

**26 April 2017**  
**[11–17]**

## **Call for submissions – Application A1127**

### **Processing Aids in Wine**

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FSANZ has assessed an Application made by the Winemakers' Federation of Australia to seek permission for the use of chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite and silver chloride as processing aids for 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 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 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](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) 7 June 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](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](#)<sup>1</sup>, which informed the assessment of this Application, is available on the FSANZ website:

SD1 Risk and technical assessment report

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<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1127-ProcessingAidsForWine.aspx>

## Executive summary

The Winemakers' Federation of Australia (WFA), the national peak body for Australia's winemakers, applied to FSANZ to permit the following processing aids for wine production, each with different technological functions: chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite (ammonium hydrogen sulphite) and silver chloride.

The European Union (EU) permits these processing aids and in light of these permissions, the EU formally requested Australia to authorise the use of these processing aids for use in wine. In response, the WFA submitted this Application to enable Australia to fulfil its treaty obligations under the Wine Agreement and satisfy the World Trade Organisation obligations to ensure equal treatment with its trading partners.

FSANZ has determined that there is sufficient evidence to provide assurance that the four processing aids are technologically justified and are effective in achieving their stated purpose. Specifications are provided by the International Organisation of Vine and Wine (OIV) and adopted as a secondary source in section S3—3(j) of Schedule 3 – Identity and purity, in the *Australia New Zealand Food Standards Code (Code)*.

FSANZ identified four issues for the assessment of the four processing aids: the identity, purity and absence of contaminants; technological use; potential presence in the final food and the absence of public health and safety issues arising from their use. Existing labelling requirements in the Code are appropriate for the labelling of foods produced for all four processing aids.

FSANZ did note that sulphur dioxide (SO<sub>2</sub>) is produced during the breakdown of ammonium bisulphite. The primary technological function for ammonium bisulphite is for a yeast nutrient and this use is technologically justified. Any manufacturer of wine would need to understand not only the primary function for using ammonium bisulphite (that of a yeast nutrient in the manufacture of wine) but also any incidental function (such as a preservative) it may provide. If sulphites are present in concentrations of 10 mg/kg or more in the wine for sale, mandatory declaration is required in accordance with section 1.2.3—4.

FSANZ has considered the potential impacts of approving a draft variation on consumers, the food industry, and enforcement agencies. FSANZ considers that the benefits that would arise from permitting the use of these four processing aids in the manufacture of wine in Australia would outweigh the costs.

FSANZ has therefore prepared a draft variation to permit the use of chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite and silver chloride as processing aids at good manufacturing practice (GMP) levels in the production of wine.

# 1 Introduction

## 1.1 The Applicant

The Winemakers' Federation of Australia (WFA) is the national peak body for Australia's winemakers. In developing this Application, the WFA has also consulted with the Australian Department of Agriculture and Water Resources and the New Zealand Winegrowers (the national organisation for New Zealand's grape and wine sector).

## 1.2 The Application

The Application seeks permission for four processing aids; chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite and silver chloride for use in wine production. The justification for the Application relates to Australia's obligations under the Agreement between Australia and the European Community on Trade in Wine (Wine Agreement).

Under the Wine Agreement if one Contracting Party proposes to authorise a new, or modify an existing, oenological practice, process or compositional requirements for commercial use in its territory which is not authorised by the other Contracting party they notify the other Contracting party. The European Union (EU) formally requested Australia authorise these four processing aids, which initiated the WFA's Application.

## 1.3 The current standards

Paragraph 1.1.1—10(6)(c) in the Code provides that a food for sale (including wine) 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'. That definition imposes certain requirements on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid. For example, that the substance not perform a technological function in the final food for sale.

Two Standards in the Code provide permissions to use processing aids in wine production.

Standard 1.3.3 provides permissions for certain substances to be used as processing aids in food (including wine) sold in Australia or New Zealand. Section 1.3.3—4, for example, provides that a food additive permitted at good manufacturing practice (GMP) listed in section S16—2 and any substance listed in section S18—2 are generally permitted processing aids that may be used in these foods.

Processing aids permitted by section 1.3.3 and Schedule 18 must also meet any relevant identity and purity specifications set out in Schedule 3.

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 in the production of wine in Australia.

Neither Standard 1.3.3, 4.5.1 or Schedule 18 currently permit chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite or silver chloride as processing aids in the production of wine.

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### 1.3.1 International standards

Codex Alimentarius (Codex) 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. The OIV has produced specifications for each of the four processing aids contained in this Application. These specifications have been adopted for the purposes of Code requirements relating to identity and purity in section S3—3(j) of Schedule 3 – Identity and purity.

The EU has specific permissions for the use of each of the four processing aids in wine production.

