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

Re: Implementation of the Food and Drug Administration Food Safety Modernization Act Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug and Cosmetic Act (Docket No. *FDA-2013-N-0590)*

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Food Drug and Administration's (FDA's or the Agency's) Advance Notice of Proposed Rulemaking (ANPR) Regarding Implementation of the Food Safety Modernization Act (FSMA) Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug and Cosmetic Act (FD&CA), published in the Federal Register on March 25, 2014. (79 Fed. Reg. 16698)

Established in 1958, PFI is the voice of US cat and dog food manufacturers. PFI members account for more than 98 percent of the cat and dog food produced in the United States. Among its members are twenty-four dog and cat food manufacturers and more than 100 affiliates who supply ingredients and raw materials to dog and cat food producers. Our members sell more than $20 billion in dog and cat food annually, and export and additional $1.5 billion.

Pet food makers 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 FSMA and looks forward to working with FDA for the successful implementation of this landmark law. We appreciate FDA's engagement with stakeholders during the rulemaking process and its readiness to engage in open dialogue during the public comment period. 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 we discuss in this comment, PFI believes that a review of statutory and ANPR language indicates clearly that the RFR amendments developed under this ANPR should apply to human food only. In addition, we believe that FDA should make every effort to ensure that responsible parties are not burdened with sending additional information to the RFR if FDA already has the information it needs to alert consumers regarding a food that is the subject of a recall. We also believe that any requirements in this rule should specifically state that they apply only to reportable foods that are the subject of a Class I recall. Finally, this rule should apply only to foods that are available, or will be available, for sale to consumers in chain grocery stores or otherwise or available for sale to consumers at the retail food market.

Scope of "Consumer-Oriented" Information Submission and Notification

Section 211 of FSMA states that "the Secretary *may* require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food." The statute also includes provisions for grocery store notification to consumers, with specific steps chain grocery stores must take if they sold a reportable food that is the subject of a FDA one-page summary. FSMA does not define a "grocery store," but we believe the term is commonly used to refer to retail establishments that sell human food directly to consumers of such food where the food will be consumed off the premises. This commonly understood definition of grocery store, coupled with the discretion the statute provides to the Secretary as to who is a responsible party subject to additional reporting requirements under FSMA, makes clear that the scope of these requirements can and should be limited to human foods.

Moreover, the use of the terms "consumer" and "consumer-oriented" throughout both the statute and the ANPR indicate a focus on human food, since humans are consumers of human food, not food for animals. Throughout PFI's comments on other FSMA proposed rules, we have drawn the distinction among humans as consumers of human food, animals as consumers of animal food and humans as *customers* of both human and animal food. Humans will be the intended recipient of information posted in grocery stores, so limiting any RFR amendments to human food is consistent with the "consumer" and "consumer-oriented" focus in both FSMA section 211 and in the ANPR.

PFI believes strongly in the need for and effectiveness of existing food recall programs, including the FDA recall program and the Rapid Recall Exchange in which many food suppliers, wholesalers and retailers participate. PFI members routinely and proactively take steps to notify customers and the entire supply chain of a product that may pose a

risk of foodborne illness, so that the product can be quickly removed from circulation and to prevent its consumption. Section 211 of FSMA does not express any congressional intent that responsible parties under the RFR should include animal food producers. To the contrary, the use of the term "grocery store," the lack of any reference in the statute to food for animals and the use of the terms "consumer" and consumer-oriented" throughout the statute lead to the conclusion that improvements to the RFR should be limited to human foods sold by grocery stores. PFI therefore urges FDA to consider these points as it begins the rulemaking process to implement section 211 of FSMA.

Using the RFR to Alert Consumers

FDA notes that under the new Reportable Food Registry (RFR) requirements of the FD&CA under FSMA, FDA "may require a responsible party to also submit to FDA 'consumer-oriented' information regarding certain reportable foods, including information necessary to enable a consumer to accurately identify whether the consumer is in possession of a reportable food." (79 Fed Reg. 16698) Submission of this information will enable FDA to prepare and publish on its website a one-page summary of the consumer-oriented information that a grocery store can use to notify consumers of a reportable food.

