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Ingredient Definitions Committee Report 9/30/2016 Webinar Meeting

IDC recommendations to the Board and Association Members:

1. Publish the new Official Feed Term in the OP for Animal Food.
2. Modify the current Official Feed Term in the OP for Feed(s).
3. Publish the new Official Feed Term in the OP for Tracer.
4. Publish the tentative definition in the OP for T6.12 Taurine.
5. Publish the new tentative definition in the OP for T73.400 Iron Nickel Tracer.
6. Publish the new official definition in the OP for: 73.026 Feed Grade Sodium Formate.



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Minutes of 9/30/2016 IDC Webinar Meeting (Meeting was web recorded and is posted in the Feed BIN/Ingredient Definitions library.)

Meeting convened at 8:30 am PDT by Chairperson Ten Eyck.

1. Role Call – 15 Members present; this is a Quorum ($\geq 50\%$)

Role:

Committee Members: Ken Bowers, Bob Church, Charlotte Conway, David Dressler, Erin Bubb, Steve Gramlich, Alan Harrison, Tim Lyons (for April Hunt), Jan Jarman, Ali Kashani, Dan King, Dave Phillips, Mark LeBlanc, Mika Alewynse, Richard Ten Eyck, Shannon Jordre,

Advisors: Jan Campbell, Pat Tovey, Leah Wilkinson, Kristi Smedley, Jean Hofve, Susan Thixton, Emily Helmes, Mollie Morrissette

2. Work Group Reports

a) **AAFCO IDC GRAS workgroup report.** Leah Wilkinson summarized the efforts made by the Workgroup to develop the proposed new Section 101 for Animal GRAS Notices on which FDA had issued a no questions letter. As part of the Workgroup efforts, a survey had been sent out to the AAFCO Membership to get insights from the states on how they regulate and handle GRAS substances. Excluded from this Section 101 list are the GRAS Notices that do not have a no questions letter from FDA, such as those that are pending or have been withdrawn. Richard Ten Eyck informed IDC that the online OP would link to the GRAS Notices and the FDA Letters. Emily Helmes pointed out ETA's editorial comments (on Feed Bin) including that the statements referred to as Alternative 1 and 2 were not needed in that the preceding paragraph should be sufficient. Jen Henderson (Cargill) and Tony Pavel (Cargill) agreed with the ETA edits and viewpoint and Tony Pavel continued that there was no need for these GRAS substances to undergo any additional FDA or AAFCO consultation in that they were already evaluated by the Agency. With the publication of the GRAS Notice Final Rule, these substances are now accepted under Federal law. The FDA NQ letter means that the Agency has no questions about the firms conclusions at this time. Therefore these substances are acceptable for use at this time. Jen Henderson said that if there was going to be a re-review, then she does not understand why we are discussing this Section at all. Kristi Smedley said that her view is that this would be a pro forma type of review by the AAFCO IDC in that the FDA had already conducted an evaluation.

Mika Alewynse explained that the GRAS Notice reflects the firm's



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conclusion and not that of the FDA, that the substance is GRAS. In contrast, for an FAP or an AAFCO Ingredient Definition, FDA actually reviews the data and information quite carefully, and FDA is making a conclusion of safety.

Kristi Smedley explained that any updates to the AAFCO OP in this section would be “covered” by the statement in Alternative 2. This would satisfy the needs of some states.

Richard Ten Eyck asked the IDC how they felt about the statements Alternative 1 and 2. Mark LeBlanc asked if it was the intent for the substances to be reviewed again. He felt that it would be a formality, and that IDC would give it an official stamp. Another state official agreed. Mika Alewynse recommended that the Notifier should be invited to attend the AAFCO Meeting, in the event that there would be any further questions. Jen Henderson asked if this would be more of an acknowledgement, and some state officials agreed. Jan Jarman (MN) said that the ingredient name and definition would need to be established by AAFCO IDC and so they would need to be acknowledged. She further asked if this table information would satisfy the needs of whether or not there are any limitations to the use of the ingredients. Mika Alewynse said that the specifications and limitations would be addressed in the notices and/or in the FDA response letters. One idea was to add language to the Section 101 text that the feed control officials need to review the GRAS Notices and the FDA Letters for information on any use limitations. Tom Phillips (MD) said that his regulations incorporate ingredients by reference, and that he would need to update the state Feed Regulations every year in order to include these new GRAS ingredients; his plan is to review and update regulations every 3 years. Al Harrison (KY) said that this will not change what they can and cannot do in his state. Ali Kashani (WA) felt that it would be a good idea to have a discussion at the AAFCO IDC before new GRAS Notice substances are added to the list. **It was agreed to send this Section 101 draft back to the Workgroup to address the comments raised during this webinar.**

b) “Feed” Definition Workgroup completed their work and submitted a modified definition for Feed and a new definition for Animal Food. **Ken Bowers moves to ACCEPT the work group report. Ali Kashani seconds. MOTION PASSES.**

3. New Definitions, deletes & edits:

a) **New Official Feed Term: Animal Food. Ken Bowers moves to ACCEPT. Ali Kashani seconds. MOTION PASSES.**

(new term) **Animal Food**. see “feed”

- b) **Modify Official Feed Term: Feed. Ken Bowers moves to ACCEPT. Dave Phillips seconds. MOTION PASSES.** Charlotte Conway explained that technical effect includes preservatives, binding agents, etc, that have an effect on the feed, and not on the animal. Other examples are in Section 73. This definition for Feed does not replace the definition for Commercial Feed in the AAFCO Model Bill. Tony Pavel (Cargill) noted that the courts case in 1983 (Nutralab v. Schweiker) resulted in the court upholding that food is primarily used for nutrition, taste, aroma, and that structure /function claims are more of a secondary effect.

