Final 3/21/18 ver 3

**AAFCO Ingredient Definitions Committee Report**

January 23, 2018 Garden Grove, CA, USA

Hyatt Regency

## Recommendations to the Board and Association membership:

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

1) Publish the following tentative definitions as Official and remove the existing Official definition if any.
   a.) T40.100 Recovered Retail Food

2) Establish and publish in the OP a new tentative definition(s) for:
   a) T69.8 Oat Fiber
   b) T71.40 Low Glucosinolate High Erucic Acid Rapeseed Meal, Solvent Extracted**
   c) T73.450 Cashew Nut Shell Liquid – add sub section 450-499 antioxidant
   d) T87.50 Cashew Nut Shell Extract

3) Publish in the OP new Official Definitions for:
   a) 73.020 Ammonium formate
   b) 73.025 Formic Acid
   c) Table 18.1 remove **Formic acid** from table on page 363 (2018 OP Print)-

4) Budget recommendations from the Chair: (forward to Ali to be considered with budget)
   a.) Establish a reserve of $20,000 for GRAS and/or AAFCO Definition Process education efforts in support of the GRAS workgroup project.
   b.) Add budget line item of $1000 for complimentary BIN access (investigators etc). –

**Board Action:**

To be considered in April 2018

**Association Action:**

To be considered in August 2018

Association of American Feed Control Officials

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# Ingredient Definitions Committee Minutes 1/23/18

**1) Role Call of Committee members present** (quorum was 22 out of 26 committee members)
Richard Ten Eyck, Mika Alewynse, Erin Bubb, Brett Boswell, Ken Bowers, Bob Church, Stan Cook, David Dressler, James Embry, George Ferguson, Jacob Fleig, Steve Gramlich, Brett Groves, Alan Harrison, Ali Kashani, Dan King, Kent Kitade, Jennifer Kormos, Mark Le Blanc, Dave Phillips, Nathan Price, Laura Scott

**2) Investigator recommendations to move tentative to official**

a.) T40.100 **Recovered Retail Food** – (Cat) make Official
Dave Dressler moves to ACCEPT the recommendation and publish the definition as Official in the OP. Jacob Fleig seconds. MOTION PASSES.

**3) Work Group Reports**

a) GRAS workgroup report – report in Appendix A.
Related documents are posted in the Feed BIN. Emily Helmes reported that the workgroup (WG) has meet twice since December. The workgroup identified and prioritized three projects. Top priority project is: 3.) Identify & pursue state acceptable alternatives to CVM review of the independent GRAS Conclusions. Project 1, which related to education, also has high votes. Project 2 was decided not to be immediately moved forward.

A summary document was presented with Regulators and Industry's position and where they concur on GRAS self-conclusion topics. Richard Ten Eyck is updating the document and posting in the BIN every couple months.

AAFCO Board has established a GRAS Policy work group lead by Doug Lueders.

b) DFM Nomenclature Changes workgroup – Tamzin
The WG has met and will be assessing the information in the table to ensure that it is correct.

c) Negative List Workgroup (need to form)
The WG is to establish sharing levels and processes for a negative list. Dave Phillips understands that industry has concerns and wondered what ingredients would be on the list. Is this ingredients that are not safe? Richard Ten Eyck state that this would be ingredients that are not in the OP. Dave Phillips stated that there are pet foods with beef listed in the ingredients, but there is no definition in the OP. Chris Cowell (PFI) pointed out that there is a negative list in 21 CFR 589. It was also mentioned that there are things that are not in the OP but are common and usual. Richard Ten Eyck stated that he would like the Work group to look at this and assess what can/should be done.

WG members: Kent Kitade (Lead), Cathy Alinovi, Dave Phillips, Leah Wilkinson, Kristi Smedley, Erin Bubb, Betty McPhee, Molly Morrissett, Kristen Green, Padma -CVM, Nathan Price and Richard Ten Eyck.

d) Confusing Pet Food Ingredient Names Workgroup (need to form)
The purpose of this WG is to establish & communicate parameters for separate common name for ingredients that can be confusing to the consumer. These ingredients can also invoke an emotional response by consumers. There was a question if this should be in the Pet Food Committee. Richard Ten Eyck believes that the nomenclature belongs in the IDC. Chris Cowell and George Ferguson believe that the WG name needs to be changed; the WG name has been revised.

Work Group members: Brett Boswell (Lead), Richard Ten Eyck, Jean Hovfe, Molly Morrissett, Leah Wilkinson, Cathy Alinovi, Dave Meeker, Chris Cowell, Erin Bubb, George Ferguson, Nathan Price

e) Guidelines for Requesting Ingredient Definitions Editing Workgroup (need to form)
The purpose of the Work Group will be the following:

- Discuss and edit tentative process in coordination with bylaw committee
- Add draft of definition as step one in the guidelines
- update quantity of copies to CVM

The goal of the WG is to have the edits to the document ready to discuss at March IDC meeting.

