

2-04
17 March 2004

FINAL ASSESSMENT REPORT

APPLICATION A474

WINEMAKING

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application, A474 – Winemaking. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

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Assessment reports are available for viewing and downloading from the FSANZ website WWW.FOODSTANDARDS.GOV.AU or alternatively paper copies of reports can be requested from FSANZ's Information Officer at INFO@FOODSTANDARDS.GOV.AU including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

FSANZ (then the Australia New Zealand Food Authority) received an Application from the Winemakers' Federation of Australia (WFA) to amend wine regulations in the *Australia New Zealand Food Standards Code* (the Code) on 24 June 2002. FSANZ accepted the Application and prepared an Initial Assessment in May 2003. Public notice inviting submissions was given on 21 May 2003. The consultation period ended on 2 July 2003.

Most of the eight submissions received in response to the Initial Assessment Report supported the requested amendments for winemaking provisions in the Code. However none of the submissions, except that of the Applicant, supported the requested amendments associated with compositional and labelling requirements for wine product, and 'low alcohol', 'reduced alcohol', and 'dealcoholised' wine. The Applicant advised FSANZ that they did not wish to continue with these parts of the Application.

FSANZ prepared a Draft Assessment in September 2003. Public notice inviting submissions was given on 8 October 2003. The consultation period ended on 19 November 2003. A summary of the five submissions received in response to the Draft Assessment Report submissions is at Attachment 3.

This Final Assessment Report evaluates the issues raised in submissions received in response to the Draft Assessment Report and recommends draft variations to the Code.

The original Application sought amendments to update and align the provisions regulating wine in the Code with those of other wine producing countries with which Australia and New Zealand trade in wine. Some of these amendments are relevant to the ratification of Australia and New Zealand's multi-lateral wine agreement on trade in wine, the World Wine Trading Group Agreement on Mutual Acceptance of Oenological Practices, or MAA, which was signed by Australia and New Zealand in December 2001. FSANZ has since progressed these matters urgently in a separate Proposal, P283, along with a number of other Code amendments that are also necessary before ratification of the MAA can be completed. The matters progressed separately in Proposal P283 that were in the original Application are indicated in the list below.

The Applicant requests the following amendments to the provisions regulating wine in the Code:

- a minor change to the definition for wine in Standard 4.1.1 – Wine Production Requirements (Australia only) to align it with the definition for wine in Standard 2.7.4 – Wine and Wine Product;
- a prohibition on the addition of ethanol to wine in Standard 4.1.1, except where explicitly permitted;
- permission for the use of gum arabic as a food additive for wine made in accordance with Standard 2.7.4 – Wine and Wine Product (being progressed separately in Proposal P283);
- permission for the use of gum arabic as a food additive for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only);

- permission for the use of argon as a processing aid for wine made in accordance with Standard 2.7.4 – Wine and Wine Product (being progressed separately in Proposal P283);
- permission for the use of argon as a processing aid for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only);
- permission for the use of the enzyme urease as a processing aid for wine made in accordance with Standard 2.7.4 – Wine and Wine Product (being progressed separately in Proposal P283);
- permission for the use of the enzyme urease as a processing aid for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only) (withdrawn by Applicant at Draft Assessment);
- permission for the use of carbon dioxide as a food additive for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only);
- inclusion of ‘yeasts’ in the list of permitted processing aids in Standard 4.1.1 – Wine Production Requirements (Australia only);
- inclusion of ‘bacteria’ in the list of permitted processing aids in Standard 4.1.1 – Wine Production Requirements (Australia only); and
- move ‘uncharred oak’ from the table listing permitted food additives to the table listing permitted processing aids in Standard 4.1.1 – Wine Production Requirements (Australia only).

Most of the requested Code amendments are to update provisions in Standard 4.1.1 – Production Requirements for Wine (Australia only). Many of the proposed amendments for Standard 4.1.1 are already permitted for wine made in accordance with Standard 2.7.4 and so are suitable for inclusion in Standard 4.1.1 without extensive re-evaluation.

Two requested amendments are for new processing aid permissions that are not permitted in the Code for wine made in accordance with either Standard 2.7.4 or Standard 4.1.1. These proposed amendments (for the use of argon and the enzyme urease) therefore need full safety and technological evaluation to ensure the requested permissions are safe and suitable.

For argon, food technology and safety assessment reports conclude that it is suitable for inclusion in the Code because its use is technologically justified and raises no public health and safety concerns.

For urease, it was not possible to undertake a safety assessment because the primary toxicological data was not provided. At Draft Assessment the Applicant advised FSANZ that they wished to withdraw the request in their original Application to permit urease in the Code. The permission for the use of urease is now being progressed separately in Proposal P283.

The original Application also requested a number of minor changes to Standard 4.1.1 – Wine Production Requirements (Australia only). These proposed amendments were of minor impact only, intending to correct minor omissions and inconsistencies, to correctly categorise permitted substances as processing aids or food additives, or to provide additional permissions that are already permitted by the joint wine standard, Standard 2.7.4 – Wine and Wine Product. Accordingly their assessment was progressed separately as part of Proposal P266 – Minor Amendments Omnibus IV. Proposal P266 has now been finalised and the proposed amendments (at Attachment 4) were gazetted in July 2003.

The main objective of this assessment is to ensure that the proposed amendments to the standards in the Code that regulate the manufacture of wine do not adversely affect public health and safety.

Recommendations and Statement of Reasons

In reaching conclusions on these matters FSANZ has considered:

- the issues raised in submissions received in response to the Draft Assessment Report;
- issues associated with technological justification for the requested amendments; and
- public health and safety issues associated with the requested amendments.

FSANZ's conclusions at Final Assessment of Application A474 are the same as its recommendations at Draft Assessment with the following exceptions:

- the previously proposed inclusion of 'lactic acid bacteria' and 'yeasts' in the definition of 'prepared cultures' in Standard 4.1.1 has been changed to 'bacteria and yeasts permitted for food use';
- permission for 'uncharred oak' has been changed to 'oak' in Standard 4.1.1 to align it with the permission for 'oak' for wine made in accordance with Standard 2.7.4;
- the previously proposed inclusion of argon in Standard 1.3.3, table to clause 3 has been progressed separately in Proposal P283 and is no longer included in the drafting for this Final Assessment of Application A474;
- the previously proposed inclusion of gum arabic in item 14.2.2, of Schedule 1, Standard 1.3.1 – Food Additives has been progressed separately in Proposal P283 and is no longer included in the drafting for this Final Assessment of Application A474; and
- a consequential minor amendment to Standard 4.1.1 to provide that the maximum level of use for permitted processing aids and food additives is to be limited by good manufacturing practice (GMP), where no other limit is specified in the Standard.

At Final Assessment, FSANZ concludes that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended as follows:

- change the definition of wine to be the same as that in Standard 2.7.4;

- include a compositional requirement that prohibits the addition of ethanol to wine except where explicitly permitted within the Standard;
- include gum arabic as a permitted food additive in the Table to clause 3 with maximum level of use to be limited by good manufacturing practice (GMP);
- include argon as a permitted processing aid in the Table to clause 4 with maximum level of use to be limited by good manufacturing practice (GMP);
- include carbon dioxide as a permitted food additive in the Table to clause 3 with maximum level of use to be limited by good manufacturing practice (GMP);
- include a provision that the maximum level of use for permitted processing aids and food additives is to be limited by good manufacturing practice (GMP), where no other limit is specified in the Standard;
- include ‘bacteria and yeasts permitted for food use’ in the definition of ‘prepared cultures’ in subclause 3(2);
- remove ‘uncharred oak’ from the list of permitted food additives in Table to clause 3 and add ‘oak’ to the list of permitted processing aids in the Table to clause 4; and
- change the title of the wine production standard from ‘Standard 4.1.1 – Wine Production Requirements (Australia only)’ to ‘Standard 4.5.1 – Wine Production Requirements (Australia only)’.

At Final Assessment, FSANZ concludes that Standard 1.3.3 – Processing Aids be amended as follows:

- in the table to clause 14, the entry for ‘oak chips’ be amended to ‘oak’.

Reasons for these conclusions are that the proposed amendments:

- for Standard 4.1.1 are already permitted for wine made in accordance with Standard 2.7.4 and so are suitable for inclusion in Standard 4.1.1 without extensive re-evaluation, thus giving Australian winemakers permissions that are available for use in wine sold in Australia;
- clarify existing drafting without changing the original intent or are consequential to a proposed amendment;
- align provisions in Standard 4.1.1 more closely with those in Code that regulate wine made in accordance with the joint wine standard, Standard 2.7.4;
- in the case of the newly proposed processing aid, argon, food technology and safety assessment reports conclude that its use is technologically justified and would raise no public health and safety concerns; and
- provide more consistency with the winemaking provisions of other countries with which Australia and New Zealand trade in wine.

