

**13 September 2018**  
**[58–18]**

## **Call for submissions – Application A1161**

### **Potassium polyaspartate as a food additive in wine**

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FSANZ has assessed an application from Enartis Pacific Pty Ltd. to permit potassium polyaspartate as a food additive (stabiliser) in wine at a maximum permitted level of 100 mg/L. FSANZ 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 we accept as confidential, 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 application number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient 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](mailto: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) 25 October 2018**

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](mailto: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:

SD1          Food technology, hazard and dietary exposure assessment

## Executive summary

FSANZ has assessed an application from Enartis Pacific Pty Ltd. to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of potassium polyaspartate as a food additive in wine at a maximum permitted level of 100 mg/L.

Potassium polyaspartate functions as a stabiliser by preventing the growth of potassium bitartrate crystals.

Based on the hazard and dietary exposure assessments, there are no public health and safety concerns from the use of potassium polyaspartate as a food additive in wine at the proposed levels.

Based on the FSANZ food technology assessment, the use of potassium polyaspartate as a food additive in the quantity and form proposed is technologically justified. It is appropriately classified as a food additive since it provides a technological function as a stabiliser.

Potassium polyaspartate has an accepted specification in a secondary source, section S3—3(j) in the Code.

There is no international Codex standard for wine, nor permission in the Codex general standard for food additives for potassium polyaspartate in wine. The European Union (EU) permits potassium polyaspartate for use as a stabiliser against tartrate crystallisation in wine at levels of no more than 100 mg/L (European Commission, 2017).

FSANZ has considered the potential impacts of approving a draft variation to the Code and concluded that the direct and indirect benefits that would arise from permitting potassium polyaspartate most likely outweighs the associated costs.

FSANZ has therefore prepared a draft variation to permit the use of potassium polyaspartate as a food additive in wine, sparkling wine and fortified wine at a maximum permitted level of 100 mg/L.

# **1 Introduction**

## **1.1 The applicant**

Enartis Pacific Pty. Ltd. is part of the international Esseco Group S.r.l. which develops, produces and sells food ingredients, food additives and processing aids for the wine industry. They also provide research, analytical and consulting services for the wine industry.

## **1.2 The application**

The purpose of the application is to amend the Code to permit potassium polyaspartate as a food additive, with the technological purpose as a stabiliser in wine, at a maximum permitted level of 100 mg/L. Potassium polyaspartate prevents the growth of potassium bitartrate crystals.

Potassium bitartrate crystals, also known as “wine diamonds” can develop during storage. The physical presence of these crystals in the base of a wine bottle or around the cork is unacceptable in terms of wine quality and can appear ‘glass like’ which results in an unacceptable appearance for consumers. Physical and/or chemical processes can be used to remove the tartrate crystals.

Potassium polyaspartate is the potassium salt of polyaspartic acid. Potassium polyaspartate is superior to other permitted food additives used as stabilisers in wine. It has no negative effects on the sensory properties of wine.

## **1.3 The current Code requirements**

Potassium polyaspartate is not currently permitted to be added to wine as a food additive - stabiliser.

Australia and New Zealand food laws require that food for sale must comply with the Code requirements (refer to Appendix 1).

## **1.4 International requirements**

There is no international Codex standard for wine, nor permission in the Codex general standard for food additives for potassium polyaspartate in wine. At the Codex Committee for Food Additives (CCFA), 50th session in 2017, potassium polyaspartate as a stabiliser in wine at a maximum permitted use level of 100 mg/L was added to the list of priority substances for evaluation by JECFA.

The EU permits potassium polyaspartate as a stabiliser against tartrate crystallisation in wine at levels of no more than 100 mg/L (European Commission, 2017). The EU requirement also references the International Organisation of Vine and Wine’s (OIV’s) International Code of Oenological Practices, and treatment with potassium polyaspartate that does not exceed 100 mg/L (OIV, 2017a and b). Although the OIV resolutions are non-regulatory the EU requirement means that relevant OIV resolutions for potassium polyaspartate must be met.

## **1.5 Reasons for accepting application**

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

## **1.6 Procedure for assessment**

The application is being assessed under the general procedure.

