

APPMA[®]

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American Pet Products Manufacturers Association, Inc.[®]

July 8, 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-0275 - Administrative Detention
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 companion animal food products to American consumers that can be manufactured 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 freely pursue trade as permitted by law.

APPMA appreciates the opportunity to submit these comments regarding the above-referenced proposed rule for administrative detention. 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 and food safety emergencies in Europe and Canada from bovine spongiform encephalopathy and foot and mouth disease. Labor strikes at US seaports also caused significant delays and loss for our industry.

The proposed rule outlines the procedure for administrative detention of food for which there is credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals. We are concerned that pet products will be detained with shipments that may contain suspect food. In addition, we are concerned that pet products will be detained due to unwarranted association with countries or geographic areas that may face, from time to time, animal health or food safety emergencies.

The proposed rule states that the detention may continue for as much as 30 days. In addition, the proposed appeal process can be lengthy and burdensome for international companies, as well as, domestic importers.

The proposed rule does not adequately address the case in which pet products are detained with shipments that may contain suspect food. The resulting delay

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could result in great loss to APPMA members exhibiting at the APPMA Show. The APPMA Show is a three-day annual exhibition. Manufacturers wait for the APPMA Show to launch new product lines. The APPMA Show receives national media coverage as well. If products are detained, manufacturers will lose this unique opportunity to market their goods without recourse to participate in another similar trade show, or by other means, to make sales.

Furthermore, in the case of products that are detained due to international food safety crisis, we ask that the Agency exercise care in determining whether there exists a bona fide necessity to detain pet products. Recently, a company suffered great economic loss at an APPMA Show. The company was an overseas maker of dog biscuits whose products were held at the port of entry for inspection due to the fact that the shipment arrived from a country with suspected foot and mouth disease. The products did not contain any ingredients of animal origin, were never in contact with a farm or other facility housing live animals, and were not in contact with any products of animal origin. Due to the delay, the exhibitor was not able to show products on the opening day of the exhibition, a very well-trafficked day and could not participate in marketing opportunities that necessitated display of product. We are concerned that similar circumstances may arise under the provisions of this proposed rule. We ask that the Agency consider alternative means of handling these circumstances.

We respectfully submit our views.

Sincerely yours,

A handwritten signature in cursive script that reads "Gina Valeri".

Gina Valeri

Director of Legislative Affairs & General Counsel