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 180th 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

residual levels [of isinglass] remain[ing] in these beverages as consumed" and that there is "no evidence of allergic reactions of fish-allergic individuals to isinglass."

We submit these points because consumers only will benefit from meaningful allergen labeling statements that provide information that an individual with allergies can rely upon in making food choices. Scientifically-based allergen labeling, which properly identifies those products containing allergenic protein capable of causing an adverse reaction, can provide beneficial information to consumers with allergies.

Labeling that is not based upon the best, reasonably available evidence, and is misleading or confusing, will limit consumer choices unnecessarily and would not be beneficial. For all of these reasons, we urge the inclusion of the above-referenced language in the Bureau's proposed regulations implementing the exemption process.

III. Implementing Exemption Determinations

The Bureau is very familiar with the production processes, raw materials and constituents of the beverage alcohol products it regulates. If necessary and/or appropriate, the confirmation of exclusion from the FALCPA could be utilized to inform both domestic and foreign beverage industry members of what products do not require an allergen labeling declaration.

As stated above, many beverage alcohol products will fall outside the scope of the FALCPA given their respective "recipes" and/or production processes. For these products that are exempted from an allergen label declaration, we urge the Bureau to put in place a mechanism indicating that these categories of products are exempted from the Act's labeling requirements. For example, an entry on a formula approval or statement of process application could indicate that the product potentially subject to the application falls outside the Act because an exemption has been granted for a category or class of products using specific methods of manufacture and/or uses as specified in the exemption that covers the product category or class subject to the application. Alternatively, a data sheet similar to the Flavor Ingredient Data Sheet could be used for this purpose and/or for flavors in that regard. The Bureau also could post on its website the categories or classes of products involving a major allergen that are exempted from an allergen container labeling requirement.

IV. Statement and Placement of Allergen Labeling Declarations

A. Location of Allergen Statement

We support TTB's proposal to allow industry members flexibility in the placement of a mandatory allergen labeling statement. Similar to sulfite labeling, this flexibility should not interfere with the consumer's ability to locate the allergen declaration. The two decades of history and experience with sulfite labeling support this course of action. No new or more stringent placement requirements should be imposed. The Bureau's approach to sulfite labeling has served its intended purpose of alerting consumers about this allergen and also has allowed the flow of global commerce. We submit that the Bureau's response to sulfite disclosures has

served well the regulated communities, the public and the Bureau, without erecting barriers to trade for products imported into the United States.

To that same end, we also urge the Bureau not to adopt its proposed rule that would require a second label indication when the allergen already is included in the name under which the beverage is sold. A second label indication would be confusing and redundant with no offsetting benefit to the consumer. TTB should take into account the EU's approach whereby a labeling indication is not necessary when the allergen already is included under its specific name on the label of a product, for example, in the statement of composition pursuant to 27 C.F.R. § 5.35, or in the name under which the beverage is sold. These approaches have served and will continue to serve all interests well – the Bureau, the consuming public and industry members both here and abroad.

In discussing this issue in the notice of proposed rulemaking, TTB raises two hypothetical products, "Wheat Creek Lager" made by Wheat Creek Brewery and "Creek's Wheat Beer" (where only the latter brand contains wheat). The Bureau asserts that the consumer should not have to guess in these hypotheticals whether they contain wheat, and that consumers should be able to look at the label and determine right away whether they contain an allergen. (71 Fed. Reg. at 42334.)

We do not believe that these hypotheticals support the issuance of a final rule that require a second indication where the allergen is included in the name of the product. First, "Creek's Wheat Beer" necessarily does indicate to the consumer that it contains wheat. TTB would not approve a COLA for a brand named "wheat beer" if it did not contain wheat because such a product name clearly would be false and misleading. (See TTB's Beverage Alcohol Manual, Volume 3 (Malt Beverages) (Ch. 4, p. 5), identifying "wheat beer" as a class and type designation of malt beverage made from a fermentable base that consists of at least 25% by weight malted wheat.)

Regarding "Wheat Creek Lager" made by Wheat Creek Brewery, we read this as identifying a place, "Wheat Creek," as well as a brewer that is named after this place. More significantly, this isolated hypothetical example is not representative of the types of product names that are commonly used in the marketplace, and it is far "outnumbered" by the numerous products actually in the marketplace that have a name which expressly identify an allergen contained in the product.

Rather than relying upon the "Wheat Creek Lager" by Wheat Creek Brewery hypothetical, we urge the Bureau to focus upon the many products that would be affected; viz., those with brand names that expressly identify the specific food allergen. In fact, TTB's proposal to require a second indication on the labels of these and similar types of products could be confusing and redundant with no offsetting benefit to the consumer.

B. Naming Fish Species Should Not Be Required

We support the approach set forth by the Bureau in its notice whereby a beverage alcohol product using isinglass or fish gelatin as a processing aid, which otherwise is not exempt from an

allergen declaration, can be labeled with the word "fish," rather than with the name of the fish species. As the Bureau correctly points out, several different fish species are used in the production of isinglass and the actual species present in any particular isinglass product may vary from time to time according to availability.