# **2 Summary of the assessment**

## **2.1 Food technology, hazard and dietary exposure assessment**

### **2.1.1 Food technology assessment conclusions**

Potassium polyaspartate (in the amount and form proposed) is more effective than other food additives in preventing the growth of potassium bitartrate crystals.

It is suitable for its proposed use in wine, sparkling wine and fortified wine. Stability studies show it is stable for up to 12 months in wine.

The Code currently sets an identity and purity specification for potassium polyaspartate, which is an internationally accepted specification (refer to section 1.3 in Appendix 1).

### **2.1.2 Hazard and dietary exposure assessment conclusions**

The submitted data, and information from other sources, were considered adequate to define the hazard of potassium polyaspartate.

Results of *in vitro* studies indicate that gastrointestinal degradation and absorption of potassium polyaspartate is likely to be minimal. Potassium polyaspartate was not genotoxic *in vitro*, and no adverse effects were observed in 14-day and 90-day repeated dose oral toxicity studies in rats at doses up to 1000 mg/kg bw/day, the highest dose tested.

A dietary exposure assessment was conducted for Australian and New Zealand population groups based on the proposed draft variation. The estimated mean and 90<sup>th</sup> percentile dietary exposures range from 0.031 mg/kg bw/day to 0.35 mg/kg bw/day and from 0.072 mg/kg bw/day to 0.79 mg/kg bw/day respectively across the population groups assessed.

The no observed adverse effect level (NOAEL) in the 90-day repeated dose oral toxicity study in rats (1000 mg/kg bw/day) is more than 1200-fold higher than the highest 90<sup>th</sup> percentile exposure to potassium polyaspartate in the dietary exposure assessment.

Based on the reviewed data, it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate for potassium polyaspartate.

There are no public health and safety concerns from the use of potassium polyaspartate as a food additive in wine at the proposed maximum permitted level of 100 mg/L.

## **2.2 Risk management decision**

Based on the food technology, hazard and dietary exposure assessment, there are no public health and safety concerns with using potassium polyaspartate as a food additive in the manner proposed in the application and that use is technologically justified.

The risk management options available to FSANZ after assessment were to: reject the application; or prepare a draft variation to amend the Code to permit potassium polyaspartate as a food additive in wine at the requested maximum permitted level of 100 mg/L. Based on the risk assessment, the decision was made to prepare a draft variation to the Code.

Providing the permission for potassium polyaspartate as a food additive – stabiliser in wine at a maximum permitted level of 100 mg/L will require amendment of item 14.2.2 in the table to section S15—5 of Schedule 15 and of clauses 3 and 5 of Standard 4.51. A consequential amendment is required to section S8—2 to include potassium polyaspartate.

### **2.2.1 Labelling**

In accordance with paragraph 1.2.4—2(3)(b) of Standard 1.2.4 as a general rule, the requirement to provide a statement of ingredients, including food additives does not apply to standardised alcoholic beverages. Therefore, like most other food additives when used in standardised alcoholic beverages, the requirement to provide a statement of ingredients will not apply when potassium polyaspartate is used in wine, sparkling wine and fortified wine.

## **2.3 Risk communication**

A basic communication strategy has been developed for this application.

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards 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.

### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are 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 is no Codex or equivalent international standard for potassium polyaspartate as a food additive in wine and amending the Code to permit potassium polyaspartate as a food additive is also unlikely to have a significant effect on international trade. Potassium polyaspartate has been included on the list of priority substances for evaluation by JECFA at a maximum use level of 100 mg/L (Codex, 2018). The EU already permits its use at the same maximum permitted level requested by the applicant (100 mg/L), so it would enable Australia to meet EU trade agreement obligations and also not competitively disadvantage Australia and Australian winemakers. Its use in winemaking would also be voluntary. Therefore, a notification to the WTO under Australia's and New Zealand's obligations 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**

### **2.4.1 Section 29**

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.

