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May 22, 2014

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

Re: FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA (Docket No. FDA-2014-N-0053)

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Food Drug and Administration's (FDA's or the Agency's) Draft Approach for Designating High-Risk Foods as Required by Section 204 of the Food Safety Modernization Act (FSMA), published in the Federal Register on February 4, 2014 (79 Fed. Reg. 6596) and hereafter referred to as the "Notice" or "Draft Approach."

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, including approximately \$1.5 billion in exports.

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.

General Observations

Similar to our observations regarding proposed regulations FDA has recently issued for comment under FSMA, we find that this Notice and the approach it proposes are geared toward addressing risks associated with foodborne illness as it relates to human food. We agree with this approach since it is our contention, based on an examination of both recall information and foodborne illness data, that processed pet food that is subject to a pathogen mitigation/kill step does not pose a credible or significant human or animal food safety risk.

PFI members are continuously improving the safety and quality of their products, and we believe that available data demonstrate that virtually all categories of pet food do not constitute a significant food safety risk. We explain below why we believe this to be the case, first by analyzing the available data and then by applying the factors proposed in FDA’s Draft Approach to conclude that virtually all pet food categories merit a low-risk designation.

While we agree that reliance on the statutorily defined factors and existing scientific data is a sound approach to identifying high-risk foods, PFI has concerns with respect to FDA’s proposed Procedure for Designating HRFs. Specifically, we seek more information regarding the process described in Factor 2 to “develop a comprehensive list of food-hazard pairs representative of FDA regulated foods or food categories.” Will the development of this list be open to stakeholder participation? PFI requests that FDA share information regarding this development of food-hazard pairs, including a timeline and opportunities for stakeholder input, participation and review of these food-hazard pairs.

FDA and CDC Data Demonstrate the Insignificant Role Pet Food Plays in Foodborne Illness in the United States

The FDA, on its website and regularly in public meetings related to FSMA, cites alarming figures with respect to the risks posed to Americans by foodborne illness each year. Specifically, FDA’s own data indicate that there are over 48 million cases of foodborne illness annually in the United States, resulting in an estimated 128,000 hospitalizations and 3,000 deaths.¹

Pet food has a strong record of safety, and PFI members strive to improve the safety of our products, in an ongoing effort to ensure they do not contribute to human or animal illness. Data from FDA and the Centers for Disease Control and Prevention (CDC) indicate that, although there is always room for improvement, we have been largely successful in our efforts to market safe, high quality dog and cat food. PFI members take very seriously the data in the Fourth Reportable Food Registry (RFR) Annual Report, which shows a slight increase in reports filed for animal food/feed (including pet food). We also note that FDA’s own collection

¹ (Foodborne Illness-Causing Organisms in the U.S. – What You Need to Know, found at <http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM187482.pdf>) Both FDA and the US Department of Agriculture have launched aggressive campaigns aimed at reducing the number of foodborne illnesses, with special emphasis on *Salmonella* and its role in foodborne illness.

and analysis of pet food found that only 2.23% tested positive for *Salmonella* spp. in fiscal year 2012₂ and that no human illnesses were attributed to dog or cat food during this period or during the period covered in the most recent RFR Annual Report.

FDA data show that dog and cat food has played a role in approximately 192 human illnesses since 1999 (with zero fatalities), an average of less than 15 per year. Even assuming an average of 15 confirmed human illnesses per year attributed to pet food since 1999, pet food-related illnesses represent 0.00003 percent of the 48 million cases of foodborne illness reported annually in the United States. These data alone should provide the basis for FDA to conclude that pet food as a category does not merit the high-risk food designation.

FDA in this Notice requests comments, scientific data and information from stakeholders, in particular “with regard to evaluating risk associated with animal food.” It is unclear whether the evaluation of risk associated with animal food should include risks to the animal for which the animal food is intended. PFI has undertaken a review of available information and believes strongly that the evaluation of risk associated with animal food should be limited to risks to humans. First, there is no reliable source of information or reporting at the national level for foodborne animal illnesses or hospitalizations. Second, these animal illnesses and hospitalizations rarely result in confirmation of the cause of the animal illness being directly attributed to food. Third, an evaluation of the risk to humans associated with animal food is a very good indication of the risks to animals for which an animal food is intended. PFI thus seeks confirmation from FDA that the evaluation of risk associated with animal food will not include risks to the animal for which the animal food is intended.

Based on this data-driven comparison of the foodborne risks posed by pet food, along with a review of illnesses related to foodborne hazards, it is clear that pet food poses an insignificant risk to humans and to their companion animals. PFI trusts that FDA agrees with this review and determination that pet food poses a low risk under the approach proposed in this Notice.

