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Pet Food Institute Public Comments on Food and Drug Administration Enforcement Policy for Association of American Feed Control Officials-Defined Animal Feed Ingredients; Draft Guidance for Industry #293

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Food and Drug Administration
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The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the agency's August 9 request for public input concerning the draft guidance document #293, "FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients." [FDA-2024-D-2977].

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our members account for the vast majority of the pet food and treats made in the United States, with more than $64 billion in domestic annual dog and cat food and treats sales and annual exports of more than $2.4 billion. PFI membership also includes companies that supply ingredients, equipment, and services to dog and cat food makers. We are proud to be providing food for dogs and cats in over 82 million U.S. households.

In general, PFI strongly supports the agency communicating its planned policy and intent not to initiate enforcement action with respect to ingredients listed in chapter six of the 2024 Association of American Feed Control Officials (AAFCO) Official Publication (OP) after the October 1 conclusion of the memorandum of understanding (MOU) between the U.S. Food and Drug Administration (FDA) and AAFCO. We believe federal oversight of pet food regulation is a productive step towards a more definitive and predictable regulatory structure for the production of pet food.

PFI members believe this draft guidance as well as draft guidance #294, "Animal Food Ingredient Consultation," provide a thoughtful transition away from the lack of uniform state agreement of the AAFCO defined ingredients while still making use of the years of volunteer effort AAFCO and FDA have devoted to publishing the model regulations and ingredient definitions found in chapter six of its publication.

Although we remain supportive of the agency's approach, in the comments below, PFI would like to mention a few points for which we ask for further clarification from FDA's Center for Veterinary Medicine (CVM) or recommend a path forward towards a thorough evaluation of its animal food review programs, in hopes of adapting to better serve public health and the needs of all stakeholders.

In part II. B. Background section of the draft guidance #293, the agency describes FDA's authority under the Federal Food, Drug and Cosmetic Act (FD&C Act) to regulate substances used in animal food. Further, the section describes AAFCO as "…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…" Although this language is taken from the MOU, PFI members have noted that the use of the word "execution" in the description is ambiguous and could be interpreted as AAFCO members as having a legislative role in the creation of state law. PFI suggests replacing the word "execution" with "implementation" or "enforcement" in the final guidance.

It is clear in the draft guidance that FDA generally does not intend to initiate enforcement action with respect to ingredient or animal food containing an ingredient that is listed in the Official Common or Usual Names section of chapter six of the AAFCO 2024 OP. PFI would like to better understand the decision to limit discretion to the 2024 version, understanding that the AAFCO ingredient definition process may take more time to define and publish those ingredients that have been submitted to the AAFCO investigator before the expiry of the MOU on October 1, 2024. PFI recommends FDA extend the practice of not initiating enforcement action for those ingredients until such time that those submissions are published.

Since those ingredients will initially, for a period of one year, be published as "tentative" in the AAFCO OP, FDA should make clear that these definitions are considered "official" for discretionary purposes mentioned in the final guidance. This approach also should be applied to those definitions already published in the 2024 OP.

PFI members are pleased to learn in the draft that FDA includes a long history of use in animal food as part of the criteria to be considered when evaluating any ingredients included in the AAFCO OP that were not subjected to an FDA review of the submission request. Many of these ingredients have been commonly used and relied upon for years by pet food makers to formulate products that provide complete and balanced nutrition to dogs and cats. PFI requests that FDA provide more information on the process it will undertake if it identifies a new concern with respect to an ingredient listed in the 2024 OP.

Lastly, PFI encourages FDA to continue to work with state governments to encourage state-level strategies that are consistent with the guidance put forward by the final version of this draft.

On behalf of PFI members, whose more than 35,000 employees in 34 states provide safe food for dogs and cats across the United States, we appreciate the opportunity to share our views and look forward to working with the agency towards an outcome from this guidance that will continue to allow for the safe use of AAFCO defined ingredients in food for U.S. pets.

Sincerely,

Dana Brooks
President and CEO Pet Food Institute