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

4-04
26 May 2004

FINAL ASSESSMENT REPORT

APPLICATION A503

COLLAGEN, PROCESSING AID FOR WINES

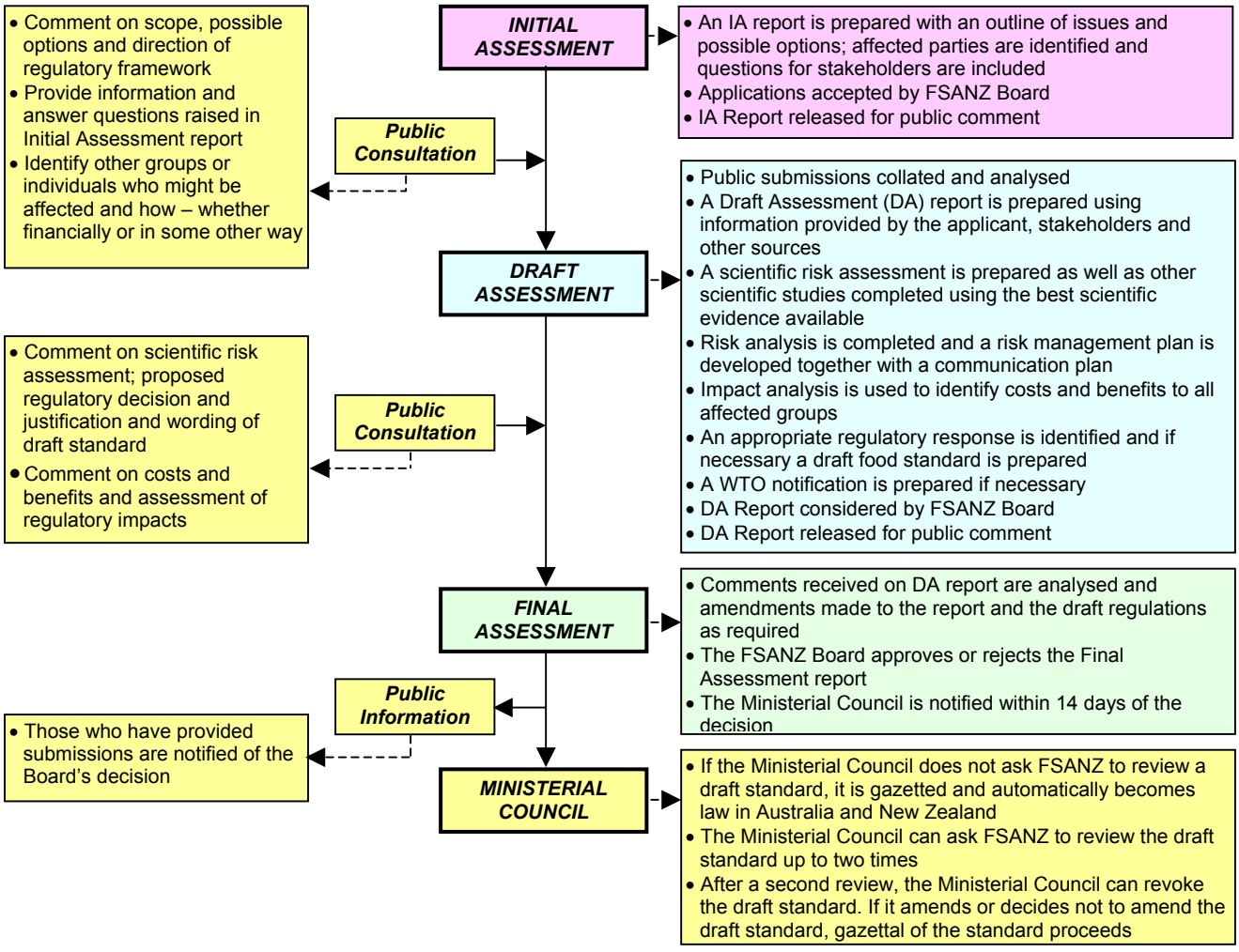
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

FSANZ has now completed two stages of the assessment process and held two rounds 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 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 of Health gazettes the food standard under the New Zealand Food Act. 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 Management Officer at one of the following addresses:

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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 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, namely collagen. Collagen is considered to be a food and therefore it is already approved as a general processing aid, under clause 3 of Standard 1.3.3 – Processing Aids. Collagen for human consumption is principally derived from the skin or hide of animals.

All wine produced in Australia must comply with Standard 4.1.1 (as well as Standard 2.7.4 – Wine and Wine Product) and an amendment to Standard 4.1.1 is requested to specifically include collagen in the list of approved processing aids for wine produced in Australia.