PFI has examined FDA’s iRISK food safety modeling tool (FDA- iRISK®). FDA describes FDA- iRISK® as “an interactive, Web-based system ... to enable users to relatively rapidly conduct fully quantitative, fully probabilistic risk assessments of food-safety hazards” (both microbial and chemical). Although there are elements of the model that could be populated for pet food, (e.g., initial contamination levels, process steps that may affect (increase or decrease) contamination levels, and final concentrations in the pet food), and several dose-response models are provided for *Salmonella*, the entire model breaks down with respect to “consumption.” Humans do not “consume” pet food (e.g., there is no such thing as number of servings per day or per year, or size of servings, as required by the model). Furthermore, it does not appear that the iRISK model can be used to estimate risk from routes of exposure other than direct ingestion, such as hand-to-mouth activity. Thus, PFI does not see how iRISK can be used to evaluate the potential risk of microbial (or any other) contamination in pet food.

² FDA CVM Presentation to the 2014 International Production and Processing Expo. January 28, 2014. Slide 22.

PFI also notes that, while the mechanics of inputting information into the iRISK tools are straightforward, the iRISK tutorial does not explain the basis for any of the input assumptions provided in the example, nor does there appear to be any way to evaluate how the system is using the input values to perform the calculations. Instead, the input information is “submitted” to the system, calculations are done in a “black box” and a report is “returned.” [Note: When an attempt was made to run the model, more than 30 minutes after submission of the request, the system still stated results were “pending.”] Based on the foregoing, PFI believes that, while the iRISK tool may be useful in evaluating foodborne illness risks posed by human food, it is not an appropriate or effective tool for evaluating animal food.

Food and Food Commodity Classification

FDA’s RFR is cited in the Notice as one source of information FDA will use to designate high-risk foods. FDA also proposes to base the classification of foods or categories of food for risk ranking on the RFR commodity definitions. The RFR classification of foods or categories of food for risk ranking identifies animal food/feed, which includes a very wide range of products that may pose a diverse range of risks. To facilitate accurate identification of high-risk foods and in order for FDA and the animal food industry to devote resources in the most efficient and effective manner, PFI proposes that FDA differentiate between processed and unprocessed animal food, with processed animal food including all animal food that has been subjected to a pathogen mitigation/kill step. Below we explain why this approach is justified and how it will lead to a more effective and efficient application of the high-risk foods designation process.

The current RFR Commodity Definition groups Animal Food/Feed (including pet food) into one broad category. However, for the purpose of creating a risk ranking system, PFI believes such a broad commodity classification will not facilitate the accurate definition of high-risk foods. Many animal foods, including many pet foods, are subjected to a pathogen mitigation/kill step designed to eliminate the presence of pathogens of significance to human and animal health. Animal foods that are not subjected to a pathogen mitigation/kill step, including raw diet pet foods, may pose a greater risk to human and animal health. The potential foodborne illness risk posed by animal foods such as raw diet pet foods is described in more detail below.

Raw diets consist of foods such as meat, poultry, milk and eggs that have not been cooked or treated to remove harmful bacteria, including *Salmonella* and *Campylobacter*.³ The FDA’s Center for Veterinary Medicine (CVM) has expressed concern regarding the potential health risks associated with raw diet pet foods. In its “Manufacturing and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores” guidance for industry, CVM recommends that, “for firms choosing to manufacture and market raw meat and raw animal tissue products for animal food, more specific guidance is warranted for how such products could be manufactured and labeled in order to protect animals and people coming in

³ May, Kimberly, Dr. " Raw Pet Foods and the AVMA's Policy: FAQ." *Raw Pet Foods and the AVMA's Policy: FAQ*. American Veterinary Medical Association, Aug. 2012. Web. 06 May 2014. Page 2.

contact with the animals and the animal’s food from risks involving food safety.”⁴ In support of its industry guidance, CVM cites “[o]ne study of 112 samples of raw meat diets manufactured for racing greyhounds[, which] isolated *Salmonella* spp. from 50 of the samples (45%) and determined 70 of 106 samples (66%) to be positive for *Salmonella* spp. by DNA probe analysis.”⁵ CVM’s guidance concludes that “the FDA does not believe raw meat foods for animals are consistent with the goal of protecting the public from significant health risks, particularly when such products are brought into the home and/or used to feed domestic pets.”⁶

