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Submitted Electronically via Regulations.gov
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards; Public Meeting and Establishment of Docket (Docket Number: FDA-2015-D-0797)

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Food and Drug Administration's (FDA's or the Agency's) Notice of Public Meeting and Establishment of Docket for The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards, published in the Federal Register on March 24, 2015 (80 Fed. Reg. 15612) and hereafter referred to as the "Notice."

Established in 1958, PFI is the voice of US cat and dog food manufacturers; our members sell more than $21 billion in dog and cat food annually and export an additional $1.5 billion. For more than 55 years, PFI has worked with its members to educate the world about pet nutrition and health, the need to balance pet ownership rights with responsibilities, and to maintain the highest standards of product integrity, safety and quality control. PFI members account for 98 percent of the cat and dog food produced in the United States. Among its members are 22 dog and cat food producers and more than 100 associate members who supply ingredients, raw materials, equipment and services to our producer members.

Pet food makers share the FDA's commitment to pet food safety and quality, and we are proud of the safety record of our products. PFI strongly supports the Food Safety Modernization Act (FSMA), as evidenced by our engagement with FDA throughout this rulemaking process, and we look forward to working with FDA for the successful implementation of this landmark law. We share FDA's goal of establishing a regulatory framework that protects public health, is science and risk-based, and is both practical and practicable.

As the rulemaking phase for FSMA draws to a close, we are focusing our energy and resources to ensure our members are prepared for FSMA implementation. We appreciate the efforts FDA made to solicit and incorporate input from stakeholders during the rulemaking process and we trust this level of openness and dialogue will continue during FSMA implementation. We have several points and concerns to share with FDA as FSMA implementation gets under way.

FDA's Operational Strategy for Implementing FSMA

FDA issued this operational strategy in May 2014 with the intent of guiding "the next phase of FSMA implementation by outlining broadly the drivers of change in FDA's approach to food safety and the operational strategy for implementing that change, as mandated and empowered by FSMA." FDA cites the "dramatic expansion in the global scale and complexity of the food system" as the main motivating factor requiring a new approach to food safety. PFI supports FDA in this effort to update the US food safety system, especially as it relates to the efficient and effective allocation of resources to address significant hazards that may be present in the human and animal food supply.

FDA mentions in its strategy document its plan to "enhance operational partnerships with states and other government counterparts…" PFI supports FDA in its plan to partner with state and other government entities. We are very interested in being active participants in this effort because we place a high priority on ensuring that enforcement of FSMA provisions – be it by FDA, state or local authorities – must be science-/risk-based, transparent and consistent. Moreover, PFI views these partnerships as an opportunity to share with relevant authorities information critical to correct application and enforcement of FSMA provisions to animal food producers, in particular the makers of pet food and treats.

FDA has made clear that it will not have the resources to conduct inspections on its own to ensure compliance with FSMA, so partnerships with state and local authorities will be critical to successful FSMA implementation. Yet state officials attending FDA's FSMA implementation public meeting last month expressed concern that they also lack the resources to act as deputies for FDA. We seek information from FDA as to what form its partnerships with state and local authorities will take and whether/how FDA will address state/local authority challenges regarding FSMA enforcement.

FDA has identified stakeholder engagement as a key element of successful FSMA implementation. This stakeholder engagement will include partnerships and collaboration, to encourage firms to comply and self-initiate corrections. PFI supports such stakeholder engagement efforts and seeks more information on what form these partnerships and collaboration will take. We believe that such partnerships and collaboration will be critical during the initial phases of FSMA implementation.

In its discussion of Strategic and Risk-Based Industry Oversight, FDA states that it will use an expanded oversight toolkit, to include, *inter alia*, "regulatory incentives for compliance, such as less frequent or intense inspection for good performers…" PFI strongly supports such an approach, which should free up FDA, state and local authorities to conduct FSMA compliance and enforcement activities that will yield the greatest benefits for the safety of the US supply of human and animal food.

