

1-04 18 February 2004

FINAL ASSESSMENT REPORT

APPLICATION A482

PLANT PROTEINS AS WINE PROCESSING AIDS

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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.



Final Assessment Stage (s.36)

FSANZ has now completed two stages of the assessment process and held one round of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Australia New Zealand Food Standards Code (the Code), an amendment to the Code is published in the Commonwealth Gazette and the New Zealand Gazette and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister for Food Safety gazettes the food standard under the New Zealand Food Act (1981). Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

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

PO Box 10559 The Terrace WELLINGTON 6036 **NEW ZEALAND** Tel (04) 473 9942 www.foodstandards.govt.nz

Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

FSANZ received an application on 18 November 2002, from Scorpex Wine Services to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of plant proteins as processing aids during production of wine. The Application is being progressed as a Group 3 (cost-recovered) application. The Applicant requested that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended accordingly.

The purpose of the Application is to permit the use of plant proteins as alternative wine clarifying agents. The most widely used clarifying agents are sourced from animals. For example, gelatine, which is the most commonly used clarifying agent is sourced from cattle. Interest in clarifying agents from non-animal sources has been stimulated by concerns about the safety of products derived from cattle. Such plant derived products would also be suitable to produce wine that is acceptable for vegan and vegetarian consumers.

The objective of this assessment is to determine whether the Code should be amended to permit the use of plant proteins derived from traditional food sources as processing aids for wine production in Australia.

The Application indicates that plant proteins may be produced from wheat, rice, peas, lupins and maize, though this would not be an exclusive or final list. The products are usually obtained as brown or yellow water soluble powders from a variety of processing techniques that includes milling, extraction, toasting, grinding, washing and ultrafiltration.

The proposed plant proteins are foods or food ingredients and meet the Codex Alimentarius Standard 174-89 for Vegetable Protein Products. They are already used in the food industry as an alternative to gelatine in a variety of food products. These plant proteins are considered to be traditional foods and foods already have approval as processing aids under Standard 1.3.3 – Processing Aids, and can therefore be used to produce wine under Standard 2.7.4 – Wine and Wine Product. However, wine produced in Australia must also comply with the wine production standard, Standard 4.1.1 – Wine Production Requirements (Australia only) which currently does not provide permissions for the use of foods as processing aids.

Clause 4 of Standard 1.2.3 requires the mandatory declaration of certain substances if they are present in food. Plant protein products that may be affected by this Standard are cereals containing gluten, tree nuts, sesame seeds, peanuts and soybeans.

FSANZ progressed the Application under section 36 of the FSANZ Act as it believed the Application raised issues of minor complexity. Therefore FSANZ did not request any public comments on the Initial Assessment Report. Public comment on the Draft Assessment Report was sought from 16 July to 27 August 2003 (with one late supplementary submission received 22 September 2003). Eighteen submissions were received with 10 supporting the Application while eight objected due to concerns about residual gluten (from gluten derived plant proteins) remaining in the wine for people with Coeliac disease. Their concerns are addressed by mandatory labeling provisions of the Code (clause 4 of Standard 1.2.3), which require mandatory declaration of certain allergenic substances if present in the final food.

The Final Assessment Report concludes that plant proteins derived from traditional food sources can be considered as alternative wine processing aids for clarifying wine. The use of such plant proteins as processing aids in wine is technologically justified and does not raise any new public health and safety concerns.

Statement of Reasons

The draft variation to Standard 4.1.1 – Wine Production Requirements (Australia only) of the Code to permit plant proteins derived from traditional food sources as processing aids for the production of wine in Australia is agreed for the following reasons.

- In general there are no public health and safety concerns with using plant proteins derived from traditional food sources as processing aids for wine. However, wine remains subject to general labelling requirements in Standard 1.2.3 that require mandatory declaration of certain substances in food including gluten and known allergens.
- Plant proteins derived from traditional food sources are technologically justified as nonanimal replacements for currently used wine clarification processing aids from international research and trials.
- As concluded by the regulatory impact analysis conducted, the costs that would arise from a variation to Standard 4.1.1 to permit plant proteins as processing aids for wine do not outweigh the direct and indirect benefits to the community, government or industry that would arise from the variation.
- The proposed draft variation of the Code is consistent with the section 10 objectives of the FSANZ Act. FSANZ is protecting public health and safety by ensuring the use of only those plant proteins which are derived from traditional food sources are permitted as wine processing aids in Standard 4.1.1. FSANZ is also ensuring consistency with international wine standards and the promotion of fair trading in wine.
- A majority of submitters were supportive of the Application. A number had concerns about the impact on consumers with Coeliac disease. These concerns are addressed by the mandatory labelling provisions of the Code.
- To achieve what the Application seeks, namely permission to use plant proteins as processing aids for wine produced in Australia, there are no alternatives that are more cost-effective than a variation to Standard 4.1.1.

1. Introduction

FSANZ received an application on 18 November 2002, from Scorpex Wine Services to amend the Code to permit the use of plant proteins as processing aids during production of wine. The Application is being progressed as a Group 3 (cost-recovered) application. The Applicant requested that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended accordingly.

