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Pet Food Institute Public Comments on CVM Virtual Public Meeting FDA and the AAFCO Animal Feed Ingredient Definition Process

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Food and Drug Administration Center for Veterinary Medicine
Docket [FDA-2022-N-3122]

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the agency's February 9, 2023, virtual public meeting in which CVM asked for public input concerning the Food and Drug Administration (FDA) Center for Veterinary Medicine's (CVM) role in the Association for American Feed Control Officials (AAFCO) committee process for defining feed ingredients.

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 dog and cat food made in the United States, with more than $50 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 all proud to be feeding over 186 million dogs and cats in U.S. households.

During the virtual public meeting on February 9, 2023, PFI provided oral comments which outlined pet food maker's concerns with the current arrangement between CVM and AAFCO. These comments are summarized below.

Pet food makers operate under two different sets of regulatory requirements. In one case, those issued by the FDA and separately those requirements found within each state's commercial feed law. Enforcement for these regulations also occurs both by federal and state officials. Label review and registration occurs at the state level, while food safety inspections under the Food Safety Modernization Act (FSMA) are conducted by federal inspectors, except in cases where the FDA sanctions state officials to perform these under federal and state cooperative agreements.

In addition, ingredients used in pet food must have gone through an approval or definition process. There are several different pathways to follow this process, some of which are federally defined while others are managed at the state level (AAFCO). In simply providing this

basic and simplified overview one can see how this multileveled regulatory approach can easily fail to provide a predictable regulatory landscape for orderly commerce.

The creation of AAFCO more than one hundred years ago was primarily to address feed laws for livestock animals. A farmer could go to the local feedstore and know what was in the feed that they were buying and how to use it because AAFCO had provided ingredient definitions, rations and other information to be included on a bag or container. Dogs and cats were included as working animals on farms and their food was naturally folded into these AAFCO discussions.

Today, dogs and cats have moved from the farm to our living spaces. When a pet owner purchases pet food, they are most likely doing so in a grocery store alongside human food. That same food will likely be stored in the pantry at home right alongside human food.

In the time since AAFCO was established pets have become companion animals and members of our families. What worked one hundred years ago for pet food, is not meeting the demands of the innovative global pet food industry of today, nor pet owners purchasing food for their family.

One challenge to the process in general and the ingredient definition process specifically is that AAFCO is a voluntary organization that creates non-binding model legislation and regulations that a state can adopt in whole, in part or not at all, into their own state's commercial feed law. As a voluntary organization that has historically been focused on animal feed, it does not have the resources or specific expertise required to effectively review ingredients for pet food, at least not in the same manner as it reviews ingredients for animal feed.

Once an ingredient is defined by AAFCO, inconsistent interpretation across states creates a muddled regulatory landscape for pet food. A regulator in one state can disrupt commerce because of an individual's interpretation of a definition that is included in the AAFCO Official Publication (OP). For example, recently a single state had concerns about a widely used and nutritionally essential ingredient. The state issued a stop sale on products containing that ingredient. This was an ingredient with nearly 60 years of safe use in dog and cat food. Instead of learning from other states, this state label reviewer attempted to amplify this perception of a problem by using the AAFCO process to create a nationwide issue that could have caused harm by excluding the ingredient from the market and at a minimum would disrupt nationwide commerce of a safe food ingredient. Issues like that, which highlight the inconsistent interpretation of a voluntary model, create a lack of trust and predictability for pet food makers.

Since 2015 AAFCO has been engaged in an initiative to modernize pet food labels by making changes to their model pet food regulations in the AAFCO OP. Ingredient statement changes are part of this modernization. These changes will affect the way our packaging looks on store shelves and create greater understanding for pet food purchasers. PFI members are generally supportive of the draft regulatory language.

Although we appreciate these efforts to improve the pet food label, PFI members are very concerned about consistent adoption, interpretation and timing across all states. It will take between five and ten years for pet food makers to implement these changes to the label with an estimated cost of over one billion dollars. Like the challenges with the ingredient definition process, the uncertainty of adoption of these proposed changes to pet food labels across all 50 states brings uncertainty to the marketplace. Even now there is a single state bringing forward an allergen labeling bill that would create a state specific requirement for labeling that could jeopardize the AAFCO labeling work. While we appreciate all the good work that has gone into drafting the language for these label changes, pet food makers have far too much at risk to rely on an organization with no regulatory authority that can only “urge” states to uniformly adopt and enforce these changes.

Another concern with the current system is the length of time it takes an ingredient to go through the approval process. AAFCO committees are run by volunteers, which makes it difficult to get ingredients on the agenda of its very limited meeting schedule. The disruption to the supply chain during COVID and the scarcity of animal fats and proteins from other sectors has made it very clear that the pet food industry needs to look for alternative novel ingredients to continue to provide sustainable, "complete and balanced” and nutritious foods for our pets. Without a structured, predictable review process by experts in pet food safety and nutrition, the pet food industry will be unable to innovate and respond quickly to meet rapid changes in the supply chain.

The AAFCO ingredient definition process was started before there was a uniform federal ingredient approval process. With the Food Additives Amendment of 1958, a clear federal process for food additive approvals was established, with an explicit exemption for substances determined to be Generally Recognized as Safe (GRAS). By states requiring pet food ingredients to go through an AAFCO ingredient definition process, outside of the federal statutory program, a system has been created where there is an additional premarket approval process at the state level for ingredients.

FDA has the GRAS process, but CVM takes a very restrictive approach in the types of data that is accepted, that results in a much longer timeframe for approval. Because the GRAS notification process can be cumbersome, industry does not usually choose this route. However, the benefit

of going through this process is the submitter has only to deal with one entity that has expertise in pet food nutrition, and there is only one interpretation of the definition after the review is completed.

Another significant benefit of working through FDA is the agency's ability to protect confidential business information, whereas if a company were to petition a novel ingredient through the AAFCO approval process, the company would run the risk of its business plans and product formulas being hung up while discussion of the committee takes place – all in front of the company's competitors.

Pet food needs an ingredient review process that fosters innovation, provides assurance to the consumer, and follows clear and consistent timelines.

In summary, our recommendation is for a more uniform and predictable regulatory pathway for ingredient approvals. Despite the noble efforts of AAFCO officials, a system run by state volunteers and given minimal support by the federal agency responsible for pet food safety is far from acceptable to meet the needs of our pets in today's environment. The entire AAFCO ingredient definition process is inefficient, overly burdensome and well beyond anything contemplated by the Food, Drug and Cosmetic Act and its amendments.

On behalf of PFI members, whose nearly 30,000 employees in 33 states provide safe food for the 186 million pets across the United States, we appreciate the opportunity to share our views and look forward to working alongside FDA to advocate for a modernized pet food regulatory process.

Sincerely,

Dana Brooks

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President and CEO Pet Food Institute