FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

7-05
5 October 2005

INITIAL ASSESSMENT REPORT

APPLICATION A490

EXEMPTION OF ALLERGEN DECLARATION FOR ISINGLASS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 16 November 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

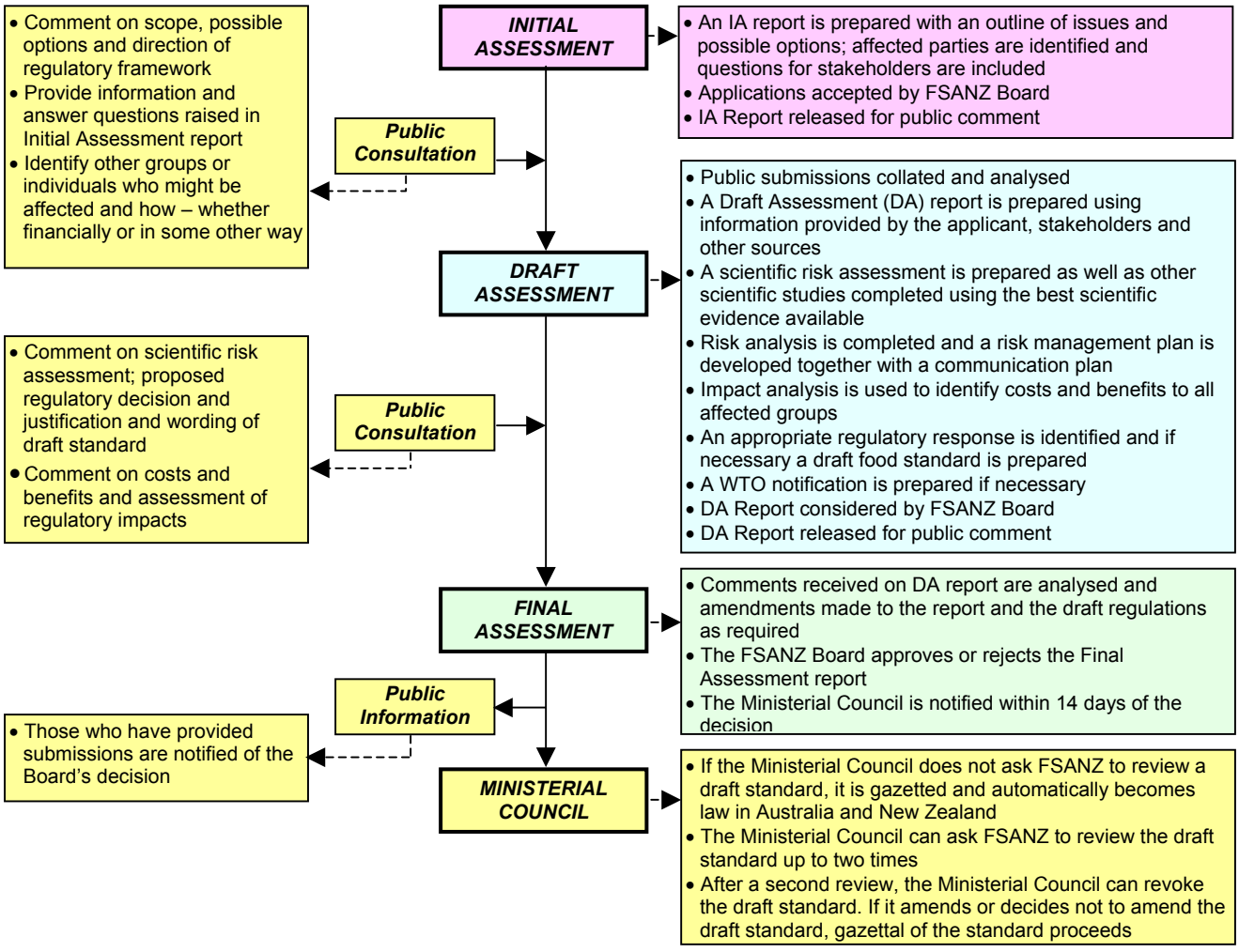
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report for Application A490, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 16 November 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

The Beer, Wine and Spirits Council of New Zealand (BWSC-NZ) has submitted an Application to amend the requirements in the Table to clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, of the *Australia New Zealand Food Standards Code* (the Code). Specifically, the Applicant is seeking an exemption from the requirement to declare isinglass (a fining agent derived from fish) on the label, when present in beer and wine.

