

December 26, 2006

Mr. Francis W. Foote  
Director  
Regulations and Rulings Division  
Tax and Trade Bureau  
1310 G Street, N.W.  
Washington, D.C. 20220

**Re: Notice No. 62 – Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages (71 Fed. Reg. 42329 (July 26, 2006))**

Dear Mr. Foote:

On behalf of the Beer Institute, the Brewers Association, the Distilled Spirits Council of the United States, Inc., the National Association of Beverage Importers, the Presidents' Forum, Spirits Canada, WineAmerica, and the Wine Institute, we welcome the opportunity to provide our views regarding the Tax and Trade Bureau's (TTB) notice of proposed rulemaking concerning the adoption of mandatory major food allergen labeling standards for beverage alcohol products subject to the labeling requirements of the Federal Alcohol Administration (FAA) Act.

We appreciate TTB's methodical approach to addressing the goals of the federal Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), including the Bureau's extensive consultation with the Food and Drug Administration (FDA) and the solicitation of substantial background information in the 2005 advance notice of proposed rulemaking. The process of reconciling TTB's longstanding FAA Act mandate to review and approve beverage alcohol labels with the recently-enacted allergen statute poses unique issues that were recognized by Congress when the FALPCA was enacted. In that regard, TTB's mandate to develop labeling standards for beverage alcohol products exists under the FAA Act. Congress did not remove TTB's jurisdiction on the labeling of beverage alcohol products as part of the FALCPA.

Our inter-industry coalition represents beverage alcohol products produced both in the United States and abroad. Many, if not most, of these distilled spirits, beer and wine brands are available for purchase in countries throughout the world. As regulated producers and marketers of distilled spirits, wine and beer, we share the goal of TTB and the intent of Congress embodied in the FAA Act and the FALCPA to provide consumers with meaningful information about the beverages they choose to purchase and ultimately consume. It is from that shared objective that we respectfully submit our views regarding the allergen matters and questions posed by the instant notice.

First and foremost, preserving the integrity, quality and value that U.S. consumers expect from our products, and TTB also demands, provide the foundation for our proffered comments. To that end, we respectfully submit that the ongoing, in-depth review by the European Union (EU) regarding the exclusions of beverage alcohol products produced with and/or processed with major food allergens be utilized to the maximum benefit to assist the Bureau in making its determinations concerning any required label declarations of the presence of a major food allergen.

Second, the Bureau already has very specific requirements for label disclosures and the preexisting flexibility for placing that information on a container should be retained. Third, the specific types of allergen label declarations should take into account the Bureau's long history of regulating our products, including the use of processing aids and/or fining agents in the production of the finished product. Finally, the timing of implementing regulations regarding an allergen labeling declaration scheme should account for all of the scientific, logistical and related steps to ensure that the objectives of the FAA Act and the FALCPA are fulfilled by providing consumers with beneficial, non-misleading information.

### **Introduction**

Under this initiative, producers, bottlers and importers of wines, distilled spirits and malt beverages would be required to declare on their respective product labels the presence of milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans unless an exemption applies to the product categories in question. (71 Fed. Reg. at 42329.) At the outset and as a predicate for our submission, however, we note that there is a seminal disconnect between the preamble language set forth in the Bureau's notice, which is consistent with the Congressional directive regarding major food allergen label declarations, and various sections of TTB's proposed regulations.

As the Bureau correctly notes in its preamble section to its proposed rules, only those products that contain a major food allergen require a label declaration unless otherwise exempted. (See, e.g., 71 Fed. Reg. at 42329-31.) Put simply, a major food allergen labeling declaration is "triggered" by the presence of that allergen in the finished product; i.e., the product contains the major food allergen, unless otherwise exempted.

As currently drafted, the proposed regulations inappropriately (perhaps inadvertently) would "trigger" the labeling declaration if a major food allergen is "used" in the production of the beverage alcohol product (see proposed sections 4.32a(b), 5.32a(b), 7.22a(b)). For example, proposed section 4.32a(b) states:

Labeling requirements. All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a wine, including major food allergens used as fining or processing agents, must be declared on a label affixed to the container, except when subject to an approved petition for exemption described in § 4.32b.

(71 Fed. Reg. at 42341; emphasis supplied.) Similar language also is employed for distilled spirits and malt beverages in the proposed regulatory sections noted above.

