

Ingredient Definitions Committee Report Virtual Meeting September 16, 2022 Accepted by IDC on 11/2/22 11:30 AM – 2:30 PM EST

Recommendations to the Board and Association membership:

OP Text is in appendix A. ODI changes in appendix B. Swine Health workgroup report in appendix C. Sunsetting Workgroup report is in appendix D.

- 1) Publish changes to the feed term "Gluten". "Gluten. (part) The tough, viscid, and complex mixture of proteins remaining when the flour of wheat, rye, barley, or their crossbred hybrids, and derivatives thereof, is washed to remove the starch."
- 2) Publish the tentative T12.8 Barley Protein Concentrate as official (page 377), **12.8 Barley Protein Concentrate** is the dried protein fraction of barley prepared by enzymatic hydrolysis of starch, beta glucans, and fiber. The ingredient is prepared from barley that is dehulled or of a hulless variety. It must not contain less than 60% crude protein on a dry matter basis. The finished ingredient should not contain more than 10% moisture. It is to be used in the feed of fish as a source of protein. (Proposed 2022 rev. 1, adopted xxxx)" (delete tentative)
- 3) Publish an update to table 101.1 to include AGRN 42. Text is in appendix A.
- 4) Publish a replacement Official Definition **30.01 Fumonisin Esterase.** The first version was approved by the committee in August of 2022. Since the source of the language is a food additive regulation the new language comes in as official. Text is in appendix A.
- 5) Add the following statement to the header (preamble) of chapters 40 and 60(page 411 and page 440): "** This ingredient may contain materials that fit the Swine Health Protection Act's definition of "garbage" (i.e., meat resulting from food waste streams). If the product is intended for the feeding of swine or used in the manufacture of an ingredient intended for swine, manufacturers using these ingredients should adhere to the provisions of the Swine Health Protection Act where appropriate. (9 CFR Part 166- Swine Health Protection Act)"



- 6) Mark these ingredients with a "**" to indicate a need to follow the swine health act: 40.96 Food Processing Waste, 40.97 Restaurant Food Waste, 60.108 Salvage Pet Food, and 60.117 Dried Black Soldier Fly Larvae
- 7) Make the following changes in ODI: (tentative ingredients do not go into ODI)
 ** -none-

IDC Meeting Date:		9/16/22			
	ODI Summary of Changes for OP				
Action	Ingredient Name	Reference Comments (meeting)			
ODI Action	Name	Reference	Comments		

****ODI updating**—in order 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:

To be considered in November 2022

Association Action:

To be considered in January 2023

Recommendations not needing further Association review

- 1.) Schedule an ODI training for investigators.
- 2.) Dan King and FASS to do close search of Gluten changes to collective terms and other OP areas including labeling examples in OP.

Referrals to other AAFCO committees: - Discussion with ETC on Ingredient education presentations. – Discussion with meeting planning workgroup on meeting agenda placement for ingredient education talks.



(draft charge) Standing up a workgroup to look at the impact and differences in ingredient definitions and laboratory testing methods for fluoride and fluorine. Workgroup to consist of Tom Phillips (lab) and Jennifer Kormos (IDC) and Ken Bowers (FIFM). Be sure to look at model bill language. Make recommendations to the appropriate committees.

Minutes IDC September 16, 2022

The Committee met virtually with over 150 attendees. Committee member roll call on Google Doc was Displayed. A quorum was present with 20 out of 26 voting members present including Erin Bubb, Richard Ten Eyck, Laura Scott, Charlotte Conway (FDA), Ken Bowers, Eric Brady, Stan Cook, Dave Dressler, Maggie Faba, Ashlee-Rose Ferguson, Jacob Fleig, George Ferguson, Ali Kashani, Alan Keller, Dan King, Mark LeBlanc, Tom Phillips, Nathan Price, Cory Skier, David Snell,

Absent: James Embry, Falina Hutchinson, Darrell Johnson, Dave Phillips, Kimberly Truett, Kelli Younker, Jennifer Kormos CAN(no vote), Shannon Jordre (FDA)(no vote), Ashley Shaw (FDA) (no Vote),

Erin Bubb, Co-Chair opened the meeting about 11:35 EST and conducted meeting.