Work Group members: Richard Ten Eyck (Lead), Leah Wilkinson, Kristi Smedley, Dave Edwards, Chris Hollinger, Betty McPhee, Laura Scott

**4) New Definitions, deletes & edits:**

a) New Feed Term "Livestock" – Ali
Ali Kashani reported that the WG has exchanged emails, but is still debating the definition. Ali Kashani asked that this be put on the August 2018 agenda.

b) New Feed Term "Common and Usual" -- Ali
Ali Kashani reported that the WG has exchanged emails, but is still debating the definition. Ali Kashani asked that this be put on the August 2018 agenda.

c) Section 30 header edits (enzymes)
This will be considered with the potential move of the Enzyme Marketing Coordination document (see agenda item 4d below).

d) Move Enzyme Marketing Document to chapter 6 (board rejected and asked ~~for more clarification~~ Why it can't stay where it is?) - Mark LeBlanc

*No motion was articulated. Discussion:*

This recommendation was previously moved to the Board, they had questions and asked that this be moved back to the committee for clarification. The Board want to know the purpose of the move. Emily Helmes stated that the ETA did not request the move. She stated that the ETA believes that it makes sense to move the Enzyme Marketing Coordination (EMC) document to Section 30, but are also ok with keeping it where it is. Emily Helmes believes that it may have something to do with the changes to the Section 30 header. Mika Alewynse proposed to move the move EMC document to Chapter 6, because it was originally in front of the enzyme table. She felt that more information was being added to the header and thought that some of this information may be being duplicated. Instead of duplicating information, she thought it would be better to move the document. Mark LeBlanc asked if this document is meant to be a header to section 30. Emily Helmes said that they are different, but we need to know where this document will reside because the header references it. Mika Alewynse said that previously it was in front of the table in Section 30. Mark LeBlanc asked if the plan is to put this document in the header. Mika Alewynse stated that the intent is for it to be in front of the table, and there will no longer be a header to the section except for the nonpathogenic/toxigenic language. Emily Helmes stated that this was not clear in the original request to move the document and is concerned that there is information in the header that is not in the Enzyme Marketing Coordination document. She requested that we have time to compare the header text to the document. Stan Cook stated that the Board was concerned that we have a nice clean set of definitions and would be breaking them up with a guidance document. Kristen Green wondered if there was a better way to highlight the information without breaking up the definitions. Mika Alewynse stated when the EMC document was moved to Chapter 5, there was a statement to reference it, but people don't seem to be looking there; FDA was receiving lots of questions. Stan Cook said that there was a motion in the Board to move this change back to IDC. Mark Le Blanc asked that the committee consider this move again. Kristi Smedley asked that this move and the edits to the header to Section 30 be considered together, since they are intertwined. Mika Alewynse and Tamzin Gonzales agreed. Mika Alewynse and Tamzin Gonzalez will request info from ETA before the next meeting and come up with a proposal. ***Action: Put on agenda for discussion at next IDC meeting.***

e) ~~T60.117(B) **Black Soldier Fly Larvae Meal**, board rejected and sent back to IDC, - Erin, Mark LeBlanc (placeholder #1)~~
~~More insect coming our way. Crickets~~

f) T69.8 **Oat Fiber** – Steve Gramlich
Dave Phillips moves to ACCEPT the recommendation and publish the definition in the OP as Tentative. Bob Church seconds. MOTION PASSES.

Nathan Price asked if the definition could say "wet or dry" instead of "wet and dry"? Cathy Peterson stated that she worked on this with CVM. She stated that if it was wet or dry, then the dry form would fit under the oat hull definition. Dave Edwards (FDA) confirmed that "wet and dry" is correct, because the process contains both wet and dry steps.

g) T71.40 **Low Glucosinolate High Erucic Acid Rapeseed Meal, Solvent Extracted**** - Bob Church

Bob Church moves to ACCEPT the recommendation and publish the definition in the OP as tentative. Dave Phillips seconds. MOTION PASSES.

