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April 3, 2003

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 Seventeenth Street, N.W., Room 10202
Washington, D.C. 20503

Re: Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations (68 Fed. Reg. 5492 (February 3, 2003))

Dear Ms. Hunt:

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 to the Office of Management and Budget (OMB) concerning its "Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations."

We specifically address OMB's request for comment concerning how to more effectively evaluate the benefits and costs of the Department of Health and Human Services/Food and Drug Administration's (FDA) regulatory proposals intended to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). (See 68 Fed. Reg. at 5499.)

As elaborated in our March 5, 2003 comments (enclosed) filed with OMB, FDA's proposals to implement the registration and prior notice provisions of the Bioterrorism Act would impose unnecessary burdens upon the government and the beverage alcohol industry because the directives of the Act already are met and satisfied by the existing statutory/regulatory schemes governing our industry. In particular, FDA's registration and prior notice proposals would duplicate requirements imposed upon the beverage alcohol industry by the Tax and Trade Bureau (previously the Bureau of Alcohol, Tobacco and Firearms) of the Department of Treasury and the Customs Service, respectively.

To avoid this redundancy, we have urged that FDA coordinate with other Federal agencies to ensure that the Federal government and the beverage alcohol industry focus their respective resources more efficiently and effectively upon efforts that will enhance security.

March 5, 2003

Mr. Stuart Shapiro
Desk Officer for FDA
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, N.W., Room 10235
Washington, D.C. 20503

RE: Docket No. 02N-0276: Food and Drug Administration/Bioterrorism Preparedness and Response Act of 2002/Registration Proposal

Dear Mr. Shapiro:

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 to the Office of Management and Budget (OMB) concerning the Food and Drug Administration's (FDA) notice of proposed rulemaking implementing the registration 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 Department of Treasury's Tax and Trade Bureau (formerly the Bureau of Alcohol, Tobacco and Firearms). In discharging its statutory responsibilities, we urge OMB to review FDA's registration proposal in terms of whether the burden of a new, but duplicative, regulation outweighs its benefit.

We submit that FDA's registration proposal would impose burdens upon industry, as well as the government, that are unnecessary because they duplicate the collection of information already required by the Tax and Trade Bureau. In light of this duplication, FDA's burden estimate for information collection is inherently flawed because it does not take into account that beverage alcohol industry members 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 statutory and regulatory requirements of the Tax and Trade Bureau clearly demonstrate these points. Since the 1930s, TTB and its predecessor agencies have regulated the beverage alcohol industry in terms of both import and domestic trade. TTB has a comprehensive set of regulations governing the production, manufacture, importation, and distribution of beverage alcohol products. All persons engaged in the business of producing, importing and distributing beverage alcohol products in the United States must obtain a permit from TTB or be registered with TTB.

Any applicant for a permit or registration with TTB is subject to an extensive background and financial investigations review. Foreign entities can import beverage alcohol products only through an entity that holds a Federal Basic Importer's Permit. (These permit and registration requirements are discussed further below.)

As a consequence, we urge OMB to take the position that FDA not propose or adopt regulations that would be duplicative of regulations already in place and administered by TTB. A means to achieve this end is to include express language in the Bioterrorism Act's final registration rule recognizing that TTB's requirements satisfy the registration 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 in implementing the Act. 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.

This clear allocation of responsible action among Federal agencies, such as TTB vis-à-vis its regulatory scheme governing beverage alcohol industry members, will best utilize the procedures and processes already in place to most efficiently "develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply," the stated purpose of Title III of the Act.

In sum, since the requirements of TTB already achieve the desired objectives of the registration requirement of the Bioterrorism Act, it should be incumbent upon FDA to liaise with TTB 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: TTB's Requirements

Section 103 of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. § 203) and its implementing regulations in 27 C.F.R. provide that it shall be unlawful, except pursuant to a basic permit issued by the Secretary of the Treasury, to engage in the business of producing, importing or wholesaling beverage alcohol products. In order to protect the integrity of the industry by ensuring that only persons who are likely to comply with the law may be granted permits, Section 104 of the FAA Act (27 U.S.C. § 204) prohibits the issuance of a permit to:

- any person who has been convicted of a felony under Federal or State law within the prior five years;
- any person who has been convicted of a misdemeanor under Federal law relating to taxation within the prior three years;
- any person who, by reason of business experience, financial standing or trade connections, is not likely to commence operations within a reasonable period or to maintain such operations in conformity with Federal law; or
- any person whose proposed operations are in violation of the law of the State in which they are to be conducted.

