

**PET FOOD INSTITUTE**

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March 24, 2003

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

Re: Docket No.02N-0276

Dear Sir or Madam:

On behalf of its members, the Pet Food Institute (PFI) presents the following comments in response to the Food and Drug Administration's Notice of Proposed Rulemaking entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Bioterrorism Act) (68 Federal Register 5428, February 3, 2003). PFI represents companies that manufacture 97 percent of the dog and cat food sold in the United States, a \$12.5 billion industry. PFI supports the agency's activities to implement the provisions of the Bioterrorism Act and stands ready to support the overall efforts of the government to improve the safety of the nation's food and feed supply. However, the proposed rule, as currently drafted, would impose a number of burdens on the US pet food industry and its suppliers that would not contribute to the overall goal of improved food safety.

PFI joins with a number of other food and feed-related trade associations who view the proposed rule as going beyond the statutory authority granted by the Bioterrorism Act. Though the goals of the rule are laudable, their effect on the food and feed industry, as well as consumers, will be quite damaging. For example, and as PFI will comment in more detail below, the proposed rules will require a vast network of registrations and recordkeeping for domestic and

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international companies, that will do little to prevent or reduce a bioterrorism event. The importation of food from foreign facilities that lack registrations, for whatever reason, will be refused and the US importer held liable for costs even though it has no responsibility to register foreign facilities. These are but two of the possible consequences of this rule unless it is modified to prevent grave disruptions in the supply of food to consumers.

PFI's comments on the proposed rule will be presented in sections corresponding to the general provisions of the proposed rule. Some of the comments utilize examples of situations faced by pet food companies that may present unique challenges from other food producers and processors. In addition, within each section of these comments, PFI presents questions on the proposed rule that require clarification.

### **Exemptions**

In its discussion under the General Provisions section of the proposal, the exemptions to the registration requirement includes "restaurants" and "retail facilities." (p. 5383). In this section the exemption for restaurants includes "pet shelters, kennels and veterinary facilities in which food is provided to animals." However, in the actual text of the proposed rule (p. 5418) §1.227(c)(10) does not include "pet shelters, kennels and veterinary facilities in which food is provided to animals" in the definition for restaurant. PFI would request that these explicit exemptions to the registration requirement also be included in the final text of §1.227(c)(10).

In addition to questions on the applicability of the restaurant exemption, the exemptions explained in the section on General Provisions that apply to any "retail facility" in proposed §1.227(c)(11) include facilities that sell "food" directly to consumers. (p. 5383). In this section, the FDA requests comments "on whether this exemption should also be applied to food for animal consumption." Since "food" is defined in §1.227(c)(4) to include "animal feed, including pet food, food and feed ingredients and additives," the exemption on registration applied to retail facilities would

apply to facilities that sell animal feed and pet food, regardless of the legislative history to the Bioterrorism Act.<sup>1</sup>

### **Foreign Shipments**

Under the Bioterrorism Act, the FDA is required to hold imported products from facilities in foreign countries that have not registered. The financial liability for such a hold lies not with the importing firm, but with the US company bringing the material into this country. This portion of the rule imposes financial penalties on US importers who are not able to enforce the rules provisions and require foreign entities to register. By holding the exporter liable for the detention of products, the Agency would have additional leverage to illustrate the importance of foreign facility registration.

### **Updates to Registrations**

The proposed rule states that facilities must update their registration information with the Agency "within 30 calendar days of any change to any of the information previously submitted" (§1.234). The proposed rule also states that a firm must update its registration if it ceases operations. PFI would request a clarification of this suspension in operations. For example, if a facility ceases production due to prolonged weather conditions, renovations or fumigations, would it be required to update its registration for that period of time?

### **Suspension of Registrations**

The proposed rule also requests comments on the FDA's authority to suspend a facility's registration. PFI does not believe that the Agency can suspend a facility registration for any reason other than a failure to provide information required under the

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<sup>1</sup> In addition, §1.227(c)(2) defines "facility" as an "establishment, structure or structures . . . that manufactures/processes, packs or holds food for consumption in the United States" and does not offer another definition for "food." PFI would argue that the agency intends "food" in this (continued) instance to be the same as "food" used in §1.227(c)(11). Therefore, a pet food "facility" would be required to register while a pet food "retail facility" would clearly be exempt.

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Bioterrorism Act. The Agency should not use the registration provisions of the Act as an enforcement tool for other violations of Agency rules. Civil and criminal penalties are already available to the agency and administrative hearing and appeals processes are also available to regulated industries. The suspension of a registration amounts to an additional punishment for infractions not necessarily covered by the Bioterrorism Act. In addition, PFI would urge the Agency to continue its aggressive education program to inform regulated facilities, particularly those in other countries, of their obligations under the Bioterrorism Act.

### **Conclusion**

PFI appreciates the opportunity to offer comments to this proposed rule implementing the prior notice provisions of the Bioterrorism Act. PFI will continue to work with the Agency and other federal and state government divisions to further increase the safety of the country's food supply. The Bioterrorism Act contains a number of provisions that can, if carefully implemented, accomplish improvements in food security. PFI, along with many other food and animal feed-related trade associations, commends the Agency's efforts in developing the proposed rule ahead of the statutory deadline. The proposed rule, however, needs to be completely considered in light of all the comments received by the Agency to determine if it meets its statutory requirement and does not duplicate the security efforts of other federal agencies. The goal of the final rules issued by the FDA should be an improvement in the safety and security of the nation's food and feed supply while not imposing over-reaching and unnecessary burdens.

Sincerely,



Duane H. Ekedahl  
Executive Director