discussion of Table 90.26 to add **Vitamin** common names for dog and cat finished foods.
- b) Correction to **36.14 Direct Fed Microbial list** *Pediococcus cerevisiae* (*damnosus*) Editorial Change Pediococcus cerevisiae (damnosus) new text to follow ", renamed to Pediococcus damnosus ***"

Text to be placed at the end of the definition *** date of compliance January 2023

c) Editorial change to **84.71 Soybean Meal**, add back in the fiber guarantee.



- d) Agreed to leave **57.167 Manganese Hydroxychloride** as Tentative, allow for more time in the publication.
- e) Decision to maintain Non-Defined Working Group.
- f) Decision to maintain GRAS Verification Working Group.
- g) Next Meeting: Thursday, September 26, 2019 11:30AM Eastern via Webinar
- h) Not discussed in meeting: IDC & CVM will host a workshop on GRAS notices on 8/5/2020 in Baltimore, Prior to the AAFCO annual meeting. (needs BOD approval yet)
- i) Not discussed in meeting: IDC & CVM will host a training for AAFCO Ingredient Investigators on 8/4/2020 in Baltimore. (needs BOD approval yet)

Meeting Minutes

Topics moved to the next meeting:

i None

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1) Roll call of Committee Members Present including five online*: Richard Ten Eyck, Kristen Green, Mika Alewynse, Erin Bubb, David Beard, Brett Boswell, Ken Bowers, Bob Church, Stan Cook, Dave Dressler, James Embry, *Maggie Faba, *George Ferguson, Jacob Fleig, Steve Gramlich, Brett Groves, Ali Kashani, *Dan King, Mark LeBlanc, *Melanie Marquez, Dave Phillips, *Nathan Price, Laura Scott, Shannon Jordre, Charlotte Conway, Kent Kitade, Jennifer Kormos, Absent: Michelle Boyd, Tom Phillips

A quorum was present (22/24 voting members). The meeting was recorded. *There were 45 people logged into the webinar including the committee members.*

- 2) Addition of new Table 90.26 to add **Vitamin** common names for dog and cat finished foods Tom Phillips (15 min); document is in the BIN
 - a) Discussion opened w/o motion or second Objections made regarding the use and content of the table. Some technical names appeared incorrect.
 - b) Motion: NONE, will leave with Investigator to develop further and report back at next IDC meeting.
- 3) 54.33 and 54.34 Editorial Addition of note on Colostrum Products. Kent Kitade (5 min) **Proposed wording of footnote:**

** A colostrum product labeled for treating "failure of passive transfer (FPT)" in newborn calves is not a feed ingredient but a USDA regulated veterinarian biologic, legally distributed under a US veterinary license or permit pursuant to 9CFR 113.499. Product labeling for the treatment of FPT must include the US veterinary license or permit number and product code per 9CFR 112.2. Labeling guidelines for the colostrum



veterinarian biologic product can be found in USDA Veterinary Services Memorandum No. 800.54.

Kent Kitade proposed change to the language, as highlighted above.

Motion: Brett Groves, 2nd Mark LeBlanc

Extensive discussion on the purpose of the footnote since the intended use of the product, as described, is not a feed ingredient.

Vote: Editorial addition w/removal of feed ingredient reference – MOTION FAILED

4) Editorial change to a 36.14 Direct Fed Microbial list *Pediococcus cerevisiae* (*damnosus*) -Maggie Faba (5 min) Pediococcus cerevisiae (damnosus) new text to follow ", renamed to Pediococcus damnosus ***"

Text to be placed at the end of the definition

- *** date of compliance January 2023
 - a) Taxonomic changes created discrepancies in the OP and market labeling. Editorial change.
 - b) Motion: Ken Bowers/2nd Brett Groves
 - c) Disc/Questions: none
 - d) Vote: MOTION PASSED
 - 5) Editorial change to 84.71 Soybean Meal, add back in the fiber guarantee Bob Church (5 min)
 - a) Motion: Bob Church/2nd Stan Cook
 - b) Editorial Change
 - c) Discussion the fiber guarantee is included in other definitions, looks like it was left out of the definition in error as it was originally stated in the CVM letter to the investigator but did not make the definition in the OP.
 - d) Questions: none
 - e) Vote: MOTION PASSED
 - 6) Move Tentative Definitions to Official (25 min)
 - a) 33.25 Stearic Acid move to Official -Brett Boswell
 - minor edits as listed

Motion: Brett Boswell/2nd Brett Groves

Vote: MOTION PASSED

- b) 33.26 Palmitic Acid move to Official -Brett Biswell
 - minor edits as listed

