Ingredient Definitions Committee Report
Meeting, January 18 and 19, 2023

January 18th, 2023 – 8:00 to 9:30 am Central

Recommendations to the Board and Association membership:
(language in attachments)

1) Publish the new feed term **"Freeze Dried"**
2) Publish a New Official Definition: **T33.29(A) Black Soldier Fly Larvae Oil** to Official and replace existing official definition.
3) Publish a New Official Definition: **T36.11 ____ Dried Fermentation Product to Official- relating to organisms to allow the use of *Lactobacillus diolivorans* as a silage inoculant.** Replace existing official definition
4) Publish an amended **Swine Health Protection Act guidance language** in Sections 40 (page 409) and 60 (page 438) of Chapter 6.
5) Add the **Sunsetting Language** to the "Guide for Submission" at beginning of Chapter 6
6) Make the following changes in ODI: (tentative ingredients do not go into ODI) **

IDC Meeting Date:	1/18/2023		
	ODI Summary of Changes for OP		
Action	Ingredient Name	Reference	Comments (meeting)
New Name and reference	***Black Soldier Fly Larvae Oil (To Official)**	T33.29(A)	Business meeting xx/xx/xx
New Name and reference	* **____ Dried Fermentation Product (To Official)**	T36.11	Business meeting xx/xx/xx
New Name and reference			Business meeting xx/xx/xx

**ODI updating—to add transparency of the impact of committee decisions on the Online Database of Ingredients (ODI) label validation tool, the committee recommendations will include a table of the anticipated changes to ODI to reflect changes to common or usual names and/or references in the OP. It is anticipated this table will also appear in the front of the OP with the dates of adoption by the Association Membership. OP section editors are responsible for the accuracy of the ODI updates.

Board Action:

Recommendations to be considered in April 2023

Association Action:

Recommendations to be considered in August 2023

Recommendations not needing further Association review

Editorial Changes to Chapter 6

1) **36.14 Direct Fed Microorganisms-** updated to reflect nomenclature changes. Date of Compliance of January 2023. This change affects *Pediococcus cerevisiae (damnosus)* and was accepted by IDC in August 2019
2) Hold Investigator Training on the ODI -Jennifer Kormos will coordinate the training with help from Dave Dressler (Feed Labeling Committee) and George Ferguson (Technology Committee).

Referrals to other AAFCO committees: -none-

Minutes IDC January 18th, 19th 2023

The Committee met in person and virtually with over 400 attendees. Committee member roll call on Google Doc was Displayed. A quorum was present with 26 out of 30 voting members present including Richard Ten Eyck, Laura Scott, Charlotte Conway (FDA), Ken Bowers, Erin Bubb, Stan Cook, Dave Dressler, James Embry, Ashlee-Rose Ferguson, Jacob Fleig, George Ferguson, Falina Hutchinson, Darrell Johnson, Ali Kashani, Alan Keller, Dan King, Nathan Price, David Snell, Jennifer Kormos, Trish Dunn, Bailey Whiten, Kent Kitade, KC Gutenberger, Bernadette Mundo, JoLynn Otero, Katie Simpson, Mark LeBlanc, Shannon Jordre, Ashley Shaw

Absent: Josh Arbaugh (Lab committee) Cory Skier, Tom Phillips, Maggie Faba

There were some minor edits with membership

OP Content

1) "Finished Feed" as a new feed term - Cynthia Scholte gave a detailed presentation on behalf of the work group. (See presentation in IDC's Feed Bin Library for Midyear January 2023)

The terms “finished feed” and “complete feed” are used throughout the AAFCO OP definitions and in the CFR. In many cases, the regulations and definitions limit the amount of an ingredient in finished or complete feed. The key question is: What is the difference between complete feed and finished feed? Are they the same or different? The shared presentation covers the main speaking points. In conclusion, the workgroup recommended: (1) establish a new feed term for finished feed, as specified in the presentation; (2) review the CFR and OP to assess whether the terms complete and finished feed have been used correctly; and (3) revise the CFR regulations and OP definitions as needed. Since this information is being presented for the first time to IDC, the workgroup further recommended that this proposed new definition be reviewed and considered by members and all stakeholders prior to any action being taken.

During discussion it was pointed out that acceptance of this definition will create a significant workload for FDA and AAFCO in that the many of the references to finished and complete feed in the AAFCO OP and the CFR will need to be scrutinized and potentially amended. A suggestion was made to focus only on instances when there is a limit on the percentage of an ingredient to be used in finished or complete feed. The rationale is that limits on level of use could relate to feed safety.

The IDC agreed to consider the WG proposal at the IDC webinar in March 2023.

2) “Freeze Dried” Publish new feed term- Ali Kashani presented the proposed new term. Jacob Fleig moved to accept this term. Mark LeBlanc seconded. **Motion passed.** ATTACHMENT A

   The WG wants to shift focus and work on revised feed terms for raw and fresh and on a new term for pasteurization. James Embry is interested in joining the WG. Additional terms include “total ration” and “total diet”.

