

# Ingredient Definitions Committee Report

Session 1: January 23, 2024 Chattanooga, TN 2:15 to 3:45 pm Eastern

## **Committee Recommendations:**

1) New OFFICIAL T73.027 Calcium Formate

73.027 The food additive calcium formate may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions: (a) The additive is manufactured by the reaction of butyraldehyde, formaldehyde, calcium hydroxide, and formic acid in water followed by purification and dried to produce a powder consisting of not less than 99.0 percent calcium formate (CAS 544-17-2). The additive meets the following specifications: (1) The additive consists of minimum 30.5 percent calcium and minimum 68.5 percent formate. (2) Trimethylolpropane (TMP) not to exceed 125 parts per million. (b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine or poultry feeds at levels not to exceed 1.2 percent of the complete feed. (c) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination. (d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain: (1) The name of the additive. (2) Adequate directions for use including a statement that calcium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing calcium formate. (3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination. (e) To assure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain: (1) Appropriate warnings and safety precautions concerning calcium formate. (2) Statements identifying calcium formate as a possible severe irritant. (3) Information about emergency aid in case of accidental exposure as follows. (i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations. (ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS). 21 CFR 573.230 (Proposed XXXX)

2) New Tentative Definition T71.5 Hempseed Seed Meal, Mechanically Extracted



T71.5 Hemp Seed Meal, Mechanical Extracted is the product obtained by grinding or milling the cake, which remains after most of the oil is removed from the seeds of Cannabis sativa L. by a mechanical extraction process. The ingredient must be labeled with guarantees for minimum crude protein and maximum crude fat on an as-fed basis. The meal shall contain no more than 20 ppm of total cannabidiol (Total CBD = CBD + (CBDA x 0.877)) and no more than 2 ppm of total tetrahydrocannabinol (Total THC = delta-9-THC + (THCA x 0.877)). It is used in diets of laying hens as a source of protein and fat at an inclusion of no more than 20% of the diet.

#### 3) New Tentative Definition T51.18 Deboned Fish Protein

T51.18 Deboned Fish Protein is the clean, dried, ground tissue of undecomposed and deboned fish cuttings, with mechanical extraction of part of the oil and exclusion of stickwater. It must contain, and be guaranteed for, not less than 75.0% crude protein, not more than 5.5% ash, not more than 1.5% salt, and not more than 10.0% moisture. It is for use in animal feed as a source of protein consistent with good feeding practices. If it bears a name descriptive of its kind, it must correspond thereto.

#### 4) Move to OFFICAL T9.41 Meat and Bone Meal

9.41 Meat and Bone Meal is the rendered product from mammal tissues, including bones, exclusive of any added blood, 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 is a source of protein in animal diets. 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, minimum Phosphorus (P) and minimum and maximum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto.

Note: \*\* Determined by AOAC method listed in the Check Sample Reference for Analytical Variations

#### 5) New Tentative Definition T60.117 Dried Black Soldier Fly Larvae

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



- 6) Add <u>Corn Protein Feed</u> and <u>Corn Protein Meal</u> to 22.5 Processed Grain Products in Collective Terms
- 7) Add AGRN 61 to Table 101.1 Phytase enzyme produced by *Pseudomonas fluorescens* strain BD50104 expressing an altered *appA* 6-phytase gene from *Escherichia coli* strain K12

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)
61	BASF Enzymes LLC	Phytase enzyme produced by Pseudomonas fluorescens strain BD50104 expressing an altered appA 6- phytase gene from Escherichia coli strain K12	Phytase	To increase the availability of phytin-bound phosphorus in swine diets at 500-2,000 U/kg in complete feed	Swine	2/10/23	FDA has no questions. (PDF - 4 pages)

8) Editorial to Table 101.1 AGRN 59 – Porcine Oligosaccharides-peptides complex

FDA changed the published notice under Intended Use. Recommend that table 101.1 be edited to reflect the new language under <u>Intended Use</u>: "Utility information not evaluated for GRAS, see FDA's letter for more information."

Editorial- does not require membership vote.