OP Content

- Approve August minutes. Stan Cook moved to accept the displayed August 8/4/22 IDC meeting minutes. Richard Ten Eyck seconded. – No corrections were offered. Motion Passed unanimously.
- 2) Gluten Feed Term. Ali Kashani moved to revise the feed term "gluten" and publish in the OP, Ken Bowers seconds. Discussion was held to refine the language. The committee finally arrived at: "Gluten. (part) The tough, viscid, and complex mixture of proteins remaining when the flour of wheat, rye, barley, or their crossbred hybrids, and derivatives thereof, is washed to remove the starch." Motion Passed unanimously.
- 3) "Finished Feed" Term (10) Ali Kashani (discuss in January)



EXPERT COLLABORATION. UNIFIED STANDARDS. — Final 10/26/2022 version 2
 4) Barley Protein Concentrate to Official. T12.8 Dan King moves, Stan cook Seconds "T12.8 Barley Protein Concentrate is the dried protein fraction of barley prepared by enzymatic hydrolysis of starch, beta glucans, and fiber. The ingredient is prepared from barley that is dehulled or of a hulless variety. It must not contain less than 60% crude protein on a dry matter basis. The finished ingredient should not contain more than 10% moisture. It is to be used in the feed of fish as a source of protein. (Proposed 2022 rev. 1)"

5) Add to table 101.1 AGRN 42 Charlotte Conway moves to add AGRN 42 to Table 101.1. Ken Bowers Seconds. Committee had no questions.

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)
42 <u>Part 1</u> (PDF - 307 pages) <u>Part 2</u> (PDF - 307 pages)	Native Microbials, Inc.	ASCUSDY19	<mark>Butyrivibrio</mark>	Utility information not evaluated for GRAS, see FDA's letter for more information	Dairy cattle	2/12/21	FDA has no questions. (PDF - 3 pages)

Communication with investigator and CVM while editing minutes: "In GRAS notice 42, which was recently passed through the AAFCO Ingredient Definitions Committee, we had the first viable microbe for animal food that received a 'no questions' letter from us. In looking deeper into the common or usual name for this one and much discussion here at CVM, we think the common or usual name should be "Dried Butyrivibrio fibrisolvens Fermentation Product" to follow the naming convention for the Direct-Fed Microbials listed in the OP. A product label would have viable microbe guarantees which would indicate that this is a viable product. We are also pretty sure the firm would want to put on the label that this is viable." Motion passes unanimously.

6) CVM placeholder #1 30.01 Fumonisin Esterase (to add poultry) Richard Ten Eyck moves to Publish as a replacement for the 30.01 IDC passed in August. Stan Cook Seconded. Definition to come into the OP as official (Food Additive Regulation). Motion passes unanimously.

"30.01 Fumonisin esterase



The food additive fumonisin esterase may be safely used to degrade fumonisins in swine feed in accordance with the following prescribed conditions:

(a) Fumonisin esterase, a carboxylesterase, is produced by a nontoxigenic and nonpathogenic yeast, Komagataella phaffii, genetically engineered to express the fumonisin esterase gene from the bacterium Sphingopyxis sp. The 493 amino acid fumonisin esterase enzyme acts to produce hydrolyzed fumonisin and two tricarballylic acid molecules. Hydrolyzed fumonisin and two tricarballylic acid molecules are the reaction products of fumonisin hydrolysis by this 493 amino acid fumonisin esterase enzyme.

(b) The additive shall meet the following specifications:

(1) The fermentation media for the Komagataella phaffii shall not contain methanol.

(2) Viable genetically engineered Komagataella phaffii shall not be present.
(3) One unit of fumonisin esterase activity is defined as the amount of enzymatic activity required to release one micromole of tricarballylic acid (CAS 99-14-9) per minute from 100 micromolar fumonisin B1 in 20 millimolar Tris-hydrochloride buffer (pH 8.0) containing 0.1 milligram per milliliter of bovine serum albumin at 30 °C.

(c) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete swine feed that cannot contain more than 10 parts per million of total fumonisins.

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

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the common or usual name of the additive's source, dried Komagataella phaffii fermentation product.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) Adequate directions for use including a statement that the additive must be uniformly applied and thoroughly mixed into complete feeds;

(ii) A guarantee for the minimum amount of fumonisin esterase activity, expressed in accordance with paragraph (b)(3) of this section, and the unit of weight being consistent with the inclusion rate stated in the directions for use;

(iii) Appropriate warning and safety precaution statements concerning the additive as a respiratory sensitizer;

(iv) A cautionary statement concerning the maximum fumonisin content as established in paragraph (c) of this section.