3) T33.29(A) Black Soldier Fly Larvae Oil to **Official**- Bernadette Mundo presented. Mark LeBlanc moved to accept the definition. Ken Bowers seconded. **Motion passed.** ATTACHMENT B

4) T36.11 ____ Dried Fermentation Product to **Official**- relating to organisms to allow the use of *Lactobacillus diolivorans* as a silage inoculant. Replace existing official definition- Charlotte Conway presented for Maggie Faba.
   This definition will replace the current Official and include a change.
   Mark LeBlanc moved to accept the definition. Ali Kashani seconded. **Motion passed.** ATTACHMENT C

5) Modification to **Swine Health Protection Act (SHPA) guidance language** in Sections 40 and 60. Will replace current SHPA guidance language subject to association vote. - Erin Bubb presented.
At the January 17th business meeting, guidance language was tabled by the membership until August. The IDC was presented with **modified** guidance language instead at this meeting. If moved forward, the membership vote will occur in August. The WG was comprised of FDA, USDA, States, and Industry

Dave Dressler moved to accept the WG report. Shannon Jordre seconded. **Motion passed**. ATTACHMENT D

George Ferguson moved to accept the proposed new language. Stan Cook seconded. **Motion passed.** ATTACHMENT D

A modification to add 4 asterisks (****) to the ingredients:
40.96 Food Processing Waste****
40.97 Restaurant Food Waste****
60.108 Salvage Pet Food****
60.117 Black Soldier Fly Larvae****
for referencing the SHPA guidance language, as recommended by the WG, was made. George Ferguson moved to accept. Falina Hutchinson seconded. **Motion passed.** ATTACHMENT D

Editorial Changes:

6) 36.14 Direct Fed Microorganisms updated to reflect nomenclature changes. Date of Compliance of January 2023. This change affects *Pediococcus cerevisiae (damnosus)* and was accepted by IDC in August 2019. Charlotte Conway presented for Maggie Faba.

This DFM nomenclature change is part of the sunsetting plan. Because the compliance date has been noted in the OP, this change does not need to be voted on by membership in August. David Dressler moved to accept. Jacob Fleig seconded. **Motion passed.**

Modification changes are going to Membership for vote. Editorial will not.

Informational Updates

7) Fish Definition: Seeking Feedback for a new definition- Charlotte Conway led the discussion.

While working on the pet food label modernization, it was raised that the OP does not have a definition for the term **Fish**, and it was thought to be beneficial to have a definition.

Charlotte asked if anyone in Industry or the States have definitions or terms that define fish and how fish should be scoped (keep examples of “meat” and “poultry” in mind for scope), she would appreciate their sending them to her. This is not a request for data but rather on identity.

FDA plans to come forward with a proposal in August and may hold a WG call as needed. Justin Hill was named the new Marine Products Investigator, and he will be involved in the process.

8) FDA Virtual listening session on February 9. Charlotte Conway presented that FDA-CVM is holding a virtual meeting to discuss CVM’s engagement with AAFCO on the ingredient definition process. CVM has in the past received criticism on how this process is working. CVM felt that they needed to ask more questions of stakeholders to determine how to work in the future.
   Past external requests have included to improve clarity and transparency in the process. CVM and AAFCO will be presenting to ensure all stakeholders understand the process and then will seek verbal and written input from all stakeholders. Speaker registration closed last week; however, the docket will be open for written comments until March 9. CVM will be reviewing all the comments and will consider updates to the AAFCO/FDA MOU and perhaps development of new industry guidance as potential outcomes. Registration to attend this virtual meeting is still open. Docket Link for comments.

9) Sunsetting workgroup report. Charlotte Conway/Ken Bowers
   a) Workgroup report on sunsetting (withdrawing) procedures for common or usual names in the OP. The scope of this workgroup may be expanded to include how to change a common or usual name.

      The WG leveraged from the experiences with DFM name changes and gluten-to-protein changes to prepare the proposed procedures.

      George Ferguson moved to accept the WG report. Ken Bowers seconded. **Motion passed.** ATTACHMENT E

      In the discussion, it was acknowledged that some edits may be needed to fit this sunsetting language into the Guide. Though editorial changes do not need membership vote, it might be good to have them reflected in the business meeting.

George Ferguson moved to accept the recommendation to publish the WG-proposed language in "A Guide to Submitting New or Modified Ingredient Definitions to AAFCO" in the OP page 345. Ken Bowers seconded. **Motion passed.** ATTACHMENT F

ODI Maintenance

10) ODI Subcommittee report -Jacob Fleig

11) ODI procedures - Jacob Fleig
The procedures are in the BIN and are ready for the investigators to pilot.

Update: Investigator training?

Richard Ten Eyck and Jacob Fleig have been working on the process of building an excel file for ODI changes.

Investigators are the experts on what needs to be done to the definitions. It is proposed that the investigators need to be trained on how to prepare the updates in ODI. Separate virtual training for investigators will be coming soon.

Jennifer Kormos will coordinate the training with help from Jacob Fleig, Dave Dressel, and George Ferguson.

*Chairs recessed committee, January 18th at 9:30 AM CT

*Chairs start second day of the meeting on January 19th at 8:00 AM CT

Committee member roll call on Google Doc was Displayed. A quorum was present with Committee member roll call on Google Doc was Displayed. A quorum was present with 26 out of 30 voting members present including Richard Ten Eyck, Laura Scott, Charlotte Conway (FDA), Ken Bowers, Erin Bubb, Stan Cook, Dave Dressler, James Embry, Jacob Fleig, George Ferguson, Falina Hutchinson, Darrell Johnson, Ali Kashani, Alan Keller, Dan King, Nathan Price, David Snell, Jennifer Kormos (no vote), Trish Dunn, Bailey Whiten, Kent Kitade, KC Gutenberger, Bernadette Mundo, JoLynn Otero, Katie Simpson, Josh Arbaugh, Shannon Jordre (FDA no vote), Mark LeBlanc, Ashley Shaw

Absent: Cory Skier, Tom Phillips, Maggie Faba, Ashlee-Rose Ferguson

Informational Updates

12) Animal Protein WG report. Stan Cook presented the report ATTACHMENT G

Current definitions may not capture current technological advancements on how the ingredients are processed.

