Final: 3/13/2020 version 4

Ingredient Definitions Committee Meeting Report

AAFCO 2020 Midyear Meeting
Albuquerque, New Mexico
Wednesday, 1/22/2020
3:30 PM – 5:30PM MST
Grand Pavilion Ballroom 1-5

Recommendations to the Board and Association membership:

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

1) Publish in the OP a New Feed Term **Common or Usual**:
common or usual name. (naming process) The common or usual name of a feed ingredient shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the ingredient or its characterizing properties. The name shall be uniform among all identical or similar ingredients and may not be confusingly similar to the name of any other ingredient that is not reasonably encompassed within the same name. Each ingredient shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from other ingredients. Common or usual names of many ingredients used in animal feed are found in the Association of American Feed Control Officials' Official Publication, Chapter 6 – Official Feed Terms and Ingredient Definitions. Some feed ingredients may be a common food, in this case the common or usual name should abide by the principles as provided in this feed term.
2) Publish in the OP a New Feed Term: **Common food**. Common foods are commercially available and suitable for use in animal food but are not defined by AAFCO, including but not limited to certain whole seeds, vegetables, or fruits. Common food for animals may include common human foods that are known to be safe for the intended use in animal food. Manufacturers are responsible for determining if a common food is safe and has utility for its intended use prior to commercial distribution as animal food.
3) Publish in the OP a tentative definition **T60.117 (B) Dried Black Soldier Fly Larvae**. This includes the addition of swine to the feed ingredient definition for black soldier fly larvae
4) Publish in the OP an official definition **57.167 Manganese hydroxychloride** to replace the tentative one.
5) Edit Table 101 to add GRAS Notification AGRN 30 **Krill Meal.**

Board Action:

To be considered in May 2020

Association Action:

To be considered in August 2020

Recommendations not needing further Association review

1) Publish in the OP an editorial change to **60.106 Inulin** to clarify that the analysis of minimum inulin is on a **dry matter basis.**
2) Publish in the Official Publication an edit of Potassium Carbonate: **57.101 Potassium Carbonate** is a potassium salt of carbonic acid generally expressed as K_2CO_3 **and its hydrated forms**. Minimum potassium (K) must be specified. (Adopted 1975, revised 2020 rev 1)
3) **Established a subcommittee (put note in OP)** Establish a subcommittee to interface with the AAFCO Technology Committee to keep ODI updated with OP data. Volunteers: Jacob Fleig (MO), Melanie Marquez (MN), Kelli Younker (NM))
4) **Established a subcommittee (put note in OP)** to interface with National Animal Nutrition Program (NANP). Volunteers: Casey Dykier (CA), Al Harrison (KY) and Mike Kopf (FDA).

Minutes

Documents supporting the agenda are posted in the BIN library / Ingredient Definitions / Investigator Recommendations -or- contact the person listed on the agenda with questions.

*1)*Roll call of Committee members. *Quorum was present*

Erin Bubb, Kent Kitade, Mika Alewynse, Ken Bowers, Stan Cook, Dave Dressler, James Embry, Maggie Faba, Ashlee-Rose Ferguson, George Ferguson, Jacob Fleig, Brett Groves, Darrell Johnson, Ali Kashani, Dan King, Mark LeBlanc, Melanie Marquez(phone), Dave Phillips, Tom Phillips(phone), Nathan Price(phone), Laura Scott, Kelli Younker, Shannon Jordre, Charlotte Conway, Jennifer Kormos.

2) Hemp Update: Bob Church introduced the new oilseed investigator Falina Hutchinson, MT. Charlotte Conway said that FDA is ready for submissions but has not received any to date. She also noted the warning letters were sent to firms supplying CBD products in late 2019.

3) **60.106 Inulin** editorial change to inulin to clarify that the analysis of minimum inulin is on a dry matter basis. -Erin Bubb made the motion; Brett Groves seconded. Motion **passed**.

