

Ingredient Definitions Committee Meeting 10/5/18 Recommendations & Minutes

Recommendations to the Board and Association membership:

When needed, new text is presented in the committee minutes, appendix A (page 8).

- 1) Delete Definition 33.19 **Hydrogenated Glycerides** as an energy source. See page 383 of the 2018 online OP revision 1.
- 2) Publish in the OP new Tentative Definitions for:
 - a) T57.167 **Manganese Hydroxychloride**
 - b) T73.311(A) **Hydrogenated Glycerides**
 - c) T73.401 **Colored Graphite Tracer**
- 3) Publish in the OP new Official Definitions for:
 - a) 90.9 **25-hydroxyvitamin D₃**
- 4) Edit tables with results to be reflected as official
 - i) Table 101.1 AGRN 24 **L-Methionine 90%**

Board Action:

To be considered in October 2018

Association Action:

To be considered in January 2019

Edits to the OP. No need for further Association action:

- 1.) An editorial change to update 36.14 with the new and old organism names and the compliance dates.
- 2.) T60.117 (B) Black Soldier Fly Larvae -edit to add poultry- Edit to occur before board reviews IDC annual meeting recommendations.

Communication to the Board:

The committee feels a feed term for “health” is not needed. The model bill should be edited to clarify that health pertains to humans and animals.

Ingredient Definitions Committee 10/5/18 meeting minutes

The meeting was convened at 9:30 am PST via webinar by Chairperson Richard Ten Eyck.

1) Role Call of Committee members

Richard Ten Eyck, Erin Bubb, Bob Geiger, David Beard, Brett Boswell, Ken Bowers, Bob Church, Stan cook, Dave Dressler, Maggie Faba, George Ferguson, Steve Gramlich, Ali Kashani, Dan King, Rick Manthei, Dave Phillips, Nathan Price, Laura Scott, Mika Alewynse, Charlotte Conway, Kent Kitade, Jennifer Kormos, Tom Phillips

A quorum was present 20/25.

2) Investigator recommendations to move tentative to official

- a.) T73.311 Hydrogenated Glycerides – Yes, Richard (triggers deletion of old 33.19)
Tabled to October 19, 2018 webinar.

3) Work Group Reports

- a) GRAS verification workgroup report – Sue Hays
Tabled to October 19, 2018 webinar.

- b) Non-Defined List Workgroup - Kent Kitade
Tabled to October 19, 2018 webinar.

- c) Confusing Pet Food Names Workgroup – Brett Boswell
Tabled to October 19, 2018 webinar.

- d) Guidelines For requesting Definitions Editing Workgroup – Kristi Smedley
Tabled to October 19, 2018 webinar.

- e) ODI Subcommittee? (new) – tbd
Tabled to October 19, 2018 webinar.

4) New Definitions, deletes & edits:

- a) New Feed Term “**Livestock**” – Ali (need recommendation)
Ali Kashani stated that there was no support for the definition at the last meeting. Richard Ten Eyck noted that the Board asked that definition be



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created for treat, livestock, and health. Ali Kashani would like to reform the Work Group and requested that previous members let him know if they would like to join and invited others to join as well. Ali Kashani said that he is not planning on developing a new feed term for health, since this should be covered by the Model Bill. Charlotte Conway from FDA agrees that it will be difficult to develop a definition for health and that treat can be defined without defining livestock. The Committee will take this information back to the Board.

- ~~b) New Feed Term Water Buffalo (placeholder)~~
- ~~c) New Feed Term American Buffalo (placeholder)~~
- ~~d) New Feed Term Bison (placeholder)~~
- ~~e) 15.xx Brewers section (placeholder) Nathan~~
- f) Delete 33.19 **Hydrogenated Glycerides** as an energy source.– Brett
Brett Boswell moves to ACCEPT the recommendation to delete the definition. Mika second. MOTION PASSES.

About one year ago, Charlotte Conway brought before IDC that there was an error in drafting the definition (no use rate limitation). The error is being addressed by creating the new definition T73.311. In an effort to broaden the use rate, industry provided some information/data; however, it was not enough to support all uses/use rates. Therefore, she would like to delete this definition and come up with another definition that is supported with the appropriate data. Charlotte Conway suggest having a call with interested individuals to go over the data gaps. She will post a meeting notice in to IDC team board.

Leah Wilkinson from AFIA stated that industry appreciates FDA's help in fixing the definition and the IDC for being patient to get the definition right. No one wanted to be in this position. Industry has been trying to get the supporting information/data to FDA. AFIA has reservations in deleting this definition. AFIA is working on gathering the data to support the energy source use and requests that the definition not be deleted at this time.

