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**Ingredient Definitions Committee Minutes –Final
committee approved verbal reading of 07/31/11 ver #0804**

DATE: July 31, 2011

TO: AAFCO Ingredient Definition Committee: members, advisors and investigators and all other interested parties.

RE: 2011 Annual Meeting IDC Minutes

The Ingredient Definitions Committee (IDC) met Sunday July 31st, 2011 3:30 – 5:45PM at the Hyatt Regency, Austin, Texas.

Roll call of members and advisors with introductions

Control Officials: (11 w/9 voting) Richard Ten Eyck, Aaron Elam, Deb Hargrove (for Don Delorme), Brett Groves, Ali Kashani, Linda Morrison (for Paul Loeven), Roger Hostenbach, Ricky Schroeder, Kent Kitade (BOD liaison), April Hunt (minutes), Neil Lanning (via conference call)

Committee Advisors: (12) David Ailor, Dave Dzanis, Jill Franks, Kurt Gallagher, Jan Campbell, David Fairfield, Matt Frederking, Leah Wilkinson, Jon Nelson, Richard Sellers, David Meeker, Vince Sewalt

Additional members were invited to join the committee

Action items are recorded in red. Comments are recorded in Blue.

1) Definitions to be moved from Tentative to Official
-none-

2) New Definitions:

2.1. Feed Term: Rendered –Ali Kashani

- motion passed (Schroeder/Groves)
Not for human consumption
Is there an assumption that it is free of microorganisms?
- 2.2. T57.28 Metal Methionine Hydroxy Analogue Chelate – Mel Bryant
motion passed (Schroeder/Groves)
From FDA communication
Why isn't there a minimum bound guarantee for the chelate? Discussion finds that this chelate is 100% available
- 2.3. Feed Term: Puffed, Popped –Ali Kashani
motion withdrawn (Schroeder/Groves) **ITEM REMOVED**
Puffable Foods - List has changed from the 3/16/11 submission. Updated 4/11/11
Puffable Foods - Grains: Corn, rice, wheat, millet, barley and buckwheat
Non-grain: soybeans
The group had other suggestions about what is puffed, more work is needed on this definition. Item pulled from list.
- 2.4. Barley Distillers Protein Concentrate – Steve Gramlich, Need Form
No form or data at time of meeting. **ITEM REMOVED**
- 2.5. Feed Term: Powder – Ali Kashani,
motion passed to use Alt definition (Schroeder/Groves)
“Powder”, powdered (process) pulverizing a feed or a feed ingredient into fine or very small particle size.
Approved Alternate: “Powder”, powdered (process) pulverizing a feed or a feed ingredient into fine or very small particle size or atomization and drying of liquids.
Question: can we define “fine”? “fine” and “very small” are relative terms
What is the intent? A process.
- 2.6. Feed Term: Baked – Ali, placeholder **SKIP**
- 2.7. Feed Term: Roasted – Ali, placeholder **SKIP**
- 2.8. Feed Term: Smoked – Ali, placeholder **SKIP**
- 2.9. Feed Term: Decharacterized (process) – Ali
motion passed (Schroeder/Groves)
“Decharacterize”, Decharacterized (process) A process using approved color additives which make a substance clearly distinguishable from the same substance for human consumption
Comment is “denaturize” is the term more commonly used in Canada.
What is an approved color additive? Previously it was dye. CFR has list of approved color additives. This term came from the raw milk issue, it does say decharacterize in the raw milk rule.
- 3) Editorial Changes or Modifications to Existing Definitions
- 3.1. Menadione added to table titled 92.25 -- Ali Kashani
motion passed (Schroeder/Groves)
Vitamin K, was omitted from OP in late 70's, need to put back into OP.
Federal Register notice from 1990 is the back-up document
- 3.2. Trichoderma reesei added to table 30.1 -- Mika Alyweynse
motion passed (Schroeder/Groves)
- 3.3. GRAS list part 582 subparts B to H to reflect CFR lists. – Mika
motion withdrawn (Schroeder/Groves) **SKIP** (with 3.8 & 3.9)

Group is to take into account that these are intended to mirror GRAS. Decided to send back at this time.