Laura Scott asked for clarification regarding the percent maximums. Dave Edwards (FDA) confirmed that they are the correct percentages. Leah Wilkinson asked about the reference in the investigator report that it can be referred to as LG HEAR meal, how will this be reflected in the definition, can people can use the abbreviated name on the label? Bob Church stated that the full name should be used on the label not the abbreviated name of LG HEAR meal. The ** next to the name allows for the solvent extracted portion of the name to be dropped when listing on a finished feed label. Bob Church asked that the LG HEAR meal comment be removed from the investigator's report to avoid confusion.

h) 73.020 21 CFR update on 573.170 **Ammonium formate** - Richard
Ali Kashani moves to ACCEPT the recommendation and publish the definition as Official in the OP. Dave Dressler seconds. MOTION PASSES.

i) 73.025 21 CFR update on 573.480 **Formic acid**,– Richard
Ali Kashani moves to ACCEPT the recommendation and publish the definition as Official in the OP.. Erin Bubb seconds. MOTION PASSES.

j) 18.1 remove **Formic acid** from table on page 363 (2018 OP Print)- Richard
Jacob Fleig moves to ACCEPT the recommendation and update the OP. Bob Church seconds. MOTION PASSES.

Leah Wilkinson understands the desire to remove the table. However, she encouraged the IDC to keep moving forward with editing/deleting items and not wait until new definitions are needed to avoid confusion on some being in the table and others not. She also asked to make sure the index is correct. She pointed out that currently the OP Index only references formic acid in the table. Kristi Smedley stated that it is helpful for industry to have the table when looking for preservatives and taking pieces out make it less valuable.

~~k) 73.046 21 CFR update on 573.940 **Silicon Dioxide** (placeholder #4)~~

l) T73.450 **Cashew Nut Shell Liquid** – add sub section 450-499 antioxidant, - Richard
Brett Groves moves to ACCEPT the recommendation and publish the definition as tentative in the OP. Brett Boswell seconds. MOTION PASSES.

Dave Edwards stated that there are two definitions -- liquid and extract. They are made by different processes and have different uses. Therefore, there are two definitions.

m) T87.50 **Cashew Nut Shell Extract** --Richard
Jacob Fleig moves to ACCEPT the recommendation and publish the definition as tentative in the OP. Mika Alewynse seconds. MOTION PASSES.

Erin Bubb asked if this would be considered a natural flavor. Kristi Smedley answered yes. There was a question if there will there be upper limits on the use of each cashew ingredient. Mika Alewynse stated that each ingredient is assessed and if needed a limit would be determined. Doug Lueders asked why there is a limit of not more than 3percent moisture for the cold pressed liquid Why is this a limit? Dave Edwards stated that the cold pressed material comes out in a liquid form, but it is more of an oil. Kristi Smedley stated they are differentiated between water and oil.

**5) Discussions:**

a) Does the **Tentative** process need to be applied to every ingredient? – Tabled to March meeting.

b) **Hemp** Update – Bob C. & Brett B., Scott Z.

Hollis Glenn (CO Department of Agriculture, Division Director) provided an update. He stated that Colorado established a stakeholder group with regulators and industry looking into the feasibility to add hemp into animal food. The report was released and it outlines a path forward. It was determined that this must be a collaborative effort. The stakeholder group determined that the best path forward would be to file a Food Additive Petition(FAP) with FDA. To help with the submission process, there must be early dialogue with FDA and a plan on what is needed. The Colorado Hemp Industry Association is looking to form a WG to move this FAP forward with willing and knowledgeable participants.

Brett Boswell has had one firm submit feeding study protocols to FDA and received feedback from FDA.

There was a question if any states have approved hemp products? No

Another question was raised as to why products containing hemp are on the market? Chelsea Kent stated that hemp is approved as a supplement. It is questionable use in pet food or pet treats, but they are still supplements. Dave Edwards stated that human supplement rules do not apply to animal food. Stan Cook stated that just because these products exist in the market doesn't mean that they are ok. He also stated that Missouri is removing those products when they come across them. Richard Ten Eyck directed people to look at the AAFCO website home page for the hemp white paper.

c) GRAS policy discussion -- cover in the GRAS workgroup report (see agenda item 3a)

d) Standard of Identity Template Functions (placeholder) – not discussed at this meeting

e) Status on high profile ingredients (if needed) – Richard / CVM – not discussed at this meeting

f) Discussion of common human foods in pet food (placeholder)- not discussed at this meeting

g) Any activities needing 18-19 Association funding? Recommend a reserve of $20K for GRAS and Definition Process educational efforts.

h) Set Webinar **meeting dates** for 2018

Proposed dates are 3/30/18 and 10/5/2018. March 30th is Good Friday. The IDC preferred not to have a meeting on this date. Richard Ten Eyck will send a doodle to figure out an alternate date.

Next meeting is 4/19/18. Check the BIN and AAFCO.org for connection details.

Meeting Adjourned. Minutes approved 3/21/2018 with 17 Affirmative votes.

Appendix A 1/23/18 IDC Meeting

GRAS workgroup report:

1/5/18:

WORKGROUP SCOPE: Deal with details and issues surrounding independent GRAS conclusions without a no-questions letter from FDA.

Goal 1.) (done 1/3/18) Establish language for work group project(s) scope:

*Project 1.) Provide Industry, consumers and regulators information about the FDA law & regulations applicable to GRAS substances.

