Ingredient Definitions Committee Report
2022 AAFCO Annual Meeting
August 4, 2022 3:30PM – 5:00PM Central

Recommendations to the Board and Association membership:

Common Food Language is in appendix A. OP text is presented in appendix B .

1) Publish the CFI procedures in the OP at page 338.
2) Publish the CFI worksheet on the AAFCO website (set up new portal).
3) Replace the existing CFI policy on OP page 337 with the one in attachment A.
4) Publish a New Official Definition **30.01 Fumonisin Esterase.**
5) Publish an amended **33.16 Methyl Esters of Conjugated Linoleic Acid** to reflect the CFR amendment.
6) Publish a New tentative definition for **T36.11(a)**, to add *Lentilactobacillus hilgardii*
7) Publish as **T42.25 Grain Sorghum Protein Feed.** Remove "Grain Sorghum Gluten feed " in the 2025 Official Publication.
8) Publish as **T42.35 Grain Sorghum Protein Meal.** Remove "Grain Sorghum Gluten meal " in the 2025 Official Publication.
9) Publish an editorial change to **48.18 Hydrolyzed Corn Protein**, ~~Gluten~~ **Protein** *language is in appendix B*
10) Publish as **T48.135 Corn Protein Feed**. Remove "corn Gluten feed " in the 2025 Official Publication.
11) Publish a new tentative definition **T48.145 Corn Protein Meal.** The intention is to remove 48.14 Corn Gluten Meal from industry use by 2025.
12) Publish a New tentative definition for **T71.41 Low Glucosinolate High Erucic Acid Rapeseed Meal, Mechanically Extracted****
13) Publish a new tentative definition for T**73.200 Xanthan Gum** in section 73, Technical Additives, in the AAFCO Official Publication to allow its use as a suspending agent in plant inoculant products.
14) Publish an Addition to table 101.1 AGRN44 **Endo-1.4-Beta xylanase enzyme**
15) Publish an Addition to table 101 AGRN 48 **Dried L-Valine Fermentation**

16) Make the following changes in ODI: (tentative ingredients do not go into ODI) **

IDC Meeting Date: 8/4/22

ODI Summary of Changes for OP

Action	Ingredient Name	Reference	Comments (meeting)
New Name and reference	Fumonisin Esterase		Business meeting xx/xx/xxx
New Name and reference	Endo-1,4-β-xylanase enzyme		Business meeting xx/xx/xxx
New Name and reference	Dried L-Valine Fermentation Product		Business meeting xx/xx/xxx

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 October 2022

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: -none-

Minutes IDC August 4, 2022

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 22 out of 26 voting members present including Richard Ten Eyck, Laura Scott, Austin Therrell, Charlotte Conway (FDA), Ken Bowers, Erin Bubb, Stan Cook, Dave Dressler, James Embry, Maggie Faba, Ashlee-Rose Ferguson, Jacob Fleig, George Ferguson, Falina Hutchinson, Darrell Johnson, Ali Kashani, Alan Keller, Dan King, Dave Phillips, Tom Phillips, Nathan Price, David Snell, Ashley Shaw (FDA) (no Vote),

Absent: Mark LeBlanc, Cory Skier, Kimberly Truett, Kelli Younker, Jennifer Kormos CAN(no vote), Shannon Jordre (FDA)(no vote),

Regulators were asked if anyone would like to join the committee.
There were some minor edits

OP Content

1) Common Food Index Procedures – Erin Bubb The CFI index procedures were displayed. Bubb moved to publish the common food index procedures (displayed) in chapter 5 of the OP next to the CFI guidelines. George seconds. PFI asked what happens if a substance is rejected from the index. Bubb responded that a rejection only indicates the substance does not meet the definition of common food. The subcommittee would include a recommendation of how the substance should pursue recognition. Motion passed with no objections or abstentions.
2) Bubb moved to the displayed worksheet to be published on the AAFCO.org website after membership acceptance of the procedures. George Ferguson seconded. Motion passed unanimously.
3) Bubb moved replace the current policy guidelines with the ones displayed on the screen. George seconds. Motion passes unanimously.