(revise existing term) **Feed**. Material consumed or intended to be consumed by animals other than humans that contributes nutrition, taste, aroma, or has a technical effect on the consumed material. This includes raw materials, ingredients, and finished product.

- c) **New Term: Tracer. Dave Dressler moves to ACCEPT. Steve Gramlich seconds. MOTION PASSES.**

Tracer. (Part) A harmless substance present at insignificant levels in an animal food to assure the presence of and thorough mixing of a component (ingredient/premix) of that food.

- d) **Publish Tentative Definition for T6.12 Taurine – add new intended use (fish). Ken Bowers moves to ACCEPT. Ali Kashani seconds. MOTION PASSES.** A question was raised about whether the term, fish, would include other aqua species such as shrimp. Charlotte Conway, CVM replied that shrimp and other aqua species are excluded from the category of fish, and a separate application would be needed.

T6.12 Taurine is a product which contains a minimum of 97% 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in cat foods, dog foods, and fish foods. Taurine may also be added to the feed of growing chickens; when added to complete chicken feed, the total taurine content shall not exceed 0.054% of the feed (21 CFR 573.980).

- e) **Make editorial change to the tentative definition, T33.21 Yellow Grease**, by changing 1.0% unsaponifiable matter to 2.5% unsaponifiable matter, so that this is the same as for animal fat, since in many cases YG will be composed mostly of animal fat. **Jan Jarman moves to ACCEPT. Bob Church seconds. MOTION PASSES.** Committee discussed how extensive the edit was and if it needed membership approval. The edit will be placed directly into the OP without an



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association vote.

T33.21 Yellow Grease, Feed Grade is the rendered product from the tissues of mammals and/or poultry blended with used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2.5% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." If the product contains tallow (from cattle) containing greater than 0.15% insoluble impurities then it must be labeled with the BSE caution statement "do no feed to cattle or other ruminants."

f) Publish new tentative definition for T73.400 Iron Nickel Tracer. Ken Bowers moves. Steve Gramlich seconds. MOTION PASSES.

T73.400 Iron Nickel Tracer are the particles resulting from water atomization of high purity iron and nickel. The nickel content of the particles is between 35 and 51% with the remainder being iron. The particle size of the iron nickel alloy must range between 150 and 300 microns. This ingredient may be used in animal foods as a tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the ingredient must not exceed 10 parts per million in the finished food. The label shall include a maximum nickel guarantee and a caution statement indicating the maximum permitted inclusion level.

g) Add new official definition for 73.026 Feed Grade Sodium Formate. Ken Bowers moves. Charlotte Conway seconds. MOTION PASSES.

73.026 Feed Grade Sodium Formate. The food additive, feed grade sodium 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 percent formic acid and 50 percent sodium hydroxide in water to produce a solution made up of at least 20.5 percent sodium salt of formic acid and not more than 61 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, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(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) Adequate directions for use, including a statement that feed grade sodium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing feed grade sodium formate.



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- (3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.
- (e) To assure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain:
- (1) Appropriate warnings and safety precautions concerning feed grade sodium formate.
 - (2) Statements identifying feed grade sodium formate 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 (OSHA) human safety guidance regulations. 8
 - (ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).
- 21 CFR § 573.696 (adopted 2017 rev 1)

4. Discussions:

- a) Montmorillonite questions for Industry - Tom
- a. *Lab methods question. Drug manufacturers take into account the interference impact and formulate to yield the correct bioavailability. **Drug manufacturers should email Tom** with how they compensate for the interference.*
 - b. *Firms can add drugs to the list on page 452 by sending a request to the section editor.*
- b) Edit Footer on Vitamin Table – Tom
- a. *Wants to find source of the original numbers on vitamin bioactivity. Is the wt to wt ratio appropriate? Jan Jarman, is willing to help with table edits to make it more understandable. **Industry should get information on the source of numbers asap.***
- c) Acceptable functionality statements on enzymes –ETA –
- a. *Modification to header for the enzyme table needs to be done. **Jan will bring to next meeting.***
- d) Materials NOT suitable for animal feed list in the BIN or website – AAFCO
- a. *Document is in the ingredient definitions library. Discuss further at next IDC meeting.*
- e) General discussion of materials advised to seek a FAP – CVM
- a. *Bring up again at next meeting.*

Meeting adjourned 10:05AM PST

Minutes accepted by the committee 10/xx/2016