

12 August 2013
[15-13]

Call for submissions – Application A1077

Fungal Chitosan as a Processing Aid

FSANZ has assessed an Application made by the Winemakers' Federation of Australia to permit the use of fungal chitosan from *Aspergillus niger* as a processing aid for a number of purposes including as a fining and clarifying agent in the manufacture of wine, beer, cider, spirits and food grade ethanol and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 23 September 2013

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at
<http://www.foodstandards.gov.au/code/applications/Pages/applicationa1077fung5726.aspx>

SD1 Risk and Technical Assessment

1. Executive summary

FSANZ received an Application from the Winemakers' Federation of Australia on 20 September 2012.

The purpose of the Application is to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of chitosan sourced from *Aspergillus niger* as a processing aid in the production of wine, beer, cider spirits and food grade ethanol. Chitosan has a number of technical functions as a processing aid, with the more common functions being as a fining and clarifying agent along with use as a microbial stabilisation agent.

Chitosan sourced from *A. niger* is permitted by the OIV (International Organisation of Vine and Wine) for a variety of functions during wine production. It is also permitted to treat wine in the European Union and Argentina, while it is self-affirmed GRAS (generally recognised as safe) for use in the manufacture of alcoholic beverages in the US.

The overall conclusion of this Risk and Technical Assessment is that the use of fungal chitosan as a processing aid for the production of wine, beer, cider, spirits and food grade ethanol is technologically justified and raises no public health and safety concerns for consumers.

Chitosan is insoluble in alcoholic beverages. The precipitates it forms with unwanted components in alcoholic beverages during processing are removed via filtration or similar processes. Therefore, no analytical method is needed to check for chitosan residues. Chitosan sourced from *A. niger* meets the OIV specification which is one of the secondary references for specifications in Standard 1.3.4 (Identity and Purity). Standard 1.3.4 requires that substances added to food, including processing aids, comply with relevant specifications /references as detailed in the Code. Therefore, no new specification is required in the Code.

The draft variations proposed for chitosan sourced from *A. niger* are for permission as a processing aid in the manufacture of wine, beer, cider, spirits and food grade ethanol with the maximum permitted level being governed by Good Manufacturing Practice (GMP).

2. Introduction

2.1 The Applicant

The Winemakers' Federation of Australia (WFA) is the Applicant and is the peak national body for the Australian wine industry. Lallemand Australia Pty Ltd, which supplies ingredients (including wine yeasts, their nutrients, enzymes, food additives and processing aids) and technical expertise to the wine industry, was also involved in providing technical input to the Application.

2.2 The Application

The Application was received by FSANZ on 20 September 2012 and the clock started on 18 February 2013. The purpose of the Application is to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of chitosan sourced from *Aspergillus niger* as a processing aid in the production of wine, beer, cider, spirits and food grade ethanol. Chitosan has a number of technical functions as a processing aid, with the more common functions being as a fining and clarifying agent and use as a microbial stabilisation agent.

The Applicant claims that the technological functions for chitosan as a processing aid for manufacture of different alcoholic beverages is as follows:

- fining agent for wine
- stabilisation agent for colour retention
- assist in clarification (riddling) of sparkling wine
- clarifying agent to remove unstable colloids and reduce cloudiness
- clarifying agent to remove mineral and organic contaminants
- removal of microbial contaminants (such as *Brettanomyces*)
- encapsulation of yeast, lactic acid and nutrients (potential future use).

2.3 The current Standard

There is currently no permission for chitosan (sourced from *A. niger* or otherwise) as a processing aid in the Code. Processing aids are regulated in Standard 1.3.3 – Processing Aids. Standard 1.3.3 applies to all types of processed foods.

The Code also contains an Australia only standard for wine manufacture, Standard 4.5.1 – Wine Production Requirements. There is also no permission to use chitosan as a processing aid to treat wine in this Standard. Clause 4 of Standard 4.5.1 deals with processing aids. Therefore, amendments will be required to be made to both Standards 1.3.3 and 4.5.1.

2.3.1 Overseas situation

Chitosan sourced from *A. niger* is currently permitted for use in winemaking for a variety of purposes through resolutions of the International Organisation of Vine and Wine (OIV). The Resolutions OIV/OENO numbers are (OIV, 2009):

- 336A – 2009 (Musts – Fining using Chitosan)
This Resolution permits the addition of chitosan of fungal origin for the purpose of fining musts. The function is to:
 - facilitate settling and clarification
 - prevent protein haze.

The recommended dose should be not greater than 100 g/hl (1 g/l, or 1 g/kg).

