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ADVISORY

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FDA Seeks to Reform Approach to Regulation of Ingredients Used in Animal Food

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In advance of the upcoming expiration of the memorandum of understanding (MOU) between the Food and Drug Administration (FDA) and the Association of Animal Feed Control Officials (AAFCO), the FDA has released two draft guidance documents related to the regulation of the ingredients used in animal food.

Background

The FDA—the federal agency responsible for the regulation of animal food—originally entered into an MOU with the AAFCO—an independent organization with voluntary membership—in June 2007 related to the regulation of the ingredients used in animal food. That MOU has been renewed and revised several times—most recently in June 2019. The existing MOU is set to expire on October 1, 2024, and the FDA has indicated that it will not be renewed.

Regulatory framework

As discussed in a previous advisory, under the Federal Food, Drug, and Cosmetic Act, a "food additive" (i.e., "any substance the intended use of which 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 … to be safe under the conditions of its intended use") must be authorized by the FDA before it can be used in food, including food intended for consumption by animals (e.g., pet food). Substances that are generally recognized as safe (GRAS) for the intended use are explicitly excluded from the definition of a "food additive" and, thus, exempt from the need for pre-market authorization by the FDA. While companies can reach a self-determined GRAS position, there is also a voluntary process by which the regulated industry can notify the FDA of this determination through the FDA's GRAS notification program.

Unless a substance intended for use as an ingredient in animal food is GRAS, or subject to an existing regulatory clearance for the intended use, it generally requires pre-market approval by the FDA. This requires submission

of a food additive petition (FAP) that is supported by evidence demonstrating that the substance is safe for the intended use.

Enforcement discretion

For substances that are not the subject of an existing regulatory clearance that encompasses the intended use as an ingredient in animal food, the MOU establishes an alternative path to market (i.e., the AAFCO ingredient definition request process), which can be used by developers of animal-food ingredients rather than filing a FAP or submitting a GRAS notification.

The MOU outlines how the FDA recognizes the AAFCO's review of various animal-food ingredients and exercises enforcement discretion for those ingredients. The MOU also describes responsibilities under the AAFCO ingredient definition request process. Through the AAFCO process, requests for review of new animal-food ingredients and modifications of existing definitions (which are included in the annual AAFCO Official Publication (OP)) are handled jointly by the FDA and the AAFCO (i.e., the process is operated by the AAFCO with scientific and technical assistance from the FDA).

However, as a result of the upcoming expiration of the MOU, the AAFCO has announced that it will *stop* accepting animal-food ingredient definition requests through the AAFCO ingredient definition request process on September 1, 2024 to allow sufficient time for the submission of all such requests to the FDA before the MOU expires. The FDA has stated it "will no longer serve as the scientific and technical reviewer for ingredients undergoing the AAFCO ingredient definition request process after October 1, 2024."

Even though the MOU will not be renewed, the FDA has indicated that it will "continue to work closely with AAFCO and state regulatory partners to help ensure the safety of the animal food supply." However, it remains to be seen what role (if any) these partners will have in the review of animal-food ingredients moving forward.

Takeaways from the FDA's Announcement

With the MOU set to expire, stakeholders faced some uncertainty about the continued use of certain animal-food ingredients listed in the 2024 AAFCO OP (i.e., ingredients that are not approved animal-food additives or GRAS for the intended use) and the path to market for new animal-food ingredients. However, the FDA has issued two draft guidance documents to clarity these issues for industry stakeholders.

FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients

In this draft guidance, the FDA suggested that much will remain the same for ingredients whose current use in animal food is based on a listing in the 2024 AAFCO OP (i.e., food additives that are unapproved by the FDA for the intended use in animal food), even after the MOU expires.

Use of Ingredients Listed in the 2024 AAFCO OP. The draft guidance clarifies that the FDA intends to continue to exercise enforcement discretion for animal-food ingredients that are listed in the 2024 AAFCO OP (and animal food containing these ingredients), assuming they are used in accordance with the intended use, specifications, and limitations set forth therein. The FDA, however, intends to take action if it identifies any issues with the safety of such ingredients, which could include notifying the public or pursuing enforcement action.

Labeling for Ingredients Listed in the 2024 AAFCO OP. The draft guidance also indicates that the FDA intends to exercise enforcement discretion for the use of animal-food-ingredient names defined in the 2024 AAFCO OP on product labels, only initiating enforcement action if the ingredient name renders the animal-food labeling false or misleading.

Labeling of Other Ingredients Reviewed by the AAFCO. Separately, the FDA has similarly indicated that it intends to exercise enforcement discretion for animal-food ingredients for which it provides scientific review and technical assistance to the AAFCO under the existing MOU that are not listed in the 2024 AAFCO OP, and the agency has requested public comments.

Animal Food Ingredient Consultation (AFIC)

In this draft guidance, the FDA stated it intends to reevaluate the FAP and GRAS notification programs and described a new interim process for the review of animal-food ingredients. This interim animal food ingredient consultation (AFIC) process is intended for developers of animal-food ingredients who would have otherwise used the AAFCO ingredient definition request process.

Upon completion of the FDA's review of an animal-food ingredient through the AFIC process, the FDA will post a letter on its website (a "consultation complete" letter) summarizing the information that was reviewed in reaching a conclusion as to the safety of the intended use of the animal-food ingredient.

Use of Ingredients Subject to the AFIC Process. As with ingredients that go through the AAFCO ingredient definition request process while the MOU is in place, the draft guidance indicates that the FDA intends to exercise enforcement discretion for ingredients, and animal food containing ingredients, that are the subject of a "consultation complete" letter issued in accordance with the AFIC process, assuming the ingredient is used in accordance with that letter and the FDA continues to have no questions or concerns about the safety of the ingredient.

Informational Requirements for the AFIC Process. The draft guidance sets forth a list of the information that should be submitted to the FDA by a developer to have a new animal-food ingredient reviewed using the AFIC review process, which includes, among other materials, a description of the ingredient, the manufacturing process for the ingredient, the safety assessment for the ingredient, and the proposed labeling.

Stakeholder Involvement in the AFIC Process. The draft guidance notes that the "AFIC also will allow for public awareness of and input on ingredients for which FDA is providing consultation." To this end, the "FDA intends to post inventories of pending and completed AFICs on [its] website," including the identity of the substance, its intended use, intended species, and the identity of the submitter. Additionally, "[s]takeholders are invited to provide additional data or information regarding the safety of ingredients posted in the consultation inventory."

The FDA has requested public comment on these draft guidance documents and posed specific questions to stakeholders on the FDA's pre-market animal-food ingredient review programs, requesting input on a variety of issues, including the perceived barriers to or benefits of submitting a FAP or GRAS notification as well as changes that could be made to improve these programs. The FDA has also indicated that it intends to hold listening sessions for stakeholders.

Conclusion

While the FDA has alleviated some concerns by indicating that it intends to continue to exercise enforcement discretion for certain ingredients used in animal food after the MOU with the AAFCO expires, many questions remain about pre-market review and approval of animal-food ingredients.

- Companies involved in the manufacture, distribution, or sale of animal food (and components thereof) should ensure that their regulatory personnel are aware of this upcoming change and continue to monitor developments in this space.
- Stakeholders may submit comments on the draft guidance documents until September 9, 2024. Comments on the FAP and GRAS notification programs are due by December 9, 2024.
- To learn more, stakeholders may also want to participate in a virtual listening session held by the FDA.

Our Food & Beverage Team will continue to keep you apprised of developments in this space and is prepared to assist stakeholders with the transition.

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