FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

APPLICATION A1047
SODIUM CARBOXYMETHYLCELLULOSE AS A FOOD ADDITIVE IN WINE
EXPLANATORY STATEMENT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from the Winemakers' Federation of Australia (WFA) on 6 May 2010. This Application soughtto amend Standard 1.3.1 – Food Additives and Australia-only Standard 4.5.1 – Wine Production Requirements of the *Australia New Zealand Food Standards Code* (the Code) to allow sodium carboxymethylcellulose (sodium CMC) as an additive in wine and sparkling wine.

Sodium CMC stabilises wine by inhibiting tartrate crystal formation and subsequent precipitation which can cause cloudiness and sediment formation and make the wine undesirable to drink. Sodium CMC is intended to be used as an additional tool, rather than as a replacement for existing tartrate crystal control methods.

Prior to any approval being granted for a new food additive or an extension of use, a pre-market assessment of its safety and technological function is required.

Food additives are regulated under Standard 1.3.1 – Food Additives, which applies to both Australia and New Zealand. Sodium CMC is already permitted under Standard 1.3.1 for a number of foods, but not wine. Thus an amendment to this Standard was sought.

Wine produced in Australia, regardless of where it is finally sold, needs to comply with Standard 4.5.1– Wine Production Requirements. As sodium CMC is currently not listed as an additive allowed in wine production under Standard 4.5.1, an amendment to this standard wasalso sought.

Approval of sodium CMC as an additive in wine wassought to meet requirements under the 2008 *Agreement between Australia and the European Community for Trade in Wine.* Currentlywines which contain sodium CMC, including those from the European Union(EU), are not legal in Australia or New Zealand.

The Application was assessed under the General Procedure.

Risk and Technical Assessment

A Risk and Technical Assessment was undertaken to determine whether the use of sodium CMC as an additive in wine is technologically justified and safe for use.

Evidence presented by the Applicant in support of the Application provided adequate assurance to FSANZ that the use of the additive for the proposed purpose is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

The hazard assessment considered the history of safe use of sodium CMC in other foods. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not assigned sodium CMC a numerical Acceptable Daily Intake (ADI) value. Instead, it has been assigned a 'not specified' ADI which applies to substances of low hazard. FSANZ agrees with the conclusions of JECFA. On the basis of this ADI and that the additional contribution to dietary exposure arising from wine consumption will be negligible, the additive is considered not to pose a risk to public health.

The overall conclusion of the risk and technical assessment is that the use of sodium CMC as an additive in wine to inhibit tartrate crystal formation is technologically justified and raises no public health or safety issues.

Risk Management

The Application stated that the maximum concentration of sodium CMC expected to be used in wine is 100 mg/L. As this Application is an extension to the use of sodium CMC and considering there are no specific public health or safety issues identified for this extended use, FSANZ proposes to permit the use of sodium CMC in wine and sparkling wine at good manufacturing practice (GMP) levels, rather than set a specific maximum limit.

Wines containing this additive will not need to be labelled as they are not subject to labelling on the final food under subclause 2(b) of Standard 1.2.4 – Labelling of Ingredients.

The additive is already permitted in other foods and a specification already exists. No amendments to the specification areconsidered necessary.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the*Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from varying the Code to allow sodium CMC as an additive in wine and sparkling wine outweigh the direct and indirect benefits to the community, Government or industry
- whether there are any other measures that would be more cost-effective than a variation to Standards 1.3.1 and 4.5.1 that could achieve the same end
- whether there are any relevant New Zealand standards
- any other relevant matters

Decision

To approvedraft variations to Standards1.3.1 – Food Additives and 4.5.1 – Wine Production Requirements to permit the use of sodium carboxymethylcellulose as an additive in wine and sparkling wine.

Reasons for Decision

- The safety assessment has concluded that the use of sodium CMC in winedoes not raise any public health or safety concerns.
- Use of the additive to stabilise wine and sparkling wine is technologically justified and would be expected to provide benefits to wine producers and consumers as an alternative to current treatments.
- Permitting use of the additive in wine and sparkling wines would not impose significant costs for government agencies, consumers or producers.
- The amended draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards that would impact on our decision to amend the Code.
- There are no other measures than variations to Standards 1.3.1 and 4.5.1 that could achieve the same end.