Project 2.) Identify & pursue solutions to CVM review resources above and beyond GRAS notifications.

**Project 3.) Identify & pursue state acceptable alternatives to CVM review of independent GRAS conclusions.

** top Priority

* Second Priority

Goal 2.) (done 1/3/18) Prioritize Projects: 3--1--2

Next steps: 1.) Update status document

2.) Meet again (after Anaheim)

# Text of Definition Recommendations accepted by IDC 1/23/18

**T40.100 Recovered Retail Food** is composed of edible human food products safe and suitable for livestock feed that are collected from retail food establishments, domestic holding facilities, and domestic packing facilities. Permitted recovered retail foods are products from overstocks, lacking consumer acceptance, or beyond their sell-by date that include items such as bruised, cut, or overly ripe produce (fruit and vegetables), bakery goods, eggs, and dairy products. It shall be safe and appropriately labeled for its intended use and shall be free of material harmful to animals. Materials excluded from
this definition include pet foods, products containing beef, lamb, pork, poultry, fish, or shellfish. It must not contain packaging materials (e.g., plastics, glass, metal, string, Styrofoam, cardboard, and similar materials), flowers, potted plants, or potting soil. The recovered foods shall be collected and intermixed in secure holding containers to exclude unauthorized addition of trash, materials harmful to animals, or infestation and adulteration by pests. Egg and dairy products (and other products ordinarily held at refrigerator temperatures) must be kept in cold storage until the scheduled pick-up. To minimize spoilage, the recovered retail food shall be collected at least weekly, or more

frequently if necessary. The establishment should have a sanitation plan in place, and the containers should be cleaned and sanitized as necessary. The collected material may be further processed or delivered as is to an animal feeding facility. The product must be handled to preserve its safety and nutritional value. (Proposed 2017, adopted xx )

**T 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 a source of insoluble fiber in animal feed and pet food. (proposed xx)

**T 71.40 Low Glucosinolate High Erucic Acid Rapeseed Meal, Solvent Extracted**** is the meal obtained after the removal of most of the oil by the prepress solvent extraction of whole seeds obtained from the genus Brassica (Brassica napus, Brassica rapa (formerly B. campestris), or Brassica juncea) from which the oil shall contain more than 2% erucic acid and the solid component shall contain less than 30 micromoles of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3-butenyl glucosinolate and 2-hydroxy-4-pentenyl glucosinolate, and allyl glucosinolate per gram of air dry, oil free solid. It must contain a maximum of 2% erucic acid, a maximum of 12% crude fiber and a maximum of 30 micromoles of glucosinolates per gram. It is used in the diets of animals as a source of protein, in accordance with good feeding practice. (proposed xx)

**T 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 xx, xx)

**T87.50 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 xx)

**73.020 Ammonium Formate.**

The food additive, 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 ensure 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 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.

**(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 ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph **(d)** 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 Safety Data Sheet (MSDS). 21 CFR 573.170 (Proposed 2011, Adopted 2013, Amended 2017, amended xxx)

**73.025 Formic Acid** is manufactured by heating carbon dioxide and NaOH under pressure and decomposing the resulting sodium formate with H2SO4, the resulting formic acid, CH2O2, has a molecular weight of 46.02. The food additive, formic acid, may be safely used in accordance with the following conditions:

(a) The additive is used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of the silage on a dry weight basis or 0.45 percent when direct cut, as follows:

(1) The top foot of silage stored should not contain formic acid and

(2) Silage should not be fed to livestock within 4 weeks of treatment.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine **and poultry** feeds at levels not to exceed 1.2 percent of the complete feed.

(1) The additive consists of not less than 85 percent formic acid (CAS 64-18-6).

(2) The additive meets the following specifications:

(i) Free methyl alcohol not to exceed 1,000 parts per million (ppm);

(ii) Methyl formate not to exceed 1,000 ppm; and

(iii) Moisture not to exceed 15 percent.

**(3) To ensure 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.**

**(4)** 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:

(i) The name of the additive.

(ii) Adequate directions for use including a statement that formic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing formic acid.

**(iii) 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.**

**(5)** To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph **(b)(4)** of this section, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formic acid (85 percent formic acid).

(ii) Statements identifying formic acid (85 percent formic acid) as a corrosive and possible severe irritant.

(iii) Information about emergency aid in case of accidental exposure.

(A) 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.

(B) Contact address and telephone number for reporting adverse reactions or to request a copy of the ~~**Material**~~ Safety Data Sheet (~~**M**~~**SDS**). 21 CFR 573.480 (Proposed 2011, Adopted 2012, 2013, Amended 2015 rev. 1, 2017, amended xxx)