5 November 2013
[20-13]

Approval Report – Application A1077

Fungal Chitosan as a Processing Aid

Food Standards Australia New Zealand (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.

On 12 August 2013, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions and one late submission.

FSANZ approved the draft variation on 30 October 2013. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 4 November 2013.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

Supporting document

The following document used to prepare this Report is available on the FSANZ website at http://www.foodstandards.gov.au/code/applications/Pages/applicationa1077fung5726.aspx

SD1 Risk and Technical Assessment Report

1. Executive summary

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

The purpose of the Application was 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, and it is self-affirmed GRAS (generally recognised as safe) for use in the manufacture of alcoholic beverages in the United States of America (US). Chitosan is also permitted in dietary supplement products in the European Union, the US and other countries, where the recommended level of consumption is 1 to 3 g/person/day.

The Risk and Technical Assessment concluded that using 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.

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. Standard 1.3.4 requires that substances added to food, including processing aids, comply with relevant specifications as detailed in the Code. 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). Therefore, no new specification was required in the Code.

The variations 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 Applicant is the Winemakers' Federation of Australia (WFA) – 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, also provided technical input to the Application.

2.2 The Application

The Application was received by FSANZ on 20 September 2012. The purpose of the Application was 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.

The Application listed the technological functions for chitosan as a processing aid for the manufacture of different alcoholic beverages 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 in the Code. Standard 1.3.3 applies to all types of processed foods.

The Code contains an Australia-only standard for wine manufacture, Standard 4.5.1 – Wine Production Requirements. Clause 4 of Standard 4.5.1 deals with processing aids. There is also no permission to use chitosan as a processing aid to treat wine in this Standard.

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 numbers of these OIV/OENO resolutions 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 GRAS (generally recognized as safe) under the United States (US) Food and Drug Administration (FDA) regulations (GRAS Notice No. GRN 000397) as a processing aid for the manufacture of alcoholic beverages. The FDA had no objections to this GRAS notification (FDA, 2011).

Chitosan sourced from *A. niger* is listed for use for European produced wine exported to Australia under the *Australia - European Community Agreement on Trade in Wine (2008)* in anticipation that approval for chitosan would be permitted in the Code via an application. 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.

Chitosan is permitted in dietary supplements in Europe, the US and other countries, with daily recommended consumption of 1-3 g/day/person.

The European Commission Regulation (EU) No 432-2012[2] requires that products provide a daily intake of 3 g of chitosan before they are able to make health claims that chitosan contributes to the maintenance of normal blood cholesterol levels. Chitosan is a listed complementary medicine in Australia while it is available for purchase in New Zealand as a dietary supplement.

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 was assessed under the General Procedure.

2.6 Decision

The draft variations as proposed following assessment were approved without change (see Attachment A). This permits the use of chitosan sourced from *A. niger* as a processing aid for the production of wine, beer, cider, spirits and food grade ethanol.

3. Summary of the findings

3.1 Risk Assessment

The available data indicated 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.

Animal toxicity studies on chitosan preparations of various molecular weights and degrees of acetylation showed a consistently innocuous hazard profile. No target organ of toxicity had 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” was 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 was 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.

[2] Commission Regulations (EU) No 432/2012 of 16 May 2012, establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:EN:PDF

- *A. niger* is a widely consumed organism in the diet of most individuals, being a widely distributed fungal contaminant commonly detected in a range of foods, 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 the Risk and Technical Assessment was that the use of fungal chitosan as a processing aid for the production of wine, beer, cider, spirits and food grade ethanol was technologically justified and raised no public health and safety concerns for consumers.

3.2 Risk management

Fining is the act of adding a product to wine (or other alcoholic beverages) 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 as sediment. The resulting sediment is removed using physical separation processes such as filtration, centrifugation or racking. Therefore, there is no requirement for analytical methods to check or quantify for chitosan residues remaining in treated alcoholic beverages.

The chitosan in this Application meets the specification contained in the International Oenological Codes of the OIV specification, though there are a number of details in the specification which need addressing and amending in the future (as noted in section 2.1.4. of SD1). The OIV specification 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 as detailed in the Code. Therefore, no new specification was 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 food.

The risk management decision was to permit the use of fungal chitosan sourced from *A. niger* as a processing aid for the production of wine, beer, cider, spirits and food grade alcohol, without making any other amendments to the Code.

3.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. All submissions are valued and all contribute to the rigour of our assessment.