Additionally, the American Veterinary Medical Association (AVMA) cites studies that indicate that a pet fed a raw meat diet can become a carrier of pathogens associated with food safety hazards, even if the pet does not exhibit signs of illness.⁷ One such study, also published in the *Canadian Veterinary Journal*, involved 91 dogs, 42 of which were fed raw meat diets; the remaining 49 were fed processed pet food diets. The study showed that 6 of 42 (14.3%) stools of dogs fed the raw meat diet tested positive for *Salmonella*, compared with 0 of 49 for dogs not on a raw meat diet.⁸ Because of these potential risks, the AVMA stressed the importance of a processed food diet, concluding that “[c]ommercial foods are nutritionally balanced and they undergo a process of quality control/inspection that is meant to catch any contaminants or pathogens before they affect pets or people.”⁹

Lisa Freeman, DVM, PhD at Tufts University has conducted considerable research on pet nutrition, including raw meat diets. Based in part on her research, Tufts University’s Cummings School of Veterinary Medicine states that:

“[a]t this time, there are no scientific studies showing any health benefits of raw meat diets. However, studies show that there are significant risks to feeding raw meat diets. For example, one study demonstrated that all homemade and commercial raw food diets tested had multiple nutritional imbalances. ... In addition to these risks, recent scientific studies have shown that nearly all raw meat diets (whether commercial or homemade) are contaminated with bacteria, with between 20-44% of commercial raw food diets contaminated with *Salmonella*.”¹⁰

These studies have led the American Animal Hospital Association (AAHA), National Association of State Public Health Veterinarians (NASPHV) and the American Association of Feline Practitioners (AAFP), to take a firm stance discouraging pet owners from feeding their

⁴ Food and Drug Administration. Center for Veterinary Medicine. Guidance for Industry: MANUFACTURE AND LABELING OF RAW MEAT FOODS FOR COMPANION AND CAPTIVE NONCOMPANION CARNIVORES AND OMNIVORES. N.p., 9 Nov. 2004. Web.

⁵ Food and Drug Administration. Center for Veterinary Medicine. Guidance for Industry: MANUFACTURE AND LABELING OF RAW MEAT FOODS FOR COMPANION AND CAPTIVE NONCOMPANION CARNIVORES AND OMNIVORES. N.p., 9 Nov. 2004. Web.

⁶ May, Kimberly, Dr. " Raw Pet Foods and the AVMA's Policy: FAQ." *Raw Pet Foods and the AVMA's Policy: FAQ*. American Veterinary Medical Association, Aug. 2012. Web. 06 May 2014. Pages 1-2.

⁷ May, Kimberly, Dr. " Raw Pet Foods and the AVMA's Policy: FAQ." *Raw Pet Foods and the AVMA's Policy: FAQ*. American Veterinary Medical Association, Aug. 2012. Web. 06 May 2014. Page 5.

⁸ Lenz, Jennifer. "Perceptions, Practices, and Consequences Associated with Foodborne Pathogens and the Feeding of Raw Meat to Dogs." *Canadian Veterinary Journal* 50 (2009): 639. Web. 6 May 2014.

⁹ May, Kimberly, Dr. " Raw Pet Foods and the AVMA's Policy: FAQ." *Raw Pet Foods and the AVMA's Policy: FAQ*. American Veterinary Medical Association, Aug. 2012. Web. 06 May 2014. Page 4.

¹⁰ Freeman, LM and Michel, KE. "Raw Meat Diets." Tufts University Cummings School of Veterinary Medicine. Web. Page 1.

pets raw food diets.¹¹ The CDC, too, has warned the public that “[r]aw diets, especially raw meat diets, are not recommended because of the risk for salmonellosis and other infections that can affect pets and their owners.”¹²

Raw diet pet foods serve to illustrate the risks that unprocessed animal foods pose to humans and to animals. It is the use of a pathogen mitigation/kill step that sets processed animal foods, including feed, apart from animal food that is not subjected to a pathogen mitigation/kill step. The differentiation between animal foods that have and have not been subjected to a pathogen mitigation/kill step must be an essential part of the assessment of foods to determine foodborne illness risk and will assist FDA in its efforts under FSMA section 204(d)(2)(A) to identify high-risk foods.

Application of FDA’s Risk Model Criteria and Scoring to Pet Food

In order to identify high-risk foods, FDA proposes a draft risk model in the Notice that includes the following criteria that account for factors (i) through (vi) identified in section 204(d)(2)(a) of FSMA: “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.” PFI applied these criteria to processed pet foods that our members produce and we share the results of this exercise below. We are confident that the application of these criteria to our members’ products provides a clear indication that these products do not merit the high-risk foods designation. The following table provides our scoring and analysis of dog and cat food under each of the proposed criterion.