4) 48.14 Corn Gluten Meal new tentative definition– Dan King moved to Publish a new tentative definition T48.145 Corn Protein Meal. Remove “corn Gluten meal “ in the 2025 Official Publication. Jacob Fleig seconded, In 2025 48.14 Corn Gluten Meal would also be removed from the OP. Industry was supportive of the changes. “name amended 2023” Need to also edit collective terms and label examples and labeling guides after this goes official. Give task to Dan King and FASS.

Definition Number: 42.145 **Name:** Corn Protein Meal

(Text/Description - attach additional page if necessary)

T48.145 Corn Protein Meal is the dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in the wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm. It may contain fermented corn extractives and/or corn germ meal. Originally called corn gluten meal (adopted 1936, amended xx, name amended 2023). Remove "48.14 Corn Gluten meal " in the 2025 Official Publication.

The ingredient 'Corn Gluten Meal' does not contain gluten and the investigator recommends defining the ingredient using the term 'protein' in lieu of 'gluten'.

5)

6) 48.18 Hydrolyzed Corn Protein - editorial change to terminology. ~~Gluten~~ **Protein** (5 min) Dan King tom Phillips seconds

Action:

- ☐ **New Tentative Definition**
- ☐ **Tentative Definition to be made Official**
- X **Editorial Change**
- ☐ **Delete Official Definition**
- ☐ **Other:** _____

Definition Number: 48.18 **Name:** Hydrolyzed Corn Protein

(Text/Description - attach additional page if necessary)

Hydrolyzed Corn Protein is the product resulting from complete hydrolysis of isolated corn ~~gluten~~ protein, and after partial removal of the glutamic acid. (Adopted 1956)

7)

8) 48.13 Corn Gluten Feed new tentative definition - Dan King (5 min) Publish as T48.135 Corn Protein Feed. Remove "corn Gluten feed " in the 2025 Official Publication. Dan moved, Jacob seconds. Industry indicated that trade agreements need to modified to accommodate this change. They are supportive of the name change but may need more time to implement it. Motion passed unanimously.

9) 42.2 Grain Sorghum Gluten Feed new tentative definition - Dan King (5 min) Publish as T42.25 *Grain Sorghum Protein Feed*. Remove "Grain Sorghum Gluten feed " in the 2025 Official Publication.
Dan moved, Jacob seconds
Sorghum producers industry is supportive of the change. Motion passes unanimously

Definition Number: 42.25 **Name: Grain Sorghum Protein Feed**

(Text/Description - attach additional page if necessary)

T42.25 Grain Sorghum Gluten Feed(Grain Sorghum Protein Feed) is that part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, by the processes employed in the wet milling manufacture of starch or syrup. Originally called Grain Sorghum Gluten Feed (adopted 19XX, amended xx, amended 2023). Remove "Grain Sorghum Gluten Feed" in the 2025 Official Publication. (Adopted 19XX, Amended 19XX)

10) 42.3 Grain Sorghum Gluten Meal new tentative definition - Dan King (5 min) Publish as **T42.35 Grain Sorghum Protein Meal.** Remove "Grain Sorghum Gluten meal " in the 2025 Official Publication. Dan Moves, Jacobs seconds. Motion passes unanimously

11) 33.16 Publish an edit of the 33.16 Official Definition (CFR 573.637 MECLA) for Methyl Esters of Conjugated Linoleic Acid – Bernadette Mundo moves to Publish an amended **33.16 Methyl Esters of Conjugated Linoleic Acid** to reflect the CFR amendment. Seconded by Erin Bubb Item should go through Board and membership. Motion passed unanimously.