This current Application is similar to another application, Application A482 – Plant Proteins as Wine Processing Aids, which FSANZ recently completed.

Collagen is claimed to act in a comparable way to other widely used proteinaceous materials such as gelatine (which is produced from collagen) and isinglass (a fish collagen) 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 anywhere else in the world specifically as a processing aid to clarify wine. However, it is used as an alternative fining agent to isinglass in the beer industry.

Representatives of the Australian Wine and Brandy Corporation and the Winemakers' Federation of Australia confirmed that the proposed permission for the use of collagen as a processing aid in Standard 4.1.1 would have no impact on the 1994 *Agreement between Australia and the European Community (EC) on Trade in Wine, and Protocol* (Australia – EC Wine Trade Agreement).

The safety assessment concludes that collagen poses no risk to public health and safety. It is internationally accepted that collagen produced from bovine skins and hides is not a Bovine Spongiform Encephalopathy (BSE) risk.

Public comment on the Initial Assessment Report was sought from 13 August 2003 until 24 September 2003. Six submissions were received, with four submitters supporting the application, one objecting due to the possible BSE risk and one raising the BSE issue and alerting FSANZ to recent changes in the international (UK, EU) regulation of collagen. These issues are addressed in the report.

Public comment on the Draft Assessment report was sought from 17 December 2003 until 11 February 2004. Six submissions were received, with four submitters supporting the application. One submitter had stated no position except that the proposed amendment would not have any regulatory impact for imported food. One submitter gave tentative support for the Application but required a written response to two concerns before they were completely satisfied. This submitter accepted FSANZ's response to the concerns raised and now supports the Application.

Statement of Reasons

The draft variation to Standard 4.1.1 – Wine Production Requirements (Australia only) (and consequential amendment to Standard 1.3.4 – Identity and Purity) of the Code to permit collagen as a wine processing aid (clarification agent) in Australia is agreed to. This is because the proposed draft variations of the Code are consistent with the section 10 objectives of the FSANZ Act, for the following reasons:

- There are no public health and safety concerns associated with using collagen as a wine processing aid. This conclusion is based on the fact that collagen is a food and has a long history of safe use. Bovine collagen derived from skins and hides is not considered a Bovine Spongiform Encephalopathy (BSE) risk, based on a separate FSANZ assessment (P238 – BSE Risk Assessment and Risk Management Strategy) and by international scientific experts.

- The use of collagen as a wine processing aid is technologically justified. Specifically, technical trials have indicated collagen can act as an alternative wine clarifying agent comparable to the commonly used agents such as gelatine (derived from collagen) and isinglass.

- As concluded by the regulatory impact analysis, the costs that would arise from a variation to Standard 4.1.1 to permit collagen as a processing aid do not outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.

1. Introduction

FSANZ received an application on 3 June 2003, from Devro Pty Ltd to amend the Code to permit the use of collagen as a processing aid during production of wine. The starting date for this cost-recovered Application was 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. Collagen is considered to be a food and therefore it is already approved as a general processing aid under clause 3 of Standard 1.3.3. 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 and New Zealand must comply with Standard 2.7.4 – Wine and Wine Product. Standard 2.7.4 sets definitional standards for wine and wine product. 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. 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 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;

Collagen is principally derived from the skin or hide of slaughtered animals. FSANZ agrees with the Applicant that collagen, like gelatine, is a food and has a wide usage in the diet, mainly in meat products. As a food collagen is a generally permitted processing aid.

All wine produced in Australia must also comply with Standard 4.1.1 - Wine Production Requirements (Australia only). Standard 4.1.1 underpins the Australia – EC Wine Trade Agreement which 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.

Clause 4 of Standard 4.1.1 contains a positive list of permitted processing aids. Only the substances listed are permitted to be used as processing aids in Australian produced wine. This list does not currently include collagen and so, the variation to Standard 4.1.1 sought by the Application would be necessary to permit the use of this processing aid in wine produced in Australia.

FSANZ has recently considered a similar application:

- **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. FSANZ approved this application with the Final Assessment completed in February 2004.

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.

The specific objectives in assessing this Application are:

- generally, to protect the public health and safety of the community in their consumption of wine containing collagen as a processing aid;
-
- in particular, to assess the best available scientific evidence on the possible BSE risk of wine containing collagen as a processing aid.

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 any residual levels of collagen present in the final wine will be present in mg/L levels. 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 (approved in Standard 4.1.1 as processing aids) are gelatine, milk, isinglass (a 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 (cattle) collagen, but they do not wish to limit the application just to bovine sources, as they would like to allow for collagen from porcine (pigs), ovine (sheep), avian (birds) and wild game sources.