21 CFR 573.485 (Proposed XXXX)



- 7) CVM placeholder #2 (10) no topic was advanced.
- 8) Swine Health Protection Act guidance for animal feed ingredients Swine Health work group update - Erin Bubb

a) Charge for Swine Health work group:

Examine the chapter 6 sections to determine if Swine Health Protection Act should be referenced and if so, develop the appropriate language to include in those section headers.

WG consists of George Ferguson, Shannon Jordre, Tom Phillips, Erin Bubb, Kristi Smedley, Leah Wilkinson, Dave Meeker, James Emerson.

Erin Bubb gave a brief summary of the workgroup activity and conclusions.

Laura moved to accept the workgroup report. Ken Bowers seconds. There were no questions from the committee. Motion Approved *workgroup report is attached as appendix C.*

- 9) Erin Bubb Moved to publish the guideline language in the headers of sections forty and sixty of the OP (page 411 and page 440). Laura seconds.
- Guidance language: "** This ingredient may contain materials that fit the Swine Health Protection Act's definition of "garbage" (e.g. meat resulting from food waste streams). If the product is intended for the feeding of swine or used in the manufacture of an ingredient intended for swine, manufacturers using these ingredients should adhere to the provisions of the Swine Health Protection Act where appropriate. (9 CFR Part 166- Swine Health Protection Act)"
- 10) Erin Bubb Moved to Mark these ingredients with a "**" to indicate a need

to follow the swine health act: 40.96 Food Processing Waste, 40.97 Restaurant Food Waste, 60.108 Salvage Pet Food, and 60.117 Dried Black Soldier Fly Larvae. Ali Kashani seconded the motion. The committee had questions on BSFL inclusion. The larvae are grown on food waste that <u>might</u> contain meat. Other ingredients may be added later to this designation. Workgroup remains in place.

Motion passes unanimously.



ODI Maintenance

Marine Products ODI placeholder Michael (5 min) no topic was advanced.

Informational Updates

- 11) Animal Protein Discussion -- Stan Cook: Workgroup has submitted an amendment to MBM definition to CVM. They are also trying to develop a definition to cover multispecies MBM and some other topics. Save time on the January agenda.
- 12) Sunsetting workgroup report Ken Bowers: Workgroup report on sunsetting (withdrawing) procedures for common or usual names in the OP. – (need a new lead) The scope of this workgroup will be expanded to include how to change a common or usual name. Workgroup members currently include Leah Wilkinson AFIA, PFI, Kristi Smedley, Jean Hofve, NGFA Dave Fairfield, US Poultry James Emmerson, Ken Bowers, Dave Edwards and Maggie Faba. – Workgroup has posted a report in the feed BIN on 8/31/22. Put consideration on the January agenda. Charlotte Conway is the new workgroup lead. Stan Cook moved to accept the workgroup report. Maggie Faba seconded. sunsetting report is in appendix D
- *13)* Ingredient submission modules Meagan Davis. *The modules are being loaded into the LMS system. Coming soon is announcements on pricing and how to enroll.*
- 14) ISW (Ingredient Submission Workshop) in Tx progress report --Meagan Davis . Workshop date and pricing are still being set. (1/16/23 1:30 – 5:30 CST) . Meagan recapped planned content. Looking for investigators to help present.
- 15) Hemp update Charlotte Conway included <u>National</u> Discussion and OSU conference announcement. Webinar went well and was well attended with over 1000 attendees registered. Call generated several new conversations. Charlotte Conway and Austin Therrell plan to attend the <u>OSU conference</u> on hemp in feed 10/26-27/2022.



- 16) CVM discussion of request tracking (placeholder) -- Charlotte Conway Working to address the transparency of ingredients under review. Public meeting for all stakeholders is being planned for early 2023. A public listening session on <u>claims on animal food</u> is scheduled for October 18, 2022.
- 17) Review parking lot Richard Ten Eyck See notes below.
- 18) ABO presentation (0) Rebecca White ABO push to January
- 19) Training Proposals Richard Ten Eyck
 - a) *From ETC* training on feed ingredients is desired, topics: new by-products, additives (CFR regulations, selenium), Refuse regulations
 - Work group charge: Working with ETC, industry SME's and an educational designer develop online Educational modules on byproduct ingredients role in sustainability.
 - ii) Learning Objectives
 - (1) Become familiar with the benefits of the particular products
 - (2) Become familiar with the hazards needing to mitigate in producing the ingredient
 - (3) Become familiar with the appropriate labeling of the ingredient
 - iii) Budget and Benchmarks:
 - (1) Multi year? Placeholder on 2022-23 budget needs request filled out
 - iv) Ingredients to start on:

Feed ingredients encouraging sustainability (6 modules) (prioritize?)

