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Chapter Six
Official Feed Terms, Common or Usual
Ingredient Names and Ingredient
Definitions

Editor—Richard Ten Eyck, OR

A Guide to Submitting New or Modified Ingredient Definitions to AAFCO

Section Editor – FASS

The following guide is offered to assist in development of new or modified feed ingredient definitions. The roles of each party are described below.

The definitions should be non-proprietary as not to favor one ingredient producer over another.

Materials to be used as feed ingredients should have the following attributes:

They should be consistent batch to batch. The material should not be a combination of other ingredients. The intended use should not be to mitigate, treat, or diagnose a disease (other than a nutritional deficiency), but rather to provide nutrition, flavor, aroma for the animal or provide a technical effect in the feed. It is the manufacturer's responsibility to produce a safe ingredient for its intended purpose.

The Requester

Prior to submitting a request for a new or modified definition, the requester (industry, public, regulatory official, etc.) should consider the current ingredient definitions and develop a draft definition that includes the intended use. The requester should then contact the appropriate investigator ([see the AAFCO Official Publication or website for current listing](#)) by email to definitions@aaftco.org to discuss the draft definition. Following the initial discussion, a requester should then make a request to the investigator in writing that contains the information described below, if pertinent, so there is sufficient information for the decision process:

- (1) Firm and contact person.
- (2) Summary of the request, including name of the ingredient, intended use,



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and rationale for the request.

- a. The proposed name shall:
 - i. Not contain commas.
 - ii. Begin with the base material and then list any needed qualifiers (Beet Pulp plain dried).
 - iii. Be In alignment with common or usual name conventions in 21 CFR 502.5(a).
 - iv. Alternate names to be used on labeling shall be clearly stated at the end of the definition. “Plain Dried Beet Pulp” shall be used on all labeling.”
 - v. Not include a trade name or be proprietary in nature.
- (3) Proposed definition.
- (4) Description of the ingredient (e.g., source, physical characteristics, any marketed formulation(s)).
- (5) Proposed labeling (can be generic).
- (6) Historical regulation of the ingredient, if any.
- (7) Description of the manufacturing processes to support identity, composition, and consistent manufacturing of the ingredient. Data to include:
 - a. A description of the manufacturing process,
 - b. A list and regulatory citation for all substances used in its preparation,
 - c. Stability data (including packaging),
 - d. Homogeneity data when ingredient is used at low inclusion rate, and
 - e. Validation information of analytical methods to support testing and/or citation of official methods.
- (8) Use limitations, if any.
- (9) Intended use of the ingredient, including target animal species, use rate, purpose, etc.
 - a. Data and observations (e.g., published literature, animal feeding trials, in vitro studies, empirical data showing technical effect, etc.) to support intended use.
- (10) Safety Assessment. The safety assessment should include a narrative specific to the target animal and, in the case of use in food producing animals, a human food safety assessment should also be provided. Intended uses specific to companion animals will only need to address target animal safety specific to the use description. The safety narrative(s) should assess all the available data. The supporting data which serves as the basis of the safety narrative and conclusion should include:
 - a. Assessment of the ingredient for known and/or potential contaminants and impurities.
 - b. Available safety information from published articles and/or



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unpublished studies.

- i. Target animal safety information should demonstrate the margin of safety for the intended use.
- ii. For microbial products (source of DFM, enzymes, fermentation products) information to demonstrate that they are produced from nonpathogenic and nontoxigenic strains.

(11) List of Cited Literature.

(12) Copies of all cited analytical reports, studies, and referenced articles. These may be provided in hard copy on a CD in PDF Optical Character Recognition (OCR) format.

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

It is imperative that the requester provides all information that is available to support their request. Confidential business information should be clearly identified in the request. Only manufacturing information can be marked confidential business information. Safety and utility data are not considered confidential business information. It may be advisable to put confidential business information in a separate document that can be sent, if needed, only to the FDA during the scientific review. Confidential business information should not be disseminated by an investigator without requester's knowledge; also see Section 14(f) of the AAFCO Model Bill or applicable governing state laws.

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

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

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 requester may get questions from the investigator or DAF. Questions should be addressed in a timely manner. Pending questions not addressed within 24 months will result in the investigator removing the request from AAFCO consideration.

Some ingredients are fed to intentionally alter the composition of human food (as when



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

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

The Investigator

The AAFCO Investigator is a one-person committee that will evaluate and manage the request for a new definition or modified definition. One of the goals of the investigator is to develop official feed definitions that are just and equitable in cooperation with the members of the industry producing the ingredient. A second goal is to assure that the production, sale, and use of ingredients will result in safe and effective feeds. The ingredient definitions should be non-proprietary, meaning they do not include a trade name that would favor one producer over another.