5. Relevant Issues

5.1 Technological Justification

5.1.1 Collagen

The Applicant claims (and FSANZ agrees) 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.

Collagen comprises one third of the total protein in mammals and is the main constituent of skin, connective tissue and the organic substance of teeth and bones. Collagen molecules consist of three polypeptide chains arranged in a triple helical conformation. The molecular weight of collagen is about 130,000 Daltons.

The commercial production of collagen as well as more information on what collagen is and how it is used is provided in the Food Technology Report (**Attachment 3**).

5.1.2 Explanation of Action of 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 result 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 historically 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 form, 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.

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. Collagen has also been used as a fining agent for beer production, where it works in a similar manner to that of isinglass or gelatine. The Winemakers' Federation of Australia in its' submission to this Application believe that collagen could provide a technological benefit for winemakers. Early assessments in the 1980's indicated that collagen was effective in binding phenolic and tannin compounds in wine.

The above would indicate there is a technological justification for the use of collagen as a wine clarification agent.

5.2 Safety Considerations

FSANZ recently investigated the risk of BSE in Proposal P238 – BSE Risk Assessment and Risk Management Strategy[1]. As part of this report the issue of BSE risk of collagen was addressed.

The summary from the risk characterisation section relevant to collagen of this Report is printed below.

> While edible collagens are produced from food-grade bovine hides, for a range of other uses including pharmaceutical, medical and cosmetic materials, collagen can be produced from a range of different animal tissues, including bovine tendons, calves skins, sheepskins, pigskins, sheep gut and bovine bones. On the basis of current knowledge, the parts of bovine hides used for the production of collagen do not present a risk with regard to the BSE agent, provided that contamination with potentially infected materials is avoided. The risk of contamination of the skin with the BSE agent through spillage of blood and/or central nervous system tissues during the slaughtering and skinning process is extremely small and the risk of exposure to the BSE agent in the corium layer used for collagen production is negligible.

[1] http://www.foodstandards.gov.au/_srcfiles/P238%20FAR%20-%20BSE.pdf

The Applicant has stated they will be using only collagen derived exclusively from Australian cattle. It is also internationally (e.g. International Office of Animal Health (OIE) and the European Commission) recognised that collagen derived from bovine skins and hides is not a BSE risk (see section 5.3 below). Collagen from non-bovine sources is also not considered a BSE risk.

The situation for collagen produced for human consumption in Australia reflects this international scientific opinion. Collagen from bovine skins and hides is exempt from having to be sourced from cattle free of BSE. This exemption is contained in clause 11 of Standard 2.2.1 - Meat and Meat Products (Australia only). If bovine derived collagen was sourced from other materials other than skins or hides the cattle would need to be free of BSE.

Extract from Standard 2.2.1 – Meat and Meat Products (Clause 11 is an Australia only provision) which relates to BSE and collagen.

11 Bovine meat and meat products must be derived from animals free from bovine spongiform encephalopathy

(1) In this clause -

minor ingredient means an ingredient that comprises no more than 300 g/kg of the food.

(2) Subject to subclause (3), bovine meat and food ingredients derived from bovines must be derived from animals free from bovine spongiform encephalopathy.

(3) Subclause (2) does not apply to –

(a) collagen from bovine skins and hides (including sausage casings produced from this type of collagen); and
(b) a minor ingredient of a processed product, where that ingredient comprises –

(i) bovine fat; and/or
(ii) bovine tallow; and

(c) gelatine sourced from bovine skins and hides; and
(d) dairy products sourced from bovines.

Editorial note:

Clause 11 applies to Australia only. Bovine products imported for sale in New Zealand are regulated by the New Zealand Food Standards.

5.3 International Regulatory Standards Related to Collagen

Collagen is not specifically approved as a wine clarification agent in any national food regulations. It is also not specified in the Australia – EC Wine Trade Agreement, or the USA Bureau of Alcohol, Tobacco & Firearms (BAFT) regulations (other proteinaceous clarifying agents are approved).

Representatives of the Australian Wine and Brandy Corporation and the Winemakers' Federation of Australia confirmed that the proposed permission for the use of collagen as a processing aid in Standard 4.1.1 would have no impact on the Australia – EC Wine Trade Agreement.

The international situation regarding the safety and use of collagen for human consumption has been reviewed and some of the important points from recent reports are listed below.

5.3.1 International Office of Animal Health (OIE)

The following extract from the OIE has been taken from the EC Scientific Steering Committee report[2].

> "Article 2.3.13.7 of the International Animal Health Code (2001) issued by the International Office of Epizootics on BSE recommends that if gelatine and collagen are prepared exclusively from hides and skins, veterinary administrations should authorise their import and transit through their territories without restriction, regardless of the status of the exporting countries."