- Rendering (Beef, Pork, Poultry, Broth)
- Oil Seeds (Soybeans, Hemp, Canola, Camelina)
- Packaged Food Reclamation (Bakery, Grocery Warehouse)
- Food Processing Reclamation (Vegetable, Animal)
- Insect Farming (BSFL, Cricket)
- Algae for food and Feed (micro, Macro)



Erin Bubb led a discussion on what AAFCO leadership desired on the topic. Surveys had indicated a desire to have more training on ingredients. The Committee weighed on in on their perspective. At the end of the discussion the committee desires were voiced as to provide a platform for educational talks provided by an ingredient industry at each face to face committee meeting. Algae will be on the schedule for January.

One trade association indicated there is a value chain behind the sustainability topic. Some of this may be business confidential business information (competitive advantage).

20) Adjourn 1:50PM ish EST

Minutes approved 11/02/2022 16 in favor, 0 opposed

Members not voting: Laura Scott, Eric Brady, Charlotte Conway (FDA), Maggie Faba, George Ferguson, Alan Keller, Dan King, Mark LeBlanc, Cory Skier, David Snell, Falina Hutchinson, Dave Phillips, Kelli Younker

Announcements

- A. Next Meetings: Midyear, January 18?, 2023 TX Possible webinar with no votes on 11/18/22.
- B. New Investigators: (needed)
 - a. Technical additives
 - b. Special Purpose
 - c. Amino Acids
 - d. Enzymes
 - e. Marine Products



- C. **Stale Ingredients:** The following are being removed from consideration as definition requests. Please submit a new request if still desired.
 - a. -none-
- D. Parking Lot topics:
 - a. Facilitate a round table discussion on the use of hemp in animal food. Webinar in August resolved this.
 - *b.* ICG workgroup report not met since June 2021 *OK to leave in Neutral*
 - c. NANP Subcommittee report -have not met -Ashley Shaw /Casey/Al -- Still waiting on NRC staff
 - d. **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. *Review in January*
 - e. Pursue formal MSBC Definition. Nothing in motion.
 - f. New feed term Total Ration. Ali
 - g. New feed term Freeze-Dried. -Ali
 - h. Establish a feed term for "Finished Feed" Ali has workgroup
 - Fluorine levels in model bill. 975.08 AOAC method for flourine (need details) Laura Scott gave an update. 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 Floride in the feed law? (Stan) IDC should look at mineral definitions that have fluorine specifications. May also be in CFR definitions. 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 flouride.
 - *j.* Particular processed/pomace vs common foods -Stan and Pat Tovey. Looking for agenda time to present industry questions on



feed term interpretations. January IDC will have a discussion on how to properly use feed terms. Industry desires a talk on Pomace at a future IDC meeting, include Ali Kashani and Dave Dressler.

- k. Use of definition request tracking sheet CVM (15 min)
- *I.* Presentation on Algae use in feed ABO, Rebecca White *Doing in January*

ODI Maintenance

- 21) ODI Subcommittee report Jacob Fleig Reported Richard and Jacob have been working on the process of building an excel file of ODI changes.
- 22) ODI procedures Jacob Fleig Report: The procedures are in the BIN and are ready for the investigators to pilot. Jacob moved to conduct a training with investigators on this draft ODI procedure. George Ferguson seconded. Discussion was held on the process flow for adding or deleting references. Motion passed unanimously. *Chair will schedule the training*.

Appendix A of IDC 9/16/22 minutes:

30.01 Fumonisin esterase

The food additive fumonisin esterase may be safely used to degrade fumonisins in swine **and poultry** feed in accordance with the following prescribed conditions:

(a) Fumonisin esterase, a carboxylesterase, is produced by a nontoxigenic and nonpathogenic yeast, Komagataella phaffii, genetically engineered to express the fumonisin esterase gene from the bacterium Sphingopyxis sp. The 493 amino acid fumonisin esterase enzyme acts to produce hydrolyzed fumonisin and two tricarballylic acid molecules. Hydrolyzed fumonisin and two tricarballylic acid molecules are the reaction products of fumonisin hydrolysis by this 493 amino acid fumonisin esterase enzyme.

(b) The additive shall meet the following specifications:

(1) The fermentation media for the Komagataella phaffii shall not contain methanol.