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

- 1) Determine if the proposed ingredient definition fits in the requested section of the AAFCO OP. If not, the request will be referred to the appropriate investigator or to the chair of the Ingredient Definitions Committee with the requesting party notified of the referral.
- 2) Confirm that the proposed ingredient does not fall within the scope of an existing ingredient definition.
- 3) Confirm that a proposed revision to an existing ingredient definition will not cause it to be moved to a different section of the OP or fall within the scope of another existing ingredient definition.
- 4) Conduct an initial evaluation to determine whether any unanswered safety questions exist. If so, the requester will be referred directly to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration** to pursue a food additive approval. If FDA issues a food additive regulation for the ingredient, the investigator will lead the process of bringing the recommendation before the IDC.
- 5) Confirm that the ingredient definition request is complete and contains all the information needed from the requester listed in the requester section above.



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

Once the administrative review is complete, the investigator will forward one copy (electronic copy is preferred, but if sent as PDF, use Optical Character Recognition (OCR) format) of the request to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. If the requestor prefers to send any manufacturing information that is confidential business information directly to FDA, that is acceptable. FDA acts in a consulting role to evaluate the safety and utility of the ingredient.

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

The expected time for FDA to complete their safety and utility review is 180 calendar days. The investigator will provide an update to the requester on the status of the submission when the requests for updates are reasonably timed. After a request has been at FDA for 180 days, the investigator may contact the FDA reviewer to determine the status.

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

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

The investigator may initiate a modification of an ingredient definition based upon their knowledge of the affected industry and not on a specific



request from an external requester. It is the responsibility of the investigator to acquire sufficient documentation to support their actions, just as it is industry's responsibility to provide sufficient documentation to support their request.

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

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

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

The FDA

The Division of Animal Feeds in FDA's Center for Veterinary Medicine performs scientific reviews of AAFCO ingredient definition requests and provides recommendations to the IDC investigators for new and amended ingredient definitions.

It typically takes at least 180 calendar days to review a request for a new ingredient definition, depending on complexity of the request and FDA's current workload. The AAFCO investigator can contact the FDA reviewer after that time to inquire about the status.



If FDA considers the request incomplete, FDA may contact the requester directly for that information but must copy the investigator on all communications. It may be necessary for additional data and information to be submitted, which may lead to multiple iterations to completely review a request. If needed to support their scientific review, FDA may directly request confidential business information from the requester.

FDA will provide a written response to the investigator with the conclusions of their review with the recommended ingredient definition. The requester should receive a copy of this response.

The Association

Once reviewed by the investigator and FDA, the proposed ingredient definition is submitted by the investigator to the chair of the Ingredient Definitions Committee. The IDC is the clearinghouse for all new or modified definitions by acting as a review panel for the investigator to 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 for submission to the chair is 30 business days before the next IDC meeting and is necessary to allow ample time for committee review and corresponding with the investigator.

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

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Firms may use the ingredient definition once the AAFCO membership vote has occurred affirming the recommended definition to appear in the Official Publication. Prior to publication in the Official Publication firms wanting to manufacture feed with the ingredient may use committee minutes and general session minutes to document the completion of the process. These are typically posted on the AAFCO website.

If deletion of an ingredient definition from the Official Publication is proposed, the investigator will follow the same dateline as if proposing any other ingredient definition change. This will allow the IDC the opportunity to review and discuss the proposed deletion.

Canadian Food Inspection Agency

The Chair of the IDC will share all completed definition recommendations with Canadian officials for their information once the forms have been forwarded to the Ingredient Definitions Committee.

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

Additional Pathways to AAFCO Published Ingredient Definitions

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Animal Food Additives Approved by FDA

Animal food additives approved by FDA are listed in 21 CFR 573. The food additive regulation specifies the requirements for safe use of the food additive and establishes the common or usual name for the new



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

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

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

GRAS Notified Substances with 'No Questions' Letters from FDA

A list of GRAS Notices filed voluntarily by the notifiers pursuant to 21 CFR 570.205 which FDA has evaluated (21 CFR 570.265) and determined that it had no questions regarding the conclusion that the notified animal food substance is generally recognized as safe (GRAS) under the intended conditions of use is provided in Section 101 of Chapter 6 of the AAFCO OP the filed notice and the FDA response letter provide information (identity, manufacture, specifications, intended effect, and safety) on the substance under the intended use conditions, and the most up to date version is posted at the following website: [<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm>] This section is provided as a convenience for the State Feed Control Officials. The Investigator of section 101 will adapt the information as provided on the FDA website and consult with FDA on an appropriate common or usual name.

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



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

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

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

Color Additives—Approved by FDA

Color Additives intended for use in animal feed are approved by FDA (specifically the Center for Food Safety and Applied Nutrition) are listed in 21 CFR 73 & 74. The color additive regulation specifies the requirements for safe use of the color additive and establishes the common or usual name for the new ingredient. To ensure that the AAFCO Official Publication listing of defined feed ingredients is complete, the approved color additive, as specified in the published final rule, will be incorporated in the AAFCO Official Publication's Official Common or Usual Names and Definition of Feed Ingredients chapter.



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

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