

January 18, 2022

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Docket Management Staff:

The Pet Food Institute (PFI) appreciates the opportunity to submit comments regarding Docket No. FDA-2021-N-1192 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure”. PFI strongly believes that the hours estimated to complete a Generally Recognized as Safe (GRAS) notification to the Food and Drug Administration Center for Veterinary Medicine (CVM) for animal food and animal feed is underestimated.

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our 24 members account for the vast majority of the dog and cat food made in the United States, with nearly \$40 billion in domestic annual dog and cat food sales and annual exports of more than \$1.5 billion. PFI membership also includes companies that supply ingredients, equipment and services to dog and cat food makers.

PFI believes that the average burden per response of 170 hours reflected in the notice for animal food and animal feed is woefully underestimated. This is due to the requirement that CVM has implemented in practice to only accept peer reviewed journal publications to support safety of ingredients rather than accepting additional, innovative ways to demonstrate general recognition of safety of an ingredient for an intended use. Under 21 CFR 570.30(b), Eligibility for classification as generally recognized as safe (GRAS), states “General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall address safety for both the target animal and for humans

consuming human food derived from food-producing animals and shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.” In practice, the Center for Food Safety and Nutrition (CFSAN), which has very similar language in the Code of Federal Regulations, allows submitters to provide scientific data that has not been peer reviewed. CVM’s more restrictive approach results in a much longer process for a submitter to gather the information needed for a GRAS submission. PFI feels this time should be included in the estimation of the average burden per response.

PFI estimates it takes a minimum of 160 additional hours for a submitter to prepare the results of a safety study into a format acceptable for a journal submission. Once submitted it can take 6-8 weeks for a decision to be made to consider publishing the study. Once a journal accepts the paper, then the review process starts which is periods of waiting for reviewers to send comments. There are usually two to three reviewers, and their comments must be addressed, which usually requires re-writing sections on the paper. Once those are satisfactorily done, the paper must be edited for publication and publication is on the journal timeline. The review duration is estimated to take six months.

A narrow focus on peer-reviewed articles as the only means of establishing general recognition of safety is a significant process barrier, as the GRAS notification process is for ingredients that already have general recognition of safety for their intended use. General recognition by experts can be established in many ways – not just by publication of studies in a peer-reviewed journal. One of the greatest challenges in getting publication in a peer-reviewed journal is finding a journal that wishes to publish on a particular topic. Requiring publication of safety studies in peer-reviewed journals makes the collection of information burdensome to ingredient sponsors, delays review of the conclusion by CVM, and ultimately delays use of the ingredient.

More flexibility is needed regarding the scientific data, information, or methods used to provide general recognition of safety on the submission to prohibit additional barriers to the GRAS notification process at CVM. The GRAS notification process for animal food and animal feed is not regularly used by industry, and this is one reason that deters industry from using the process. Pathways, other than peer-reviewed articles, must be accepted to reach a scientific conclusion on the safety assessment and determination of the ingredient’s use. A more modern- and current-day example of scientific review would be experts in the field coalescing to make a determination on the safety of an ingredient. CVM taking a more CFSAN-like approach would result in a simpler system to determine the GRAS status of new ingredients that would have a positive impact on pet wellbeing and longevity. Absent CVM providing such flexibility, PFI asks that the average burden hours for animal food and animal feed be increased to at least 330 to more accurately reflect the burden on industry.

On behalf of PFI members, whose nearly 25,000 employees in 32 states provide safe food for hundreds of millions of dogs and cats in the United States and around the world, we thank you for this opportunity to share our views.

Sincerely,



Dana Brooks  
President & CEO