As stated in the attached August 30, 2002 FDA comment filed by the Bureau of Alcohol, Tobacco and Firearms (BATF) (prior to its reorganization resulting in the establishment of TTB), the beverage alcohol permit application process for producer, importer and wholesaler applicants encompasses an extensive investigation of the applicant, including:

- verification of citizenship or business visas issued by the Immigration and Naturalization Service (which recently was succeeded by the Department of Homeland Security's Bureau of Immigration and Citizenship Services);
- review of the applicant's business structure to discover any hidden ownership; and
- investigation of investors and owners through multiple criminal databases to discover criminal histories and/or affiliations.

(BATF's August 2002 FDA comment identified the Bioterrorism Act provisions redundant with the Bureau's requirements and "encourage[d] collaboration between our respective agencies to avoid duplication of efforts and undue burden upon the alcohol industry.")

Brewers are not required to obtain a permit from TTB; they, however, must register with TTB. Foreign producers are not required to obtain permits or register with TTB, but they can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit. Further,

the importer routinely is required to produce letters from the foreign supplier about the product as part of the application process.

The Internal Revenue Code and its implementing regulations that also are administered by TTB require that persons wishing to establish operations as a distilled spirits plant (DSP), bonded winery (BW) or brewer also must qualify to engage in such operations. See, e.g., Subpart G of 27 C.F.R. Part 19 (DSP); Subpart D of 27 C.F.R. Part 24 (BW); and Subpart G of 27 C.F.R. Part 25 (Brewery). As stated in BATF's August 30, 2002 FDA comment, these regulations establish a rigorous application process to allow the Bureau to evaluate the applicant's likelihood to comply with the law.

Finally, an applicant for a permit or registration with BATF also must obtain a license or permit from each State in which it does business. Similar to TTB's scrutiny of applicants, the States subject beverage alcohol license or permit applicants to rigorous application processes.

In addition, beer, wine and distilled spirits are taxed at the Federal level and by each State. An extensive tracking system exists to verify the location of products in the stream of commerce. In fact, beverage alcohol products are sold only at licensed retail establishments, providing an additional means of identifying their location that is far beyond what is contemplated in the FDA proposal.

With respect to potential product tampering or similar activities, members of the beverage alcohol industry periodically have met with the Tax and Trade Bureau to make officials aware of changes in serial numbers and other characteristics that would enable Federal investigators to locate quickly products in the event of any such occurrence. Further, TTB has a statutory obligation to approve each label and distinctive container used to identify products in the marketplace further enhancing the government's ability to work with industry members to implement an immediate product recall or inspection, if necessary.

Finally, TTB and FDA jointly have established guidelines in the form of a Memorandum of Understanding dealing with a variety of matters where the statutory responsibilities of the two agencies overlap. By simply updating that Memorandum, FDA can focus upon other food and beverage categories where no existing regulatory or registration system is in place.

Conclusion

We urge OMB to direct FDA to coordinate with TTB to ensure that there is no duplication of government resources and regulation and to include express language in the Bioterrorism Act's final registration rule which recognizes that a TTB beverage alcohol registration or permit satisfies the registration requirement under the Bioterrorism Act.

This course of action will enable the Federal government and the beverage alcohol industry to focus their resources more 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 these views concerning FDA's actions to implement the registration 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
General Counsel
Wine Institute

Lynne J. Omlie
Senior Vice President & General Counsel
Distilled Spirits Council of the United States, Inc.

Donald MacVean
Executive Director
The Presidents' Forum

Craig A. Purser
Vice President
National Beer Wholesalers Association

Craig Wolf
General Counsel
Wine and Spirits Wholesalers of America, Inc.

