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25 September 2006

COMMENT 5

Director, Regulations and Rulings Division
Alcohol and Tobacco Tax and Trade Bureau
Attn: Notice No. 62
PO Box 14412
Washington, DC 20044-4412
UNITED STATES

Dear Sir/Madam,

Please find enclosed a submission from the Beer, Wine and Spirits Council in response to the notice on Major Food Allergen Labelling for Wines, Distilled Spirits and Malt Beverages.

The Beer, Wine and Spirits Council of New Zealand (BWSC) represents the non-commercial interests of New Zealand's two leading drinks companies, Lion Nathan NZ Limited and DB Breweries Limited. These companies make up the majority of the New Zealand beer market, and have significant interests in other sectors of the drinks market. The BWSC supports minimisation of harm to the community through the promotion of a moderate and responsible drinking culture.

In this submission we would like to take the opportunity to explain the production and use of Isinglass by the brewing industry in New Zealand, as well as argue the case for its non-allergenicity.

If you require further information, please do not hesitate in contacting us. We are available to discuss this issue further at a convenient time.

Sincerely,

Nicki Stewart
Chief Executive



**BEER, WINE & SPIRITS COUNCIL
OF NEW ZEALAND**

**MAJOR FOOD ALLERGEN LABELLING FOR WINES,
DISTILLED SPIRITS AND MALT BEVERAGES**

25 September 2006

Contents

Contents	2
Executive Summary.....	3
Introduction.....	4
Isinglass and Brewing in New Zealand.....	5
The Case for Non-Allergenicity of Isinglass.....	5
Isinglass in Europe	7
Australian Research	8
Conclusion.....	9



Executive Summary

- Given its long history of safe use, we believe Isinglass should be granted a temporary exemption from mandatory allergen labeling, particularly while the overseas studies are being completed. It is our belief these studies will show that Isinglass is not a known allergen.
- Currently, neither Lion Nathan NZ Limited nor DB breweries Limited are using any fish derivatives in their brewing processes, as they do not want to label their products as containing fish.
- Breweries in New Zealand and Australia, due to their British associations, have been designed around the benefits of Isinglass. This allows the use of maturation storage vessels and filtration equipment in a more efficient manner.
- Prior to the year 2000, the potential allergenicity of Isinglass in beer was never considered, as there had never been a recorded case of human allergenic response where Isinglass was implicated.
- There is a 200-year history of consumers of cask beer in the UK drinking at least 1000 fold concentrations of Isinglass, relative to any potential levels in New Zealand, without a recorded case of allergenicity. As Isinglass had never been implicated, scientific literature on this topic is not available.
- We believe the importance of accurate labelling should firmly focus on the allergen and not on the food where the allergen originates.

Introduction

The Beer, Wine and Spirits Council (BWSC) is currently under going a similar submission process with Food Standards Australia New Zealand (FSANZ), addressing the issue of Isinglass, and also Application A490 – the Mandatory Declaration of the Presence of Allergenic Substances in Food.

Our submission to the Alcohol and Tobacco Tax and Trade Bureau includes information previously provided to FSANZ in support of our case, as well as reference to recent scientific research published on the detection of Isinglass in filtered and cask conditioned beers.

There has been considerable work undertaken by the brewing industry on this matter, not only in New Zealand, but also by our counterparts in Europe and Australia. Research in relation to the allergenicity of Isinglass in beer is currently being conducted by the Brewers of Europe and the Brewing Food and Beverage Industry Suppliers Association (BFBI), and in relation to wine, by the Australian Wine Research Institute (AWRI), in conjunction with the Department of Allergy Immunology and Respiratory Medicine at The Alfred and Monash University. We expect results of these studies to be released later this year.

Some of this research is being undertaken at the behest of the Scientific Panel on Dietetic Products, Nutrition and Allergies, of the European Food Safety Authority (EFSA). In response to an earlier submission made by the Brewers of Europe, the Panel concluded that they considered it *“...not very likely that Isinglass, under the conditions of use specified by the applicant, will cause allergic reactions in fish allergic individuals”*. They also stated that *“studies investigating laboratory and clinical responses in fish allergic individuals are needed to establish whether Isinglass may cause allergic reactions in fish allergic individuals¹”*.

It has been proposed that the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) be amended to require that the alcoholic beverages produced using finfish proteins are labeled with ‘fish’. Given its long history of safe use, we believe Isinglass should be granted a temporary exemption from mandatory allergen labeling, particularly while the overseas studies are being completed. It is our belief these studies will show that Isinglass is not a known allergen.

