September 26, 2005

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. 41 – Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages – Allergen Labeling (70 Fed. Reg. 22274 (April 29, 2005))

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 implementing the Food Allergen Labeling and Consumer Protection Act of 2004 for those beverage alcohol products that will be subject to the labeling provisions pursuant to this Act.

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 Federal Alcohol Administration (FAA) Act of providing consumers with meaningful information about the beverages they choose to purchase. It is from that shared objective that we respectfully submit our views regarding the allergen questions posed by the instant notice.

Introduction

The Bureau's advance notice poses several questions regarding the implementation of the Food Allergen Labeling and Consumer Protection Act of 2004. Allergen labeling is not new for beverage alcohol products as evidenced by the current requirement for sulfite labeling and, as in the past, we are confident that the Food and Drug Administration (FDA) and TTB working in tandem will provide guidance and rules that will serve the interests of the consuming public and meet the objectives of the Allergen Act.

One of the United States' largest trading partners, the European Union, also recently adopted allergen labeling requirements for food products. With a global economy and with free travel among

consumers, we urge that determinations made by respective government bodies about allergen labeling be harmonized 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.

To that end, we respectfully submit that TTB's sulfite labeling requirements should be used as a template in promulgating regulations for the labeling of beverage alcohol products pursuant to the Allergen Act. 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. Similarly, the EU's determinations regarding what and how products are to be labeled pursuant to its allergen law should be accorded due regard and credence.

In the discussion below, we offer some suggested procedures germane to implementing the labeling requirements of the Allergen Act and append separate responses for the discrete questions posed by the Bureau in its advance notice regarding allergen labeling. Separately, we also will be submitting an inter-industry petition on behalf of our coalition of both domestic and international organizations pertaining to any additional allergen labeling matters that may arise once FDA provides guidance concerning thresholds for labeling requirements and the process for exemption and notification petitions.

I. Allergen Labeling

Pursuant to the Food Allergen Labeling and Consumer Protection Act of 2004, food products, including beverage alcohol products, that contain an ingredient that bears or contains a major food allergen (milk, egg, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) must include this information on their labels unless the food ingredient does not cause an allergic response that poses a risk to human health or does not contain allergenic protein.

For all food products, including beverage alcohol products, and pursuant to the 1987 Memorandum of Understanding between FDA and the Bureau, FDA will be making decisions regarding what food products will or will not require allergen labeling. In that regard, we understand that FDA is in the process of promulgating guidance in establishing thresholds for these major food allergens in terms of the application of the Act's labeling requirement. We applaud that undertaking and, as stated above, also encourage due regard to the actions taken by the European Union regarding what products do or do not require labeling under the EU Allergen Directive (2003/89/EC).

Many beverage alcohol products are outside the scope of the Food Allergen Labeling and Consumer Protection Act since they do not contain protein. Other beverage alcohol products also will fall outside the Act either because their food ingredients do not cause an allergic response posing a human health risk or do not contain allergenic protein. For these other beverage alcohol products, we urge FDA and the Bureau to follow the approach taken by the EU that excludes

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. To that end, we have appended a copy of the European Commission Directive (2005/26/EC) establishing a list of food ingredients and substances provisionally excluded from Annex IIIa of Directive 2000/13/EC.

Finally, for those products that will require labeling, we urge the Bureau to follow the approach currently utilized in Parts 4, 5 and 7 regarding sulfite labeling. We also urge the Bureau to take into account the approach adopted by the EU 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. For the convenience of the Bureau, we would be pleased to prepare suggested revisions to Parts 4, 5 and 7 reflecting these proposed amendments to TTB's current rules.

We submit that this proposed framework for products requiring allergen labeling will meet and satisfy the Congressional directive to the Bureau set forth in the Act's conference report: "The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products."

We trust that, working in tandem, TTB and FDA will implement the Food Allergen Act in a manner that meets its objectives. In that regard, the Food Allergy & Anaphylaxis Network (FAAN) has stressed during the recent FDA stakeholder meetings 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, and 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.

A robust, scientifically-based allergen labeling schema, which properly identifies those products containing allergenic protein capable of causing adverse reaction, will satisfy all of these interests and concerns by providing consumers with beneficial, non-misleading information.