¹¹ May, Kimberly, Dr. " Raw Pet Foods and the AVMA's Policy: FAQ." *Raw Pet Foods and the AVMA's Policy: FAQ*. American Veterinary Medical Association, Aug. 2012. Web. 06 May 2014. Page 2.

¹² May, Kimberly, Dr. " Raw Pet Foods and the AVMA's Policy: FAQ." *Raw Pet Foods and the AVMA's Policy: FAQ*. American Veterinary Medical Association, Aug. 2012. Web. 06 May 2014. Page 2.

Factor	Processed Animal Food*	Unprocessed Animal Food*	Notes/Comments
Occurrence of illness	3	1	<p>FDA proposes that this criterion would be applicable to both microbial and chemical food safety hazards, focusing first on acute effects as well as “the public health impact of chronic exposure to chemical hazards.” PFI applied the formula presented in Figure 2 of the Draft Approach, which provides scoring for the frequency of outbreaks and the occurrence of illnesses for a food-hazard pair. Pairing <i>Salmonella</i> spp. (as the hazard) with processed animal food, PFI’s review of government, academic and industry data found that our members’ products are not a significant contributor to either outbreaks or illnesses. As noted earlier in this comment, pet food products have been implicated in five reported outbreaks, resulting in 192 confirmed cases of foodborne illness, with no fatalities, since 1999. Of these 192 confirmed cases, 128 were associated with dry (processed) pet food and 64 were associated with chews. Again, we must recall that the number of illnesses associated with pet food since 1999 is less than fifteen per year, constituting about 0.00003 percent of the 48 million foodborne illnesses reported annually in the United States.</p>
Severity of illness	1	1	<p>FDA proposes that available data on hospitalization and mortality be used for severity scoring, citing Scallan et al (2011) as a possible source of such data. Scallan et al (2011) indicates that <i>Salmonella</i> spp. (nontyphoidal) had a hospitalization rate of 27.2 percent and a mortality rate of 0.5 percent. The data presented by Scallan et al (2011) indicate that <i>Salmonella</i> spp. are indeed significant contributors to serious foodborne illness in the United States, accounting for approximately 1 million illnesses, 19,000 hospitalizations and 378 deaths annually.</p> <p>Applying the scoring method proposed in Table 1 of the Draft Approach to processed animal food produced by PFI members, the rate of hospitalizations (approximately 19,000 of approximately 1,000,000 illnesses) is approximately 1.9 percent and the mortality rate (378 of approximately 1,000,000 illnesses) is approximately 0.0378 percent. These figures would produce a score of 1 for <i>Salmonella</i> spp., the hazard for which FDA has a stated zero tolerance policy in pet food.</p>
Likelihood of contamination	3	9	<p>FDA states that “[s]ection 204(d)(2)(A)(v) of FSMA requires consideration of the likelihood that consuming a particular food will result in a foodborne illness due to the contamination of the food.” A variety of resources is listed for determining the likelihood of contamination for microbial hazards. PFI notes that all of these resources (Anderson et al (2011), Gombas et al (2003), USDA Microbiological Data Program and FDA surveillance data) relate to human food that may pose a hazard. FDA notes that, “[w]here data are not available for contamination rate, other indicators for contamination would be used for scoring, e.g., RFR reports, FDA recall database, and FDA compliance programs.”</p> <p>Since most of the resources FDA identifies for the determination of likelihood of contamination do not include information related to animal food, PFI has reviewed the RFR reports, FDA’s recall database and FDA compliance programs. As noted earlier in our comments, whether an animal food has been subjected to a pathogen mitigation/kill step is critical to an accurate assessment of the risks each food poses. FDA’s own collection and analysis of pet food indicates that the likelihood of contamination was around 2.23% in fiscal year 2012. Commercially sterile canned pet food product, which is subject to 21 CFR Part</p>

