

20 February 2017
[06–17]

Call for submissions – Application A1126

Pectins & Carrageenan as Processing Aids in Wine (Fining Agent)

FSANZ has assessed an Application made by the Winemakers' Federation of Australia to permit pectins and carrageenan as processing aids to remove heat unstable proteins from Australian produced wine 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) 3 April 2017

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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Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.3.1 <i>Nomenclature</i>	3
1.3.2 <i>Australia and New Zealand</i>	3
1.3.3 <i>International and national standards</i>	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE ASSESSMENT	4
2.1 RISK ASSESSMENT	4
2.2 RISK MANAGEMENT	5
2.2.1 <i>Levels of addition</i>	5
2.2.2 <i>Specification</i>	5
2.2.3 <i>Labelling</i>	5
2.3 RISK COMMUNICATION.....	6
2.3.1 <i>Consultation</i>	6
2.3.2 <i>World Trade Organization (WTO)</i>	6
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	6
2.4.1 <i>Section 29</i>	6
2.4.2 <i>Subsection 18(1)</i>	8
2.4.3 <i>Subsection 18(2) considerations</i>	8
3 DRAFT VARIATION	9
ATTACHMENTS	9
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	10
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT	12

Supporting document

The [following document](#)¹ which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical Assessment

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1126Pectins-Carrageenan-asPAs.aspx>

Executive summary

The Winemakers' Federation of Australia (WFA), the national peak body for Australia's winemakers, submitted an Application to amend the Australia only Standard 4.5.1 – Wine Production Requirements in the *Australia New Zealand Food Standards Code* (the Code). The purpose is to permit Australian winemakers to use pectins and carrageenan to help remove heat unstable proteins from wine.

The Application is seeking to extend current permissions in the Code. Pectins and carrageenan are already permitted as processing aids in the manufacture of all foods. However, wine produced in Australia must also comply with the requirements of Standard 4.5.1. Only those processing aids listed in the Table to clause 4 in Standard 4.5.1 can be used in the production of wine in Australia. Pectins and carrageenan are not listed in this Table.

FSANZ has determined that there is sufficient evidence to provide assurance that pectins and carrageenan are technologically justified and are effective in achieving their stated purpose (i.e. as fining agents that remove heat unstable proteins). Specifications already exist in the Code.

FSANZ's risk assessment concludes that there are no public health and safety concerns from using pectins or carrageenan as processing aids in the manufacture of wine in Australia. In the absence of any identifiable hazard an Acceptable Daily Intake (ADI) 'not specified' remains appropriate for both pectins and carrageenan. A dietary exposure assessment is therefore not required.

The risk management issues considered include the identity and characteristics of pectins and carrageenan; the absence of public health and safety issues arising from their use; information about purity and absence of contaminants, including allergens, and the technological use and potential presence in the final food. In regards to labelling, FSANZ considers that existing labelling requirements in the Code are appropriate for the labelling of foods produced using these substances as processing aids.

FSANZ has considered the potential impacts of approving this Application on consumers, the food industry, and enforcement agencies. FSANZ considers that the benefits that would arise from permitting the use of pectins and carrageenan as processing aids in the manufacture of wine in Australia would outweigh the costs.

Therefore, a draft variation to amend Standard 4.5.1 to permit pectins and carrageenan as processing aids in the production of wine in Australia has been prepared.

1 Introduction

1.1 The Applicant

This Application was submitted by the Winemakers' Federation of Australia (WFA)—the national peak body for Australia's winemakers.

1.2 The Application

The Application seeks an amendment to the *Australia New Zealand Food Standards Code* (the Code) to permit Australian winemakers to use pectins and carrageenan as processing aids, with the technological purpose of fining agents, to help remove heat unstable proteins from wine.

1.3 The current Standard

1.3.1 Nomenclature

There are various sources and types of pectin and carrageenan used in foods.

As their purpose and characteristics are the same, the various forms of pectin and carrageenan are usually each considered collectively when considering technological permissions. However, the safety of each type (of pectin, for example) has been considered independently before being permitted in the group (for example, of approved pectins).

The normal nomenclature, which will be used in this document, is pectins and carrageenan.

1.3.2 Australia and New Zealand

Paragraph 1.1.1—10(6)(c) in the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted. Section 1.1.2—13 defines the expression 'used as a processing aid'.

Section 1.3.3—4 provides that a food additive permitted at GMP (Good Manufacturing Practice) listed in section S16—2 and any substance listed in section S18—2 are generally permitted processing aids that may be used for all foods. Both carrageenan (food additive INS number 407) and pectins (INS 440) are listed in the tables in section S16—2, and so are permitted processing aids in food (including wine) sold in Australia or New Zealand.