II. Implementation Procedures

As stated above, the matter of allergen labeling is not new for the Bureau. The Bureau has required sulfite labeling for allergenic purposes since 1987 where sulfur dioxide or a sulfiting

agent is detected at a level of ten or more parts per million, measured as total sulfur dioxide. In implementing this requirement, the Bureau set forth procedures in terms of how to proceed with existing and revised labels; the submission and approval of new applications for label approval; formula and statement of process submissions; and analyses of product samples.

A. Certificates of Label Approval and Existing Inventory

We submit that the staged approach undertaken by the Bureau for sulfite labeling provides a successful template in terms of now implementing the Allergen Act. First, the Bureau implemented a tripartite, phased process for the label declaration of sulfites for products affected by the 10 or more parts per million of sulfites label declaration once that action level was determined.

The Bureau established an effective date for the final sulfite rule, followed by a one-year transition period for the full implementation of the rule. As of the effective date of the sulfite rule, the Bureau's rules provided that all labels submitted for approval for affected beverage alcohol products were required to bear the mandatory label disclosure. Six months after the effective date of this rule, all beverage alcohol products affected by the sulfite rule were required, at the time of bottling, to be labeled with the mandatory label disclosure.

Twelve months after the effective date of the rule, the labels of all beverage alcohol products affected by the sulfite rule were required to include the mandatory declaration upon removal of domestically-bottled products from bonded premises, brewery premises or from a taxpaid wine bottling house and from customs in the case of foreign-bottled products. During the 180-day period beginning on the first day of the sixth month after the effective date of the sulfite rule, producers, bottlers and importers were allowed to remove beverage alcohol products affected by the sulfite rule from bottling premises or from customs custody without a sulfite disclosure provided such products were bottled prior to the first day of that six-month period.

On or after 12 months from the effective date of the sulfite rule, the labels of all beverage alcohol products affected by this rule were required to bear a sulfite declaration upon the removal of such products from bottling premises in the case of domestically-bottled products or withdrawal from customs custody in the case of foreign-bottled products. As of that date, beverage alcohol products affected by the rule could no longer be removed from bottling premises or from customs custody without the mandatory sulfite label declaration, regardless of the dates of bottling.

Given that the volume of applications for certificates of label approval covering previously approved labels would impose a large burden upon the Bureau and upon industry, the Bureau deemed that product labeling covered by an existing certificate of label approval, which solely was revised to include the mandatory sulfite label declaration, was deemed approved without the necessity of submitting a new certificate of label approval. In that regard, the Bureau also permitted the addition of a separate strip or neck label that showed the mandatory sulfite declaration and determined that the use of such a strip label with a previously-approved label would not require the submission of a new certificate of label approval.

Further, the Bureau also determined that the addition of the sulfite label declaration with no other changes to a previously-approved strip or neck label bearing other information also did not require the submission of a new label application. Finally, the Bureau's sulfite implementation rules also provided for the approval of new certificates of label approval for products with a qualification statement indicating when the label must be revised to include the mandatory label declaration.

By all of these actions, the Bureau set up a system that allowed the flow of existing inventory into the marketplace and provided a clear "rules of the road" for both domestic and foreign product in terms of requirements for new certificates of label approval and the removal from bonded premises of previously produced and/or bottled product. These implementation procedures were predicated upon the previous determination by FDA of thresholds for declarations of this allergen, with the Bureau then creating a smooth system to satisfy its own statutory and regulatory requirements regarding product label approvals.

We respectfully submit that these procedures again should be followed by the Bureau in implementing the labeling requirements for beverage alcohol products that will be affected by the provisions of the 2004 Allergen Act.

B. Beverage Alcohol Products Excluded or Included in the Allergen Act

Once FDA promulgates guidance in terms of what products will be subject to the labeling requirements of the Allergen Act, we urge that the Bureau follow the EU scheme in terms of exclusions and the Bureau's approach to products affected by the sulfite label declaration.

As stated above, many beverage alcohol products are outside the scope of the Allergen Act given their respective "recipes" and/or production processes. For other beverage alcohol products, the Allergen Act also 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 determines otherwise.

For products that fall outside of the Act due to these exemptions, 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 subject to the application falls outside the Act because an exemption has been granted for a category of products using specific methods of manufacture and/or uses as specified in the exemption that covers the product subject to the instant 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.