The purpose of this Application is to permit the use of plant proteins as alternatives to currently used wine clarifying agents that are sourced from animals, such as gelatine (cattle), isinglass (fish), milk and milk products (milk) and egg white (egg) with proteins derived from plant matter. Gelatine is the most widely used clarifying agent. With the recent concerns about the safety of products derived from contaminated cattle due to the Bovine Spongiform Encephalopathy (BSE) agent there has been greater interest in developing non-animal derived alternatives to gelatine. Such products would also be available to produce wine that is acceptable for vegan and vegetarian consumers.

2. Regulatory Problem

The regulatory problem is that Standard 4.1.1 does not permit the use of plant proteins as processing aids. However these same plant proteins are currently permitted for use in wine made in accordance with Standard 2.7.4 – Wine and Wine Product, because they are considered as traditional foods and thus are generally permitted for use as processing aids as provided by clause 3(a) to Standard 1.3.3, which states:

The following processing aids may be used in the course of manufacture of any food at a level necessary to achieve a function in the processing of that food –

(a) foods, including water;

Standard 2.7.4 was developed during the review as the joint wine standard that applies to wine produced in New Zealand and wine imported into Australia and New Zealand. It is a minimally prescriptive standard which defines wine and wine product and provides permissions for the addition of certain specified foods during the production of wine.

Standard 4.1.1 is an Australia-only standard which was developed in order to underpin the 1994 Agreement between Australia and the European Community (EC) on Trade in Wine and Protocol (Australia – EC Wine Trade Agreement). This agreement relies on Australian wine being recognised as wine of designated quality and origin (e.g. appellation controllé, DOC, qualitätswein, etc). It contains many provisions which are not appropriate in a joint wine standard and the permissions in Standard 1.3.3 do not apply. All wine produced in Australia must comply with Standard 4.1.1. Therefore in order to permit Australian wine producers to use plant proteins, a variation is required to Standard 4.1.1. Clause 4 of Standard 4.1.1 contains a positive list of permitted processing aids. Only the substances listed in clause 4 of Standard 4.1.1 are permitted to be used as processing aids in Australian produced wine.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of plant proteins derived from traditional food sources for use as processing aids during wine production in Australia.

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.

Public health and safety is protected by ensuring that any plant proteins which are approved for the purpose of wine clarification are safe. The promotion of consistency with international wine standards and the promotion of fair trading in wine is also addressed in assessing this Application.

4. Background

A number of proteinaceous materials derived from animal products are permitted by the Code for use to clarify grape juice and wine. These proteinaceous materials irreversibly bind with phenolic structures extracted from grapes to form insoluble precipitates, which are removed by techniques such as filtration. Commonly used proteinaceous clarifying materials include gelatine, skim milk powder, isinglass (fish collagen) and egg white.

The most common and widely used clarifying product is gelatine, which is derived from cattle. The emergence of variant Creutzfeldt-Jakob disease (vCJD) has caused worldwide concern about the use of bovine materials from Bovine Spongiform Encephalopathy (BSE) infected animals in the production of food for human consumption. BSE, commonly known as "mad cow disease", is a chronic degenerative disease affecting the central nervous system of cattle. Recently with the concerns of potential transmission of the BSE agent to humans from contaminated cattle products there has been greater interest in replacing products derived from cattle. This is the case in the wine industry where there have been moves, prompted by consumer concerns, to replace the use of gelatine with a product not derived from cattle (or animals).

Alternative clarifying products, sourced from plants, could also be used to produce wine suitable for vegan and vegetarian consumers.

Trials have been carried out in Europe evaluating the efficacy of using plant proteins as an alternative for gelatine during wine production. Initial results have been promising and form the basis for this Application. The Applicant requests that these plant proteins can be used as alternatives for animal-derived clarifying agents.

5. Relevant Issues

5.1 Nature of the Products

The plant proteins proposed for use are foods or food ingredients. They are composed of hydrolysed proteins derived from cereals and legumes. The plant proteins proposed for use comply with the Codex Alimentarius Standard 174-89 for Vegetable Protein Products. Such products are prepared by various separation techniques from vegetable sources. The Codex Standard applies to products that are used during food manufacturing of foods that require further processing.

The sources of the plant proteins which have been evaluated in trials by the wine industry and which have potential for commercial use include cereals (rice, wheat, barley, maize), legumes (peas, soya, lupin, haricot), oilseeds (rape, sunflower, sesame), tubers (potato, beetroot) and foliage crops (lucerne). The final products can undergo a variety of processing techniques including, milling, extraction, concentration, toasting, grinding, washing and ultrafiltration. Such plant proteins may be flours, concentrates, isolates, protein isolates or enzymatic or chemical hydrolysates. They are usually dried powders of a brown or yellow colour, which are soluble in water. The production of plant proteins is explained in more detail in the Food Technology Report (Attachment 2).

Based on these trials, the products having the best potential for development as commercial products have been obtained from wheat, rice, peas, lupin and maize, though this is not an exclusive list.

5.2 Technological Need

Wine makers in several countries have initiated production trials to evaluate the effectiveness of the plant proteins as alternatives to gelatine for the clarification of wine and musts. Results to date from such trials, included in the Application, have been positive indicating that different products and different treatments can be used to give similar performance compared to gelatine. From the information in the Application it would seem that individual wine makers would need to evaluate the performance of the products for their individual wines to determine the optimal treatment required.