1. Introduction

Standard 4.1.1 – Wine Production Requirements (Australia only) carries forward into the Code the provisions that regulated the production of wine, sparkling wine and fortified wine that were in Standard P4 of the former Australian *Food Standards Code*. The wine production provisions of Standard P4 were carried forward into Standard 4.1.1 without substantive amendment.

The wine production provisions were last modified in 1995 following extensive consultation. These consultations coincided with the establishment of the *Agreement between Australia and the European Community on Trade in Wine, and Protocol*. The 1995 changes to the wine standard underpinned the Agreement by maintaining the ‘Australian’ wine style. These provisions included quality-allied winemaking provisions that were not appropriate for inclusion in the joint Australia New Zealand wine standard, Standard 2.7.4 – Wine and Wine Product.

2. Regulatory problem

2.1 Reasons for seeking amendments to wine provisions in Code

Since 1995, when the last substantive amendments were made to wine production provisions, there have been advances in wine technology, which are reflected in the regulations of many winemaking countries. These technological innovations enable the production of a better quality product with lower production costs.

Australia is at a competitive disadvantage when wine may be produced more efficiently and effectively in other countries, which use certain food additives and processing aids that are not permitted for use during the manufacture of Australian wine.

In this Application the Winemakers’ Federation of Australia (WFA) seeks amendments to update and align the provisions regulating wine in the Code with those of other wine producing countries with which Australia and New Zealand trade in wine. Where a requested amendment is not permitted for either wine made in Australia only (i.e., wine made in accordance with Standard 4.1.1) or for wine made in accordance with Standard 2.7.4 (i.e., wine sold in Australia), the Applicant has requested that the Code be amended to include permission for wine made in accordance with both standards.

2.2 Nature of proposed amendments in Application

2.2.1 Amendments necessary for MAA ratification progressed in separate Proposal P283

Some of the amendments in the Application are relevant to the ratification of Australia and New Zealand’s multi-lateral wine agreement on trade in wine, the World Wine Trading Group Agreement on Mutual Acceptance of Oenological Practices (MAA), which was signed by Australia and New Zealand in December 2001. FSANZ has since progressed these matters urgently in a separate Proposal, P283, along with a number of other Code amendments that are also necessary before ratification of the MAA can be completed. The matters progressed separately in Proposal P283 that were in the original Application are indicated in the list below.

The Application requests the following amendments to the provisions regulating wine in the Code:

- a minor change to the definition for wine in Standard 4.1.1 – Wine Production Requirements (Australia only) to align it with the definition for wine in Standard 2.7.4 – Wine and Wine Product;
- a prohibition on the addition of ethanol to wine in Standard 4.1.1, except where explicitly permitted;
- permission for the use of gum arabic as a food additive for wine made in accordance with Standard 2.7.4 – Wine and Wine Product (being progressed separately in Proposal P283);
- permission for the use of gum arabic as a food additive for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only);
- permission for the use of argon as a processing aid for wine made in accordance with Standard 2.7.4 – Wine and Wine Product (being progressed separately in Proposal P283);
- permission for the use of argon as a processing aid for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only);
- permission for the use of the enzyme urease as a processing aid for wine made in accordance with Standard 2.7.4 – Wine and Wine Product (being progressed separately in Proposal P283);
- permission for the use of the enzyme urease as a processing aid for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only) (withdrawn by Applicant at Draft Assessment);
- permission for the use of carbon dioxide as a food additive for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only);
- inclusion of ‘yeasts’ in the list of permitted processing aids in Standard 4.1.1 – Wine Production Requirements (Australia only);
- inclusion of ‘bacteria’ in the list of permitted processing aids in Standard 4.1.1 – Wine Production Requirements (Australia only); and
- move ‘uncharred oak’ from the table listing permitted food additives to the table listing permitted processing aids in Standard 4.1.1 – Wine Production Requirements (Australia only).

Most of these amendments are to update provisions in Standard 4.1.1 – Production Requirements for Wine (Australia only). Many of the proposed amendments for Standard 4.1.1 are already permitted for wine made in accordance with Standard 2.7.4 and so are suitable for inclusion in Standard 4.1.1 without extensive re-evaluation.

Two requested amendments are for new processing aid permissions that are not permitted in the Code for wine made in accordance with either Standard 2.7.4 or Standard 4.1.1. These proposed amendments (for the use of argon and the enzyme urease) therefore need full safety and technological evaluation to ensure the requested amendments are safe and suitable.

For urease, it was not possible to undertake a safety assessment because the primary toxicological data was not provided. At Draft Assessment the Applicant advised FSANZ that they wished to withdraw the request in their original Application to permit urease in the Code. The permission for the use of urease is now being progressed separately in Proposal P283 along with other Code amendments necessary before ratification of the MAA can be completed.

2.2.2 Withdrawal of requested amendments relating to wine product and 'low', 'reduced' and 'dealcoholised' wine

The original Application also requested a number of amendments relating to compositional and labelling requirements for wine products, and 'low alcohol', 'reduced alcohol', and 'dealcoholised' wine. However none of the submissions received in response to the Initial Assessment Report, except that of the Applicant, supported these amendments. The Applicant advised FSANZ that they did not wish to continue with these parts of the Application.

2.2.3 Minor amendments progressed separately in Proposal P266, Minor Amendments Omnibus IV

The original Application also requested a number of minor changes to Standard 4.1.1. These proposed amendments were of minor impact only, intending to correct minor omissions and inconsistencies, to correctly categorise permitted substances as processing aids or food additives, or to provide additional permissions that are already permitted by the joint wine standard, Standard 2.7.4. Accordingly, their assessment was progressed separately as part of Proposal P266, Minor Amendments Omnibus IV. Proposal P266 has now been finalised and the proposed amendments (at Attachment 4) were gazetted in July 2003.

2.2.4 Additional amendments requested at Draft Assessment

In a supplementary submission at Draft Assessment, the WFA requested two minor changes to Standard 4.1.1 in addition to those in the original Application. These proposed amendments are of minor impact only, intending to include in Standard 4.1.1 permissions that are already included in the joint wine standard, Standard 2.7.4. These additional amendments cannot be dealt with in this Application because they may not be legally sustainable. They have been referred to FSANZ's next minor amendments omnibus proposal.

2.3 Current regulations

The Application requests a number of changes to winemaking provisions in the Code (see Section 5). The current regulations in Australia and other winemaking countries are included, where appropriate, in the relevant section that details each amendment.

3. Objective

The main objective of this assessment is to ensure that the proposed amendments to the standards in the Code that regulate the manufacture of wine (see Section 5 for details) do not adversely affect public health and safety. The assessment will also need to be consistent with the other section 10 objectives of the FSANZ Act.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Historical background

During the review of wine regulations in Australia and New Zealand, the Australia New Zealand Food Authority (ANZFA), now FSANZ, determined that some of the production provisions for wine that underpin the *Agreement between Australia and the European Community on Trade in Wine, and Protocol* (and that were contained in the then Australian *Food Standards Code*) were inappropriate in a joint wine standard because they prescribed practices relating to wine quality that could become technical barriers to trade. As a result of the review, ANZFA developed a minimally prescriptive joint standard on wine, Standard 2.7.4, which recognises accepted winemaking practices throughout the world. Wine made in New Zealand or imported from other wine producing countries need comply only with this Standard. However the *Agreement between Australia and the European Community on Trade in Wine, and Protocol* relies on Australian wine being recognised as wine of designated quality and origin (e.g. *appellation contrôlée*, DOC, *qualitätswein* etc.) and the provisions in Standard 2.7.4 did not implement these requirements.

As a temporary measure until a more appropriate legislative vehicle was found, Standard 2.7.4 of the then Volume 2 of the *Food Standards Code* referred directly to provisions contained in Standard P4 – Wine, Sparkling Wine and Fortified Wine and in Standard P6 – Wine Products and Reduced Alcohol Wine in the then Volume 1 of the *Food Standards Code*.

It was intended at the time of the review that the *Australian Wine and Brandy Corporation Act 1980* (AWBC Act) might incorporate these provisions. However, officers in the Department of Agriculture, Fisheries and Forestry – Australia (DAFF) informed FSANZ that there were difficulties associated with placing such provisions in AWBC Act. This was because the AWBC Act did not have coverage of all wine made and sold within Australia, particularly wine manufactured by unincorporated bodies and not traded interstate or internationally.