Bill Nelson
Vice President – Government Relations
WineAmerica

Attachment

DEPARTMENT OF THE TREASURY
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS

Washington, DC 20226

Rec'd 9,

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August 30, 2002

Ms. Linda A. Skladany
Senior Associate Commissioner for External Relations
Food and Drug Administration
5600 Fishers Lane (HF-10)
Rockville, MD 20857

RE: Public Law 107-88, Docket Nos. 02N-0276, 02N-0277, and 02N-0278

Dear Ms. Skladany,

This letter responds to your request for comments regarding Title III, Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-88, (the Act of 2002). The Act is directed at protecting the safety and security of the nation's food and drug supply and requires in relevant part that the Food and Drug Administration (FDA) impose certain registration, recordkeeping, and notice requirements to effect its purpose. The Bureau of Alcohol, Tobacco and Firearms (ATF) regulates the alcohol beverage industry and imposes many of the same requirements upon the industry that are required under the Act of 2002. This letter identifies these requirements and encourages collaboration between our respective agencies to avoid duplication of efforts and undue burden upon the alcohol industry.

Background

As background, section 305 of the Act of 2002 (Docket No. 02N-0276) requires the registration of domestic and foreign food facilities. The registration must contain information necessary to notify the Secretary of Health and Human Services (HHS) of the name and address of each facility, trade names under which the

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address of each facility, trade names under which the facility conducts business and, when the Secretary of HHS deems necessary, the general food category.

Section 306 of the Act of 2002 (Docket No. 02N-0277) requires the promulgation of regulations to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food, which records would be kept for no more than two years. This section would authorize the Secretary of HHS to have access to these records when there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Finally, section 307 of the Act of 2002 (Docket No. 02N-0278) requires that the owner, importer, or consignee provide prior notice of imported food shipments. The notice must identify the article, the manufacturer and shipper, the grower (if known within the time within which notice is required under regulations), the country of origin, the country from which the article is shipped, and the anticipated port of entry. Providing this notice is a condition of the article's admission into the United States.

ATF-Enforced Statutory Requirements

Registration of the Industry Member

The Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 203, and implementing regulations in title 27 C.F.R., imposes many of the same requirements as those imposed under the Act of 2002. Specifically, like the registration requirements in the Act of 2002, the FAA Act and implementing regulations provide that it shall be unlawful, except pursuant to a basic permit issued by the Secretary of the Treasury, to engage in the business of importing, wholesaling, producing, blending, or rectifying alcohol beverages. The FAA Act and implementing regulations identify the limited class of persons entitled to a basic permit and condition the permit upon compliance with all Federal laws relating to alcohol. 27 U.S.C. 204. This requirement is intended to protect the integrity of

the industry by ensuring that only those persons who are likely to comply with the law enter the industry.

The basic permit approval process entails a multi-layered investigation of the permit applicant, involving verification of citizenship or business visas issued by the Immigration and Naturalization Service, review of the applicant's business structure to discover any hidden ownership, and investigation of investors and owners through multiple criminal databases to discover criminal histories and/or affiliations.

In addition to ensuring the integrity of the regulated industry, the permit requirement, along with labeling requirements identifying the bottler or importer, and other required records under the Internal Revenue Code of 1986 (IRC)[1] (discussed below), facilitates the tracing of product to the responsible party (permittee) in cases of a problem with the product. See, e.g., 27 C.F.R. 1.20-1.22, 4.35a, and 24.300, et seq.[2] In the case of imported products, while the foreign producer is not registered with ATF, the importer is routinely required to produce letters from the foreign supplier about the product as part of the application process.

We would also point out that State liquor control boards also require that persons engaged in the alcohol beverage business obtain a State license, and impose similar application standards, for engaging in business in this industry. An FDA registration requirement for domestic and foreign facilities producing alcohol beverages would appear to be

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[1] The IRC and implementing regulations require that persons wishing to establish operations as a distilled spirits plant (DSP), bonded winery (BW), or brewer must also qualify to engage in such operations. See, e.g. 27 C.F.R. Part 19 (DSP), Subpart G; 27 C.F.R. Part 24, SubpartD (BW); and 27 C.F.R. Part 25, Subpart G (Brewery). The regulations establish a rigorous application process, to allow ATF to evaluate the applicant's likelihood to comply with the law.