- 3.4. 25-Hydroxyvitamin D3 – Clarify only approved in broiler diets – Ali Kashani
 motion passed to amend to the following: (Schroeder/Groves)
 “Reg. 584.725, Broiler chickens, up to 69 parts per billion in feed or up to 34.5 parts per billion in drinking water”
- 3.5. T87.27 Formic acid – sync with cfr – Roger H
 motion passed (Groves/Schroeder)
- 3.6. T9.40 Meat Meal – Neil Lanning
 motion to accept as a new tentative definition with editorial correction passed (Schroeder/Groves)
 Editorial correction to the last sentence in the Text/Description “...description of its kind...” to “...descriptive of its kind...”
 Rabbit, venison meal – were all of these considered? Phosphorus levels
 Two definitions in the book, one is official and one is tentative
 Intention was to make a distinction between ‘meat meal’ and ‘meat and bone meal’
- 3.7. T9.41 Meat and Bone Meal – Neil Lanning
 Motion to accept as a new tentative definition passed (Schroeder/Groves)
- 3.8. GRAS list part 582.10 and 582.20 –Mika
 Motion withdrawn (Schroeder/Groves) SKIP with 3.3 & 3.9
- 3.9. GRAS list parts 582.30, 40, 50 and 60 –Mika
 Motion withdrawn (Schroeder/Groves) SKIP with 3.3 & 3.8
- 3.10. Edits to page 348 from workgroup – Aaron Elam
 Motion to accept the workgroup report passed (Schroeder/Groves)
 Motion to adopt this recommendation for publication in the OP with editorial change passed (Schroeder/Groves)
 Editorial change: in CFIA sections, change “petition” to “application” (this edit will be in 3 places in the report)
- 3.11. Recommendations to Board on GRAS determinations with No-Questions Letters – Richard
 Motion for IDC Committee to hold at least one conference call before the Midyear Meeting in January to discuss this issue further passed (Schroeder/Groves)
 Richard Ten Eyck gave a Powerpoint presentation on GRAS process Acceptance to the group.
 Kristi Smedley gave a presentation discussing an industry perspective.
 AFIA agreed with Kristi’s presentation. Wants to keep process
 AFIA states that there is no higher review than the GRAS process
 ETA agrees. PFI agrees.
 Group looked at what was palatable from the Enforcement Committee Meeting
 - AAFCO continue to utilize the existing definition process for GRAS notification ingredients that have no questions letters from FDA.
 - This will involve expert review, through AAFCO, of the safety data for the intended use of the ingredient. (versus taking them at face value)
 - FDA’s no questions letter will serve as the notice of their concurrence.
 - Common name and ingredient definition will be published in the regular section of the OP with other similar ingredients.

Questions about the “extra” level of review: who is going to do this, cost, what will the review be, why is it necessary?

- To be listed in AAFCO OP, it needs to go through some form of AAFCO process. Hinges on where these substances are going to be listed. There are some that would like these ingredients to be listed right along with AAFCO definitions. If listed in a separate section like the current GRAS substances are, that would be acceptable.
 - o Industry agrees that listing them in separate section (CVM reviewed GRAS...) is ok
- Safety assessment by AAFCO is important and relied on by states, especially smaller state programs that do not have in house review staff.
- Where is the expert panel for AAFCO? Will not be from FDA. FDA is not willing to do a safety review on something they've already looked at.
- Decision by January is desirable.
- Reiterated Kristi's presentation that no food additives were approved by FDA last year, it was all GRAS (approx 300). Food is using GRAS process.
- Trying to establish the bar of what it takes to get into the OP.
- Who is the expert review panel? Is this the AAPFCO Investigator?
- Where will the line be drawn for the proprietary status? Seems like it will be just the ingredient name and not specific to the company? Could other companies that manufacture the same ingredient submit an application to AAFCO instead of FDA, after the first company went to FDA Answer is yes, that's the case currently. Benefit is you are accepted in 50 states, downside is that you lose your proprietary status.
- Not every self determination has to have the expert panel. If it is not equal, how is that used? As a state regulator, how do you know if an expert panel is used?
- The FDA review is different than before. The level of scrutiny is different, as discussed after the IDC meeting (during minute prep), the main group might not recognize this distinction.

