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# Animal Food Ingredient Consultation (AFIC)

## Guidance for Industry

### Draft Guidance

*This guidance document is being distributed for comment purposes only.*

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2024-D-2978.

For further information regarding this document, contact Charlotte Conway, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6768, [charlotte.conway@fda.hhs.gov](mailto:charlotte.conway@fda.hhs.gov).

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, and may be viewed on the Internet at <https://www.fda.gov/animal-veterinary>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <http://www.regulations.gov>.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine (CVM)  
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*Contains Nonbinding Recommendations*  
*Draft — Not for Implementation*

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## **Animal Food Ingredient Consultation (AFIC)**

### **Draft Guidance for Industry**

*This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, we, or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.*

#### **I. Introduction**

This draft guidance describes FDA’s interim Animal Food Ingredient Consultation (AFIC) process, which, when finalized, will explain one way FDA intends to work with firms that are developing animal food ingredients after the Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO)<sup>1</sup> expires on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and GRAS Notification programs. In addition, this draft guidance describes FDA’s enforcement policy for certain ingredients reviewed using the AFIC process.

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

#### **II. Background**

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food, including substances that are food additives and substances that are generally recognized as safe (GRAS)<sup>2</sup> for their intended uses in food.

Since 1920, AAFCO has maintained the AAFCO Official Publication (OP), which contains, among other things, a comprehensive list of animal food ingredients, including FDA-approved animal food additives, substances that are GRAS for one or more intended uses, and animal food ingredient definitions established through the AAFCO ingredient definition request process. In 2007, FDA entered into an MOU with AAFCO that outlines how FDA would provide its scientific and technical expertise to AAFCO in reviewing ingredient definitions requested by

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<sup>1</sup> MOU #225-07-7001 (<https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001>). AAFCO is an independent organization with voluntary membership of State and Federal regulatory officials in the United States, as well as officials from government agencies in other countries, that are responsible for the execution of laws, including regulations, in their jurisdictions pertaining to the production, labeling, distribution, use, or sale of animal food (including ingredients).

<sup>2</sup> See 21 CFR part 570, subpart E.

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industry or AAFCO. This MOU has been renewed and revised several times. The current MOU 225-07-7001 expires on October 1, 2024, and it will not be renewed. See <https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafo-mou>.

Following the expiration of the MOU, FDA plans to assess its animal Food Additive Petition and GRAS Notification programs to determine if changes are needed to promote the efficient development and review of new animal food ingredients. To provide an additional way for engagement during this evaluation period, the AFIC process will be available for assessment of ingredients for which firms may have otherwise utilized the AAFCO ingredient definition process. AFIC will provide a process that will help FDA be aware of new ingredients that are marketed in interstate commerce and any potential safety concerns associated with them. AFIC will serve to provide a baseline of safety information available about such an ingredient, making it easier to compare developments that might occur during marketing. AFIC also will give FDA an opportunity to discuss any potential safety concerns with the developer, ideally before the ingredient is marketed.

### **III. AFIC**

AFIC is intended be an interim process after the expiration of FDA's MOU with AAFCO, and while FDA evaluates the animal Food Additive Petition and GRAS Notification programs, to help support firms developing animal food ingredients for which they may have otherwise utilized the AAFCO ingredient definition process. AFIC will provide an additional way for firms to consult with FDA regarding these animal food ingredients and for FDA to review such ingredients and identify any safety concerns associated with them. This would include ingredients that make up a significant proportion of an animal's diet, such as, but not limited to, plant materials, grains, or human food by-products. AFIC also will allow for public awareness of and input on ingredients for which FDA is providing consultation.

Firms that would like to market ingredients are invited to discuss with FDA whether AFIC fits their proposed ingredient and should contact FDA via email at [Animalfood-premarket@fda.hhs.gov](mailto:Animalfood-premarket@fda.hhs.gov).