The exemption is being sought on the basis that isinglass, has a long history of use as a fining agent in the manufacture of beer and wine and has not been known to cause adverse reactions in susceptible individuals.

This Initial Assessment Report is not a detailed assessment of the Application, but rather an assessment of whether the Application should be accepted for further consideration. It provides a summary of the information provided by the Applicant, and outlines the relevant issues and questions to assist FSANZ in the identification of affected parties and the impacts of the regulatory options.

Regulatory Problem and Objective

Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires the mandatory declaration of certain substances and their products when present in food as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive, or a processing aid or component of a processing aid. The term 'and their products' refers to all products derived from the substances listed in the Table to clause 4. As fish and fish products are included in the Table to clause 4, isinglass, which is a fish product, must also be declared when present in a food.

The purpose of clause 4 is to protect individuals who may suffer from adverse reactions to certain food allergens, by ensuring that adequate information is provided regarding the presence of allergens in foods.

The objective of this Application is to determine whether the proposed amendment to clause 4 of Standard 1.2.3 to exempt isinglass from the mandatory declaration requirements, should be made, and particularly whether the clause as amended would adequately protect individuals who suffer from severe adverse reactions to certain substances in foods.

Safety Assessment

Isinglass is a pure form of collagen, which is derived from the dried swim bladders of certain tropical and subtropical fish. It is used as a processing aid in the clarification of beer and wine. Isinglass removes yeast proteins by forming large flocs that settle at the bottom of the vessel. The flocs, consisting of isinglass and yeast, are then removed by sedimentation and filtration or centrifugation.

Isinglass is added to beer at low levels, typically, at 10-25 ppm. Only very low residual amounts of isinglass are likely to remain in the final product. The Applicant states that the level of isinglass detected in three brands of beer is between 0.04 ppm and 0.16 ppm. No information has been provided by the Applicant on the levels of isinglass residues in wine.

The major fish allergenic proteins are the parvalbumins. The molecular weight of this group of proteins is 12 kDa to 80 kDa, a range typical of many known food allergenic proteins. Isinglass consists mainly of collagen, which has a higher molecular weight of 300 kDa. Based on the anatomical location and tissue composition of fish swim bladder, isinglass is not likely to contain the major allergenic fish protein, parvalbumin. Further research in this area is being conducted in Europe and the USA.

The Applicant claims that there is no evidence in the published medical and scientific literature to suggest that isinglass, or beer clarified with isinglass, provokes allergic reactions in fish sensitised individuals. Isinglass has been used for over a hundred years as a clarifying agent.

This Initial Assessment Report also identifies research-in-progress in Europe and the USA to address a number of questions relating to the allergenic potential of isinglass.

Labelling Issues

Under the current provisions in Standard 1.2.3, the substances listed in the Table to clause 4 must be declared whenever they are present in a food. The only permitted exemption is for the declaration of cereals containing gluten, when present in beer and spirits. As fish and fish products are included in the Table to clause 4, isinglass must also be declared when present in a food.

The European Commission has granted a temporary exemption from labelling, until 25 November 2007, for specified derivatives of allergenic ingredients or substances on the basis that they are not likely to cause adverse reactions in susceptible individuals. The provisional list of exemptions includes 'fish gelatine or isinglass used as a fining agent in beer, cider and wine'. Similarly, the United States has established a process whereby a food ingredient may be granted an exemption from allergen labelling if the ingredient does not cause an allergic response that poses a risk to human health or does not contain allergenic protein. Canada is also considering exemptions from allergen labelling for fining agents derived from milk, egg or fish used during the manufacture of standardised alcoholic beverages.

Regulatory Options

The two regulatory options available for this Application are:

Option 1. Maintain the current provisions in clause 4, Standard 1.2.3 for the mandatory declaration of certain substances in food; and

Option 2. Amend Standard 1.2.3 in the Code to exempt isinglass from the mandatory declaration requirements when it is present in beer and wine.

Affected Parties

The affected parties to this Application include the following:

1. manufacturers of beer and wine;

2. manufacturers of isinglass;

3. consumers; and

4. Australian Government, State, Territory and New Zealand Government agencies that enforce food regulations.

Conclusion and Recommendation

Having regard to the criteria for Initial Assessments in section 13 of the FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is seeking to exempt beer and wine from the requirement to declare isinglass on the label when it is present in these products.