¹ http://www.efsa.eu.int/science/nda/nda_opinions/755_en.html

Isinglass and Brewing in New Zealand

Isinglass is primarily sourced from overseas (e.g. from AB Vickers in the United Kingdom), so the quality of the Isinglass will be the same as used by brewers across the world. There are numerous suppliers of Isinglass products, such as the Dunedin Malthouse (Brewcraft Isinglass Finings), Cryer Malt (Magifine 300) and www.yourshout.co.nz. A product similar to Isinglass called C-Fine, made from hoki skins, had been on trial at DB Breweries with the help of Food and Crop New Zealand. It is pure collagen and is an ingenious use of an otherwise waste material. Trials have shown it to be slightly superior to Isinglass.

Currently, neither Lion Nathan NZ Limited nor DB breweries Limited are using any fish derivatives in their brewing processes, as they do not want to label their products as containing fish. We are unable to confirm whether or not the microbreweries use Isinglass, but we presume that some of them do.

Breweries in New Zealand and Australia, due to their British associations, have been designed around the benefits of Isinglass. This allows the use of maturation storage vessels and filtration equipment in a more efficient manner.

The consequences of not using Isinglass in our processes have been:

- Significantly increased use of diatomaceous earth, which is a health hazard if not handled correctly and increases the issue of appropriate ecological disposal.
- Significantly increased internal wastage and loss, impacting operating costs and effluent discharge.
- Limited maturation systems due to longer periods required for unaided settling.
- Restricted volume of beer that can be filtered by our filtration system.

The cost impacts of wastage, additional materials usage and operating hours have been added to the breweries' operation expenses, and as such, they have increased significantly.

The Case for Non-Allergenicity of Isinglass

Prior to the year 2000, the potential allergenicity of Isinglass in beer was never considered, as there had never been a recorded case of human allergenic response where Isinglass was implicated.

There is a 200-year history of consumers of cask beer in the UK drinking at least 1000 fold concentrations of Isinglass relative to any potential levels in New Zealand without a recorded case of allergenicity. As Isinglass had never been implicated, scientific literature on this topic is not available.

To understand the nature of allergenicity, it is important to define what an allergen is.

The Food Allergy Research and Resource Program (FARRP) at the University of Nebraska describe food allergens as “naturally occurring proteins that exist in the foods. While foods contain literally millions of different proteins, only a few of these proteins are allergens”². Therefore by this definition, it is not the whole of the food that is allergenic, but only the certain proteins within the food.

With this in mind, it is duly possible for someone with, for example, an allergy to wheat, to eat a product that contains wheat where the gluten has been removed without any adverse affect. If we follow the requirements of FSANZ Standard 1.2.3, then the product needs to be labelled as containing wheat, which of course it does. However, as it no longer contains an allergen, it no longer provides a danger to someone who is allergic to gluten. Is there then a necessity to label the product as containing wheat? **We believe the importance of accurate labelling should firmly focus on the allergen and not on the food where the allergen originates.**

Beer and wine producers have for hundreds of years used Isinglass as a processing aid to assist in the fining of the beverage. After the fining process, there is very little Isinglass residue left in the finished product, certainly not enough to elicit an allergic reaction, even if it was capable of one. However, under FALCAPA, if Isinglass was used as a fining agent in beer or wine then it must be declared on the product that it contains fish or fish products.

The BFBI (Brewing, Food and Beverage Industry Suppliers Association) Isinglass Committee, in their submission in response to the European Union Directive 2000/13/EC, states that the molecular size of Isinglass precludes it from being an allergen, along with the view that there is no historical evidence of Isinglass allergenicity. Most protein allergens have a molecular weight between 10-80KDa, which is considerably smaller than the large molecular size of Isinglass, which is between 800-1300KDa³.

² From the FARRP website: www.foodsci.unl.edu/farrp/whatfarpp.htm#Development

³ BFBI Isinglass Committee Submission, page 10

Isinglass carries different characteristics to what is known about fish allergen. The main proteins found in Isinglass are collagen, elastin and gelatin, which are not known to be major fish allergens. The main causes of allergens in fish are from a group of muscle proteins called parvalbumins. It is not known whether swim bladders contain parvalbumin as it has not been systematically studied. However, tests are currently being studied to determine whether or not they do.

Regardless of this, the level of Isinglass residues in beers as consumed is very low. The BFBI in their amendment submission to the European submission state that a moderate drinker (drinking 1.136 litres of beer/day) would intake around 0.568 mg of Isinglass per day, using the highest indicative residues found in brewery-conditioned beers to date⁴. Taylor et al in their research on threshold levels state that the LOAEL (lowest observed adverse effect level) for fish is 5mg⁵, which is over 10 times above that consumed by a moderate drinker.