We submit that the proposed system will serve the interests underpinning the Allergen Act and the interests of the Bureau and its regulated communities. Further, the Bureau is very familiar with the production processes, raw materials and constituents of the beverage alcohol products it regulates. This familiarity should provide the Bureau with an added reason to adopt this approach, an approach that also has been adopted by the EU in terms of implementing its allergen label law.

A product-by-product analysis 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 Allergen Act or otherwise.

Conclusion

On behalf of our collective 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 Allergen Act and stand ready to work with TTB in the implementation of this Act. 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. Charlie Papazian
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

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Enclosures

TTB Notice No. 41 Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages	
Allergen Labeling in response to Federal Allergen Labeling & Consumer Protection Act of 2004 (FALCP)	**Inter-Industry Position**
Should TTB require allergen labeling on alcohol beverage containers to be part of or adjacent to a larger list of all ingredients found in the product, similar to the requirements of the Food Allergen Labeling and Consumer Protection Act of 2004? Why or why not?	No. First, there should be no requirement for ingredient labeling or an ingredient statement. Given the substantial transformation of the raw materials used to produce beverage alcohol products in their respective production processes, there is little, if any, relationship between these raw materials and the contents of the finished product. Second, for those products that will require allergen labeling pursuant to the Food Allergen Labeling and Consumer Protection Act, we urge the Bureau to follow the approach currently utilized in Parts 4, 5 and 7 regarding sulfite labeling. We also urge the Bureau to take into account the approach adopted by the EU whereby a labeling indication is not necessary when the allergen already is included under its specific name on the label of a product 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.
1	
If the product name appearing on the label of an alcohol beverage container indicates that an allergen is present in the product, is it helpful to the consumer to have the allergen labeled again in a standardized allergen statement elsewhere on the container? To illustrate: If a product is called "Wheat Beer," should it also have a label elsewhere on the container that reads: "Allergens: wheat"? Why or why not?	No. A second label indication would be confusing and redundant with no offsetting benefit to the consumer. This approach is consistent with the EU determinations regarding allergen labeling requirements whereby a labeling indication is not necessary when the allergen already is included in the name under which the beverage is sold.
2	

Allergen Labeling in response to Federal Allergen Labeling & Consumer Protection Act of 2004 (FALCP)	Inter-Industry Position
TTB's current regulations allow certain allergens such as milk, albumen (egg), isinglass (a protein from fish bladders), and soy flour to be used as fining, processing, and filtering agents in the production of alcohol beverages. While fining, processing, and filtering agents are not primary ingredients in an alcohol beverage product, low levels of an agent may remain in the final product after production. When an allergen is used as a fining, processing, or filtering agent to produce an alcohol beverage, should TTB require that the product be labeled "Processed with [a specific 3 allergen]" or "May contain [a specific allergen]"? Why or why not?	When an allergen is used as a fining, processing or filtering agent to produce a beverage alcohol product, the finished product will require allergen labeling pursuant to the Food Allergen Labeling and Consumer Protection Act if the allergenic protein remains in the finished product unless that ingredient does not cause an allergic response that poses a risk to human health. For all food products, including beverage alcohol products, and pursuant to the MOU between FDA and the Bureau, FDA will be making decisions regarding what food products will or will not require allergen labeling. In that regard, we understand that FDA is in the process of promulgating guidance in establishing thresholds for these major food allergens in terms of the application of the Act's labeling requirement. We applaud that undertaking and also encourage due regard to the actions taken by the European Union regarding what products do or do not require labeling under the EU Allergen Directive (2003/89/EC). Many beverage alcohol products are outside the scope of the Food Allergen Labeling and Consumer Protection Act since they do not contain protein. Other beverage alcohol products also will fall outside the Act either because their food ingredients do not cause an allergic response posing a human health risk or do not contain allergenic protein. For these other beverage alcohol products, we urge FDA and the Bureau to follow the approach taken by the EU that excludes 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.
Should allergenic fining, processing, and filtering agents 4 be labeled in the exact same fashion as all other allergen ingredients? Why or why not?	Please see the responses set forth above.
Testing methods for detecting allergens in food and beverage products typically can only detect an allergen if it is present at or above a certain minimum value. In light of that fact, would it be helpful to consumers for 5 TTB to require an allergenic fining, processing, or filtering agent to be labeled regardless of whether a detection test shows that the allergen is or is not present in the final product? Why or why not?	Please see the responses set forth above. In addition, it is never possible to prove a negative. Modern test methods have evolved to test at extremely low levels and should be sufficient to scientifically establish that no allergenic protein exists. A labeling requirement regardless of whether a detection test shows that an allergen is not present would be misleading to the consumer and would remove a multitude of selection choices for the consumer based upon misleading information.