- The Application relates to a matter that may warrant a variation of a food regulatory measure in Standard 1.2.3.

- The Application is not so similar to a previous application that it ought not be accepted.

- At this stage of the assessment, FSANZ is not able to determine whether the costs that would arise from a variation to the Code to exempt beer and wine from the mandatory declaration of isinglass, would outweigh the direct and indirect benefits to the community, Government or industry. FSANZ will call for specific submissions on this issue and re-address the matter at Draft Assessment.

- There are no alternative measures available to address the Applicant's issue.

1. Introduction

1.1 Nature of Application

The Beer, Wine and Spirits Council of New Zealand (BWSC-NZ) has submitted an Application to amend the requirements in the Table to clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, of the Code. Specifically, the Applicant is seeking an exemption from the requirement to declare isinglass (a fining agent derived from fish) on the label, when present in beer and wine.

The exemption is being sought on the basis that isinglass has a long history of use as a fining agent in the manufacture of beer and wine and has not been known to cause adverse reactions in susceptible individuals.

1.1.1 Background to the Application

On 12 August 2002, the BWSC-NZ, on behalf of the Brewing Industry of New Zealand wrote to FSANZ requesting that an exemption be granted for isinglass from the mandatory declaration requirements in clause 4 of Standard 1.2.3 of the Code. In the accompanying documentation that was provided to FSANZ, the BWSC-NZ requested a permanent exemption, although if this was not possible, a temporary exemption, to allow further scientific evidence to be obtained regarding the non-allergenicity of isinglass.

On 20 September 2002, FSANZ responded to this request, advising that, in the absence of substantial scientific evidence on the relationship between residual levels of isinglass in beer and associated allergenicity, it was not in a position to favourably consider exemptions to the requirements in clause 4 of Standard 1.2.3. However, FSANZ advised that it would consider an application to amend the Standard should further research provide persuasive new evidence in this area.

On 6 January 2003, the BWSC-NZ resubmitted the document dated 12 August 2002 and requested that it be considered as an application. It was formally accepted and placed in Group 2 on the FSANZ Work Plan on 7 February 2003, and estimated to commence in the 4th quarter of 2003.

On 15 October 2003, the Applicant requested that wine also be considered within the scope of their Application. Additionally, the Applicant requested a four-year exemption from the requirement to label for isinglass, in line with the European Commission's proposed amendment to Directive 2000/13/EC. Under this amendment, the European Commission could consider temporary exemptions from allergen labelling, until November 2007, for derivatives of allergens that are unlikely to cause allergic reactions, while awaiting further scientific evidence for a permanent exemption.

On 19 December 2003, FSANZ agreed to increase the scope of the Application to include wine. However, FSANZ did not agree to the request for a temporary exemption and sought further information from the Applicant under subsection 34(1) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). A response to this request was received on 28 June 2004. However, it was considered to be insufficient and a subsequent request for information under subsection 34(1) of the FSANZ Act was sent in December 2004.

In October 2004, the Applicant provided FSANZ with a copy of the dossier that was submitted to the European Commission by the Brewers of Europe and the Brewing, Food and Beverage Industry Suppliers Association (BE/BFBi) under the requirements of Commission Directive 2003/89/EC. This dossier, titled 'Notification for the temporary exemption from labelling for isinglass used as a clarifying agent in brewing' (the BE/BFBi notification) has been used by FSANZ in the assessment of this Application. On 16 May 2005, FSANZ received further information from the Applicant, and has now proceeded to the Initial Assessment of Application A490.

2. Regulatory Problem

2.1 Current Standard

Clause 4 of Standard 1.2.3 requires the mandatory declaration of certain substances and their products when present in food as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive, or a processing aid or component of a processing aid. The term 'and their products' refers to all products derived from the substances listed in the Table to clause 4. As fish and fish products are included in the Table to clause 4, isinglass, which is a fish product, must also be declared when present in a food. A copy of clause 4 of Standard 1.2.3 is provided at Attachment 1.

The purpose of the Standard is to protect individuals who may suffer from adverse reactions to certain food allergens, by ensuring that adequate information is provided regarding the presence of allergens in foods.