Further, the proposed regulations also are internally inconsistent insofar as the other sections of the proposed rules recognize that the “triggering” requirement for a major food allergen label declaration is whether the product itself contains the allergen. To that end, once again, the Bureau correctly notes the objective of and directive by Congress in the discussion of its proposal wherein TTB states:

Furthermore, the House committee report that directed TTB to work with FDA to implement allergen labeling for alcohol beverages stated that “[s]ince there is currently no cure for food allergies, consumers need to be empowered to know whether or not food allergies are present in the food they consume.”

(71 Fed. Reg. at 42333; emphasis supplied.)

As stated above, we are operating under the assumption that employing the word “use” in terms of “triggering” an allergen label declaration was an oversight by the Bureau and we would be pleased to provide suggested regulatory language to correct that oversight, as well as language to accomplish the recommended revisions to TTB’s proposed rules discussed below.

With the above-referenced critical point taken into account, our comment addresses seven seminal categories underpinning the Bureau’s proposal to implement allergen labeling for beverage alcohol products that contain a major food allergen:

- (1) how best to determine what products will be required to declare the presence of a major food allergen on container labels and what products will be exempted from such a declaration, as well as what products are not affected by the FALCPA;
- (2) the process and procedure to be utilized in making those determinations;
- (3) how best to implement these determinations;
- (4) for products that ultimately require a label declaration, how such declaration should be stated and where this statement can be made on a product container;
- (5) codification of the “cross-contact” exception to allergen labeling;
- (6) the timing and implementation steps for any required labeling for the presence of a major food allergen; and
- (7) how best to implement allergen labeling for beverage alcohol products without erecting unnecessary barriers on international trade given the existence of analogous allergen labeling requirements in other nations.

Our comment also responds to the specific queries identified by the Bureau in its notice of proposed rulemaking that are discussed herein and set forth in the attached chart.

## **I. Allergen Label Declarations: Exclusion of Products and Product Categories**

We fully support the Bureau's determination that any exemptions from allergen labeling should apply to categories or classes of products using a particular process involving a major allergen. (71 Fed. Reg. at 42337.) This approach is sound from a scientific, consumer protection and marketplace perspective. As the Bureau well knows, the EU follows an identical approach in terms of excluding categories of products that are produced and/or processed in a similar manner, i.e., the exclusions from the allergen labeling requirement are linked to the specific methods of manufacture and/or uses identified in the documentation supporting the exclusions.

Any other approach would be an unnecessary expenditure of TTB resources, without any commensurate benefit for either the Bureau or the consuming public. It only would serve to impede commerce for both domestically-produced and foreign-produced goods with no countervailing purpose served pursuant to the FAA Act, the FALCPA or otherwise.

To that end, we submit that the same rationale supports, if not dictates, a complementary approach whereby the Bureau would act concordantly with the EU in terms of, at a minimum, taking into account the timing of the European Scientific Panel on Dietetic Products, Nutrition and Allergies' review and determinations for usages of major food allergens in production processes that also are utilized by industry members in the United States, Europe and elsewhere. This approach also appears to have been anticipated by TTB itself in the instant notice: "TTB is not proposing a provisional exclusion for any ingredients or substances at this time." (71 Fed. Reg. at 42337; emphasis supplied.) Given the ongoing work of the EU that is near completion, we submit that the timing now is appropriate for adopting a provisional exclusion.

As stated in the Bureau's notice, the European Commission, after receiving notice of several scientific studies and after consultation with the European Food Safety Authority (EFSA), provisionally excluded from an allergen label requirement beverage alcohol products that are produced and/or processed with major food allergens until November 25, 2007. These exclusions are: (1) distillates made from cereals containing gluten; (2) distillates made from whey (milk); (3) distillates made from nuts; (4) lysozyme (egg) used in wine; (5) albumen (egg white) used as a fining agent in wine and cider; (6) fish gelatin or isinglass used as a fining agent in beer, cider or wine; (7) milk (casein) products used as fining agents in cider and wines; and (8) nuts used as a flavor in spirits. (European Commission Directive (2005/26/EC).)

The EFSA Scientific Panel based its interim decisions upon a substantial record, which includes a number of detailed scientific analyses, as well as practical input from industry members and researchers in the United States and other nations. Industry members and associations from Europe, Australia and New Zealand, as well as from the U.S. and elsewhere, contributed to this scientific record by, among other things, providing product samples. The beverage alcohol products of these industry members are widely sold in the United States; consequently, the record contains relevant information for U.S. policymakers that should be taken into account.