5.3.2 EC

The EC amended its Council Directive (92/118/EEC) of 10 January 2003 as regards requirements for collagen as Commission Decision 2003/42/EC[2].

The following raw materials may be used in the production of collagen intended for human consumption:

(a) hides and skins of farmed ruminant animals;
(b) pigskins, bones and intestines;
(c) poultry skin and bones;
(d) tendons;
(e) wild game hides and skins; and
(f) fish skin and bones.

The EC Scientific Steering Committee adopted a similar opinion on the safety of collagen produced from ruminant hides on 10-11 May 2001 with respect to TSE (Transmissible Spongiform Encephalopathies, includes BSE) risks[3].

> On the basis of current knowledge it can be considered that the parts of ruminant hides used for the production of collagen do not present a risk with regard to TSEs, provided contamination with potentially infected materials is avoided. The risk of contamination of skin with TSE agent by spillage of blood and/or CNS tissues is small if slaughter and skinning are appropriately performed.

The United Kingdom (UK) has implemented the EC Commission Decision 2003/42/EC which came into effect on 30 September 2003.

5.3.3 Canada

The Canadian Food Inspection Agency website has a Frequently Asked Questions section on BSE under Animal Health (updated 20/5/03)[4]. They also state collagen is not a BSE risk.

> There are exempt products which are not considered to be a risk for the transmission of BSE. These include milk and milk products, hides and skins, gelatine and collagen, and protein free tallow and its derivatives.

[2] Official Journal of the European Communities, Commission Decision of 10 January 2003 amending Council Directive 92/118/EEC as regards requirements for collagen (2003/42/EC).
[3] European Commission, Opinion and report on safety with respect to TSE risks of collagen produced from ruminant hides. Adopted by the Scientific Steering Committee at its meeting of 10-11 May 2001.
[4] http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bsefaqe.shtml

5.3.4 New Zealand

The situation regarding collagen for New Zealand is covered by a New Zealand Food Safety Authority (NZFSA) document published in December 2001, which is available from NZFSA's website[5]. All bovine meat products exported to New Zealand must be categorised according to their BSE risk status with accompanying certification. However gelatine and collagen prepared exclusively from skins and hides are exempt from these BSE certification requirements (gelatine and collagen for food use prepared from bones are subject to their BSE certifications).

5.4 Labelling Issues

There are no labelling requirements within the Code which are directly relevant to the use of collagen. 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, and therefore there is no need to disclose the use of collagen on the label.

5.5 Issues addressed from submissions

5.5.1 BSE safety issues

Two out of 6 submitters to the Initial Assessment raised the BSE safety issue of collagen. This has been fully discussed in the above section 5.2 – Safety Considerations. This concludes that collagen produced from bovine skins and hides is not a BSE risk. Studies have confirmed that the BSE agent has not been found in animal skin or hair.

5.5.2 Concern of wine consumers over the use of animal products in wine production

One submitter to the Initial Assessment raised the issue that there are a number of wine consumers, who for various cultural, ethical or religious reasons, including vegans, Moslems, Hindus and Jews, would not wish to purchase wine that have been treated by any animal products (such as collagen if this application is successful). There is no way wine consumers can tell from a wine label what processing aids have been used to treat the wine since processing aids, in general, do not need to be listed on the label of food. This is true and is an issue currently for wine that is clarified using gelatine. Consumers who are concerned may contact wine makers to find out which clarifying agents the wine makers use. This issue is one of the justifications for another similar application (A482 – Plant Proteins as Wine Processing Aids) which FSANZ has recently assessed. Approval of application A482 would give wine makers a non-animal product clarifying agent for wine which is plant based and could be used to produce wine for such consumers. These would be commercial decisions but both applications together will, if approved, expand the range of choices that wine makers may have for wine clarifying.

[5] http://www.nzfsa.govt.nz/imported-food/bse-categorisation/bse-final-measure.pdf, Measure to provide ongoing management of the human health risks associated with imported food products potentially containing the bovine spongiform encephalopathy agent, New Zealand Food Safety Authority, Dec 2001.

5.5.3 Issues raised by a submitter to the Draft Assessment

Public Health Services, Queensland Health tentatively supported the Application but raised two matters about which they asked for a written response. They have accepted FSANZ's written response on these matters.

These two matters and FSANZ's response are summarised below.

1. The safety of collagen not sourced from bovine skins and hides, from BSE risk is queried. The submitter agrees that collagen sourced from bovine skins and hides is not a BSE risk. For any other source of collagen from bovines subclause 11 (2) of Standard 2.2.1 operates which ensures that collagen must be derived from BSE free bovines. This is the same situation that currently exists for collagen that is used in food (such as sausage casings) and gelatine which is used and approved as a wine clarifying agent.