3.12. 36.14 add sentence to table for clarity – Mika

Motion withdrawn (Schroeder/Groves)

There is product in the marketplace that this change will disrupt, as there is a yeast that is not in section 96.

3.13. Bacillus licheniformis added to table 30.1 – Mika

Motion passed (Schroeder/Groves)

4.) Withdrawn Definitions:

-none-

The following agenda sections 5 through 8 are provided as information for the committee and advisors. They may prompt development of future definitions:

5.) Food Additive Petitions received by FDA Not Discussed during the meeting.

5.1 CLA in dairy cattle

5.2 Safflower seed meal in cattle and poultry

6.) Discussion Items:

Discussion of establishing web-based tracking of petitions for new or modified AAFCO ingredient Definitions – *Richard Ten Eyck an example of a tracking form. Industry (AFIA, PFI, NGFA, NOPA) stated they did not need it. They will just call the investigator. IDC may still want to use as a management tool for the process. It would reside in the member only side of the IDC portal.*

Progress report from Page 348 (old 312) edit workgroup – Richard - *members: Richard Ten Eyck, Aaron Elam, John Machado, Shannon Jordre, Dave Fairfield, Vince Sewalt, Richard Sellers, Nancy Cook, Emily Helms, Gary Yingley, and Kristi Smedley see item 3.10 Work group is still operational to implement outcome of GRAS discussions.*

Progress report from Animal Protein Product Definitions Work Group – Neil. *Workgroup to report on proposed changes to deal with the calcium and Phosphorus levels in MBM.(Neil Lanning, David Meeker, PFI, AFIA, Ricky Schroeder, Richard Ten Eyck) see items 3.6, 3.7 Work Group has completed their task. Meat & MBM definitions were changed. Motion to disband was approved.*

Rendered Food Processing waste –Neil. *Workgroup to report on proposed definition changes to accommodate rendering plant-derived waste.(Neil, Roger Hoestenbach, Shannon Jordre) Work Group has completed their task. No definitions are needed at this time. Motion to disband was approved.*

AAFCO publication of self-determined GRAS and GRAS w/ no questions letter. –*Richard Ten Eyck. See item 3.11*

Maqui Berry (a.k.a., Chilean Wineberry), *Aristotelia chilensis* and Hardy Kiwiberry, *Actinidia arguta*, fruit extracts, when used possibly as flavorings and/or coloring agents with limits of 600 mg per "reference amounts customarily consumed as listed in 21 CFR 101.12", GRAS for use in foods, considered GRAS for animal feeds?- *Roger Hoestenbach is working on a definition. Please provide him input.*

T60.115 (_____) Pomace - *Roger Hoestenbach is working on a definition. Please provide him input.*

T87.26 Maltodextrin - *Roger Hoestenbach is working on a definition. Please provide him input.*

T60.111 Hydrolyzed Whole Cassava Meal – *Roger Hoestenbach is working on a definition. Please provide him input.*

T87.27 Sodium Hydroxide Lignin Dehydrated - *Roger Hoestenbach is working on a definition. Please provide him input.*

7.) GRAS Notifications to FDA: [Not Discussed during the meeting](#)

7.1 Chlorine Dioxide as processing aid in distillers at 55ppm

7.2 Penicillin G Potassium to control contaminants in distillers at 2.7ppm.

7.3 Alpha-lipoic acid as cellular antioxidant in dry adult dog food up to 150ppm.

7.4 Virginiamycin as processing aid in ethanol production at 3ppm.

7.5 Hydrophobic Silica as a component of a defoamer used as a processing aid up to 20 ppm in distillers grains with solubles.

