

**7 July 2017**  
**[17–17]**

Approval report – Application A1126

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

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Winemakers' Federation of Australia to seek permissions for pectins and carrageenan as processing aids to remove heat-unstable proteins from Australian produced wine

On 20 February 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 22 June 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 6 July 2017.

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

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### Supporting document

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

SD1          Risk and Technical Assessment

## 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 sought to extend current permissions in the Code. Pectins and carrageenan are generally permitted as processing aids in the manufacture of all foods, including wine. However, wine produced in Australia must also comply with the requirements of Standard 4.5.1, which sets out requirements particular to Australian domestic wine production and operates as a limitation of the general permissions in Part 1.3 of the Code. Only the processing aids listed in the Table to clause 4 in Standard 4.5.1 can be used in wine production in Australia. Pectins and carrageenan are not currently listed in this Table and the proposed variation removes a restriction imposed by Standard 4.5.1.

FSANZ 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 concluded that there are no public health and safety concerns from using pectins or carrageenan as processing aids to manufacture 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 was therefore not required.

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 and allergens, and the technological use and potential presence in the final food.

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 approved.

# **1 Introduction**

## **1.1 The Applicant**

The 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 to amend 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**

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 it is 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 number 407) and pectins (food additive number 440) are listed in the tables in section S16—2, and so are already 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, which sets out requirements particular to Australian domestic wine production and operates as a limitation of the general permissions in Part 1.3 of the Code. Only the processing aids listed in the Table to clause 4 in Standard 4.5.1 can be used in wine production in Australia. Pectins and carrageenan are not currently listed in this Table and the proposed variation removes a restriction imposed by Standard 4.5.1.

## **1.4 Reasons for accepting Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2), and
- it related to a matter that warranted the variation of a food regulatory measure.

## **1.5 Procedure for assessment**

The Application was assessed under the General Procedure.

## **1.6 Decision**

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related 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.

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

Two submissions were received.

One, from a government department, supported the draft variation and raised no issues. The other, from the Food Intolerance Network, raised two issues.

**Table 1: Summary of issues**

| Issue   | FSANZ response   |
|---|--|
| <b>Opposed to permitted food additives being reclassified as processing aids, thereby denying consumers label information and choice, because, in general, processing aids are exempt from declaration in the statement of ingredients.</b> | This variation is not a reclassification as pectins and carrageenan are already permitted as processing aids in wines. This variation to the Australian wine production standard also allows Australian made wines to use these processing aids during wine manufacture. |
| <b>Some enzymes are not safe</b>  | This Application does not relate to enzymes  |

### 2.2 Risk assessment

FSANZ 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.

Pectins and carrageenan are not genotoxic.

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

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 using pectins and carrageenan as processing aids in the manufacture of wine in Australia.

## **2.3 Risk management**

Evidence provided demonstrates that there are no public health and 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 approve the draft variation or reject the draft variation. These options are considered in section 2.5.1.1 and take account of the safety of pectins and carrageenan.

Other risk management issues are discussed below.

### **2.3.1 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 extending the use of pectins and carrageenan, in particular that an ADI 'not specified' remains appropriate for both processing aids, there is no reason to limit the levels of addition apart from the requirement to use in accordance with GMP.

### **2.3.2 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.

### **2.3.3 Labelling**

As a general rule, wine as a standardised alcoholic beverage is exempt from the requirement to provide a statement of ingredients, including processing aids, in accordance with paragraph 1.2.4—2(3)(b) of Standard 1.2.4 – Information requirements – statement of ingredients.

The risk assessment concluded that the use of pectins and carrageenan as processing aids in wine poses no risk to public health and safety. Therefore, the generic exemption above will apply to wine produced using these processing aids.

### **2.3.4 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 (also known as the 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.

Pectins and carrageenan may also be used as food additives, where they have a functional purpose in the final food. Pectins and carrageenan have had their safety assessed by the Joint Expert Committee for Food Additives (JECFA), the EU, and the USA.

**2.4 Risk communication**

**2.4.1 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 were sought to obtain the views of interested parties on the Application and the impacts of the regulatory options. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ’s social media tools and Food Standards News on 20 February 2017 with a closing date of 4 March 2017.

Two submissions were received. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on an application or proposal was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

**2.5 FSANZ Act assessment requirements**

**2.5.1 Section 29**

**2.5.1.1 Consideration of costs and benefits**

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

The likely impacts of the draft variation are summarised in Table 2 below.

**Table 2: Summary of likely effects of the draft variation**

| Sector    | Costs or benefits of draft variation  |
|-----------|---|
| Consumers | <ul style="list-style-type: none"> <li>• There will be no costs to consumers.</li> <li>• 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.</li> </ul> |
| Industry  | <ul style="list-style-type: none"> <li>• These fining agents are more costly than bentonite.</li> <li>• The wine industry would benefit by having alternative wine fining agents sourced from plants and seaweed.</li> </ul>  |

|             |   |
|-------------|---|
|             | <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul> |
| Governments | <ul style="list-style-type: none"> <li>• This variation adds two more permitted processing aids to the wine production standard. There would be no more (or less) impact on compliance than currently.</li> </ul>   |

### **2.5.1.2 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.

### **2.5.1.3 Any relevant New Zealand standards**

The amendment is proposed to Standard 4.5.1 which is an Australia only food production Standard. Wine produced in New Zealand already has permission to use pectins and carrageenan as processing aids to fine wine because of the general permission in Standard 1.3.3.

### **2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

## **2.5.2. Subsection 18(1)**

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

### **2.5.2.1 Protection of public health and safety**

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

### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The labelling approach for the processing aids is discussed in Section 2.3.3 above. This approach is consistent with the existing provisions in the Code for the labelling of permitted processing aids.

### **2.5.2.3 The prevention of misleading or deceptive conduct**

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



### 2.5.3 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 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 section 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 also 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.

- **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](#) 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.

## **Attachments**

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

## Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1126 – Pectins & Carrageenan as Processing Aids in Wine (Fining Agent)) 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 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 – 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 permissions for pectins and carrageenan as processing aids to remove heat-unstable proteins from Australian produced wine. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, 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 sunseting under the *Legislation Act 2003*.

### **2. Purpose**

The Authority has approved 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 20 February 2017 for a six-week consultation period.

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.

### **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, sparkling wine or fortified wine in Australia.

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.