The WG seeks comments on the proposed revisions to the definitions presented.

Meat and Bone Meal definition was discussed for modification. Stan presented the draft definition. No action taken.

March 2nd IDC virtual meeting may have the proposed definition of **Meat and Bone Meal** introduced for committee consideration.

The **Recovered ____ food** definition is recommended to be moved to Dave Dressler. The definition would replace **40.97 Restaurant Food Waste** and **40.100 Recovered Retail food**.

"Recovered _____ Food" Discussion: Options to have "with meat" or "without meat" needs to be part of the solution. For any comments on the draft definition, please reach out to Dave Dressler.

For **Recovered Household Food**, California, Oregon, and CVM will work with Dave Dressler on this definition. A proposed definition is expected at the August meeting.

Dave will have something to present at the August IDC meeting.

Next was a discussion on "organ" definition. How will the "organ" definition work with the "meat by-products" definition? One would still be able to use the meat by-products definitions.

The WG still needs to work on these definitions.

Ken Bowers moves to accept the WG report. Jacob Fleig seconds. **Motion passes**. ATTACHMENT G

13) Common Food Index Portal, Next steps- Erin Bubb reported that the CFI subcommittee will be meeting to discuss the first round of Common Foods and the development of the submission portal. Until the time it is created, Common Food inquiries and submissions can be sent definitions@aafco.org

14) Hemp update -Falina Hutchinson provided the update.

Hemp seed meal is currently under review at FDA. Hemp Feed Coalition has submitted a response to questions to FDA last week, which contains an additional study that was suggest by FDA. FDA has the response for review.

ASM will be hosting a follow-up virtual workshop on cannabidiol analysis on April 24 and 25.

15) Ingredient Submission Workshop- Meagan Davis provided information on the in-person workshop and the on-line modules.

The training had 130+ attendees (including FDA, state, and industry volunteers). The online modules can be found at the AAFCO learning management system (LMS). A link to the AAFCO LMS will be available on the new AAFCO website under the Resources tab. Issues accessing online modules have been noted. If you are experiencing any trouble with the modules, please submit issues through aafco@aafco.org.

Appreciation to the IDC committee, AAFCO, CVM, and the industry volunteers was expressed. Overall, it was a good sharing of information.

16) Ingredient submission modules - George Ferguson provided an update. https://aafcolms.digitalchalk.com/learn/animal-feed-ingredient-submission-course-1 Comprehensive on-line training course is part of the AAFCO LMS. If you have not taken the courses, consider doing so. The new AAFCO website will have links to easily access AAFCO's LMS or you can access through the link above. Any issues, contact aafco@aafco.org . More training content will be added to the AAFCO LMS.

17) Algae Biomass Organization (ABO) presentation -- Dr. Jesse Traller gave a presentation on behalf of the ABO. Presentation is in the BIN under the Ingredient definitions library folder; Midyear January 2023.

Announcements

A. Next Meetings: Virtual March 2, 2023

The education topic for Annual meeting in August will be **Recovered Food.** Pre-, Pro-, and Postbiotics will be a future topic.

B. New Investigators Needed:

a. Marine Products - Justin Hill
b. Amino Acids
c. Enzymes – Marissa Kost
d. Fermentation Products
e. DFM
f. Technical Additives- Dave Snell
g. Special Purpose Products
h. Preservatives

C. **Stale Ingredients:** The following are being removed from consideration as definition requests. Please submit a new request if still desired.
   a. Faba beans- Pulse Ingredients
   Stale ingredient to be removed.

D. Parking Lot topics:
   a. 30.01 Fumonison Esterase- Remove extra sentence in paragraph A to match regulation. **(Done)**
   b. Complete gluten review. Dan King has completed this review and will provide an update at the March meeting.
   c. ICG workgroup report – not met since June 2021. **The workgroup was dissolved.**
   d. NANP Subcommittee report –have not met -Ashley Shaw /KC Gutenberger /Al Harrison
   The committee is on standby.
   e. FROM PFC (draft): *Vitamin common names for pet food should be addressed by IDC independent of the PFLM project. Information from the qualitative consumer research should be provided to the IDC. Work of the IDC common vitamin name workgroup should be quantitively consumer panel tested preferably at the same time as the PFLM changes.* **NEED UPDATE, Review?** There is nothing additional. Richard Ten Eyck moved to remove this item from the parking lot list. Falina Hutchinson second. **Motion passed.**
   f. Pursue formal MSBC Definition. **Nothing in motion**
   g. Fluorine levels in model bill. Tom Phillips (lab) and Jennifer Kormos (IDC) and FIFM (Ken Bowers) form a workgroup to look at impact of testing and definitions parse out questions for the appropriate committees concerning Flourine vs fluoride.
   (975.08 AOAC method for fluorine. There are challenges in the methods in animal food and lab capacity. Do we need to send a methods request to LMC? Should Fluorine (gas) be changed to Fluoride in the feed law?
   (Stan) IDC should look at mineral definitions that have fluorine specifications. May also be in CFR definitions) **Workgroup formed was formed and will meet.**

h. New feed term *Total Ration, Total Diet, Raw, Fresh, Pasteurized*. **Ali Kashani**
   Richard Ten Eyck noted that there will be more coming from the Model Bill committee.
i. Proper use of process terms. **Ali Kashani will present at the August meeting.**
j. Next IDC speaker/presenter? Suggestions for topics include Pre, pro, and postbiotics. Request for presentation on cricket rearing for feed ingredient purpose.

