

**Attachment 1: Application to amend the
Australia New Zealand Food Standards Code – General**

SECTION 2 SUBMITTING AN APPLICATION

2.1.1 Application inquiries

WFA has consulted with FSANZ in the preparation of this application.

2.1.2 Lodging an application

This application has been lodged electronically and with two hard copies.

2.1.3 Information requirements for an application

See Section 3

2.1.4 Fees

There are no exclusive commercial benefits as this is not a proprietary product. This is an unpaid application. We also believe that Europe will request this additive to be added to the annex of the Australian-EC wine agreement in the near future, and this will enable Australia to meet its treaty requirements.

2.1.5 Confidential commercial information

There is no confidential commercial information in this application.

2.1.6 Food Standards Development Work Plan

To be supplied by FSANZ on acceptance of the Application

2.1.7 Confidential and other information

There is no confidential information in this application.

SECTION 3.1 GENERAL REQUIREMENTS

3.1.1 Executive Summary

This Application is made to have Sodium carboxymethylcellulose (CMC) (which is a currently approved food additive 466 in Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1) added to Schedule 1 of Standard 1.3.1, to enable wine imported to Australia to be treated with CMC. We would also seek to have CMC added to the list of Additives approved for use in the Wine Production Requirements Standard 4.5.1.

This Application will enable wine produced in Australia and wine imported into Australia to be stabilised using CMC. CMC is a highly effective additive with significant cost and environmental advantages over alternative methods.

This Application is also consistent with *The 2008 Australia - European Community Agreement on Trade in Wine* (2008 Wine Agreement). The 2008 Wine Agreement was signed in December 2008 and the treaty is expected to take effect in mid-2009, after Australia has amended the *Australian Wine and Brandy Corporation Act 1980* and *Trade Marks Act 1995*. The European Union has recently approved the use of CMC for wine produced in Europe, and under the Wine Agreement signed with Australia we would expect that they will request the addition of CMC to Annex 1 to permit product to be exported to Australia. The proposed changes will also permit Australia to export wine to Europe according to requirements in Annex I of the 2008 Wine Agreement.

3.1.2 APPLICANT DETAILS

Applicant:
Winemakers Federation of Australia
NFF House 14-16 Brisbane Avenue
(PO Box 3891, Manuka, ACT 2603)
Barton Act 2600

Contact: Tony Battaglione
Phone: +61(0) 413014807
Fax: +61 2 62732678
Email: tony@wfa.org.au

Business: Industry Advocacy Group.

This application is on behalf of the Australian wine sector. It is also supported by NZ Winegrowers on behalf of the New Zealand wine industry and producers of CMC including Laffort and IMCD.

3.1.3 PURPOSE OF APPLICATION

(a) This Application is made to have Sodium carboxymethylcellulose (CMC) (which is a currently approved food additive 466 in Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1) added to Schedule 1 of Standard 1.3.1, to enable wine imported to Australia to be treated with CMC. We would also seek to have CMC added to the list of Additives approved for use in the Wine Production requirements Standard 4.5.1.

(b) This Application is made on behalf of WFA, the peak industry body for the Australian Wine Industry.

Section 3.1.3 asks for the status of similar applications. Annex 1 provides details of international organisations and treaties relevant to this application.

The OIV adopted resolution 2/2008 in 2008 concerning the addition of carboxymethylcellulose to white wines and sparkling wines in order to enhance their tartaric stabilisation following a proposal made by the "Specifications of oenological products" experts group.

Commission Regulation EC 606/2009 was adopted on 10 July 2009 which permitted the addition of carboxymethylcellulose (cellulose gums) to ensure tartaric stabilisation at a level of no more than 100g/ml.

Australia has been requested to supply the information for this application to other members of the World Wine Trade Group to enable approval of CMC in their jurisdictions.

3.1.5 INFORMATION TO SUPPORT THIS APPLICATION

WFA as the peak industry body representing the Australian producers of wine and wine products is putting forward this Application. The New Zealand wine industry supports this Application.