Motion: Brett Boswell/Mark LeBlanc

Vote: MOTION PASSED



- c) 57.167 Manganese Hydroxychloride Stays Tentative Jennifer Kormos
 this ingredient has not been in the book very long, so will stay tentative.
 Motion: none
- d) 69.8 Oat Fiber move to Official Motion: Steve Gramlich/2nd Brett Groves. Extensive Discussion on the narrow scope of the definition as favoring one company, however, an amendment which will remedy this situation has been submitted and is pending review/approval by FDA. Vote: MOTION PASSED
- e) 73.311(A) Hydrogenated Glycerides move to Official Richard Ten Eyck

Motion: Brett Groves/2nd Ken Bowers

Disc: – this tentative definition is not in the print version OP, need to refer to online OP for correct tentative.

Vote: MOTION PASSED

f) 73.401 Colored Graphite Tracer – move to Official – Richard Ten Eyck Motion: Brett Groves/2nd Ken Bowers

Disc: none

Vote: MOTION PASSED

g) 73.450 Cashew Nut Shell Liquid – move to Official – Richard Ten Eyck Motion: Brett Groves/2nd Ken Bowers

Disc: none

Vote: MOTION PASSED

h) 87.50 Cashew Nut Shell Extract – move to Official – Richard Ten Eyck

Motion: Jacob Fleig/2nd Brett Groves

Disc: none

Vote: MOTION PASSED

- 7) New feed term Bison Brett Boswell (10 min)
 - a) Brett adds language to allow "North American buffalo" used interchangeably with bison.
 - b) Motion: Dave Beard/2nd Bob Church
 - c) Discussion: "Buffalo" as a standalone name will no longer be allowed.
 - d) Vote: Publish as displayed, MOTION PASSED
 - e) Roll Call: AYE 14, NAYS 6, Abstain 2
- 8) New feed term Water Buffalo -Brett Boswell (20 min)
 - a) Brett Two versions are in the BIN, latest dated 6/1/19.



- b) Motion: Bob Church/2nd Mark LeBlanc
- c) Discussion This species is the predominant type being imported at this time.
- d) Audience comments: Natl Bison Association support this definition, encourage to adopt both recommendations.
- e) Vote: Publish as displayed on screen, MOTION PASSED
- f) Roll Call: AYE 17, NAYS 4, Abstain 1
- 9) New feed term "treat" Ali Kashani (5 min) "**Treat**: a food provided occasionally for enjoyment, training, entertainment, or other purposes, and not generally intended or represented to be a complete feed or supplement."
 - a) Motion: Ali/2nd Jacob Fleig
 - b) Disc: no previous definition, just looking for clarification. Consensus between pet and livestock treats. The phrase "generally not intended" allows for flexibility in feeding.
 - c) Vote: MOTION PASSED
- 10) Revise Feed Term "carrier" Ali Kashani (5 Min) "Carriers Materials suitable for use in animal food to which ingredients such as but not limited to vitamins and minerals are added to facilitate uniform incorporation of the latter into feeds. The active particles are absorbed, impregnated, or coated into or onto the materials in such a way as to physically carry the active ingredient."
 - a) Ali as displayed on screen is a revised definition. The language noted here is a revised since presented at last webinar in July 2019.
 - b) Motion: Ali Kashani/2nd Brett Groves
 - c) Extensive discussion on "diluent" versus "carrier". FDA recommends staying with the new definition of carriers that is technically correct. There doesn't appear to be a conflict with the use of the term "carrier" in other definitions.
 - d) Amendment to the motion? None made
 - e) Vote: MOTION PASSED
- 11) Revise Feed Term "_____ Stabilized" Ali Kashani (5 min) "Stabilized (Process) When an ingredient which may deteriorate has been processed to improve stability, the expression "stabilized", "stability improved" or "with improved stability" may appear following the ingredient in the statement of ingredients. The process used is to be specified. e.g. heat stabilized"
 - a) Ali language as displayed on screen was proposed for consideration.
 - b) Motion: Ali Kashani/2nd Ken Bowers
 - c) Discussion: There was some confusion about how to use the other forms of the term, "stability improved" or "with improved stability". FDA it refers to a process. Example: OP pg 447, 75.10 _____ Stabilized Rice Bran.