With the strong support of Ministers of the former Australia New Zealand Food Standards Council, FSANZ developed the Australia-only wine production standard, Standard 4.1.1. The provisions of Standard 4.1.1 were based substantively on Standard P4. They ensure that all wine made in Australia (i.e., wine for export as well as for domestic consumption) is recognised by the European Community (EC) as being wine of designated quality and origin (e.g., *appellation contrôlée*, DOC, *qualitätswein* etc.) rather than as table wine thus ensuring continuation of the current access of Australian wine to the EC market.

5. Relevant issues

5.1 Provisions regulating wine in the Code

Standard 4.1.1 is an Australia-only wine production standard with the main purpose of assisting to uphold the *Agreement between Australia and the European Community on Trade in Wine, and Protocol*. Wine made in Australia must be made in accordance with Standard 4.1.1 whether it is intended for export or domestic sale. All wine made in accordance with Standard 4.1.1 would also comply with Standard 2.7.4.

There are no public health or safety reasons to prohibit the use in Standard 4.1.1 of any processing aid or food additive that is already permitted for use in wine made in accordance with Standard 2.7.4. Therefore there are no grounds for not duplicating permissions in Standard 4.1.1 that are already permitted for wine made in accordance with Standard 2.7.4 except if such a permission would be likely to undermine the *Agreement between Australia and the European Community on Trade in Wine, and Protocol*.

Requested amendments that are not permitted in the Code for wine made in accordance with either Standard 2.7.4 or Standard 4.1.1 need full safety and technological evaluation to ensure the requested amendments are safe and suitable for inclusion in the Code.

5.2 Alignment of the definition in Standard 4.1.1 with that in Standard 2.7.4

The current definition for wine in Standard 2.7.4 is:

Wine means the product of the complete or partial fermentation of fresh grapes, or a mixture of that product and products derived solely from grapes.

The current definition for wine in Standard 4.1.1 is:

Wine means the product of the complete or partial fermentation of fresh grapes or products derived solely from fresh grapes.

The Applicant requests a change to the current definition for wine contained in Standard 4.1.1 that restricts the source of products to those from ‘fresh’ grapes. The requested change is to align the definition with that of the joint wine standard, Standard 2.7.4.

5.2.1 Issues raised in submissions

All submissions received in response to the Draft Assessment Report supported the alignment of the definition for wine in Standard 4.1.1 with that in Standard 2.7.4.

5.2.2 Evaluation and impact analysis

The definition for wine in Standard 2.7.4 was developed during the review whereas the definition in Standard 4.1.1 was carried forward into the new Code without benefit of review. The proposed alignment of the definition for wine in Standard 4.1.1 with that in Standard 2.7.4 would remove ambiguity about the permitted use of concentrated grape juice and extracts from grape skins for wine made in accordance with Standard 4.1.1 because these are definitely ‘products derived solely from grapes’ but arguably may not be ‘products derived solely from fresh grapes’.

The proposed change also is desirable from a regulatory point of view to keep discrepancies between the two standards to a minimum. If the proposed amendment were to go ahead there would be benefits for Australian wine producers in reducing ambiguity as well as to food law enforcers and regulators due to the closer alignment of the two standards. There are no additional costs associated with the proposed amendment for any of the affected parties identified in section 7.

5.2.3 Preferred approach

At Final Assessment, as at Draft Assessment, FSANZ proposes to align the definition of wine with that in Standard 2.7.4.

5.3 Prohibition of addition of ethanol to ‘wine’ in Standard 4.1.1

The Applicant also requests an additional sentence to be added to the definition of wine, which would prohibit the addition of ethanol to wine except where explicitly permitted by the Standard.

The Applicant is concerned that both the current and the proposed definitions in Standard 4.1.1 are ambiguous as to whether grape ethanol is permitted to be added to ‘wine’. The original intent of the drafting was that ethanol addition would only be permitted as specified by the compositional provisions for ‘fortified wine’ or ‘sparkling wine’. The Applicant wishes to clarify the distinction between ‘fortified wine’, ‘sparkling wine’ and ‘wine’ in Standard 4.1.1, which includes that ‘wine’ may not have ethanol added to it, by adding a provision that explicitly prohibits the addition of ethanol to ‘wine’.

The requested definition is:

Wine means the product of the complete or partial fermentation of fresh grapes, or a mixture of that product and products derived solely from grapes. The alcoholic content cannot be increased by the addition of ethanol unless elsewhere specified.

5.3.1 Issues raised in submissions

All submissions received in response to the Draft Assessment Report support the requested amendment for additional drafting to prohibit the addition of ethanol to wine in Standard 4.1.1 except where explicitly permitted. However, the New Zealand Food Safety Authority (NZFSA) in its submission considered that urgent clarification was required as to whether addition of ethanol to wine made in accordance with 2.7.4 was permitted for other than fortified or sparkling wine. NZFSA considered that the proposed drafting would result in inconsistency between the two standards.

NZFSA and FSANZ have discussed this issue and agree on the evaluation and regulatory approach proposed below.

5.3.2 Evaluation and impact analysis

5.3.2.1 Standard 4.1.1

The current and proposed definitions are ambiguous in this respect and it could be argued either way that grape ethanol is ‘a product derived solely from grapes’ or ‘a product derived solely from fresh grapes’. In an Australia-only production standard for wine, the distinction between ‘fortified wine’, ‘sparkling wine’ and ‘wine’ is appropriate and therefore an amendment that clarifies this distinction can be justified.

If the proposed amendment were to be accepted, Australian wine producers would benefit from a reduction in ambiguity in Standard 4.1.1, as would food law enforcers and regulators in Australia and New Zealand. There are no additional costs associated with the proposed amendment for any of the affected parties identified in section 7.

A compositional requirement in Standard 4.1.1, rather than a modification of the definition for wine, will give effect to the requested amendment without complicating the definition for wine unnecessarily.

5.3.2.2 Standard 2.7.4

The definition for wine in Standard 2.7.4 does not distinguish between ‘wine’, ‘sparkling wine’ and ‘fortified wine’ because there are no issues associated with public health and safety that warrant making that distinction. Therefore there is no need to amend provisions in Standard 2.7.4 to prevent the addition of ethanol to ‘wine’. Standard 2.7.4 recognises a wide range of legitimate winemaking practices, and it is not necessary to prohibit the addition of ethanol to ‘wine’.

There are no health or safety reasons to specifically prohibit the addition of ethanol to wine. There are general Code provisions that require labelling to accurately describe the nature of a product. Thus if wine were fortified or sparkling or still, the overall representation would need to be different to distinguish the different types of wine. These requirements, together with the Code's specific mandatory labelling requirements for wine, would ensure that consumers were adequately informed about the nature of a particular product they were intending to purchase.

FSANZ cannot make substantive amendments to standards without adequate consultation. To make changes to Standard 2.7.4 that prevent the addition of ethanol to wine would be a substantive change which, without consultation with consumers and winemakers worldwide, cannot be done at Final Assessment. As indicated above FSANZ and NZFSA are in agreement that no change is needed in Standard 2.7.4 to specifically prohibit the use of ethanol during winemaking.

5.3.3 Preferred approach

At Final Assessment, as at Draft Assessment, FSANZ proposes to include a compositional requirement in Standard 4.1.1 that prohibits the addition of ethanol to wine except where explicitly permitted in that Standard.

FSANZ does not propose to amend Standard 2.7.4 to prohibit the addition of alcohol to wine.

5.4 Permission to use gum arabic (acacia) as a food additive

Gum arabic or acacia gum or arabic gum, is the dried gummy exudate from tropical and subtropical *Acacia senegal* trees and related *Acacia* species. It is used in winemaking in many countries for stabilisation as it prevents the formation of cloudiness and deposits by stopping unstable colloid particles from aggregating in clarified wine.

In the Code, gum arabic is a generally permitted food additive (Standard 1.3.1, Schedule 2). However these generally permitted Schedule 2 substances are not permitted for use as food additives in some foods, including wine made in accordance with Standard 2.7.4 (Standard 1.3.1, Schedule 1, item 14.2.2). The Code currently has no permission for the use of gum arabic for wine made in accordance with Standard 4.1.1.

The New Zealand *Food Regulations, 1984*, (revoked in December 2002) permitted the use of gum arabic as a food additive in wine.

Gum arabic is approved by the Office International de la Vigne et du Vin (OIV) for use in wine as a food additive. It is permitted for use in wine made in the EC, in South Africa and in the USA. The *Agreement between Australia and the European Community on Trade in Wine, and Protocol* also permits the use of gum arabic in wines made in the EC for sale in Australia.