Kristi Smedley supports AFIA's position. She stated that there are products on the market that would be affected if this definition were to be deleted.

Jan Campbell supports AFIA's and Kristi Smedley's positions. She stated that they have been using the product as an energy source for the past 5 years and haven't seen any safety issues.

Richard Ten Eyck stated that if the IDC accepts the deletion, the deletion would have to go through the normal channels (voting on by the Board and the membership).

The safety concerns are related to nickel and other contaminants. FDA does not have data to support safety at the higher use levels that are associated with the use as an energy source. There may be enough information in the literature, but FDA doesn't have the time to conduct this search.

Kristi Smedley agrees that this deletion will take some time but cautioned that the replacement will also take time to be implemented.

Erin Bubb asked when did this come up for deletion and how long has this been going on? It has been at least one year (August 2017). FDA received additional supporting data in December 2017, but the safety assessment did not address the higher use rate when used as an energy source. Charlotte Conway stated that FDA has finished the safety review to expand the technical use include coating.

g) 36.14 Nomenclature update – Maggie

Maggie moves to ACCEPT the recommendation to make an editorial change to update 36.14 with the new and old names and the compliance dates. Mika Alewynse second. MOTION PASSES.

h) T57.167 Manganese Hydroxychloride – Jennifer Kormos

Jennifer Kormos moves to ACCEPT the recommendation to publish the definition as tentative. Ali Kashani second. MOTION PASSES.

Cathy Alinovi expressed concerns regarding the heavy metals, which are toxic to all animals and will accumulate in the animals. Kristi Smedley stated that this definition is consistent with the AAFCO guidance on contaminants and has less heavy metals than specified by the guidance.

A question was asked regarding use level in premix and then in the final feed? Ali Kashani stated that the manganese levels are very low. Kristi Smedley agrees with Ali Kashani and stated that like all ingredients this product should be used only at levels decided by a nutritionist.

i) T60.117 (B) Black Soldier Fly Larvae -edit to add poultry- Erin

Erin Bubb moves to ACCEPT the recommendation to edit the tentative definition. Dave Phillips second. MOTION PASSES.

Erin Bubb recommends an editorial change to add “and poultry” to the tentative definition. The association membership did not vote on the recommendation to have the definition official yet. This modification would



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become official in January after board/membership vote.

Kent Kitade asked if this is more than an editorial change and if more information would need to be given to FDA. Kristi Smedley stated the supporting information has already been provided to FDA. There is a letter from CVM to accept the addition of “and poultry” to the definition.

- j) T73.311(A) Hydrogenated Glycerides – Richard Brett Boswell moves to ACCEPT the recommendation to publish the definition as tentative (T73.311(A)). Mika second. MOTION PASSES.

Charlotte Conway stated that this was a very late addition and that it was only sent to Richard Ten Eyck this morning. She has been working on getting all the supporting information and to finish the safety assessment. She would like for this tentative definition to move forward but understands if the IDC would like more time to review.

Leah Wilkinson encouraged the IDC to vote on this since it includes additional intended uses and given the previous action to delete the original definition. Kristi Smedley expresses the same as Leah Wilkinson, but also wondered what happens if it waits to January. Richard Ten Eyck stated that there is another definition that is ready to move to official for hydrogenated glycerides but it does not contain these edits.

- k) T73.401 Colored Graphite Tracer – Richard Mika Alewynse moves to ACCEPT the recommendation to publish the definition as tentative. Ali Kashani second. MOTION PASSES.

- l) Table 101.1 AGRN 24 L-Methionine 90% - Nathan Nathan Price moves to ACCEPT the recommendation to add AGRN 24 to Table 101.1. Ali Kashani second. MOTION PASSES.

Dave Edwards if you look at the investigator there is a link to the GRAS Notice and it should be added. (done)

- ~~m) Update Chapter 6 header to clarify ODI nomenclature (placeholder)~~

- n) Edit the comma out of OP common names (list provided) – Phillips Tabled to October 19, 2018 webinar.

- o) Update Guidelines document in chapter 6 (placeholder) Tabled to October 19, 2018 webinar.

- p) Vitamin names (placeholder) – Tom
a. Vitamin A

- b. Vitamin C
- c. Vitamin E

Tom Phillips would like a general definition for all forms of these vitamins that are used in animal food. IDC Consideration of these definitions will be moved to January 2019 meeting. Tom Phillips is looking for help on wordsmithing these definitions. Jim Barritt stated that PFI has worked on these vitamins and will provide what they have to support these definitions.

