

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0278: Food and Drug Administration/Bioterrorism Preparedness and Response Act of 2002/Prior Notice Proposal

Dear Sir or Madam:

The undersigned are a coalition of trade associations representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States. On behalf of our respective members, we welcome the opportunity to submit this comment in response to the Food and Drug Administration's (FDA) notice of proposed rulemaking implementing the prior notice provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

We fully support a focused regulatory scheme to guard against a threatened or actual terrorist attack on the U.S. food supply. A focused scheme takes into account existing regulatory requirements that already are in effect, despite the fact that they may be implemented by various Federal agencies. Such a coordinated strategy makes both "government sense" and "business sense." Redundant regulation only serves to burden business and cause confusion, without any commensurate benefit in achieving our collective goal of a safe and secure food supply.

For beverage alcohol, the directives of the Bioterrorism Act already are met and satisfied by the existing obligations imposed by the Customs Service and the Department of Treasury's Tax and Trade Bureau (formerly the Bureau of Alcohol, Tobacco and Firearms). In discharging its statutory responsibilities, we urge FDA to review the prior notice proposal in terms of whether the burden of a new, but duplicative, regulation outweighs its benefit.

We submit that FDA's prior notice proposal would impose burdens upon industry, as well as the government, that are unnecessary because they duplicate the collection of information already required by, for example, the Customs Service. In light of this duplication, FDA's burden estimate for information collection is inherently flawed because it does not take into

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account that importers would be required to satisfy two regulatory schemes with redundant dictates. To the same effect, FDA's burden estimates regarding cost, impact and other factors similarly are flawed.

The requirements of the Customs Service's "24-hour" rule clearly demonstrate this point. Pursuant to that rule, the Customs Service requires an ocean carrier to provide Customs with detailed manifest information 24 hours prior to the loading of the cargo on the ship in the port of embarkation. The manifest information, the entry paperwork and the OASIS system, all on file with the Customs Service, clearly satisfy the prior notification requirement in the Bioterrorism Act.

To that end, we urge FDA not to propose or adopt regulations that would be duplicative of regulations already in place and administered by the Customs Service. A means to achieve this end is to include express language in the Bioterrorism Act's final prior notice rule recognizing that the Customs Service's 24-hour rule satisfies the prior notice requirement under the Bioterrorism Act.

Coordination of action, not duplication of action, should be the keystone in implementing the provisions of the Bioterrorism Act. Congress recognized that the Act called upon functions of other Federal agency activities and intended to coordinate, rather than duplicate, such functions.

Sections 302(c) and 314 of the Act clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of Federal agency activities.

One of the sponsors of this legislation also underscored this course of action in his supporting statement that "[t]he Secretary shall closely coordinate this prior notice regulation with similar notifications that are required by the U.S. Customs Service with the goal of minimizing or eliminating unnecessary, multiple or redundant notifications." (147 Cong. Rec. E2388 (December 20, 2001) (statement of Rep. Shimkus).)

Since the 24-hour rule administered by the Customs Service already achieves the desired objectives of the prior notice requirement of the Bioterrorism Act, it should be incumbent upon FDA to liaise with the Customs Service to coordinate their actions, rather than unduly burden industry due to a lack of coordination. Any other course of action would impose unnecessary burdens upon regulators and the regulated community and thereby divert valuable time and resources away from government and industry efforts to protect the food supply from bioterrorist threats -- an objective that all of us fully support.

Background: Information Required by the Customs Service

The Customs' checklist requires fifteen (15) information elements that are far more detailed than the directives of the Bioterrorism Act. These information elements are: (1) foreign port of departure; (2) carrier SCAC code; (3) voyage number; (4) date of scheduled arrival in

first U.S. port; (5) numbers and quantities from carrier's master or house bill of lading; (6) first port of loading, or first port of receipt, of the cargo by the inbound carrier; (7) a precise description (or the Harmonized Tariff Schedule numbers if the HTS classification is provided by the shipper) and weight of the cargo, or, if the container is sealed, the shipper's declared description and weight of the cargo (generic descriptions, specifically freight-all-kinds, general cargo, and STC (said to contain) are not acceptable); (8) shipper's name and address, or an identification number, from all bills of lading; (9) consignee's name and address, or the owner's or owners' representative's name and address, or an identification number, from all bills of lading; (10) advise Customs when actual boarded quantities do not equal quantities indicated on the relevant bills of lading (carriers are not required to verify quantities in sealed containers); (11) vessel name, national flag and vessel number; (12) foreign country of origin where cargo is loaded onto vessel; (13) hazardous-material indicator; (14) container number (for containerized shipments); and (15) seal number affixed to container.

Customs' efforts to improve security impose requirements beyond the dictates set forth in the Bioterrorism Act. U.S. companies must educate their suppliers not only about the new manifest rules referenced above, but also about the Customs-Trade Partnership Against Terrorism (C-TPAT) and other security measures. Although technically a voluntary program, C-TPAT is becoming a Customs standard.

In addition, Customs requires an approved "certificate of label approval" (COLA) as a condition for releasing a beverage alcohol import at the port of entry. (See, e.g., 27 C.F.R. § 4.40.) The Department of Treasury's Tax and Trade Bureau, which regulates the beverage alcohol industry in terms of both import and domestic trade, requires industry members to apply for and obtain a COLA prior to introducing product into interstate commerce. The COLA must contain certain information including the brand name of the product, the class and type designation, the alcohol content, the name and address of the bottler or packer (domestic product or imported bulk product bottled in the U.S.) or importer, and the country of origin. (See Section 105 of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. § 205)) and its implementing regulations in 27 C.F.R. Parts 4, 5 and 7.)

Appended hereto is a copy of the August 30, 2002 FDA comment filed by the Bureau of Alcohol, Tobacco and Firearms (prior to its reorganization resulting in the establishment of TTB), which identifies the Bioterrorism Act provisions that are redundant with the Bureau's requirements and "encourages collaboration between our respective agencies to avoid duplication of efforts and undue burden upon the alcohol industry." (The Customs Service already coordinates with TTB.)

Conclusion

We urge FDA to coordinate with the Customs Service to ensure that there is no duplication of government resources and regulation and to include express language in the Bioterrorism Act's final prior notice rule recognizing that the Customs Service's 24-hour rule satisfies the prior notice requirement under the Bioterrorism Act. This course of action will enable the Federal government and the affected industry members to focus their resources more

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efficiently and effectively upon efforts that will enhance security and will avoid unnecessary and redundant burdens that otherwise could be imposed upon both enforcement and compliance efforts.

Thank you for the opportunity to present our views concerning FDA's actions to implement the prior notice provision of the Bioterrorism Act. We stand ready to work with you at any time to assist in the development of implementing regulations that will result in the efficient and effective implementation of this Act. If we can be of any further assistance, please do not hesitate to contact us.

Sincerely,

Robert J. Maxwell
President
National Association of Beverage Importers, Inc.

Harry Wiles
Executive Director
American Beverage Licensees

Arthur DeCelle
Executive Vice President & General Counsel
Beer Institute

C.M. Wendell Lee
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Craig A. Purser
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National Beer Wholesalers Association

Craig Wolf
General Counsel
Wine and Spirits Wholesalers of
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Attachment