12) Publish a New tentative definition for T36.11(a), to add *Lentilactobacillus hilgardii -(10 min) Maggie* Faba moves, George Ferguson Seconds Motion passes unanimously https://aafco.mocaworks.com/viewer/?eID=2071444

13) Publish a new tentative definition for T**73.200 Xanthan Gum** in section 73, Technical Additives, in the AAFCO Official Publication to allow its use as a suspending agent in plant inoculant products. T73.200 Erin Bubb Moves, George Ferguson Seconds . Current definition to remain in place. Motion passes unanimously Richard Ten Eyck

14) CVM Placeholder #1 for FAP if Published. Publish a New Official Definition **30.01 Fumonisin Esterase -** George Ferguson moves, Stan Seconds. Motion passes unanimously

15) CVM Placeholder #2 (10 min) Publish a New tentative definition for **T71.41 Low Glucosinolate High Erucic Acid Rapeseed Meal, Mechanically Extracted**** (Falina moves, Erin Bubb seconds. The micromoles units was discussed. It is used in other definitions. Motion passes unanimously.

16) Nathan Price moved to Add to table 101.1 AGRN44 Endo-1.4-Beta xylanase enzyme George Ferguson Seconded. Motion passes unanimously.

17) Nathan Price moved to Add to table 101 AGRN 48 Dried L-Valine Fermentation Product George Ferguson seconded. Motion passes unanimously.

ODI Maintenance

18) ODI Subcommittee report – Jacob Fleig Reported Richard and Jacob have been working on the process of building an excel file of ODI changes.

19) 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.*

20) Marine Products ODI placeholder Michael Blume (5 min) (not addressed)

Informational Updates

21) 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.

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

    Erin Bubb reported the work group has met 4 times and determined there are ingredients that need to follow the Federal Swine Health Protection Act prior to being fed to swine. Sections 40 and 60 should be looked at first. The workgroup has some model guidelines for the committee to review at the next IDC meeting.

22) 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. – New lead needed *Ken Bowers reported that the group has not met. There is policy information drafted in the BIN. Hanging questions include where this gets published and how does this impact direct fed microbials.*

    Add to the existing policy:

    When the revision includes the modification or change in the ingredient name, the old name should be "sunsetted" which provides time for the old name to expire and the transition to use of the new name. The 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 anything that needs to be deleted in their annual review. The date should typically be 2-3 years unless some situation warrants a longer sunset period.

23) Human Grade feed term edits accepted by IDC in January 2021 are being held until the human grade guidelines are passed out of model bill committee. *The feed term was accepted by membership this morning and will be in the 2023 OP.*

24) Animal Products Section updates, collagen etc. (15 min) Stan Cook Not dealt with today, schedule

25) Update on the ingredient submission workshop modules – *Nathan Price reported that final narration was sent to instructional design on Tuesday. Modules should be in the LMS by the end of August. Looking for volunteers for the workshop in January 2023. AFIA ,Kristy Smedley and CVM volunteered. Erin Bubb is the point of contact for IDC.*

26) Hemp Update – Falina Hutchinson, MT Webinar scheduled: Hemp as a Feed Ingredient; A National Discussion 8/9/22 Noon Eastern
    Falina Hutchinson Reported Hemp seed meal was submitted to FDA in January 2021 for review as a definition. FDA asked the the submitter questions. Hemp Seed Coalition answered. FDA recently asked additional questions.

Erin Bubb reported that over 800 people have registered for the National Discussion on Hemp.
Hemp Seed Coalition representative indicated frustration on the timelines for FDA review and the depth of questions. They desire clear guidelines from FDA to reduce the back and forth. Falina is aware of the conversations. Chair verified that communications channels are open between the investigator, CVM and the firm.
No one is working on defining Hemp Oil for animal food.

27) Training Proposals (10 min) - Richard Ten Eyck *(not addressed this meeting)*
   a) ***From ETC*** training on feed ingredients is desired, topics: new by-products, additives (CFR regulations, selenium), Refuse regulations
      i) Work group charge: Working with ETC, industry SME's and an educational designer develop online Educational modules on by-product ingredients role in sustainability. Lead: ___ ETC_____ group:

      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)

28) Adjourn 5:10pm CST

Minutes approved 9/16/22 by voice vote on zoom meeting.