Gum arabic is classified by the Joint Expert Committee of Food Additives (JECFA) as an emulsifier, thickening agent and stabiliser. According to the latest evaluation of gum arabic by JECFA in 1989, its ADI is 'not specified', if used according to, and limited by, good manufacturing practice (GMP).

The Applicant requests that the Code be amended to permit the use of gum arabic as a food additive for wine made in accordance with Standard 2.7.4 and for wine made in accordance with Standard 4.1.1. The Applicant claims that this permission will assist free trade in wine, provide consistency with international standards, and give force to Australia's international obligations under Annex 1 of the *Agreement between the European Community and Australia on trade in wine* and the New World Wine Producers' Mutual Acceptance Agreement on Oenological Practices (MAA).

5.4.1 Issues raised in submissions

All submissions received in response to the Draft Assessment Report supported the proposed amendment.

5.4.2 Evaluation and impact analysis

Gum arabic is already a generally permitted food additive (Standard 1.3.1, Schedule 2). However, these generally permitted Schedule 2 substances are not permitted for use as food additives in wine and some other foods because they are prohibited by specific provisions within Schedule 1 (eg, Standard 1.3.1, Schedule 1, item 14.2.2).

Listing in Schedule 2 means gum arabic has been assessed and deemed safe for use in food at GMP levels and therefore that there are no public health or safety issues associated with extending its use wherever there is a need to use it in processed foods.

The use of gum arabic as a food additive in wine is a widely accepted winemaking practice and amending the Code to permit its use for wines made in accordance with either Standard 2.7.4 or Standard 4.1.1 will benefit all affected parties and align these wine standards more closely with those of other wine producing countries with which Australia and New Zealand trade in wine.

5.4.3 Preferred approach

At Draft Assessment FSANZ proposed to amend Standard 1.3.1, Schedule 1, item 14.2.2 to include permission for gum arabic (INS 414) for wine made in accordance with Standard 2.7.4. This amendment is being progressed urgently as part of Proposal P283, which seeks amendments necessary before ratification of the MAA can be finalised. Therefore there is no longer any need for its inclusion in the Assessment of this Application, A474.

At Final Assessment, as at Draft Assessment, FSANZ proposes to amend Standard 4.1.1, Table to clause 3, to include gum arabic as a permitted food additive with maximum level of use to be limited by good manufacturing practice (GMP).

5.5 Permission to use argon as a processing aid

Argon is a colourless, odourless, inert gas. It is heavier than carbon dioxide or nitrogen, more readily displacing oxygen than these other gases. Therefore it provides a better protective gas cover over wine during production, thus better preventing oxidation of wine and the growth of unwanted bacteria and yeast.

Argon is not currently a permitted processing aid for wine made in accordance with Standard 2.7.4 or for wine made in accordance with Standard 4.1.1.

Argon is approved for use in wine as a processing aid by the Office International de la Vigne et du Vin (OIV). It is permitted for use in wine made in the EC. The *Agreement between Australia and the European Community on Trade in Wine, and Protocol* also permits the use of argon for wines made in the EC for sale in Australia and also for wines made in Australia for sale in the EC.

In addition, argon is listed in the *Codex inventory of all compounds used as processing aids* (Appendix A), as a propellant and packaging gas, as are carbon dioxide and nitrogen (Codex Committee on Food Additives and Contaminants 1999); the initial Inventory of Processing Aids was adopted by the Codex Alimentarius Commission at its 18th Session in 1989, from whence it had been sent to all Member Nations and Associate Members of FAO and WHO as an advisory text.

The Applicant requests that the Code be amended to permit the use of argon as a processing aid for wine made in accordance with Standard 2.7.4 and for wine made in accordance with Standard 4.1.1.

5.5.1 Issues raised in submissions

All submissions received in response to the Draft Assessment Report supported the proposed amendment.

5.5.2 Safety assessment of argon

Argon is an inert noble gas, which is a normal component of atmospheric air, and is colourless, odourless and tasteless, non-corrosive, non-flammable and non-toxic. It is stable as a gas. Since argon is a gas (boiling point: -185.9 °C), exposure through ingestion is unlikely. Argon can be absorbed into the body by inhalation. The use of argon has some occupational health and safety risks associated with its use because on loss of containment it can cause suffocation by lowering the oxygen content of the air in confined areas. However at the consumer level, its use as a bottling gas raises no health and safety concerns.

From the available information, it is concluded that the use of argon as a processing aid in food would pose no public health and safety risk.

5.5.3 Technological justification for use of argon

The food technology report on the use of argon as a processing aid in wine (at Attachment 2) recommends that argon should be approved for use in winemaking as a processing aid since it has a technological purpose during wine production or processing, including bottling, as a covering gas that displaces air and oxygen.

5.5.4 Evaluation and impact analysis

There are no public health or safety issues associated with the use of argon as a processing aid during winemaking and packaging. The use of argon as a processing aid during wine production is a widely accepted practice in other wine producing countries.

Amending the Code to permit the use of argon for wines made in accordance with either Standard 2.7.4 or Standard 4.1.1 will benefit all affected parties and align the Code's provisions regulating wine more closely with those of the wine producing countries with which Australia and New Zealand trade in wine.

Due to its complete chemical inertness, there are no public health and safety issues associated with the use of argon as a processing aid for any food. Therefore, provided there is technological justification for its use, argon would be a suitable processing aid for use during the manufacture of any food. Providing a general permission for the use of argon, rather than just for wine, will prevent the need for future Applications to amend the Code to permit the use of argon during manufacture of various individual foods.

5.5.5 Preferred approach

At Draft Assessment FSANZ proposed to amend Standard 1.3.3, Table to clause 3 to include argon as a generally permitted processing aid for use in all foods, which includes wine made in accordance with Standard 2.7.4. This amendment is being progressed urgently as part of Proposal P283, which seeks amendments necessary before ratification of the MAA can be finalised. Therefore there is no longer any need for its inclusion in the Assessment of this Application, A474.

At Final Assessment, as at Draft Assessment, FSANZ proposes to amend Standard 4.1.1, Table to clause 4, to include permission for argon as a processing aid with maximum level of use to be limited by good manufacturing practice (GMP).

5.6 Permission to use urease as a processing aid

At Draft Assessment it was not possible to undertake a safety assessment for urease because the primary data toxicological data was not provided. The Applicant advised FSANZ that they wished to withdraw this part of their original Application.

This amendment is being progressed urgently as part of Proposal P283, which seeks amendments necessary before ratification of the MAA can be finalised. Therefore there is no longer any need for its inclusion in the Assessment of this Application, A474.

5.7 Permission to use carbon dioxide as a food additive

For wine made in accordance with Standard 2.7.4, carbon dioxide is permitted for use as a food additive (item 14.2.2, Schedule 1, Standard 1.3.1) and as a processing aid (subclause 3(b), Standard 1.3.3). For wine made in accordance with Standard 4.1.1, carbon dioxide is permitted only for use as a processing aid (Table to clause 4, Standard 4.1.1).

Permission to use carbon dioxide as a food additive is also listed in the Annex 1 of the *Agreement between Australia and the European Community on Trade in Wine, and Protocol* (List of oenological practices authorised for wines originating in Australia and List of oenological practices authorised for wines originating in the Community).

The Applicant requests that the Code be amended to permit the use of carbon dioxide as a food additive for wine made in accordance with Standard 4.1.1 – Wine Production Requirements (Australia only).

5.7.1 *Issues raised in submissions*

All submissions received in response to the Draft Assessment Report supported the proposed amendment.

5.7.2 *Evaluation and impact analysis*

Standard 4.1.1 is an Australia-only wine production standard whose main purpose is to assist in upholding the *Agreement between Australia and the European Community on Trade in Wine, and Protocol*. There are no public health or safety reasons to prohibit the use in Standard 4.1.1 of any processing aid or food additive that is permitted for use in wine made in accordance with Standard 2.7.4. Therefore there are no grounds for not duplicating permissions in Standard 4.1.1 that are permitted for wine made in accordance with Standard 2.7.4 except if such permission would be likely to undermine the Agreement. The use of carbon dioxide is permitted by the Agreement and for wine made in accordance with Standard 2.7.4. Therefore there would be no adverse impact on any affected parties if the proposed amendment were to be accepted. The proposed permission in Standard 4.1.1 would duplicate the existing permission for use in wine made in accordance with Standard 2.7.4 and align with the existing permission in the *Agreement between Australia and the European Community on Trade in Wine, and Protocol*.

If the amendment were not to go ahead, Australian winemakers would not be permitted to use carbon dioxide as a food additive, while all other winemakers of products sold in Australia are permitted to use it. Clearly this would be a considerable disadvantage to Australian winemakers, which cannot be justified.