FSANZ objectives

Section 18 of the FSANZ Act sets out FSANZ's objectives (in descending priority order) in developing food regulatory measures and variations of food regulatory measures as:

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

In developing food regulatory measures and variations of food regulatory measures, FSANZ must also have regard to the following:

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

This proposal proposes to promote consistency with Europe as the United Kingdom is Australia's major trading partner in wine. All initiatives to harmonise wine regulations internationally reduce complexity and enhance international trade. The international Standard Setting Organisation of which the Australian government is a member (the OIV) adopted resolution 2/2008 in 2008 concerning the addition of carboxymethylcellulose to white wines and sparkling wines in order to enhance their tartaric stabilisation following a proposal made by the "Specifications of oenological products" experts group.

Commission Regulation EC 606/2009 was adopted on 10 July 2009 which permitted the addition of carboxymethylcellulose (cellulose gums) to ensure tartaric stabilisation at a level of no more than 100g/ml.

Australia has been requested to supply the information for this application to other members of the World Wine Trade Group to enable approval of CMC in their jurisdictions.

This proposal will reduce the cost of stabilisation for wine and enhance the environmental impact and is consistent with FSANZ objectives.

Australian Wine and Brandy Corporation Objectives

The Australian Wine and Brandy Corporation (AWBC) has the following objectives under the *Australian Wine and Brandy Corporation Act 1980*:

- (a) to promote and control the export of grape products from Australia; and
- (b) to promote and control the sale and distribution, after export, of Australian grape products; and
- (c) to promote trade and commerce in grape products among the States, between States and Territories and within the Territories; and
- (d) to improve the production of grape products, and encourage the consumption of grape products, in the Territories; and
- (e) to enable Australia to fulfil its obligations under prescribed wine-trading agreements; and
- (f) for the purpose of achieving any of the objects set out in the preceding paragraphs:
 - (i) to determine the boundaries of the various regions and localities in Australia in which wine is produced; and
 - (ii) to give identifying names to those regions and localities; and
 - (iii) to determine the varieties of grapes that may be used in the manufacture of wine in Australia.

The WFA contends that this Application is needed under AWBC objectives (a), (b) and in particular (e) above. The AWBC supports this application.

3.1.6 ASSESSMENT PROCEDURE

This is an unpaid application and will benefit the Australian and New Zealand wine industries and facilitate trade. We also believe that Europe will request this additive to be added to the annex of the Australian-EC wine agreement in the near future, and this will enable Australia to meet its treaty requirements.

3.1.7 CONFIDENTIAL COMMERCIAL INFORMATION

There is no confidential commercial information in this application.

3.1.8 EXCLUSIVE CAPURABLE COMMERCIAL BENEFIT (ECCB)

There are no exclusive commercial benefits as there are many products available on the market.

3.1.9 INTERNATIONAL AND OTHER STANDARDS

A. International Standards

The relevant international standard setting body is the International Organisation of Vine and Wine (OIV) replaced the International Vine and Wine Office was established by the Agreement of 3 April 2001.

The OIV is an intergovernmental scientific and technical organization with recognised competence for its works concerning vines, wine, wine-based beverages, table grapes, raisins and other vine-based products established in its current form in April 2001. It has a permanent secretariat located in Paris, and conducts its work through a structure co-

ordinated by a scientific and technical committee and implemented by four commissions responsible for viticulture, oenology, and law and economy and health and safety.

The OIV adopted resolution 2/2008 in 2008 permitting the addition of carboxymethylcellulose to white wines and sparkling wines in order to enhance their tartaric stabilisation following a proposal made by the "Specifications of oenological products" experts group (<http://news.reseau-concept.net/pls/news/>)

In 2009, Resolution OIV/Oeno 366/2009 Monograph on Carboxymethylcellulose (Cellulose Gum) was adopted by the General Assembly of the OIV (Annex 2).