#### **Board Action**

None

#### **Association Action**

None

#### **MINUTES:**

#### **Committee members present:**

Erin Bubb, Charlotte Conway, Trish Dunn, James Embry, Maggie Faba, Ashlee-Rose Ferguson, KC Gutenberger, Justin Hill, Dave Husner, Falina Hutchinson, Shannon Jordre, Ali Kashani, Alan Keller, Dan



King, Ken Kitade, Jennifer Kormos, Marissa Kost, Mark LeBlanc, Bernadette Mundo, Jo Lynn Otero, Nathan Price, Laura Scott, Ashley Shaw, Katie Simpson, Cory Skier, David Snell, Richard Ten Eyck, Kimberly Truett, Ely Walker, Bailey Whiten, Robert Tolton, Stan Cook

#### **Advisors present:**

Cathy Alinovi, Hunter Buffington, Janet Campbell, David Fairfield, Patrick Fulling, Emily Helmes, Jillian Nash, Kristi Smedley, Renee Streeter, Katie Vassalli, Leah Wilkinson, Aaron Hobbs, Amy Tryon DaPrato, Bill Bookout, Charles Starkey, Jean Hofve, Dave Dzanis

- T73.027 Calcium Formate David Snell
   David Snell moves to accept. Mark LeBlanc seconds. Motion passes.
- 2) T71.5 Hempseed Seed Meal, Mechanically Extracted Falina Hutchinson Falina Hutchinson moves to accept. Ali Kashani seconds. Motion passes. Idaho abstains from voting.

Discussion: Hunter Buffington stated that 2ppm was below the 10ppm that had previously been accepted by the FDA in its GRAS notices for human consumption of hemp seed by-products and is well below the submissions limit of 10ppm. She was unaware of any CBD action limits in any jurisdiction regulating hempseed meal. The U.S. Pharmacopeia global researchers and policymakers' recommendation is 75 PPM. This is the first time an action limit has been set on CBD for animal feed. The likelihood of processors meeting this CBD concentration in the meal is very good because cannabinoids are hydrophilic. However, if processors do not remove the seed shell, contamination greatly increases. It could also become problematic when AAFCO starts examining hemp seed oil. Charlotte Conway stated that the proposed limits and definitions are based on specification data that correlates with the completed animal and human food safety work. There is sufficient evidence indicating that the specifications can be achievable. There is flexibility in amending the definition in the future to address the processors and their specifications as data warrants. Morgan Tweet questioned if there is a way to increase the value without increasing feed trials with concentrated CBD methods or applications. Charlotte Conway stated this issue is outside the scope of what could be addressed during the committee meeting because additional research needs must be discussed. Hunter Buffington confirmed that the U.S. Pharmacopeia has an international standard for hemp seed meal that does not delineate between animal and human consumption. Another member stated there is a food chemical codex monograph for hemp seed protein where hemp seed meal is listed as a synonym. The monograph is primarily a human food resource and has a limit of total THC of 10 PPM and total CBD of 75 PPM.

- T51.18 Deboned Fish Protein Justin Hill
   Justin Hill moves to accept. Falina Hutchinson seconds. The motion passes.
- 4) T9.41 Meat and Bone Meal Stan Cook



#### Stan Cook moves to accept. Mark LeBlanc seconds. Motion passes.

Discussion: Stan Cook stated phosphorus in pork meat and bone meal is lower due to phytase, and 4% phosphorus is no longer attainable. Our team is working on a potential change in evaluating and separating the definition of meat and bone meal from meat meal through nutritional analysis. It will most likely include the addition of an ash guarantee.

- T60.117B Dried Black Soldier Fly Larvae Erin Bubb
   Erin Bubb moves to accept. Robert Tolton seconds. Motion passes.
- 6) Add Corn Protein Feed and Corn Protein Meal to 22.5 Processed Grain Products, Collective Terms Falina Hutchinson
  - Falina Hutchison moves to accept. Dan King seconds. Motion passes.
- 7) AGRN 61 addition to table 10.1 Phytase enzyme produced by *Pseudomonas fluorescens* strain BD50104 expressing an altered *appA* 6-phytase gene from *Escherichia coli* strain K12 Nathan Price
  - Nathan Price moves to accept. Falina Hutchinson seconds. Motion passes
- 8) **Editorial change** to Table 101.1 AGRN 59 Porcine Oligosaccharides-peptides complex. FDA changed the notice under Intended Use.
  - Nathan Price moves to accept. Robert Tolton seconds. Motion passes.
- 9) Deletion of "gluten" names in 2025 (date of sunset)
  - 42.25 Grain Sorghum Gluten Feed (Grain Sorghum Protein Feed)
  - 42.35 Grain Sorghum Gluten Meal (Grain Sorghum Protein Meal)
  - 48.135 Corn Gluten Feed (Corn Protein Feed)
  - 48.145 Corn Gluten Meal (Corn Protein Meal)