Later in its discussion of Strategic and Risk-Based Industry Oversight, FDA states that it will "improve the quality and quantity of data it uses in order to fully evaluate and make the most informed, risk-based decisions." PFI is interested in how FDA will go about improving the quality and quantity of data it uses in its decision making. Will this effort involve increased collection and testing of samples? Can or will data collected by industry in its own food safety efforts be included in FDA's evaluation and decision making? What criteria will be used to determine the foods that will be subject to increased sampling and testing? We note that FDA's own data and that gathered by the CDC do not appear to support increased sampling or testing of processed pet food and treats.

FDA, in its May 2014 Operational Strategy document, discusses collaboration within FDA, including the establishment of "internal performance metrics that are aligned with the risk-based, public health-focused prevention vision." PFI supports FDA's effort to more effectively integrate FSMA implementation efforts across the Office of Foods and Veterinary Medicine. We are also interested in how these internal performance metrics will be used to allocate FDA resources with respect to FSMA compliance and enforcement activities. We believe that this approach, coupled with FDA's stated goal for "seamless data sharing and collaborative data analysis among all elements of the Foods and Veterinary Medicine Program related to risk-based priority setting and resource allocation," will lead to a more efficient allocation of FDA resources to address the most significant challenges to the safety of the US human and animal food supply.

PFI supports FDA's plan to employ streamlined processes that "enable real-time decisions regarding frontline corrective actions, enforcement, and other measures to achieve public health and consumer protection." FDA inspectors, or state/local officials carrying out FSMA compliance and enforcement activities, must have access in real-time to information and expertise that allows them to make informed decisions during inspections. This real-time approach must complement training prior to FSMA implementation – real-time access to information during inspections is no substitute for a complete and correct understanding by any inspector of key FSMA provisions.

In its discussion of Guiding Principles for Implementation of FSMA's New Import System, FDA indicates it will rely "primarily on importers providing documented assurances that their foreign suppliers have taken proper steps to prevent problems." As PFI has stressed in its comments on the animal food proposed and supplemental rules, there must be a method for importers of ingredients to be used in pet food/treats to confirm that these ingredients, after importation and as part of their use in processed pet food/treats, will be subjected to a pathogen mitigation/kill step. These products may

pose foodborne illness risks if they are not subjected to an appropriate pathogen mitigation/kill step, so it is critical that importers of such ingredients can notify FDA that any risks will be addressed before they are placed into the market.

Efficient Allocation of FDA Resources

PFI notes with some concern that FDA readily admits, in the presentations it gave during the FSMA Implementation public meeting, held 23-24 April in Washington, DC, that it will be unable to conduct routine on-farm inspections to ensure compliance with provisions of the produce safety rule under FSMA. FDA and CDC data indicate that produce accounts for a significant portion of the 48,000,000 annual cases of foodborne illness. We encourage FDA to take this fact into account when allocating resources to enforce FSMA provisions. Our comment (attached) dated 22 May 2014, in response to FDA's request for input on its proposed methodology for identifying high-risk foods (Docket No. *FDA-2014-N-0053),* showed, using FDA and CDC data, the extremely low risk processed pet food/treats pose to human health. We encourage FDA to take all necessary steps to allocate FSMA compliance and enforcement resources where they are most needed and will have the greatest impact on improving the safety of the US food supply.

Food Safety Preventive Controls Alliance (FSPCA)

PFI is an active participant in the FSPCA, which is developing guidance for both animal food producers and those charged with ensuring compliance with FSMA. While we support this effort to develop information that will facilitate FSMA awareness and compliance, we remind FDA that the FSPCA's focus and work product should address known/reasonably foreseeable and significant (SAHCODHA) hazards, in accordance with FSMA's animal food rule. The curricula, manuals and guidance that the FSPCA effort develops must be clear and concise, ensuring food producers and regulators dedicate their limited resources towards activities that will have the greatest food safety benefit.

Conclusion

PFI thanks FDA for the opportunity to provide this comment. We also acknowledge the Agency's willingness over the past several years to engage with stakeholders throughout the FSMA rulemaking process. We share FDA's interest in realizing the goal of improved food safety through science- and risk-based regulations. We look forward to a continued and productive dialogue as the critical phase of FSMA implementation gets under way.

Sincerely,

Cathleen Enright, PhD
President

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