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**FLAVOR AND EXTRACT MANUFACTURERS  
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December 19, 2003

Dockets Management Branch  
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 Flavor and Extract Manufacturers Association of the United States (FEMA), 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). FEMA is the national association of flavor manufacturers and represents the vast majority of flavor companies in the United States. FEMA members create flavors for use in a wide variety of food and beverage products.

Exemption for Samples Used for Analysis and Evaluation

We are utilizing this comment period to request that the Food and Drug Administration (FDA) establish a limited and clearly defined exemption from the prior notice requirement for trade samples in the final regulation. The circumstances surrounding the importation and use of trade samples justify such an exemption. Trade samples do not expose the general public to potential bioterrorist attacks and requiring prior notice before importing them inappropriately drains FDA resources away from potential more problematic shipments.

Impact of Interim Final Rule

Transferring small samples between food and beverage manufacturers for analysis and evaluation is a common activity. A finished food manufacturer in another country typically sends a small product sample to a flavor or food manufacturer in the U.S. In addition, samples are sometimes transferred from a company's facility outside the U.S. to one of their facilities in the U.S. In all cases, the purpose of providing the sample is so that the U.S. customer can conduct qualitative analysis and evaluation of the product. The analysis and evaluation typically consumes the entire sample. Any leftover material is discarded and no portion of the sample is provided to the general public. These samples do not end up in commercial food products sold to consumers, and therefore they do not present a risk of food supply contamination.

As implementation of the interim final rule began, we polled our member companies to assess the impact of the prior notice requirement on the importation of food samples. The survey results indicated that FEMA member companies received an average of 230 sample shipments over the past twelve months. These samples are generally one ounce or less and they are not intended for human consumption. Instead, they are usually subjected to laboratory analysis and evaluation and then discarded.

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### Purpose of Prior Notice Requirement

Because consumers are not exposed to these samples the expense and inconvenience of providing prior notice is unjustified. Furthermore, requiring prior notice for such small quantities of food diverts FDA inspection resources away from potentially problematic shipments. The preamble to the interim final rule references the purpose behind 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. To require prior notice on such low risk shipments increases the risk of harm being caused by other food imports.

### Existing Exemptions from Prior Notice

An exemption for small trade samples used only for analysis and evaluation is consistent with existing exemptions under the interim final regulation. Under the interim final regulation, prior notice is not required for certain 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 could adversely affect the health of the general public. For the same reason, an exemption should be added for samples used for analysis and evaluation purposes.

### Definition of Exempted Samples and Shipment Procedures

The exemption from prior notice for samples should include a clear definition of the kind of samples and sample shipment procedures that are exempted from the prior notice requirement. The final regulation should establish that the intended use of exempted samples must be for analysis and evaluation purposes only. In addition, the final regulation should establish that exempted samples can not be larger than necessary for laboratory analysis.

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 view of the above factors, we request that the final prior notice regulation contain an exemption from the prior notice requirement for the import of limited and clearly defined trade samples. Providing an exemption from the prior notice requirement for samples used only for analysis and evaluation purposes would not compromise FDA's ability to protect consumers from contaminated food. Instead, exempting these low risk shipments would allow the FDA to focus their limited resources on larger shipments with greater exposure to bioterrorist tampering. This realignment of agency resources is consistent with existing exemptions and with the goal of the prior notice requirement found in 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,



Glenn Roberts  
Executive Director