However, wine produced in Australia must also comply with the requirements of Standard 4.5.1 – Wine Production Requirements, which is an Australia only Standard. Only those processing aids listed in the Table to clause 4 of Standard 4.5.1 are permitted to be used in the production of wine in Australia. Carrageenan and pectins are not listed in this Table.

1.3.3 International and national standards

Codex Alimentarius does not have specific standards for processing aids, and many countries do not regulate processing aids in the same manner as the Code. There is no Codex Alimentarius standard for wine.

The Organisation Internationale de la Vigne et du Vin or International Organisation of Vine and Wine (OIV) is a scientific and technical intergovernmental organisation recognised for its competence in work concerning vines, wine, wine-based beverages, table grapes, raisins and other vine-based products.

There are no OIV resolutions or other OIV documents for pectins or carrageenan.

Carrageenan is permitted in the manufacture of wine in [Japan and the USA](#)². There is no evidence that pectin is permitted in wine outside NZ and Australia – reflecting that normal practice is to remove pectin during wine manufacture.

However, pectins and carrageenan may also be used as food additives, and in some jurisdictions (e.g. USA) both direct and indirect food additives are under the same regulations. Pectins and carrageenan have had their safety assessed by the Joint Expert Committee for Food Additives (JECFA), the EU, and the USA.

1.4 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 warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the evidence on the safety of pectins and carrageenan as processing aids in wine. The data provided with the Application, together with information from other sources, are considered adequate for hazard assessment.

Both pectins and carrageenan have a long history of safe use in the human food supply and are approved as food additives at GMP in Schedule 16 – Types of substances that may be used as food additives.

The evidence presented to support the proposed use provides adequate assurance that pectins and carrageenan are technologically effective as fining agents in wine manufacture and provide alternatives to the use of bentonite for this purpose. The residual levels in wine are very low and do not perform any technological purpose in the final product. There are identity and purity specifications for pectins and carrageenan in the primary reference sources listed in Schedule 3 – Identity and purity.

Pectins are resistant to digestion in the small intestine but are broken down by large intestinal flora. No adverse effects from their metabolites have been identified. Carrageenan is not broken down in the gastrointestinal tract.

Neither pectins nor carrageenan are genotoxic.

A review of recent animal and human studies by JECFA in 2015 did not identify any adverse effects of either pectins or carrageenan.

²http://www.awri.com.au/industry_support/regulatory_assistance/additives/?country=9&search=Display

Allergic reactions to ingested pectins appear to be extremely rare and may represent cross-reaction with allergens of cashew nuts and/or pistachio nuts. There is no robust evidence of allergic reactions to ingested carrageenan.

Based on the reviewed toxicological data, it is concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' remains appropriate for both pectins and carrageenan.

In conclusion, pectins and carrageenan achieve the technological function in the quantity and form proposed to be used as a food processing aid, and there are no potential public health and safety concerns from the use of pectins and carrageenan as processing aids in the manufacture of wine in Australia.

2.2 Risk management

Evidence provided demonstrates that there are no safety risks from the additional use of pectins and carrageenan as intended, that the use of pectins and carrageenan are technologically justified, and their use meets the definition of a processing aid.

As processing aids require permissions in the Code, the risk management options available to FSANZ are either to prepare a draft variation or reject the Application. These options are considered in section 2.4.1.1 and take account of the safety of pectins and carrageenan.

Other risk management issues are discussed below.

2.2.1 Levels of addition

This Application is seeking to extend existing permissions in the Code for pectins and carrageenan as processing aids in wine and to permit their use during manufacture of wine in Australia.

In the absence of any public health or safety issues associated with this extended use identified by the risk assessment conducted by FSANZ, in particular that an ADI 'not specified' remains appropriate for both pectins and carrageenan, there is no reason to limit the levels of addition apart from the requirement to use in accordance with GMP.

2.2.2 Specification

As this Application is seeking an extension of use and specifications already exist in primary references in the Code, no new specifications are required.

Analytical methods are available for detection and quantification of pectins and carrageenan.

2.2.3 Labelling

As the risk assessment concludes that the use of pectins and carrageenan poses no risk to public health and safety, FSANZ considers that the existing labelling requirements in the Code are appropriate for the labelling of foods produced using these substances as processing aids.

As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraph 1.2.4—3(2)(d) of Standard 1.2.4 – Information requirements – statement of ingredients.

The risk assessment did not identify any need for a warning statement.

2.3 Risk communication

FSANZ has developed a basic communication strategy for this Application.

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are sought to obtain the views of interested parties on the Application and the impacts of the regulatory options. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

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.

Following consultation, the FSANZ Board will consider the proposed variation taking into account comments received through submissions. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation. 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 via email alert and the Circular.

2.3.2 World Trade Organization (WTO)

As a member of the World Trade Organization (WTO), Australia is obliged to notify WTO members 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 universal international standards (e.g. Codex) and amending the Code to permit pectins and carrageenan as processing aids to remove heat unstable proteins from Australian-produced wine is unlikely to have a significant effect on international trade as this permission already exists for wine produced in a number of other countries. Therefore, a notification to the WTO under Australia's obligation (the proposed variation affects an Australia only standard) under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders.