END SESSION TWO Meeting Adjourned 9:30 AM CT

See attachments:
A, B, C, D, E, F, G

Minutes approved 03/02/2023. Following members did not vote: Josh Arbaugh, Cory Skier (Not Present)

IDC Midyear meeting 2023 Attachments

Attachment A

Freeze Dried. (process) Freeze dried, also known as lyophilized or cryodesiccated, is a low temperature dehydration process that involves freezing the product, lowering pressure, then removing the water/moisture by sublimation. Product must be dried to reach a moisture and/or water activity level needed to be shelf stable.

Attachment B

33.29 Black Soldier Fly Larvae Oil is the product obtained by mechanically extracting the oil from dried larvae of Black Soldier Fly, *Hermetia illucens*, that have been raised on a feedstock composed exclusively of feed grade materials. It is intended for use in swine, finfish feed, **and adult dog food** as a source of energy consistent with good feeding practices. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2% unsaponifiable matter and not more than 1% insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative".

Attachment C

T36.11 Dried ____ Fermentation Product is the product derived by culturing ____ on appropriate nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and dried in accordance with approved methods and good manufacturing practices. Protein, amino acids, fat, fiber, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. Use of *Lactobacillus buchneri* and *Lactobacillus diolivorans* is limited to silage and high moisture corn grain in plant inoculant products. [For label identification the source must be indicated such as *Bacillus subtilis*, *Aspergillus oryzae*, *Aspergillus niger*, *Lactobacillus acidophilus*, *Lactobacillus buchneri*, *Lactobacillus diolivorans*, *Lactobacillus delbrueckii or Enterococcus faecium*, or as permitted by FDA.]

Attachment D

Swine Health Workgroup Recommendation.
Modify page 409 & 438 by adding this Guidance language:
***This ingredient may contain materials subject to the Swine Health Protection Act and may require additional processing controls, if fed to swine. Prior to the use of this ingredient for the feeding of swine or its use in the manufacturing of an ingredient or*

feed intended for swine, manufacturers and/or feeders should adhere to the provisions of the Swine Health Protection Act where appropriate. (9 CFR Part 166-Swine Health Protection Act)

Reminder:
This language will appear in the preamble of sections 40 and 60 and the following ingredients in those sections will be marked with a double asterisk:
40.96 Food Processing Waste
40.97 Restaurant Food Waste
60.108 Salvage Pet Food
60.117 Black Soldier Fly Larvae

If Committee accepts this language, it will go to the Board as a recommendation and then to membership in August 2023 for consideration at the Annual business meeting. If accepted, it will replace the guidance language tabled by membership at the January 2023 business meeting.

Attachment E

Sunsetting Workgroup report

2022 workgroup participants:

Charlotte Conway, Leah Wilkinson, Kristi Smedley, Jean Hofve, Dave Fairfield, Dave Edwards, Maggie Faba, James Emerson, Pat Tovey, Carlos Gonzalez, Ken Bowers

After a call and further email discussion, the workgroup recommends the following:

Add to the existing edit/removal policy in the procedures manual:

When the revision includes a modification or change to the ingredient name, the old name should be removed through a sunsetting process which will provide time for the old name to expire and for transition to the new name to occur. The sunset date should be printed at the end of any ingredient that would need to be sunset in a bold parenthetical so that the section editor can easily identify any ingredient name that needs to be deleted in their annual review. The date should typically be 2 years unless the situation warrants a longer sunset period. A new ingredient number shall be assigned to the new name, and the date and action of change shall be noted in the parenthetical revision history [e.g., (proposed 1999, adopted 2000, name amended 2022)]. In the case of microorganism nomenclature changes, the new name shall be added after the old name. In definition 36.14, the new name will also need to be added on its own line if it is

not currently listed. The old name will be deleted upon completion of the sunsetting period.

Attachment F

Revised Draft 2/14/23 replace highlighted language

A Guide to Submitting New or Modified Ingredient Definitions to AAFCO

Section Editor—Tammy Plank, FASS

The following guide is offered to assist in development of new or modified feed ingredient definitions. The roles of each party are described below. The definitions should be non-proprietary as not to favor one ingredient producer over another. Materials to be used as feed ingredients should have the following attributes: They should be consistent batch to batch. The material should not be a combination of other ingredients. The intended use should not be to mitigate, treat, or diagnose a disease **(other than a nutritional deficiency)**, but rather to provide nutrition, flavor, aroma for the animal or provide a technical effect in the feed. It is the manufacturer's responsibility to produce a safe ingredient for its intended purpose.

The Requester

Prior to submitting a request for a new or modified definition, the requester (industry, public, regulatory official, etc.) should consider the current ingredient definitions and develop a draft definition that includes the intended use. The requester should then contact the appropriate investigator (see the AAFCO *Official Publication* or website for current listing) by email to definitions@aafco.org to discuss the draft

definition. Following the initial discussion, a requester should then make a request to the investigator in writing that contains the information described below, if pertinent, so there is sufficient information for the decision process:

1) Firm and contact person.
2) Summary of the request, including name of the ingredient, intended use, and rationale for the request. ~~A~~ The proposed name shall:
   a) Not contain commas.
   b) Begin with the base material and then list any needed qualifiers (Beet Pulp plain dried).
   c) Be in alignment with common or usual name conventions in 21 CFR 502.5(a).
   d) Alternate names to be used on labeling shall be clearly stated at the end of the definition. "'Plain Dried Beet Pulp' shall be used on all labeling."
   e) Not include a trade name or be proprietary in nature.