Announcements

A. Next Meetings: Online, September 16, 2022

B. New Investigators:
   a. Feed Terms – Ali Kashani

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.~~
   b. ICG workgroup report – not met since June 2021 -

c. NANP Subcommittee report –have not met -Ashley Shaw /Casey/Al
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.*
e. Pursue formal MSBC Definition.
f. New feed term Total Ration.
g. New feed term Freeze-Dried.
h. Establish a feed term for "Finished Feed"
i. Fluorine levels in model bill 975.08 AOAC method (need details)
~~j. Clean up Chapter 5 CFI guidelines~~
k. Particular processed/pomace vs common foods -TBD
l. Use of definition request tracking sheet – CVM (15 min)
m. Presentation on Algae use in feed – ABO, Rebecca White

Appendix A:

Common Food Index Guidelines & Questions were accepted by IDC 8/4/22.

AAFCO COMMON FOOD INDEX PROCEDURES

Introduction

The Common Food Index Subcommittee was established by the AAFCO Ingredient Definitions Committee (IDC) as the body to facilitate the addition of new items to the Common Food Index (CFI). Members of the CFI Subcommittee are appointed by the Chair of the Ingredient Definition Committee. The number of members, identification of the subcommittee chair, and terms of service are at the discretion of the IDC Chair. The IDC Chair should consider the volume of work and availability of the volunteers when making these appointments. This document will describe how items are added to the CFI. All the items in the CFI must meet the AAFCO Feed Term "Common Food" as found in the AAFCO Official Publication. The CFI will reside on the AAFCO.org website and within the AAFCO Online Database of Ingredients (ODI).

Procedures

I. Suggesting additions to CFI – Initiating the process
   a. A suggestion may be made by any stakeholder (consumer, regulator, CFI Subcommittee, industry representative, etc.)
   b. A suggestion is made by completing the CFI Worksheet found on AAFCO.org
   c. More information may be requested by CFI subcommittee if needed/helpful to confirm that the suggestion meets the criteria in the AAFCO feed term "Common Food"

II. Reviewing the suggestions received
   a. The CFI Subcommittee Coordinator (with the assistance of the CFI Subcommittee) will review the submission. The Subcommittee will notify the submitter if the item will be posted for public review or if the item will not be accepted by the subcommittee within 30 days of the submission.
   b. The responses to the questions on the worksheet broadly establish a profile for the suggested item. The profile must fit the criteria set in the AAFCO Feed Term "Common Food"
   c. Review of the submissions will be conducted as they are received. Suggestions that meet the AAFCO feed term "Common Food" will go for public comment in monthly intervals

d. Suggestions that do not meet the AAFCO feed term “Common Food” will also be included in the CFI Subcommittee report to IDC with explanation on criteria not met.

III. Public Comment Period
   a. Pending additions to the CFI are posted monthly on AAFCO.org and in the Feed Bin with submission of comments to a portal.
   b. A notice targeting animal nutritionists (ARPAS), veterinarian toxicologists (ABVT), veterinarians, FDA-CVM, USDA, consumer groups, and general public is issued. The notice should encourage animal scientists to share their professional opinion including support of/disagreement with inclusion into the CFI.
   c. Duration: Although comments on the safety of items listed in the Common Food Index are always accepted, comments received within 30 days of posting will be evaluated by the subcommittee.
   d. The CFI Subcommittee should screen the comments as they are received to avoid a backlog
   e. Public comments are reviewed as to the product’s risk, utility, and appropriateness for that item’s inclusion in the CFI by the CFI Subcommittee

IV. Reporting to Ingredient Definition Committee
   a. Suggestions that pass though the public comment period without issue will be listed in the CFI Subcommittee report to IDC
   b. Suggestions that do not pass the screening process will also be reported to IDC along with summarized comments to explain what criteria were not met
   c. CFI Subcommittee shall submit their report at least 30 days prior to the next IDC meeting

V. Acceptance of common foods into the CFI
   a. The IDC will vote to accept the CFI Subcommittee report
   b. The IDC can discuss the CFI Subcommittee’s findings
   c. IDC has the prerogative to amend the findings
   d. In a separate vote, IDC shall vote whether to accept the recommendations for indexing with or without modifications
   e. Upon acceptance of the IDC meeting minutes by the AAFCO Board of Directors, the new common foods will be added to the CFI.
   f. New additions will be noted in the ODI Change Table found in the AAFCO Official Publication biannually.