5.7.3 *Preferred approach*

At Final Assessment, as at Draft Assessment, FSANZ proposes to amend Standard 4.1.1, Table to clause 3, to include carbon dioxide as a permitted food additive with maximum level of use to be limited by good manufacturing practice (GMP).

5.8 Limits for permitted processing aids and food additives where no specific maximum limit is set

In Standard 4.1.1, the Tables to clauses 3 and 4 list processing aid and food additive permissions for wine made in Australia. Clause 5 then provides specific limits for certain substances in wine including some of the permitted processing aids and food additives. However, unlike other parts of the Code (e.g., Standards 1.3.3 and 1.3.1), there is no general limit set.

5.8.1 *Evaluation and impact analysis*

Generally in the Code, where no specific maximum permitted level is specified for a permitted processing aid or food additive, the maximum level of use is limited by good manufacturing practice (GMP). This limit is set for the permitted food additives and processing aids in Standards 1.3.1 and 1.3.3 where no other maximum permitted level is specified. These standards apply to foods including wine in accordance with Standard 2.7.4 but not to wine made in accordance with Standard 4.1.1.

The original intent of the drafting in Standard 4.1.1 was that, where no maximum permitted limit was specified for a processing aid or food additive, GMP limits should apply. This is generally agreed and understood but has not been explicitly provided in the Standard.

To amend Standard 4.1.1 to specify that, where no specific limit is set for a permitted processing aid or food additive, the maximum level of use is to be limited by GMP is a minor amendment, which would have no significant adverse impact on any person or body because it is clarifying the intent of existing drafting.

5.8.2 *Preferred approach*

At Final Assessment, FSANZ proposes to specify in Standard 4.1.1, clause 5 that, where no specific limit is set for a permitted processing aid or food additive, the maximum level of use is to be limited by good manufacturing practice (GMP).

5.9 Inclusion of yeasts in list of permitted processing aids

The Code does not explicitly permit the use of yeasts in wine production. However, the definition for wine contained in Standard 2.7.4 states that wine is the ‘... product of the complete or partial fermentation of ...’. The fermentation process relies on yeasts or bacteria and so permissions for the use of yeasts and bacteria are implied within the definition for wine. In Standard 4.1.1, as well as being implied in the definition for wine (as in Standard 2.7.4), ‘prepared cultures’, which arguably would include ‘yeasts’, are permitted for use in wine production.

The Applicant requests that the Code be amended to include ‘yeasts’ in the Table to clause 4, Processing aids, of Standard 4.1.1. ‘Yeasts’ refers to specific strains of yeast, rather than wild yeast, which may be added to facilitate the primary alcoholic fermentation, where sugar is converted to ethanol. The Applicant claims that the inclusion of ‘yeasts’ would complement the requested inclusion of ‘bacteria’ (see section 5.9) on the list of processing aids, which also may be added to facilitate secondary malolactic fermentation. The Applicant claims that these inclusions, if approved, would make the list of substances that may be added during wine production completely inclusive.

The Applicant indicates that in the USA ‘yeast, cell wall/membranes of autolyzed yeast’ to facilitate the fermentation of juice/wine are included in the list of ‘Materials authorised for treatment of wine and juice’ in 27 CFR 24.246, as is bacteria. Also, yeasts are included in Annex 1 ‘List of oenological practices and processes authorised for wines originating in Australia’, in the *Agreement between the European Community and Australia on trade in wine, and Protocol* and in Annex IV, ‘List of authorised oenological practices and processes’ of *EC Council Regulation No 1493/1999 on the common organisation of the market in wine*.

5.9.1 *Issues raised in submissions*

All submissions received in response to the Draft Assessment Report supported the proposed amendment to include yeasts explicitly in the definition of ‘prepared cultures’. However WFA requested a slight amendment to the proposed drafting to clarify further that there would be permission only for ‘yeasts permitted for food use’.

5.9.2 *Evaluation and impact analysis*

Permission for the use of ‘yeasts permitted for food use’ would not raise any health or safety concerns because, by definition, ‘yeasts permitted for food use’ are those yeasts used traditionally in foods and in food manufacture, which are therefore known and accepted to be suitable and safe for use in food. Arguably such permission is already encompassed in the definition of ‘prepared cultures’ but this proposed amendment would make the current implied permission unambiguous.

Those yeasts and bacteria not traditionally used for food use may be regulated under Standard 1.5.1 – Novel Foods if they raised safety concerns. This would be considered on a case-by-case basis. Thus the term ‘yeasts permitted for food use’ is preferable to the term ‘yeasts’ as it more correctly indicates the regulatory status of yeasts used in wine production.

It is in the interests of all affected parties to amend Standard 4.1.1 to explicitly include ‘yeasts permitted for food use’ because it would remove ambiguity. There are no costs involved in clarifying the intent of existing drafting other than the costs associated with amending the Code itself.

5.9.3 *Preferred approach*

At Draft Assessment FSANZ proposed to amend the definition of ‘prepared cultures’ in Standard 4.1.1, subclause 3(2) to include ‘yeasts’.

At Final Assessment FSANZ proposes to amend the definition of ‘prepared cultures’ in Standard 4.1.1, subclause 3(2) to include ‘yeasts permitted for food use’.

5.10 Inclusion of bacteria in list of permitted processing aids

The Code does not explicitly permit the use of bacteria in wine production. However the definition for wine contained in Standard 2.7.4 states that wine is the ‘... product of the complete or partial fermentation of ...’. The fermentation process relies on yeasts or bacteria and so the permission for the use of yeasts and or bacteria is implicit within the definition for wine. In Standard 4.1.1, as well as being implied in the definition for wine (as in Standard 2.7.4), ‘prepared cultures’, which arguably could include ‘bacteria’, are permitted for use in wine production.

The Applicant requests that the Code be amended to include ‘bacteria’ in the Table to clause 3, Processing aids, of Standard 4.1.1. ‘Bacteria’ in the Application refers to malolactic bacteria, which are added to facilitate secondary malolactic fermentation, where malic acid is converted to lactic acid. The Applicant claims that inclusion of ‘bacteria’ would complement the requested inclusion of ‘yeasts’ (see section 5.8) on the list of processing aids, which also may be added to facilitate primary alcoholic fermentation. These inclusions, if approved, would make the list of substances that may be added during production completely inclusive.

The Applicant indicates that in the USA ‘malo-lactic bacteria to stabilise grape wine’ are included in the list of ‘Materials authorised for treatment of wine and juice’ in 27 CFR 24.246, as are yeasts.

Also, ‘lactic acid bacteria’ are included in Annex 1 ‘List of oenological practices and processes authorised for wines originating in Australia’, in the *Agreement between the European Community and Australia on trade in wine*, and in Annex IV, ‘List of authorised oenological practices and processes’ of *EC Council Regulation No 1493/1999 on the common organisation of the market in wine*.

5.10.1 Issues raised in submissions

Most submissions agreed that the definition for ‘prepared cultures’ in Standard 4.1.1 would not exclude lactic acid bacteria but supported the proposal to amend the drafting to explicitly permit such use. However WFA requested that the drafting be changed from ‘lactic acid bacteria’ to ‘bacteria permitted for food use’. This amendment would not restrict the use of bacteria other than lactic acid bacteria that in future may find applications in winemaking.

5.10.2 Evaluation and impact analysis

Permission for the use of ‘bacteria permitted for food use’ would not raise any health or safety concerns because, by definition, ‘bacteria permitted for food use’ are those bacteria used traditionally in foods and in food manufacture, which are therefore known and permitted to be suitable and safe for use in food. Arguably such permission is already encompassed in the definition of ‘prepared cultures’ but this proposed amendment would make the current implied permission unambiguous.

Those bacteria not traditionally used for food use may be regulated under Standard 1.5.1 – Novel Foods if they raised safety concerns. This would be considered on a case-by-case basis. Thus the term ‘bacteria permitted for food use’ is preferable to the term ‘bacteria’ (as was requested in the original Application) or ‘lactic acid bacteria’ (as was proposed at Draft Assessment) because it more correctly indicates the regulatory status of bacteria used in wine production.

It is in the interests of all affected parties to amend Standard 4.1.1 to explicitly include ‘bacteria permitted for food use’ because it would remove ambiguity. There are no costs involved in clarifying the intent of existing drafting other than the costs associated with amending the Code itself.

5.10.3 Preferred approach

At Draft Assessment FSANZ proposed to amend the definition of ‘prepared cultures’ in Standard 4.1.1, subclause 3(2) to include ‘lactic acid bacteria’.