Consultation

This Application was assessed under the General Procedure with one round of public consultation.

Public comment on the draft variation arising from this Application was sought from 31 May to 11 July 2011. Comments were specifically requested on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of the additive to be used as an additive in wine and sparkling wine. Six submissions were received. The issues raised in these submissions have been carefully considered by FSANZ. A summary of the submissions and FSANZ responses are provided at **Attachment 2** to this Report.

CONTENTS

SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this ApprovalReport, is available on the FSANZ website athttp://www.foodstandards.gov.au/foodstandards/applications/applicationa1047sodi4816.cfm

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from the Winemakers' Federation of Australia (WFA) on 6May 2010. The WFA is the peak national body for the Australian wine industry.

This application sought to amend Standard 1.3.1 – Food Additives, of the *Australia New Zealand Food Standards Code* (the Code), to permit the use of sodium carboxymethylcellulose (sodium CMC, INS Number 466) as an additive in wine and sparkling wine. As wine produced in Australia must comply with Standard4.5.1 – Wine Production Requirements, an amendment to this Standard was also sought.

1. The Issue / Problem

Application A1047seeks an extension of use of sodium CMC to enable it to be used in wine and sparkling wine production as an additional tool for preventing clouding and sediment formation resulting from the precipitation of tartrate crystals. The tartrate is mainly potassium tartrate; however calcium tartrate can also be present. As a result of changes in temperatureduring transport and storage, tartrate can crystallise in wine, resulting in cloudy wine with sediment which is undesirable to many consumers.

The Applicant submitted data that supports the claim that the additive works by inhibiting crystal growth in wine. Sodium CMC is added to the wine towards the end of the production process, and unlike other existing tartrate crystal control methods, chilling or filtration steps are not required.

Approval of sodium CMC as an additive in wine wasalso sought to meet requirements under the 2008 *Agreement between Australia and the European Community for Trade in Wine*(Australia – EU Wine Agreement). Currently,European Union(EU) wines which contain sodium CMC cannot be legally sold in Australia or New Zealand.

A pre-market assessment and approval is required before any new additive or, as in this case, an alternative use of an approved additive is permitted. A safety assessment of the additive, as well as an assessment of the technological suitability of the additive for its purported use, must be undertaken and considered before any permission may be granted.

2. Current Standard

2.1 Background

Additives used in wine production are regulated under Standards 1.3.1 and 4.5.1.

Afood additive is described in the Purpose of Standard 1.3.1as follows:

> *A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its product may remain in the food.*

Schedule 5 to Standard 1.3.1 contains a list of technological functions which may be performed by food additives. This additive is considered to be consistent with the Stabiliser functional class.

Stabiliser is described in Schedule 5 as follows:

Functional class *sub-classes*	Definition
Stabiliser binder, firming agent, water binding agent, foam stabiliser	maintains a homogeneous dispersion of two or more immiscible substances in a food

Standard 1.3.1 details which additives are permitted in which foods. Although sodium CMC is permitted under this Standard for a variety of foods, it is not currently permitted in wine. For sodium CMC to be permitted in wine,item 14.2.2 of Schedule 1 of Standard 1.3.1 needs to be amended as this details which additives are permitted to be added to wine, sparkling wine and fortified wine.

The Table to clause 3 in Standard 4.5.1 contains a list of additives permitted to be used in wine production. Currently,sodium CMC is not included.

2.2 Scope of the Application

The proposed amendment to Standard 1.3.1, applies to wine and sparkling wine sold in Australia and New Zealand regardless of where it is produced.

The proposed amendment to Standard 4.5.1 applies to the production of wine and sparkling wine in Australia only, no matter where it is sold.

2.3 International and New Zealand Regulations

Sodium CMC has been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The most recent assessment was at its 35th meeting (WHO 1990). At this meeting,JECFA established an ADI of 'not specified' reflecting the low toxicity and history of safe use of this additive in food.

The additive is approved for use in wine in the European Union (EU 2009).

In New Zealand, winemakers must comply with the Wine Act 2003 and the Regulations, Specifications and notices made under this Act. This Act does not address additives and therefore this application does not impact on New Zealand-specific legislation. However, all wine sold in New Zealand must meet the composition and labelling requirements of the Code.

2.4 Nature of the additive

CMC is a cellulose derivative that is extracted from plant fibres by treating them with an alkali and chloroacetic acid.