The Republic of South Africa permits the use of ammonium bisulphite as a processing aid in wine production.

The United States of America has permissions for chitin-glucan, PVI/PVP co-polymers and ammonium bisulphite in wine production.

Further details on international standards are contained in SD1.

### 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

The risk assessment considered two questions:

- Is the technological function clearly stated for each substance and is that function justified in the quantity and form proposed for use as a food processing aid?
- Are there any potential public health and safety concerns that may arise from the use of these substances as processing aids in the manufacture of wine in Australia and New Zealand?

The technical assessment concluded that the technological purposes of the four processing aids are justified at levels consistent with good manufacturing practice (GMP), which limits the amount of the substances added to the lowest levels necessary to accomplish their desired effects.

The risk assessment determined that there are no potential public health and safety

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concerns from the use of these substances when used as processing aids in the manufacture of wine.

FSANZ did note that sulphur dioxide (SO<sub>2</sub>) is produced during the breakdown of ammonium bisulphite. The primary technological function of ammonium bisulphite considered for the present Application is as a yeast nutrient and its use as such is technologically justified.

Details of the risk assessment are in SD1.

## 2.2 Risk management

There are no public health and safety concerns from the use of chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite and silver chloride when used as processing aids in the manufacture of wine. These processing aids are technologically justified for use in wine and their use meets the definition of a processing aid.

The Applicant had requested that ammonium bisulphite be listed in section S18—5 (Permitted microbial nutrients and microbial nutrient adjuncts). However, FSANZ proposes that ammonium bisulphite be listed in the table to section S18—9 (Permitted processing aids—various technological purposes) with the technological purpose “microbial nutrient and microbial nutrient adjunct for wine”. Since the risk assessment focussed on the use of ammonium bisulphite in wine only, FSANZ concludes that permissions must be limited to wine under section S18—9.

Any manufacturer of wine would need to understand not only the primary function for using ammonium bisulphite (that of a yeast nutrient in the manufacture of wine) but also any incidental function it may provide. For example, if there is formation of SO<sub>2</sub> resulting from the use of ammonium bisulphite and sulphites are present in concentrations of 10 mg/kg or more, mandatory declaration requirements apply (see section 2.2.3 below).

As the use of a substance as a processing aid requires an express permission in the Code, the risk management options available to FSANZ are either to prepare a draft variation or reject the Application.

Therefore, FSANZ has prepared a draft variation, noting the following variations from the Applicant’s original request:

- ammonium bisulphite is listed in the table to section S18—9 (Permitted processing aids—various technological purposes) with the technological purpose “microbial nutrient and microbial nutrient adjunct for wine”.

### 2.2.1 Levels of addition

In the absence of any public health or safety concerns identified by the risk assessment conducted by FSANZ, there is no reason to limit the levels of addition apart from the requirement to use in accordance with GMP.

### 2.2.2 Specifications

As OIV specifications already exist in secondary references in section S3—3(j), no new specifications are required. Analytical methods are available for detection and quantification of these processing aids (Refer to SD1).

### 2.2.3 Labelling

FSANZ considers that the existing labelling requirements in the Code are appropriate for

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wine 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 paragraphs 1.2.4—3(2)(d) and (e) of Standard 1.2.4 – Information requirements – statement of ingredients.

The use of ammonium bisulphite as a processing aid may result in the incidental presence of SO<sub>2</sub> in the final wine for sale. Added sulphites in concentrations of 10 mg/kg or more are required to be declared if present in a food for sale, including when present as a processing aid, or an ingredient or component of a processing aid (section 1.2.3—4 of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations). The declaration must be provided in accordance with Standard 1.2.1 (Requirements to have labels or otherwise provide information).

Wine manufacturers who use ammonium bisulphite as a processing aid need to ensure compliance with the declaration requirements in Standards 1.2.3 and 1.2.1.

## **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 called for 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.

Following consultation, the FSANZ Board will consider the proposed variation taking into account comments received through submissions.

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

Australia is obliged to notify WTO members when 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 international Codex standards for wine or processing aids. However, chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite, and silver chloride are permitted under EU law as processing aids and in some other countries. Amending the Code to permit the use of these processing aids for wine production is unlikely to have a significant effect on international trade. If a draft variation is ultimately approved, permissions will be voluntary and will be alternatives for other already permitted processing aids. Therefore, a notification to the WTO under Australia and New Zealand's obligations under the WTO Technical Barriers to Trade 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 section 29 of the FSANZ Act:

## **2.4.1 Section 29**

### **2.4.1.1 Consideration of costs and benefits**

FSANZ has considered the benefits and costs associated with the proposed amendments based on regulatory impact principles. The level of analysis is commensurate to the nature of the Application and the significance of the likely impacts.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (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.