Discussion: In chapter 6, there is a sunset period established for these types of changes. The deletion of "gluten" names is scheduled for sunset in the 2025 OP. Leah Wilkinson thanked the committee for making the name changes and getting the terms correctly named in the public since they do not contain gluten. The primary concern is that AAFCO changing these names is a big and costly change to pet food label regulations and the industry. Companies will incur more costs having to change their labels before additional changes occur. Uniformity must be established so all label changes are easily done and business costs are more appropriate. Falina Hutchinson confirmed she has no issue with trying to coincide changes with the pet food labeling changes. Other members stated there is precedence since making the change because it may take people longer to get used to it. These changes may also conflict with pending contracts.

Nathan Price moves to reschedule the sunset date to correlate with the PFLM changes. James Embry seconds. (motion tabled, see below)



Discussion: Stan Cook stated there is a wide difference between a pet food label and corn protein on feed labels. Many companies producing livestock feed can make these changes now. He questioned taking six years to change all the labels. He further stated that most members will not act against corn gluten, but he doesn't think it will take six years to change these labels because they are simple. Dan King agreed that six years is too long and recommended that the committee revisit this topic during the spring virtual meeting in March. Laura Scott recommended giving committee members time to think about voting on the change.

Dave Husner moves to table this motion until the next IDC meeting. Mark LeBlanc seconds. Motion passes.

Discussion: Cathy Alinovi questioned if the coalition that proposed the change to the gluten word to protein considered a timeline. It was confirmed that the coalition previously discussed the timeline.

# **Workgroup Updates**

- 10) Feed Labeling Committee workgroup report. Charlotte Conway states that the investigator should ask CVM to help update the definition of ammonium chloride. Once the request is submitted, the committee will take action. Mineral Product Investigator Jennifer Kormas will send the committee a note.
- 11) Model Bill and Regulation Committee's SUIP workgroup report. SUIP #4 Ash and nutrient elements are not analytically equivalent and should be deleted. Ali Kashani will provide new feed terms.
- 12) Model Bill and Regulation Committee's SUIP workgroup report. SUIP #6 Spent Bleaching Clay should be retained in the OP at least until the Ingredient Definition Committee completes its review and makes a recommendation. A workgroup update will be provided soon.
- 13) Model Bill and Regulation Committee's SUIP workgroup report. SUIP #7 Chews, Bones, and Toys for Pets and Specialty Pets currently states that "rawhide generally refers only to beef, and many of these chews use other types of animal skins or hides." Ali Kashani will provide new feed term for rawhide.
- 14) Multiple 30-minute and one-hour virtual investigator trainings will be held in the late winter or early spring.

David Snell moved that the Ingredient Definitions Committee recess until 9 am on Wednesday, January 24, 2024.Mark LeBlanc seconds. Motion carries.



END SESSION ONE Meeting recessed 3:18 pm EST.

# Ingredient Definitions Committee Report Session 2: January 23 and 24, 2024, Chattanooga, TN 9:00 to 10:00 am Fastern

#### **Committee members present:**

Erin Bubb, Charlotte Conway, Stan Cook, Trish Dunn, James Embry, Maggie Faba, Ashlee-Rose Ferguson, George Ferguson, KC Gutenberger, Justin Hill, Dave Husner, Falina Hutchinson, Dan King, Darrell Johnson, Shannon Jordre, Ali Kashani, Alan Keller, Kent Kitade, Jennifer Kormos, Marissa Kost, Bernadette Mundo, Jo Lynn Otero, Nathan Price, Laura Scott, Ashley Shaw, Katie Simpson, Cory Skier, David Snell, Richard Ten Eyck, Robert Tolton, Kimberly Truett, Ely Walker, Bailey Whiten

### **Advisors present:**

Cathy Alinovi, Hunter Buffington, Janet Campbell, David Fairfield, Patrick Fulling, Emily Helmes, Jillian Nash, Kristi Smedley, Renee Streeter, Katie Vassalli, Leah Wilkinson, Aaron Hobbs, Amy Tryon DePrato, Bill Bookout, Charles Starkey, Jean Hofve, Dave Dzanis