The manufacture and specification of sodium CMC for the use in wine and sparkling wine does not vary from sodium CMC used for other food additive purposes in other foods. The International Organisation of Vine and Wine monograph on CMC (OIV 2009)states that CMC for oenological use should be prepared exclusively from wood.

2.5 Technological Purpose

Sodium CMC is intended to be used in wine production as an additional tool for preventing clouding and sediment formation resulting from the precipitation of tartrate crystals. Cloudy wine with sediment may be undesirable to consumers.

Information provided by the Applicant states that in contrast to the existing metatartaric acid method the effectiveness of sodium CMC additive is temperature insensitive and thus crystal stability is obtained even with temperature fluctuations, such as those which occur during transport. However,other currently available methods for tartrate crystal control need to be retained as under certain circumstances e.g. for high quality wine, wine which is strongly saturated with tartrate or wines with high levels of calcium tartrate, the existing methods may be more suitable.

The Applicant provided data showingthe additive works by inhibiting tartrate crystal growth in wine. The additive acts as a protective colloid which attaches to the surface of dissolved tartrate and prevents tartrate crystals seeding and subsequently precipitating. Sodium CMC is added to the wine towards the end of the production process.

The Application proposed a maximum use level of 100 mg/L. Information provided with the Application, namely results of tests to investigate the degree of tartrate crystal precipitation overtime,wasdeemed sufficient by FSANZ to demonstrate that the use of sodium CMC at this proposed level is effective.

As there is no specific public health or safety concerns identified for this extended use and for other approved uses of sodium CMC the maximum permitted level is GMP, FSANZ proposes to set the maximum permissible level of sodium CMC in wine and sparkling wine also at GMP.

3. Objectives

The objective of theAssessment was to determine whether it is appropriate to amend Standards 1.3.1 and 4.5.1 to permit the use of sodium CMC as an additive in wine and sparkling wine.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- 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.

The Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Mineral*sincludespolicy principles in regard to substances added to achieve a solely technological function such as food additives and processing aids. According to these guidelines, permissions 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.

4. Questions answered

For this Application, FSANZ considered the following key questions to address the objectives described in section 3:

- Does the additive present any food safety issues?
- Does the additive achieve its stated technological purpose?

RISK ASSESSMENT

An assessment of the safety and technical function of sodium CMC was undertaken and presented in the Assessment Report.

In addition to information supplied by the Applicant, other available resource material, including published scientific literature and general technical information, was usedby FSANZ in this assessment.

5. Risk and Technical Assessment Summary

5.1 Summary

Sodium CMC is already a permitted food additive in Australia and New Zealand. Its use as an additive in wine has, however, not previously been assessed under the Code.

The hazard assessment considered the long history of safe use of sodium CMC as a food additive. At its last consideration, the 35th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake (ADI) of 'not specified' for CMC (WHO 1990). An ADI of 'not specified' is applicable to a substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other) and the total daily intake of the substance arising from its use or uses at the levels necessary to achieve the desired effect, does not represent a hazard to health. In such cases, establishment of an ADI expressed in numerical form is not considered necessary.

FSANZ agrees with this assessment. Based on the maximum proposed use level stated in the Application (100 mg/L), a 750 mL bottle of wine will only contain a small amount (75 mg) of sodium CMC.

There are no reports of allergy to sodiumCMC in food (Dumond et al, 2009).

Evidence presented in support of the Application provided adequate assurance that the additive is technologically justified and has been demonstrated to be effective in achieving its stated purpose. In addition, the Application explains that the use of sodium CMC in wine for tartrate crystal control has economic benefits over other available methods as it does not require energy dependent steps such as chilling or filtration.

Sodium CMC is currently approved for other foods.No amendments to the specification are required.

5.2 Conclusions

The FSANZ overall conclusion of this risk and technical assessment is that the use of sodium CMC as an additive in wine is technologically justified, is effective at the maximum expected use level in wine of 100 mg/L, and raises no public health or safety issues.

Risk Management

6. Risk Management Issues

FSANZ's regulatory approach differs depending on the nature of the risks identified and there are a number of approaches used to manage identified risks. These may include prescribing specifications for the identity and purity of the substance, compositional and/or labelling requirements, and where necessary, restriction or prohibition. Drawing on the conclusions from the risk assessment, the following sections discuss other broader issues requiring consideration in the development of regulations for addition of sodium CMC to wine.