- 337A – 2009 (Wines – Fining using chitosan)
This Resolution permits the addition of chitosan of fungal origin for the purpose of fining wines. The function is to:
 - Reduce turbidity by precipitating particles in suspension
 - Prevent protein haze by partial precipitation

The recommended dose should be not greater than 100 g/hl (1 g/l, or 1 g/kg).
Precipitates are removed by physical procedures such as filtration.

- 338A – 2009 (Wines – Treatment using chitosan)
The function of chitosan treatment is to:
 - a) Reduce heavy metal content, notably iron, lead, cadmium and copper
 - b) Prevent haze due to presence of iron and copper
 - c) Reduce possible contaminants, especially ochratoxin A
 - d) Reduce microorganism contamination, especially *Brettanomyces*

The maximum dose must not exceed:

- 100 g/hl (1 g/l or 1 g/kg) for a) and b)
- 500 g/hl (5 g/l or 5 g/kg) for c)
- 10 g/hl (100 mg/l or 100 mg/kg) for d)

Precipitates are removed by physical procedures such as filtration.

- 339A – 2009 (Wines – Fining: Modification of the existing sheet – chitosan)
This updates the fining procedures in the International Code of Oenological Practices to allow chitosan to be used.

The OIV also has specifications for fungal chitosan in its International Oenological Codex as Resolution 368 – 2009, which is a monograph on chitosan. The OIV International Oenological Codex is a secondary source of specifications in clause 3 of Standard 1.3.4 – Identity and Purity.

Fungal chitosan is approved for clarification and for other treatment of wine according to the European Commission Regulation (EU) No 53/2011 (EU, 2011). The specific permissions and functions are very similar to those provided in the OIV Resolutions noted above and are provided in Appendix 13 of the Regulation.

Chitosan sourced from *A. niger* has been self-assessed as generally recognized as safe (GRAS) under the US Food and Drug Administration (FDA) regulations (GRAS Notice No. GRN 000397). The FDA had no objections to this GRAS notification (FDA, 2011).

Chitosan sourced from *A. niger* is permitted for use for European produced wine exported to Australia under the Australia – European Community Agreement on Trade in Wine (2008). The European Union requested the permission in November 2010 with subsequent provisional approval granted.

Chitosan sourced from *A. niger* is also approved for treating wine in Argentina.

2.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that might be developed as a food regulatory measure.

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

The available data indicate that fungal chitosan is an efficacious treatment of wine and alcoholic beverages as a processing aid to improve clarity and stability of the products by removing unwanted components during production and that it does not perform a technological function in the final food.

Fining is the act of adding a product to wine to remove suspended solids. Most of the suspended solids in wine have an electrical charge. Chitosan performs this function by carrying a positive charge and attracting particles of opposite charge, resulting in the formation of insoluble aggregates which then sink to the bottom of the wine as sediment. When used with negatively-charged Kieselsol (silicon dioxide) it is an effective remover of most suspended proteins and solids. The resulting sediment is removed from the wine, usually by filtration.

Animal toxicity studies on chitosan preparations of various molecular weights and degrees of acetylation show a consistently innocuous hazard profile. No target organ of toxicity has been identified following oral administration at high doses. A published review of human data from 13 clinical trials of up to 6 months duration found no adverse effects associated with oral chitosan (average daily dose 3.5 g) as a weight loss supplement. Because chitosan is of very low toxicity an Acceptable Daily Intake (ADI) “not specified” is considered appropriate.

Information was provided indicating negligible levels of fungal chitosan in wine following processing. Negligible levels would also be expected in beer and cider, while no residual fungal chitosan would be expected in alcoholic products derived from distillation.

The allergenic potential of products derived using fungal chitosan as a processing aid is considered to be negligible for the following reasons:

- residual levels of *A. niger* proteins in products derived using fungal chitosan would be expected to be extremely low
- *A. niger* is a widely consumed organism in the diet of most individuals and to date, there are no reports in the medical literature of allergic reactions to foods attributable to proteins derived from *A. niger*.
- a number of approved enzyme processing aids in the Code are produced using *A. niger* as a source organism

The overall conclusion of this Risk and Technical Assessment is that the use of fungal chitosan as a processing aid for the production of wine, beer, cider, spirits and food grade ethanol is technologically justified and raises no public health and safety concerns for consumers.

3.2 Risk management

The risk assessment conclusion does not require any specific risk management measures to be considered for approval of this form of chitosan.

Chitosan is insoluble in alcoholic beverages. The precipitates it forms with unwanted components during processing are removed via filtration or similar processes. Therefore, there is no requirement for analytical methods to check or quantify for chitosan residues remaining in treated alcoholic beverages.