- q) **90.9 25-hydroxyvitamin D₃** (late add 10/1/18) – Tom / CVM
Tom Phillips moves to ACCEPT the recommendation to publish the definition as official. Mika Alewynse second. MOTION PASSES.

Dave Edwards stated this is a new food additive regulation. Mika Alewynse suggested to add the definition in a more complete sense instead for just adding it to the table, due to the toxicity that can occur in turkeys.

Richard Ten Eyck stated that an official definition number is needed. Additionally, “Proposed” needs to be changed to “adopted 2019 revision 1”. This will be reformatted to match the rest of the OP.

Dave Dressler asked if this needs to be removed from Table 90.25? Kristi Smedley stated that the table is the GRAS affirmed use for broilers (affirmed GRAS use), which is different than this use. It should not be removed from the table. Mika Alewynse stated that it may be possible to move from the table to this definition. FDA work with Tom Phillips on editorial changes to make sure all uses are in on place. Dave Dressler would like to see what it looks like before voting on this definition. Richard Ten Eyck asked if the IDC can move forward with this definition and then make the changes to merge the two at a later date. Kristi Smedley state that she agreed with this approach and was supported by Charlotte Conway and Leah Wilkinson. FDA and Tom Phillips will work on a new definition that merges intended uses for the two for January meeting.

5) Discussions:

a) **Hemp** Update – Bob C. & Brett B., Scott Z. // 9/7/18 *no change in status, not approved for animal feeding* // direct questions to Bob or Brett.
Tabled to October 19, 2018 webinar.

~~b) GRAS policy discussion – Doug Lueders~~

~~c) Status on high profile ingredients (if needed) – Richard / CVM~~



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- ~~d) Discussion of common human foods in pet food (placeholder)~~
- ~~e) Any activities needing 19 – 20 Association funding?~~
- f) Set Webinar **meeting dates** for:
 1. October 19, 2018
 2. April meeting needs to be set

- g) Next Meeting, AAFCO Midyear, Savannah Georgia, January xx 2019 The committee will meet by webinar 10/19/18 at 11:30AM PST to address issues tabled during this meeting.

Meeting was adjourned at 11:05 AM PST

Minutes approved 10/19/18 by 21 committee members



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Appendix A for 10/5/18 IDC meeting

Table 36.14 edits:

Enterococcus faecium Delete “”

*Enterococcus intermedius new text to follow “, correct to Streptococcus intermedius**”

*Enterococcus thermophilus new text to follow “, correct to Streptococcus thermophilus**”

There would be text at the end of the definition that states “** date of compliance January 2022”. The same date would be used for these changes.

T57.167 Manganese Hydroxychloride is the reaction product of manganese oxide and hydrochloric acid at the appropriate stoichiometric ratio, having the empirical formula $Mn_2(OH)_2Cl$. Particle size must not exceed 100 microns. It must contain not less than 44% manganese and is intended to be a source of manganese for use in livestock, poultry, and companion animal diets. It must not contain more than 20% chloride, 50 ppm lead, 50 ppm arsenic, 10 ppm cadmium, and 0.5 ppm mercury.

T73.311 (A) 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.”

T73.401 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.



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90.9 25-hydroxyvitamin D₃ The food additive, 25-hydroxyvitamin D₃, may be safely used in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a source of vitamin D₃ activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

(1) In feed or drinking water of layer and breeder chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.

(2) In feed or drinking water of turkeys not to exceed:

(i) 92 ppb in feed; or

(ii) in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94 percent 25-hydroxyvitamin D₃ (9,10-secocholesta-5,7,10(19)-triene-3 β , 25-diol).

(c) The additive meets the following specifications:

(1) Not more than 1 percent of any individual sterol.

(2) Not more than 5 percent water.

(3) Not more than 20 parts per million (ppm) lead.

(4) Not more than 20 ppm aluminum.

(5) Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.

(6) Not more than 1 ppb 1,25-dihydroxycholecalciferol.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) A statement to indicate the maximum use level of 25-hydroxyvitamin D₃ must not exceed 69 ppb in feed or 34.5 ppb in drinking water for layer and breeder chickens.

(3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D₃ must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(4) Adequate use directions to ensure that 25-hydroxyvitamin D₃ (and all premixes) is uniformly blended throughout the feed or drinking water.

(5) An expiration date on all premix labeling.

(6) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D₃ cannot be used simultaneously in both feed and water.
21 CFR 573.550

Addition to table 101.1 _____

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)
24 (PDF - 194 pages)	CJ CheilJedang Corporation	L-methionine 90% produced by a bioengineered Escherichia coli K-12	L- methionine 90%	To be used as a nutrient in animal food.	All animals	8/17/2017	FDA has no questions. (PDF - 4 pages)