The benefits and costs associated with the proposed amendments to the Code have been considered based on 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 (OBPR reference 12065), provided a standing exemption from the need to determine whether 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 qualitative impact analysis.

The likely impacts of the draft variation were considered but this is not intended to be an exhaustive, quantitative economic analysis. Rather, the qualitative effects are described below, and are deliberately limited to broad areas such as trade and consumer choice.

Sector	Costs or benefits if draft variation approved
Consumers	<p>There will be no costs to consumers.</p> <p>Consumers are unlikely to see a direct economic benefit from this option. However, indirectly they may receive quality or environmental benefits if it means that wine manufacturers are able to produce well fined clear wine via a process based on sustainable raw materials rather than the use of mined bentonite.</p>
Industry	<p>These fining agents are more costly than bentonite.</p> <p>The wine industry would benefit by having alternative wine fining agents sourced from plants and seaweed.</p> <p>There are claimed to be benefits for the efficacy of the fining process and less fining agent needed for some wines and so less waste produced; however, FSANZ has not made an economic assessment of the claimed benefits.</p> <p>In practice these fining agents will only be used if there is a net benefit, and the fact that research has been conducted and the application has been made by the Winemakers Federation of Australia implies that a net benefit is possible.</p>
Governments	<p>There would be no impact on governments.</p>

Overall, the direct and indirect benefits that would arise from the draft variation as a result of the Application outweigh the costs to the community, government or industry that would arise from the draft variation.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application. See section 2.2 above.

2.4.1.3 Any relevant New Zealand standards

The amendment is proposed to Standard 4.5.1 which is an Australia-only Standard. Wine produced in New Zealand already has permission to use pectins and carrageenan as processing aids to fine wine.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment and concluded there are no public health and safety concerns with permitting pectins and carrageenan as processing aids for wine produced in Australia.

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

Labelling aspects of this Application have been considered in section 2.2.3. Processing aids are not required to be labelled in general and specifically for packaged wine. The risk assessment did not identify any requirement for warning statements.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues were identified for this Application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis which is provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

- **the promotion of consistency between domestic and international food standards**

As explained in para 1.3.3, pectins and carrageenan are permitted for use as processing aids for wine produced overseas, including New Zealand.

However, Australian wine producers must comply with the Australian wine production standards in the Code. These standards currently prevent the use of pectins and carrageenan as processing aids in Australian produced wine.

This draft variation aligns the Australian wine production standard with respect to pectins and carrageenan as processing aids with that already in the Code for all wines and also with international standards.

- **the desirability of an efficient and internationally competitive food industry**

The proposed variation will align Australian wine production standards with international or overseas standards and enable Australian wine producers to use a wider range of fining agents.

Permission to use pectins and carrageenan as fining agents for wine production provides the wine industry with alternatives to the current approach of using bentonite, with potential for improved wine quality. Individual wineries will make commercial decisions on which approach is best for their products.

- **the promotion of fair trading in food**

No issues were identified for this Application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Policy Guideline on the [Addition to Food of Substances other than Vitamins and Minerals](#)³ 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 pectins and carrageenan as processing aids (fining agents) during wine production is consistent with these specific order policy principles.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

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

³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

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



Food Standards (Application A1126 – Pectins & Carrageenan as Processing Aids in Wine (Fining Agent)) 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 variation 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 A1126 – Pectins & Carrageenan as Processing Aids in Wine (Finning Agent)) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 4.5.1 is varied by inserting each of the following into the Table to clause 4 in alphabetical order

Carrageenan
Pectins

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.

The Authority accepted Application A1126 which seeks to permit pectins and carrageenan as processing aids in the production of wine in Australia to act as fining agents helping to remove heat unstable proteins from wine. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has prepared a draft variation to Standard 4.5.1 – Wine Production Requirements in the Code (an Australia only standard) to permit pectins and carrageenan as processing aids in the production of wine in Australia with the technological purpose of acting as fining agents that help remove heat unstable proteins from wine.

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 A1126 will include one round of public consultation following an assessment and the preparation of a draft variation and associated report.

A Regulation Impact Statement was not required because the proposed variations to Standard 4.5.1 are likely to have a minor impact on business and individuals (OBPR reference 12065).

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] amends Standard 4.5.1 by inserting references to carrageenan and pectins into the Table to clause 4. The effect of this amendment will be to permit the use of carrageenan and pectins as processing aids in the production of wine in Australia with the technological purpose of acting as fining agents that help remove heat unstable proteins from wine.

The use of these substances must be consistent with conditions of Good Manufacturing Practice (GMP) in accordance with subclause 5(8) of Standard 4.5.1.