

11/03
13 August 2003

INITIAL ASSESSMENT REPORT

APPLICATION A503

COLLAGEN – PROCESSING AID FOR WINE

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

24 September 2003

(See 'Invitation for Public Submissions' for details)

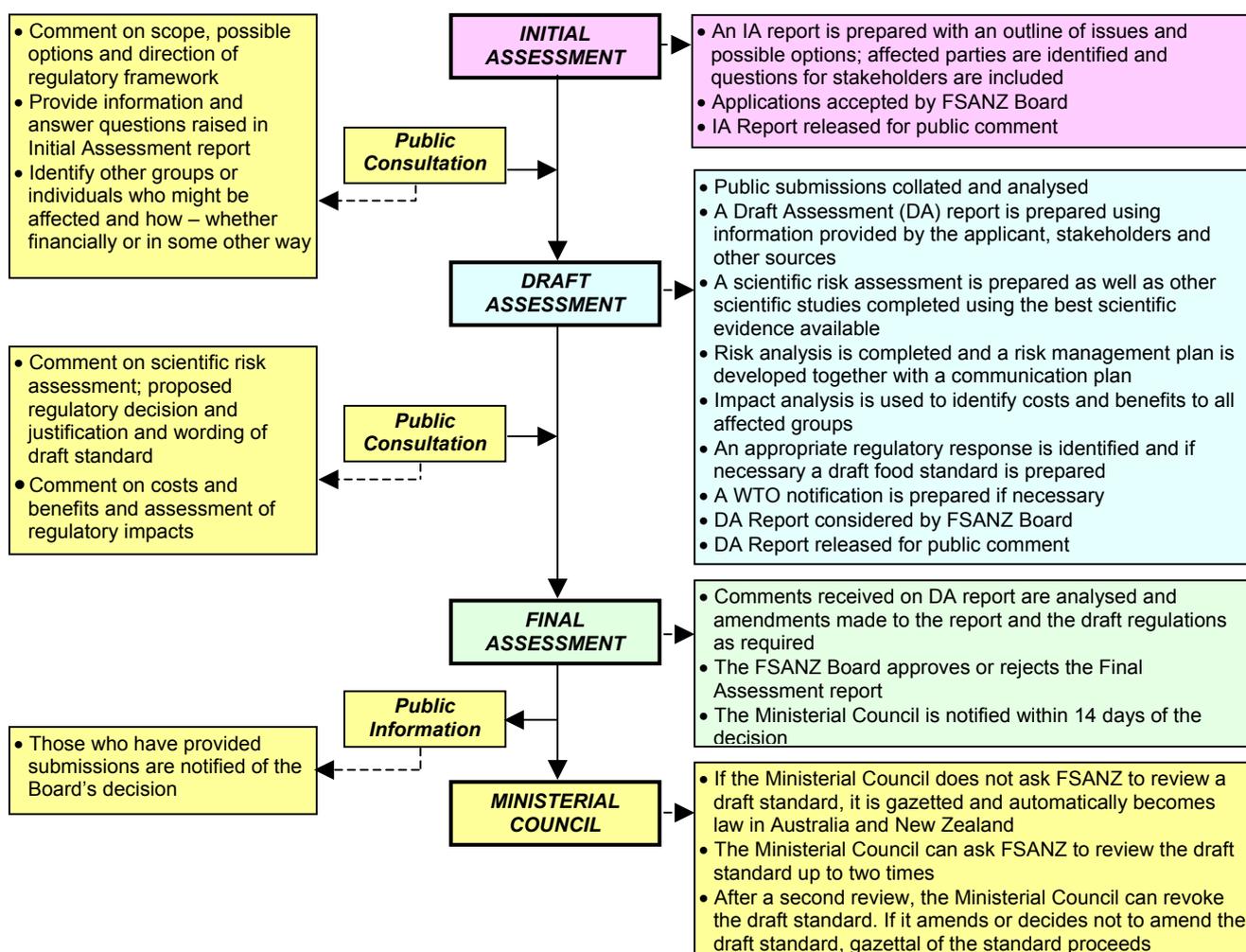
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A503, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report 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 for this Application. 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 should be received by FSANZ by **24 September 2003**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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 Liaison 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 and Statement of Reasons

FSANZ received an application from Devro Pty Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of collagen as a processing aid during production of wine. It is 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 an alternative wine clarifying agent. The applicant claims that collagen is considered as a traditional food and therefore it is already approved as a general processing aid, under Standard 1.3.3 – Processing Aids. All wine produced in Australia must comply with Standard 4.1.1 (as well as Standard 2.7.4 – Wine and Wine Product) so an amendment to Standard 4.1.1 is requested to specifically include collagen in the list of approved processing aids.

This current Application is similar to another application A482 – Plant Proteins as Wine Processing Aids which FSANZ is currently considering.

Collagen is claimed to act in a comparable way to other widely used proteinaceous materials such as gelatine and fish collagen (isinglass) to irreversibly bind and remove polyphenolic and tannin materials from wine. These materials precipitate out and are removed along with most of the added collagen.