In light of the fact that isinglass producers purchase the raw material from various sources depending upon availability of good quality product, it currently is not possible to accurately identify which species of fish are found in the final product. Consequently, the vintners and brewers purchasing the isinglass or fish gelatin would have no way of easily or reasonably ascertaining the particular species of fish used in producing these products.

C. TTB Regulations Should Provide for a "Processed With" Statement for Processing Aids and Fining Agents

In the interest of providing accurate product information to the wine or beer consumer and in response to the Bureau's specific query posed in the instant notice, the use of a "Processed with" statement instead of "Contains" would allow for a more accurate description of a product treated with fining agents or processing aids during production.

The intentional use of fining agents or processing aids in winemaking and beermaking is based upon millennia of practical experience and upon an understanding of the unique chemistry of these products. These materials precipitate out of the wine and beer during use, leaving minimal (if any), residues in the final product. In such circumstances, to place a statement on a label that indicates that the final product "Contains" the specific allergen potentially would be misleading and unhelpful to the consumer. On the other hand, "Processed with" is more specific information which acknowledges that the fining agent or processing aid has been used during the production process, but does not necessarily imply that there are quantifiable residues in the final product.

D. The Use of Processing Aids and Fining Agents Can Vary Batch to Batch

The decision of what fining agents or processing aids are to be used in a particular batch is often only made just prior to bottling. This sequence poses a very significant timing problem since labels must be designed, ordered and printed before the winery or brewery is likely to know which fining agent, if any, will be used. Therefore, an appropriate and practical statement would have to be more inclusive than necessarily definitive. These facts should be taken into account in the Bureau's determination regarding the most appropriate allergen labeling statement, such as "Contains," "May Contain" or "Processed with," so as to achieve the highest level of accuracy for consumers.

V. Codifying the "Cross-Contact" Exception to Allergen Labeling

FDA's Final Guidance to Industry regarding "Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004" issued in October 2006 notes that the FALCPA's allergen disclosure requirements "do not apply to

major food allergens that unintentionally are added to a food as the result of cross-contact." FDA stated that "'cross-contact' occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment." (See also FDA's July 2006 Report to the Senate Committee on Health, Education, Labor, and Pensions and to the House Committee on Energy and Commerce, "Food Allergen Labeling and Consumer Protection Act of 2004 Public Law 108-282.")

In other words, although an allergen residue or trace amount might be present in a product through cross-contact, FDA's determination is that the FALCPA does not require disclosure of the presence of the allergen. We submit that this cross-contact policy also should be embodied in TTB's allergen labeling regulations. We urge TTB to consider this issue together with our proposals set forth above regarding the evaluation of exemption notifications and petitions, as well as the use of the nomenclature "Processed with" and "May Contain" for those products that may require an allergen label declaration.

VI. Timing and Implementation of Allergen Labeling Declaration

We propose a mandatory compliance date of at least 24 months after the issuance of the Bureau's final rule. Any affected product labeled on or after that date would be subject to allergen label requirements. This timeframe takes into account the preparation and submission of exemption notifications and petitions after the EU has made its final decisions regarding permanent exclusions from its analogous allergen labeling scheme for major food allergens vis-à-vis the relevant beverage alcohol products.

It also takes into account the circumstance of the possibility of resubmitting such exemption notifications and petitions along with supporting materials to the Bureau for reconsideration as set forth in TTB's proposed regulations. Finally, this timeframe also takes into account the necessary lead time for the preparation of labels, the submission of COLAs if an industry member so chooses and consequent State registrations/notifications for new COLAs.

This compliance date schema would ensure that TTB has the opportunity to review the best, reasonably available scientific information upon which to base its exemption decisions, as well as providing adequate time for industry members to complete the exemption process under the TTB rules and, if the petition ultimately is denied, to make changes to bring their operations into compliance with allergen labeling requirements.

Under the proposed compliance timeframe, the Bureau will be able to most effectively ensure the protection of consumers if its exemption determinations are based upon the best, reasonably available scientific data and analyses available. This scientific data is contained in the dossiers submitted to the EFSA by the beverage alcohol industry in support of the requests to make permanent the provisional exclusions from allergen labeling requirements previously granted by the EU. Opinions from EFSA that will direct the EU's final exemption decisions are expected to be issued prior to November 25, 2007 (more than likely by the second or third quarter of 2007) so as to permit the EU to prepare the necessary legislation formalizing the

definitive exemptions by that required deadline. As stated above, the pertinence to TTB of the data under consideration by the EFSA is further underscored by the fact that it is based, in part, on product samples submitted by the U.S. beverage alcohol industry.

Absent the EU information, TTB possibly may deny exemptions where the best, reasonably available scientific evidence does not support requiring allergen labels. Such action would adversely affect consumers by leading to further restricted diets, increased frustration and risk-taking; thereby undermining the integrity of labeling statements.

