

Monday, February 22, 2021

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

RE: Docket No. FDA-2014-N-0053 for “Requirements for Additional Traceability Records for Certain Foods”

Dear Sir or Madam:

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the U.S. Food and Drug Administration’s (FDA) proposed rule titled “Requirements for Additional Traceability Records for Certain Foods,” which was published on September 23, 2020 (21 CFR Part 1, Federal Register Number 2020-20100).

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our 22 members account for the vast majority of the dog and cat food made in the United States, with more than \$35 billion in annual domestic dog and cat food sales and exports of around \$1.7 billion to more than 90 countries. PFI membership also includes companies that supply ingredients, equipment and services to dog and cat food makers. We are proud of our strategic alliance with the National Grain and Feed Association, as well as our coordination with the American Feed Industry Association and the North American Renderers Association on a range of issues.

Our members, who feed the vast majority of the 180 million pets in U.S. households, operate under regulations issued by FDA and enforced by both federal and state officials. Our members’ products are also subject to state regulations. This means dog and cat owners throughout the United States and around the world benefit from science-based regulation that provides the safest animal food supply available anywhere.

We share FDA’s interest in improving traceability of foods that pose safety risks and we support the agency’s efforts under the Food, Drug and Cosmetic Act to regulate based on science and risk. The proposed rule, which would establish additional traceability records requirements for certain foods per section 204 of the Food Safety Modernization Act (FSMA), is an important step to reduce the risks to public health that certain foods may pose if adulterated. PFI supports FDA’s approach, which is based on data regarding foods that have resulted in foodborne illness and evaluations of risks posed by certain foods.

In issuing this proposed rule, FDA notes that “section 204(d) of [the Food Safety Modernization Act] FSMA directed FDA to establish additional recordkeeping requirements for certain foods.” In order to help FDA designate high-risk foods that might be subject additional recordkeeping requirements under FSMA, FDA in 2014 sought input from food producers regarding the risks certain foods posed. PFI shared comments with FDA at that time, using the process and methodology FDA proposed to analyze whether

a food might pose a high risk to public health. Applying to processed pet food FDA’s draft risk model (which included the following factors: “outbreak frequency, illness occurrence, severity of illness, the likelihood microbial or chemical contamination, potential for the food to support pathogen growth, food consumption patterns, the probability of contamination and steps taken during manufacturing to reduce contamination),” our analysis showed that processed pet foods – those subjected to a validated pathogen mitigation process (also referred to as a “kill step”) – pose a relatively low risk to public health and therefore should not be considered high-risk. PFI members stand by our 2014 conclusions regarding the safety of processed pet food products. We are committed to continuous improvement to ensure the safety of pet food products we produce and sell to pet owners here and abroad.

FDA, in its proposed rule, notes that “[a]lthough FDA and state animal food regulatory programs have begun efforts to collect data on animal food-related illnesses, there are no requirements for reporting such illnesses, which has led to significant gaps in the data.” FDA further notes that “[a]lthough animal foods are not included in FDA’s risk-ranking model, we may revisit the issue of animal foods when we conduct any future reassessments of the model. We welcome comments on whether and how we should consider incorporating animal foods or animal food-related illness into this or a separate model.”

PFI has two comments with respect to whether and how animal foods and animal food-related illness might be incorporated into any risk-ranking model. First, we agree with FDA that there currently does not exist a reliable, evidence-based method for accurately connecting illness in animals, dogs and cats in particular, to regulated foods those animals may have consumed. We have shared with FDA information in support of our contention that processed pet foods incorporating a validated pathogen mitigation (or kill) step do not pose an unacceptable risk to pets or their owners. Accordingly, we urge FDA to clarify in the final rule that animal foods are not subject to the enhanced traceability requirements and that this exclusion applies to all animal foods, including those that incorporate foods identified on the Food Traceability List. We also urge FDA to engage with stakeholders via the formal notice and comment process if the agency at any point contemplates steps to incorporate animal foods and animal food-related illness into any risk-ranking model or food traceability list.

Second, we note in the proposed rule that FDA expresses interest in “explor[ing] using artificial intelligence to mine nontraditional sources of information, such as customer online reviews” as part of its data collection for potential use in a risk-ranking model. PFI recognizes that new technologies can and should be leveraged to enable food producers and regulators to more efficiently allocate resources to identify and address food safety risks. While customer reviews often contain useful information for pet food makers, PFI does not believe such reviews will contribute to a science-based risk-ranking of foods. We therefore urge FDA to exclude customer reviews from any risk-ranking model information.

PFI members understand and embrace the important role they play in feeding dogs and cats, many of whom are considered family members. Our commitment to product safety is and will continue to drive our members’ pursuit of improvements in this area. We welcome the opportunity to discuss with FDA how more accurate information related to foodborne illness in animals can be collected and used to limit injury to animals that might be caused by foodborne pathogens.

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. We support FDA's efforts to identify high-risk foods and to utilize traceability tools that enhance product safety. We trust our comments are considered in the manner intended and that they encourage FDA to continue constructive engagement with both the regulated community and consumers to ensure the regulation of animal food is science-based and consistent with statutory intent.

Sincerely,



Dana Brooks
President & CEO