3. Objective

The objective of Application A490 is to determine whether the proposed amendment to exempt isinglass, a product derived from fish, from the mandatory declaration requirements in clause 4 of Standard 1.2.3, and particularly whether the clause as amended would adequately protect individuals who suffer from severe adverse reactions to certain substances in foods.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Historical Background

The current mandatory declaration requirements in Standard 1.2.3 were developed during the review of the Code, as part of Proposal P161 – Review of Specific Labelling Statements. The list of substances included in the Table to clause 4 of Standard 1.2.3 are based on the recommendations of an Expert Panel commissioned by the then Australia New Zealand Food Authority (ANZFA). To qualify for mandatory declaration, the substance(s) needed to be recognised by medical experts as a frequent cause of severe systemic reactions resulting in significant morbidity or mortality.

The justification for the mandatory declaration requirements in Standard 1.2.3 was based on the requirement to protect the health and safety of those individuals who are susceptible to adverse reactions from certain foods or substances in foods.

5. Relevant Issues

5.1 Identity and Purity of Isinglass

5.1.1 *Definition*

5.1.1.1 Definition used by the Applicant (submission 16 May 2005):

Isinglass is a pure form of collagen, which is derived from the dried swim bladders of certain tropical and subtropical fish. In brewing, only isinglass from catfish, croakers and threadfins is used.

5.1.1.2 Definition from the BE/BFBi notification

Isinglass is the usual term for piscine collagen. Within the BE/BFBi notification, the term is used exclusively to mean the collagen obtained from the swim bladders and does not include collagen from fish skins.

The BE/BFBi notification provides an example of typical specifications for commercial isinglass. The specifications include microbiological and heavy metals as well as protein and moisture parameters. The BE/BFBi notification also addresses metabisulphite, which is added to isinglass paste and liquid formulations as a preservative. The notification states that at the dilutions of isinglass used in beer production, the amount of resulting sulphur dioxide does not reach ≥10 mg/litre.

5.1.2 Commercial Production of Isinglass

The swim bladders of tropical and subtropical fish are used to produce isinglass on a commercial scale for use in the alcoholic beverage industry. Approximately 250 tonnes of swim bladders per year are required for the manufacture of isinglass worldwide. The process of isinglass production may vary between individual manufacturers, however, a number of steps are considered standard practice. Dried swim bladders are blended according to specific quality and other criteria, followed by granulation, washing, sterilisation with dilute hydrogen peroxide and rinsing. A temperature of less than 15ºC is maintained throughout the wet steps. The product is then sold as powder, paste or liquid. The paste and liquid forms include a source of sulphur dioxide as a preservative.

5.1.3 Products used by the Applicant

The Applicant states that they source their isinglass primarily from overseas (e.g. from AB Vickers in the United Kingdom) and from other suppliers of isinglass products such as the Dunedin Malthouse (Brewcraft Isinglass Finings), Cryer Malt (Magifine 300) and www.yourshout.co.nz.

The Applicant also states that a product called 'C-Fine' has been on trial by one brewer in New Zealand. C-Fine is made from hoki skins and is described by the applicant as pure collagen. The Applicant submitted two analytical reports on residual collagen in beer samples clarified with C-Fine and other unidentified agents. The Applicant has not provided any information on the production process of C-Fine, particularly steps taken to prepare fish skin to minimise the presence of fish muscle tissue and proteins in typical batches of the product. FSANZ is unaware that this product is available commercially, or that it is widely used as a clarifying agent by the beer and wine industry. Therefore, this assessment addresses isinglass derived from fish swim bladders only and no further reference to C-Fine will be made in this document.

5.2 Use of Isinglass as a Processing Aid/ Clarifying Agent

Isinglass is used in the clarification of beer and wine. In the natural state, isinglass exists in the form of fibres, assembled from collagen fibrils, which are composed of collagen molecules. Isinglass is dissolved in dilute solutions of food grade acids, which breaks the weak bonds within the fibre/fibril structure but leaves the helical structure of collagen intact. The Applicant states that isinglass is added at low levels of 10-25 ppm. Other data submitted by the Applicant suggest that the level may be 35 ppm. Once added, the highly active collagen aggregates yeast particles and proteins forming a matrix that sediments rapidly at the base of the storage vessel. Once the sediment is removed, further clarification of the beverage is achieved by filtration or centrifugation. The process of sedimentation and filtration removes the aggregated solids and particles resulting in very low residual levels of isinglass in the final product.

5. 3 Safety Assessment

5.3.1 Toxicological Assessment

Isinglass is a natural product derived from swim bladders of tropical and subtropical fish. FSANZ is not aware of any toxicity concerns related to the use of isinglass as a clarifying agent.