The New Zealand situation is even clearer as the tested range of residual Isinglass has been between 0.16ppm to 0.04ppm. Taking the highest New Zealand residual value, moderate beer consumption would lead to an intake of Isinglass of 0.18 mg per day, or less than 25 times the LOAEL for fish generally (not that Isinglass has ever been found to be allergenic at any rate).

Isinglass in Europe

Directive 2003/89/ED of the European Parliament and the Council of the European Union states that it should be mandatory to include in the labelling of alcoholic beverages all ingredients with allergenic effect present in the beverage concerned. Their list of ingredients covers all foods listed in Table to Clause 4 of FSANZ's Food Standards Code, but also includes nuts, celery, mustard and their products.

Under European Commission Directive 2005/26/EC, European breweries currently have a temporary exemption from labelling Isinglass until 25 November 2007, as gazetted in the Official Journal of the European Union 22/03/2005. European breweries have until this time to present evidence proving the non-allergenicity of Isinglass for a permanent exemption to be granted.

⁴ BFBI Isinglass Committee Submission, Amendment2003/89/EC, page 26

⁵ Taylor et al "Factors Affecting the Determination of Threshold doses for Allergenic Foods: How Much is Too Much?", 2002, Jnl Allergy & Clinical Immunology 109, 204-30

The Brewers of Europe have proposed a series of scientific studies, some of which have already begun, to evaluate the allergenicity of Isinglass. These include:

- Pepsin digestion of Isinglass (allergenic proteins are resistant to digestive breakdown)
- Testing Isinglass for the presence of parvalbumin (main muscle protein allergen in fish)
- Testing of Isinglass source fish for allergenicity using skin prick tests
- Double blind placebo-controlled food challenge tests with Isinglass
- Analysis of Isinglass residues in beer

These studies will be carried out by some of the world's leading laboratories, including FARRP (Food Allergy Research Resource Programme at the University of Nebraska), The National University Hospital, Copenhagen and BRi (Brewing Research International).

Australian Research

In Australia, the Grape and Wine Research and Development Corporation (GWRDC) has funded a two-year research project as a result of the lack of data available on the residuals of processing aids in wine. The project is being carried out at the Department of Allergy, Immunology and Respiratory Medicine at The Alfred and Monash University, in conjunction with the Australian Wine Research Institute.

The objectives of the project are: to establish sensitive and reliable tests to detect and measure allergenic proteins from processing aids (including Isinglass) in final bottled wine; to determine if there are any detectable residual allergenic proteins from the processing aids; and to determine whether individuals with known allergies (including fish) show an allergic reaction to blind consumption of wine that has been fined with a known food allergen source.

We understand from the Australian Wine Research Institute that not all phases of the project have been completed. They are anticipating that the initial study will be finished by next year at the latest.

Earlier this year Chlup et al⁶ presented a paper reporting on a simple and sensitive method for detecting the presence or absence of Isinglass in filtered or cask-conditioned beers. The method involved hydrolysing beer samples with acid, and measuring levels of hydroxyproline. This amino acid is found in, but not in brewing raw materials.

⁶ PH Chlup, KA Leiper, GG Stewart "A Method of Detection for Residual Isinglass in Filtered and Cask-Conditioned Beers" 2006 Jnl Inst Brew 112(1), 3-8



When the beer samples were tested, they reported that no hydroxyproline was present in the untreated beers – indicating that none of the brewing raw materials contained the amino acid. The treated beers also tested negative, indicating that filtration had removed all Isinglass used.

Conclusion

As outlined in our previous correspondence on the issue with FSANZ, and during this submission, we are avidly awaiting the results of the studies being carried out in Europe and Australia. As can be appreciated, the research is very specific and requires a great amount of time to complete. It would be near impossible to carry out such research in New Zealand, specifically trying to locate a large enough number of people clinically diagnosed with a fish allergy.

Under Section 10 of the Food Standards Australia New Zealand Act 1991, one of the objectives in developing or reviewing food regulatory measures and variations of food regulatory measures is the regard to the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. Given the long and safe history of use and the scientific evidence provided to date, we asked that a temporary exemption from mandatory labelling of Isinglass be granted, similar to that given by the European Union.

Furthermore, if the results from the European and Australian studies concludes that Isinglass is not an allergen and is permitted a permanent exemption from mandatory allergen labelling in Europe, we would think it reasonable that the same be granted for New Zealand and Australia.

We are available to discuss this issue further with you at a convenient time.

Thank you for your time.

Sincerely



Nicki Stewart

Chief Executive