4) **T60.117 (B) Dried Black Soldier Fly Larvae**. Addition of swine to the feed ingredient definition for black soldier fly larvae -Erin Bubb made the motion; Stan Cook seconded. Motion **passed.**

5) **73.052 Sodium Aluminosilicate** as an anticaking agent. Add to the OP as Official (CFR) Richard Ten Eyck. Shannon Jordre made the motion to add these changes including the synthetic form; David Dressler seconded. Voting inconclusive – no one voted aye or nay. *Dave Phillips made a motion (Ken Bowers seconded) to table to March 4, 2020 IDC webinar*. Motion **passed.**

According to Mika Alewynse, FDA agreed that the synthetic form was safe for the intended use some time ago, but not bringing it to the committee was an oversight. Leah Wilkinson clarified that both names of this additive are used commercially, are used in the AAFCO OP and provided as a GRAS substances in the CFR (21 CFR 582), used internationally, and in organic-certifications (OMRI). AFIA further questioned why the detailed FCC specifications are included in this ingredient and not in other anti-caking agents. She also noted that the FCC specifications differ from the EU specifications.

Mika Alewynse said that a phase in period could be allowed for the different names (precedent is the reclassification changes for the direct-fed microorganisms). A single common or usual name is preferred rather than having multiple names to avoid user confusion. Ingredient definitions, such as that for selenium, can differ from the Code of Federal Regulations. Until January 2018, the Division had objected to synthetic sources.

73.052 Sodium aluminosilicate is hydrated sodium aluminum silicate having Na2O:Al2O3:SiO2 in molar ratios of approximately 1:1:13, respectively. It can be naturally occurring **or synthetic.** It consists of 66.0 to 76.0% silicon dioxide; 9.0 to 13.0% aluminum oxide; and 4.0 to 7.0% sodium oxide, on a dry basis. It is used as an anticaking agent not to exceed 2% in finished feed. 21 CFR 582.2727.

6) Delete (editorial) the entry in table 73.001 (page 432 2019 rev 1OP) in section 73, Technical Additives, for sodium silicoaluminate be deleted to avoid confusion when the definition for sodium aluminosilicate is accepted by the AAFCO membership. Sodium silicoaluminate is an older name for sodium aluminosilicate. – Richard Ten Eyck (5Min) *No Action taken, deal with at the Next IDC meeting.*

7) Common food workgroup report – Ali Kashani, Charlotte Conway, CVM (20min)

Charlotte Conway presented the WG report (see slides on Feed Terms in the Feed Bin "Feed Terms common food etc, round next.pdf") including the history of how the WG arrived at its current recommendations. Every ingredient needs to be labeled with its common or usual name. A common or usual name means that everyone can understand what a substance is. The AAFCO defined names are the common or usual name of those ingredients. Having an acceptable common or usual name does not mean it is acceptable for food, e.g., lead. Whether or not a food is a common food should be straightforward, but does require both thought and information. Blueberries or corn would readily be considered common food. Hemp seed might be safe, though has not been used as a food until recently and does not fit the common food category. Another example is salt – is it of a purity that is safe for use in animal food? Road salt – maybe not safe.

Cathy Alinovi asked how one can decide what is a Common Food, e.g., button mushrooms, different types of salt. Manufacturers should be able to respond regarding safety data or information according to Charlotte Conway and need to ensure the ingredient is labeled correctly.

*Shannon Jordre moved to accept **both** the Common or Usual and Common Food terms; Dave Phillips seconded*. Motion **passed.**

Dave Dressler is concerned about there being confusion. However others felt it was solving problems rather than creating them. Chris Cowell (PFI) expressed support.

George Ferguson asked if there should be a boundary year like 1958. Can it be processed? It can't be a by-product. Should the term say, "whole" seeds or "in its entirety"? He felt that AAFCO should keep an eye on whether or not these Feed Terms are used incorrectly. Charlotte explained that "whole" was meant to apply to seeds, vegetables, and fruits – byproducts would not be considered a common food.

8) New Feed Term **Common or Usual** -- Ali Kashani (5 minutes)
common or usual name. (naming process) The common or usual name of a feed ingredient shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the ingredient or its characterizing properties. The name shall be uniform among all identical or similar ingredients and may not be confusingly similar to the name of any other ingredient that is not reasonably encompassed within the same name. Each ingredient shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from other ingredients. Common or usual names of many ingredients used in animal feed are found in the Association of American Feed Control Officials' Official Publication, Chapter 6 – Official Feed Terms and Ingredient Definitions. Some feed ingredients may be a common food, in this case the common or usual name should abide by the principles as provided in this feed term.