(2) Viable genetically engineered Komagataella phaffii shall not be present.
(3) One unit of fumonisin esterase activity is defined as the amount of enzymatic activity required to release one micromole of tricarballylic acid (CAS 99-14-9) per minute from 100 micromolar fumonisin B1 in 20 millimolar Trishydrochloride buffer (pH 8.0) containing 0.1 milligram per milliliter of bovine serum albumin at 30 °C.

(c) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete-swine feed:

(1) Complete swine feeds cannot contain more than 10 parts per million of total fumonisins.

(2) Complete feed for poultry being raised for slaughter cannot contain more than 50 parts per million of total fumonisins.

(3) Complete feed for breeding poultry and hens laying eggs for human consumption cannot contain more than 15 parts per million of total fumonisins
(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the common or usual name of the additive's source, dried Komagataella phaffii fermentation product.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) Adequate directions for use including a statement that the additive must be uniformly applied and thoroughly mixed into complete feeds;

(ii) A guarantee for the minimum amount of fumonisin esterase activity, expressed in accordance with paragraph (b)(3) of this section, and the unit of weight being consistent with the inclusion rate stated in the directions for use;

(iii) Appropriate warning and safety precaution statements concerning the additive as a respiratory sensitizer;

(iv) A cautionary statement concerning the maximum fumonisin content as established in paragraph (c) of this section.

21 CFR 573.485 (Proposed XXXX, Amended XXXX)

Add to table 101.1:



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AGRN (select for detailed record)	Notifier	Su	bstance	Common or Usual Name	Intended Use	Intend Specie		Date of Filing	FDA's Letter (select to view letter)
42 <u>Part 1</u> (PDF - 307 pages) <u>Part 2</u> (PDF - 307 pages)	Native Microbials, Inc.	fib	risolvens CUSDY19	Dried Butyrivibrio fibrisolvens Fermentation Product	Utility information not evaluated for GRAS, see FDA's letter for more information	Dairy ca	ıttle	2/12/21	FDA has no questions. (PDF - 3 pages)
AGRN (select for detailed record)	Notifie	r	Substance	Common or Usual Name		Intended Species		ate of iling	FDA's Letter (select to view letter)

Attachment B ODI Updates 9/16/22 (none)

IDC Meeting Date:	9/16/22						
	ODI Summary of Changes for OP						
Action	Ingredient Name	Reference	Comments (meeting)				
None	None	None	None				

Attachment C :Swine Health workgroup report to IDC 9/16/22

Food Waste Used in the Production of Animal Food Food waste directed to the production of animal food:

• Must meet the most current requirements of the U.S. Department of Agriculture's (USDA) **Swine Health Protection Act**. The Swine Health Protection Act



(SHPA) regulates food waste containing any meat or meat by-products fed to swine. Under this Act, the food waste containing the animal material is known as *garbage. Compliance with this act ensures that all food waste fed to swine is properly treated to kill disease organisms.

Garbage- as defined by the SHPA:

- "All waste material derived in whole or in part from the meat of any animal (including fish and poultry) or other animal material, and other refuse of any character whatsoever that has been associated with any such material, resulting from the handling, preparation, cooking or consumption of food, except that such term shall not include waste from ordinary household operations which is fed directly to swine on the same premises where such household is located" (per SHPA)
- Garbage definition is not necessarily intended to capture all animal products, (e.g., dairy). SHPA is intended to prevent diseases in swine through the consumption of untreated meat or meat by-products, from <u>food waste</u> streams.

IDC Work Group recommendation:

- Create a new guidance in the preambles for section 40, Human Food By-Products and section 60, Miscellaneous Products (these are the two sections that food waste materials containing meat or are comingled with food waste containing meat are likely to be listed)
- Guidance language: "** This ingredient may contain materials that fit the Swine Health Protection Act's definition of "garbage" (i.e., meat resulting from food waste streams). If the product is intended for the feeding of swine or used in the manufacture of an ingredient intended for swine, manufacturers using these ingredients should adhere to the provisions of the Swine Health Protection Act where appropriate. (9 CFR Part 166- Swine Health Protection Act)"
- Does not exclude the ingredient from being fed to swine, but it must be treated (i.e. cooked) before feeding to swine.
- A decision tree (attachment A) can be used by the IDC, AAFCO investigator, etc. to help determine if a feed ingredient should be designated with a symbol to reference the guidance in the preamble of that section.



Attachment D :Sunsetting workgroup report to IDC 9/16/22 (accepted by IDC no action taken)

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 sunsetted 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.