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Pet Food Institute Public Comments on Animal Food Ingredient Consultation; Draft Guidance for Industry #294

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The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the August 9 request for public input concerning draft guidance #294 setting forth the agency's interim "Animal Food Ingredient Consultation" (AFIC) process [FDA-2024-D-2978].

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.

We appreciate the agency providing a temporary process for firms to engage with the U.S. Food and Drug Administration (FDA) regarding ingredient reviews for which they may have otherwise used the Association of American Feed Control Official's (AAFCO) ingredient definition process. PFI members support AFIC as a short-term, interim solution while the FDA Center for Veterinary Medicine (CVM) considers efficiency improvements to the Food Additive Petition (FAP) and Generally Recognized as Safe (GRAS) Notification programs.

PFI members believe this draft guidance, as well as draft guidance #293 ("FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients"), provide a thoughtful transition away from the lack of uniform state agreement of the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 their publication. We believe federal oversight of pet food regulation is a productive step towards a more definitive and predictable regulatory structure to produce pet food.

While we clearly align with the goals, concepts, and priorities of AFIC to avoid a regulatory gap and continue to encourage innovation in food for pets, we would like to raise a few points for which we ask for further clarification from FDA CVM or recommend a path forward which we feel will assist the AFIC process in achieving success.

PFI members were pleased to read in the draft guidance that FDA plans to discuss at the outset of the consultation whether the AFIC process will be the most useful ingredient review pathway for a firm's proposed ingredient.

While we appreciate FDA's willingness to comment on the expected review time for agency response to the AFIC process, we feel it would be helpful to include in the final guidance the expected turnaround time for an ingredient review following this pathway for any new ingredients. CVM could use language similar to that found in 21 CFR 570.265 for this purpose.

On the same topic, since the AFIC process will allow for public awareness of and input on ingredients participating in the process, we ask FDA CVM to address how it expects this public feedback may affect the timing of completion of ingredient consultations.

On a related note, the GRAS Notification process utilizes Freedom of Information (FOI) redaction policies for certain information that firms may consider confidential commercial information or otherwise qualify for an exemption from FOI. In order to encourage firms to fully utilize the AFIC process, it would be helpful for FDA to clearly articulate any options or plans to protect from public disclosure certain confidential information provided in the consultation.

Part III, subsection D. ("Completion of FDA Consultation") and Part IV ("Enforcement Policy") make it clear that the FDA does not intend to initiate enforcement action against those ingredients (or foods containing those ingredients) that have completed the AFIC process. PFI members are very interested in better understanding FDA's current thinking concerning the regulatory standing of any ingredients that receive a "consultation complete" letter should the agency discontinue the AFIC process (which seems like a distinct possibility given that the draft guidance describes its interim nature) We request that FDA clarify that consultation complete letters are binding for purposes of enforcement, even after the AFIC process is discontinued, should it be discontinued.

Furthermore, concerning consultation complete letters, PFI urges FDA to work with state governments to encourage state-level policies that will recognize ingredients that have completed the AFIC process.

As mentioned above, PFI believes the AFIC guidance should be utilized by the agency as an interim measure only during the transition process from the MOU and during such time as it takes to evaluate and realize efficiency improvements to Food Additive Petition and GRAS Notification programs. We look forward to those improvements to yield workable, practicable outcomes which foster ingredient innovation in the pet food space. Ultimately those will lead to clearer expectations for industry, regulators and pet owners who seek better understanding of the ingredients going into their pet's diet.

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 an outcome from this draft that will continue to allow for the safe use of ingredients in food for U.S. pets.

Sincerely,

Dana Brooks
President and CEO Pet Food Institute