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			113 for low acid canned food (LACF) regulation, should always test negative for pathogens due to the heat process to which it is subjected. FDA’s sampling and testing of raw diet foods and unprocessed chews showed a significant prevalence of <i>Salmonella</i> .
Growth potential/shelf life	1	9	<p>FDA proposes this criterion to account for the fact that “[f]oods differ in shelf life and their ability to support pathogen growth.” FDA notes that a score of zero would be given to a food-hazard pair in which the hazard is a chemical or an allergen, a microbial hazard of such a nature that it does not replicate in food (e.g., viruses and parasites), or the food does not support pathogen growth.”</p> <p>Processed pet foods typically have a shelf life up to two years depending on package type, much longer than the shelf life of foods commonly associated with foodborne illness, including produce. These pet foods are subjected to a pathogen mitigation/kill step designed to eliminate <i>Salmonella</i> spp. and FDA’s own collection and analysis indicate these treatments are overwhelmingly effective.</p>
Contamination probability	1	9	<p>This criterion is designed to address “the ability to control contamination that could be introduced during the manufacturing process” ... including “hazards that may be introduced during manufacturing, in particular for products that do not receive an adequate kill step, ... or products that are exposed to the processing environment post-lethality.” FDA also provides qualitative guides for both contamination probability and steps taken to reduce contamination. The guides serve as the parameters for the scoring of foods to determine risk.</p> <p>As discussed earlier in our comments, the distinction between animal foods that undergo processing that includes a pathogen mitigation/kill step and those that do not is critical when determining which foods pose a high-risk under FSMA section 204(d)(2)(A). Processed pet foods – including dry and semi-moist pet food, wet (heat processed) pet food and treats – are subjected to pathogen mitigation/kill steps. Industry and FDA collection and analysis data indicate these methods are very effective, with only 2.23 percent of pet food sampled and tested by FDA found to contain <i>Salmonella</i> spp. Conversely, FDA’s data from its own sampling and testing indicate that animal foods not subjected to a pathogen mitigation/kill step, such as raw diet pet foods, routinely test positive for <i>Salmonella</i> spp.</p>
Consumption	0	0	<p>FDA indicates in the Draft Approach that contaminated foods “that are consumed frequently are more likely to cause widespread outbreaks” and that for scoring purposes, “consumption would be defined as the percent population consuming the food.”</p> <p>PFI strongly believes that analysis of consumption for the purpose of assigning risk must be based on consumption of the food by the human or animal for which the food is intended. Pet food is intended for consumption by companion animals, not humans. PFI likewise believes that any analysis of animal foods must be limited to human illnesses only – no accurate, reliable data exists regarding consumption of potentially contaminated animal food by target animals to make any determination of foodborne illness risk to that animal.</p> <p>As mentioned earlier in our comment, FDA data suggest that pet food is associated with fewer than fifteen human illnesses per year and that these illnesses may be attributed to contact with contaminated pets or pet food, not consumption of contaminated pet food.</p>
Economic Impact	0	0	For this criterion, FDA seeks to use the estimated annual incidence and illness cost and premature mortality “to calculate the annual costs of illness attributed to food-hazard pairs.”

			<p>FDA states that this criterion “may consider additional economic factors such as lost productivity and lost utility due to foodborne illness.”</p> <p>Similar to the our points made above with respect to consumption criteria, PFI firmly believes that this analysis is only appropriate and can only be undertaken for humans. Available data indicate that pet food is potentially associated with less than fifteen human illnesses per year (and that this figure is dropping). There are no known deaths associated with these human illnesses. Applying the factors FDA proposes to use – costs of diagnosis, medical treatment, lost quality adjusted life years and premature mortality – to determine economic impact, PFI concludes that all pet food would score a zero for this criterion.</p>
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* PFI’s analysis of processed versus unprocessed animal food is limited to dog and cat food. It is PFI’s contention that all animal food would score similar based on whether it has been subjected to a pathogen mitigation/kill step.

The scoring targets or ranges for low, medium and high risk foods (totals for scores in each range) are the following: 7 for low-risk; 21 for medium-risk; and 63 for high-risk. Applying the Draft Approach criteria to processed and unprocessed animal food and totaling the scoring for each criterion yields the following results: processed animal food: 9; unprocessed animal food: 29. Based on this analysis, animal foods subjected to a pathogen mitigation/kill step would be designated as low-risk. These results are consistent with FDA and industry data, which indicate a low (and dropping) incidence of hazards associated with all pet foods (except for raw diet foods) and a very low correlation between pet food and human illness. PFI believes the application of the proposed Draft Approach criteria to animal foods, with attention paid to whether the animal food has been subjected to a pathogen mitigation/kill step, will lead to the efficient and effective allocation of FDA and industry resources to address legitimate food-hazard pairs that pose actual human illness concerns.

Conclusion

PFI wishes to thank FDA for this opportunity to comment on FDA’s Draft Approach for designating high-risk foods under section 204 of FSMA. We trust that we have demonstrated, by referring to FDA data, publicly available research and through application of the Draft Approach proposed criteria, that animal food, including pet food that has been subjected to a pathogen mitigation/kill step, poses a very low foodborne illness risk to humans and animals. We look forward to continued dialogue on this and other topics that relate to FDA’s implementation of FSMA.

Sincerely,



Duane Ekedahl
President

Pet Food Institute Members

Ainsworth Pet Nutrition	Merrick Pet Care, Inc.
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Bil-Jac Foods, Inc.	Ohio Pet Foods, Inc.
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