2. How the possibility of chemical residues in collagen will be addressed. Again this is no different to the current situation where collagen is currently used in food. Collagen is covered by the specifications of secondary sources under clause 3 of Standard 1.3.4 – Identity and Purity (in this case the Merck Index). The Applicant has also stated that the collagen of this Application would be no different, and would meet the same specifications, as the collagen they supply for sausage casings.

6. Regulatory Options

Given that collagen can be regarded as a food, then it already has approval as a generally permitted processing aid under Standard 1.3.3 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. Australian Government, 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.

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. 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

Public comment on the Initial Assessment report was sought from 13 August 2003 till 24 September 2003. Six submissions were received, with four submitters supporting the application, one objecting and one not explicitly stating but having two comments.

The main issue of concern was the possible BSE risk of using bovine sourced collagen. This is addressed in section 5.2 as well as the Food Technology Report (**Attachment 3**).

Public comment on the Draft Assessment report was sought from 17 December 2003 till 11 February 2004. Six submissions were received, with four submitters supporting the application. One submitter tentatively supported option 2, supporting the Application but raised two matters which they asked for a written response to ensure their support. They accepted FSANZ's written response. This is discussed in section 5.5.3.

One other submitter (Australian Government Department of Agriculture, Fisheries and Forestry) did not state a position except that the proposed amendment would have no regulatory impact under the *Imported Food Control Act 1992*.

Attachment 2 summarises the submissions received during the first and second rounds of public comment.

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 no 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 FSANZ did not notify the WTO.

9. Conclusion

The draft variation to Standard 4.1.1 – Wine Production Requirements (Australia only) (and consequential amendment to Standard 1.3.4 – Identity and Purity) of the Code to permit collagen as a wine processing aid (clarification agent) in Australia is agreed to. This is because the proposed draft variations of the Code are consistent with the section 10 objectives of the FSANZ Act, for the following reasons:

- There are no public health and safety concerns associated with using collagen as a wine processing aid. This conclusion is based on the fact that collagen is a food and has a long history of safe use. Bovine collagen derived from skins and hides is not considered a Bovine Spongiform Encephalopathy (BSE) risk, based on a separate FSANZ assessment (P238 – BSE Risk Assessment and Risk Management Strategy) and by international scientific experts.

- The use of collagen as a wine processing aid is technologically justified. Specifically, technical trials have indicated collagen can act as an alternative wine clarifying agent comparable to the commonly used agents such as gelatine (derived from collagen) and isinglass.

- As concluded by the regulatory impact analysis, the costs that would arise from a variation to Standard 4.1.1 to permit collagen as a processing aid do not outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of public submissions
3. Food technology report

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

To commence: on gazettal

[1] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by omitting subclause 3(g), substituting –*

> *The Merck Index*, 13th Edition, Merck and Co. Ltd. Whitehouse Station, N.J. (2001); or

[2] ***Standard 4.1.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 4 –

Collagen

Attachment 2

Summary of public submissions

Round One

#	Submitter Organisation	Name
1	Crop and Food Research	James Anderson
2	Coles Myer Ltd (representing Liquorland)	Andrea Currie
3	New Zealand Food Safety Authority	Carole Inkster
4	Australian Food and Grocery Council	Tony Downer
5	Food Technology Association of Victoria	David Gill
6	Winemakers' Federation of Australia	Tony Battaglene

Submitter	Position	Comments
Crop and Food Research	Have concerns, do not support	They have two concerns about the application: • A number of consumer groups (including religious groups such as Moslems, Hindus, Jews and vegans) that have concerns about using animal derived products as processing aids would not be able to make a fully informed purchase of wine. (This situation is the same as for the currently approved wine processing aid, gelatine. Concerned consumers could find this out by communicating with the wine producer. Further discussed in section 5.5.2). • The potential safety concern of BSE from deriving collagen from bovine sources. (Again this is the same issue with gelatine, and a risk assessment for BSE believes there are no BSE concerns with either gelatine or collagen. Discussed in section 5.2 and 5.5.1 as well as in the Food Technology Report, Attachment 3).
Coles Myer Ltd (representing Liquorland)	Support	They believe it is advantageous for the wine industry to have an alternative clarifying agent to choose from. Also animal derived collagen is not derived from an allergenic source so providing an advantage to consumers allergic to clarifying agents sourced from milk, egg and fish.
New Zealand Food Safety Authority	Not explicitly stated	They had two comments and queries to make. • Does the applicant and FSANZ have data on actual residue levels of collagen remaining in the final treated wine and what concentration is likely (listed in the Initial Assessment Report in mg/L levels)? (FSANZ discussed this with the Applicant and they do not have any actual residue data. Wine is expected to be treated at between 10-20 mg/L (trials undertaken) with the expectation that the large majority of added collagen precipitates out of the wine and is removed). • They agreed that the safety considerations needed to be addressed at Draft Assessment. They made the comment that collagen may be imported from countries that are not BSE free. Also the UK has recently introduced regulations for collagen (as a BSE measure) (these measures are not stated). (The international situation regarding the safety issue of collagen produced from non BSE-free countries is discussed in section 5.3 as well as the general safety of collagen which is contained in section 5.2 as well as the Food Technology Report (Attachment 3)).