Collagen is not approved elsewhere in the world specifically for wine treatment as a processing aid to clarify wine.

This Initial Assessment is not an assessment of the merits of the Application but rather whether it warrants further consideration according to the criteria laid down in section 13 of the *Food Standards Australia New Zealand Act 1991*. FSANZ accepts this application following initial assessment for the following reasons:

- The application seeks approval for the use of collagen as a processing aid in wine production.
- Under Standard 4.1.1, only those substances specified in the Table to clause 4 may be used as processing aids in the production of wine. Currently, collagen is not specified as a permitted processing aid in this Table.
- Therefore, the application relates to a matter that warrants a variation to Standard 4.1.1, if further assessment supports such a variation.
- This application is not so similar to any previous application that it ought not be accepted.
- There is no basis for considering, at this stage of assessment, that the costs that would arise from a variation to Standard 4.1.1 to permit collagen as a processing aid would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- There are no measures other than a variation to the Code available to permit a processing aid for wine production.

The application has been accepted following Initial Assessment on this basis.

1. Introduction

FSANZ received an application on 3 June 2003, from Devro Pty Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of collagen as a processing aid during production of wine. The starting date for this cost-recovered Application is 28 July 2003. The applicant requested that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended accordingly. FSANZ has not previously received any applications for collagen as a processing aid in wine production.

1.1 Nature of Application

The purpose of this Application is to permit the use of an alternative wine clarifying agent to those currently approved and used, such as gelatine, egg white, milk and milk products, and isinglass. The applicant claims that collagen is considered as a traditional food and therefore it is already approved as a general processing aid. However Standard 4.1.1 – Wine Production Requirements (Australia only) does not include collagen as an approved processing aid so an amendment to this standard is requested.

2. Regulatory Problem

All wine sold in Australia must comply with Standard 2.7.4 – Wine and Wine Product. Standard 2.7.4 sets definitional standards for wine and wine product. The Applicant claims that collagen is a food, and is thereby a generally permitted processing aid for food, by virtue of clause 3 to Standard 1.3.3, which provides:

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;*

Collagen is principally derived from the hide or skin of slaughtered animals. Standard 2.2.1 – Meat and Meat Products defines meat flesh as including any attached animal rind or connective tissue.

All wine produced in Australia must also comply with Standard 4.1.1-Wine Production Requirements (Australia only). Standard 4.1.1 underpins Australia's 1994 Agreement with the European Community (EC) on trade in wine, which relies on Australian wine being recognised as wine of designated quality and origin (e.g. *appellation contrôlée*, DOC, *qualitätswein* etc).

Clause 4 of Standard 4.1.1 does not currently permit the use of collagen as a wine processing aid. Therefore the Application relates to a matter that warrants a variation to Standard 4.1.1 in order to permit collagen as a processing aid for wine produced in Australia, if further assessment supports such a variation.

FSANZ is currently considering a similar application:

- **A482 - Plant Proteins as Wine Processing Aids.** This application seeks to amend Standard 4.1.1 to allow plant proteins, which are sourced from traditional foods, as processing aids for wine clarification.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of collagen for use as a processing aid for wine manufacture 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.

4. Background

4.1 Historical Background

There are a number of proteinaceous materials that are approved as processing aids for the clarification (fining) of grape juice, wine and wine products. These fining agents work by irreversibly binding with phenolic structures extracted from grapes to form insoluble precipitates, which are subsequently removed by techniques such as filtration. The applicant states that the residual levels of collagen present in the final wine will be present in the mg/L levels and present as protein. The removal of polyphenols from wine clarifies the resultant wine as well as removes some precursors that would subsequently precipitate out in the final aged wine. Winemakers may also wish to modify the polyphenol content of their wine to adjust the final colour and flavour (adjust the astringency due to polyphenol and tannin contents).

Commonly used proteinaceous clarification agents (and approved in Standard 4.1.1 as processing aids) are gelatine, milk, isinglass (fish collagen) and egg white. For gelatine the animal source is not specified. Collagen derived from fish (including isinglass) is currently approved. This Application is for the general approval of collagen sourced from animal species. The Applicant states that they have more experience with bovine collagen, but they do not wish to limit the application just to bovine sources, as they would like to allow for collagen from porcine, ovine, avian and wild game sources.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 2 (level of complexity) and placed in Group 3 (cost-recovered) on the FSANZ standards development Work Plan. This Initial Assessment amends the Category of Assessment to category 1 after review because the application relates to a simple variation to a food regulatory measure requiring limited public consultation, thus fulfilling the criteria for being designated as a category 1 cost-recovered Application.

Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Nature of the Product

The Applicant claims that collagen is a food and has wide usage in the diet, mainly in meat products. Collagen is the chief protein component of the skin, bones and connective tissues of animals. Gelatine (which is approved as a wine processing aid) is produced by the acid, alkaline or enzymatic hydrolysis of collagen. Due to its similarity to gelatine and fish collagen (including isinglass) collagen is expected to behave similarly as a wine clarification agent. The applicant states that trials conducted with the National Wine & Grape Industry Centre indicate equivalent functionality relative to isinglass when used at equivalent concentrations for wine fining.