9) New Feed Term **Common Food** -- Ali Kashani (10 minutes).
common food. Common foods are commercially available and suitable for use in animal food but are not defined by AAFCO, including but not limited to certain whole seeds, vegetables, or fruits. Common food for animals may include common human foods that are known to be safe for the intended use in animal food. Manufacturers are responsible for determining if a common food is safe and has utility for its intended use prior to commercial distribution as animal food.

10) Establish a workgroup or subcommittee to interface with National Animal Nutrition Program (NANP) (see BOD minutes from 11/21/19 for charge) https://animalnutrition.org/feed-composition-database Three person group (TBD) – Erin Bubb made a motion to establish this Sub Committee. Kent Kitade seconded. Motion **passed.**

Casey Dykier (CA) volunteered. Richard asked for other AAFCO Member volunteers. Al Harrison (KY) and Mike Kopf (FDA) volunteered.

NANP is in academia (see animalnutrition.org) and NANP and AAFCO have formed a working relationship. NANP maintains the Feed Composition Database and it references the AAFCO OP definitions and feed terms. A continuous interface with this Sub Committee will be required in order to make sure that the data in the NANP database is aligned with the OP.

11) Establish a subcommittee to interface with the AAFCO Technology Committee to keep ODI updated with OP data. Three person group (TBD)– Jacob Fleig made the motion; George Ferguson seconded. Motion **passed.**

Volunteers: (Jacob Fleig (MO), Melanie Marquez (MN), Kelli Younker (NM))

12) ICG Verification workgroup report – Richard Ten Eyck.
Linda Morrison relayed that the SAC was asked in August to set up a survey to see if AAFCO Members are still interested in this ICG WG activity. Received 24 member replies; with 68% supporting. Some replies were from the same states. In 2016, 22 members responded, and most were in support. The Board was apprised of these results, and felt that the WG should proceed. Report was accepted. (in attachment a)

Leah Wilkinson, Emily Helmes, and Chris Cowell voiced that Industry would only use this process if all states would accept it, as stated in the ICG WG goal. The survey response is difficult to interpret since several replies came from the same states. It really didn't answer the question raised by the WG. Emily suggested that the survey be repeated and sent to individual voting members, one from each state. Justifying the repeat survey is the fact that building the AAFCO ICG process would take considerable effort on behalf of both the states and industry.

The WG will need to discuss the next steps.

13) Not-Defined workgroup update – Kent Kitade updated that a conference call was held in December. Most important question was that if AAFCO did not get support from Industry that they would take it private. Question raised on legality of private list. Kent prefers to go back to take it public and determine legality of this step.

Kristi Smedley stated that she is a member of the WG and continues to wonder what is the real intent of this ND List. Richard Ten Eyck said that they have some interesting ideas and will share with the WG at their next meeting.

14) MSBC Workgroup Report – Tom Phillips. The report is posted on the Feed Bin (See MSBC workgroup report 010220.docx) and was shared. Historical data alone will not be sufficient to support MSBC being GRAS, more data are needed. Chris Cowell added that this substance has been used for a long time. Perhaps it

would be helpful to convene a GRAS Panel to review the available data. Charlotte Conway recommended that if that is done, that the FDA Guidance on convening a GRAS Panel be followed. Tom Phillips said that he is seeing it in pet food and ruminant food, and it is not needed for ruminants. Leah Wilkinson says that we need a creative solution that works for Industry and the states and appreciates the WG input on this. Cathy Alinovi pointed out that when fresh food is fed, the animals make it themselves. She is concerned of toxic effects. Per Dave Dzanis, no evidence of toxic effects orally.