Australian Food and Grocery Council	Support	Their support is contingent on an appropriate safety assessment by FSANZ (at Draft Assessment). However they believe FSANZ will find animal collagen, including bovine collagen, to be safe. It is considered a food and is widely used in processed meat casings. They believe the potential safety issue of BSE for bovine collagen is covered by clause 11 of Standard 2.2.1 – Meat and Meat Products where meat and meat products must be derived from animals free from BSE. (Collagen and gelatine are not covered by this clause, being exempted by subclause 2 since they are not viewed as being a BSE risk). They consider the use of animal collagen as a wine processing aid is technologically justified. They also believe this application should be treated the same as A482 – Plant Proteins as Wine Processing Aids. A482 was processed under section 36 of the FSANZ Act where FSANZ agreed with the applicant to remove one round of public comment since the application raised issues of minor complexity. They believed this application could have been treated the same way. (FSANZ decided to allow the full 2 rounds of public comment since the applicant did not request it be processed using section 36 and FSANZ thought it best to allow both rounds to receive comments on the possible BSE issue).
Food Technology Association of Victoria	Support	They support option 2.
Winemakers' Federation of Australia	Support	They believed collagen could provide a technological benefit for winemakers. They believed there is no probable risk to public health and safety. Early assessments in the 1980's indicated collagen was effective in binding phenolic and tannin compounds in wine. Their only question was whether the source of the collagen will be restricted to bovine and ovine. (The answer is no, the application is for no restriction for collagen source).

Round Two

#	Submitter Organisation	Name
1	Winemakers' Federation of Australia	Tony Battaglene
2	Dietitians Association of Australia	Sue Cassidy
3	Queensland Health	Gary Bielby
4	Australian Food and Grocery Council	Tony Downer
5	Department of Agriculture, Fisheries and Forestry	Trent Brady
6	Food Technology Association of Victoria	David Gill

Submitter	Position	Comments
Winemakers' Federation of Australia	Supports	They support the Application believing: • there are no public health and safety concerns; and • it is technologically justified.
Dietitians Association of Australia	Supports	They support option 2 to approve the use of collagen (from any animal source) for wine production in Australia under Standard 4.1.1.

Queensland Health Public Health Services	Tentatively supports but have some concerns which they have asked be addressed in writing.	They have expressed tentative support for the Application however they had a number issues. • They note the Applicant will use collagen exclusively sourced from Australian cattle. This may not always be the case (and there is no requirement for this). • They note collagen sources other than skins or hides of animals may be (or must be used if not exclusively from hides or skins). They agree that bovine collagen derived from hides and skins is not a BSE risk. However how can the safety from BSE be ensured especially from overseas sources if not sourced from skins and hides. • How is the possibility of chemical residues in collagen to be addressed. A letter outlining FSANZ's response to these issues has been sent to the submitter which they accepted.
Australian Food and Grocery Council	Supports	The AFGC confirms their earlier support they had at Initial Assessment, which then was conditional on an appropriate safety assessment. Now that has been performed and they support its conclusions that there are no safety issues they have no conditions on their support. They reiterate that because the processing aid is safe and it is shown to be technological justified in being able to act as a wine clarifying agent it should be approved. They believe approval of the Application meets the section 10 objectives of the FSANZ Act. It also removes an anomaly where imported wine could use collagen under Standard 2.7.4 but wine produced in Australia could not do so under Standard 4.1.1. They are also comfortable that representatives of the Australian Wine and Brandy Corporation and the Winemakers' Federation of Australia believe approval of the Application will have no impact on the Australia – EC Wine Trade Agreement.
Department of Agriculture, Fisheries and Forestry	Do not object to the Application	They believe the Application will be a routine amendment to the Code, and as such should have no regulatory impact on the *Imported Food Control Act 1992*.
Food Technology Association of Victoria	Supports	They support option 2, to approve the use of collagen (from any animal source) for wine production in Australia under Standard 4.1.1.

