#293

FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients

Guidance for Industry

Draft Guidance

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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.

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville MD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
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Table of Contents

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, Agency, or we) on this topic.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This draft guidance, when finalized, will describe the FDA's policy regarding the marketing of certain unapproved food additives, or animal food containing those food additives, in interstate commerce. It will also set forth FDA's current thinking with respect to animal food labels that identify ingredients by names defined by the Association of American Feed Control Officials (AAFCO). This draft, when finalized, will replace the Compliance Policy Guide Sec. 665.100[1] published in October 1980 and revised in March 1995, the content of which is reflected in section III.B. *Policy regarding AAFCO ingredient names on animal food labels*.

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

A. Food Additives and GRAS Substances

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to regulate substances used in animal food. Section 201(s) of the FD&C Act defines a food additive, in part, as any substance whose intended use "results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety . . . to be safe under the conditions of its intended use." Substances that are "generally recognized as safe" (GRAS)[2] for their intended uses in food are not food additives.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-665100-common-or-usual-names-animal-feed-ingredients

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

Section 409(b) of the FD&C Act and FDA's implementing regulations at Title 21 of the Code of Federal Regulations (21 CFR) part 571 describe the animal food additive petition process and the data and information that must be submitted to FDA as part of an animal food additive petition to support premarket approval. 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. Approved food additives for animal food use are found in 21 CFR parts 573 and 579.

FDA has affirmed certain substances as GRAS for their intended used in animal food and these are listed in 21 CFR parts 582 and 584. Because the GRAS use of a substance is not subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in food on the basis of a conclusion of GRAS status, therefore these lists are not all-inclusive. However, FDA strongly encourages any person who intends to market a food substance on the basis of a conclusion of GRAS status to submit a GRAS notice to FDA.[3]

B. Association of American Feed Control Officials (AAFCO) and Ingredients Listed in its Official Publication (OP)

AAFCO is an independent organization with voluntary membership of State and Federal regulatory officials in the United States (U.S.), as well as officials from government agencies in other countries, that are responsible for the execution of laws and regulations in their jurisdictions pertaining to the production, labeling, distribution, use, or sale of animal food (including ingredients). AAFCO provides a mechanism for developing and facilitating the adoption of uniform State laws, regulations, standards, definitions, and enforcement policies for the manufacturing, labeling, and sale of animal food. In addition, AAFCO develops model laws and regulations that nearly all States have adopted as the basis for their animal feed-control programs. AAFCO is governed by officers and a board of directors (known collectively as the Board) elected by the membership at the annual meeting of AAFCO. FDA is a member of AAFCO and provides scientific and technical expertise to the organization.

Since 1920, AAFCO has maintained the AAFCO Official Publication (OP) and publishes it annually. The AAFCO OP contains, among other things, a comprehensive list of animal food ingredients, many of which include definitions established through the AAFCO ingredient definition request process for which FDA has historically provided scientific and technical review. The definitions adopted through the AAFCO ingredient definition request process are not Federal regulations and they do not bind FDA or animal food manufacturers under Federal law. The list of animal food ingredients in the AAFCO OP includes:

[3] https://www.fda.gov/animal-veterinary/animal-food-feeds/generally-recognized-safe-gras-notification-program

- FDA-approved color additives, FDA-approved animal food additives, and substances that are determined by FDA to be generally recognized as safe (GRAS) for an intended use in animal food;

- A separate listing of substances that are the subject of GRAS notices that have undergone FDA evaluation and received FDA's "no questions" letters[4]; and

- Animal food ingredient definitions established through the AAFCO ingredient definition request process.

Because most States adopt the ingredient definitions listed in the AAFCO OP under their State laws, the AAFCO ingredient definition request process facilitates the marketing of animal food ingredients under those State laws.

FDA is announcing it will no longer serve as the scientific and technical reviewer for ingredients undergoing the AAFCO ingredient definition request process after October 1, 2024.[5] FDA is also issuing draft guidance for industry (GFI) #294, "Animal Food Ingredient Consultation (AFIC)."[6] When finalized, GFI #294 will provide an additional way for stakeholders involved with the development of animal food ingredients to consult with CVM while CVM evaluates the animal Food Additive Petition and GRAS Notification programs.

C. Common or Usual Names

Under section 403(i)(1) and (2) of the FD&C Act, the label of a food must bear the common or usual name of the food, if any, and, if fabricated from two or more ingredients, the common or usual name of each ingredient (see also 21 CFR 501.4(a)). A common or usual name is the name by which an article is known to the American public. Common or usual names are generally established by common usage, though in some cases they may be established by regulation pursuant to sections 401, 403(a)(1), 403(i), and 701(a) of the FD&C Act (see 21 CFR 502.5(d)). Common or usual names must not be misleading (see section 403(a)(1) of the FD&C Act).