6.1 Specifications for sodium CMC

Standard 1.3.4 – Identity and Purity adopts specifications for food additives (and other substances in foods) by reference to specific sources, including specifications established by JECFA.

The purpose of Standard 1.3.4 is to regulate the identity and purity of substances.
As sodium CMC is not a novel additive, and a JECFA specification (JECFA 2006) already exists, no amendment to the specification is considered necessary.

6.2 Methods of analysis

As FSANZ proposes to permit the use of sodium CMC in wine and sparkling wine at good manufacturing practice (GMP) levels, rather than set a specific maximum level, the provision of a specific analytical method for sodium CMC in wine is not necessary.

FSANZ,howevernotes that a 2010 OIV Resolution (OIV 2010) provides a method for the determination of sodium CMC in white winesand the JECFA specification (JECFA 2006) provides a specification for sodium CMC itself.

6.3 Labelling of sodium CMC-containing wine products

Labelling provisions are included within the Code to protect public health and safety and to provide adequate information to enable consumers to make informed choices.

Under subclause 2(b) of Standard 1.2.4 – Labelling of Ingredients, alcoholic beverages standardised in Standard 2.7.2 to Standard 2.7.5 are exempt from ingredient labelling including food additives. Wine and sparkling wine are standardised in Standard 2.7.4 – Wine and Wine Product. Therefore, as with any other additive that is not allergenic or genetically modified, sodium CMC would not be required to be declared on the label.

6.4 Risk Management Strategy

This application sought permission for sodium CMC to be used in wine and sparkling wine but not fortified wine. Therefore, consistent with this request, FSANZ is proposing to permit the use of sodium CMC in wine and sparkling wine but not fortified wine. This is also consistent with the OIV resolution (OIV 2009) and the current EU approval (EU 2009). The latter point is important as one of the justifications the Applicant has made for the use of sodium CMC in wine is to allow EU produced wines which contain sodium CMC to be imported into Australia and New Zealand.

6.5 Consistency with Policy Guidelines

As noted in Section 3, FSANZ is required to have regard to the Policy Guideline on the Addition of Substances other than Vitamins and Minerals to foods. Since the purpose for addition of sodium CMC to food falls under 'Technological Function', regard has been given particularly to the specific order policy principles for 'Technological Function'.

It has been determined that the Applicant provided a clear stated purpose, sodiumCMC is safe for human consumption, there is a clear technological function and sodium CMC is added in a quantity and form which is consistent with delivering the stated purpose. There are no proposed nutrition, health or related claims to be made in regard to sodium CMC.Therefore, FSANZ concludes that the addition of sodium CMC to wine is consistent with the specific order policy principles for the addition of substances having a technological function.

7. Options

Use of a new food additive in wine requires a pre-market approval. Therefore, it is not appropriate to consider non-regulatory options in this case. Two regulatory options were consequently identified:

Option 1: Reject the draft variation, thus maintaining the status quo.

Option 2: Approve the draft variation to Standards 1.3.1 and 4.5.1 to permit the use of the sodium CMC, as an additive in wine and sparkling wine.

8. Impact Analysis (RIS ID: 12065)

The Office of Best Practice Regulation in a letter dated 24 November 2010 (reference 12065) provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to maximum residue limits, food additives, processing aids, or genetically modified foods as they are machinery in nature.

8.1 Affected Parties

The parties potentially affected by the regulatory options outlined above include:

- Australian and New Zealand wine producers

- Australian and New Zealand wine importers

- wine consumers in Australia and New Zealand
- Australian, State, Territory and New Zealand Government agencies that enforce food regulations.

8.2 Benefit Cost Analysis

As medium to significant competitive impacts or compliance costs are unlikely for this Application, FSANZ has not sought specific advice from the OBPR to estimate compliance costs of regulatory options. However, FSANZ has performed, for the two options outlined above, a qualitative assessment of the benefits and costs.

8.2.1 Option 1–Reject the draft variations

8.2.1.1 Consumers

There are no costs or benefits to consumers from this Option.