FSANZ considers the direct and indirect benefits arising from the requested regulatory amendment to outweigh the costs to the community, Government and industry. The use of these substances is voluntary and therefore the changes are deregulatory in nature.

In considering the costs and benefits of permission for the use of chitin-glucan, PVI/PVP copolymers, ammonium bisulphite and silver chloride as processing aids for wine, FSANZ concluded that there would be benefits to the wine industry and consumers in particular.

The wine industry benefits by having more processing aids available, which may see gains in production efficiencies. Improvements in workplace health and safety are possible in the case of ammonium bisulphite as the addition of an aqueous form of this processing aid is safer than current alternatives, which are in powdered form. Importers of wine will also benefit, as they will be able to offer a wider range of imported wines.

Consumers will benefit by having increased choice from the importation of international wines that use these processing aids. Consumers may also benefit from superior wines where Australia and New Zealand manufacturers adopt the processing aids, or reduced prices where the processing aids leads to efficiency gains.

Permitting the processing aids also satisfies WTO obligations to ensure equal treatment with our trading partners.

No costs to consumers, Governments or other stakeholders were identified that would outweigh these benefits. No costs were identified in accepting the Application.

### **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 proposed amendment is to both Standard 4.5.1 (applies in Australia only) and Schedule 18 which is a joint standard.

### **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.

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

FSANZ has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the four processing aids for wine production.

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

The labelling requirements are discussed in Section 2.2.3 above. The existing labelling requirements in the Code are considered to be appropriate for the use of the four processing aids in wine production.

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

No issues were identified.

## **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, provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was used in assessing the Application.

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

As explained above, the four substances are permitted internationally as processing aids in the production of wine. The draft variation will bring domestic food standards into line with those international standards or permissions.

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

Permission to use the four processing aids for wine production provides the wine industry with alternatives to the current permitted processing aids. Individual wineries will make commercial decisions on which processing aids are best suited to their particular products and their style of wine production.

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

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

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

The Policy Guideline for the [Addition to Food of Substances other than Vitamins and Minerals](#)<sup>2</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
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the four processing aids for 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

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<sup>2</sup><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 A1127 – Processing Aids in Wine) 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.

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**1 Name**

This instrument is the *Food Standards (Application A1127 – Processing Aids in Wine) 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 inserting each of the following into the Table to clause 4, in alphabetical order

Ammonium bisulphite  
Chitin-glucan  
Polyvinylimidazole–polyvinylpyrrolidone co-polymers  
Silver chloride

**[2] Schedule 18** is varied by inserting each of the following into the table to subsection S18—9(3), in alphabetical order

Ammonium bisulphite	For use in the manufacture of wine as a microbial nutrient and microbial nutrient adjunct.	GMP
Chitin-glucan	For use in the manufacture of wine as a decolourant, clarifying, filtration and absorbent agent.	GMP
Polyvinylimidazole–polyvinylpyrrolidone co-polymers	For use in the manufacture of wine as a decolourant, clarifying, filtration and absorbent agent.	GMP
Silver chloride	For use in the manufacture of wine to remove fermentation and storage-related odours.	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 A1127, which seeks to permit the use of four processing aids, silver chloride, ammonium bisulphite, chitin-glucan and PVI/PVP as processing aids for 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 and Schedule 18 to permit the use of four processing aids, chitin-glucan, PVI/PVP co-polymers, ammonium bisulphite, and silver chloride as processing aids for 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 A1127 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 variations to Standard 4.5.1 and Schedule 18 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 the following references into the table to clause 4 in alphabetical order: chitin-glucan; polyvinylimidazole-polyvinylpyrrolidone co-polymers; ammonium bisulphite; and silver chloride. The effect of this amendment will be to permit the use of these four substances as processing aids in the production of wine in Australia.

Item [2] amends Schedule 18 by inserting into the table to subsection S18—9(3) entries for chitin-glucan, polyvinylimidazole-polyvinylpyrrolidone co-polymers, ammonium bisulphite and silver chloride.

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The new entry for ammonium bisulphite provides that that substance may be used as a processing aid in the manufacture of wine for the technological purpose of acting as a microbial nutrient and microbial nutrient adjunct.

The new entries for chitin-glucan and for polyvinylimidazole-polyvinylpyrrolidone provide that each substance may be used as a processing aid in the manufacture of wine for the technological purpose of acting as a decolourant, clarifying, filtration and absorbent agent.

The new entry for silver chloride provides that that substance may be used as a processing aid in the manufacture of wine for the technological purpose of removing fermentation and storage-related odours.

Each new entry also states that the maximum permitted level for each substance is that which is consistent with GMP