7.6 Polyethylene glycol (400) dioleate as a component of a defoamer used as a processing aid up to 64 ppm in distillers grains with solubles.

7.7 Polyoxyethylene (20) sorbitan monostearate as a component of a defoamer used as a processing aid up to 20 ppm in distillers grains with solubles

- 8.) Topics Left from past meetings: (parking lot for future action items) **Not Discussed during the meeting.**
- a. Edits in Chemical Preservatives Section – Linda B.
 - b. Unrefined salt –Mel Bryant
 - c. Adding animal fat source to glycerin definition – Linda B. / David Meeker
 - d. Other Definitions with Chromium levels –Mika
 - e. Glycerin from animal fat biodiesel – NRA/CVM
 - f.
- 9.) Topics from this meeting to carry forward:
1. Conference call to discuss acceptance of Gras Notifications with No Questions letters.
 2. Feed Term Puffed-Ali , **Puffable Foods - List has changed from the 3/16/11 submission. Updated 4/11/11**
 - Puffable Foods - Grains: Corn, rice, wheat, millet, barley and buckwheat**
 - Non-grain: soybeans**
 - The group had other suggestions about what is puffed, more work is needed on this definition. Motion and second to accept were withdrawn.**
 3. Barley Distillers Protein Concentrate – Steve Gramlich, Need Form
 4. Feed Term: Baked – Ali, placeholder
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 7. GRAS list part 582 subparts B to H to reflect CFR lists. – Mika
 - motion withdrawn (Schroeder/Groves) SKIP (with 3.8 & 3.9)**
 - Group is to take into account that these are intended to mirror GRAS. Decided to send back at this time. Some ingredients not on new list.**
 8. GRAS list part 582.10 and 582.20 –Mika
 - Motion withdrawn (Schroeder/Groves) SKIP with 3.3 & 3.9**
 9. GRAS list parts 582.30, 40, 50 and 60 –Mika
 - Motion withdrawn (Schroeder/Groves) SKIP with 3.3 & 3.8**
 10. 36.14 add sentence to table for clarity – Mika
 - Motion withdrawn (Schroeder/Groves)**
 - There is product in the marketplace that this change will disrupt, as there is a yeast that is not in section 96.**

Attachment A has text of definitions recommended for board action.

Meeting was adjourned at 5:45. Committee held in place while the minutes were read and approved.

Attachment A

Ingredient Definition Committee Recommendations to the AAFCO board

DATE: August 4, 2011

TO: AAFCO Board of Directors

The Ingredient Definitions Committee (IDC) met Sunday, July 31, 2010, from 3:30 – 5:45 PM, in Austin, Texas and approved the following items be forwarded to the board and membership for acceptance. The committee has 4 recommendations for the board to pass to the membership for approval.

General Comments and background information:

In addition to regular business the Ingredient Definition Committee had an educational discussion on the GRAS process and tried to formulate how to reflect ingredients with no-question letters in the Official Publication. No solution was reached but the committee and advisors agreed to discuss on a conference call before the mid-year meeting.

Details and comments on particular definitions are in the meeting minutes.

1) The committee recommends the following New Feed Terms be published in the Official Publication:

Rendered, rendering (process) A cooking and separating process in which conditions such as time and temperature, with or without pressure are sufficient to remove water, kill pathogenic microorganisms, and separate fats and oils from other components.”

“**Powder**”, **powdered** (process) pulverizing a feed or a feed ingredient into fine or very small particle size of atomization and drying of liquids.

Decharacterize”, **Decharacterized** (process) A process using approved color additives which make a substance clearly distinguishable from the same substance for human consumption.

