



**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-0278

Prior Notice of Imported Food 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 interests of importers of beer, wine and distilled spirits. These comments relate to "Prior Notice of Imported Food, Docket Number 2002N-0278."

Again, we would like to compliment the Food and Drug Administration (FDA) and its staff for publishing this interim final regulation in such a timely manner. In addition, we think the FDA outreach program headed by Mr. Lou Carson of your staff was perhaps one of the best programs that we have ever seen FDA or any other agency conduct.

However, we think there is room for improvement when the final regulations are published. We suggest the following:

1) First Port of Arrival

The interim final regulation establishes times by which "prior notice" must be filed before the food arrives at the "first port of arrival." The regulations however do not do a very good job of defining "first port of arrival." The interim regulation seems to define the "first port of arrival" as being the first port where a ship

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enters a U.S. territory. In our discussions with FDA experts, we were advised that it means something else. We were told that when a ship arrives from Europe, only goods “off loaded” in that port must be given prior notice within the time frames required. If the ship has food destined to be “off loaded” in other ports, prior notice must be filed for each port in accordance with the time frames required by regulations. In any case, because this is such an important requirement, “first port of arrival” should be carefully and completely defined in the regulations so that there is no misunderstanding on the part of regulators or the regulated.

2) Definition of Manufacturer

Prior notice requires the filer to include the registration number of the manufacturer. The prior notice ABI/ACS System allows only two registration numbers to be entered. If our understanding is correct, there are many times when three, four or even more numbers will be involved. We will try to demonstrate through the following example: 1) Wine is produced and bottled at winery “X” and sent to winery “B” for labeling (de minimis facility). 2) Winery “B” labels and transfers the wine to another facility for storage “S.” 3) Storage facility “S” transfers the wine to the freight forwarder “F” who stores and consolidates the wine with other wines for shipment to the United States. “X,” “B,” “S,” and “F” have all registered under the act. The interim final regulation does not make clear which of the facilities and registration numbers need to be listed in a prior notice under manufacturer and shipper in this example. The confusion might be cleared up by FDA developing a clearer definition of manufacturer.

4) Old/Aged Product

Frequently in the wine business, older rare wine is purchased at auction or from retailers. It might have been produced 10, 15, or 20 years ago or longer. In some cases, the producer is no longer in business. In these cases, there will be no registration number. If the importer must have a manufacturer’s registration number in order to file prior notice, the importer is in a very difficult position and stands to lose a lot of money because the product cannot be imported without prior notice and yet he/she cannot get a number. We believe that some exceptions or exemptions must be given to these very old, rare, and expensive products.

We realize that this is a complex problem but, it must be resolved by FDA. If not resolved, the American consumer will be deprived from owning and drinking very old and rare wines and other alcohol beverages. Perhaps food produced prior to December 12, 2003 should be exempt.

5) Samples

The interim final regulation does not clearly address the issue of imported samples. Samples of alcohol beverages are imported for many reasons. They are imported: 1) for quality control; 2) to be taste tested by prospective importers; 3) to be analyzed by government laboratories for pre-import classification; 4) for consumer/trade tasting at trade shows held in the United States; and 5) for use in market research. This is not an exhaustive list of reasons for the importation of samples but, the interim final regulation does not provide guidance to the importers as to when prior notice must be filed. Perhaps FDA could define samples requiring prior notice to mean “only those samples used in any type of consumer tasting.”

6) Need for Prior Notice

We believe that FDA has issued an interim final regulation that requires prior notice needlessly. If a container contains red wine, under 14% alcohol and in multiple varietals and sizes from the same manufacturing facility, we see no need for multiple prior notice. It is our understanding that a prior notice would be required for each size of each varietal even though the entire container is covered by one HTS number and one FDA code. We request that FDA reconsider its position on the need for prior notice. The regulations should require a separate prior notice for each HTS number in the container and no more. We see nothing gained by FDA requiring the number of prior notices that the interim final regulation appears to require.

7) Prior Notice Form

Finally, we believe that FDA should develop and publish a form that could be used if it were ever necessary to file prior notice by fax. A form would also assist importers in gathering the information necessary to file a prior notice. A form would also clear up the confusion that currently exists in foreign countries. It was obvious the FDA contemplated issuing a form when it first proposed the prior notice regulations. No explanation has been given by FDA for not producing the form.

Sincerely,


Robert J. Maxwell
President - NABI