



American Pet Products Manufacturers Association, Inc.®

April 4, 2003

Stuart Shapiro
FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
New Executive Office Building
Room 10235
725 17th St. NW
Washington, DC 20503

Submitted to:

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

Re: Docket No. 02N-0278 --Notice of Proposed Rulemaking - Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 Fed. Reg. 5428, February 3, 2003)

Dear Mr. Shapiro:

The American Pet Products Manufacturers Association, Inc. (APPMA) is a trade association representing approximately 650 pet product manufacturers. Close to 40% of our members are small manufacturers, i.e., with gross annual sales of less than \$500,000 nationally. We represent many larger manufacturers as well. Our industry employs more than 250,000 individuals in the manufacturing, distribution and marketing of pet products, many of which include manufacturers who make pet food, treats, supplements, as well as, other pet care products necessary for the health and welfare of companion animals. A national survey of pet owners conducted by APPMA shows that there are as many as 280

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million pets in the United States and that 62% of American households have at least one pet. **Be they furry, feathered or finned, Americans love their pets.**

Moreover, this year, APPMA hosted the largest annual pet products trade show in the world, distinguished in the Trade Show 200, a listing of the largest shows in America. In fact, 8,000 visitors came to see products from all over the world on a show floor totaling 300,000 gross square feet. Our exhibitors provide animal food products to American consumers that can be made overseas or include ingredients or components from overseas. The APPMA Show is a three-day event in which it is critical that exhibitors are able to ship product into the US in a timely fashion, show products in booths and otherwise pursue trade freely as permitted by law.

APPMA appreciates the opportunity to submit these comments regarding the above-referenced proposed rule for the prior notice of imported food. The US Food and Drug Administration (FDA) was given a challenging and worthy task in implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C. 331 et seq. (2002), especially given such a short timeframe for publication of final rules. We fully support the need to safeguard the US food supply from terrorist threats and acts and hope to contribute to the maintenance of controls already in place to assure this. However, we believe that sections of the proposed rule are overly burdensome without providing added protections that the Act intends.

Our industry has weathered policy changes as a result of animal health crisis in Europe from bovine spongiform encephalopathy and foot and mouth disease. Labor strikes at US seaports also caused significant delays and loss for our industry. Now our members are being asked to comply with prior notice requirements that are overly detailed on a new unfamiliar system that has not been tested.

The rule should focus on the information required by the Act that includes basic product, manufacturer, shipper, and grower identification, as well as, specification of country of origin, country from which the article was shipped, and anticipated port of entry. In requiring this information, Congress's intent was to enable FDA to inspect food articles at ports of entry for potential hazards related to terrorist threats or acts upon the US food supply. In contrast, FDA is asking for information that is, in many cases, not only unavailable to the incumbent notice provider, i.e., the importer or purchaser, but will make prior notice reporting so cumbersome that the added cost will slow US trade.

In addition, the timeframe for prior notice is not flexible and will cause certain inadvertent and unintentional violations of the rule. The prior notice proposed

rule suggests that submissions should be completed no more than 5 days before arrival but no later than noon on the calendar day before the shipment's arrival. These limited parameters will hamper the free flow of trade because importers will be required to constantly monitor the progress shippers and common carriers are making on long hauls. It is unclear whether importers currently have the capability to obtain information precise enough to properly gauge arrival times. In contrast, shippers from neighboring Canada and Mexico will be required to provide prior notice 36 hours before border-crossing, another example of an impracticable situation. In addition, it will be very costly in the event that an unseasoned importer does not fully comply. Holding products at the port of entry or at a secure location will result in not only storage charges but also the loss of precious time in delivery.

Also, in many instances, pet product manufacturers will employ overseas facilities for only a portion of the processing of products that originate in the US; are in the continued custody of the US-based manufacturer or agent; and are then returned to them. For example, rawhide manufacturers often start with US beef cattle and have the rawhide processed in a neighboring Mexico or Canada. It is then returned for packaging or further processing. Since rawhide treats are fungible and interchangeable, in many cases, the rawhide batch coming back over the border will include products that will later be apportioned, partly for export and partly for domestic sales. However, there is no way to know at the stage where it comes back into the US.

Moreover, relying on only one means of providing prior notice could jeopardize the steady flow of information and goods if the electronic system is down. In fact, there is the likelihood that the FDA electronic registration system will be overloaded by the immense and unprecedented volume of activity it, presently, has no way of calculating. This is compounded by the fact that many importers responsible for prior notice requirements may be unfamiliar with Internet-based reporting and be unable to access the system online without professional assistance and/or translation into their native language and then back again into English for completion. Lastly, FDA provides no other mechanism for importers who are unable to gain access to Internet services for these purposes. In the end, should the system fail, the purpose of the Act will not be fulfilled because FDA will not have had a fallback that a more flexible system could provide. Therefore, APPMA strongly urges the Agency to consider alternative modes of fulfilling prior notice requirements other than relying on a new single electronic reporting system.

FDA should consider alternatives that would incorporate pre-existing information collection systems from not only other federal agencies, but FDA itself. For example, Congress directed FDA to consult with the US Department

of the Treasury in implementing provisions of the Act. US Customs currently collects much of the same information required by the prior notice proposed rules through its Automated Broker Interface. This information is then provided to FDA via its Online and Administrative System for Import Support. Thus, FDA already has access to many portions of the prior notice requirements now being considered. FDA claims that two separate systems are justified because they fulfill two different purposes, i.e., the inspection of products for contamination to protect the public health; and the inspection of products for contamination as a result of a terrorist threat or act, in other words, to protect the public health. We believe that these purposes are essentially the same and warrant a consolidated system. Moreover, coordinated efforts would reduce cumbersome duplication and facilitate each agency's responsibility to preserve the steady flow of commerce while protecting the US food supply.

Lastly, we request that FDA provide a grace period to allow industry to become aware of the new requirements and comply. This is particularly important for our members who exhibit at the APPMA annual trade show. Many times exhibitors ship products to the trade show for the limited purpose of exhibition and ship goods back to their respective facilities. An exhibitor who is ignorant of the new prior notice, as well as, the registration requirements could find itself in the unfortunate position of having an empty booth because the goods are being held at the port of entry or a secure location. We hope to avoid these incidents as much as possible by educating our members and otherwise assisting them with the rising challenges of importing pet products. However, a grace period would ensure that trade is not hindered.

We respectfully submit our views.

Sincerely yours,



Gina Valeri
Director of Legislative Affairs & General Counsel