Industry support for this Application is shown by letters from two major Australian wine producers included in the Application. Both these companies expressed support to have an alternative to animal products for wine clarification and phenolic adjustment to their wines. They have indicated interest in trialling such products on their wines.

It would appear that there are no dietary or nutritional implications of using plant proteins as wine processing aids since the proteinaceous materials added as clarifying agents react with components in the wine to form insoluble precipitates which are subsequently removed by filtration, racking or centrifugation.

5.3 Safety Assessment

A safety assessment has not been conducted on the plant proteins proposed to be used since they are derived from traditional foods. The plant proteins also meet the Codex Alimentarius Standard 174-89 for Vegetable Protein Products. Such plant proteins are currently used in the food industry as an alternative to gelatine in cherry candies and fruit chews, in products derived from meat or fish, in soups and sauces, dietary products and children's foodstuffs.

In order to ensure the safety of plant proteins used as wine processing aids, it is necessary to specify which plants will be used as a source of proteins. To that end FSANZ has written the proposed draft variation to Standard 4.1.1 to allow only those plant proteins that are derived from traditional food sources to be approved as processing aids for wine production. This has been done by linking the permission back to the relevant subclause (subclause 3(a) of Standard 1.3.3) that allows foods to be considered generally permitted processing aids. The proposed draft variation is listed in Attachment 1.

5.4 International Regulatory Standards

Plant proteins are not currently used as processing aids for wine in other countries. The Applicant has provided two documents from the Office International de la Vigne et du Vin (OIV) showing trials are underway to evaluate the use of plant proteins for wine through the OIV process. The Applicant believes that approval from the OIV is likely in 2004. An application to allow the use of plant proteins as wine clarifying agents has also been made to the EU and the Applicant believes permission may occur in early to mid 2004.

The Italian government has authorised the Asti Instituto Sperimentale di Enologia to conduct plant trials where over 500,000 litres of grape juice, and white and red wine has been treated with plant proteins.

5.5 Labelling Issues – Cereals Containing Gluten

A number of recent Australian wines have labels which indicate that the wine has been treated by isinglass (a fish product). This is not saying that there is definitely isinglass residues in the final treated wine, just that it has been used. Examples of labels statements which are used in Australia (information obtained from the Winemakers' Federation of Australia) are:

- Produced with isinglass (fish product)
- Contains / produced with fish product
- Produced with isinglass (fish product). Traces may remain.
- Produced with fish products. Traces may remain.

There is no data indicating that this has caused any consumer concern or negative response. A similar reaction may be expected for the use of plant proteins containing gluten used to treat wine. Such advisory labelling would be useful information for people with Coeliac disease.

The presence of gluten-containing cereals and their products in the final wine will evoke mandatory labelling requirements (clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations).

The relevant section of clause 4 of Standard 1.2.3 is printed below.

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) Any substances required to be declared by subclause (1) 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) displayed on or in connection with the display of the food; or
 - (ii) provided 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

Evidence from recent research papers that have evaluated the efficacy of plant proteins (including gluten based) that have used ELISA (enzyme-linked immunosorbent assay) have failed to detect residual gluten in the final treated wine to the detection limit of these tests.^{1,2}

If these products were to be used commercially the onus would be on manufacturers to determine whether cereals containing gluten and their products are present in the wine and, if so, to label accordingly.

Clause 4 of Standard 1.2.3 requires mandatory declaration of certain substances if they are present in food. These substances require mandatory declarations because they may cause severe adverse reactions in susceptible individuals. In addition to cereals containing gluten and their products, wine containing plant proteins sourced from tree nuts and sesame seeds and their products; and peanuts and soybeans and their products would also require these declarations if they are present in the final wine.

¹ Marchal, R.; Marchal-Delahaut, L.; Lallement A.; Jeandet, P. Wheat gluten used as clarifying agent of red wines, *J. Agric. Food Chem.* 2002, 50, 177-184

² Marchal, R.; Lallement, A.; Jeandet, P.; Establet, G. Clarification of muscat musts using wheat proteins and the flotation technique, *J. Agric. Food Chem.* 2003, 51, 2040-2048

5.6 Issues Addressed from Submissions

5.6.1 Gluten issue

There were eight submissions that objected to the Application because of concerns of residual gluten from the plant proteins remaining in the final wine which they believe will cause serious health concerns for those consumers that have Coeliac disease (which is an intolerance to gluten).

One of these submitters was the Coeliac Society of Australia which sent their submission to the review of the gluten labelling requirements (P264 – Review of Gluten Claims with Specific Reference to Oats and Malt). FSANZ staff discussed the issue with the submitter and then formally responded to their submission with legal advice to correct the submitter's interpretation. The submitter's interpretation of clause 4 of Standard 1.2.3 was that labelling of the final food is required if processing aids derived from gluten containing cereals are used in the production of the food rather than when present in the final food.

The other seven submissions that objected to the Application were from private citizens that also have a concern about the use of gluten products to clarify wine and the possibility of residual gluten remaining in the wine affecting the health of wine consumers who have Coeliac disease. A number of these submitters were from overseas and said they would not consume Australian wine if this Application is successful. A number of submissions stated that various other non-gluten products such as mineral type filter media are suitable for wine clarification and filtration.