15) 90.25 Update to vitamin table 90.25– MSBC intended uses – Tom Phillips – *Postponed discussion to March 2020.*

16) 90.27 (NEW) Pet food parenthetical Vitamin name table (workgroup update with possible action item) --- Tom Phillips *No Action taken, deal with at the Next IDC meeting.*

17) GRAS Notice Training Baltimore 8/5/2020- workgroup update—Dave Edwards *No Action taken, deal with at the Next IDC meeting.*

Charge: Develop and deliver a public workshop on submitting GRAS notifications to FDA on feed ingredients.

a) Lead – Dave Edwards
b) Team: (CVM), Nathan Price, Louise Calderwood (AFIA), Kristi Smedley, Chris Cowell (PFI), Emily Helmes (ETA), Jan Campbell (NGFA), Meagan Davis
c) ETC Liaison: George Ferguson, NC

18) AAFCO Investigator Training - Baltimore 8/4/2020 workgroup update - Charlotte Conway. *No Action taken, deal with at the Next IDC meeting.*

Charge: Using materials from the last investigator workshop develop and deliver regulator-only training for the AAFCO ingredient investigators.

d) Lead – Charlotte Conway
e) Team – Richard, Kent, Ali,
f) ETC Liaison: Kate Nelson, CT

19) Next Meetings: e-meeting March 4, 2020 11:00AM PST; Following PFLM webinar. F2F August 7, 2020, Baltimore Richard Ten Eyck

20) 9.XX Animal Products Edits (placeholder) – Brett Boswell, *No Action taken, deal with at the Next IDC meeting.*

21)Table 101 GRAS Notification AGRN 30 **Krill Meal** —Nathan Price made the motion. Ken Bowers seconded. Motion **passed.**

Question raised by Kristen Green on whether it was intended for use in complete and balanced dog food only or if it could be used in adult dog treats. Charlotte Conway reminded everyone that FDA tries to summarize as best they can in the OP; however, the best place to look is in the FDA letter reply. The GRAS notice and FDA response letter say its for use in adult dog food but does not elaborate on complete and balanced or not. Elizabeth Lewis on behalf of sponsor said that there was no intent to use krill meal in dog treats, but rather in dry adult dog food. Dave Edwards reminded everyone that the GRAS Notice is the firm's conclusion and that FDA had no questions on the safety or utility of this ingredient under the conditions of use in the notice.

22)CVM late add Item #1 57.101 Potassium Carbonate (placeholder) (5 min) Jennifer Kormos made motion to make an editorial change to add "in its hydrated forms". Shannon Jordre seconded. Motion **passed.**

23) Another late add Item: **57.167 Manganese hydroxychloride** Jennifer Kormos made the motion to move it to official since it was published as Tentative for over a year. Brett Groves seconded. Motion **passed.**

Minutes accepted 3/4/2020 19/24 not voting: Kent kitade, George ferguson, Dan King, Mark LeBlanc, Madison Starnes

Appendix A to IDC 1/23/2020 meeting report

60.106 Inulin is a polysaccharide product obtained from plant sources such as chicory (Cichorium intybus L.), agave (Agave azul tequilana), and Jerusalem artichoke (Helianthus tuberosus) by hot water extraction. It is intended as a source of soluble, fermentable fiber. It must contain not less than 90% inulin ***on a dry matter basis.*** It may contain products of partially hydrolyzed inulin.

T60.117(B) Dried Black Soldier Fly Larvae is the dried larvae of the Black Soldier Fly, *Hermetia illucens*, with or without mechanical extraction of part of the oil, that has been raised on a feedstock composed exclusively of feed grade materials. The ingredient must be labeled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is dried by artificial means to no more than 10% moisture. It is for use in salmonid, poultry and

swine feed as a source of protein and fat consistent with good feeding practices. (Proposed 2018 rev. 1, Adopted 2019 rev. 1,)

57.101 Potassium Carbonate is a potassium salt of carbonic acid generally expressed as K_2CO_3 **and its hydrated forms.** Minimum potassium (K) must be specified. (Adopted 1975)
IFN 6-09-336 Potassium carbonate K_2C0_3

Add AGRN 30 Krill meal to table 101:

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
30 (PDF – 307 pages)	Aker BioMarine Antarctic	*Euphausia superba* (krill) meal	Krill meal	To be used as a source of protein and lipid in food for adult dogs at a maximum inclusion level of 3% by weight of dry food.	Adult dogs	2/19/2019	FDA has no questions. (PDF - 4 pages)

SAC Workgroup Report on ICG:

Independent Conclusion of GRAS - AAFCO Review Process
Survey 2 Report 1/20/2020

Background

A regulator survey was conducted in the summer of 2016 to determine how states were handling GRAS related issues (e.g. notifications, self-determination) and whether they would accept an AAFCO led process to review GRAS self-determinations. The survey questions are provided for reference at the end of this document. Thirty-two surveys were completed. The results can be found in the FeedBin by searching: GRAS Regulator survey 081516.pdf

A Working Group (WG) was established under IDC (summer 2018) with the charge: to identify and pursue state acceptable alternatives to CVM review of independent GRAS conclusions. The WG Goal was: to develop an animal food ingredient review system for independent conclusions of GRAS that is acceptable to all AAFCO member states.