At Final Assessment FSANZ proposes to amend the definition of ‘prepared cultures’ in Standard 4.1.1, subclause 3(2) to include ‘bacteria permitted for food use’.

5.11 Uncharred oak as permitted processing aid

The Applicant requests that, in Standard 4.1.1, ‘uncharred oak’ be moved from the table listing permitted food additives to the table listing permitted processing aids.

The Applicant claims that this would align with the permission for the use of ‘oak chips’ during wine manufacture in Standard 1.3.3, Table to clause 14, Permitted processing aids with miscellaneous functions, which permits its use as a processing aid for wine made in accordance with Standard 2.7.4.

5.11.1 Issues raised in submissions

All submissions received in response to the Draft Assessment Report supported the requested amendment to move ‘uncharred oak’ from the table listing permitted food additives to the table listing permitted processing aids in Standard 4.1.1.

All but one submission received in response to the Draft Assessment Report supported the proposed amendment to change the listing for ‘oak chips’ in Standard 1.3.3, Table to clause 14, to ‘oak’. In their submission, the Australian Food and Grocery Council (AFGC) considers that there is still a discrepancy between the Code permission to use ‘oak’ (for wine made in accordance with Standard 2.7.4) and the permission to use ‘uncharred oak’ (for wine made in accordance with Standard 4.1.1). AFGC recommends that FSANZ re-examine this discrepancy.

5.11.2 Evaluation and impact analysis

5.11.2.1 Use of oak as process or processing aid

In general a food additive is a substance that is present in the final food and performs a technological function in that food. Wine may be stored in oak containers or with pieces of oak during manufacture to impart distinguishing characteristics to the wine. The oak treatment of wine does not fit any of the permitted technological functions listed in Standard 1.3.1, Schedule 5, and so the use of oak is more appropriately categorised as a process or processing aid.

5.11.2.2 Changing ‘oak chips’ and ‘uncharred oak’ to ‘oak’

FSANZ proposed at Draft Assessment to change the listing in Standard 1.3.3 to ‘oak’ in the interests of improving consistency in the permissions for the use of oak for wine made in accordance with Standards 2.7.4 and 4.1.1. While not aligning the permissions exactly, the proposed drafting made the permissions more consistent.

The AFGC submission suggested that FSANZ re-examine the inconsistency that still remains after the drafting proposed at Draft Assessment.

Many of the provisions in the Australia-only wine production standard, Standard 4.1.1, are not suitable for inclusion in the joint wine standard, Standard 2.7.4 because they are more prescriptive and restrictive. ‘Uncharred oak’ is more prescriptive than ‘oak’ and is therefore more appropriate in a wine production standard than in provisions regulating imported wine. However in order to keep differences to a minimum, the provisions in the two standards should align wherever possible.

As already mentioned, there are no public health or safety reasons to prohibit the use in Standard 4.1.1 of any processing aid or food additive that is already permitted for use in wine made in accordance with Standard 2.7.4.

Therefore, there are no grounds for not duplicating permissions in Standard 4.1.1 that are already permitted for wine made in accordance with Standard 2.7.4 except if such a permission would be likely to undermine the *Agreement between Australia and the European Community on Trade in Wine, and Protocol*. On inquiry from FSANZ, the WFA agreed that ‘uncharred oak’ could be changed to ‘oak’ in Standard 4.1.1, without any compromise to the integrity of the EC Agreement.

5.11.3 Preferred approach

5.11.3.1 Use of oak as process or processing aid

At Final Assessment, as at Draft Assessment, FSANZ proposes to move the permission for oak from the list of permitted food additives to the list of permitted processing aids in Standard 4.1.1.

5.11.3.2 Changing ‘oak chips’ and ‘uncharred oak’ to ‘oak’

At Final Assessment, as at Draft Assessment, FSANZ proposes to change the listing for ‘oak chips’ in the Standard 1.3.3, Table to clause 14, to ‘oak’.

In addition, at Final Assessment, FSANZ proposes to change the permission for ‘uncharred oak’ to ‘oak’ in Standard 4.1.1.

5.12 Restoration of definitions, and compositional and labelling requirements for wine products and ‘low alcohol’, ‘reduced alcohol’ and ‘dealcoholised’ wine

The original Application requested amendments concerning wine products and with ‘low alcohol’, ‘reduced alcohol’ and ‘dealcoholised’ wine.

None of the submissions received in response to the Initial Assessment Report, except that of the Applicant, supported the requested amendments for the compositional and labelling requirements. The Applicant advised FSANZ advising that they do not wish to continue with these parts of the Application.

5.13 Other minor proposed changes treated in separate omnibus amendments Proposal

The Application also requested a number of changes to Standard 4.1.1. These proposed amendments were of minor significance only, intended to correct minor omissions and inconsistencies, to correctly categorise permitted substances as processing aids or food additives, or to provide additional permissions that are already permitted by the joint wine standard, Standard 2.7.4.

These minor amendments were progressed separately as part of Proposal P266. These amendments (listed at Attachment 4) to Standard 4.1.1 were approved by the Board in May 2003, notified to the Australia and New Zealand Food Regulation Ministerial Council, and gazetted in July 2003.

5.14 Change to title of wine production standard

Ongoing work in the development of primary production and processing standards within Chapter 4 of the Code requires a restructuring of the Chapter 4 Index. The restructure does not involve the amendment of the legally enforceable part of the Code and is not an amendment ‘to a standard’. The restructure merely involves a change in the title of the wine production standard from ‘Standard 4.1.1 – Wine Production Requirements (Australia only)’ to ‘Standard 4.5.1 – Wine Production Requirements (Australia only)’.

6. Regulatory options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles.

The following regulatory options are available for this Application:

Option 1 Approve all the proposed changes to the wine regulations in the Code.

Option 2 Not approve any of the proposed changes to the wine regulations in the Code.

7. Impact analysis

7.1 Affected parties

The affected parties to this Application include those listed below:

1. wine producers, importers and exporters in Australia, New Zealand and worldwide;
2. wine consumers in Australia and in New Zealand;
3. Australian State and Territory and New Zealand government enforcement agencies that enforce food regulations; and
4. enforcement agencies in countries importing wine made in Australia or New Zealand.

7.2 Impact analysis

The costs and benefits relating to the proposed amendments and issues raised in submissions that are associated with these costs and benefits are analysed under the relevant issue-specific headings in Section 5 above.

8. Consultation

Five submissions were received in response to the Draft Assessment Report:

- one from the peak national organisation representing Australia’s packaged food, drink and grocery products industry (Australian Food and Grocery Council);

- one from an Australian State Government Department (Department of Human Services (Food Section), South Australia);
- one from a state based food technology association (Food Technology Association of Victoria Inc.);
- one from a New Zealand Government Authority (New Zealand Food Safety Authority); and
- one from the peak organisation representing the wine industry in Australia (Winemakers' Federation of Australia).

Specific issues raised in submissions are covered and evaluated under the relevant headings in Section 5.

A summary of submissions received in response to the Draft Assessment report is at Attachment 3.

8.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations 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 widely accepted international standards for winemaking. Amending the Code to allow the proposed changes to wine regulation is likely to assist trade in wine, especially in countries with which Australia has existing agreements on trade in wine, because the proposed changes are consistent with those countries' domestic wine regulations. Therefore the WTO was not notified.

9. Conclusion and recommendation

In reaching its conclusions on these matters FSANZ has considered:

- the issues raised in submissions received in response to the Draft Assessment Report;
- issues associated with technological justification for the requested amendments; and
- public health and safety issues associated with the requested amendments.

FSANZ's conclusions at Final Assessment of Application A474 are the same as its recommendations at Draft Assessment with the following exceptions:

- the previously proposed inclusion of 'lactic acid bacteria' and 'yeasts' in the definition of 'prepared cultures' in Standard 4.1.1 has been changed to 'bacteria and yeasts permitted for food use';

- permission for ‘uncharred oak’ has been changed to ‘oak’ in Standard 4.1.1 to align it with the permission for ‘oak’ for wine made in accordance with Standard 2.7.4;
- the previously proposed inclusion of argon in Standard 1.3.3, table to clause 3 has been progressed separately in Proposal P283 and is no longer included in the drafting for this Final Assessment of Application A474;
- the previously proposed inclusion of gum arabic in item 14.2.2, of Schedule 1, Standard 1.3.1 – Food Additives has been progressed separately in Proposal P283 and is no longer included in the drafting for this Final Assessment of Application A474; and
- a consequential minor amendment to Standard 4.1.1 to provide that the maximum level of use for permitted processing aids and food additives is to be limited by good manufacturing practice (GMP), where no other limit is specified in the Standard.