The chitosan for which permission is applied for meets the specification contained in the International Oenological Codes of the OIV specification which is a secondary source of specifications in Standard 1.3.4. Standard 1.3.4 requires that substances added to food, including processing aids, comply with relevant specifications /references as detailed in the Code. Therefore, no new specification is required in the Code.

Processing aids are not required to be labelled in the ingredients list of treated foods since they are used in the processing and manufacture of the products and do not have a technological function in the final product.

3.3 Regulatory options and impacts

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure. These are discussed below in section 3.3.1.
- Whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application. There are no other measures which could achieve the same result other than amendments to Standards 1.3.3 and 4.5.1.
- Any relevant New Zealand standards. Standard 1.3.3 applies to New Zealand and there are no New Zealand only standards.
- Any other relevant matters. None were identified. Section 18 matters are considered below in section 3.3.2.

3.3.1 Cost/benefit analysis

Two regulatory options were considered:

- (1) prepare draft variations to Standards 1.3.3 and 4.5.1 to permit chitosan sourced from *A. niger* as a processing aid for the manufacture of wine, beer, cider, spirits and food grade ethanol
- (2) reject the Application.

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code have been analysed using regulatory impact principles.

The level of analysis is commensurate to the nature of the Application and significance of the impacts.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids as they are machinery in nature and their use is voluntary. However, FSANZ has undertaken a limited impact analysis.

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value.

Rather, the assessment seeks to highlight the qualitative effects of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare draft variations to Standards 1.3.3 and 4.5.1

Sector	Costs or benefits to sector
Consumers	There may be advantages in product functionality and appearance arising from use of chitosan in alcoholic beverages, and wine imports may be facilitated allowing broader consumer choice.
Industry	There are specific benefits to the various alcoholic beverage industries for this option, especially for the wine industry. Chitosan has been approved and used by European wine manufacturers as a processing aid for a range of different technological functions to improve the final quality of their products. Australian and New Zealand manufacturers will benefit from having alternative methods to produce better quality products at lower costs of production. Permitting the processing aid will make Australian and New Zealand industries competitive and consistent with other trading countries where its use is already permitted.
Governments	There are no costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There are no benefits to industry with this option. However, there are likely to be costs by not allowing industry the option to use new current improved technology to ensure the final quality of their products like their international competitors are able to do.
Governments	There are no benefits or costs to governments for this option.

The above brief analysis indicates the preferred option is to prepare draft variations to Standards 1.3.3 and 4.5.1 to permit chitosan sourced from *A. niger* as a processing aid for the manufacture of various alcoholic beverages. There are no costs linked to permitting the processing aid, while there are benefits to the various alcohol industries to having an alternative processing aid and therefore process to produce improved quality products at potentially lower costs of production.

3.3.2 Addressing FSANZ’s objectives for standards-setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.3.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded that there are no public health and safety concerns related to the consumption of alcoholic beverages produced using chitosan sourced from *A. niger* as a processing aid.

3.3.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

No issues were identified. Processing aids are not required to be labelled in the ingredients list of treated foods since they are used in the processing and manufacture of the products and do not have a technological function in the final product. For chitosan sourced from *A. niger* there are not expected to be any residues of the processing aid remaining in the final treated alcoholic product.

3.3.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

3.3.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

- the need for standards to be based on risk analysis using the best available scientific evidence

This Application was assessed using the best available scientific evidence. The Applicant submitted a dossier of scientific studies in support of their Application. Other resource material including published scientific literature and general technical information was also used in assessing this Application.

- the promotion of consistency between domestic and international food standards

The proposed variation is consistent with international food standards. Chitosan sourced from *A. niger* is approved by the OIV to treat wine. It is also permitted in Europe, the United States and Argentina for wine production. It is also considered GRAS in the United States to treat alcoholic beverages.

- the desirability of an efficient and internationally competitive food industry

The proposed variation is expected to have a positive impact on competitiveness of the alcoholic beverage industry. The proposed use of chitosan sourced from *A. niger* provides alcoholic beverage manufacturers, especially wine makers, with an alternative processing aid to improve the quality of their products.

- the promotion of fair trading in food

The proposed variation will assist in promoting fair trading in food by allowing Australian and New Zealand alcoholic beverage manufacturers the same permission to use chitosan sourced from *A. niger* that their international competitors currently have.

- any written policy guidelines formulated by the Ministerial Council¹.

The *Addition to Food of Substances other than Vitamins and Minerals*² includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the ‘stated purpose’)
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of chitosan sourced from *A. niger* as a processing aid in the production of alcoholic beverages is consistent with the specific order policy principles for ‘Technological Function’.

