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 animal and or 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 90-180 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 180 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 3-6 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.