



**NATIONAL ASSOCIATION
OF BEVERAGE IMPORTERS, INC.**

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December 24, 2003

Food and Drug Administration
Dockets Management Branch
HFA-305
5630 Fisher Lane
Room 1061
Rockville, MD 20850

RE: Docket Number 2002N-0276

Registration of Food Facilities Under the Public Health Security and Bioterrorism
Preparedness and Response Act of 2002

Dear Sir/Madam:

These comments are being submitted by the National Association of Beverage Importers, Inc. (NABI) and its member companies. NABI is an international trade association that represents United States importers of alcohol beverages. NABI is the only trade association that represents the interest of importers of beer, wine and distilled spirits. These comments relate to the Interim Final Regulations on Registration only. We will submit separate comments on the Interim Final Regulation on Prior Notice.

First, we would like to compliment the Food and Drug Administration (FDA) on accomplishing what appeared to be an impossible task. You were able to get the Registration Regulations published in what appeared to be an impossible time frame.

Having said that, we think that certain issues must be dealt with if we are to accomplish the ultimate goal of consumer protection from terrorist's acts while at the same time, interfering with the flow of trade as little as possible. The following are areas in which we feel either need change or clearer definition:

1) Trade Names

During the registration process, many members had problems complying with what they believed was required by the regulation. Many producers and importers of alcohol beverages operate under many (as many as 200) trade names or d/b/a's. However, the form only permitted a maximum of four names to be shown on the on-line registration

2002N-0276

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form. If FDA requests on-line registration and it truly wants all trade names associated with the registrant, it must provide for a “drop down” page or allow for another attachment. On the other hand, FDA could revise the regulations to require only the four most active names.

Members of NABI do not care which option FDA chooses, we only care that we operate in compliance with FDA regulations.

2) Retailer Registration

Your regulations are unclear as to when a retailer must register. In our industry we have brewpubs (retail operations/restaurants) that have a small brewing operation as a part of their retail operations. The vast majority of their beer is sold at retail to consumers in the restaurant or as take out beer. Does a brewpub have to register? What is the determinative factor? Your regulations dealing with retailers are in need of more definition as to when a retailer is exempt.

3) Winery Registration

The same problem exists with wineries. Many of the wineries are vineyards that grow grapes (farm exemption). However, these vineyards often produce either juice or wine for sale to the trade and to a lesser extent directly to the consumer. Your regulations are unclear as to whether a vineyard that also produces juice or wine must register. A better definition of exempt “farm” would help.

4) U.S. Agent

We think that FDA should rethink its position on the number of U.S. agents that a foreign supplier can have. Foreign suppliers having multiple importers object to designating only one agent on the grounds that it subjects them to divulging confidential information and might also lead to situations where the agent does not represent all involved importers adequately. As an example, a supplier that produces both wine and olive oil may have two different importers who lack knowledge or interest in each other’s products and may be reluctant or unable to answer FDA’s questions should a terrorist incident occur. We see nothing in the law that says a foreign supplier can have only one U.S. agent. It seems simple enough for FDA to contact a foreign supplier through multiple U.S. agents depending upon who the foreign supplier list as his/her U.S. agent when the foreign supplier registered.

Page – 3 –

FDA should also clearly define the role/responsibility of the U.S. agent. Some importers are reluctant to become U.S. agents for their foreign supplier because they are not certain what FDA expects of a U.S. agent. In addition, foreign suppliers experienced difficulty in finding a U.S. agent due to some reluctance on the part of the agent in being available 24/7. Is the trade to interpret this by it's literal definition - 24 hours, 7 days, 365 days, or does FDA provide more latitude in response time during non-business hours? Please clarify.

Sincerely,


Robert J. Maxwell
President - NABI