[2] While the legal citations in this letter refer to wine, a similar regulatory scheme applies to both distilled spirits and malt beverages/beer as well (except that no permit is required for brewers of malt beverages).

duplicative of existing registration requirements and unnecessary.

Recordkeeping

The recordkeeping requirements required under section 306 of the Act of 2002 are similar in nature and purpose to the recordkeeping requirements under the IRC, 26 U.S.C. chapter 52. The importer, wholesaler, producer, and blender of alcohol beverages are required to maintain records of production and importation. 27 CFR Part 24, Subpart O (wine); 27 CFR Part 19, Subpart W (distilled spirits); 27 CFR Part 25, Subpart U (beer); 27 CFR Part 251, Subpart I (imported distilled spirits, wine and beer). These record keeping requirements are intended to ensure that the tax due on the product is paid, or that the tax is not reimposed upon the product by virtue of the manner in which it is disposed. Therefore, required records track the product from the point of production or importation to its ultimate disposition. Thus, required records under the IRC already establish the immediate previous sources and the immediate subsequent recipients of the alcohol beverages, as is required by the Act of 2002. A requirement that the same or similar information be maintained under FDA regulations would be duplicative and unnecessary.

Prior Notice

As indicated above, section 307 of the Act of 2002 requires prior notice describing the article, the manufacturer and shipper; the grower (if known), the country of origin, and the country from which the article is shipped. This information is also required under regulations implementing the FAA Act. While there is no formal "prior notice" requirement under FAA Act regulations, the information collection is essentially the same and serves the same purpose.

In particular, the FAA Act requires that industry members apply for and obtain a certificate of label approval (COLA) covering the bottled product before the product is introduced into interstate or foreign commerce. The COLA, which is intended to ensure that

the product identifies the product in a non-deceptive way, must contain mandatory alcohol beverage label information, which includes the brand name of the product, the class and type designation, the alcohol content, the name and address of the bottler of packer (domestic product or imported bulk product bottled in the United States) or importer, and the country of origin. The COLA forms are valid indefinitely, provided the beverage content, label and importer remain the same.

Significantly, the Act of 2002 does not define "prior notice" and leaves the amount of time required to satisfy "prior notice" to be established by regulation. Since an approved COLA form must be submitted to Customs at the port of entry as a condition of releasing the product (see, e.g., 27 C.F.R. § 4.40), we believe the purpose of the prior notice requirement is fully satisfied. That is, the purpose of the prior notice requirement is to enable the Government to establish the identity and origin of the product prior to the product's importation into the country. The submission of the COLA forms as a condition to importation satisfies this purpose.

Other ATF Regulation of the Industry

In addition to the above, ATF conducts periodic testing of alcohol beverages and laboratory analyses, as appropriate, to ensure product integrity and compliance with applicable regulations. Numerous alcohol beverage products will not be issued COLA forms without first performing a product evaluation at the ATF Laboratory. ATF conducts occasional alcohol beverage samplings, both targeted and random, testing the integrity and regulatory compliance of alcohol beverage products on the market. ATF also investigates consumer complaints and, in consultation with the FDA, requests voluntary recalls of the product where a health concern is presented.

After attending the Constituent Roundtable: Interagencies meeting on August 6, 2002, I followed up with a telephone call to Ms. Leslye M. Fraser, (Associate Director for Regulations, Office of Regulations and Policy), to discuss the information

outlined in this memorandum and encourage the exchange of information and open dialogue between FDA and ATF, to avoid duplication of registration and recordkeeping requirements of our industry members. ATF believes that the requirements we currently impose on the alcohol beverage industry meet the requirements of P.L. 107-188. ATF recommends further discussion between our agencies to minimize duplication of efforts and unnecessary redundancy in regulating the alcohol beverage industry.

I hope that this information concerning ATF's mission and regulatory functions assists you in your regulations writing process. Should you require further assistance on this matter, please do not hesitate to contact me. I may be reached at the ATF Domestic and International Trade Division (202) 927-8100.

Sincerely yours,

Theresa M. Gladscock
Chief
Domestic and International Trade Division

Attachments

C: Leslye Fraser