#### **2.4.1.1 Cost and benefit considerations**

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new food additives (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting food additives is machinery in nature as they are part of implementing a regulatory framework where the use of the new additive is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (see paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from developing a draft variation as opposed to maintaining the status quo by rejecting the application. This analysis considers permitting potassium polyaspartate as a food additive. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting potassium polyaspartate as a food additive.

#### *Costs and benefits of permitting potassium polyaspartate as a food additive*

The food additive stabilises wine by preventing the growth of potassium bitartrate crystals. Although the presence of the crystals in wine does not pose a health risk, their presence affects the aesthetics and consumer acceptability of the wine. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists. Industry will benefit from having additional choice available to them. The additive may be a superior production method than costly physical processes like cold stabilisation and currently permitted food additives.

The food additive is permitted in wine by the EU which may be a trade opportunity for Australia and New Zealand wine industries, although there may also be competing imports from these countries into the domestic market.

Benefits to consumers include wine with improved sensory quality attributes. There may be downward price pressure on wine as costs for physical processes like cold stabilisation are not needed.

Permitting potassium polyaspartate may result in a small cost to government in terms of adding it to the current range of food additives that are monitored for compliance.

### *Conclusions from cost benefit considerations*

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting potassium polyaspartate as a food additive in wine most likely outweigh the associated costs.

#### **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.

#### **2.4.1.3 Any relevant New Zealand standards**

The Standards in question apply in both Australia and New Zealand (with the exception of Standard 4.5.1). There are no relevant New Zealand only Standards.

#### **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 completed a hazard and dietary exposure assessment (SD1) which is summarised in section 2.1.2. The safety assessment concluded there are no public health and safety concerns in permitting potassium polyaspartate as a food additive in wine at a maximum permitted level of 100 mg/L.

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

As discussed in section 2.2.1, the existing labelling provisions for food additives will apply consistent with those for wine and other standardised alcoholic beverages.

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

There are no issues identified with 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 food technology, hazard and dietary exposure assessment (SD1). The applicant submitted supporting information, including scientific studies, product information and relevant literature, as part of their application. FSANZ also considered other information relevant to the application (referenced in the document and reference list).

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

The EU permits potassium polyaspartate at levels of no more than 100 mg/L (European Commission, 2017). There is no international Codex standard for wine or permission in the Codex general standard for food additives for potassium polyaspartate in wine. At the 50<sup>th</sup> session of CCFA, potassium polyaspartate as a stabiliser in wine at a maximum use level of 100 mg/L was added to the list of priority substances for evaluation by JECFA (Codex, 2018).

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

Permitting this food additive gives the applicant and winemakers the opportunity to improve wine quality and provides cost and time efficiencies.

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

FSANZ did not identify any relevant issues relating to this consideration.

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

The Ministerial Policy Guideline for [Addition to Food of Substances other than Vitamins and Minerals](#)<sup>1</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. 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, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting potassium polyaspartate as a food additive – stabiliser in wine is consistent with the Ministerial Policy Guideline and the specific order principles for 'Technological Function' as a food additive - stabiliser.

### **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.

### **4 References**

Codex Alimentarius Commission, Codex committee on food additives 50<sup>th</sup> session. (2018). [Agenda item 7, Proposals for additions and changes to the priority list of substances proposed for evaluation by JECFA](#). Accessed 30 July 2018.

European Commission (2017). Official Journal of the European Union. Commission Delegated Regulation (EU) 2017/1961 of 2 August 2017 amending [Regulation \(EC\) No 606/2009 as regards certain oenological practices](#). Accessed 29 Jun 18.

International Organisation of Vine and Wine (OIV) (2017a). International Code of Oenological

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<sup>1</sup> <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

Practices. [Resolution OIV-OENO 572-2017. Monograph on potassium polyaspartate.](#)  
Accessed 27 Jun 18.

International Organisation of Vine and Wine (OIV) (2017b).International Code of Oenological Practices. [Resolution OIV-OENO 543-2016. Treatment with potassium polyaspartate in wine.](#) Accessed 27 Jun 18.

## Attachments

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

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



### **Food Standards (Application A1161– Potassium polyaspartate as a food additive) 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 the Delegate]

Insert Delegate's details  
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 A1161 – Potassium polyaspartate as a food additive) Variation*.