B. Other National Standards or regulations

Commission Regulation EC 606/2009 was adopted on 10 July 2009 which permitted the addition of carboxymethylcellulose (cellulose gums) to ensure tartaric stabilisation at a level of no more than 100g/ml.

Australia has been requested to supply the information for this application to other members of the World Wine Trade Group to enable approval of CMC in their jurisdictions.

3.1.10 Statutory Declaration

A statutory declaration was supplied with the original application. (Annex 3)

3.1.11 CHECKLIST

A completed checklist was supplied with the application (Annex 4).

SECTION 3.3 STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

A. GENERAL INFORMATION

1. Purpose of the application

This Application is made to have Sodium carboxymethylcellulose (CMC) (which is a currently approved food additive 466 in Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1) added to Schedule 1 of Standard 1.3.1, to enable wine imported to Australia to be treated with CMC. We would also seek to have CMC added to the list of Additives approved for use in the Wine Production Requirements Standard 4.5.1.

2. Justification for the application

(a) Technological function of the food additive

Sodium carboxymethylcellulose (CMC) is a stabilizer used for Tartrate Stabilization of wine.

(b) The safety of the food additive

CMC is permitted for food use in Australia under the Food Standards Code at GMP and as we understand the Food Standards code, this would indicate it poses no health risks to consumers. CMC is also legal for use in wine in the European Union.

Sodium carboxymethyl cellulose, was considered by the JECFA in its evaluations of modified celluloses at its fifth, seventh, tenth, thirteenth, seventeenth, twenty-sixth, twenty-seventh, thirtieth and thirty-fifth meetings and of ethyl cellulose and ethylhydroxyethyl cellulose at the twenty-sixth and twenty-seventh meetings. At its thirty-fifth meeting, the Committee reviewed new data on seven modified celluloses including sodium carboxymethyl cellulose. The data consisted of the results of studies in rats on caecal enlargement, effects on caecal flora and developmental toxicity and studies of mutagenicity *in vitro*. New data on humans were also available, indicating that some individuals may experience laxative effects at a dose as low as 5 g per person per day. The Committee concluded that modified celluloses are of low toxicity and allocated a group ADI 'not specified' to seven modified celluloses: methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, ethyl cellulose and ethylhydroxyethyl cellulose. The Committee pointed out that their laxative properties should be taken into account when they are used as food additives.

Enzymatically hydrolysed sodium carboxymethyl cellulose was evaluated by the Committee at its fifty-first meeting. The Committee compared the toxicity and absorption, distribution and metabolism of enzymatically hydrolysed carboxymethyl cellulose with that of the parent compound and concluded that the similarities in the results were consistent with the absence of any toxicologically significant difference between the two. Therefore, the enzymatically hydrolysed form was included in the group ADI 'not specified' with the other seven modified celluloses.

(c) The costs and benefits for industry, consumers and government associated with use of the food additive

Consumers prefer to drink white and sparkling wines that are clear and without sediment or crystals. This is a challenge for winemakers, to achieve crystal stabilization in early

bottled wines and wines which are sent long distances, to withstand greater temperature variation. There are a number of methods available to stabilise wine. This Application will enable wine produced in Australia and wine imported into Australia to be stabilised using CMC. CMC is a highly effective additive with significant cost and environmental advantages (uses less energy) over alternative methods.

This Application is also consistent with *The 2008 Australia - European Community Agreement on Trade in Wine* (2008 Wine Agreement). The 2008 Wine Agreement was signed in December 2008 and the treaty is expected to take effect in mid-2010, after Australia has amended the *Australian Wine and Brandy Corporation Act 1980* and *Trade Marks Act 1995*. The European Union has recently approved the use of CMC for wine produced in Europe, and under the Wine Agreement signed with Australia we would expect that they will request the addition of CMC to Annex 1 to permit product to be exported to Australia. The proposed changes will also permit Australia to export wine to Europe according to requirements in Annex I of the 2008 Wine Agreement.