8.2.1.2 Industry

Rejection of this Application may have an adverse effect on:

- the wine industry both with respect to the inability to capture the potential energy savings and improved wine quality

- importers of wines from the EU and other counties which permit the use of sodium CMC in wine production.

8.2.1.3 Government

There would be an impact on government as not approving this application will mean the Australian Government would not be fulfilling its obligation under the Australia – EU Wine Agreement. There are no benefits to governments in maintaining a prohibition as there are no public health or safety issues or perceived costs on jurisdictions that enforce the food regulations. Lack of approval may be regarded as unnecessarily trade restrictive.

8.2.2 Option 2 – Approve the draft variations to Standards 1.3.3 and 4.5.1

8.2.2.1 Consumers

Consumers may benefit from wines containing sodium CMC because:

- improved wine quality could be available without an increase in cost because the use of sodium CMC does not require energy dependent processes such as chilling and filtration

- greatermarket choice as wines from regions such as the EU which contain sodium CMC would be allowed to be imported into Australia and New Zealand.

8.2.2.2 Industry

Industry may benefit from approval of this application because they would have:

- increased market opportunities as wines containing sodium CMC could be imported into Australia and New Zealand

- reduced production costs as the chilling and filtration steps are not necessary with use of sodium CMC.

FSANZ's assessmentindicated that a slight disadvantage to Australian and New Zealand wine producers may result from approval of this Application, as it may result in increased supplies from outside of Australasia. However, this Application was supported by both Australian and New Zealand wine producers and this is no longer considered to be an issue.

8.2.2.3 Government

FSANZ considered there would be no additional cost to government agencies that enforce the regulations. Sodium CMC is already permitted in other food types and thus validated analytical methods of analysis for sodium CMC already exist (JECFA 2006, OIV 2010). Also, as the ADI is 'not specified', the level of sodium CMC in wine is not a food safety matter and therefore routine testing for sodium CMC in wine is unlikely. This view is supported by the submission received from Queensland Health.

8.3 Comparison of Options

Overall, Option 2 waspreferred. An assessment of the costs and benefits of the twooptions indicates that there would be a net benefit in permitting the use of sodium CMCas an additive in wine (Option 2).

Specifically, it is anticipated that the extension of the use of sodiumCMC to wine wouldprovide greater opportunities for tartrate crystal stabilisation forwine producers and allow them to benefit fromincreased wine quality, potential reduction in production costs and the opportunity for market development both domestically and overseas. There are no significant impacts on government enforcement agencies arising from the addition of sodium CMC to wine. As other alternatives exist for tartrate stabilisation in wine,sodium CMC will only be used by industry where there is a perceived benefit.

Option 2 provides potential benefits to industry in terms of lower production costs and potential sales of wines containing sodium CMC, while consumers may benefit from possible improved quality wines and greater choice. Option 2 does not appear to impose any additional costs on industry, consumers, public or government.

The majority of submissions (5/6) received in relation to this Application supported Option 2.

Communication and Consultation Strategy

9. Communication

FSANZ applied a basic communication strategy to this Application.This involved using the media, website, and Facebook and Twitter sites to encourage people to comment.
Email alerts were sent to more than 4500subscribers to the FSANZ Notification Circular and to interested parties, including the Applicant.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the Application and the impacts of regulatory options.The issues raised in the public submissions were evaluated and addressed in this Report.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. The FSANZ Board's decisionhas been notified to the Ministerial Council. If no request for a review of the decision is made by the Ministerial Council, the Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code in the national press and on the FSANZ website.

10. Consultation

10.1 Public Consultation

The Assessment Report was notified for public comment between 31 May and 11 July 2011. Comments were specifically requested on the scientific aspects of the Application including its technological function and safety considerations, as well as information relating to any potential costs or benefits associated with use of sodium CMC in wine or sparkling wine. As this Application was assessed under a General Procedure, only one round of public comment was applicable.

Six submissions were received during the public consultation period. Five submitters supported the Application, being two government agencies, two professional organisationsand one wine producer. One member of the public did not support the application.

FSANZ thanks all submitters for their comments, and has taken these comments into account in preparing the Approval report for this Application. A summary of these and FSANZ's response is provided in **Attachment 2.**

10.2 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.

The proposed amendments to Standards 1.3.1 and 4.5.1 are likely to enable increased international trade as amending the Code will align it with relevant international standards written by the EU and the International Organisation of Vine and Wine.

Notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

Primary Legislative Objectives

11. Addressing the Primary Objectives of Section 18 of the FSANZ Act.

The legislative objectives that FSANZ is required to meet when developing or varying a food standard are noted in section 3. FSANZ considers the primary objective of most relevance to this Application is the protection of public health and safety. The other two have less direct relevance although are also taken into consideration.

11.1 Risk to Public Health and Safety

FSANZ concludes that approval for use of sodium CMC as an additive in wine does not pose a public health and safety risk to Australian and New Zealand consumers.

11.2 Providing Adequate Information to Enable Informed Choice – Labelling

As noted in Section 6.3, FSANZ considers no mandatory labelling is necessary for the use of sodium CMC as an additive in wine.

This means that the use of sodium CMC as an additive in wine will not be required to be declared. However, sodium CMC is not unique in this respect.

11.3 Prevention of Misleading and Deceptive Conduct

FSANZ has considered this objective and concludes there are no particular misleading or deceptive conduct aspects to this assessment.

Conclusion

12. Conclusion and Decision

This Application has been assessed against the requirements of section 29 of the FSANZ Act.

The Assessment Report concluded that use of sodium CMC in wine and sparkling wine is technologically justified and does not pose a public health and safety risk.

FSANZ has consideredwhether specific additional information requirements are needed to enable consumers to make informed choices. Alcohol products are generally exempt from ingredients labelling unless concerns regarding allergenicity or GM modification are relevant. These concerns are not relevant in this application. No specific additional information requirements are proposed.

FSANZ has concluded there are no misleading or deceptive conduct aspects to this assessment.

The relevant Ministerial Council Policy Guideline has been addressed in this assessment. The technological function of using the additive has been articulated and assessed as being met. Its use as proposed has been assessed as being safe and suitable.

An amendment to the Code giving permission for the use of sodium CMC in wine and sparkling wine in Australia and New Zealand is recommended on the basis of the available scientific information.

Decision

To approvedraft variations to Standards1.3.1 – Food Additives and 4.5.1 – Wine Production Requirements to permit the use of sodium carboxymethylcellulose as an additive in wine and sparkling wine.

12.1 Reasons for Preferred Approach

An amendment to the Code approving the use of sodium CMC in wine in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- The safety assessment has concluded that the use of the additive does not raise any public health or safety concerns.
- Use of the additive to stabilise wine and sparkling wine is technologically justified and would be expected to provide benefits to wine producers and consumers.
- Permitting use of the additive in wine and sparkling wines would not impose significant costs for government agencies, consumers or producers.
- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards that would impact on our decision to amend the Code.
- There are no other measures than variations to Standards 1.3.1 and 4.5.1 that could achieve the same end.

The proposed draft variation is provided in **Attachment 1**.

13. Implementation and Review

If no review of the Board's decision is requested by the Ministerial Council, the amended draft variations will come in to effect on gazettal.

14. References

Dumond P, Franck P, Morisset M, Sainte Laudy J, Kanny G, Moneret-Vautrin DA (2009) Pre-lethal anaphylaxis to carboxymethylcellulose confirmed by identification of specific IgE--review of the literature. Eur Ann Allergy Clin Immunol, 41(6):171-176

European Union (Commision Regulation (EC), No.606/2009) laying down certain detailed rules for implementing Council Regulation (EC) No.479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions, viewed April 2011, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:193:0001:0059:EN:PDF

JECFA (Monograph 1, 2006) *Combined Compendium of Food Additive Specifications – Carboxymethyl cellulose*, viewed April 2011, http://www.fao.org/ag/agn/jecfa-additives/details.html?id=388

OIV (2009) Monograph on Carboxymethylcellulose (cellulose gum) viewed April 2011 http://online.foodchemicalscodex.org/online/pub/indix?fcc=7&s=1&oYr=2010&0Mo=11&oDa=28

OIV (2010) Method for the determination of carboxymethylcellulose (cellulose gum CMC) in white wines viewed May 2001http://news.reseau-concept.net/images/oiv_uk/Client/OIV-OENO_404-2010_EN.pdf

WHO (1990) Evaluation of certain food additives and contaminants. Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization Technical Report Series; 789.