These submissions contend that to allow the use of gluten to clarify wine raises issues of public health and safety concerns for people with Coeliac disease who wish to consume wine. It will reduce their choice of beverages.

There a number of points to be made to address these concerns.

- 1. The Application is not only about the use of gluten containing plant proteins as wine clarifying agents. Possible plant protein products that may be used for this purpose could include those derived from various non-gluten containing cereals and plants including but not limited to rice, peas, lupins and maize.
- 2. There are technological differences associated with the use and the action of mineral type filtration agents such as bentonite, diatomaceous earth, activated carbon and kaolin compared to clarifying agents such as gelatine, isinglass and plant protein products. They can act in concert with each other but they can not completely replace one with the other. Clarifying agents aid in settling very fine particulate matter found in freshly fermented wine and musts by aggregating these to larger particles which can settle out. This is explained in more detail in Attachment 2 Food Technology Report. Mineral filtration agents are very porous materials which form a complex physical barrier that absorb particulates and are used to filter precipitates from the wine. Very fine haze particles that have not been fined to produce larger aggregates can pass through filter beds and then form unacceptable hazes or precipitates in the aged wine.

- 3. Research work has been undertaken to investigate the effectiveness of replacing gelatine with plant proteins as wine clarifying agents. Researchers analysed for gluten residues in the final treated wine and have not found any to the limits of the very sensitive analytical methods (section 5.5 above). This indicates that the gluten added has been bound to particulates from the wine, settled out, filtered and removed from the final bottled wine to below the level of detection in wine. Individual winemakers will need to do their own analyses on their treated wine to ensure this is the case for their processes if they use gluten based plant proteins as clarifying agents.
- 4. The mandatory labelling requirements (clause 4 of Standard 1.2.3) for the presence of gluten-containing cereals and their products in the final wine, means that consumers who have Coeliac disease will be able to identify these wines and avoid them if they wish. There will be many other wines that do not have declarations for plant proteins (gluten) for these consumers to choose from.
- 5. It is expected that winemakers in Europe and possibly other regions will also soon have approval to use plant proteins as wine clarifying agents.
- 6. Winemakers may decide to label that they have used gluten products in the production of the wine in an analogous way many are now indicating the use of fish collagen (isinglass). This would be added information for wine consumers, especially those with Coeliac disease.

5.6.2 Editorial note, linking approval to mandatory labelling for gluten

New Zealand Food Safety Authority (NZFSA) made a suggestion in its submission that an editorial note be written linking the approval for plant proteins as a processing aid to the mandatory labelling requirements for gluten if present in the final food (clause 4 of Standard 1.2.3). This is to ensure that Australian winemakers would be aware of the labelling requirements in Standard 1.2.3.

FSANZ considers that a cross reference is not necessary. The Australian wine industry is generally aware of the requirements for mandatory labelling of allergenic substances. Further, if the course of action suggested by NZFSA was followed, this would set a precedent for a large number of consequential amendments for which there is not sufficient justification. It is FSANZ's view that the appropriate vehicle for addressing the concerns of NZFSA is through the relevant user guides to the Code and these will be amended to address this issue when they are next updated. Finally, FSANZ has before it an Application (A480) to limit mandatory labelling requirements to the substances listed in the Table to clause 4 of Standard 1.2.3 and their protein containing derivatives. If the course of action suggested by NZFSA was followed it may indicate pre-judgement of the outcome of A480.

5.6.3 Incorporate plant protein specifications within the Code

One submission suggested that the specifications for plant proteins (which are listed within the Food Technology Report (Attachment 3)) should be included in the Code. There is no justification for the inclusion of specifications for materials that are considered foods within the Code. This course of action would set a precedent for a number of other processing aids that are also foods.

6. **Regulatory Options**

Plant proteins which are foods or food ingredients already have approval as general processing aids and can be used during wine manufacture under Standard 2.7.4 – Wine and Wine Product (but not for wine produced in Australia under Standard 4.1.1).

The two regulatory options available for this situation are:

- 1. Not approve the use of plant proteins derived from traditional food sources as processing aids for wine production in Australia under Standard 4.1.1;
- 2. Approve the use of plant proteins derived from traditional food sources for wine production in Australia under Standard 4.1.1, which duplicates their current approval for use in wine made in accordance with Standard 2.7.4.

Plant proteins not derived from traditional food sources would not be considered to be foods. They would need to be assessed as novel foods under Standard 1.5.1 - Novel Foods.

7. Impact Analysis

The affected parties to this Application are:

- 1. wine producers and suppliers to wine producers in Australia;
- 2. consumers of Australian wine; and
- 3. Commonwealth, State and Territory regulatory departments that enforce food regulations in Australia. There should be no impact in New Zealand since the proposed amendment is an Australia only standard.

Option 1

There are no perceived benefits to the Australian wine industry, consumers or government agencies if this option is taken.

There are disadvantages to the Australian wine industry if this option is taken since they would have less choice in which clarifying agents they can use. They would not have access to a non-animal derived clarifying agent. This limits the ability of Australian wine-makers to produce wine for vegan and vegetarian consumers, as well as consumers that have a concern about the use of gelatine.

It also puts Australian wine producers at a disadvantage because wine may soon be produced overseas using plant proteins as clarifying agents. These wines could be sold in Australia since they would meet Standard 2.7.4, but Australian wine producers could not use plant proteins.