- d) Motion to revise the term as it appears: MOTION PASSED
- 12) Non-Defined workgroup update Kent Kitade (10 min)
 - a) Kent follow up to the midyear meeting to establish a list for regulator use only.
 - b) Motion to accept the report: Brett Groves/2nd Mark LeBlanc
 - c) Extended discussion on the intent of the list and why is it is not public. There are concerns the list has negative connotations, and ETA has requested more transparency and the ability for firms to respond to questions. Per the WG, the list is meant to hold the "history" of an ingredient and to be a reference for regulators seeking clarity on whether it is a common and usual or has some other status. It is not public at the perceived request of industry; the WG is open to making it public. Industry has raised a number of questions that have not been adequately addressed.
 - d) Action: Leave the WG standing and ask them to discuss the concerns expressed.
- 13) Hemp Update (5 min) Bob Church
 - a) No submissions for a definition to date.
 - b) Industry studies are in the works. Comments were offered by Hunter Buffington and Steve McGarrah,
 - c) Discussion: Applications for Hemp Seed Oil for Dogs and Cats and Hemp Seed Meal – for poultry are being compiled for submission. Cold Pressed Hemp Seed Oil – for non-food animals, expect request to AAFCO in next 60 days.
- 14) Limestone workgroup update Jennifer Kormos (5 min)
 - a) Jennifer Kormos received a submission for precipitated limestone. Working with FDA, application still pending.
- 15) GRAS verification workgroup update Richard (5 min)
 - a) Goal is established.
 - b) A Verification Process draft document is in the BIN. Section editors have been assigned, looking for additional volunteers from States and Industry.
 - c) Comment the Board has asked whether the ICG verification process is in alignment with AAFCO's scope but will allow work to continue on the process. The AAFCO strategic affairs committee will discuss this and make a presentation at the midyear AAFCO meeting.
- 16) Next Meeting: Thursday, September 26, 2019 11:30AM Eastern via Webinar



17) Late addition to agenda Item

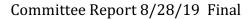
AGRN **Dried** *Methylobacterium extorquens* **biomass**, to be used as a source of protein to replace soybean or fish meal in food for finfish species. Received a No Questions Letter from FDA Feb 11, 2019.

Motion to edit Table 101: Nathan Price/ 2^{nd} Brett Groves

Vote: MOTION PASSED

Meeting Adjourned 5:28PM	Thanks to the team that assisted with the meeting.
Sandy Tuttle, Kent Kitade, Su	e Hays and Jennifer Roland.

Minutes approved 8/28/2019 __14__ aye _0__ nay __0_ abstain. The following members did not vote: Mika Alewynse, Dave Dressler, James Embry, Ashlee-Rose Ferguson, Ali Kashani, Mark LeBlanc, Melanie Marquez, Dave Phillips, Tom Phillips





Appendix A, IDC meeting 8/6/19

1) Publish the New Feed Term "Bison" ,
Bison. Common name for <i>Bison bison</i> . The meat or other ingredients derived from the animal (e.g. by-products, meal, fat) must be referred to as "bison," "North American buffalo," "bison," or "North American buffalo" with the specific non-meat ingredient filling in the blank.
2) Revise the Feed Term "Carrier" . Carriers. An edible material to which ingredients are added to facilitate uniform incorporation of the latter into feeds. The active substances are absorbed, impregnated or coated into or onto the edible materials in such a way as to physically carry the active ingredient.
3) Revise the Feed Term " Stabilized " Stabilized. (Process) – When an ingredient which may deteriorate has been processed to improve stability, the expression "stabilized", "stability improved" or "with improved stability" may appear following the ingredient in the statement of ingredients. The process used is to be specified. e.g. <i>heat stabilized</i>
4) Publish New Feed Term "Treat". Treat. a food provided occasionally for enjoyment, training, entertainment, or other purposes, and not generally intended or represented to be a complete feed or supplement.
5) Publish the New Feed Term "Water Buffalo" . Water Buffalo. Common name for <i>Bubalus bubalis</i> . The meat or other ingredients derived from the animal (e.g. by-products, meal, fat) must be referred to as "water buffalo" or "water buffalo" with the specific non-meat ingredient filling in the blank.
6) Move to Official w/minor edits - 33.25 Stearic Acid 33.25 Stearic Acid is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats. It is used as an energy source in growing and adult ruminant diets up to a maximum inclusion of 3% (w/w) in the finished feed. It cannot be used in pre-ruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly stearic acid, with lesser amounts of palmitic acid. It must contain, and be guaranteed for, minimum 92% stearic acid, maximum 5% palmitic acid, minimum 99% total free fatty acids, maximum

1% sulfated ash, and maximum 5 ppm lead. Maximum moisture must also be

guaranteed. Animal fats and vegetable oils used in the hydrolysis reaction to produce stearic acid must meet the specifications stated in the respective AAFCO definitions, 33.1



(for Animal Fat) and 33.2 (for Vegetable Fat or Oil). If tallow is used, the starting material must comply with the BSE feed regulation under 21 CFR 589.2000 and 589.2001.