FSANZ called for public comment between 12 August 2013 and 23 September 2013 following assessment of the Application. Four submissions were received, as well as one late submission (which raised no issues). The four submissions were received from two jurisdictions, one food industry association and one food technology association. No submissions opposed the progression of the Application and three submissions did not raise any issues. One submission raised a number of issues which have been addressed in Table 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
An assumption is made that no chitosan residues will remain in alcoholic beverages so no analytical method is required. But that may not always be the case, e.g. due to production failures or processes used may not aim to remove particulates. Therefore details of a mentioned HPLC method should be provided so jurisdictions can check for suitability if chitosan residues are needed to be checked.	Department of Health, Queensland	As noted in the assessment summary, information was provided in the Application indicating negligible levels of fungal chitosan in wine following processing (less than 10 mg/L, the limit of detection of the analytical method used). It was also stated that negligible levels would also be expected in beer and cider, while no residual fungal chitosan would be expected in alcoholic products derived from distillation. If residual chitosan remained in commercial products then this would only be a potential product quality/aesthetic concern as chitosan is poorly soluble and the resulting haze or formed particulates may be visible in the commercial beverage. However, as concluded from the risk assessment, there are no public health and safety issues associated with inadvertent ingestion of residues of chitosan.
More concrete evidence is requested to support the claim that residual levels of *A. niger* in alcoholic products treated with fungal chitosan would be expected to be extremely low.	Department of Health, Queensland	As discussed in section 3.1, added chitosan is removed from the alcoholic beverage as part of the clarification process to remove particulates and haze proteins using techniques such as filtration or centrifugation. Additional information is provided in the response above indicating that negligible levels of chitosan will remain in treated products.
The negligible allergenic potential of *A. niger* was discussed, but the same assessment has not occurred relating to any adverse reactions to chitosan itself for some consumers.	Department of Health, Queensland	There have been a number of human studies (provided in the Application and in the literature) on chitosan (both shellfish derived and some on fungal derived). Some of these studies have specifically investigated adverse reactions attributable to chitosan and no evidence has been found for such reactions. Chitosan has been used for many different purposes in the pharmaceutical, medical and cosmetics industries. Chitosan is an approved dietary supplement in Australia, the United States and the European Union, and no adverse effects are evident even at intakes as high as several grams per day. Chitosan is not a protein and so would not elicit an allergic reaction on consumers.

3.4 Risk communication

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

Subscribers and interested parties are also notified via email about the availability of reports for public comment.

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. Documents relating to A1077 are available on the website[3].

The draft variations were considered and approved by the FSANZ Board taking into account public comments received from the call for submissions.

The Applicant, individuals and organisations that made submissions on this Application will be notified at each stage of the assessment.

The FSANZ Board's decision has been notified to the COAG Legislative and Governance Forum on Food Regulation (the Forum). If the Forum does not request a review of the Board's decision, 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.

4. Reasons for decision

The draft variations to Standards 1.3.3 and 4.5.1, as proposed following assessment, were approved without change.

The approval was based on the best available evidence 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 was 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).

4.1 Section 29 of the FSANZ Act matters

FSANZ had regard to the following matters under 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.

[3] http://www.foodstandards.gov.au/code/applications/Pages/applicationa1077fung5726.aspx

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 the permission, if granted, is voluntary. However, FSANZ performed a summary cost benefit analysis. FSANZ concluded that permitting chitosan sourced from *A. niger* as a processing aid for the manufacture of various alcoholic beverages provides an overall benefit. There were no costs linked to permitting the processing aid while there were benefits to the various alcoholic industries to having an alternative processing aid to produce improved quality products at potentially lower costs of production.

- Whether other measures (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 the Code.

- Any relevant New Zealand standards.

Standard 1.3.3 applies to New Zealand while Standard 4.5.1 is an Australia only standard, without a comparable New Zealand only counterpart.

- Any other relevant matters.

None were identified. Section 18 matters are considered in section 4.2.

4.2 Addressing FSANZ's objectives for standards-setting

FSANZ had considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

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

4.2.2 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.

4.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

4.2.4 Subsection 18(2) considerations

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

- 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 variations are consistent with international food standards. Chitosan sourced from *A. niger* is approved by the OIV to treat wine. It is also permitted in Europe 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 variations are expected to have a positive impact on competitiveness of the alcoholic beverage industry. The 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 variations 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 Council[4].

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] 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'.

[4] Now known as the COAG Legislative and Governance Forum on Food Regulation

[5] http://www.foodstandards.gov.au/_srcfiles/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf

4.3 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
Or
Off J Eur Union 52(L28):3-87.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:028:0003:0087:EN:PDF
Both 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. Approved variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

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

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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 *Aspergillus niger*	Manufacture of wine, beer, cider, spirits and food grade ethanol	GMP

"

[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 – 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 chitosan sourced from *A. niger* as a processing aid for the manufacture of various alcoholic beverages. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved draft variations to Standards 1.3.1 and 4.5.1.

Following consideration by COAG Legislative and Governance Forum on Food Regulation[6], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose

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

The Authority has prepared a 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 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.

[6] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1077 included one round of public consultation following an assessment and the preparation of draft variations and associated reports. Submissions were called for on 12 August 2013 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

Item [1] 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.

Item [2] permits the use of chitosan sourced from *Aspergillus niger* as a processing aid for the manufacture of Australian produced wine.