The BE/BFBi notification reports that in addition to being a source of isinglass, the fish swim bladders (also known as fish maws) are consumed as food by some ethnic Asian communities around the world and traded as part of 'dried fish products'.

5.3.2 Allergenicity Assessment

Allergy to fish is well documented in the scientific and clinical literature, including double-blind-placebo-controlled food challenge (DBPCFC) studies. Fish muscle, skin and roe have been reported to cause allergic reactions, the latter only rarely. Fish allergy appears to be common in coastal communities where fish is a major component of the diet, such as Japan and Scandinavia and is more common among adults than children. There is currently no data on the prevalence of fish allergy in the Australian and New Zealand populations.

Parvalbumins are the major allergenic fish proteins, and possibly the sole allergens for most individuals with IgE-mediated allergy to fish. They are small, calcium-binding proteins abundant in the muscle tissue of various fish species. Eight parvalbumin proteins with molecular weights ranging from 10.5 kDa to 12 kDa have been identified as allergens. One parvalbumin, named Gad c 1, is present in muscle tissue of most fish species. This is why fish sensitised individuals are likely to react to many types of fish.

Parvalbumin has been identified in the swim bladder tissue of a western Atlantic fish (*Opsanus tau* or the oyster toadfish), a species not used in isinglass production. There is no information on other fish species, including tropical and subtropical species used in the production of isinglass.

There is some published information suggesting that fish collagen may be allergenic in some individuals, however further verification of these findings is required. In a DBPCFC study, a mild, subjective reaction was reported by one out of 30 fish-allergic patients given 7.6 g codfish skin gelatin.

Collagen is a protein with a molecular weight of approximately 300 kDa and is present in fish muscle, skin and swim bladder. The fish swim bladder is the source of collagen, known commercially as isinglass. Intact collagen has a triple helical structure stabilised by cross linkages. Soluble collagen exists mainly as trimers and tetramers with a molecular weight of 800-1300 kDa. The large size of collagen contrasts with known allergenic proteins, which are usually small, compact proteins with molecular weight ranging between 10 kDa and 80 kDa.

Collagen is thermally labile and denatures to gelatin, where the triple helix is unwound to form random coils. Collagen from tropical fish species is most suitable for isinglass production because it remains intact in temperatures up to 29ºC, while collagen from coldwater fish species denatures at about 5ºC. There is no evidence that gelatin is an important allergen in fish sensitised individuals.

The major component of isinglass is type 1 collagen and its denaturation product, gelatin. Isinglass also contains small quantities of elastin, a highly hydrophobic, 72 kDa protein. Collagen, gelatin and elastin constitute about 95% of the dry weight of isinglass. There is no evidence to suggest that elastin is allergenic and, as mentioned above, the allergenicity of collagen/gelatin is yet to be confirmed.

Therefore, the three main components of isinglass (collagen, elastin and gelatin) are not major fish allergens. Based on the anatomical location and tissue composition of fish swim bladder, isinglass is not likely to contain the major allergenic fish protein parvalbumin. However, analytical evidence is being generated in the USA and Europe to confirm that commercial isinglass preparations do not contain parvalbumin.

Isinglass is believed to be, but yet to be confirmed, highly susceptible to pepsin digestion. As allergenic proteins are generally resistant to pepsin digestion, the susceptibility of isinglass to enzyme digestion would suggest that it is unlikely to be allergenic. Further studies are underway in Europe to establish the susceptibility of isinglass to pepsin.

There are no reports of clinical studies testing the allergenicity of isinglass in fish allergic individuals.

5.3.3 History of Safe Use

The Applicant states that isinglass has been used in the clarification of beer and wine for over a hundred years. The BE/BFBi notification makes a similar statement and, based on a rigorous literature search, concludes that no isinglass-related allergy cases have been reported. The literature search also indicates that 18 out of 23 reported allergic reactions to beer relate to the allergenicity of wheat or barley, and more rarely to yeast or hops.