5.2 Safety Considerations

Any safety issues will be discussed and evaluated at the Draft Assessment. One possible area for investigating is that of potential contamination of collagen with the Bovine Spongiform Encephalopathy (BSE) infectious agent. However, it is not anticipated that this should be an issue since Australia is BSE free and collagen is not considered a BSE risk. Hides which are the raw material for collagen are not considered to present a BSE risk. Studies have indicated that the BSE agent has not been found in skin or hide.

5.3 International Regulatory Standards

The applicant maintains that international legislation recognises collagen as a food. There is no Codex monograph on collagen.

Collagen is not specifically approved as a wine clarification agent in any national food regulations. It is also not specified in the *Agreement between the European Community and Australia on trade in wine* and the USA Bureau of Alcohol, Tobacco & Firearms (BAFT). The impact of the proposed permission for the use of collagen as a processing aid in Standard 4.1.1 on the Australia EU wine Agreement will need to be considered.

5.4 Labelling Issues

Using collagen (from non-fish sources) for wine clarification would not currently require mandatory labelling. Collagen from non-fish sources is not derived from egg, fish or milk or

other relevant groups in the Table to clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

Clause 4 of Standard 1.2.3 requires the mandatory declaration of substances that most frequently cause severe adverse reactions, when present in a food. The relevant section from this clause 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....

Relevant extract from the Table to clause 4

Egg and egg products
Fish and fish products
Milk and milk products

One of the substances that require this mandatory declaration is fish and fish products, which includes fish collagen and isinglass that are approved for wine clarification. Other substances that have relevance for wine clarification are egg products and milk products. Therefore if fish collagen, egg white or milk and milk products are present in the final bottled wine as processing aids or components of processing aids, a mandatory declaration on the wine label is required.

6. Regulatory Options

If collagen is regarded as a food, then it already has approval as a generally permitted processing aid and therefore can be used during wine manufacture under Standard 2.7.4 – Wine and Wine Product (but not for wine produced in Australia).

There are no options other than a variation to the Code to permit collagen as a processing aid to be used in wine production in Australia. Therefore the two regulatory options available for this situation are:

Option 1. Not approve the use of collagen as a processing aid for wine production in Australia under Standard 4.1.1;

Option 2. Approve the use of collagen (from any animal source) for wine production in Australia under Standard 4.1.1.

7. Impact Analysis

7.1 Affected Parties

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.

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 following is the initial assessment of the costs and benefits of the two regulatory options identified. At initial assessment there is no basis for considering that the costs that would arise from a variation to Standard 4.1.1 to permit collagen as a processing aid would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.

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 agent they can use.

It also puts Australian wine producers at a disadvantage because wine produced overseas using collagen as a clarifying agent could be sold in Australia since they would meet Standard 2.7.4, but Australian wine producers could not use collagen.

Option 2

There are advantages to the Australian wine industry, giving them a choice of using an alternative clarifying agent that they can use. Using collagen would not cause wine-makers any concern for mandatory allergen labelling so it has advantages over a number of other used clarifying agents.

There should be no or minimal costs associated with such changes to wine producers. The applicant believes the cost of collagen derived from bovine sources will be cost neutral relative to isinglass.

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

8. Consultation

8.1 Public Consultation

FSANZ is seeking public comment in order to assist in assessing this application at Draft Assessment. There will also be a further round of public comment after the Draft Assessment report is completed.

Comments on the following topics would be useful:

- whether there is interest in the wine community in using collagen for wine clarification;
- likely costs and benefits of using collagen;
- affected parties to this application; and
- if there are any safety considerations.

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.

There are not any relevant international standards and amending the Code to allow collagen as a processing aid for wine treatment is unlikely to have a significant effect on international trade as collagen is considered a food.

If this application was approved it is not expected that there would be a major replacement of the use of currently permitted and used wine clarification agents with collagen. The overall market for the major wine clarification agent, gelatine, is relatively small (100 tonnes at AUD \$1.2M per annum).

Any amendment to Standard 4.1.1 – Wine Production Requirements applies only to wine produced in Australia. For the above reason it is not expected that FSANZ will recommend relevant agencies notify the World Organization (WTO).

9. Conclusion and Recommendation

FSANZ accepts this Application following initial assessment for the following reasons:

- The application seeks approval for the use of collagen as a processing aid in wine production.
- Under Standard 4.1.1, only those substances specified in the Table to clause 4 may be used as processing aids in the production of wine. Currently, collagen is not specified as a permitted processing aid in this Table.
- Therefore, the application relates to a matter that warrants a variation to Standard 4.1.1, if further assessment supports such a variation.
- This application is not so similar to any previous application that it ought not be accepted.

- There is no basis for considering, at this stage of assessment, that the costs that would arise from a variation to Standard 4.1.1 to permit collagen as a processing aid would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- There are no measures other than a variation to the Code available to permit a processing aid for wine production.