3) Proposed definition.
4) Description of the ingredient (e.g., source, physical characteristics, any marketed formulation(s)).
5) Proposed labeling (can be generic).
6) Historical regulation of the ingredient, if any.
7) Description of the manufacturing processes to support identity, composition, and consistent manufacturing of the ingredient. Data to include:
    a) A description of the manufacturing process,
    b) A list and regulatory citation for all substances used in its preparation,
    c) Stability data (including packaging),
    d) Homogeneity data when ingredient is used at low inclusion rate, and
    e) Validation information of analytical methods to support testing and/or citation of official methods.
    f) Use limitations, if any.
8) Intended use of the ingredient, including target animal species, use rate, purpose, etc.
9) Data and observations (e.g., published literature, animal feeding trials, in vitro studies, empirical data showing technical effect, etc.) to support intended use.
10) Safety Assessment. The safety assessment should include a narrative specific to the target animal and, in the case of use in food producing animals, a human food safety assessment should also be provided. Intended uses specific to companion animals will only need to address target animal safety specific to the use description. The safety narrative(s) should assess all the available data. The supporting data, which serves as the basis of the safety narrative and conclusion, should include:
    a) Assessment of the ingredient for known and/or potential contaminants and impurities.
    b) Available safety information from published articles and/or unpublished studies.
        i) Target animal safety information should demonstrate the margin of safety for the intended use.
        ii) For microbial products (source of DFM, enzymes, fermentation products), information to demonstrate that they are produced from nonpathogenic and nontoxigenic strains.
11) List of cited literature.
12) Copies of all cited analytical reports, studies, and referenced articles. These may be provided in hard copy on a CD in PDF Optical Character Recognition (OCR) format.

More specific description of information listed above may be found in FDA Guidance for Industry 221 Recommendations for Preparation and Submission of Animal Food Additive Petitions.

It is imperative that the requester provide all information that is available to support their request. Confidential business information should be clearly identified in the request. Only manufacturing information can be marked confidential business information. Safety and utility data are not considered confidential business information. It may be advisable to put confidential business information in a separate document that can be sent, if needed, only to the FDA during the scientific review. Confidential business information should not be disseminated by an

investigator without requester's knowledge; also see Section 14(f) of the AAFCO Model Bill or applicable governing state laws.

If not enough information is available in the published literature, a feeding trial may be needed. Please contact FDA CVM Division of Animal Feeds (DAF) for consultation on study design and requirements. Protocols should be submitted to DAF for review prior to conducting the studies.

Once a request has been submitted, the firm should wait to market the ingredient until the definition has been voted on by the AAFCO Ingredient Definition Committee (IDC), AAFCO Board, and AAFCO members.

The requester may contact the investigator to determine whether the request has been submitted to FDA for their review at the 30-day mark and every 30 days after that time.

The requester may get questions from the investigator or DAF. Questions should

be addressed in a timely manner. Pending questions not addressed within 24 months will result in the investigator removing the request from AAFCO consideration.

Some ingredients are fed to intentionally alter the composition of human food (as when making human health benefit claims); these ingredients are not appropriate for review by AAFCO and need to be submitted through the Food Additive Petition (FAP) process to FDA. Additional unanswered safety questions for the ingredient may necessitate an FAP as well. FAP issues will be addressed to the **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. Check the *Official Publication* for further contact information.

A requester wanting approval pursuant to the Canadian Feeds Act and Regulations is required to file a formal application with the Canadian Food Inspection Agency. Inquiries should be addressed to **Director, Animal Feed Division, Canadian Food Inspection Agency**. Check the *Official Publication* for further contact information.

The Investigator

The AAFCO Investigator is a one-person committee that will evaluate and manage the request for a new definition or modified definition. One of the goals of the investigator is to develop official feed definitions that are just and equitable in

cooperation with the members of the industry producing the ingredient. A second goal is to ensure that the production, sale, and use of ingredients will result in safe and effective feeds. The ingredient definitions should be non-proprietary, meaning they do not include a trade name that would favor one producer over another.

Upon receipt of the request for a new AAFCO ingredient definition or request for modification of an existing ingredient definition, the investigator will:

Determine whether the proposed ingredient definition fits in the requested section of the AAFCO OP. If not, the request will be referred to the appropriate investigator or to the chair of the Ingredient Definitions Committee with the requesting party notified of the referral.

Confirm that the proposed ingredient does not fall within the scope of an existing ingredient definition.

Confirm that a proposed revision to an existing ingredient definition will not cause it to be moved to a different section of the OP or fall within the scope of another existing ingredient definition.

Conduct an initial evaluation to determine whether any unanswered safety questions exist. If so, the requester will be referred directly to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**, to pursue a food additive approval. If FDA issues a food additive regulation for the ingredient, the investigator will lead the process of bringing the recommendation before the IDC.

Confirm that the ingredient definition request is complete and contains all the information needed from the requester listed in the requester section above.

Upon receiving a request for a new or modified AAFCO ingredient definition, the expected administrative review time for the AAFCO investigator is 30 calendar days. If the investigator expects their review to take longer than 30 days, he/she may request an extension from the chair of the Ingredient Definitions Committee or request the chair of the Ingredient Definitions Committee assign the definition to another investigator.

Once the administrative review is complete, the investigator will forward one copy (electronic copy is preferred, but if sent as PDF, use Optical Character Recognition (OCR) format) of the request to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. If the requestor prefers to send

any manufacturing information that is confidential business information directly to FDA, that is acceptable. FDA acts in a consulting role to evaluate the safety and utility of the ingredient.