Agreement between Australia and the European Community on Trade in wine.Available from various websites including the Department of Agriculture, Fisheries and Forestry (DAFF).http://www.daff.gov.au/__data/assets/pdf_file/0011/913754/wine-agreement.pdf Accessed 26 April 2011.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*

2. Summary of Public Submissions on the Assessment Report

Attachment 1

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

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1047 – Sodium Carboxymethylcellulose as a Food Additive in Wine)Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

[Signature to be inserted]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1047 – Sodium Carboxymethylcellulose as a Food Additive in Wine) Variation*.

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

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

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

[1] ***Standard 1.3.1****is varied by inserting the following entry in numerical order under item* 14.2.2 Wine, sparkling wine and fortified wine of Schedule 1 –

466	Sodium carboxymethylcellulose	GMP	Wine and sparkling wine only

[2] ***Standard 4.5.1****is varied by inserting in alphabetical order in the* Table to clause 3 –

sodium carboxymethylcellulose

Attachment 2

Summary of Public Submissions on the Assessment Report

The Assessment Report for this Application was advertised for public comment from 31 May to 11 July 2011. Comments were specifically sought on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of the additive to be used as an additive in wine and sparkling wine. A summary of the issues raised and the response from FSANZ is provided in Table 1 below.

Six submissions were received during the public consultation period in response to the Assessment Report.

Five submitters supported the Application, being two government agencies, two professional organisations and one winemaker. The sixth submissionwas from a member of the public who did not support the application.

Table 1: Summary of Submissions

Submitter	Comments	FSANZ Response
Pierre's Wines, Owner and Winemaker	Supports Option 2. Comments on the monetary, environmental and processing advantages of using CMC compared with traditional cooling techniques.	Support noted
Food Technology Association of Australia	Supports Option 2. Also comments 'The matter of exemption from ingredient labelling of wine, sparkling wine and most alcoholic beverages raises the issue of providing information, including the declaration of food additives on labels to consumers, as is mandatory for all packaged foods.'	Support noted The issue of ingredient labelling for standardised alcoholic beverages was thoroughly considered during the review of ingredient labelling, Proposal P143, and was subject to public comment at the various stages of the review process. The primary reason for the exemption from ingredient labelling is that the ingredients used in the manufacture of alcoholic beverages are 'substantially transformed' during fermentation and therefore a provision of a list of ingredients isconsidered to not likely benefit consumers. FSANZ is aware of the varying opinions which surround the issue of ingredient labelling of standardised alcoholic beverages and notes the comment. However, as the purpose of this Application is around the inclusion of sodium CMC in wine and sparkling wine, this labelling comment is deemed to be outside the scope of this Application.
MAF New Zealand	Supports Option 2.	Support noted

Submitter	Comments	FSANZ Response
Queensland Health (whole of Queensland Government response)	Supports Option 2.	Support noted
Gary Osborne (private consumer)	Concern raised regarding: • '....addition of another chemical to artificially modify wine' • 'The number of chemicals already approved for use and **not listed on labels** whether used in wine or in the 'processing of wine'... • risks to users • change in the physical characteristics as the additive can also act as a thickening agent • the application mainly being for the benefit of '....larger 'industrial wineries' but should adverse effects been seen there is '....little chance of proving that this or that multi-national was at fault?'	• The proposed use of sodium CMC in wine as described in this Application is as an alternative to currently permitted additives which carry out the same technological function; the intention is to use sodium CMC, where appropriate, as a replacement to other tartrate crystal stabilising additives notin addition to them. • See response above to Food Technology Association of Australia regarding the issue of ingredient labelling for standardised alcoholic beverages. • As mentioned in the Assessment report, the risk to users was considered and the conclusion was the proposed use of sodium CMC in wine does not pose any public health or safety risk to consumers. • From information available e.g. that contained in the Application or from other sources, there is no evidence that the low levels of sodium CMC use in wine alter the physical characteristics of wine. • As indicated above in the third bullet point and consistent with FSANZ's overall goal to ensure Australia and New Zealand have a safe food supply, the use of sodium CMC in wine is not expected to result in adverse effects. Due to the potential reductions in processing costs, permission to use sodium CMC in wine is, at least, as attractive to small independent wineries as the larger corporate ones. This is demonstrated by the submission in support of this application from Pierre's wine, a small boutique winery.
New Zealand WineGrowers	Supports Option 2.	Support noted.