VI. Removal of indexed items from the CFI
   a. CFI Subcommittee receives new information that raises a safety or other concern.
   b. The CFI Subcommittee immediately alerts the IDC chair of the new information and may recommend the removal of the indexed item from the CFI.
   c. The IDC chair may elect to remove the item immediately from the CFI in the case of an emergency, or otherwise refer to IDC for vote.
   d. The CFI Subcommittee recommendation to IDC chair will be reported to the IDC.
   e. The IDC shall acknowledge the removal at its next meeting by accepting the CFI Subcommittee report. The IDC has the prerogative to override the removal.

f. Items removed from the CFI shall be posted on the “Withdrawn from CFI” list in the IDC library in the Feed BIN.

VII. Appeal Process

a. Any stakeholder may appeal an IDC decision regarding CFI listings by providing further information for the subcommittee to evaluate.
b. Actions subject to appeal
    i. Subcommittee decision to not accept for public review
    ii. IDC decision to accept or not to accept an item for inclusion in the CFI
    iii. IDC decision to remove an item from the CFI
c. An appeal can be submitted by emailing aafco@aafco.org
d. While there is no deadline to file an appeal, it is preferred that one is filed as early as possible after the IDC vote on the item in question to avoid unnecessary or duplicative work.
e. The appeal will be discussed by the CFI Subcommittee. The subcommittee’s recommendation shall be included in the next CFI Subcommittee report to the IDC.
f. The IDC’s vote on the appeal is final.

AAFCO Common Food Index (CFI) Worksheet
Version 8/4/22
Status: accepted by IDC

Common foods (AAFCO Feed Term)- 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 whether a common food is safe and has utility for its intended use prior to commercial distribution as animal food.

To submit an ingredient to be added to the AAFCO Common Foods Index, please complete the following worksheet. The worksheet will help the Common Food Index Subcommittee determine if the ingredient meets the qualifications of a Common Food as described in the AAFCO feed term.

The worksheet has YES and NO responses denoted in Green or Red to help guide the submitter if the suggested item meets the definition of "common food." Green responses may indicate that the suggested item complies with the Common Foods feed term. The red responses may indicate that the suggested item **does not** comply with the Common Food feed term. The responses in black provide further information for the CFI Subcommittee

Name:
Affiliation: Regulator, Firm, or Consumer:
Email address:
Name of ingredient:
General description of the ingredient:
Date of submission: (assigned by software)

1. Is the purpose of the item other than providing general nutrition, taste, aroma, or technical effect? **YES** or **NO**
    a. If YES, what is the general purpose?

2. Is this a single item and not a combination of items (mixed)? **YES** or **NO**

3. Is the item defined by AAFCO or otherwise exist in chapter 6 of the AAFCO Official Publication, OR already exists in the CFI/ODI? **YES** or **NO**

4. Does the submitter have adequate safety data and information available for this item? **YES** or **NO**

5. Is the item a refined product or a fraction of a whole ingredient? **YES** or **NO**

6. Is the item a manufactured or synthetic substance? **YES** or **NO**

7. Is the item distributed with a therapeutic health claim? **YES** or **NO**

8. Is the item commercially available in the United States? **YES** or **NO**
    a. If NO, is the item only commercially available in another country? YES or NO
    b. If 3.a. is YES, then which country?

9. Is the item a conventional human food? **YES** or **NO**

10. Is this item a human food supplement under DSHEA? **YES** or **NO**
    (DSHEA- Dietary Supplement Health Education Act)

11. Is the item a by-product of a food manufacturing process? **YES** or **NO**

12. Has the item undergone a manufacturing process (drying, cooking, grinding, fermenting, pureed, etc.)? **YES** or **NO**
    a. If YES, what is the process?