Confidential business information should not be disseminated by an investigator without knowledge of the requester (also see Section 14(f), AAFCO Model Bill or applicable governing state laws).

The expected time for FDA to complete their safety and utility review is 180 calendar days. The investigator will provide an update to the requester on the status of the submission when the

requests for updates are reasonably timed. After a request has been at FDA for 180 days, the investigator may contact the FDA reviewer to determine the status.

It may be necessary for additional data and information to be submitted, which may lead to multiple iterations to completely review a request. If the FDA determines that additional data and information are necessary, they will notify the requestor and copy the investigator.

When FDA has completed their review and recommended publication of the ingredient definition, the investigator will prepare and forward an "Investigators Report" form to the chair of the Ingredient Definitions Committee. These reports will be added to the agenda of the next committee meeting and are open for viewing and comments.

The investigator may initiate a modification of an ingredient definition based upon their knowledge of the affected industry and not on a specific request from an external requester. It is the responsibility of the investigator to acquire sufficient documentation to support their actions, just as it is industry's responsibility to provide sufficient documentation to support their request.

Once a new ingredient definition is approved by the Ingredient Definitions Committee, they forward a recommendation to the AAFCO Board to place the definition in the *Official Publication* in Tentative status. The Board will vote for or against this recommendation before the next membership meeting so members can vote on the recommendation during the Annual or Midyear meetings. Once approved by the membership, the Tentative ingredient definition will be published in the *Official Publication*. Status of a definition only changes upon a vote of the association membership.

The AAFCO bylaws require that each OP-published Tentative definition be reviewed by the responsible investigator 30 business days prior to the IDC meeting at the Annual meeting. The investigator shall recommend to the IDC that the definition be deleted, modified, or moved to official or remain at Tentative.

After 90 business days in Tentative status, the responsible investigator may recommend the definition be moved to Official (or any other action deemed appropriate). Any recommended change in designation will be voted on by the IDC during the Annual, Midyear, or Webinar committee meetings and forwarded to the board for recommendations and then to membership for a vote.

When the revision includes a modification or change to the ingredient name, the old name should be removed through a sunsetting process which will provide time for the old name to expire and for transition to the new name to occur. The sunset date should be printed at the end of any ingredient that would need to be sunset in a bold parenthetical so that the section editor can easily identify any ingredient name that needs to be deleted in their annual review. The date should typically be 2 years unless the situation warrants a longer

sunset period. A new ingredient number shall be assigned to the new name, and the date and action of change shall be noted in the parenthetical revision history [e.g., (proposed 1999, adopted 2000, name amended 2022)]. In the case of microorganism nomenclature changes, the new name shall be added after the old name. In definition 36.14, the new name will also need to be added on its own line if it is not currently listed. The old name will be deleted upon completion of the sunsetting period.

The FDA

The Division of Animal Feeds in FDA's Center for Veterinary Medicine

performs scientific reviews of AAFCO ingredient definition requests and provides recommendations to the IDC investigators for new and amended ingredient definitions.

It typically takes at least 180 calendar days to review a request for a new ingredient definition, depending on complexity of the request and FDA's current workload. The AAFCO investigator can contact the FDA reviewer after that time to inquire about the status. If FDA considers the request incomplete, FDA may contact the requester directly for that information but must copy the investigator on all communications. It may be necessary for additional data and information to be submitted, which may lead to multiple

iterations to completely review a request. If needed to support their scientific review, FDA may directly request confidential business information from the requester. FDA will provide a written response to the investigator with the conclusions of their review with the recommended ingredient definition. The requester should receive a copy of this response.

The Association

Once reviewed by the investigator and FDA, the proposed ingredient definition is submitted by the investigator to the chair of the Ingredient Definitions Committee. The IDC is the clearinghouse for all new or modified definitions by acting as a review panel for the investigator to ensure that definitions are acceptable and consistent with

AAFCO policies and existing definitions. Membership of the committee is drawn from the ranks of AAFCO members. The deadline for submission to the chair is 30 business days before the next IDC meeting and is necessary to allow ample time for committee review and corresponding with the investigator. Once a new or modified ingredient definition is approved by the Ingredient Definitions Committee, the chair will forward a recommendation to the AAFCO Board to place the definition in the *Official Publication* in Tentative status. The Board will vote for or against this recommendation before the next membership meeting so members can vote on the recommendation during the Annual or Midyear meetings. Once approved by the membership, the Tentative ingredient definition will be published in the *Official Publication*. Status of a definition only changes upon a vote of the association membership. The AAFCO bylaws require that each OP- published Tentative definition be reviewed by the responsible investigator 30 business days

prior to the IDC meeting at the Annual meeting. The investigator shall recommend to the IDC that the definition be deleted, modified, or moved to Official or remain at Tentative. After 90 business days in Tentative status, the responsible investigator may recommend the definition be moved to Official (or any other action deemed appropriate). Any recommended change in designation will be voted on by the IDC during the

Annual, Midyear, or Webinar committee meetings and forwarded to the board for recommendations and then to membership for a vote. Firms may use the ingredient definition once the AAFCO membership vote has occurred affirming the recommended definition to appear in the *Official Publication*. Prior to publication in the *Official Publication*, firms wanting to manufacture feed with the ingredient may use committee minutes and general session minutes to document the completion of the process. These are typically posted on the AAFCO website. If deletion of an ingredient definition from the *Official Publication* is proposed, the investigator will follow the same dateline as if proposing any other ingredient definition change. This will allow the IDC the opportunity to review and discuss the proposed deletion.