5.3.4 Residues of Isinglass in Beer and Wine

The Applicant states that the level of residual isinglass in beer is very low ranging between 0.04 ppm and 0.16 ppm. Analytical data supporting this statement was provided to FSANZ by the Applicant in the form of three reports on isinglass residues in three brands of beer (Confidential Reports No. 703, 713 and 719). Beer samples were collected before pasteurisation and kept chilled during the period from fining to analysis. The samples were processed to extract intact collagen and analysed by sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE). To provide a quantitative reference, a known amount of the soluble fraction of isinglass was added to a test sample to determine the lowest amount of collagen that could be reported with confidence using this method. The amount of isinglass residue in the test samples was estimated by a direct comparison with a spiked sample. Assuming that the fining agent was added at 35 ppm, the results reported for the three brands of beer represent a removal of 99.75% to 99.9% of isinglass.

The Applicant has not provided information on the levels of isinglass residues in wine.

The BE/BFBi notification reports on a more sensitive method, than described above, developed in the UK to detect isinglass residues in beer. Preliminary analytical data suggest that isinglass residues in beer range from below detection limit to about 0.5 mg/litre.

5.4 Dietary Exposure to Isinglass

The BE/BFBi notification provides an estimate of the dietary intake of isinglass. The estimate assumes that all beer is clarified using isinglass and uses the highest of the indicative values for residues found in brewery-conditioned beer, which represents at least 92% of beer consumed in Europe.

The results show an intake of isinglass per serving (350 ml) of 0.175 mg. This equates to a daily intake of isinglass of 0.568 mg/day for a moderate consumer (consumes 1.136 litres/day); and 1.5 mg/day for a heavy consumer (consumes 3 litres/day).

The Applicant highlights this estimate and states that using the highest residual level of isinglass tested in three brands of commercial beers from Australia and New Zealand, the intake of isinglass for a moderate consumer (based on the BE/BFBi consumption figure of 1.136 litres/day) is 0.18 mg/day.

Dietary exposure based on Australian and New Zealand consumption data will be determined at a subsequent stage, pending progress of the Assessment.

5.5 Research-in-Progress

5.5.1 Europe and the USA

The European Food Safety Authority's Scientific Panel assessed data currently available on isinglass and concluded that:

> *On the basis of the data provided by the applicant, the Panel considers that it is not very likely that isinglass, under the conditions of use specified by the applicant, will cause a severe allergic reaction in fish allergic individuals.*
>
> *However, appropriate analytical methods to determine possible residual levels of parvalbumin in isinglass preparations and further studies on residual levels of isinglass in beers are needed to support the above conclusion. Studies investigating laboratory and clinical responses in fish allergic individuals are needed to establish whether isinglass may cause allergic reactions in fish allergic individuals.*

The BE/BFBi notification outlines a number of scientific studies in progress in Europe and the USA to address outstanding questions on the allergenic potential of isinglass. These are:

5.5.1.1 Is isinglass resistant to pepsin digestion?

Using a specific SDS-PAGE methodology, studies will be undertaken to determine whether isinglass is susceptible or resistant to pepsin digestion. Resistance to pepsin digestion is used as a general indicator of the allergenicity of a protein. The TNO Food Research Institute, Amsterdam, the Netherlands will be conducting these studies.

5.5.1.2 Can isinglass provoke an allergic reaction in people allergic to fish?

Clinical studies using DBPCFC will be carried out specifically to test the allergenicity of isinglass. These studies are expected to determine whether isinglass can cause allergic reactions in fish sensitised individuals.

5.5.1.3 Does commercial isinglass contain the major fish allergen parvalbumin?

The proposed studies will screen samples of swim bladders from a range of fish species, and commercial isinglass for the potential presence of parvalbumin. Two methodologies will be used in these studies: Western blot and the enzyme-linked immunosorbent assay (ELISA).

5.5.1.4 Are the types of fish used in the production of commercial isinglass allergenic using skin prick testing?

Although the allergenicity of fish used in the production of commercial isinglass has not been documented in the literature, it should be assumed that all fish are capable of provoking a reaction in fish sensitised individuals. The allergenicity of eight species of fish typically used to provide swim bladders for isinglass will be investigated using skin-prick tests of fish-allergic subjects.

5.5.1.5 What are the levels of residual isinglass remaining in beer and wine?

A sensitive method has been developed in the UK recently and is being refined for application to detect the residual levels of isinglass in various brands of beer commercially available in Europe. The method uses isinglass-specific antibody, which will confirm the identity of the detected residue.

5.5.2 Australia

The Applicant states that the Australian Grape and Wine Research and Development Corporation (GWRDC) has funded a two-year research project to examine 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 Hospital 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 clarified with a known food allergen source.

