

Tuesday, March 3, 2020

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

[Docket No. FDA-2019-N-3325]
RIN 0910-AH31

Dear Sir or Madam:

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the United States Food and Drug Administration's proposed rule titled Laboratory Accreditation for Analyses of Foods, published in the Federal Register on Monday, November 4, 2019 and hereafter referred to as the proposed rule.

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our 24 members account for approximately 98% of the dog and cat food made in the USA, with more than \$30 billion in domestic annual dog and cat food sales and annual exports of \$1.6 billion. 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.

PFI members and their products are subject to regulatory oversight by both the U.S. Food and Drug Administration (FDA) and state departments of agriculture or health. We share the FDA's commitment to pet food safety, and we're proud of pet food's strong safety record. PFI strongly supports the objectives of the Food Safety Modernization Act (FSMA) and we are leading the industry effort to promote compliance with this landmark law and its regulations, including the Preventive Controls for Animal Food (PCAF) rule.

PFI would like to comment on this proposed rule specifically to address the new broad authority granted by this rule to issue a food testing order. A food testing order would require an owner or consignee of food to perform food product or environmental testing in response to an identified or suspected food safety problem.

PFI members are concerned that the circumstances triggering a food safety testing order are not clearly defined by the agency in the proposed rule. We believe that basing this regulatory action on a "suspicion" could lead to issuance of a testing order based on the individual bias of

an investigator rather than an identified problem. PFI asks the agency to provide clarity regarding the specific conditions under which a food testing order may be authorized, including a direct reference to relevant food safety regulations established by the Federal Food, Drug and Cosmetics (FD&C) Act as justification for any testing order.

PFI has questions with respect to section 1.1102 of the proposed rule. First, we note that, for the purposes of this proposed rule, FDA indicates in section 1.1102 that it will use the definition of food as it appears in section 201(f) of the FD&C Act. PFI agrees with and supports this approach. FDA then proposes defining “food testing” and “testing of food” to mean the “analysis of food product samples or environmental samples.” FDA further notes that “the terms food testing in sections 422(b)(1) and 422(d) of the FD&C Act, and testing of food in section 422(a)(1)(A) of the FD&C Act, are not defined in the statute.” While these terms may not be defined in the statute, the term “food” is so defined. We question how FDA can indicate it will use the statutory definition for food provided in section 201(f) of the FD&C Act and then propose to define two terms containing the word “food” more broadly than the statutory definition could reasonably be understood to allow. Accordingly, we urge FDA, in the final rule, to define food testing and testing of food as the analysis of food product samples. We believe this narrower definition is consistent with the definition of food FDA proposes using.

While we urge FDA to adopt definitions of food testing and testing of food consistent with the statutory definition of food, we wish to make clear that we recognize the value of environmental monitoring as a tool pet food and pet food ingredient makers can use to ensure product safety and identify potential avenues for the introduction of contaminants.

Section 1.1108 (b) is particularly vague with respect to describing a reasonable timeline for which the food testing order will be in place. The subsection only explains that a timeline will be specified as part of a food testing order. This is particularly concerning since the same subsection explains that environmental pathogen monitoring may be part of the requirements. Environmental testing is normally employed as part of a pet food facility’s food safety program. Our position in the previous two paragraphs of this comment regarding environmental samples as part of a food testing order notwithstanding, PFI asks the agency to provide more clarity as to what constitutes a reasonable timeline for such testing to be conducted under a mandatory food testing order.

Finally, PFI supports FDA’s position on using risk assessments to determine the best allocation of resources to proactively improve product safety for animal health. We issued public comments in May 2014 generally supporting FDA’s notice for Designation of High Risk-Foods and urge the agency to take a similar risk-based approach when requiring that food be tested under section 422(b)(1) of the FD&C Act.

PFI thanks FDA for this opportunity to comment on this proposed rule as it relates to the production of safe and nutritious pet food. Our mission is to promote long and healthy lives for dogs and cats and we believe that the manufacture of safe pet food products is integral to that mission. We stand ready to work with the agency to advance the shared effort to improve product safety, for the benefit of dogs, cats and their owners.

Sincerely,



Dana Brooks
President & CEO