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Animal Food Ingredient Consultation (AFIC)

Guidance for Industry

Submit comments on this guidance at any time. 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 AskCVM@fda.hhs.gov.

Additional copies of this 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.

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Center for Veterinary Medicine (CVM)
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The information collection provisions in this guidance are under OMB review and are not for current implementation. See additional PRA statement in Section V of this guidance.

Table of Contents

I. Introduction 1
II. Background 1
III. AFIC 2
A. Information Supporting Consultation 2
B. Public Disclosure 3
C. Interested Party Input on AFIC Ingredients 3
D. Completion of FDA Consultation 3
IV. Enforcement Policy 4
V. Paperwork Reduction Act of 1995 4

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This guidance represents 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 guidance describes FDA's interim Animal Food Ingredient Consultation (AFIC) process and explains one way FDA intends to work with firms that are developing animal food ingredients with the expiration of the Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO)[1] on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and GRAS Notification programs. In addition, this 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)[2] 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 outlined how FDA would provide its scientific and technical expertise to AAFCO in reviewing ingredient definitions requested by

[1] 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).

[2] See 21 CFR part 570, subpart E.

industry or AAFCO. This MOU was renewed and revised several times. The most recent MOU 225-07-7001 expired on October 1, 2024, and was not renewed. See https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou.

Following the expiration of the MOU, FDA is assessing 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 to 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. The Food Additive Petition and GRAS Notification programs remain available; however, 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. 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.

A. Information Supporting Consultation

Firms interested in participating in the AFIC process should submit materials containing the following information:[3]

a. firm and contact person
b. proposed ingredient name and definition
c. summary of the request (explain purpose of request, summarize rationale)
d. description of the ingredient (chemical/botanical name, composition, physical/biological/chemical properties)

[3] In general, firms should not resubmit information they have already provided to FDA.

e. manufacturing information (description of manufacturing, formulations, batch analysis, stability information, methods)

f. purpose of the ingredient (describe intended use and intended target species), including:

- data to support intended use

g. safety assessment (narrative summarizing cited safety studies and exposure assessment), including:

- target animal safety (including use limitation, if applicable)
- human food safety (if applicable)

h. copies of cited literature and reports

i. proposed labeling

j. any other information considered relevant by the firm

B. Public Disclosure

The confidentiality of information received will be handled in accordance with our obligations under 21 CFR part 20, "Public Information." For example, 21 CFR 20.61 addresses trade secret and commercial or financial information.

To facilitate transparency and support public engagement, FDA intends to post inventories of pending and completed AFICs on our website.[4] 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. Interested Party Input on AFIC Ingredients

Interested parties 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).

To facilitate FDA's consideration of this data and information before we issue a "consultation complete" letter, submissions to the docket should include the AFIC number for the referenced consultation and be submitted no later than 90 days after the consultation has been added to the pending inventory. Failure to include the AFIC number may impede FDA's timely consideration of the submission; FDA does not intend to consider submissions that do not contain relevant data or information. FDA also welcomes data or information regarding the safety of ingredients following issuance of a consultation complete letter.

D. Completion of FDA Consultation

[4] https://www.fda.gov/animal-veterinary/animal-food-feeds/animal-food-ingredient-consultations-afics

Upon completion of the consultation, the AFIC completed inventory webpage will be updated with the substance, intended use, intended species, submitter, and FDA's consultation complete 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.

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.

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. §§ 3501-3521). The time required to complete this information collection is estimated to average 3,000 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Policy and Regulations Staff
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place, Rockville, MD 20855

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995 and **are not for current implementation**. Before implementing the information provisions in the guidance, we will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove those information collection provisions.