5.6 Labelling Issues

5.6.1 Relevant International Standards

5.6.1.1 Codex

The Codex General Standard for the Labelling of Prepackaged Foods, Codex Stan 1-1985 (Rev.1-1991) requires the mandatory declaration of substances that are known to cause adverse reactions. The list of substances that are required to be declared includes 'fish and fish products', in addition to other major food allergens. There are no exemptions to these labelling requirements.

5.6.1.2 European Union

Annex IIIa of Commission Directive 2000/13/EC contains a list of food ingredients that are required to be declared on food labels as they are likely to cause adverse reactions in susceptible individuals. This list includes 'fish and fish products', in addition to other major food allergens.

As a result of Commission Directive 2005/26/EC of 21 March 2005, the Commission has granted a temporary exemption until 25 November 2007, for specified derivatives of allergenic ingredients or substances on the basis that they are not likely or very likely to cause adverse reactions in susceptible individuals. The provisional list of exemptions is based on the European Food Safety Authority (EFSA) Opinions of the Scientific Panel on Dietetic Products, Nutrition and Allergens in response to individual notifications submitted to the Commission seeking specific exemptions. The provisional list of exemptions includes 'fish gelatine or isinglass used as a fining agent in beer, cider and wine', which is relevant to this Application.

To qualify for permanent exemption, food manufacturers or their associations are required to conduct scientific studies to establish whether isinglass may cause allergic reactions in fish allergic individuals. Additionally, appropriate analytical methods to determine possible residual levels of parvalbumin in isinglass preparations and further studies on residual levels of isinglass in beer and wine are needed to support a permanent exemption.

5.6.1.3 United States

The Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282) (FALCPA) amends the Federal Food, Drug and Cosmetic Act and requires that the label of a food product that is or contains an ingredient that bears or contains a 'major food allergen' declare the presence of the allergen. FALCPA defines a 'major food allergen' as one of eight foods or a food ingredient that contains protein derived from one of those foods and includes milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g. crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. Highly refined oils and ingredients derived from these oils are exempt from allergen labelling. The allergen labelling requirements take effect from 1 January 2006.

FALCPA has established a petition process through which a food ingredient may be exempt from FALCPA's labelling requirements if the ingredient does not cause an allergic response that poses a risk to human health. FALCPA has also established a notification process under which a food ingredient described above may be exempt from FALCPA's labelling requirements if the ingredient does not contain allergenic protein, or if FDA previously has determined, under section 409 of the FFDCA, that the food ingredient does not cause an allergic response that poses a risk to human health.

5.6.1.4 Canada

Canada has proposed regulatory amendments to the Food and Drug Regulations to require labelling of the following foods or any protein-containing derivatives of these if added directly as an ingredient in prepackaged foods: peanuts, tree nuts (by name); sesame; milk; eggs; fish/shellfish/crustacean (by name); soy; and wheat (including spelt and kamut, or oats, barley, rye or triticale, or any protein-containing part thereof and hybridised strains of these grains).

In September 2004, Health Canada amended its original proposal such that fining agents derived from milk, egg or fish used during the manufacture of standardised alcoholic beverages would be exempt from the allergen labelling requirements. This exemption will be reconsidered when research data on the potential presence of protein-containing residues in alcoholic beverages becomes available.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and Governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles at Draft Assessment.

The two regulatory options available for this Application are:

Option 1. Maintain the current provisions in clause 4, Standard 1.2.3 for the mandatory declaration of certain substances in food; and

Option 2. Amend Standard 1.2.3 in the Code to exempt isinglass from the mandatory declaration requirements when it is present in beer and wine.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

1. manufacturers of beer and wine;

2. manufacturers of isinglass;

3. consumers; and

4. Australian Government, State, Territory and New Zealand Government agencies that enforce food regulations.

7.2 Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, and its health, economic and social impacts.

The regulatory impact of the proposed variation to the Code will be assessed at Draft Assessment.

8. Consultation

FSANZ is seeking public comment to assist in assessing this Application at Draft Assessment.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application during the second round of public consultation. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties, as they come to the attention of FSANZ, will also be added to the mailing list for a further round of public consultation after the Draft Assessment.

