



30 May 2011
[10-11]

APPLICATION A1047

SODIUM CARBOXYMETHYLCELLULOSE AS A

FOOD ADDITIVE IN WINE

ASSESSMENT REPORT

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 seeks to amend Standards 1.3.1 – Food Additives and 4.5.1 – Wine Production Requirements (Australian-only Standard) of the *Australia New Zealand Food Standards Code* (the Code) to allow sodium carboxymethylcellulose (CMC) as an additive in wine and sparkling wine.

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. CMC is intended to be used as an additional tool, rather than as a replacement for existing 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. CMC is already permitted under Standard 1.3.1 for a number of foods, but not wine. Thus an amendment to this Standard is being sought.

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

Approval of CMC as an additive in wine is sought to meet requirements under the 2008 *Agreement between Australia and the European Community for Trade in Wine*. Currently EU wines which contain CMC are not legal in Australia or New Zealand.

The Application is being assessed under the General Procedure.

Risk and Technical Assessment

A Risk and Technical Assessment was undertaken to determine whether the use of 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 CMC in other foods. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not assigned it 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 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 states that the maximum concentration of CMC expected to be used in wine is 100 mg/L. As this application is an extension to the use of CMC and considering there are no specific public health or safety issues identified for this extended use, FSANZ proposes to permit the use of 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.

As the additive is already permitted in other foods and a specification already exists no amendments to the specification is considered 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 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.

Preferred Approach

To prepare a draft variation to Schedule 1, item 14.2.2 of Standard 1.3.1 – Food Additives, to permit the use of carboxymethylcellulose as an additive in wine and sparkling wine according to Good Manufacturing Practice (GMP)

To prepare a draft variation to the Table to item 3 of Standard 4.5.1 – Wine Production Requirements, to include the use of carboxymethylcellulose as an additive.

Reasons for Preferred Approach

- 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.

Consultation

Public submissions are now invited on this Assessment Report. Comments are 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.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Assessment Report will be used to develop the Approval Report for this Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 11 July 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the Application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1047sodi4816.cfm>

SD1 Risk and Technical Assessment Report

Introduction

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

This application seeks 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 (CMC, INS Number 466) as an additive in wine and sparkling wine. As wine produced in Australia must comply with Standard 4.5.1 – Wine Production Requirements, of the Code, an amendment to this standard is also required.

1. The Issue / Problem

The Application requests an extension of use of 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 change in temperatures during transport and storage, tartrate can crystallise in wine, resulting in cloudy wine with sediment which is undesirable to many consumers.

The Applicant has submitted data that supports the claim that the additive works by inhibiting crystal growth in wine. 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 CMC as an additive in wine is also sought to meet requirements under the 2008 *Agreement between Australia and the European Community for Trade in Wine*. Currently EU wines which contain 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. Background

2.1 Current Standards

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

A food additive is described in the Purpose of Standard 1.3.1:

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 <i>sub-classes</i>	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 CMC is permitted under this Standard for a variety of foods it is not currently permitted in wine. For CMC to be permitted in wine clause 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 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

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 this New Zealand specific Act. 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 CMC for the use in wine and sparkling wine does not vary from 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

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 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 has provided data showing the 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. 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 over time, is deemed sufficient by FSANZ to demonstrate that the use of CMC at this proposed level is effective.

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

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend Standards 1.3.1 and 4.5.1 of the Code to permit the use of 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 Minerals* includes policy 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 to be answered

For this Application, FSANZ has considered the following key questions:

- 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 the additive has been undertaken for this Application (Refer to Supporting Document 1).

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

5. Risk and Technical Assessment Summary

5.1 Summary

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 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. For this reason the 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 CMC.

There are no reports of allergy to CMC 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 as the use of 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.

As 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 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 CMC to wine.

6.1 Risk to public health and safety

FSANZ concludes that the extension of the use of CMC in wine as an additive does not pose any public health or safety risk to Australian or New Zealand consumers.

6.2 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 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, CMC is safe for human consumption, there is a clear technological function and 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 CMC. Therefore, FSANZ concludes that the addition of CMC to wine is consistent with the specific order policy principles for 'Technological Function'.

6.3 Labelling of 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, CMC would not be required to be declared on the label.

6.4 Specifications for 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 CMC is not a novel additive, and a JECFA specification (JECFA 2006) already exists, no amendment to the specification is considered necessary.

6.5 Methods of analysis

As FSANZ proposes to permit the use of 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 CMC in wine is not necessary. However a 2010 OIV Resolution (OIV 2010) provides a method for the determination of CMC in white wines. Although the limit of detection of this method is only 20 mg/L and the limit of quantification 60 mg/L, considering the proposal is to allow CMC in wine at GMP levels and the maximum level is expected to be around 100 mg/L, FSANZ is satisfied that this method is suitable for CMC in wine.