#### A. Common Food Index Update – George Ferguson

- a. CFI submission periods are September through February for the Annual Meeting in August, and March through August for the Mid-year Meeting in January. Requests for comments will be emailed to the AAFCO email distribution lists, the larger academic community, and other associations.
- b. The automated email system for the CFI has not been working properly, but it will be updated and functioning accordingly next week. Everyone will receive a status update then.
- Any communication about the Common Food Index should be emailed to george.ferguson@aafco.org
- d. To access the Common Food Index submission form on the AAFCO website, type CFI or Common food index in the search bar. Afterward, scroll down to the bottom of the page and select the submission page link. On the submission page, click all the boxes in the digital form and click submit to finish. The form must be completed with a valid email address; otherwise, you won't receive any communication.
- e. The submission form is to provide comments, not questions, about non-AAFCO ingredients that have yet to be approved.
- f. For definition and ingredient questions, email <u>definitions@aafco.org</u> and general AAFCO questions can sent to <u>aafco@aafco.org</u>



g. The public comment period begins 60 days before the Annual and Mid-year Meetings. After the workgroup reviews all submissions, the committee will receive the final recommendation list 30 days before the annual and mid-year meetings.

# B. Work Groups Update:

- a. Animal Protein WG, Collagen update There has been discussion about collagen being a new ingredient submission. However, a submission hasn't been completed. A possible proponent is available to bring a draft definition forward. To express interest in participating or commenting, contact Laura Scott laura.scott@inspection.gc.ca or Stan Cook stan.cook@aafco.org
- b. Spent Bleaching Clay Workgroup Spent bleaching clay has been in the SUIP at an inclusion rate of 0.2% in many oil seed meals. It is not a technical additive nor has much function at this inclusion level. To develop a solid definition, the workgroup needs to modify its inclusion rate and look at its function, utility, and safety study like a traditional ingredient. It is considering adding spent bleaching clay to the definition of soy meal and other relevant seed meals when maintained at a 0.2% inclusion rate. The workgroup may have a recommendation for the spring virtual IDC meeting.
- c. Fluorine Workgroup -There are limited regulatory labs testing for fluorine in animal feed. The AOAC 975.08 method is commonly used for detecting fluorine in animal feed. However, it detects fluoride but reports it as fluorine. The workgroup has held two meetings over the past year and continues to discuss necessary changes to the OP. It attempts to obtain historical information on the AOAC 975.08 method that dates back to the 1970s to understand why fluoride is being reported as fluorine when fluoride is being detected. The PTP committee and LMSC have confirmed that only two regulatory labs are testing for fluorine in animal feed. Private labs use this method regularly and can support the workgroup's efforts. The workgroup is drafting a note that can be inserted in the OP at the beginning of section 57 of chapter 6 for consideration by the committee. It is recommended that similar language be used in chapters 4 and 5 of the OP, where fluorine is mentioned. Approximately 20 mineral product ingredient definitions have guarantees or specifications for fluorine in which there may need to be a change from fluorine to fluoride in the ingredient definitions, the Model Bill and Regulations, and the AV table. This change could have an international impact as standards/specifications are set for fluorine instead of fluoride. The workgroup intends to make a recommendation at the next IDC meeting.
- d. Dried Insect Ingredients for Specialty Workgroup The workgroup has held two robust conversations about addressing the issues surrounding dried insect products for specialty products. The workgroup intends to recommend that IDC request Model Bill Committee add



specialty pets to SUIP 9 for dried insects for wild birds. Recommendation will be made at next IDC meeting.

e. Tentative Definition Workgroup – AAFCO and CVM are collaborating to develop language and procedures that meet the requirements of both agencies and to best service the industry needs to submit new ingredient definitions successfully. Workgroup has been disbanded until the revised MOU becomes official.

# C. Parking Lot Update:

- a. Presentation / Speaker Ken Kitade suggested a presentation on new research on how ingredients can play a role in reducing emissions from production animals. Cathy Alinovi also suggested that a company that produces equipment for HPP (high-pressure pasteurization) give us a presentation so that it's easier to develop a future definition for the HPP process.
- b. Feed Terms: Pre, pro, and postbiotics Ali Kashani. Committee recommended that definitions not be developed by AAFCO.
- c. Change all definition notations referring to the "Check Sample Program." OP should state the "AAFCO Proficiency Testing Program." Request the proficiency program to find where in the OP and report them to the committee for editing request.
- d. "As-fed" or "as-is" is used in the OP for ingredient definitions. Discussion will be on the next agenda.

George Ferguson moved that the Ingredient Definitions Committee adjourn. Jo Lynn Otero seconds. Motion carries, meeting adjourned

END SESSION TWO Meeting adjourned 9:56 am EST.