Canadian Food Inspection Agency

The chair of the IDC will share all completed definition recommendations with Canadian officials for their information once the forms have been forwarded to the Ingredient Definitions Committee. A requester wanting approval pursuant to the Canadian Feeds Act and Regulations is required to file a formal application with the Canadian Food Inspection Agency. Inquiries should be addressed to **Director, Animal Feed Division, Canadian Food Inspection Agency**. Check the *Official Publication* for further contact information.

Additional Pathways to AAFCO Published Ingredient Definitions

Section Editor—Tammy Plank, FASS

Animal Food Additives Approved by FDA

Animal food additives approved by FDA are listed in 21 CFR 573. The food additive regulation specifies the requirements for safe use of the food additive and establishes the common or usual name for the new ingredient. To ensure that the AAFCO *Official Publication* listing of defined feed ingredients is complete, the approved food additive, as specified in the published final rule, will be incorporated in the AAFCO *Official Publication's* Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions chapter. The designated FDA representative to the IDC will provide the appropriate investigator with the food additive regulation and will prepare a recommendation form and forward it to the chair of the Ingredient Definitions Committee for consideration at the next committee meeting.

Since the ingredient has gone through the formal FDA approval process, once the AAFCO Ingredient Definitions Committee, the AAFCO Board, and AAFCO membership have approved the definition, the entry will be incorporated in the AAFCO *Official Publication* as Official.

GRAS Notified Substances with "No Questions" Letters from FDA

A list of GRAS Notices filed voluntarily by the notifiers pursuant to 21 CFR

570.205 that FDA has evaluated (21 CFR 570.265) and determined that it had no questions regarding the conclusion that the notified animal food substance is generally recognized as safe (GRAS) under the intended conditions of use is provided in Section 101 of Chapter 6 of the AAFCO OP. The filed notice and the FDA response letter provide information (identity, manufacture, specifications, intended effect, and safety) on the substance under the intended use conditions, and the most up to date version

is posted at the following website: http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm. This section is provided as a convenience for the State Feed Control Officials. The Investigator of Section 101 will adapt the information as provided on the FDA website and consult with FDA on an appropriate common or usual name.

While the information on the substance and the intended use is specific to that provided by the notifier, other firms may use information within the notice along with other data specific to their substance to support the GRAS conclusion (see 21 CFR 570.3-570.280). Such other firms who

conclude that an animal food substance is GRAS under the conditions of its intended use by relying on a posted GRAS notice submitted by another person shall carefully evaluate whether their production process, product

specifications and intended conditions of use, fall within the parameters addressed by the referenced GRAS notice. GRAS conclusions are not legally required to be submitted to FDA, but may be voluntarily submitted in accordance with the GRAS Notice regulation (21 CFR Part 570.205). Nevertheless, firms that elect to make use of the independent GRAS provision must document their Independent Conclusions of GRAS prior to marketing a substance for a particular intended use. State Feed Control Officials may request the Independent Conclusion of GRAS documentation to support their registration or inspection duties.

The table in Section 101 is adapted from the FDA Animal GRAS Notification website and includes ingredient definition information (substance, common or usual name (from the FDA response letter), and intended use (including use limitations, if any)). For

other information, see the FDA response letter for the GRAS Notice (available at link provided above).

At each AAFCO IDC meeting, the section editor will provide an updated list of animal food GRAS Notices that have been evaluated by the FDA and have received a no questions letter from the Agency. Firms making GRAS conclusions should be prepared to answer questions from the Ingredient Definitions Committee or Association if needed. The notices are voted on by the Ingredient Definitions Committee, the AAFCO board, and accepted by the Association membership for publication in the AAFCO *Official Publication.*

Color Additives Approved by FDA

Color Additives intended for use in animal feed approved by FDA (specifically the Center for Food Safety and Applied Nutrition) are listed in 21 CFR 73 & 74. The color additive regulation specifies the requirements for safe use of the color additive and establishes the common or usual name for the new ingredient. To ensure that the

AAFCO *Official Publication* listing of defined feed ingredients is complete, the approved color additive, as specified in the published final rule, will be incorporated in the AAFCO *Official Publication's* Official Common or Usual Names and Definition of Feed Ingredients chapter.

The designated FDA representative to the IDC will provide the appropriate investigator with the color additive regulation and will prepare a recommendation form and forward it to the Chair of the Ingredient Definitions Committee for consideration at the next committee meeting.

Since the ingredient has gone through the formal FDA approval process, once the AAFCO Ingredient Definitions Committee, the AAFCO Board, and AAFCO Membership have approved the definition, the entry will be incorporated in the AAFCO *Official Publication* as Official.

Attachment G

Animal Products Work Group Report

The animal products work group is providing this report in an effort to make the Ingredient Definitions Committee and wider community aware of some the things we have been working on.

Work group charge:

1. Review of Animal Products descriptions, some of which are 50-60 years old, to ensure that they remain relevant to what is in the market place.
2. Discover how processes that are utilizing new technologies or agricultural practices may have changed the parameters of the existing definitions.
3. Explore the existence for new processes which have potentially created new products not appropriately described by old definitions.
4. To generally explore the potential of creating or modifying descriptions to better define animal product materials in the market place.

For a good portion of the last year, this group has met every other week on Friday afternoons.

Work Group Members:

Dr Charles Starke, National Renders Association
Dr. Jean Hofve, DVM
Dr. George Collings, Nutrition Services
James Emerson, National Poultry and Egg Council, Darling
James Embry, Office of the Texas State Chemist
Dr. Jennifer Vandelight, Tox Strategies
Miriam Johnson, North Carolina Feed program
Laura Scott, Canadian Food inspection agency
Loretta Hunter, PFI, Nestle

Members that served, but have retired the last year
David Meeker, National Renders
Chris Cowell, PFI Nestle

Organs Definition

____ organs are the products obtained from any combination of heart, liver, kidney, lung, spleen, or gizzard derived from slaughtered animals. If it bears a name descriptive of its kind it must correspond thereto.