Allergen Labeling in response to Federal Allergen Labeling & Consumer Protection Act of 2004 (FALCP)	Inter-Industry Position
What is the lowest amount of an offending food allergen (or minimum threshold level) in an alcohol beverage product necessary to provide a mild, yet perceptible adverse allergic reaction in consumers with the most sensitive food allergies?	Please see the responses set forth above.
Is it possible to define a minimum threshold level for each major food allergen? If so, what are the minimum threshold levels for each major food allergen?	Please see the responses set forth above. In addition, TTB should follow the lead of FDA and the scientific community in terms of exemptions from allergen labeling requirements.
If FDA and/or the scientific community establish conclusively a minimum threshold level for a particular allergen, should TTB exempt from any allergen labeling requirements products containing the allergen proteins, but at a level below the established minimum threshold level? Why or why not?	Please see the responses set forth above. In addition, TTB should follow the lead of FDA and the scientific community in terms of exemptions from allergen labeling requirements.
What would be the costs associated with mandatory allergen labeling to the industry and, ultimately, the consumer?	Mandatory allergen labeling requirements pursuant to the Food Allergen Labeling and Consumer Protection Act were signed into law by the President in August 2004.
How might consumers benefit from allergen labeling?	Consumers 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 scientific fact, and is misleading or confusing, will limit consumer' choices unnecessarily and would not be beneficial.

COMMISSION DIRECTIVE 2005/26/EC

of 21 March 2005

establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], and in particular second subparagraph of Article 6(11) thereof,

Whereas:

(1) Annex IIIa of Directive 2000/13/EC establishes a list of food ingredients to be indicated on the label as they are likely to cause adverse reactions in susceptible individuals.

(2) In accordance with Directive 2000/13/EC the Commission may provisionally exclude certain ingredients or products of those ingredients from Annex IIIa to that Directive, while food manufacturers or their associations conduct scientific studies to establish that those ingredients or products comply with the conditions for definite exclusion from that Annex.

(3) The Commission received 27 applications regarding 34 ingredients or products thereof, of which 32 fall within the scope of this Directive, and have been submitted to the European Food Safety Authority (EFSA) for a scientific opinion.

(4) Based on the information provided by the applicant, and other information available, the EFSA has considered that certain products of ingredients are not likely, or not very likely, to cause adverse reactions in susceptible individuals. In certain cases, EFSA has concluded that it cannot draw a firm conclusion, though no reported cases were mentioned.

(5) Those products or ingredients complying with these conditions should therefore provisionally be excluded from Annex IIIa of Directive 2000/13/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The ingredients or substances listed in the Annex to this Directive shall be excluded from Annex IIIa of Directive 2000/13/EC until 25 November 2007.

Article 2

1. Member States shall adopt and publish, by 21 September 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 25 November 2005.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 21 March 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

ANNEX

List of food ingredients and substances provisionally excluded from Annex IIIa of Directive 2000/13/EC

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	— Wheat based glucose syrups including dextrose (1) — Wheat based maltodextrins (1) — Glucose syrups based on barley — Cereals used in distillates for spirits
Eggs	— Lysozym (produced from egg) used in wine — Albumin (produced from egg) used as fining agent in wine and cider
Fish	— Fish gelatine used as carrier for vitamins and flavours — Fish gelatine or Isinglass used as fining agent in beer, cider and wine
Soybean	— Fully refined soybean oil and fat (1) — Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources — Vegetable oils derived phytosterols and phytosterol esters from soybean sources — Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk	— Whey used in distillates for spirits — Lactitol — Milk (casein) products used as fining agents in cider and wines
Nuts	— Nuts used in distillates for spirits — Nuts (almonds, walnuts) used (as flavour) in spirits
Celery	— Celery leaf and seed oil — Celery seed oleoresin
Mustard	— Mustard oil — Mustard seed oil — Mustard seed oleoresin

(1) And products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.