The Strategic Affairs Committee was charged by the Board (January 2019) to consider whether AAFCO should continue this work. The relevant question from the 2016 regulator survey is number 6:

Would your state support the AAFCO organization's establishment of a process that provides expert review of industry GRAS self determinations to base an AAFCO defined ingredient?

Responses to this question:
Yes - 22
Probably (with conditions) - 5
No - 2

Action

The SAC determined that a follow up survey should be utilized to assess member support at this time.

A one question survey, slightly modifying former question 6, was used to facilitate responses. The pre-amble was:

AAFCO surveyed members in July 2016 regarding AAFCO establishing a process to provide expert review of independent conclusions of GRAS which was supported. A working group has been established to address this.

This is a second survey to touch base to see if members still support this work.

The survey title and header information was:

Independent Conclusions of GRAS (ICG) - AAFCO review process
Member survey to obtain information on support for AAFCO establishing a process that provides expert review of independent conclusions of GRAS for an animal food ingredient. This is the second survey to reaffirm support; original July 2016.

The question was:

Would your state support AAFCO establishing a process that provides expert review of independent conclusions of GRAS for an animal food ingredient?

The response options were yes or no with a comment option as well.

The survey was opened on November 25th. Each time a member signed in to the FeedBin they were prompted to complete the survey. The response rate was very low. A reminder was also sent to prompt uptake. The survey was left open until January 19th.

There were 24 member responses with 68% supporting AAFCO proceeding. Conversely 31% were not in favour. A number of the 24 were from the same state but it was not possible to determine if they had voted the same or differently.

The first survey was not a straight yes/no format. Opinions could be provided as well. It was difficult to determine if the opinions were part of the yes/no respondents. So, the report didn't give a percentage for comparison. The clear yes no answers showed 22 yes versus 2 no.

Both surveys, indicate that the majority of member respondents are interested in AAFCO pursuing a path to address independent conclusions of GRAS. A lack of response was assumed to mean neutral opinion on the subject.

The Board were apprised January 19th, 2020. Since IDC meets before SAC, the information was provided to them for their ICG working group so they can proceed. Their activities were on hold while SAC re-surveyed members.

Linda Morrison
Strategic Affairs Committee

Reference information

Survey 1 (July 2016)

Preamble text:
GRAS Notifications Regulator Survey
The AAFCO IDC requests your cooperation in completing a brief 7 question survey to understand how your state view
Generally Recognized As Safe (GRAS) substances for use in animal food. Please complete by 7/15/16.

Questions:
1. Does your state currently allow distribution of GRAS substances with animal food intended uses which have been submitted to FDA, reviewed, and received a No Question Letter from FDA (as demonstrated on the FDA website)? (Answer: yes, no, it depends)
2. Would your state allow distribution of an ingredient based on a simple OP listing of GRAS substances with animal food intended uses that the FDA had issued a No Questions Letter? The listing would be similar to what is provided for food additives and GRAS regulations in section 100, where there is no specific definition. (Answer: yes, no, it depends)
3. Would your state accept as adequate for the basis of distribution a specific ingredient definition established through a yet to be determined IDC process which is based on the FDA issued GRAS No Question Letter in response to filed GRAS Notifications. (Answer: yes, no, comments)
4. Does your state accept as a basis for distribution a company's self-determination of GRAS status of the intended use of a substance? (Answer: yes, no, comments)
5. Would your state accept as a basis for distribution a GRAS or other safety determination for use of a substance made or supported by another state? (Answer: yes, no, comments)

6. Would your state support the AAFCO organization's establishment of a process that provides expert review of industry GRAS self determinations to base an AAFCO defined ingredient? (Answer: yes, no, comments)
7. Do you have any additional comments? (space to explain above answers or provide additional information) (Answer: open text box)