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For the attention of:
Director
Regulations and Procedures Division
Alcohol and Tobacco Tax and Trade Bureau
P.O. Box 14412
Washington
DC 20044-4412
United States

Comment 36

December 26th, 2007

**Re: Notice No. 62
Major Food Allergen Labeling for Wines, Distilled Spirits and Malt
Beverages**

Dear Sirs,

We appreciate the opportunity presented by the Alcohol and Tobacco Tax and Trade Bureau to comment on the advance notice concerning the proposed rulemaking for adoption of mandatory food allergen labelling statements for alcoholic beverage products.

AB Vickers is a UK based manufacturer of fining agents for use in the production of alcoholic beverages and has been producing and selling isinglass products to alcoholic beverage producers for more than 200 years.

AB Vickers is supportive of any legislation concerning foods and beverages that is designed to provide consumers with factually correct information, based on best scientific evidence, in order to allow them to make informed choices, particularly with respect to the safety of particular foods. The information should be presented in a clear and unambiguous manner if the consumer is to be able to make these informed choices with confidence.

Isinglass – Production and Application in Beverages

The raw material used for the production of isinglass is the swim bladder of certain fish species. These swim bladders are commonly referred to as 'maws'. The maws are carefully selected and assessed for suitability before undergoing several processing operations resulting in the product 'isinglass' as would be used by a brewer or winemaker. These operations consist primarily of sterilisation, milling, thorough washing and blending to specific formulations. Finished isinglass products are sold in different physical forms, typically powders, pastes or liquids. Isinglass is prepared for addition to the beverage by hydrating in an acidic aqueous solution in order to hydrolyse the collagen structure and enable it to interact with the proteins and yeast in the beverage to be fined.

Isinglass is typically added to the beverage at the end of the fermentation process. For the vast majority of beverage types the isinglass will be allowed to settle to the bottom of the storage vessel together with yeast and proteins and the beverage will then be filtered to a high specification, producing a visually bright beverage ready for packaging. In the beer type commonly known as 'traditional cask ale' the isinglass, yeast and protein will be allowed to settle in the container from which the beverage is actually dispensed.

Approximately 250 tonnes of isinglass is used in the fining of an approximate combined volume of 13 billion litres of beers, wines and ciders per annum. It is estimated that several thousand tonnes of fish maws are also used directly as a food ingredient (for example as a thickener in certain soups). Fish maw soup is to be found on the menus of ethnic Chinese restaurants in Europe and the USA.

Extensive searches of the scientific and medical literature have not identified any documented cases of allergic reaction due to isinglass.

Comments

Comments are made from the perspective of a manufacturer and supplier of isinglass products to the alcoholic beverage industry.

Are there ways in which the proposed regulations can be modified to reduce the regulatory burdens and associated costs imposed on the industry?

Allergen labelling of alcoholic beverages is under close scrutiny in the EU just now. A temporary exemption for isinglass from a requirement to label under the EU allergen labelling legislation was confirmed by the EU Commission in March 2005 after the European Food Safety Authority (EFSA) had published an opinion that isinglass was 'not very likely' to cause severe allergic reaction in fish sensitive individuals as a result of consuming beer in which isinglass had been used as a processing aid. The temporary exemption was granted for beers, wines and ciders.

The Brewing Food and Beverage Industry Suppliers Association (BFBI) and The Brewers of Europe subsequently submitted a dossier of scientific evidence to EFSA on October 31st 2006 in support of the case for permanent exemption of isinglass from EU allergen labelling. A key element of the scientific data in the dossier involves a double blind placebo controlled food challenge (DBPCFC) study managed by the Food Allergy Research and Resource Program (FARRP). None of the fish-allergic individuals tested reacted when challenged with very high levels of isinglass.

Regulatory burdens and associated costs could be reduced if the TTb were to recognise the current status of EU exemptions and of the progress of the scientific arguments being made for permanent exemptions. Some European beverage producers will be exporting products to the USA in which isinglass will have been used as a fining agent. There is no requirement under current EU legislation to make any related allergen statement concerning the use of isinglass in these products. If the exemption for isinglass in the EU proceeds to be permanent then these producers might be required to adopt two entirely different allergen labelling strategies. The potential for consumer confusion will be significant since they could be presented with two identical products – except one will have an allergen warning and one will not. It is also possible that such differential approaches to labelling could inadvertently result in a barrier to trade.

Do the proposed rules provide adequate information to consumers about the use of finings or processing agents? Should processing or fining agents be subject to a

different labelling requirement, for example, a “processed with” labelling statement instead of a “contains” labelling statement? Would requiring a distinction between primary ingredients and finings and processing agents be informative to the consumer or would it mislead consumers? Would distinct labelling for processing and finings agents allow industry members to impart more specific information about the use of processing and fining aids?

Analysis of beers that are fined with isinglass finings and which are then filtered (as is the case for the vast majority of beers and wines produced around the world) demonstrates that filtration will, in many cases, remove isinglass to the extent that it is not detectable in the finished beer using best available scientific techniques. In this case to label as “Processed with” would indeed be an accurate statement but would not necessarily be an accurate indicator of the risk of allergic reaction should a fish sensitive person consume the beverage. This may therefore mislead the consumer and could result in an unnecessary restriction of dietary choice.

In a situation where isinglass residues are more likely to be consumed (for example in traditional cask ales) the levels of residual isinglass have been confirmed as extremely low.

The DBPCFC study described in the dossier for permanent exemption in the EU was designed to challenge fish allergic consumers with very high levels of isinglass, higher even than would be experienced through consumption of large volumes of cask ales. The lack of reaction at these very high challenge rates confirms that although isinglass is derived from fish, its use as a fining agent does not pose a risk of allergic reaction in fish-allergic consumers.

We therefore suggest that to use the term “Processed with” may actually mislead consumers with respect to the allergenic risk associated with a particular beverage.

Should mandatory allergen labelling 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 agree with the proposed approach that “fish” be used rather than naming specific species since isinglass products may vary from time with regard to the specific species of fish used in any particular product.

Summary

There is anecdotal evidence supporting the assertion that alcoholic beverages in which isinglass is used as a fining agent do not present a risk to fish-allergic consumers. Isinglass has a long history of safe use, particularly in countries with developed systems for monitoring severe allergic reactions.

Residual isinglass levels in packaged beverages can range from ‘non-detectable’ to ‘trace’. Clinical challenges have failed to demonstrate that fish-allergic consumers react even when challenged with very high levels of isinglass. It is the opinion of allergy experts (Prof. S. Taylor, Food Allergy Research and Resource Program), after reviewing the scientific data, that “ingestion of isinglass does not present a risk to fish-allergic individuals”.

The scientific dossier supporting the case for non-labeling of isinglass has been submitted to the European Food Safety Authority and we anticipate an opinion will be published mid-2007

We respectfully submit that legislation concerning the requirement for allergen labeling when isinglass is used in the production of alcoholic beverages should take account of all available scientific evidence and should be approached from a ‘risk-based’ perspective. Such an

approach will best serve concerned consumers in deciding which beverages they may safely consume without unnecessarily restricting dietary choice.

The undersigned would be happy to respond to any queries you may have,

Sincerely,

A handwritten signature in black ink, appearing to be 'Brent Jordan', written in a cursive style.

Brent Jordan
Managing Director
AB Vickers