13. Is the item intended for use by ALL animal species? **YES** or **NO**
    b. If NO, why?
    c. Intended for which species?

///////

Replace current guideline at OP page 337 with this language.

Common Food Index Guidelines

Editor Chair of Ingredient Definitions Committee

Version 8/4/22

Purpose:

The Common Food Index (CFI) is a repository of common foods that may be appropriate for use in animal food and are not defined by AAFCO. The CFI is provided as a tool for use during review of ingredients on an animal food label and provides harmonization and transparency. Label reviews will continue to rely on the expertise of the individuals performing the reviews. The acceptance of indexed items in animal food continues to be at the discretion of regulatory agencies.

These common foods must align with the feed term *Common Foods* in the Feed Terms and Definitions within Chapter 6 of the AAFCO *Official Publication.* The CFI is not a substitute for the AAFCO process for new feed ingredient definitions; Chapter 6 of the *Official Publication*, alone, contains the officially recognized feed ingredient definitions.

Subcommittee:

A CFI subcommittee of four (4) AAFCO members will be appointed by the Chair of the Ingredient Definition Committee (IDC).

The subcommittee will investigate the proposed common foods alone or with assistance of experts anytime the subcommittee deems it necessary. Experts are not limited to regulatory officials or academia and may include other stakeholders with relevant knowledge. Experts shall declare any conflicts of interest as a condition of consideration of their participation.

Indexing:

The CFI will be maintained on the AAFCO.org website and the indexed common foods incorporated into the Online Database of Ingredients (ODI) for reference.

Note:

Feed/food manufacturers are still responsible for evaluating and documenting the safety of all ingredients for their intended use prior to distribution.

Appendix B of IDC 8/4/22 minutes:

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)

33.16 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) may be safely used in swine feed **and feed for early lactation dairy cows (less than 100 days-in-milk)** in accordance with the prescribed conditions:
(a) The food additive is manufactured by the reaction of refined sunflower oil with methanol to produce fatty acid methyl esters, which then undergo conjugation to yield methyl esters of octadecadienoic acid. The additive consists of not less than 28 percent methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28 percent methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed 4 percent. The additive shall contain not less than 35 percent of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.
(b) The additive is used or intended for use in the feed of:

(1) growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

(2) early lactation dairy cows to reduce the energy concentration in milk when fed at levels not to exceed 33 grams per cow per day.

(c) The additive meets the following specifications:

(1) Free methyl alcohol not to exceed 0.015%.
(2) Insoluble impurities not to exceed 0.1%.
(3) Moisture not to exceed 0.5%.
(4) Unsaponifiable matter not to exceed 1.0%.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive and any feed premix shall bear the following:

(i) The name of the additive.
(ii) A statement to indicate that methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) must not be added to vitamin or mineral premixes.

(2) The label and labeling of the additive, any feed premix, or complete feed prepared there from shall bear adequate directions for use.

21 CFR 573.637 (Proposed 2009, Adopted 2013, Amended XXXX)

36.11 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 *Lentilactobacillus hilgardii* 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*, *Lentilactobacillus hilgardii,* *Lactobacillus* ~~*bulgaricus*~~*delbrueckii* or *Enterococcus faecium*, or as permitted by FDA.] (Proposed 1976, Adopted 1983, Amended 1997, Amended 1999, Amended 2001, Adopted 2003, Amended 2010, Adopted 2014 rev.1, Amended XXXX)
~~IFN 5-06-154 *Lactobacillus bulgaricus* fermentation product dehydrated~~

T42.25 Grain Sorghum Protein Feed is that part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, by the processes employed in the wet milling manufacture of starch or syrup. Originally called Grain Sorghum Gluten Feed (adopted 19XX, amended xx, amended 2023). Remove “42.2 Grain Sorghum Gluten Feed“ in the 2025 Official Publication.
(Adopted 19XX, Amended 19XX, Name amended 2023)