Comments on, but not limited to, the following would be useful:

1. **Can stakeholders provide further information regarding any of the issues identified in Section 5.3 - Safety Assessment of this Initial Assessment Report, and particularly in relation to wine? If so, please provide supporting evidence.**
2. **What are the likely costs and benefits to beer and wine manufacturers, isinglass manufacturers, consumers and government if an exemption is granted for beer and wine from the requirement to declare isinglass under clause 4, Standard 1.2.3 of the Code?**
3. **What are the likely costs and benefits to beer and wine manufacturers, isinglass manufacturers and importers, consumers and government if the status quo is retained?**
4. **Are there any other affected parties to this Application?**
5. **Are stakeholders aware of any specific labelling issues associated with this Application? If so, please provide supporting evidence.**

8.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to allow an exemption for isinglass from the mandatory declaration requirements in Standard 1.2.3 is unlikely to have a significant effect on international trade as the requirements in Australia and New Zealand will be more closely aligned with the European Union and the United States. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

10. Conclusion and Recommendation

Having regard to the criteria for Initial Assessments in section 13 of FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is seeking to exempt beer and wine from the requirement to declare isinglass on the label when it is present in these products.

- The Application relates to a matter that may warrant a variation of a food regulatory measure in Standard 1.2.3, if further assessment supports such a variation.

- The Application is not so similar to a previous application that it ought not be accepted.

- At this stage of the assessment, FSANZ is not able to determine whether the costs that would arise from a variation to the Code to exempt beer and wine from the mandatory declaration of isinglass, would outweigh the direct and indirect benefits to the community, Government or industry. FSANZ will call for specific submissions on this issue and re-address the matter at Draft Assessment.

- There are no alternative measures available to address the Applicant's issue.

It is recommended that this Application now be progressed to Draft Assessment. Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

11. References

Hofman, K., Bulling, K. and Chadderton, T.C., 2002. Crop and Food Research Confidential Reports Nos. 703, 713 and 719.

Notification for the temporary exemption from labelling for isinglass used as a clarifying agent in brewing. Dossier submitted by The Brewers of Europe and the Brewing, Food and Beverage Industry Suppliers Association (BFBi) on behalf of the users and suppliers of isinglass. 2004. (Provided to FSANZ by the BWSC and is referred to in this Initial Assessment Report as the 'BE/BFBi notification').

Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of allergenic foods for labelling purposes - adopted on 19 February 2004. Published on the EFSA website at: http://www.efsa.eu.int/science/nda/nda_opinions/341_en.html

Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from Brewers of Europe and BFBi on isinglass used as a clarifying agent in brewing pursuant to Article 6 paragraph 11 of Directive 2000/13/EC – adopted on 2 December 2004. Published on the EFSA website at: http://www.efsa.eu.int/science/nda/nda_opinions/755_en.html

ATTACHMENT

1. Clause 4, Standard 1.2.3 of the *Australia New Zealand Food Standards Code.*

Attachment 1

Clause 4, Standard 1.2.3

4 Mandatory declaration of certain substances in food

(1) The presence in a food of any of the substances listed in the Table to this clause, must be declared in accordance with subclause (2), when present as –

(a) an ingredient; or
(b) an ingredient of a compound ingredient; or
(c) a food additive or component of a food additive; or
(d) a processing aid or component of a processing aid.

(2) The presence of the substances listed in the Table to this clause must be –

(a) declared on the label on a package of the food; or
(b) where the food is not required to bear a label pursuant to clause 2 of Standard 1.2.1 –

(i) declared on or in connection with the display of the food; or
(ii) declared to the purchaser upon request.

Editorial note:

Paragraph 4(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.

Table to clause 4

Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and soybeans, and their products
Added Sulphites in concentrations of 10 mg/kg or more
Tree nuts and sesame seeds and their products

Editorial note:

1. Clause 4 can be complied with by listing those substances in the Table in the ingredient list.

2. Any exemptions in relation to ingredient listing do not override the requirement to declare the presence of the substances listed in the Table to clause 4.

3. Manufacturers occasionally substitute one ingredient for another within the same class of foods. Where this involves a substance listed in the Table to clause 4 there must be an indication on the label that the substance is in the food. Manufacturers may indicate in the ingredient list that the product contains one substance or another (e.g. brazil nuts or cashew nuts) in cases where substitutions occur regularly.

4. Expressions such as 'egg and egg product' or 'crustacea and their products' include all products derived from the substance listed in the Table to clause 4.

5. Sulphites should be declared in the same manner as other food additives.

6. Coconut is the fruit of the palm (*Cocos nucifera*) and is not generally considered to be a tree nut.