Option 2

There are advantages to the Australian wine industry, giving them a choice of using a nonanimal derived clarifying agent that they can use to appeal to a broader range of wine consumers. There are benefits for wine consumers who are vegan and vegetarian and do not wish to purchase wine made using animal derived products. Also it would satisfy consumers who have health concerns about using gelatine (derived from cattle) in wine manufacture.

There should be minimal costs for such changes to wine producers. One possible cost for wine producers would be new labelling if there is the presence of any of the substances that require mandatory declarations required by clause 4 of Standard 1.2.3 in the final wine, caused by the use of plant proteins.

There should be no added costs or concerns for food regulators.

The Applicant states that the EU currently does not allow the use of plant proteins for use in winemaking but it is probable that they will provide regulations for plant proteins in wine in 2003.

Representatives of the Australian Wine and Brandy Corporation, Winemakers' Federation of Australia, and the Department of Agriculture, Fisheries and Forestry - Australia have advised the Applicant that they consider the proposed permission for the use of plant protein processing aids in Standard 4.1.1 will have no impact on the Australia - EC Wine Trade Agreement.

There should also be no issues with trade with other signatories to the Mutual Acceptance Agreement on Oenological Practices (including New Zealand, USA, Canada and Chile) since there are no consumer health or deception issues associated with the permission in Standard 4.1.1.

8. Consultation

8.1 Public Consultation

FSANZ did not request any public comments on the Initial Assessment Report. The Applicant requested the Application to be progressed under section 36 of the FSANZ Act, since it raises issues of minor complexity.

Public comment on the Draft Assessment Report was sought from 16 July to 27 August 2003 (with one late supplementary submission accepted on 22 September 2003). Eighteen submissions were received. **Attachment 3** summarises the submissions received. Of the eighteen submissions received 10 supported the Application while eight objected. The eight submitters who objected to the Application all had concerns about the use of gluten as a clarifying agent and possible gluten residues in the final treated wine which may cause serious health concerns to people with Coeliac disease. This issue is addressed within section 5.5 (labelling issues – cereals containing gluten) and section 5.6 (issues addressed from submissions) of this report.

NZFSA suggested that an editorial note linking permission to use plant proteins as wine processing aids, with the mandatory labelling requirements of clause 4 of Standard 1.2.3, if residual gluten is present in the final wine. This is to make Australian wine makers aware of their labelling obligations. The issue is addressed in section 5.6.2 above of this report.

8.2 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.

Plant proteins comply with the Codex Alimentarius General Standard for Vegetable Protein Products Codex Stan 174-1989 for use as foods and food ingredients. This Codex standard does not provide specific approval for use in wine. However, FSANZ understands approval is being sought through the OIV.

Additionally, it is not expected that permitting the use of plant proteins for wine production in Australia and/or New Zealand would have any significant effect on international trade. This is because the overall market for wine clarification agents (gelatine) is relatively small (100 tonnes at AUD \$1.2M per annum). Approval would only provide wine producers with an optional alternative to gelatine and displacement of this market is not expected to be rapid or significant.

Any amendment to Standard 4.1.1 – Wine Production Requirements applies only to wine produced in Australia. For the above reasons FSANZ did not recommend relevant agencies notify the WTO.

9. Conclusion and Approval

The Final Assessment Report concludes that plant proteins derived from traditional food sources can be considered as alternative wine processing aids for clarifying wine. These products have a technological justification and do not raise any public health and safety concerns beyond the current permission for foods as processing aids.

The draft variation to Standard 4.1.1 – Wine Production Requirements (Australia only) of the Code to permit plant proteins derived from traditional food sources as processing aids for the production of wine in Australia is agreed for the following reasons.

- In general there are no public health and safety concerns with using plant proteins derived from traditional food sources as processing aids for wine. However, wine remains subject to general labelling requirements in Standard 1.2.3 that require mandatory declaration of certain substances in food including gluten and known allergens.
- Plant proteins derived from traditional food sources are technologically justified as nonanimal replacements for currently used wine clarification processing aids from international research and trials.
- As concluded by the regulatory impact analysis conducted, the costs that would arise from a variation to Standard 4.1.1 to permit plant proteins as processing aids for wine do not outweigh the direct and indirect benefits to the community, government or industry that would arise from the variation.

- The proposed draft variation of the Code is consistent with the section 10 objectives of the FSANZ Act. FSANZ is protecting public health and safety by ensuring the use of only those plant proteins which are derived from traditional food sources are permitted as wine processing aids in Standard 4.1.1. FSANZ is also ensuring consistency with international wine standards and the promotion of fair trading in wine.
- A majority of submitters were supportive of the Application. A number had concerns about the impact on consumers with Coeliac disease. These concerns are addressed by the mandatory labelling provisions of the Code.
- To achieve what the Application seeks, namely permission to use plant proteins as processing aids for wine produced in Australia, there are no alternatives that are more cost-effective than a variation to Standard 4.1.1.