2.) The committee recommends the following New Definitions be published in the Official Publication as tentative:

T57.28 Metal Methionine Hydroxy Analogue Chelate is the product resulting from the reaction of a metal salt with 2-hydroxy-4-methylthiobutanoic acid (HMTBa), having a chelated molar ratio of one mole of metal to two moles of HMTBa to form coordinate covalent bonds. This ingredient is intended to be used as a source of trace minerals. The specific metal chelate must be declared as a metal methionine hydroxyl analogue chelate; i.e. copper methionine hydroxy analogue chelate, manganese methionine hydroxy analogue chelate, or zinc methionine hydroxy analogue chelate. The minimum metal content must be declared, and must be at least 15% for copper, 13% for manganese and 16% for zinc.

T9.40 Meat Meal – The rendered product from mammal tissues, 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 added extraneous materials not provided for by this definition. It shall contain less than 4.5% phosphorous, and the actual Calcium (Ca) level shall not exceed the actual level of Phosphorus (P) by more than 2.2 times. 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 minimum and maximum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto.

T9.41 Meat and Bone Meal is the rendered product from mammal tissues, including bone, 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 added extraneous materials not provided for in this definition. It shall contain a minimum of 3.5% Phosphorus (P) and the actual Calcium (Ca) level shall not be more than 2.2 times the actual Phosphorus (P) level. 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 minimum and maximum Calcium (Ca). If it bears a name descriptive of its kind, composition or origin it must correspond thereto.

T87.27 Formic Acid is manufactured by heating carbon monoxide and NaOH under pressure and decomposing the resulting sodium formate with H₂SO₄, the resulting formic acid, CH₂O₂, has a molecular weight of 46.02. Formic acid may

be safely included in swine feed as a PH control agent at levels not to exceed 1.2% in the finished feed.

Formic acid is currently approved for use in hay crop silage up to 2.25% of the silage on a dry weight basis or 0.45% when direct cut under 21 CFR 573.480. This additional approval is confirmed by the 21 December 2010 letter from Bernadette M. Dunham, DVM, PhD, Director, CVM.

3) The committee recommends the following Modifications to Existing Definitions be reflected in the Official Publication:

Table 30.1 Change organism name:

Classification / Name	Source Organism	Typical Substrate	Function	Current supported use
Phytase	Trichoderma reesei Pichia pastoris expressing an altered phytase gene from a Risk Group 1 Escherichia Coli	Corn, soybean meal, hominy, tapioca, plant byproducts	hydrolyses phytate	Increases the digestibility phytin-bound phosphorus in swine and poultry diets

In table 30.1 change the name of the source organism in column 2 from Pichia pastoris to Trichoderma reesei.

As indicated in a previous letter, this definition should be placed above the double line to be in the group of phytase enzymes accepted for both swine and poultry feeds.

Table 30.1 Add new organism & its supported use:

Classification / Name	Source Organism	Typical Substrate	Function	Current supported use
Protease (general)	Bacillus licheniformis expressing serine protease genes from Nocardiosis prasina	Plant & Animal Proteins	hydrolyzes Proteins	Increases the digestibility of protein in corn-soybean meal based diets

Because this enzyme has a new current supported use, its listing should go after "Bacillus subtilis, var" in the protease (general) section and before the entry for "Bacillus subtilis containing a Bacillus amyloliquefaciens gene for protease." Page 394 of 2011 OP.

Table 90.25 clarification: Insert the following statement in the third column, first row of table 90.25 on page 458 of 2011 edition of Official Publication of the Association of American Feed Control Officials to read.

Recognized English Name	Article or substance indicated	Status Under Food Additive Amendments 21 CFR
25-Hydroxyvitamin D ₃	Source of Vitamin D ₃ Activity 25-Hydroxyvitamin D ₃ Commercial Feed Grade	Reg. 584.725, only for Broiler chickens, up to 69 parts per billion in feed or up to 34.5 ppb in drinking water.

Table 92.25 Add Menadione to the table titled 92.25:

Recognized English name	Article or Substance Indicated	Status under Food Additive Amendments
Menadione	Crystalline menadione - Commercial Feed Grade	Poultry 2 to 4 g/ ton

Menadione was omitted from the OP in the late 70's, need to put back into the OP.