T42.35 Grain Sorghum Protein Meal is the part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, and the separation of the bran by the processes employed in the wet milling manufacture of starch or syrup Originally called Grain Sorghum Gluten Meal (adopted 19XX, amended xx, amended 2023). Remove “42.3 Grain Sorghum Gluten Meal “ in the 2025 Official Publication. Name amended 2023

48.18 Hydrolyzed Corn Protein is the product resulting from complete hydrolysis of isolated corn ~~gluten~~ **protein**, and after partial removal of the glutamic acid. (Adopted 1956, revised 2023)

T48.135 Corn Protein Feed is that part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, protein, and germ by the processes employed in the

wet milling manufacture of corn starch or syrup. It may or may not contain one or more of the following: fermented corn extractives, corn germ meal. Originally called corn gluten meal (adopted 1936, amended xx, amended 2023). Remove “48.13 Corn Gluten Feed “ in the 2025 Official Publication.
(Adopted 19XX, Amended 19XX, Name amended 2023)

T48.145 Corn Protein Meal is the dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in the wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm. It may contain fermented corn extractives and/or corn germ meal. Originally called corn gluten meal (adopted 1936, amended xx, name amended 2023). Remove “48.14 Corn Gluten meal “ in the 2025 Official Publication.

T71.41 Low Glucosinolate High Erucic Acid Rapeseed Meal, Mechanically Extracted,** is the meal obtained after the removal of most of the oil by mechanical extraction of whole seeds obtained from the genus Brassica [Brassica napus, Brassica rapa, or Brassica juncea] from which the oil shall contain more than 2% erucic acid and the solid component shall contain less than 30 micromoles of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3-butenyl glucosinolate, 2-hydroxy-4-pentenyl glucosinolate, and allyl glucosinolate per gram of air dry, oil free solid. When produced from Brassica juncea it must also contain less than 5 micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a maximum of 6% erucic acid, a maximum of 12% crude fiber, and a maximum of 30 micromoles of glucosinolates per gram. It is used in the diets of animals as a source of protein, not to exceed a 5% inclusion rate.

T**73.200 Xanthan Gum** as per 21 CFR 573.1010 is classified as a food additive as a stabilizer, emulsifier, thickener, suspending agent, or bodying agent in calf milk replacer and liquid feed supplements. Also per informal review processes, it can be used in canned dog and cat foods **and as a suspending agent in plant inoculant products.**
Maximum inclusion levels are 0.1% in calf milk replacers (as fed), and 0.25% in liquid feed supplements and canned dog and cat foods, **and 2% in plant inoculant products**. (Proposed 2013, Adopted 2015 rev. 1, **Amended XXXX**)

Add to table 101.1:

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)
44 (PDF - 424 pages)	BioResource International, Inc.	Xylanase enzyme prepared from Komagataella phaffii expressing the gene encoding xylanase from Orpinomyces sp.	Endo-1,4-β-xylanase enzyme	Utility information not evaluated for GRAS, see FDA’s letter for more information.	Swine and Poultry	2/25/21	FDA has no questions. (PDF - 4 pages)

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)
48 (PDF - 1119 pages)	CJ CheilJedang Corporation	Dried L-Valine Fermentation Product	Dried L-Valine Fermentation Product	To be used as a source of L-Valine in livestock and poultry feed.	Livestock and Poultry	5/14/21	FDA has no questions. (PDF - 4 pages)

Attachment C ODI Updates 8/4/22

IDC Meeting Date: 8/4/22

ODI Summary of Changes for OP

Action	Ingredient Name	Reference	Comments (meeting)
New Name and reference	Fumonisin Esterase		Business meeting xx/xx/xxx
New Name and reference	Endo-1,4-β-xylanase enzyme		Business meeting xx/xx/xxx
New Name and reference	Dried L-Valine Fermentation Product		Business meeting xx/xx/xxx