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

ATTN: Docket No. 02N-0278 (Prior Notice)

On behalf of the American Spice Trade Association (ASTA), I am pleased to submit comments on the interim final regulation: "Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," (The Bioterrorism Act) 68 Fed. Reg. 58974 (October 10, 2003). ASTA was founded in 1907 and represents the interests of approximately 300 members including companies that grow, dehydrate, and process spices in the United States for domestic consumption and for export. ASTA's members include U.S.-based agents, brokers, and importers, companies based outside of the U.S. that grow spices and ship them to the U.S., and other companies associated with the U.S. spice industry. ASTA's members manufacture and market the vast majority of spices sold in the U.S. at retail, and to food processors. ASTA is active in research and education on spices, government relations, and trade relations.

On behalf of our members, ASTA is utilizing this comment period to request that the Food and Drug Administration (FDA) establish in the final prior notice regulation, a limited and clearly defined exemption from the prior notice requirement for trade samples. We believe that the circumstances surrounding the importing of trade samples justify such an exemption and do not expose the general public to bioterrorism attacks.

Need for Sample Exemption Under Prior Notice Requirement

As we assist our member companies with implementation of the interim final rule, the issue causing the greatest difficulty is the requirement to provide prior notice before importing trade samples to be used exclusively for qualitative analysis and evaluation. Members of the U.S. spice industry routinely receive samples from affiliates, customers and suppliers outside the country.

There are several reasons for importing a spice or other food sample. A supplier may want their U.S. customer to examine a sample of a particular lot or crop due to quality fluctuations over time. Occasionally a customer may want to send samples of other commercial products and ask their U.S. supplier to perform an analysis and offer a

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competitive product. Whatever the reason for providing the sample, what follows is generally laboratory analysis of a sample of five pounds or less, with the analysis usually consuming the entire sample. Any leftover material is discarded and no portion of the sample is provided to the general public. Following completion of the analysis, if a manufacturer or processor decides to import a larger quantity of the food product, then prior notice would of course be required.

The preamble to the interim final rule references The Bioterrorism Act that clearly establishes the purpose of requiring prior notice:

> "The stated purpose of requiring notice of imported food shipments before arrival in the United States is to enable FDA to conduct inspections of imported food at U.S. ports (see section 801(m)(1) of the FD&C Act). Thus, FDA intends to use prior notice information to make decisions about which inspections to conduct at the time of arrival. Currently, we intend to focus on conducting these inspections when our information suggests the potential for a significant risk to public health." 68 Fed. Reg. 58976 (October 10, 2003)

In light of this stated purpose of providing prior notice, it is difficult to imagine a situation where prior notice to import a sample would provide information suggesting the potential for a significant risk to public health. In fact, small quantities of food that are not available to the public could never be said to pose such a risk.

Current Exemptions

Under the interim final rule prior notice is not required for several categories of food including, food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use, and food that was made by an individual in his/her personal residence and sent by that individual as a personal gift to an individual in the United States. These exemptions from the prior notice requirement are justified by the extremely low risk that these categories of food, if contaminated, would be highly unlikely to affect general public health. For the same reason, an exemption should be added for samples used for evaluation and/or analysis purposes.

Definition of Exempted Samples

In order to limit the use of the sample exemption, FDA should clearly define what samples and sample shipment procedures are exempted from prior notice requirements. The final regulation should establish that the intended use of exempted samples must be for evaluation and/or analysis purposes only. In addition, the final regulations should establish that exempted samples can not be larger than a certain size. Typical qualitative evaluations performed by FDA or industry laboratories require a 5 pound spice sample. We suggest this as the maximum size for exempted samples.

It will be important for exempted samples to be marked correctly to avoid confusion at the border. The final regulation should provide instructions on how to mark exempted samples for import. The prescribed marking might read:

"SAMPLE – FOR ANALYSIS AND EVALUATION PURPOSES
ONLY - RESALE PROHIBITED"

In addition, the paperwork accompanying the shipment should include a reference to the final regulation as the authority for the exemption from prior notice.

Conclusion

In light of the above arguments, we request that in the final regulation an exemption for samples be provided. We believe that providing an exemption from the prior notice requirement for samples used only for evaluation and/or analysis purposes would not compromise FDA's ability to protect consumers from contaminated food. In fact, under the interim final rule, limited FDA resources are being used to process and review the notices on these extremely low risk products when larger more exposed shipments cannot receive the extra scrutiny envisioned by the drafters of The Bioterrorism Act.

We appreciate the opportunity to comment on this interim final regulation. We are of course available to discuss this issue at your convenience.

Sincerely,

Elizabeth Erman

Elizabeth Erman
Executive Director