TTB Notice No. 62 Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages	
TTB Questions	**Inter-Industry Position**
1. What would be the costs associated with mandatory allergen labeling to the industry and, ultimately, the consumer?	There obviously will be costs associated with mandatory allergen labeling. We, however, submit that there will be incalculable costs and burdens, economic and otherwise, from the perspective of the marketplace and, most importantly, consumers if disparate decisions are made under analogous allergen labeling requirements in other countries whereby the same exact product is not required to be labeled as containing allergens in one country, but is so required in another country. 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 any such action is potentially misleading and confusing to the very consumers that the allergen laws are intended to serve – again such cost is incalculable. To that end, concordant determinations regarding allergen labeling among countries will serve all interested parties. 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.

2. Does the proposed rule adversely impact small businesses? If so, explain how. If you are a small business and you expect that the proposed rule would have an adverse impact on you, please provide us with specific data on the expected adverse impact.	We believe label declarations that provide consumers with meaningful information about the beverages they choose to purchase should be consistent for industry members regardless of size. A sufficient period of time between publication of the final rule and its effective date to, for example, allow for the requisite decisions and determinations regarding what products may require an allergen labeling declaration, the necessary lead time for the preparation of labels and obtaining a new COLA if an industry member so chooses, with the consequent State registrations/notifications for new COLAs, will permit all industry members to so comply. If TTB decides to make additional changes in regulations setting forth mandatory label information while this rulemaking is pending, we respectfully propose that the effective dates be the same so that industry members only have to revise their labels one time.

3. Are there ways in which the proposed regulations can be modified to reduce the regulatory burdens and associated costs imposed on the industry?	We submit that there are several ways in which the Bureau's proposed regulations and approach to allergen container label declarations can be modified to reduce associated regulatory burdens. Preserving the integrity, quality and value that U.S. consumers expect from our products, and TTB also demands, provide the foundation for our proffered suggestions. First, the ongoing, in-depth review by the European Union regarding the exclusions of beverage alcohol products produced with and/or processed with major food allergens should be utilized to the maximum benefit to assist the Bureau in making its determinations concerning any required declarations of the presence of a major food allergen. 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. Under this approach, the synchronization of activities to implement analogous allergen labeling requirements represents sound public policy and will achieve the objectives of the FAA Act and the FALCPA. Second, to streamline the exemption process proposed by the Bureau, 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. The specifics of each of these modifications are amplified in our comment. Third, the Bureau already has very specific requirements for label disclosures and the preexisting flexibility for placing that information on a container should be retained. Fourth, 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.

4. The proposed rule allows industry members a great deal of flexibility in the placement of mandatory allergen labeling statements. Does this flexibility reduce the costs of compliance? Would this flexibility interfere with the consumer's ability to locate the allergen declaration? Alternatively, should TTB mandate specific placement, type size, and presentation requirements for these labeling statements in addition to the requirements already applicable to all mandatory information on alcohol beverage labels? For example, should the required allergen disclosure statement be set off by a box? Should the statement of major food allergens be combined with existing required disclosures of FD&C Yellow No. 5, sulfites, and aspartame?	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, such as those posed in the Bureau's query. 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. As discussed more fully in our comment, we submit that the hypotheticals raised by the Bureau in its notice, "Wheat Creek Lager" made by Wheat Creek Brewery and "Creek's Wheat Beer," are not supportive of the proposition requiring a second indication where the name of the allergen already is included in the name under which the beverage is sold. 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.

5. Do the proposed rules provide adequate information to consumers about the use of fining or processing agents? Should processing or fining agents be subject to a different labeling requirement, for example, a "processed with" labeling statement instead of a "contains" labeling statement? Would requiring a distinction between primary ingredients and fining and processing agents be informative to the consumer or would it mislead consumers? Would distinct labeling for processing and fining agents allow industry members to impart more specific information about the use of processing and fining aids?	In the interest of providing accurate product information to the wine or beer consumer, 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. Further, 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.

6. Should mandatory allergen labeling statements for alcohol beverages disclose the specific species of fish, or is it sufficient to merely label the allergen as "fish," as TTB proposes?	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.

7. How much time does industry require to comply with mandatory food allergen labeling requirements? What delayed effective date would reduce the regulatory burdens on affected industry members and at the same time ensure the protection of consumers?	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. 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.