3.4. Risk communication

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ’s social media tools and *Food Standards News*.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the COAG Legislative and Governance Forum on Food Regulation (the Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

¹ Now known as the COAG Legislative and Governance Forum on Food Regulation

² [http://www.health.gov.au/internet/main/publishing.nsf/Content/00E8A0712A1A5C3BCA2578A7007FBE77/\\$File/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20Policy%20Guideline.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/00E8A0712A1A5C3BCA2578A7007FBE77/$File/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20Policy%20Guideline.pdf)

3.4.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged 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.

Amending the Code to permit the use of chitosan sourced from *A. niger* as a processing aid to treat alcoholic beverages is unlikely to have a significant effect on international trade as it is an alternative processing treatment. Chitosan sourced from *A. niger* is permitted by the OIV and a number of countries to treat wine during manufacture. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variation

The conclusion of the assessment is that permitting the use of chitosan sourced from *A. niger* as a processing aid to treat alcoholic beverages is both safe and appropriate with technological benefits from this treatment. Therefore, it is appropriate to permit chitosan sourced from *A. niger* as a processing aid in both Standard 1.3.3 to treat wine, beer, cider, spirits and food grade ethanol and Standard 4.5.1 to treat Australian produced wine.

The draft variations have been added into the Table to clause 14 (Permitted processing aids with miscellaneous function) in Standard 1.3.3 since the functions of chitosan are broader than simply being a clarifying, filtration or adsorbent agent (covered by the Table to clause 6 of Standard 1.3.3).

The draft variations to Standards 1.3.1 and 4.5.1 are at Attachment A.

A draft Explanatory Statement is at Attachment B.

4.1 Implementation

The variation takes effect on gazettal.

5. References

Australia - European Community Agreement on Trade in Wine (2008)
http://www.daff.gov.au/_data/assets/pdf_file/0011/913754/wine-agreement.pdf
Accessed 4 April 2013

EU (2011) Commission Regulation (EU) No 53/2011 of 21 January 2011 amending Regulation (EC) No 606/2009 laying down certain detailed rules for implementing Council Regulations (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions. Off J Eur Union 54(L19):1-6.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:019:0001:0006:EN:PDF> Accessed 4 April 2013

FDA (2011) US Food and Drug Administration, Generally Recognized as safe (GRAS) substance under the US FDA regulation. GRAS Notice No. GRN 000397, FDA response letter, 19 December 2011
<http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=397>
Accessed 4 April 2013

OIV (2009) International Organisation of Vine and Wine Resolutions

OIV-OENO 336A-2009

OIV-OENO 337A-2009

OIV-OENO 338A-2009

OIV-OENO 339A-2009

OIV-OENO 368-2009

Located from <http://www.oiv.int/oiv/info/enresolution> Accessed 4 April 2013.

Attachments

- A. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1077 – *Fungal Chitosan as a Processing Aid*) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1077 – Fungal Chitosan as a Processing Aid) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variations commence on the date of gazettal.

SCHEDULE

[1] **Standard 1.3.3** is varied by inserting in alphabetical order in Table to clause 14

“

Chitosan sourced from <i>Aspergillus niger</i>	Manufacture of wine, beer, cider, spirits and food grade ethanol	GMP
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”

[2] **Standard 4.5.1** is varied by inserting in alphabetical order in the Table to clause 4 “Chitosan sourced from *Aspergillus niger*”.

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1077 which seeks to permit the use of chitosan sourced from *A. niger* as a processing aid in the production of wine, beer, cider, spirits and food grade ethanol. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared draft variations to Standards 1.3.3 and 4.5.1.

2. Purpose

The Authority has proposed permission to use chitosan sourced from *A. niger* as a processing aid in the manufacture of alcoholic beverages.

The Authority has prepared a draft variation to Standard 1.3.3 to permit chitosan sourced from *A. niger* as a processing aid to be used in the manufacture of wine, beer, cider, spirits and food grade alcohol.

The Authority has also prepared a draft variation to Standard 4.5.1 – Wine Production Requirements which is an Australian only Standard for permission to use chitosan sourced from *A. niger* as a processing aid in the production of Australian produced wine. A separate permission is required to be incorporated into this Standard since it is a standalone Australian only Standard that covers Australian produced wine. Processing aid permissions for imported wine and New Zealand produced wine are covered by Standard 1.3.3.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1077 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (including the draft variation) will occur for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.3.3 and 4.5.1 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

6.1 Item [1]

The variation permits the use of chitosan sourced from *Aspergillus niger* as a processing aid for the manufacture of wine, beer, cider, spirits and food grade ethanol at GMP.

6.2 Item [2]

The variation permits the use of chitosan sourced from *Aspergillus niger* as a processing aid for the manufacture of Australian produced wine.