6.6 Prevention of misleading and deceptive conduct

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

6.7 Risk Management Strategy

As this application is an extension to the use of CMC, considering there are no specific public health or safety issues identified for this extended use and there are other approved uses of CMC in the Code, FSANZ proposes to permit the use of CMC in wine and sparkling wine at GMP levels.

This application is seeking permission for 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 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 later point is important as one of the justifications the Applicant has made for the use of CMC in wine is to allow EU produced wines which contain CMC to be imported into Australia and New Zealand.

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 have consequently been identified:

Option 1: Reject the Application

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

8. Impact Analysis (RIS ID 12065)

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts. The level of analysis is commensurate to the nature of the application and significance of the impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ will seek further advice from the Office of Best Practice Regulation (OBPR) and estimate compliance costs of regulatory options.

OBPR considers this type of application is machinery in nature because it is part of implementing a regulatory framework where the extension of the use of an additive is voluntary once the application has been successfully approved. Consequently, it is not necessary to have input from OBPR regarding this application.

8.1 Affected Parties

The affected parties to this Application include:

- Australian 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 Office of Best Practice Regulation (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

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 countries which permit the use of 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 will not be fulfilling its obligation under the 2008 Australian–European Community Agreement on Trade in Wine. 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*

8.2.2.1 Consumers

Consumers may benefit from wines containing CMC because:

- Improved wine quality could be available without an increase in cost because the use of CMC does not require energy dependent processes such as chilling and filtration
- Greater market choice as wines from regions such as the EU, which contain 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 CMC could be imported into Australia and New Zealand.
- Reduced production costs as the chilling and filtration steps are not necessary with use of CMC

Approval of this Application may result in a slight disadvantage to Australian and New Zealand wine producers as it may result in increased supplies from outside of Australasia.

8.2.2.3 *Government*

FSANZ considers there will be no additional cost to Government agencies that enforce the regulations. CMC is already permitted in other food types and thus validated analytical methods of analysis for CMC already exist (JECFA 2006, OIV 2009). Also as the ADI is 'not specified' the level of CMC in wine is not a food safety matter and therefore routine testing for CMC in wine is unlikely.

8.3 Comparison of Options

Overall Option 2 is preferred. An assessment of the costs and benefits of the two options indicates that there would be a net benefit in permitting the use of CMC as an additive in wine (Option 2).

Specifically, it is anticipated that the extension of the use of CMC to wine would provide greater opportunities for tartrate crystal stabilisation for wine producers and allow them to benefit from increased 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 CMC to wine. As other alternatives exist for tartrate stabilisation in wine 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 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.

Communication and Consultation Strategy

9. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the assessment report for public comment and placing the report on the FSANZ website.

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 are evaluated and addressed in FSANZ approval reports.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code, if approved by the Ministerial Council, in the national press and on the FSANZ website.

10. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to scientific aspects of the Application including the technological function and any safety considerations, as well as information relating to any potential costs or benefits associated with use of CMC as an additive in wine.

10.1 World Trade Organization

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

Conclusion

11. Conclusion and Preferred Option

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variations to Standards 1.3.1 and 4.5.1.

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

FSANZ has considered whether 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 CMC in wine and sparkling wine in Australia and New Zealand is recommended on the basis of the available scientific information.

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

Preferred Approach

To prepare a draft variation to Schedule 1, item 14.2.2 of Standard 1.3.1 – Food Additives to permit the use of carboxymethylcellulose as an additive in wine and sparkling wine according to Good Manufacturing Practice (GMP).

To prepare a draft variation to the Table to clause 3 of Standard 4.5.1 – Wine Production Requirements to permit the use of the use of carboxymethylcellulose as an additive.

11.1 Reasons for Preferred Approach

An amendment to the Code approving the use of the additive 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 is a New Zealand wine Act however it does not address additives. Therefore consideration of this is not necessary for this application.

- There are no other measures than variations to Standards 1.3.1 and 4.5.1 that could achieve the same end.

12. Implementation and Review

Following the consultation period for this document, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. If the draft variation is approved, the FSANZ Board's decision will then be notified to the Ministerial Council. If no review of the Board's decision is requested by the Ministerial Council, the proposed draft variation to the Code is expected to come into effect on gazettal.

13. References

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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.

ATTACHMENT

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

Attachment 1

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

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

Commencement: On gazettal

[1] **Standard 1.3.1** of the *Australia New Zealand Food Standards Code* 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
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[2] **Standard 4.5.1** of the *Australia New Zealand Food Standards Code* is varied by inserting in alphabetical order in the Table to clause 3 –

sodium carboxymethylcellulose