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

The Schedule varies Standards 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**

[1.1] inserting in the table to clause 3, in alphabetical order

Potassium polyaspartate

[1.2] omitting paragraph 5(5)(h), substituting

- (h) 200 mg/L of added dimethyl dicarbonate; and
- (i) 100 mg/L of potassium polyaspartate.

**[2] Schedule 8 is varied by**

[2.1] inserting in the table to section S8—2 entitled ‘Food additive names—alphabetical listing’, in alphabetical order

Potassium polyaspartate –

[2.2] omitting the following from the table to section S8—2 entitled ‘Food additive names—numerical listing’,

– Sodium hydrosulphite

substituting

– Potassium polyaspartate

– Sodium hydrosulphite

**[3] Schedule 15 is varied by omitting from item 14.2.2 in the table to section S15—5,**

150a	Caramel I – plain	GMP
substituting		
	Potassium polyaspartate	100
150a	Caramel I – plain	GMP

## **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 A1161 which seeks to permit the use of potassium polyaspartate as a food additive - stabiliser in 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 the Code to permit potassium polyaspartate as a food additive – stabiliser in wine at a maximum permitted level of 100 mg/L.

### **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 A1161 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A Regulation Impact Statement was not required because the proposed variation to Schedules 8 and 15 and to Standard 4.5.1 are likely to have a minor impact on business and individuals and its use is voluntary.

### **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. Item [1.1] inserts in the table to clause 3, in alphabetical order, an entry for 'Potassium polyaspartate'. Item [1.2] adds paragraph 5(5)(i) to set a maximum permitted level for potassium polyaspartate of 100 mg/L. The effect of this amendment will be to permit the use of potassium polyaspartate in the production of wine in Australia subject to a maximum permitted level of 100 mg/L.

Item [2] amends Schedule 8 by inserting a reference to 'Potassium Polyaspartate' in each of the two tables to section S8—2. No number is prescribed as there is not yet an INS number for potassium polyaspartate.

Item [3] amends Schedule 15 by inserting in item 14.2.2 in the table to section S15—5 an entry for potassium polyaspartate with a maximum permitted level of 100 mg/L. The effect of this amendment will be to permit, for the purposes of Standard 1.3.1, the use of potassium

polyaspartate subject to maximum permitted level of 100 mg/L.

# Appendix 1 Relevant code requirements for this application

## 1.1 Food additive permissions

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a food additive’ unless that substance’s use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is ‘used as a food additive’ if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table to section S14—2 provides that use as a stabiliser is a permitted technological purpose.

Schedule 15 lists the specific food additive permissions for different classes of food products. Item 14.2.2 in the table to section S15—5 lists the permitted food additives for wine, sparkling wine and fortified wine. It also sets a maximum permitted level for each. Wine, sparkling wine and fortified wine meet the definition of ‘wine’ as defined in section 1.1.2—3.

Schedule 8 lists food additive names and code numbers for labelling purposes.

## 1.2 Labelling requirements

Paragraph 1.2.4—2(3)(b) of Standard 1.2.4 provides that a statement of ingredients is not required for a standardised alcoholic beverage.

## 1.3 Identity and purity requirements

Food additives permitted by section 1.3.1 and Schedule 15 must also meet any relevant identity and purity specifications set out in Schedule 3. Section S3—3 of Schedule 3 provides a list of specifications contained in secondary sources. These secondary sources include the resolutions of the OIV— see paragraph S3—3(j). There is an OIV resolution for potassium polyaspartate; namely, OIV resolution OIV-OENO 572-2017 Monograph for potassium polyaspartate (OIV, 2017a). This means that if potassium polyaspartate is permitted, a new specification is not needed.

## 1.4 Australian production requirements

Wine manufactured in Australia must also comply with the requirements of Standard 4.5.1 – Wine Production Requirements, which is an Australia-only Standard. Only those food additives listed in the Table to clause 3 of Standard 4.5.1 are permitted to be used in the manufacture or production of wine in Australia. Those substances may be used subject to any limit imposed by clause 5 of Standard 4.5.1.