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December 23, 2003

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Re:

Docket No. 02N-0276 – Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Docket No. 02N-0278 – Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Ms. Fraser and Ms.Ralston:

Please find enclosed the comments of my client, the National Association for the Specialty Food Trade, Inc. (NASFT) regarding Docket No. 02N-0276 and Docket No. 02N-0278.

NASFT is the trade association for the manufacturers, retailers, brokers, distributors, publishers, importers and all others involved in the specialty food trade. Most are small, independent businesses. The twenty four hundred plus (2,400+) members are located throughout the United States. A much smaller number of approximately fifty (50) associate members have their businesses in Canada and many other countries. NASFT publishes the monthly magazine *Specialty Food News* and hosts three NASFT Fancy Food Shows (New York, San Francisco and Chicago) each year. The three NASFT Fancy Food Shows attract over four thousand (4,000) exhibitors. Most of the exhibitors are small companies for which the Shows are their principal means of finding customers among the almost fifty five thousand (55,000) attendees and entering the U.S. market. At the New York Show in 2003 forty-seven (47) countries were represented. A major proportion of NASFT's membership and the foreign exhibitors at the NASFT Fancy Food Shows are affected by the two Interim Final Rules.

2002N-0276

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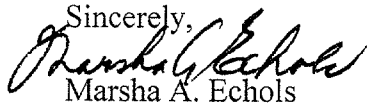
On behalf of its members, NASFT submits the attached comments regarding the two Interim Final Rules. If there is any question regarding those viewpoints or if additional information is needed, it would be pleased to respond.

NASFT congratulates the Food and Drug Administration (FDA) on its decision to be flexible for at least eight (8) months in implementing the complex Interim Final Rules. NASFT urges the FDA to extend this period of flexibility and to consider favorably the attached comments.

Sincerely,



Marsha A. Echols

Enclosure

NATIONAL ASSOCIATION FOR THE SPECIALTY FOOD TRADE, INC.

Comments

in

Docket No. 02N-0276 – Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Docket No. 02N-0278 – Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

1. Extend the period of flexible enforcement of both Interim Final Rules.

The Food and Drug Administration (FDA) should extend beyond August 2004 the period of flexible enforcement of the Interim Final Rules and the eventual rule regarding recordkeeping. Time is needed to ensure that more businesses are aware of the new rules and understand them. While online registration and certain portions of the two rules are fairly easily implemented, other portions are problematic, especially for small businesses.

It is likely that unexpected questions and problems will arise for many months into the future. During this period FDA should study carefully the various situations. The agency should develop solutions that adapt to business practices whenever possible and that permit international trade to continue. Customs and FDA officials on site (or with little delay) must be able to determine that commerce will not be stopped unnecessarily.

In each circumstance in which it is clear that FDA's implementation or enforcement is problematic – especially for small businesses – FDA should re-examine its rules and revise them. A revision will be warranted in particular when FDA's rules are broader and more detailed than the Bioterrorism Act.

Under the two Interim Final Rules, the consequences of mistakes can include criminal sanctions and the loss of a shipment. Given these circumstances, the period of flexible enforcement should end only when it is clear that the rules are understood, are fair and do not unnecessarily interfere with commercial practices.

2. Revise the Registration and Prior Notice rules to be more flexible regarding imports destined for trade shows and regarding imported samples. Usually these foods are not imported for consumption in the United States.

NASFT urges FDA to revise its registration and prior notice rules to exempt foods for exhibit.

The Prior Notice rules now apply to foods for trade shows and food samples. Usually these foods are not intended for consumption in the United States. The current Interim Final Rules make clear that FDA does not completely understand these facts. The food that is imported for the shows is for "show" and sampling at the show, not for later general consumption. Moreover, the quantity involved with each shipment is minuscule, usually no more than five hundred (500) consumer units. This quantity is too small to pose a potential national security threat. Under these circumstances, the requirements that foreign facilities register, employ a U.S. Agent and file a prior notice create an unnecessary burden on international trade and commerce.

The logic explained in the preceding paragraph could be applied to trade samples, which are imported in very small quantities for the purpose of evaluating the viability of a product prior to its entering the market.

For the NASFT Fancy Food Shows, exhibitors bring into the United States foods for exhibition. The exhibitors are seeking buyers (*e.g.*, retailers or distributors) but the foods on exhibit are not sold for consumption. Thus the words "exhibit" and "exhibitor" accurately describe what occurs. Orders are taken, but the seller ships different foods (not those on exhibit) to customers. The food that is imported for the shows is for "show", not for general consumption. Under these circumstances, the requirements that foreign facilities register, employ a U.S. Agent and file a prior notice create an unnecessary burden on international trade and commerce.

3. Clarify in the rules and in public statements FDA's position regarding the confidentiality of facility registration numbers and when they are required to be included in the prior notice.

The registration number of a facility is a trade secret. FDA explained that it will protect the confidentiality of the numbers and that a registration number is not proof of compliance with the law. Unfortunately, the trade does not understand the role of the registration number. Many importers, retailers, shippers and others are demanding the registration numbers before they will do business with the owner of a facility. Others require that the registration number be placed on the commercial invoice, which is not kept confidential. Often the owner of a facility, especially if it is a small business, is at a disadvantage and would lose the ale if it refused to give the customer or shipper the registration number.

FDA should revise its two Interim Final Rules to clarify that those doing business with the owner of a facility should not and have no reason to demand the facility registration number. FDA also should issue a public statement to this effect as part of its educational efforts.

An important component of the educational effort must be to explain to the public whether and when a registration number is required information on the prior notice and, if a registration number is required, whose number. A clear statement of FDA's position should be announced in plain English (not only on the prior notice tutorial or in the Interim Final Rule).

FDA's position regarding the use of the facility registration number also will influence the gray market. FDA's position should make it more difficult for unauthorized sellers to market goods for which they do not have distribution rights.

4. Conclusion

NASFT urges the FDA to continue the flexible enforcement of the two Interim Final Rules and to consider favorably the above recommendations.