The RFR, established under the FDA Amendments Act, is "an electronic portal that is used to submit mandatory and voluntary reports to FDA regarding 'reportable' foods." (79 Fed. Reg. 16699) The RFR reporting requirements apply to reportable foods not under the exclusive jurisdiction of the US Department of Agriculture, including human food and animal food/feed (including pet food) regulated by FDA. FDA notes, however, that the RFR is separate from FDA's recall food recall program – "the RFR gathers information to identify and track a reportable food in the supply chain." (79 Fed. Reg. 16699) The ANPR, following the statutory language, represents a critical addition to the function of the RFR, from a tracking mechanism to an element in the effort to inform consumers in the event of a potential public health emergency. PFI believes that any new function of the RFR should complement, but not duplicate, already existing tools and efforts the FDA has in place to ensure foods that pose a public health risk do not reach consumers.

Responsible Parties Should Not Be Required to Repeatedly Submit the Same Information to FDA

Responsible parties for reportable foods that are subject to a recall must already submit extensive information that is routinely made available to FDA in support of a recall effort.

As FDA states in the ANPR, the RFR, which "gathers information to identify and track a reportable food in the supply chain," is distinct from FDA's food recall program, which has been "the primary channel of food product safety communication between FDA, consumers, and others in the supply chain." (79 Fed. Reg. 16700) In addition, using the RFR as a method for grocery stores to convey consumer-oriented information must be done in concert with other effective systems already in place, such as the Rapid Recall Exchange, that were specifically designed to convey this important information quickly and efficiently to consumers. The current RFR system would have to be significantly modified to capture additional data, data that is captured by FDA and grocers through already existing food recall programs. Accordingly, PFI requests that responsible parties should not be required to submit to the RFR information for a reportable food that FDA already has through its network of district office recall coordinators.

New Requirements Should Apply to Class I Recalls Only

The RFR system is designed to provide a "reliable mechanism to track patterns of adulteration in food … [to] support efforts by the [FDA] to target limited inspection resources to protect public health." (Pub. L. 110-085, § 1005(a)(4)) The broad scope of the RFR means that it includes information related to many submissions that are not the subject of a (voluntary or mandatory) recall. Information for consumers should be limited to information that is essential to public health and safety – FDA indicates in the ANPR that the RFR was intended to "track patterns of adulteration in food … [in support of FDA's efforts to] target limited inspection resources to protect the public health." (Pub. L. 110-085, § 1005(a)(4)) Accordingly, PFI believes that amendments to the RFR regarding "consumer-oriented information" should be limited to foods that are the subject of a Class I recall only.

Additional Information Should be Required Only for Foods that Are Available or Will Be Available to Consumers

FDA notes that one of the purposes of the RFR is "to identify makers of foods sold at retail who have received an ingredient that is the subject of a reportable food report to stop shipment of possibly contaminated foods before they are sold at retail." (79 Fed. Reg. 16702) FDA seeks comments or other information regarding "whether FDA should require responsible parties to submit the consumer-oriented information described in section 417(f) for all reportable foods, *including those that have not been available, or will not be available, for sale to consumers in chain grocery stores or otherwise available for sale to consumers at the retail food market*." (79 Fed. Reg. 16702, emphasis added)

Congress, in the changes to section 417 of the FD&CA it mandates in FSMA, stresses the importance of "consumer-oriented information regarding a reportable food." (Pub. L. 111-353 § 211(a)(2)) Reportable foods may be (and often are) foods that are not available, or will not be available, for sale to consumers in chain grocery stores or otherwise available for sale to consumers at the retail food market. Accordingly, for FDA to require information related to such foods would provide no discernible benefit to consumers and might actually reduce the value of legitimate notices regarding reportable foods that do pose a public health risk by desensitizing consumers or "burying" information on products in the marketplace among irrelevant information regarding products not available for retail sale. PFI thus urges FDA to specify in any rule that responsible parties are only required to submit to FDA consumer-oriented information regarding reportable foods that are or will be available to consumers in chain grocery stores or otherwise available for sale to consumers at the retail food market.

Conclusion

PFI wishes to thank FDA for this opportunity to comment on FDA's ANPR regarding Implementation of the FSMA Amendments to the Reportable Food Registry Provisions of the FD&CA. We trust that these comments are received in the manner in which they were developed – with a shared interest in ensuring the continued improvement of the safety of the US supply of human and animal food. We look forward to continued dialogue on this and other topics that relate to FDA's implementation of FSMA.

Sincerely,

Duane Ekedahl
President

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