The dossiers submitted to support these provisional exclusions provided sufficient scientific information and data to allow EFSA's Scientific Panel to make their respective

determinations, which were affirmed by the Directorate General of Health and Consumer Protection (DG SANCO). For example, in reviewing the dossiers on distillates made from cereals, whey and/or nuts, the Panel concluded that it is generally acknowledged that proteins, peptides or fragments will not be carried over into the distillate; therefore, distillates made from cereals, whey and/or nuts are unlikely to cause an adverse reaction in cereal, whey or nut allergic individuals, respectively. In that regard, it also is significant to note that the overwhelming number of provisional exclusions from EU Allergen Directive (2003/89/EC) are for categories of beverage alcohol products.

The distillate dossiers and the dossiers for usages of a major food allergen as a processing aid or fining agent in producing the finished beverage alcohol products have been filed with EFSA for its review and approval in making the beverage alcohol provisional exclusions permanent. To make decisions prior to EFSA's deliberations being finalized will not produce the best results to protect consumers for several reasons. First, as discussed above, United States industry members have cooperated in the scientific analyses and studies undertaken in the EU to determine which product categories should or should not be labeled for major food allergens based upon sound science and what is best to protect consumers. These data from U.S. industry members that employ the same processes in producing their respective products obviously will be the predicate for exemption sought under the Bureau's proposed scheme, whether for distillates using a major food allergen as a raw material prior to fermentation and distillation and/or for other beverage alcohol products that use a major food allergen as a processing aid or a fining agent in their respective production processes.

Second, a scenario that ignores the EU research and decisions could result in the exact same products being labeled as containing allergens in the U.S. and not in the EU. In today's global marketplace, such a result would be misleading and confusing to the very consumers the allergen laws are designed to serve. Third, the synchronization of activities to implement analogous allergen labeling requirements represents sound public policy and recognizes the preceding, ongoing efforts of the EU that also will achieve the objectives of the FAA Act and the FALCPA.

The legislative history of the FALCPA also supports the wisdom of this approach. For example, Congressman Radanovich stated in support of this legislation as follows:

I anticipate that the Tax and Trade Bureau, in consultation with the FDA, will take the results of this international research into account in determining whether additional regulations requiring allergen labeling would be appropriate for wine and other alcoholic beverages. Among other things, the Tax and Trade Bureau should evaluate whether any such regulation would create an inadvertent international trade barrier.

(150 Cong. Rec. H6101 (July 20, 2004).)

Such action by TTB will allow for the completion of the work that currently is being conducted domestically and internationally, and, in terms of labeling, the sound scientific evidence presented therein will be of true benefit to consumers. The results of these undertakings should be available by the fourth quarter of next year at the latest.

To effectuate this approach, TTB should provide for temporary exclusions from allergen labeling for the product categories currently exempted by the EU and allow until at least the first quarter after the EU renders its final determinations for the filing of appropriate exemptions under the Bureau's labeling schema, followed by reasonable periods of time to render decisions in these exemption petitions and for the implementation of new labeling requirements, if necessary.

Any other approach potentially could force industry members who export their respective beverage alcohol products to the United States to label those products as containing allergens, though those industry members have a temporary exclusion from such labeling in the EU and most likely will obtain a permanent exemption. Conversely, precipitous action could result in the same products being labeled for the U.S. domestic market, with no such requirement for the EU and other markets.

## **II. Allergen Labeling Exemptions: Process and Procedure**

TTB and FDA officials informed industry members that beverage alcohol products, which do not contain protein, such as distillates using the major food allergens as their raw materials prior to fermentation and distillation, are outside the scope of the FALCPA. This advisory makes common sense and we equally were informed by both TTB and FDA that, for those products, industry members would not be required to invoke any exemption process for the purposes of an allergen labeling scheme. We understand that the Bureau now has revised its position in that regard; nevertheless, we urge the Bureau to reconsider its current stance. Further, other beverage alcohol products also will fall outside the Act either because their finished products do not cause an allergic response posing a human health risk or do not contain allergenic protein.