At Final Assessment, FSANZ concludes that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended as follows:

- change the definition of wine to be the same as that in Standard 2.7.4;
- include a compositional requirement that prohibits the addition of ethanol to wine except where explicitly permitted within the Standard;
- include gum arabic as a permitted food additive in the Table to clause 3 with maximum level of use to be limited by good manufacturing practice (GMP);
- include argon as a permitted processing aid in the Table to clause 4 with maximum level of use to be limited by good manufacturing practice (GMP);
- include carbon dioxide as a permitted food additive in the Table to clause 3 with maximum level of use to be limited by good manufacturing practice (GMP);
- include a provision that the maximum level of use for permitted processing aids and food additives is to be limited by good manufacturing practice (GMP), where no other limit is specified in the Standard;
- include ‘bacteria and yeasts permitted for food use’ in the definition of ‘prepared cultures’ in subclause 3(2);
- remove ‘uncharred oak’ from the list of permitted food additives in Table to clause 3 and add ‘oak’ to the list of permitted processing aids in the Table to clause 4; and
- change the title of the wine production standard from ‘Standard 4.1.1 – Wine Production Requirements (Australia only)’ to ‘Standard 4.5.1 – Wine Production Requirements (Australia only)’.

At Final Assessment, FSANZ concludes that Standard 1.3.3 – Processing Aids be amended as follows:

- in the Table to clause 14, the entry for ‘oak chips’ be amended to ‘oak’.

Reasons for these conclusions are that the proposed amendments:

- for Standard 4.1.1 are already permitted for wine made in accordance with Standard 2.7.4 and so are suitable for inclusion in Standard 4.1.1 without extensive re-evaluation, thus giving Australian winemakers permissions that are available for use in wine sold in Australia;
- clarify existing drafting without changing the original intent or are consequential to a proposed amendment;
- align provisions in Standard 4.1.1 more closely with those in Code that regulate wine made in accordance with the joint wine standard, Standard 2.7.4;
- in the case of the newly proposed processing aid, argon, food technology and safety assessment reports conclude that its use is technologically justified and would raise no public health and safety concerns; and
- provide more consistency with the winemaking provisions of other countries with which Australia and New Zealand trade in wine.

10. Implementation and review

FSANZ recommends that the effective date for the proposed amendments be from the date of gazettal.

ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*
2. Food technology report for argon
3. Summary of submission received in response to Draft Assessment Report
4. Minor changes to Standard 4.1.1 – Wine Production Requirements (Australia only) progressed separately as part of Proposal P266, Minor Amendments Omnibus IV

Draft Variations to the *Australia New Zealand Food Standards Code*

To commence: On gazettal

[1] **Standard 1.3.3** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting from the Table to Clause 14, the Substance –*

Oak chips

substituting –

Oak

[2] **Standard 4.1.1** of the *Australia New Zealand Food Standards Code* is varied by –

[2.1] *omitting from the heading of the Standard –*

Standard 4.1.1

substituting –

Standard 4.5.1

[2.2] *omitting from clause 1, the definition of wine, substituting –*

wine means the product of the complete or partial fermentation of fresh grapes, or a mixture of that product and products derived solely from grapes.

[2.3] *omitting from subclause 3(2), the definition of prepared cultures substituting –*

prepared cultures means cultures of micro-organisms such as yeasts or bacteria permitted for food use (including yeast ghosts) used in wine manufacture with or without the addition of any one or more of thiamine hydrochloride, niacin, pyridoxine, pantothenic acid, biotin and inositol.

[2.4] *inserting in the Table to clause 3 –*

Carbon dioxide
Gum Arabic

[2.5] *omitting Uncharred oak from the Table to clause 3 and inserting in the Table to clause 4 –*

Oak

[2.6] *inserting in the Table to clause 4 –*

Argon

[2.7] *omitting clause 5, substituting –*

5 Composition

- (1) Wine and sparkling wine must contain no less than 80 mL/L of ethanol at 20°C.
- (2) Notwithstanding subclause (1), wine must not contain added ethanol.
- (3) Fortified wine must contain no less than 150 mL/L and no more than 220 mL/L of ethanol at 20°C.
- (4) Wine, sparkling wine and fortified wine must not contain methanol –
 - (a) in proportion exceeding 2 g/L of ethanol content at 20°C in the case of white wine and white sparkling wine; and
 - (b) in the case of other products, in proportion exceeding 3 g/L of ethanol content at 20°C.
- (5) Wine, sparkling wine and fortified wine must contain no more than –
 - (a) 250 mg/L in total of sulphur dioxide in the case of products containing less than 35 g/L of sugars, or 300 mg/L in total of sulphur dioxide in the case of other products; and
 - (b) 200 mg/L of sorbic acid or potassium sorbate expressed as sorbic acid; and
 - (c) 100 mg/L of polyvinyl polypyrrolidone; and
 - (d) 1 g/L of soluble chlorides expressed as sodium chloride; and
 - (e) 2 g/L of soluble sulphates expressed as potassium sulphate; and
 - (f) 400 mg/L of soluble phosphates expressed as phosphorus; and
 - (g) 1.5 g/L of volatile acidity excluding sulphur dioxide, expressed as acetic acid; and
 - (h) 0.1 mg/L of cyanides and complex cyanides expressed as hydrocyanic acid; and
 - (i) 200 mg/L of dimethyl dicarbonate.
- (6) If potassium ferrocyanide has been used as a processing aid in the manufacture of a wine, sparkling wine or fortified wine, the final product must have residual iron present.
- (7) Wine, sparkling wine and fortified wine may contain water in proportion not exceeding 30 mL/L where the water is necessary for the incorporation of any substance specified in clause 3 or clause 4.

Food Technology Report for Argon

Argon (Ar) is colourless, odourless, inert, monoatomic gas (being one of the noble elements, group O or VIIIA of the Periodic Table). Other inert noble gases in this group are helium and neon. Noble gases are characterised by having an entirely filled electronic outer p subshell, which is the reason they are inert. Argon's atomic number is 18 and it has an atomic weight of 39.948. It is found at low levels in air. It is normally obtained from the liquefaction and separation of air. Its abundance is 93.4 $\mu\text{L/L}$ in dry air. Argon's density at Standard Temperature and Pressure (STP: 0°C, 1 atmosphere pressure) is 1.78 mg cm^{-3} compared to 1.25 mg cm^{-3} for nitrogen. Its solubility in water at 20°C is 33.6 cm^{-3}/kg (mL/L), which is greater than nitrogen but a lot less than carbon dioxide^{1,2}.

Argon is one of three gases (the others are carbon dioxide and nitrogen) that the wine industry wishes to use to displace air (oxygen) during wine production and bottling. The use of such gases is to displace oxygen, thereby limiting deleterious oxidation of wine and preventing the growth of unwanted bacteria and yeast during wine production. Argon is the heaviest of the three gases so is best able to displace oxygen.

Argon is more expensive and is more soluble in water (and wine) than nitrogen but it has the advantage of being heavier than nitrogen so can displace air (oxygen) and so acts as an inert blanket gas better than nitrogen. Which displacement gas wine producers use will depend on the job they wish it to do and the balance of advantages and disadvantages.

Argon is a permitted processing aid for winemaking in various international organisations, including Codex (*Codex inventory of all compounds used as processing aids*, 1989), the Office International de la Vigne et du Vin (OIV) and the European Community (contained in Annex 1 of the *Agreement between Australia and the European Community on trade in wine, and Protocol*).

Argon is an inert gas, which if used in winemaking would not be considered a food additive since it has no function in the final food and does not meet any of the technological functions listed in Schedule 5 of Standard 1.3.1 of the *Australia New Zealand Food Standards Code*. Argon is technologically justified for use in winemaking as a processing aid because since it has a technological purpose during wine production or processing including bottling, as a covering gas that displaces air (oxygen), and does not perform this function in the final food.

References:

1. Greenwood N N and Earnshaw A *Chemistry of the Elements* 1984 Pergamon Press New York pp 1042-1045.
2. The Merck Index (13th Ed) 2001 Merck & Co. Inc. Whitehouse Station NJ.

Summary of submissions received in response to the Draft Assessment Report

List of submitters:

- 1 Australian Food and Grocery Council
- 2 Department of Human Services (Food Section), South Australia
- 3 Food Technology Association of Victoria Inc
- 4 New Zealand Food Safety Authority
- 5 Winemakers' Federation of Australia

Australian Food and Grocery Council

- Continues to support the outcome that many of the amendments requested in the original Application [those relating to wine product and labelling] are not to be included in the Code.
- Considers that there is still a discrepancy in the Code permission for 'oak' and 'uncharred oak' for wine made in accordance with Standard 2.7.4 and Standard 4.1.1 respectively and recommends that FSANZ re-examines the discrepancy.
- With this exception, AFGC supports the proposed changes recommended in the Draft Assessment Report.

