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OFFICE OF THE PRESIDENT

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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 International Federation of Essential Oils and Aroma Trades (IFEAT) a London, UK, based trade association of which I am President and as a past President of the Flavor and Extract Manufacturers' Association of the U.S. (FEMA), I am pleased to submit comments on the proposed regulation "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002".

I would like to endorse and support the comments of Glenn Roberts, the Executive Director of FEMA, submitted on April 3, 2003. I trust the concerns he expressed and the difficulties of implementation he noted will be addressed. In the interest of brevity, I will limit my comments to the issue of Prior Notification for samples of Flavor Ingredients including Essential Oils, Aroma Chemicals, Spice and Related Oleoresins and Natural Plant Extracts. The countries that produce and export these ingredients to the U.S. include: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Israel, Mexico, South Africa, Tunisia and Turkey.

Because of the unique nature of our industry, within and outside of the U.S., many companies are small or medium size and family owned and operated. The samples they submit to their U.S. customers are only for quality evaluation and approval. These sample represent specific quantities of flavor ingredients offered by the foreign supplier and are small usually ¼ to 1 ounce. Because of their small size, the use of samples in flavor production is totally impractical and would violate GMP rules. We therefore believe they do not present a risk of food supply contamination. We estimate that 40,000 to 60,000 samples of flavor ingredients enter the U.S. annually via Air Parcel Post and courier service. It is impossible for the sender to accurately predict when samples will arrive in the U.S. due to factors including weather, which influences Air Parcel Post service and operations of courier services available locally. To expect a foreign producer to adhere to the time limitation requirements for the delivery of samples is an impossibility and should be eliminated.

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I have restricted my comments to the issue of samples as the exporters of flavor ingredients recognize the importance of prior notification for shipment of these ingredients to the U.S. under the provisions of the Bioterrorism Act. On behalf of the membership of IFEAT and U.S. importers of these flavor ingredients, we request that samples of these materials be designated exclusively for quality evaluation and use in research and development and not be considered food for consumption in the U.S. under the Bioterrorism Act. The final rule should specify procedures for clearly identifying samples such as the inclusion of a statement on the airway bill of lading that says:

“QUALITY EVALUATION AND RESEARCH AND DEVELOPMENT USE ONLY –
RESALE PROHIBITED”

We believe that the exclusion of these samples will not compromise the FDA's ability to protect consumers against contaminated food and also enable the FDA to allocate its resources in areas it may determine are more important.

We appreciate the opportunity to comment on this proposed regulation and are enclosing photographs of typical sample bottles used by foreign suppliers for sending samples of flavor ingredients as well as the sample bottles themselves.

If you have any questions regarding my comments, we are available to discuss these issues at your convenience.

Sincerely yours,



Richard C. Pisano
President, IFEAT

RCP:ga
cc Glenn Roberts, Executive Director FEMA
Skip Roskam, President FEMA
Michael Boudjouk, Chairman IFEAT
Julie Young, Executive Secretary IFEAT
(for distribution to the Executive Committee)