Attachment 3

Food Technology Report

(This report has been taken, and slightly updated, from FSANZ's Final Assessment Report for Proposal P238 – BSE Risk Assessment and Risk Management Strategy. This also includes some safety assessment information.)

What is collagen?

Collagen is a polypeptide with an average molecular weight of 130,000 Daltons. It comprises approximately one third of the total protein in mammalian organisms, and is the highest component in mammalian proteins. Collagen is the main constituent of skin, connective tissue, and the organic substance of bones and teeth (Merck Index 13th Edition, 2001). Collagen formation in the mammalian body is preceded by the formation of a much larger molecule—procollagen. There are different types of collagens. However, they are all composed of molecules containing three polypeptide chains, the α-chains. The α-chains are arranged in a triple helical conformation. The amino acid sequence of the α-chain is mostly a repeating structure with glycine in every third position and proline or 4-hydroxyproline frequently preceding the glycine residues. Slight differences in the primary structure establish the differences between types of collagens. Collagen is differentiated from the accompanying fibrous proteins (elastin and reticulin) by (1) its contents of proline, hydroxyproline and hydroxylysine, and (2) the absence of tryptophan and its low tyrosine and sulfur content, but particularly by (3) its high content of polar groups originating from the difunctional amino acids. The polar groups are responsible for the swelling properties leading eventually to dispersion of collagen in diluted acid. Denaturation of collagen is the conversion of the rigidly coiled structure to random coiled gelatine. Collagen can be dissolved and isolated from its natural sources by mild extraction with dilute acid, dilute alkali, and neutral salt solution.

How is Collagen used

The film-forming ability of collagen has traditionally been utilised in the meat industry for production of edible sausage casings[4]. Various product lines are classified unofficially under the name of sausage casings including:

- fresh sausage collagen
- smoked sausage collagen
- coloured snack sausage collagen
- hand link sausage collagen
- butchers sausage collagen
- collagen ring casings.

The information available indicates that there is only one manufacturer of edible collagen in Australia. The company sources its bovine hides exclusively from Australia and strict measures are applied to their quality control.

It is estimated that Devro Pty Limited produces approximately 600 tonnes of dry collagen per year in Australia. Market information from the edible collagen industry indicates that close to 170 tonnes per year of edible collagen are imported into Australia (J. Glen, Devro Pty Limited, personal communication). Origins and amounts of imports are given in Table 1.

Commercial uses of collagen depend primarily, but not exclusively, on the physical structure and chemical reactivity of the native or intact collagen molecule. Extruded edible sausage casings, extruded sutures, and natural sutures are examples of useful intact or native collagen products.

Table 1. Current Australia importation of edible collagens

Country of origin	Amount (tonnes)
Germany	68.5
UK	47.6
United States of America	45.6
Japan	7.2
Poland	0.6
Spain	0.2

The collagen process

Ruminant hides which are the raw material for collagen production, are not considered to present a risk with respect to BSE[1,2,3]. Studies have confirmed that BSE infectivity has not been found in skin or hair. The risk of contamination of the hide during slaughter is negligible since contamination with brain tissue resulting from stunning would occur over a small area of the facial part of the hide. The underlying layer of the hide after removal of the internal fatty layer is used for making collagen and the outside layer, which may have been contaminated, is removed and used to make leather.

Two general methods have been developed for the industrial-scale production of edible collagen casings: the 'dry process' was developed in Germany; the 'wet process' was developed in North America[4].
Steps in the 'wet process' are as follows.

a) Acid- or alkaline-unhairing of the hides
b) Decalcification of hide corium and grinding into small pieces
c) Mixing of ground collagenous material with acid to produce a swollen slurry (4–5% solids)
d) Slurry homogenisation
e) Extrusion into tubular casings (8–10% solids)
f) Washing casings free of salts
g) Treatment with plasticising and cross-linking agents
h) Drying.

The 'dry process' involves the following steps:

a) Alkaline treatment of hide corium and acidification to pH 3
b) Shredding of acid-swollen corium to preserve maximum fibre structure
c) Mixing of acid-swollen fibres to produce dough with high solid content (i.e. >12%)
d) Addition of plasticising and cross-linking agents,
e) High-pressure pumping and extrusion of dough to form tubular casings

f) Drying, conditioning, neutralising, and/or providing additional cross-linking.