**4.) The committee recommends the following be published:
in the OP to replace the text on page 348- 350 of the 2011 OP;
and immediately on the IDC website:**

A Guide to Submitting New Ingredient Definitions to AAFCO

To assist in development of new feed definitions the following guide is offered. 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, but rather to provide nutrition, color, taste, or 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

A requester (industry, public, regulatory official, etc.) should make the request to the appropriate investigator (See the AAFCO Official Publication or website for current listing) in writing that contains the information described below.

The following information should be provided, **if pertinent**, in the request 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
3. Proposed definition.
4. Description of the ingredient.
5. Prior Sanctioned use (common use in United States pre 1958) and/or historical regulation of the ingredient
6. General Description of the Manufacturing processes
7. The purpose of the ingredient
8. Use limitations, if any.
9. Data and observations to support intended use. Data may include controlled feeding trials, if necessary.
10. Summary of safety assessment. The safety assessment should include:
 - A. Reports of available safety studies such as: target animal safety, toxicity, carcinogenicity, mutagenicity, and chronic effects.
 - B. For microbial enzymes, information to demonstrate that they are produced from nonpathogenic and nontoxigenic strains.
 - C. Levels of known impurities and/or potential contaminants and explanation of how to assure the safety of the ingredient.
 - D. Statement of risk for Target Animals
 - E. Statement of risk related to Human Food.
 - F. Statement of environmental safety
11. List of Cited Literature
12. Proposed labeling (can be generic)

It is imperative that the requester provides all information that is available to support their request. Proprietary information should be clearly identified in the request. It may be advisable to put proprietary information in a separate document that can be sent, if needed, only to the FDA during the scientific review. Materials that are of a proprietary nature should not be disseminated in by an investigator without requestors knowledge, also see Section 13f, AAFCO Model Bill or applicable governing state laws.

It is encouraged that protocols supporting the ingredient definitions (especially long-term feeding trials and other significant research studies) be submitted to FDA for review prior to conducting the studies.

Some ingredients may have human health concerns and these ingredients are not appropriate for review by AAFCO but need to be submitted through the Food Additive Process to FDA. Food additive petition issues will be addressed by the **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.**

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, 59 Camelot Drive, Ottawa, Ontario, Canada K1A 0Y9.**

Once a request has been submitted the firm should wait to market the ingredient until the definition has been reviewed and voted on by the AAFCO Ingredient Definitions Committee, Board and General Membership. Marketing prior to the board and membership vote is at the firm's discretion. Some states require an ingredient definition to be accepted for publication in the Official Publication prior to distributing feed containing the ingredient.

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

THE INVESTIGATOR

As an AAFCO Investigator you are a one-person committee and may have to make decisions on data/specifications without counsel in your area of concern. One of the goals is to develop official feed definitions and standards that are just and equitable in cooperation with the members of the industry producing the product. A second goal is to assure that the production, sale, and use of ingredients will result in safe and effective feeds. The definitions should be non-proprietary as not to favor one producer over another.

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

Upon receipt of the request for an AAFCO definition, the investigator must decide:

1. Is the ingredient in their area of concern? If not, then it should be referred to the appropriate investigator or to the Chairman of the Ingredients Definition Committee and the requesting party notified of referral.
2. Does the proposed ingredient fully meet an existing AAFCO definition? (Notify the requester of such)

3. If in the initial contact with the requester it appears that the proposed ingredient may have human safety concerns causing it to be a "food additive", then the requester should be referred directly to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. If FDA issues a food additive regulation for the ingredient, the investigator may proceed with the writing of a new AAFCO definition.
4. Is the request a modification of an existing definition?
5. Is this a request for a new definition?