(Proposed 2017 rev 1)

7) Move to Official w/minor edits - 33.26 Palmitic Acid

33.26 Palmitic Acid is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats. It is used as an energy source in growing and adult ruminant diets up to a maximum inclusion of 2% (w/w) in the finished feed. It cannot be used in pre-ruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly palmitic acid, with lesser amounts of myristic acid. It must contain, and be guaranteed for, minimum 98% palmitic acid, maximum 0.8% myristic acid, minimum 99% total free fatty acids, maximum 1% sulfated ash, and maximum 5 ppm lead. Maximum moisture must also be guaranteed. Animal fats and vegetable oils used in the hydrolysis reaction to produce palmitic acid must meet the specifications stated in the respective AAFCO definitions, 33.1 (for Animal Fat) and 33.2 (for Vegetable Fat or Oil). If tallow is used, the starting material must comply with the BSE feed regulation under 21 CFR 589.2000 and 589.2001.

(Proposed 2017 rev 1)

8) Move to Official – T**69.8 Oat Fiber**

69.8 Oat Fiber is obtained from oat hulls that have been processed through a continuous wet and dry process to modify soluble and insoluble fractions of the fiber, and to reduce the content of lignin. The ingredient must be guaranteed for neutral detergent fiber, acid detergent fiber, and acid insoluble lignin. Oat fiber is to be used **as** a source of insoluble fiber in animal feed and pet food. (proposed 2019)

9) Move to Official T73.311(A) Hydrogenated Glycerides

73.311 Hydrogenated Glycerides are obtained by hydrogenation of animal fats or vegetable oils and are used as a coating agent for ingredients or a binder and lubricant in pelleting of feed (pelleting aid) of all animal species. The maximum use rate of hydrogenated glycerides is 4 lb per ton of complete feed. Specifications of animal fats or vegetable oils used to produce the hydrogenated glycerides must meet the requirements stated in AAFCO definition 33.1 (for Animal Fat) and AAFCO definition 33.2 (for Vegetable Fat, or Oil), respectively. The specification for tallow must specify insoluble impurities not more than 0.15% to be consistent with BSE feed regulation 21 CFR 589.2000 and 589.2001, and a guaranteed titer above 40°C. The source of the hydrogenated glycerides must be indicated on the label. The hydrogenated glycerides must contain, and be guaranteed for, not less than 90% total ester content, not more than 0.8 % unsaponifiable matter, not more than 0.001% heavy metals, and not more than 5 of iodine value. The maximum moisture, maximum insoluble matter, maximum free fatty acids, saponification value and



melting range must also be guaranteed on the label. If an antioxidant is used, the common name or names must be indicated on the label, followed by the words "used as a preservative." (Proposed 2019 rev. 1)

10) Move to Official T73.401 Colored Graphite Tracer

73.401 Colored Graphite Tracer are the particles resulting from the milling of naturally occurring graphite coated with a color additive(s) approved for use in animal food. The graphite must be of feed grade material and may be used in animal food as a colored tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the tracer must not exceed 50 ppm in the finished food. The label shall include a caution statement indicating the maximum permitted inclusion level. (Proposed 2019 rev. 1)

11) Move to Official 73.450 Cashew Nut Shell Liquid

73.450 Cashew Nut Shell Liquid is the heat extracted liquid from cashew nut shells to be used as an antioxidant in fats and oils (excluding highly unsaturated oils with iodine value higher than 150) that are suitable for use in animal food. Cashew nut shell liquid can be used at levels up to 6000 mg/kg in fats and oils. The level of cashew nut shell liquid in complete feed must not exceed 600 mg/kg. The liquid ingredient must contain, and be guaranteed for, not less than 10% cardol, not less than 55% cardanol, and not more than 1 % moisture. (Proposed 2019)

12) Move to Official T87.50 Cashew Nut Shell Extract

87.50 Cashew Nut Shell Extract is the mechanical cold-pressed liquid from cashew nut shells to be used as a flavor additive in cattle feeds in amounts not to exceed 500 ppm in complete feed. The liquid ingredient must contain not less than 59% anacardic acid, not less than 18% cardol, and not more than 3% moisture. Minimum percent anacardic acid must be guaranteed. (Proposed 2019)

13) Edit Table 101 to add: Dried Methylobacterium extorquens biomass AGRN 26



AGRN (select for detailed record)	Notifier	Substance	Common and Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
26 Part 1 (PDF - 385 pages) Part 2 (PDF - 190 pages) Part 3 (PDF - 191 pages)	KnipBio, Inc.	Dried Methylobacterium extorquens biomass	Dried Methylobacterium extorquens biomass	To be used as a source of protein to replace soybean or fish meal in food for finfish species at a level up to 10% of the diet	Finfish species	2/7/18	FDA has no questions. (PDF - 5 pages)