Common usage can be determined by looking at different sources, including names used in common parlance, names already used on ingredient labels, names used in grocery stores and animal food stores, names used to refer to the ingredient in other consumer or public contexts, and dictionary definitions.[7] The names of ingredients defined by AAFCO and

[4] FDA evaluates the notifier's supporting data and responds to the notifier with a letter stating whether FDA has questions about the notifier's conclusion. If FDA does not have questions, it issues a "no questions" letter.

[5] https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou

[6] https://www.fda.gov/media/180442/download (August 2024); see also the Animal Food Ingredient Consultation Program webpage (https://www.fda.gov/animal-veterinary/animal-food-feeds/animal-food-ingredient-consultations-afics).

[7] Here we refer to dictionary definitions that reflect lay usage rather than definitions that reflect scientific or technical meaning.

listed in its OP may be common usage names, either because AAFCO has selected the common usage name or because the name selected by AAFCO has come into common usage over time.

III. Policies

A. Policy regarding unapproved animal food additives in interstate commerce that are ingredients defined by AAFCO and listed in the 2024 Official Publication

Historically, FDA has participated in the AAFCO ingredient definition request process by providing scientific and technical assistance to AAFCO. Since 2007, Memoranda of Understanding (MOUs) have described FDA and AAFCO's respective roles in reviewing proposed AAFCO ingredient definitions. The current MOU is set to expire on October 1, 2024, and will not be renewed.[8]

Generally, to be legally introduced into interstate commerce, a substance added to animal food (commonly referred to as an ingredient) must be an approved animal food additive or GRAS for its intended use. However, FDA generally does not intend to initiate enforcement action with respect to the food additive approval requirements of the FD&C Act for ingredients listed in the 2024 AAFCO OP that are not approved food additives or GRAS. We have reviewed many of these ingredients through our participation in the AAFCO ingredient definition request process and recommended that the ingredient definitions, including specifications for use, be added to the AAFCO OP. For those ingredients listed in the 2024 AAFCO OP that are not approved food additives or GRAS and that we did not review as part of the AAFCO ingredient definition request process, at this time, we are also not aware of any safety concerns that would cause us to recommend that an ingredient be withdrawn from the AAFCO OP, and many have a long history of use in animal food. We anticipate that our policy generally not to initiate enforcement action regarding the marketing of these ingredients may help minimize disruptions in access to, or shortages of, ingredients that have been commonly used and relied upon for years. Additionally, this approach would allow us to focus our resources on reviewing new ingredients before they are marketed and addressing unsafe ingredients in the marketplace.

Therefore, if an animal food ingredient listed in the 2024 AAFCO OP is an unapproved animal food additive, 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,[9] taking into account the following factors:

1. The ingredient is included in the Official Common or Usual Names and Definitions of Feed Ingredients section of chapter six of the 2024 AAFCO OP (Ref. 1);

2. The ingredient is used according to the intended use, specifications, and limitations in the definition listed in the 2024 AAFCO OP. If the ingredient definition contains

[8] https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001

[9] See sections 402(a)(2)(C)(i) and 409 of the FD&C Act.

no specifications or limitations on the ingredient's use, then FDA generally does not intend to initiate enforcement action with respect to its use if the ingredient is used in animal food in accordance with good feeding practice as defined in 21 CFR 582.1(b); and

3. FDA has no questions or concerns about the safety of the ingredient.

FDA also intends to consider any other relevant information when making an enforcement decision. If FDA identifies a concern with respect to an unapproved animal food additive listed in the 2024 AAFCO OP, 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.

B. Policy regarding AAFCO ingredient names on animal food labels

All animal food labels must bear the common or usual name, if any, of the food and its ingredients.[10] To the extent an animal food label bears the name of a food or ingredient that is not its common or usual name, FDA generally does not intend to initiate enforcement action with respect to use of the name for an ingredient included in the "Official Common or Usual Names and Definitions of Feed Ingredients" section of chapter six of the 2024 AAFCO OP on an animal food label unless use of the name causes the label to be false or misleading.

IV. References

1. Association of American Feed Control Officials. (2024). Chapter 6 "Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions." *2024 Official Publication of the Association of American Feed Control Officials*. Champaign, IL 61820.

[10] See section 403(i)(1) and (2) of the FD&C Act; 21 CFR 501.4(a).