June 30, 2014

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Via Regulations.gov

Re: Docket No. FDA-2013-N-1425 and RIN 0910-AG63 Focused Mitigation Strategies To Protect Food Against Intentional Adulteration

Dear U.S. Food and Drug Administration:

The American Feed Industry Association (AFIA), founded in 1909, is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the United States animal feed industry and its suppliers. AFIA is a nonprofit organization that represents more than 575 feed and pet food manufacturing and supplier companies, regional and state associations and international firms. Member companies represent more than 75 percent of all commercial feed manufactured and supplied to the U.S. market and consist of livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, feed additive suppliers, equipment manufacturers and companies, which supply other products, services, and supplies to feed manufacturers.

The feed industry makes major contributions to food and feed safety, nutrition and the environment, and it plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. In addition to commercial feed and pet food, approximately 70 percent of the non-grain ingredients, including soybean meal, distillers co-products, vitamins, minerals, amino acids, yeast products and other miscellaneous/specialty ingredients are also manufactured by AFIA members.

AFIA's primary founding purposes were to promote and assure feed safety and to promote harmonization of all state feed laws with uniform labeling and regulations. Today, every state except Alaska has a feed law based on the Association of American Feed Control Officials' Model State Feed Bill. AFIA and its predecessor organizations have developed a number of animal food safety programs, the latest of which is AFIA's Safe Feed/Safe Food Certification Program.

Nearly all AFIA members that manufacture, process, pack or hold animal food are registered with the U.S. Food and Drug Administration under the Bioterrorism Act. These registered facilities are very interested in these proposed rules and must comply with all final animal food specific rules that FDA issues. Therefore, rules promulgated under the Food Safety Modernization Act (FSMA) impact AFIA members, and these comments represent their views.

AFIA is committed to a continuing dialogue with FDA on FSMA rules and implementation. We are also strongly committed to a full and successful implementation of FSMA across all our varied industries. We greatly appreciate FDA's approachability, openness to new ideas, offers to discuss the rules and assistance in notifying our members of the law and rules via FDA's participation at our meetings and webinars. We look forward to more cooperation as the rules are finalized and implemented.

FSMA Background

FSMA represents a shift towards prevention through risk-based preventive controls rather than focusing on the response to contamination. AFIA fully supports this tenet of FSMA, which is why AFIA advocated for passage of the law. Industry shares FDA's goal of preventing the adulteration of food before it ever happens.

The proposed FSMA rule on "Current Good Manufacturing Practices and Hazard Analysis Risk-Based Preventive Controls for Food for Animals" provides several important foundations for food safety. Although AFIA provided extensive revisions, the association values hazard identification, preventive controls and good manufacturing practices that are relevant, practical and based on actual industry practices. It is crucial, however, that they are reflective of the potential risk. AFIA offered major revisions to the animal food rule to ensure it was appropriate for animal food, rather than human food. Every type of known or reasonably foreseeable hazard—be it microorganisms, hazardous debris, mycotoxins or terrorist action—has a unique level of risk associated with it. The extent of that risk is dependent on a plethora of factors.

Risk varies by facility, which is why FDA is proposing each facility to have a food safety plan, identify any hazards and design and implement a system of preventive controls. AFIA has already begun training seminars for industry to aid facilities in developing these plans. Risk also varies by species, which is why FDA requires animal food label information and instructions for the intended animal species. What is nutritious for a ruminant cow may not be nutritious for a pig. Sheep, for example, have an increased sensitivity to copper. Risk varies between humans and animals as well. For example, humans can be allergic to a host of things from peanuts to shellfish, while animals simply do not have this same risk.

When it comes to the particular risk of intentional adulteration, there is even more separation between humans and animals as the proposed rule is aimed at preventing intentional adulteration from acts intended to cause massive public health harm, including acts of terrorism. Congress recognized this when it created section 418 (m) in the Federal Food, Drug, and Cosmetic Act (FD&C Act), which provides for the option for exemption or changes between animal and human preventive control rules. Because risk is significantly different between humans and animals, Congress specifically allowed for modified requirements for animal food.

Proposed Exemption

In creating Section 420 in the FD&C Act, FSMA required FDA to establish regulations for facilities to consider the potential risk of intentional adulteration of food. Part C indicates that the

secretary shall make these rules applicable only to food "for which there is a high risk of intentional contamination, as determined by the Secretary, in consultation with the Secretary of Homeland Security, under subsection (a), that could cause serious adverse health consequences or death to humans or animals…." FDA has concluded in this proposed rule that animal food is not at a high risk for intentional contamination.

Indeed, if intentional contamination does occur, the threat of serious adverse health consequences or death to humans or animals is significantly less when compared to other scenarios. AFIA supports this conclusion by FDA and its proposed exemption for animal food. FDA has made the appropriate distinction in determining the level of risk between humans and animals in consultation with the Department of Homeland Security (DHS), and is recognizing this distinction as Congress intended.

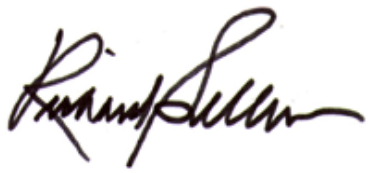
This distinction between human and animal food is supported by the purpose of the proposed rule—which FDA has indicated is "to protect food from intentional adulteration when the intent is to cause large-scale public harm." More specifically, FDA should distinguish between human food and animal food in this intentional adulteration proposed rule because animal food has a significantly lower risk of impacting *human* health. Clearly, a terrorist organization contaminating animal food could cause harm to animals, however, it is highly unlikely any contaminant would have the same effect on humans.

Moreover, the effects of contaminants fed to meat, milk or egg-producing animals would likely be observed in those animals well before any risk to humans would occur. Even pet food does not rise to the same level of risk as human food when considering foreseeable targets for terrorist organizations. The statute states that these regulations "shall apply only to food for which there is a high risk of intentional contamination." Animal food simply does not meet that level of risk. In the end, this proposed rule is about health safety risks to humans. Animal food does not present a high health safety risk to humans.

AFIA is not aware of any additional data that FDA and DHS would not have already considered that would change this conclusion and again reiterates that it fully supports FDA's conclusion to exempt animal food from this proposed rule on intentional adulteration.

AFIA appreciates FDA's consideration of these comments.

Sincerely,



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