To that end, the FALCPA provides for an exemption process from its labeling requirements via two routes: (1) the filing of a petition with FDA demonstrating that the food ingredient does not cause an allergic response that poses a risk to human health, which FDA must act upon within 180 days of receipt or the petition shall be deemed denied unless an extension of time is afforded; (2) the filing of a notification with FDA demonstrating that the food ingredient does not contain allergenic protein and such food may be introduced into interstate commerce 90 days after the date of receipt of the notification by FDA unless FDA within that 90-day period objects in writing.

To streamline the exemption process proposed by the Bureau and to effectuate the FALCPA, we propose four modifications to the exemption process set forth in TTB's proposed rules: (1) the addition of a 90-day notification procedure demonstrating that the finished beverage alcohol product does not contain allergenic protein; (2) an interactive process between the Bureau and the petitioner upon filing for an exemption; (3) the requirement for a statement of

reasons for denial of an exemption; and (4) an articulation in the regulations recognizing that the best, reasonably available scientific evidence and methods will be utilized in determining exemptions.

**A. Incorporate a 90-day Notification Procedure for Allergen Labeling Exemptions**

In addition to the 180-day petition process set forth in TTB's proposed rule, the Bureau should adopt the 90-day notification procedure, which also is set forth in the FALCPA. To that end, as provided for in the FALCPA, TTB's final rule should state that the notification must contain scientific evidence (including the analytical method used) demonstrating that the distilled spirit, wine, or beer (or categories or classes of these products produced and/or processed in a similar manner) does not contain allergenic protein. In response to receiving the notification with accompanying evidence, TTB would have 90 days to determine the sufficiency of the evidence that the distilled spirit, wine, or beer (or categories or classes of these products produced and/or processed in a similar manner) does not contain allergenic protein. Unless the Bureau acts within the 90-day period, the allergen labeling requirement does not apply to the products (or categories or classes of these products produced and/or processed in a similar manner) subject to the notification. The inclusion of the FALCPA's notification procedure is appropriate and necessary since Congress intended to provide more expeditious determinations of exemptions for products that have no allergenic protein and thus fall outside of the scope of the Act.

We respectfully submit that the Bureau's proposal to provide for one petition procedure, rather than separate petition and notification procedures, will not simplify the process for industry and/or facilitate the Bureau's allocation of resources to review the evidence presented in each request for an exemption as suggested in the Bureau's notice. (See 71 Fed. Reg. at 42339.) Congress clearly recognized the need and benefits of the two exemption procedures. By providing for the notification exemption process, Congress set forth an expeditious route where, absent any objection, the food, including beverage alcohol products, is exempt from any major food allergen labeling requirement, thereby providing for a better allocation of agency resources. We urge the Bureau to follow this course of action.

**B. Incorporation of an Interactive Petition Process to Expedite Decision-Making**

Under the proposed rules, an industry member that files a petition for an exemption from allergen labeling may obtain no feedback from the Bureau and then, for example, on the 180<sup>th</sup> day after the filing of the petition, learn – with no explanation (or even a notification) from TTB - that the petition has not been granted. This process can be improved significantly to the benefit of TTB, industry members and the consuming public by adding provisions to provide the Bureau and the petitioner with the opportunity to exchange views and information regarding the petition during the decision-making process.

To that end, we urge that the Bureau post within 14 days of receipt the fact that a petition has been filed with TTB and notify the petitioner within 45 days after receipt of the petition whether the petition meets the basic criteria upon which a decision for exemption can be made (e.g., the inclusion of the analytical methods used to produce the evidence), and within 60 days

after receipt to require from the petitioner the submission of product samples and/or other additional information in support of the petition. These proposed procedural steps are similar to those included in the Bureau's current interactive process for applications in labeling proceedings. (Numerous provisions in 27 C.F.R. Part 13 Subparts C and E concerning respectively, COLA applications and revocations, give the COLA applicant or owner the right to request informal discussions, conferences, etc. with TTB.)

We submit that the proposed procedures will provide a more robust and expeditious process in examining exemption petitions, and should equally apply to both the 180-day petition and 90-day notification exemption process. As currently set forth in the notice, the exemption procedures could result in an endless cycling and recycling of information. In that regard, the proposed regulations provide that, "unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition." (71 Fed. Reg. at 42342-42344.)

