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Monday, July 23, 2018

U.S. Food and Drug Administration  
Dockets Management Staff (HFA-305)

Dear Sir or Madam:

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the food safety guidance given in the Food and Drug Administration's (FDA's or the Agency's) Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, Guidance for Industry, Draft Guidance, released on January 22, 2018 and published in the Federal Register on February 6, 2018 (FDA-2018-D-0388-0002) and hereafter referred to as the "Draft Guidance."

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our 24 producer members account for approximately 98% of the dog and cat food made in the USA; selling more than \$29 billion in dog and cat food annually and exporting an additional \$1.4 billion. PFI also represents 65 associate members who supply ingredients and raw materials to dog and cat food producers. We are also proud of our strategic alliance with the National Grain and Feed Association.

PFI members share FDA's commitment to pet food safety and quality, and we are proud of the strong safety record of pet food. PFI strongly supports the Food Safety Modernization Act (FSMA) and looks forward to working with FDA on the successful implementation of this landmark law.

In these comments, PFI provides both general and specific comments regarding the Draft Guidance.

General comment and observations:

PFI would like to thank FDA CVM for drafting this guidance for industry for successful implementation of the FSMA Preventive Controls for Animal Food (PCAF) rule. Particularly, we appreciate the agency's focus on stressing the flexibility in the PCAF rule, which animal food producers can use to tailor preventive controls to address hazards in their facilities.

We notice the abundance of pet food examples in the Draft Guidance and appreciate the applicability to the pet food industry's own



processes and practices. However, we believe the final guidance could benefit from more examples relating to ingredient producers, who are also subject to the rule and often play a critical role in addressing hazards.

The Food Safety Preventive Controls Alliance Animal Food Curriculum states that FDA expects limited application of supply chain-applied controls to animal food facilities. While we agree that this is likely true in most cases, we urge FDA to ensure all entities subject to the rule understand and meet their FSMA obligations. We believe there are certain animal food hazards, including pentobarbital, that are most effectively addressed through the application of supply chain programs (including contract specifications between customer and supplier) and CGMPs. If, however, these hazards were determined to rise to the level of requiring a preventive control, it may be appropriate to manage that hazard with a supply chain-applied control. In addition, we strongly believe that in many cases ingredient suppliers, including salvage operations and renderers, are best positioned to identify and mitigate certain hazards using their own hazard analysis and risk-based preventive controls. This again emphasizes the need for all animal food producers to be aware of and meet their obligations under FSMA.

Chapter-specific comment and observations:

Chapter 2.2, page 15: PFI would like to thank FDA CVM for acknowledging the importance of good judgment and knowledge of ingredients in conducting a hazard analysis. Regarding ingredient knowledge, PFI has previously commented on the need for shared responsibility for product safety – safer ingredients make for safer finished pet food.

Chapter 2.2, page 15: Following up on our previous comment, PFI recommends that FDA also include ingredient suppliers in the list of entities with whom an animal food producer might consult to complement the expertise of the food safety team, as they develop their hazard analysis.

Chapter 2.4.2, page 20: In the Draft Guidance, FDA CVM recommends consulting with outside experts if a facility lacks the in-house expertise to assess the severity of an illness or injury that could result from a known or reasonably foreseeable hazard. We believe in some cases a facility could conduct something as simple and accessible as gathering scientific data through an online search to make this assessment – this option should be identified in the final guidance.

Chapter 2.4.2, page 21: In the 2nd paragraph on page 21 and again on page 28 and several places throughout the document the phrase "such as copies of your SOPs." PFI members would like to confirm that the paperwork associated with the hazard analysis, food safety plan and corresponding SOPs will often be maintained in electronic formats.

Chapter 2.4.2, page 23: Under the section on Data from the Reportable Food Registry (RFR), FDA reminds responsible parties that they are "required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals." We support this guidance

and urge FDA to include a reminder that ingredient suppliers, including salvage operations that supply animal food producers, are themselves animal food producers, are subject to the FSMA PCAF rule and are or may be responsible parties as defined under the RFR.

Chapter 2.4.2, page 24: PFI believes FDA CVM should remove the section on Facilities historical information, specifically reference to customer complaints. FDA has previously mentioned that its interest in customer complaints is based not in FSMA but in its broad authority under the Food, Drug and Cosmetic Act. We agree with FDA that FSMA does not grant FDA access to customer data, which many PFI members consider to be confidential business information. Further, we don't consider all historical customer data, including customer complaint data/information, to be subject to FDA review. Rather, we see information related to customer complaints as fertile ground for collaboration with FDA, where FDA and PFI members could share information to better understand customer complaints and their relationship to product safety.

Chapter 2.7, page 29: We note in the Draft Guidance that FDA cites as an example a preventive control "that will significantly minimize the *Salmonella* hazard." Pet food makers take extensive measures to eliminate, rather than significantly minimize, *Salmonella* in their ready-to-eat products so we urge FDA to include in this section, as a reminder to all pet food makers, the agency's zero tolerance for *Salmonella* in processed, ready-to-eat pet food products, consistent with the approach outlined in FDA's [Compliance Policy Guide 690.800 Salmonella in Food for Animals](#).