Regarding the second component of the proposed compliance timeframe, industry members that file notification or exemption petitions with TTB may not know until 90 or 180 days later whether they will be subject to allergen labeling requirements. Further, industry members may choose to resubmit their respective exemption requests depending upon, among other things, the reasons proffered by the Bureau to support its denial. Throughout this process, industry members with categories or classes of products using a particular process involving a major allergen subject to a pending petition should not be subject to an allergen label declaration until the ultimate decision is made to so require.

For categories or classes of products that were the subject of a notification or exemption petition that ultimately was denied, those affected industry members will need adequate time to prepare an allergen label declaration and make the necessary changes to their respective labeling process. Although the Bureau's notice does not envision a requirement to submit a new COLA for a product before adding a major food allergen declaration to the label, many industry members may choose to follow that course as they have done when other mandatory information was required on container statements.

Thus, the third component of the proposed compliance timeframe takes into account not only the preparation of new labels, but also the time period subsumed in submitting and obtaining an approved COLA. As the Bureau well knows, various States require new brand registration/notifications for products with new COLAS. The State process also can be lengthy, taking up to at least three months and, given the potential increase of applications in a discrete period of time, the State process may be even longer.

If the labeling date is not used as a "trigger point" for a product subject to an allergen label declaration as is the case under the FALCPA, we again urge that the Bureau adopt the staged approach utilized for sulfite labeling incorporating the proposed compliance timeframe discussed above. We outlined the phased approach for the label declaration of sulfites for products so affected in our September 26, 2005 comment. As discussed therein, the Bureau's system for compliance with the sulfite label declaration was proven to be efficient and effective.

Regarding the proposed implementation timeline discussed above, the Bureau may wish to note that FDA provides for a two to three-year transition compliance date for any new labeling requirements issued by FDA between January 1, 2007 and December 31, 2008. (See 71 Fed. Reg. 76599 (December 21, 2006).) In establishing a twenty-four to thirty-six month period for implementing its labeling rules, FDA in its final rule provides the following rationale:

> Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices.

(71 Fed. Reg. at 76599-76600.)

VII. Consumer Protection and International Trade: Allergen Labeling for Similarly Produced Products

We again applaud the Bureau's methodological approach to the FALCPA. This approach has served the Bureau well given the very unique circumstances surrounding allergen labeling and beverage alcohol products. These circumstances are unique insofar as these classes of products have been the subject of exclusions from analogous allergen laws more than any other food categories.

As described above, the EU permanent exclusions for a variety of uses of major food allergens in the production and/or processing of beverage alcohol products will be forthcoming. Similarly, Food Standards Australia New Zealand (FSANZ) has under consideration an exemption from an allergen declaration for fining agents and processing aids used to produce beer and wine, and already has explicit exemptions from its labeling schema for distilled spirits and beer when cereals, including wheat, are present in those products. As the Bureau also may be aware, Health Canada also has exempted beverage alcohol products from allergen label declarations where the food allergen was used as a raw material in the distillation process and/or used as a fining agent or processing aid in producing these products. (See attached 2004 Health Canada correspondence.)

We respectfully submit that no country has a monopoly on the best scientific evidence or the best scientific judgment. We also submit that the quintessential concern underpinning the decision to include or exclude product categories from an allergen label declaration rests in how best to protect the consumer. To that end, concordant determinations regarding allergen labeling among countries will serve all interested parties. A scenario where the exact same product is being labeled as containing allergens in one country, but not another country, serves no interests.

With a global economy and with free travel among consumers, we urge that determinations made by respective government bodies about allergen labeling be synchronized so that the applicability of an allergen labeling requirement for a particular product is the same from one country to another and the ability to comply with such a requirement does not impede trade without serving a public interest. The associated costs of disparate labeling requirements are incalculable from the perspective of the marketplace, industry members and, most importantly, consumers.

Putting aside the enormous cost and burden for industry members of disparate labeling requirements and revising relevant labels for the same products, the result of such action is potentially misleading and confusing to the very consumers that the allergen laws are intended to serve – again such cost is incalculable.

Conclusion

On behalf of our respective members representing distilled spirits, wine and beer brands produced both in the United States and countries around the world, we appreciate the opportunity to comment upon the Bureau's allergen labeling initiative. We fully support the purpose and objectives of the FALCPA and stand ready to work with TTB in the implementation of this Act.

A mandatory allergen labeling scheme that is scientifically-based and properly identifies those beverage alcohol products containing allergenic protein capable of causing adverse reaction serves the objectives of TTB, the FAA Act and the FALCPA by providing consumers with beneficial, non-misleading information regarding food allergens.

If you have any questions concerning our comment and/or otherwise, please do not hesitate to contact us.

Sincerely,

Mr. Arthur J. DeCelle
Beer Institute

Mr. Paul Gatza
Brewers Association

Ms. Lynne J. Omlie
Distilled Spirits Council

Mr. Robert J. Maxwell
National Association of Beverage Importers

Mr. Donald C. MacVean
Presidents' Forum

Mr. Jan H. Westcott
Spirits Canada

Mr. Bill Nelson
WineAmerica

Mr. Wendell Lee
Wine Institute

Enclosures

LJO:stn