ATTACHMENTS

- 1. Draft Variation to the Australia New Zealand Food Standards Code
- 2. Food Technology Report
- 3. Summary of Submissions

ATTACHMENT 1

Draft variation to the Australia New Zealand Food Standards Code

To commence: on gazettal

[1] Standard 4.1.1 of the Australia New Zealand Food Standards Code is varied by –

[1.1] *inserting in the* Table to clause 4 –

Plant proteins permitted as processing aids under clause 3(a) to Standard 1.3.3

[1.2] *inserting after the* Table to clause 4 –

Editorial note:

Clause 3(a) to Standard 1.3.3 permits the use of foods, including water as processing aids. Therefore, plant proteins that are foods are permitted under that Standard, and would also be permitted under this Standard.

ATTACHMENT 2

Food Technology Report

A482 – Plant Proteins as Wine Processing Aids

Introduction

An Application has been received from Scorpex Wine Services (acting on behalf of Esseco S.p.A., Italy) to amend the *Australia New Zealand Food Standards Code* to allow the use of certain plant proteins to be used as approved processing aids for the production of wine in Australia.

These products would be used as alternative non-animal derived products for currently used wine clarifying agents derived from animal sources, such as gelatine (cattle), isinglass (fish), milk protein and egg albumin.

The Applicant requests to have their plant proteins added to the approved positive list of processing aids within Standard 4.1.1 – Wine Processing Requirements (Australia only).

Discussion of the products, how produced

The products covered by this Application for use by the wine industry comply with the Codex Alimentarius General Standard for Vegetable Protein Products (Codex Stan 174-1989). The scope of that Standard states:

This standard applies to vegetable protein products (VPP) intended for use in foods, which are prepared by various separation and extraction processes from proteins from vegetable sources other than single cell protein.

These products are currently used as ingredients in the food industry, due to their rheological properties where they are used as food integrators or emulsifying agents. They have been used as gelatine replacements in cherry candies and fruit chews, in products derived from meat or fish, in soups and sauces, dietary products and children's foodstuffs.

The protein products this Application refers to have been sourced from wheat, rice, peas, lupin and maize but would not be limited to just these plants. The Applicant states that other possible sources could be barley, sesame, soya, haricot, rape seeds, sunflower seeds, potato, beetroot and lucerne. A wide range of products sourced from different materials have been investigated for possible use as wine clarifying agents. It would be anticipated in the future that new plant proteins would also be evaluated for their effectiveness.

The plant proteins would have undergone a range of processing steps including milling, extraction, concentration, toasting, grinding, washing and ultrafiltration. The products may be flours, concentrates, isolates, protein isolates, enzymatic or chemical hydrolysates. They are usually cream, brown or yellow water-soluble powders.

Fig. 1 contains a schematic for the production of the plant proteins.

Specifications

The specifications for the products are listed in Table I and II.

	Table I	
Specifications of	f the plant proteins from	m the Application

SPECIFICATIONS	DETAILS
CHEMICAL FEATURES	
Dried substance	94 % min
Proteins	70 % min
Fat materials	5 % min
Carbohydrates	10 % max
Ash	3 % max
Sodium	0.4 % max
Calcium	0.15 % max
Phosphorus	0.5 % max
Magnesium	0.2 % max
Potassium	0.5 % max
PHYSICAL FEATURES	
pH (10% solution)	6-8
Colour	powder cream
Odour	neutral
Taste	neutral
MICROBIOLOGY	
Total flora	<10,000/g
Yeasts and moulds	<200/g
Coliforms	<20/g
Pathogenic germs and salmonella	absent in 25 g

Table II Extra Specifications from the Office International de la Vigne et du Vin (OIV) for Plant Proteins

SPECIFICATIONS	DETAILS
CHEMICAL	
Loss on drying	≤12 %
Total nitrogen	>10 % of dried powder (corresponds to approx. 65 %
	protein)
Ash	<8 %
Iron	<150 ppm
Chromium	<10 ppm
Copper	<40 ppm
Zinc	<100 ppm
Heavy metals	<10 ppm
MICROBIOLOGY	
Total viable micro-organism	$<5 \text{ x } 10^5 \text{ cfu/g}$
Escherichia coli	absent in 1 g
Salmonella	absent in 25 g
Coliforms	<100/g
MYCOTOXINS AND PESTICIDES	
Aflatoxins B1 and B2	<4 ppb
Aflatoxin G1	<1 ppb
Aflatoxin G2	<1 ppb
Ochratoxin	<5 ppb
Organophosphorus residues	<10 ppm
Organochlorine residues	<0.1 ppm

Action of plant proteins as clarifying agents

Wine and musts (grape juice before fermentation is completed) contain naturally occurring insoluble material which can not always be removed by filtration or can form hazes at a later time, after filtration. Such insoluble material is mainly protein and polyphenol (tannins) compounds present in grape products, and enzymes and yeasts responsible for fermentation. Often these insoluble materials are very fine flocculants which have similar particle densities to the liquid and do not readily settle. Also electrical repulsion forces between the charged particles as well as diffusion phenomena results in very slow settling and clarification of wines. Hazes can form at a later date after initial clarification by filtration.

To improve wine quality, wine producers have historically used a variety of different products to assist in clarifying wines more rapidly. These are commonly called fining agents. The most commonly used fining agent in wine production is gelatine. Other commonly used wine fining agents are bentonites, tannins extracted from chestnuts, egg albumin, casein and silica gels. Isinglass, derived from fish swim bladders, is the most common fining agent used in beer production.