Department of Human Services (Food Section), South Australia

Supports option 1 – recommending amendment of wine regulations in the Code.

Food Technology Association of Victoria Inc

Agrees with Option 1 – to approve all the proposed changes to the wine regulations in the Code.

New Zealand Food Safety Authority

- Agrees that the definitions of wine in Standard 2.7.4 and Standard 4.1.1 should be consistent and so agrees with the proposed changes to the definition of Standard 4.1.1. However NZFSA considers that urgent clarification is needed as to whether ethanol may be added to wine if made in accordance with Standard 2.7.4. Considers that the treatment of ethanol addition to wine is inconsistent for wine made in accordance with Standard 2.7.4 and Standard 4.1.1. Also considers that clarification in Standard 2.7.4 on this issue is within the scope of this Application and could be addressed here.
- Agrees with the recommendation that gum arabic should be permitted in wine made in accordance with Standard 2.7.4 and Standard 4.1.1.

- Agrees with the recommendation that argon should be permitted as a processing aid in wine made in accordance with Standard 2.7.4 and Standard 4.1.1.
- Requests an amendment to remove permission for use of urea as a microbial nutrient in wine.
- Agrees with the proposed amendments concerning yeasts and bacteria.
- Agrees with changing ‘oak chips’ to ‘oak’ to make terminology more consistent.

Winemakers’ Federation of Australia

Requests change of drafting proposed at Draft Assessment for inclusion in definition of ‘prepared cultures’ in Standard 4.1.1 from ‘yeasts and lactic acid bacteria’ to ‘yeasts and bacteria approved for food use’.

Minor changes to Standard 4.1.1 – Wine Production Requirements (Australia only) progressed separately as part of Proposal P266 – Minor Amendments Omnibus IV

Application A474 from the Winemakers' Federation of Australia, received on 24 June 2002, contained a number of requested amendments that were of minor impact only and that were progressed separately in a minor amendments omnibus Proposal, P266.

The Board agreed the amendments proposed in P266 in May 2003 and the amendments were gazetted in July 2003. The extract below details these changes.

Extract from Final Assessment Report P266 – Minor Amendments Omnibus IV:

Standard 4.1.1 – Wine Production Requirements (Australia only)

Location: Table of permitted additives (Table to clause 3) and Table of permitted processing aids (Table to clause 4).

Explanation: The following list of proposed amendments are of minor impact only, intending to correct minor omissions and inconsistencies, to correctly categorise permitted substances as processing aids or food additives; or to provide additional permissions that are already permitted by the joint wine standard, Standard 2.7.4 – Wine and Wine Product.

- in Table to clause 3, change 'potassium metabisulphite' to 'potassium sulphites' to make consistent with wine standard and wine standards in other countries;
- in Table to clause 3, change 'tannin' to 'tannins' to make consistent with joint wine standard and wine standards in other countries;
- in Table to clause 4, add permission to use 'lysozyme' (already permitted for use as a processing aid in wine standard via subclause 3(b) of Standard 1.3.3);
- in Table to clause 3, replace 'diammonium hydrogen phosphate' with 'ammonium phosphates' and move permission to Table 4 (ammonium phosphates are used as yeast nutrients and hence are processing aids but are listed currently with food additives);
- in Table to clause 3, add permission to use 'thiamin chloride' as well as 'thiamin hydrochloride' and move thiamin permissions to Table to clause 4 (thiamin is used as a yeast nutrient and hence these substances are processing aids but are listed currently with food additives);
- in Table to clause 3, move qualification for use of thiamin to Table to clause 4 (to accompany the moved permission for thiamin);
- in Table to clause 3, move 'potassium hydrogen tartrate' to Table to clause 4 (used as a processing aid but is currently listed as a food additive);

- in Table to clause 3, move ‘prepared cultures’ to Table to clause 4 (used as a processing aid but is currently listed as a food additive);
- in Table to clause 3, replace ‘prepared cultures’ with ‘cultures of micro-organisms’, which is more specific and unambiguous wording;
- in Table to clause 3, permit use of dimethyl dicarbonate with a maximum permitted level of 200 mg/kg (the maximum permitted level to be included as paragraph 5(4)(i))(permitted as a food additive in wine standard through listing in Schedule 1 of Std 1.3.1);
- in Table to clause 4, add permission for use of ‘calcium tartrate’ as processing aid (permitted as processing aid in wine standard through listing in Schedule 2 of Standard 1.3.1);
- in Table to clause 4, add permission to use ‘perlite’ (permitted as processing aid in joint wine standard through listing in Table to clause 3 of Standard 1.3.3);
- in Table to clause 4, add permission for use of ‘cellulose’ as a processing aid (inert filtration agent) (permitted as processing aid in wine standard through listing in Schedule 2 of Standard 1.3.1);
- in Table to clause 4, delete ‘calcium alginate’ and ‘potassium alginate’ and replace with ‘alginates, calcium and potassium salts’. This listing is more consistent with common drafting practice; and
- in Table to clause 4, consolidate listings for different milk products by deleting ‘casein’, ‘evaporated milk’, ‘milk’, and ‘potassium caseinate’ and replacing with ‘milk and milk products’.

Solution: Replace Table to clause 3 and Table to clause 4 with Tables below; add a maximum permitted level for dimethyl dicarbonate of 200 mg/kg as paragraph 5(4)(i).

Table to clause 3

Additive
Ascorbic acid
Calcium carbonate
Citric acid
Dimethyl dicarbonate
Erythorbic acid
Grape juice including concentrated grape juice
Lactic acid
Malic acid
Metatartaric acid
Mistelle
Potassium carbonate
Potassium hydrogen carbonate
Potassium sulphites
Potassium sorbate
Sorbic acid

Sulphur dioxide Tannins Tartaric acid Uncharred oak
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Table to clause 4

Processing aid
Activated carbon
Agar
Alginates, calcium and potassium salts
Ammonium phosphates
Bentonite
Calcium tartrate
Carbon dioxide
Cellulose
Copper sulphate
Cultures of micro-organisms
Diatomaceous earth
Egg white
Enzymes
Gelatine
Hydrogen peroxide
Ion exchange resins
Isinglass
Lysozyme
Milk and milk products
Nitrogen
Oxygen
Perlite
Phytates
Polyvinyl polypyrrolidone
Potassium ferrocyanide
Potassium hydrogen tartrate
Silicon dioxide
Thiamin chloride*
Thiamin hydrochloride*

*Thiamin chloride and thiamin hydrochloride may only be added to wine, sparkling wine and fortified wine to facilitate the growth of micro-organisms.

Location: Paragraph 6(1)(a).

Explanation: Provisions concerning the strength of the fortifying grape-derived alcohol were previously prescribed in Standard P4 in order to reduce the level of potential impurities in sparkling and fortified wine. These provisions were carried over without amendment into Standard 4.1.1. However these matters are adequately covered in Sections 57A and 57B of the *Distillation Act 1901* and so are not required in the Code. That is, the qualification for ‘grape spirit’ used in the manufacture of ‘sparkling wine’ is no longer required in Standard 4.1.1.

Solution: After ‘grape spirit’ delete ‘containing no less than 740 mL/L of ethanol at 20°C’.

Location: Paragraph 6(1)(b).

Explanation: Provisions concerning the strength of the fortifying grape-derived alcohol were previously prescribed in Standard P4 in order to reduce the level of potential impurities in sparkling and fortified wine. These provisions were carried over without amendment into Standard 4.1.1. However these matters are adequately covered in sections 57A and 57B of the *Distillation Act 1901* and are not required in the Code. That is, the qualification for ‘brandy’ used in the manufacture of ‘sparkling wine’ is no longer required in Standard 4.1.1.

Solution: After ‘brandy, delete ‘containing no less than 571 mL/L of ethanol at 20°C’.

Location: Clause 7.

Explanation: Provisions concerning the strength of the fortifying grape-derived alcohol were previously prescribed in Standard P4 in order to reduce the level of potential impurities in sparkling and fortified wine. However these matters are adequately covered in Sections 57A and 57B of the *Distillation Act 1901* and so are not required in the Code. That is, qualifications for ‘brandy’ and ‘grape spirit’ used in the manufacture of ‘fortified wine’ are no longer required in Standard 4.1.1.

Solution: Delete subclauses (1) and (2) and renumber subclause (3) as subclause (1).