In the process of writing the definition based on the requesters proposal, the investigator will have to consider several components:

1. Correct nomenclature (common and usual name and appropriate scientific name)
2. Origin of the ingredient
3. Ingredient processing or the process derived from
4. Use restrictions
5. Physical/chemical properties
6. Impurities

Upon receiving a complete request for a new AAFCO 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 they may request the chair of the Ingredient Definitions Committee to assign the definition to another investigator.

Once the administrative review is complete the investigator will ask the requester to send 2 hard copies (or one hard copy and one electronic copy) of the request to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. The investigator will email a request to the Director to review the request for a definition on behalf of AAFCO. FDA acts in a consulting role to evaluate the safety and efficacy of the ingredient. AAFCO investigators should send review requests directed to: **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855**.

Materials that are of a proprietary nature should not be disseminated by an investigator without knowledge of the requestor also see Section 13f, AAFCO Model Bill or applicable governing state laws.

The expected time for FDA to complete their safety and efficacy review is 90 calendar days. When FDA has finished their review 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 public viewing and comments.

The Investigator will respond to the submitter's request for update on the status of the submission when the requests for updates are reasonably timed. Typically after a review request has been at FDA for 90 days, the investigator may need to contact the FDA reviewer to determine the status.

When the FDA provides a written response to the investigator regarding the request for definition, the investigator will contact the requestor and relay the FDA response.

If the FDA does not believe that the new definition has been fully supported they will notify the investigator. The investigator will then work with the requester to obtain more information.

THE EXPERT PANEL

A panel of experts may be consulted at any time if the investigator so deems it necessary to assist in the decision making process. If AAFCO has not identified any experts in specific fields, then the investigator is free to make their own selection. The experts are not limited to academia but should not have corporate financial interest for or against, the proposal.

THE FDA

Since the Food and Drug Administration (FDA) recognizes AAFCO definitions, it is imperative that FDA does not disagree with AAFCO's investigators findings and recommendations on definitions and therefore critical that investigators submit all materials in the request to FDA for its review. If in the initial contact with the requester it appears that the proposed ingredient may have human safety concerns causing it to be a "food additive", then the requester should be referred directly to FDA. Upon the completion of FDA's review, which may result in a publication of a 21 CFR regulation, the investigator may proceed with the writing of a new AAFCO definition.

AAFCO investigators should send review requests directed to: **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.**

It typically takes 3 months depending on complexity of the request and workload for FDA's review. The AAFCO investigator can contact the FDA reviewer every 30 days to inquire as to the progress of reviewing the request.

If FDA considers the request incomplete, but the needed information to be likely quickly available from the requester, FDA may contact the requester directly for that information (keeping the investigator informed of all communications). Should the FDA reviewer believe significant information is required to complete the request, FDA will notify the AAFCO investigator, who will inform the requestor that AAFCO will need additional information to proceed. If needed to support their scientific review, FDA may directly request proprietary information from the requester.

FDA will provide a written response to the investigator with the conclusions of their review.

CANADIAN FOOD INSPECTION AGENCY

The Chair of the IDC will share all investigator proposals with Canadian officials for their information when the information is 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, 59 Camelot Drive, Ottawa, Ontario, Canada K1A 0Y9.**

THE ASSOCIATION

Once reviewed by the investigator and FDA the proposed definition is submitted, by the investigator, to the Chair of the Ingredient Definitions Committee (IDC) by **December 1st** or **June 15th** of each year. The IDC is the clearinghouse for all new or modified definitions by acting as a peer review panel for the investigator to assure 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 is necessary to allow ample time for committee review, corresponding with the

investigator, and referral to the AAFCO Board of Directors for consideration by the general membership at the Annual Meeting or Mid Year meeting.

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 on this recommendation before the next membership meeting so members can vote on the recommendation during the annual or mid-year meetings. Once approved by the membership the ingredient definition will be published in the next Official Publication. The fastest this step happens is one year.

Firms may use the ingredient definition once the AAFCO membership vote has occurred affirming the recommended definition to appear in the OP. Prior to publication in the Official Publication the next year, 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 shall 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.