#### **A. Information Supporting Consultation**

Firms interested in participating in the AFIC process should submit materials containing the following information:

- a. firm and contact person
- b. summary of the request (explain purpose of request, summarize rationale)
- c. description of the ingredient (chemical/botanical name, composition, physical/biological/chemical properties)
- d. manufacturing information (description of manufacturing, formulations, batch analysis, stability information, methods)

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- e. purpose of the ingredient (describe intended use and intended target species), including:
  - data to support intended use
- f. safety assessment (narrative summarizing cited safety studies and exposure assessment), including:
  - target animal safety (including use limitation, if applicable)
  - human food safety (if applicable)
- g. statement of environmental risk<sup>3</sup>
- h. copies of cited literature and reports
- i. proposed labeling
- j. any other information considered relevant by the firm

### **B. Public Disclosure**

To facilitate transparency and support public engagement, FDA intends to post inventories of pending and completed AFICs on our website.<sup>4</sup> The AFIC pending and completed inventories webpage(s) will identify the substance, intended use, intended species, and submitter; therefore, firms making a submission should not expect that this information will be kept confidential.

### **C. Stakeholder Input on AFIC Ingredients**

Stakeholders are invited to provide additional data or information regarding the safety of ingredients posted in the consultation inventory through the docket for this guidance (FDA-2024-D-2978).

### **D. Completion of FDA Consultation**

Upon completion of the consultation, the AFIC completed inventory webpage will be updated with the substance, intended use, intended species, submitter, and FDA's letter. This letter will summarize the information that FDA reviewed in order to conclude whether we have questions about the safe use of the proposed ingredient.

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<sup>3</sup> Environmental risk means potentially significant environmental impacts caused by use of the ingredient, such as impacts on terrestrial and aquatic environments from excretion or disposal. The National Environmental Policy Act (NEPA) requires that Federal agencies consider the environmental impacts of any "major Federal action." 42 U.S.C. § 4332(2)(C). Approval of a food additive petition is a major Federal action that triggers the requirement for environmental analysis under NEPA. 40 CFR 1508.1(q); 21 CFR 25.20(i); *cf.* 21 CFR 25.32 (describing actions that are categorically excluded from NEPA review). However, a decision not to enforce requirements, as described in this draft guidance, is not a "major Federal action." *See Int'l Ctr. for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1, 8 (D.D.C. 2006). Even though NEPA does not apply, CVM intends to consider whether the ingredient might pose an environmental risk.

<sup>4</sup> <https://www.fda.gov/animal-veterinary/animal-food-feeds/animal-food-ingredient-consultations-afics>

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### **IV. Enforcement Policy**

An animal food substance that is not GRAS for an intended use is a food additive. In general, to be legally marketed and used, a food additive must be approved, covered by an FDA regulation, and used as described in the FDA regulation. Otherwise, the food additive is considered unsafe under section 409(a)(2) of the FD&C Act, and the food additive and any food that bears or contains it is adulterated under section 402(a)(2)(C)(i) of the FD&C Act.

FDA generally does not intend to initiate enforcement action with respect to the food additive approval requirements of the FD&C Act for the ingredient, or animal food containing the ingredient, if such ingredient is reviewed and is the subject of a “consultation complete” letter under the AFIC process, and is used in accordance with the “consultation complete” letter, as long as there continues to be no questions or concerns about the safety of the ingredient.

This policy does not alter the status of an ingredient that is an unapproved food additive and does not mean that the product is lawfully marketed. FDA may reevaluate our intent to refrain from enforcement if we become aware of information that raises a concern about the safety of an ingredient or under any other circumstance covered by our authorities. If FDA identifies a concern with respect to an unapproved animal food additive, we intend to take appropriate action to ensure the safety of the animal food supply, including notifying the public or pursuing enforcement action as warranted.

More information on AFIC can be found at <https://www.fda.gov/animal-veterinary/animal-food-feeds/animal-food-ingredient-consultations-afics>.