The following describes the general procedure of edible collagen casing production by Devro Pty Limited (Pers. Comm. Devro, 2001) the largest edible collagen manufacturer in the world. In many cases, the Devro procedure is similar to the generic 'wet process' described earlier.

a) Separation of corium layer – Disease free bovine hides are unhaired and limed before the separation of the collagen-rich corium from the outer grain layer.
b) Grinding – The corium collagen is ground in a series of stages through progressively smaller gaps until a fibrous pulp is obtained.
c) Acidification and fortification – The pulp is acidified and cellulose powder is added to a specific composition dependent on casing type being produced. The process is aided by applying shearing forces and homogenisation to the structure as it swells to enable the formation of a desired gel structure.
d) Extrusion and coagulation – The gel is then passed through an annular extruder to form a thin-walled tube, which is coagulated by adjusting the pH upwards to neutralise the acidic dough.
e) Remove salt and plasticising – The neutralised casing is washed thoroughly to remove the salt formed in the neutralisation step and then plasticised by the addition of glycerol, which confers flexibility on the casing after drying.
f) Drying – Drying is effected by passing the inflated tube through a hot air dryer to reduce the moisture content to approximately 15–20%. The dried casing is cut to convenient lengths and shirred before packaging in hermetically sealed containers. The casing is ready to be used in sausage manufacture, or other food packing. It has a water activity of approximately 0.8.

The process of edible collagen manufacturing involves pH adjustment, including the early stage of lime treatment to raise the pH (up to a maximum of pH 13 for 12–48 hours), and collagen extraction through acidification (down to a minimum of pH 0.8 for 6–72 hours. The production process also involves vacuum pressurisation, up to 30 MPa, and temperature variation where the maximum is at the casing drying stage. Currently there is not comprehensive experimental data on the residual infectivity levels of the BSE agent during the collagen manufacturing process, however the risk of exposure to the BSE agent is negligible since the raw material for collagen is the corium layer of the hide which is a negligible risk tissue.

Estimated collagen consumption in Australia

Consumption of collagen was estimated for the Australian population assuming that consumption would be in the form of edible collagen casings used in sausages and frankfurts. Based on industry use data, the average collagen content in casings is approximately 55%. This translates into a maximum collagen content in sausages and frankfurts of 0.55% or 5.5 mg/kg, based on the percentage of casing in a sausage. This level was used in the dietary modelling.

Estimated intakes of collagen from the consumption of sausages and frankfurts are shown in Table 2. The consumption figures in Table 2 were derived from FSANZ's dietary modelling computer program, DIAMOND.

Overall intakes were low, with the 95th percentile of estimated collagen consumption being less than 1 g/day for children aged 2 to 12 years, and 1.3 g/day for the whole population. Sausage consumption was the major contributor to collagen intake for both children (2-12 years) and for the whole population (Table 3).

Table 2. Estimated intake of collagen from the consumption of sausages and frankfurts for the Australian population (1995 NNS)

Age	Number of consumers	Consumers as % respondents	Consumption (g/day)		
			Respondent mean*	Consumer mean**	95th %ile
2-12	412	19.8	0.08	0.4	0.9
All	1916	13.8	0.07	0.5	1.3

* This is the mean consumption from all respondents on day of survey regardless of whether they consumed sausages or frankfurts.
** This is the mean consumption of only those respondents on day of survey who reported consuming sausages and/or frankfurts.

Table 3. Contribution of sausage and frankfurt consumption to estimated intake of collagen in Australia

Population	Food	% of total contribution
2-12 years	Sausages	86.6
	Frankfurts	13.4
All	Sausages	86.4
	Frankfurts	13.6

Conclusions

Collagen for use in food applications is manufactured from the corium layer of food-grade bovine hides. The process of edible collagen manufacturing involves pH adjustment, including the early stage of lime treatment to raise the pH (up to a maximum of pH 13 for 12–48 hours), and collagen extraction through acidification (down to a minimum of pH 0.8 for 6–72 hours). Although these conditions of collagen production would not inactivate the BSE agent, bovine hides which are the raw material for collagen are not considered to present a risk with respect to BSE infectivity. Studies have confirmed that the BSE agent has not been found in skin or hair.

References

1. European Commission, Updated Report and Scientific Opinion on the safety of hydrolysed proteins produced from bovine hides. Initially adopted by the Scientific Steering Committee at its meeting of 22-23 October 1998 and updated at its meeting of 25-26 May 2000.

2. Official Journal of the European Communities, Commission Decision of 10 January 2003 amending Council Directive 92/118/EEC as regards requirements for collagen (2003/42/EC).

3. European Commission, Opinion and report on safety with respect to TSE risks of collagen produced from ruminant hides. Adopted by the Scientific Steering Committee at its meeting of 10-11 May 2001.

4. Ginnadios, A., McHugh, T.H., Weller, C.L.. and Krochta, J.M. 1994. Edible coatings and films based on proteins. In Edible Coatings and Films to Improve Food Quality. Editor J.M. Krotcha, E.A. Baldwin and M. Nisperus-Carriedo. Technomic Publishing Co. Inc. Lancaster, p201-207.