The primary reaction of protein finings is to form a complex between polyphenols in the wine and the added protein to produce larger particles which are less soluble and big enough to settle out of solution. The larger complexes between polyphenols and proteins are usually formed by hydrogen bonding between OH groups on polyphenol groups and keto-imide $\{C(O)NH\}$ groups on the proteins.

There can also be protein–protein complexes formed to yield insoluble particles. For such reactions to occur, the two different types of proteins need to have different charges so they can form ionic bonds.

Formation of insoluble particles, which settle out, improves the clarity of the wine. They tend to settle out at the bottom of tanks to form wine lees. The resultant semi-clarified wine is subsequently filtered (or racked or centrifuged). Finings also remove some of the problem compounds which can flocculate with ageing of the produced wine therefore improving the quality of the bottled wine.

References

Cole, C.G.B., The use of gelatine in wine fining, *Proceedings of the 1st SAAFoST Technical Symposium, Emulsifiers, Stabilisers and Thickeners in the Food Industry 1*, Durban, South Africa, April 1986, Natal Technikon Printers.

Marchal, R.; Marchal-Delahaut, L.; Michels, F.; Parmentier, M.; Lallement, A.; Jeandet, P., Use of wheat gluten as clarifying agent of musts and white wines, *Am. J. Enol. Vitic.* 2002, 53(4), 308-314.

Sarni-Manchado, P.; Deleris, A.; Avallone, S.; Cheynier, V.; Moutounet, M., Analysis and characterisation of wine condensed tannins precipitated by proteins used as fining agent in enology, *Am. J. Enol. Vitic.* 1999, 50(1), 81-86.

Marchal, R.; Marchal-Delahaut, L.; Lallement A.; Jeandet, P. Wheat gluten used as clarifying agent of red wines, *J. Agric. Food Chem.* 2002, 50, 177-184.

Marchal, R.; Lallement, A.; Jeandet, P.; Establet, G. Clarification of muscat musts using wheat proteins and the flotation technique, *J. Agric. Food Chem.* 2003, 51, 2040-2048.

Abstracts from the following:

Restani, P.; Beretta, B.; Ballabio, C.; Galli, C.L.; Bertelli, A.A. Evaluation by SDS-Page and immunoblotting of residual antigenicity in gluten-treated wine: a preliminary study, *Int. J. Tissue React.* 2002, 24(2), 45-51.

Fischerleitner, E.; Wendelin, S.; Eder, R. Effects of conventional and new protein containing fining agents on quality, composition and tolerance of wine, *Mitt. Klosterneuburg Rebe Wein*, 2002, 52 69-88.



Fig. 1
PLANT PROTEIN PRODUCTION SCHEMATIC

ATTACHMENT 3

Summary of Public Submissions

Submitters

#	Submitter Organisation	Name
1	Australian Food and Grocery Council	Tony Downer
2	The Coeliac Society of Australia Inc	Graham Price
3	Food Technology Association of Victoria	David Gill
4	Winemakers' Federation of Australia	Tony Battaglene
5	Environmental Health Unit Oueensland Health	Gary Bielby
6	Agriculture Fisheries and Forestry – Australia Department of	Trent Brady
Ũ	(Australian Quarantine and Inspection Service, AQIS)	Kerrie Boulton
7	New Zealand Food Safety Authority	Carole Inkster
8	Stephen and Liz Spain, York, UK	
9	Toby Anderson, Bournemouth, UK	
10	Stephen Rowe, Ferntree Gully, Victoria	
11	Constance Rieper-Estes, Australia	
12	Steve Cox, Huntington, UK	
13	Emma Wright	
14	David McIlfatrick	
15	Newton Che, student, Department of Food Science, University	
	of Auckland	
16	Keren Ward, student, Department of Food Science, University of Auckland	
17	Mavank Joshi, student, Department of Food Science, University	

- Mayank Joshi, student, Department of Food of Auckland Coles Myer Ltd (representing Liquorland) ence, University
- 18

Andrea Currie

Submitter	Position	Comments
Australian Food and Grocery Council	Supports	It supports the Application, including the approval of the use of plant proteins derived from traditional food sources, the impact analysis and the drafting. It also recommends that FSANZ considers including the specifications from Codex Alimentarius Standard 174- 89 for Vegetable Protein Products into the Code. (FSANZ believes there is no reason to include specifications for materials that are considered foods within the Code. It would set a precedence for a number of other processing aids that are also foods. See section 5.6.3).
The Coeliac Society of Australia Inc.	Issue with gluten	It has an issue with section 5.5 – Labelling Issues – Cereals Containing Gluten of the report. It is their understanding that clause 4 of Standard 1.2.3 requires labelling of the final product if processing aids derived from gluten containing cereals are used in the production of the product rather than the presence in the final product. They have requested that FSANZ provide advice to clarify this situation and to review the interpretation. A meeting between the submitter and FSANZ has taken place as well as formal advice confirming that it is the presence of the processing aid in the final food that requires mandatory labelling.
Food Technology Association of Victoria	Supports	The committee agrees with option 2, to approve the Application. This would duplicate current approval for wine in accordance with Standard 2.7.4.