Table 3.1, page 32: In this table, FDA provides examples of known or reasonably foreseeable hazards (KORFs), broken down by category (biological, chemical, physical). PFI appreciates FDA's inclusion of examples of KORFs in this Draft Guidance. We note that many of the heavy metals, including the three listed, are naturally occurring. FDA in the Draft Guidance indicates that other chemical hazards can be naturally occurring. Accordingly, we recommend that, for consistency, the table and discussion of heavy metals also make reference to their natural occurrence so that stakeholders and consumers understand that these heavy metals may be present in ingredients used, as opposed to being introduced.

Chapter 3.3.4, page 41: PFI supports FDA's statement in the Draft Guidance that a facility "must conduct activities that include environmental monitoring for an environmental pathogen, or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples." PFI members believe that environmental monitoring is a valuable tool to help ensure product safety. In addition, we note that an effective environmental monitoring program diligently seeks to find environmental pathogens. To that end, we urge FDA to ensure its inspectors understand that a facility's findings of environmental pathogens, instead of indicating a problem exists, may be a characteristic of a robust and effective environmental pathogen detection program.

Chapter 3.4, page 47: FDA states that, "[w]here no established action level exists, FDA may take legal action against the product at the minimal quantifiable (or in some cases

detectable) level of the contaminant.” FDA goes on to state that “[a]ction levels and tolerances are established based on the unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.” PFI understands this approach and notes that it must take into account improvements in sampling and testing methods, with lower levels of detection now possible. Given this reality, and absent established action levels or tolerances for many chemical and biological hazards (including heavy metals) in animal food, we urge FDA to share with all entities subject to the facility registration requirement under section 415 of the Food, Drug and Cosmetic Act its thinking on and approach to employing sampling and testing to ensure product safety. We also ask FDA to share with us how it determines for which chemical hazards it will set tolerances or maximum residue levels.

Chapter 3.4, page 49: PFI appreciates FDA’s work to develop estimated tolerances for certain heavy metals in pet food, found in its [2011 memorandum](#). This Draft Guidance also notes that many of these heavy metals are naturally occurring and that certain human activities may lead to elevated levels of certain heavy metals. PFI agrees with these statements and notes that our members, who source ingredients from the human food supply, work hard to ensure these hazards are not present or present at levels that pose no unacceptable risks to target animals or humans.

Chapter 3.4.1, page 52: FDA’s discussion of thyroid hormone in this Draft Guidance and in recent letters to industry, are of concern to PFI in that they have the effect of regulation but were not subject to the rulemaking process. PFI members ardently support FDA’s regulatory mandate and its use of evidence-based regulation to improve food safety. FDA’s letters to industry and the language in this Draft Guidance amount to an effective prohibition on the use of beef and lamb gullet in pet food (effectively a regulation banning gullet), with no notice and comment period that would normally accompany proposed rulemaking.

Chapter 3.4.1, page 54: PFI fully supports FDA’s recommendation that “operations that salvage skeletal muscles, organs, or other tissues for processing determine whether animals have been euthanized using pentobarbital and, if so, exclude those animals from use as animal food.” This recommendation is sufficiently tailored to address the chemical hazard posed by use of ingredients from animals that have been euthanized using pentobarbital.

Chapter 4.6.1, page 89: PFI members have noted that the language in this section is written such that a preventive control for nutrient deficiencies and toxicities circumvents the hazard analysis and instead becomes a requirement under FSMA. This can be illustrated in the highlighted Draft Guidance language below which compares texts of Vitamin D for animal food with Thiamine in food for cats.

*“If you identify vitamin D deficiency or toxicity in your animal food as a hazard requiring a preventive control, your preventive control will depend on your manufacturing procedures and could include several types of controls.”*

And

*“If you are manufacturing a cat food that will undergo LACF thermal processing, you should identify thiamine deficiency as a chemical hazard requiring a preventive control.”*

The Vitamin D statement acknowledges that a facility (using sound judgement and scientific data) can determine whether a preventive control is required, while the thiamine statement stipulates that a LACF cat food should identify thiamine as a chemical hazard requiring a preventive control.

In the example provided, PFI believes that formulation of a LACF cat food that allows a safety margin to account for any nutrient content change in the retort process should follow the same approach to hazard analysis as that for other animal food products. The current Draft Guidance language does not provide a facility the flexibility to perform its hazard analysis and determine its preventive controls based upon its own internal analysis.

PFI believes the language in chapter 4.6.1 should be modified to allow for the application of effective hazard analysis to all animal food nutrients.

Chapter 5.8.5, page 121: FDA states that “[a]n effective environmental monitoring program diligently tries to find the pathogen. To be effective, the sampling is conducted with sufficient frequency and samples are taken in places in the facility where the pathogen is likely found, such as areas that may have been contaminated with raw material food ingredients, or areas that are frequently wet.” PFI fully supports these statements and the approach they encourage animal food producers to follow with respect to environmental monitoring. We also encourage FDA, in training inspectors on subpart C to ensure they enforce the PCAF rule in a manner consistent with the approach FDA espouses in this Draft Guidance, specifically that a robust environmental monitoring program will likely find pathogens in a facility and that such a program can lead to improved product safety.

Conclusion:

PFI thanks FDA for this opportunity to comment and for FDA’s willingness to engage with pet food makers on a range of topics related to pet food safety and nutrition. As always, we stand ready to work with FDA to advance the shared effort to improve product safety, for the benefit of dogs, cats and their owners.

Sincerely,

A handwritten signature in cursive script that reads "Dana Brooks".

Dana Brooks  
President & CEO