Certainly, if the Bureau and/or the petitioner deem that additional information would amplify the petition, each party should have the opportunity to so advise, communicate and supplement without "restarting" the entire process, which would be of no commensurate benefit to any interested party. The FALCPA, as well as the draft amendments to 27 CFR Parts 4, 5, and 7, expressly provide for an extension of time during the petition process, and the use of a mutually-agreed upon extension would be far more efficient for TTB and industry members than beginning again the entire process. This is particularly true of the current heightened interest in allergen research since enactment of the FALCPA. Ongoing and pertinent research could be published while a petition is pending and could guide agency and industry personnel toward a sound decision. With a more interactive process, TTB and industry would more readily provide each other guidance regarding any concerns, issues or other matters that may be raised regarding the notification procedure and/or the exemption petition.

### **C. TTB Should Provide a Statement of Reasons for Denial of a Notification or Petition for Exemption**

We support TTB's proposed provisions that allow for the resubmission of an exemption petition, but such procedures only create a vicious circle of submission and resubmission unless the petitioner can be responsive to the reasons for the denial. To that end, we urge that the proposed regulations be revised to require TTB to provide a written statement of its reasons for denial of an exemption petition and/or a notification submission.

In that regard, FDA posts a written response if it objects to an exemption request. A similar requirement in TTB's regulations not only would be consistent with FDA's actions to date by providing the reasons for such actions, but also would be consistent with the Bureau's procedures and rules for applications and labeling proceedings as noted above.

Finally, a petitioner that is provided with a statement of reasons for a denial is better able to make an informed decision regarding its future course of action. In sum, by requiring TTB to provide the petitioner with a written statement of reasons for the denial of a request for an

exemption, all interested parties are served insofar as providing for an understanding of the underlying record and an appropriate future course of action.

**D. TTB Regulations Should Recognize the Use of the Best, Reasonably Available Scientific Evidence and Methods in the Exemption Process**

We trust that, working in tandem, TTB and FDA will respond to the FALCPA in a manner that meets its objectives. In that regard, the Food Allergy & Anaphylaxis Network (FAAN) stressed during FDA stakeholder meetings conducted after the passage of the FALCPA that any labeling for food allergens must take into account whether or not that food will produce an allergic reaction, and that labeling for all allergen levels may lead to further restricted diets, increased frustration and risk-taking; thereby undermining the integrity of labeling statements. Consumers need to trust that the allergen labeling information is reliable and not be subjected to precautionary statements where the statement will be ignored based upon, for example, prior experience consuming the food product in question.

To accomplish that goal, we urge that the Bureau specifically recognize in its regulations that notification submissions and exemption petitions should be based upon the best, reasonably available scientific evidence and methods, and that decisions regarding these submissions also will utilize these criteria. By including provisions that permit exemption requests, Congress must have intended that potentially affected producers would be able to meet their burden of proof using the best, reasonably available scientific evidence and methods. Certainly, Congress would not have intended exemption requests to be a futile exercise resulting in systematic agency denials.

To that end, TTB's regulations explicitly should recognize that the "best, reasonably available scientific evidence and methods" will be utilized as the basis for making exemption decisions. This approach is in accord with the Senate Committee Report's guidance in implementing the FALCPA's exemption provisions: "The committee encourages FDA to adopt a reasonable standard for determining whether a food ingredient 'does not contain an allergenic protein.'" (S. Rep. No. 108-226 at 7.)

The recognition of such a standard also is in accord with the approach advised by food allergen experts. For example, Dr. Steve Taylor, Professor and Co-Director of the Food Allergy Research and Resource Program at the University of Nebraska, stated that: "Labeling should be based on risk. If there's no risk, there should be no label....Unless certain provisions are made to account for this kind of thing, there will be hundreds of products with those ingredients listed. Consumers will say, 'I've been eating this for 20 years and never had a problem, and now it has this allergen on the label.'" (Martha Filipic, "New Food Allergen Law Could Cause Confusion," Ohio State University Extension, Nov. 3, 2004; see also proceedings of the December 5-6, 2006 FARRP Workshop.)

At the December FARRP Workshop, Dr. Taylor also noted in that regard that there is "no clinical reason to 'chase molecules'" in his handout materials regarding detection limits. In discussing various food ingredient issues in his Workshop presentations, Dr. Taylor pointed to isinglass used "as a clarifying agent in beers, ales, wines, and champagnes," with "extremely low