Multiple Species Animal Meat and Bone Meal

Overview of the proposed changes to the Canadian Feed Ingredients Table - Canadian Food Inspection Agency (canada.ca)

(Multiple species animal meat and bone meal)
Mixed animal meat and bone meal rendered (or mixed animal meat and bone meal) is the product obtained by rendering animal tissues, including bones, exclusive of any hair, hooves, horns, feathers, hide trimmings, scales, manure and stomach contents except in such amounts as may occur unavoidably during good manufacturing practices.. It shall not contain specified risk material (SRM) as defined in Section 6.1 of *the Health of Animals Regulations* or other extraneous materials not provided in this description. If the product bears a name descriptive of its kind or origin (for example, bovine and porcine, bovine and poultry, poultry and fish, poultry and ovine, bovine, fish and poultry), it shall correspond thereto and it may be indicated on the label. This product is obtained by rendering animal tissues from a mixture of species. If an antioxidant is used, it must be approved for use in livestock feeds, it shall be used at the approved rate and the common name or names shall be indicated on the label. If a preservative is used, it must be approved for use in livestock feeds, it shall be used at the approved rate and the common name or names shall be indicated on the label. If a mould inhibitor is used, it must be approved for use in livestock feeds, it shall be used at the approved rate, and the common name or names shall be indicated on the label. If the product contains “prohibited material” as set forth in Section 162(1) of the *Health of Animals Regulations*, it shall be labelled with the following statement required by the Minister: “Feeding this product to cattle, sheep, deer or other ruminants is illegal and is subject to fines or other Punishment under the *Health of Animals Act*. / Il It shall be labelled with guarantees for minimum percent crude protein, minimum percent pepsin digestible protein, maximum percent moisture, maximum percent ash, maximum percent calcium, and minimum percent phosphorus.

Propose to revise 9.41 Meat and Bone Meal

*Meat and Bone Meal is the rendered product from mammal tissues, including bones, in combination with not more than 15 percent fresh raw blood exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents, except in such amounts as may occur unavoidably in good processing practices. It shall not contain extraneous materials not provided for in this definition. It shall not contain more than 12% Pepsin indigestible residue** and not more than 9% of the crude protein in the product shall be pepsin indigestible**. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and maximum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto.*

Rationale for modifying the definition of Meat and Bone Meal

Dave Meeker, National Renders Association dmeeker@nara.org

James Emerson, USA Poultry and Egg Association JPEmerson@darlingii.com

The current definition of Meat and Bone Meal became official in 2000. The manufacturing process, labeling, substances used in preparation of the modified description of the product remains the same as the 2000 Meat and Bone Meal Definition. None of the proposed changes will affect the original safety assessment as the substances used in the ingredient have not changed. Changes proposed are as follows:

- Remove the lower phosphorus limit to allow Meat and Bone Meal to go lower than 4%.
- Remove minimum calcium requirement.
- Remove the 2.2 phosphorus/calcium multiplier.

Rationale: Pork diets containing Phytase is the principal reason for the change. Phosphorus amounts are changing in feed rations of the animals, the raw materials are generated from, e.g., Phytase in pork rations which results in differing values from historical levels in the animals the raw material is derived from. These changes are resulting in Meat and Bone Meal in the market place that is unable to meet the requirements of the current definition.

Recovered Food

The United Nations Food and Agriculture Organization estimates the world wastes about 1.4 billion tons of food every year, the Environmental Protection Agency estimates the United States discards more food than any other country in the world: nearly 40 million tons — 80 billion pounds — every year. That's estimated to be 30-40 percent of the entire US food supply, and equates to 219 pounds of waste per person. In fact, food is the single largest component taking up space inside US landfills,

Dave Dressler Human Food Byproducts Investigator and Dr. Christy Smedley joined in the discussion of the discussion of Recovered food. There are companies working on this problem. Before they can convert food waste to animal food they must first have an animal food definition.

***xx.xx Recovered ____ Food** is composed of edible food materials offered for human consumption that are safe and suitable for livestock feed. Permitted recovered foods include edible plate waste, food preparation trimmings, products from overstocks, lacking consumer acceptance or beyond sell-by dates. Processing and handling must remove all undesirable constituents including but not limited to crockery, glass, metal, string, plastic, cardboard, packaging or similar materials that would be harmful to animals. The recovered food shall be collected in secure holding containers to exclude unauthorized addition of trash, materials harmful to animals, or infestation and adulteration by pests. Recovered food shall be stored, processed and collected in a manner that adequately prevents spoilage and controls food safety hazards. The guaranteed analysis shall include maximum moisture, unless the product is dried to less than 12% moisture and designated as "Dried Recovered ___ Food". If part of the grease and fat is removed, it must be designated as "Degreased". The source must be declared as part of the ingredient name.

Acceptable products: Recovered Restaurant Food and Recovered Retail Food

Actions Going Forward:

- Delete 40.97 Restaurant Food Waste and 40.100 Recovered Retail Food.
- If Recovered Household Food goes through the committee, it shall be suggested as an addition to the acceptable products.

Recommendation

It is the recommendation of the work group that this definition be referred to Dave Dressler for further investigation as a Human Byproducts definition.

Respectfully submitted
Stan Cook, AAFCO Animal Products Investigator