Winemakers'	Supports	Their first submission:
Federation of		They do not have a formal position on the introduction of plant
Australia		proteins as a processing aid for winemaking. They understand that
		internationally (especially Europe) there are moves to approve the
		use of plant proteins so they believe Australia should support the
		Application to prevent any future technical barrier to trade. They do
		not believe there would be any adverse political ramifications of
		such approval.
		A second late (supplementary) submission which FSANZ accepted:
		This submission was sent after the Application had been discussed
		by their Technical Advisory Committee.
		They still supported the Application but they raised two issues which
		they suggested FSANZ need to consider.
		1. The Application is broad based and possible products may be
		derived from a number of sources. They also made comment about
		the rather low level of refinement and specification listed in the
		Report. They also mentioned possible allergen issues with other
		beens)
		Utalls). (Unlagg there are issued of mublic health and safety the first point is a
		(Onless there are issues of public health and safety the first point is a
		covered by mandatory labelling requirements within the Code)
		2. They point out the issue of residual gluten for people with Coeliac
		disease for those plant protein products that may be gluten based
		(This issue has been raised by a number of other submitters and is
		addressed by mandatory labelling provisions within clause 4 of
		Standard 1 2 3 of the Code. It is discussed in section 5 6 1 of the
		report)
Environmental	Tentative	They acknowledge there appears no obvious public health and safety
Health Unit.	support (option	implications in the Application. It would also allow the Australian
Queensland Health	2)	wine industry greater choice to use non-animal derived clarifying
	,	agents.
		However they believe advice needs to be provided assuring there are
		no chemical residues remaining in the final hydrolysed protein
		products, or providing residue data on such.
		(The products would meet the specifications listed in Attachment 2,
		which gives specifications of chemical residues).
Agriculture, Fisheries	Supports	They believe the Application will have no impact on AQIS imported
and Forestry –		food operations.
Australia,		
Department of		
(Australian		
Quarantine and		
Inspection Service,		
AQIS)		
New Zealand Food	Supports	They support measures that harmonise Australia and New Zealand
Safety Authority		permissions.
		I ney suggest an editorial note linking the permission to use plant
		proteins as processing ands for while to the mandatory labelling for
		for discussion see section 5.6.2 of the report ESANZ desided that
		(10) discussion, see section 5.0.2 of the report. FSAINZ decided that
		as processing aids since other products may also have mandatory
		labelling requirements. Industry need to be aware of all their
		obligations of the Code including mandatory declarations FSANZ
		also believes industry is quite aware of these requirements from
		current experience and discussions.)
		They believe it would be expected that plant proteins would be
		filtered from the final wine but a reminder of the requirements for
		Australian winemakers should be made.

	Essing alus
Spain with gluten, for wine will cause residual gluten protein to remain in th	e final
Coeliac disease wine, which many people with Coeliac disease will no log	nger be able
to consume. He states that he has stopped drinking beer (produced
from malted barley, may contain gluten) because of he ha	is Coeliac
disease so drinks more wine. The Application would be a	further
restriction of foods that people with Coeliac disease could	d consume.
He also believes there are other non animal wine clarifyir	ng
alternatives that are not gluten based, such as products de	rived from
rice, peas, lupins, maize (all of which are covered by this	•
Application, since the Application is not just for gluten pi	roducts) as
well as mineral type filter media (such as bentonite, diato	maceous
(for discussion see section 5.6.1)	
(101 discussion see section 5.0.1)	and cafaty
with gluten is used in Australian wine because it will cause l	health
Coeliac disease concerns for people with Coeliac disease who inadvertent	tly drink
such wine	try trink
(for discussion see section 5.6.1)	
Stephen Rowe Object, issues He believes the Application raises issues of public health	and safety
with gluten, if gluten is used in Australian wine because it will cause l	health
Coeliac disease concerns for people with Coeliac disease who inadvertent	tly drink
such wine.	
(for discussion see section 5.6.1)	1
Constance Rieper- Object, issues She believes the Application raises issues of public health	n and safety
Estes with gluten, if gluten is used in Australian wine because it will cause f	health
Coeffac disease concerns for people with Coeffac disease who inadvertent	tly drink
(for discussion see section 5.6.1)	
Stephen Cox Object issues He believes the Application raises issues of public health	and safety
with gluten.	health
Coeliac disease concerns for people with Coeliac disease who inadvertent	tly drink
such wine.	-
(for discussion see section 5.6.1)	
Emma Wright Object, issues She believes the Application raises issues of public health	n and safety
with gluten, if gluten is used in Australian wine because it will cause h	health
Coeliac disease concerns for people with Coeliac disease who inadvertent	tly drink
such wine.	
(Ior discussion see section 5.0.1)	and safaty
bavid Memaulick Object, issues in even because it will cause life duten is used in Australian wine because it will cause l	health
Coeliac disease concerns for people with Coeliac disease who inadvertent	tly drink
such wine.	
(for discussion see section 5.6.1)	
Newton Che Supports They supported the Application and provided justification	n for their
position.	
Keren Ward Supports They supported the Application and provided justification	n for their
position. The one point of concern raised was about possi	ble gluten
residues in wine which people with Coeliac disease have	concerns
with. They have also provided a number of recent researc	h articles
Indicating low gluten residues in treated wine.	a for their
nosition as well as a couple of references	
Coles Myer Ltd Supports They believe the Application will give the wine industry	greater
(representing choice for additional non-animal derived processing aids.	appealing
Liquorland) to a wider range of consumers.	