CMC is permitted for food use in Australia under the Food Standards Code and poses no health risks to consumers. CMC is also legal for use in wine in the European Union. There are considerable benefits for the Australia industry in lower energy costs and a very effective method of achieving wine stability. Consumers will benefit as they winemakers will achieve wine stability much easier. The government will benefit by meeting its treaty obligations under the 2008 Wine Agreement.

The OIV which is the relevant international standard setting body for wine has done extensive research on the use of CMC and approved its use for wine, recognising it is an effective, environmentally friendly additive. Australia and New Zealand are a signatory to this Treaty and an active participant in the OIV. I would suggest FSANZ contacts the Head of the Australian delegation, Mr John Power (Mr Power's contact details are: Manager , Wine Policy/Horticulture Code of Conduct , Agricultural Productivity, Australian Government Department of Agriculture, Fisheries and Forestry ; ph. 02 6272 5713 ; fax 02 6272 4414; mobile 0448 200 918; john.power@daff.gov.au; and/or the relevant officer in New Zealand) for any further information on the efficacy of this product and Australia's obligations under this Treaty and the 2008 Wine Agreement

The European Union has adopted this Resolution into regulation.

3. Support for the application

WFA has been approached by a number of producers seeking support to use this additive. In addition several major companies have trialled the additive. In addition, the European Union has recently approved the use of CMC for wine produced in Europe, and under the Wine Agreement signed with Australia we would expect that they will request the addition of CMC to Annex 1 to permit product to be exported to Australia.

WFA has also agreed to provide copies of this application to the regulatory bodies associated with member countries of the World Wine Trade Group to enable approval of CMC in their jurisdictions. The wine industries in each of these countries have expressed an interest in approving CMC.

B. Technical Information on the food additive

1. Nature and technological function of the additive

- (a) Sodium carboxymethylcellulose is used for the purpose of tartrate stabilisation in wine. It is particularly effective in white wine
- (b) Consumers prefer to drink white and sparkling wines that are clear and without sediment or crystals. This is a challenge for winemakers, to achieve crystal stabilization in early bottled wines and wines which are sent long distances, to withstand greater temperature variation.

There are several methods of achieving crystal or tartrate stabilization (Dharmadhikari, M (2002); Rankine (1989)):

1. Chilling or Cold Stabilization with or without seeding the wine with Potassium bitartrate (KHT).
2. Stabilization by Ion Exchange
3. Contact process
4. Metatartaric Acid
5. Sodium Carboxymethyl cellulose (CMC)

Method 1

In a conventional method of cold stabilizing, a wine is chilled to a temperature just above its freezing point and is held at that temperature for two to three weeks. Chilling the wine lowers the solubility of Potassium bitartrate and facilitates its crystallization and precipitation.

This method takes time, requires a great amount of energy for the refrigeration to freezing. This is a major cost to wineries. In addition to this, it also requires the wine to undergo a filtration step to recover the crystals. As most wineries prefer to use this method, they incur large costs.

Additional cost may also be incurred if they use Potassium bitartrate to seed or facilitate the precipitation of crystals during chilling.

Method 2 Ion Exchange.

Wine stabilization by an ion exchange treatment is practiced by many large wineries, producing bulk wine. The treatment consists of passing the wine through a column containing resin in cationic or anionic form. In cation form, the resin may be charged with sodium (Na^+) or Hydrogen (H^+), or a mixture of Na^+ and H^+ . Then the wine is treated with cationic resin in Sodium form, the Na^+ of the resin is exchanged with K^+ (and other cations such as Ca^{++} and Mg^{++}) from the wine. This results in the formation of sodium bitartrate which is more soluble. There is a slight reduction in acidity. The increase in sodium content of the wine could be undesirable. In such a situation a mixed resin in Na^+ and H^+ form could be used. This would limit the amount of the Na^+ in the wine. However, the acidity of the wine would increase due to the exchange between the H^+ ion (from resin) and the K^+ ion (from wine). This may be suitable for treating low acid wine, which would benefit from increased acidity while being stabilized.

When a wine is treated with anionic resin in hydroxyl (OH^-) form, the OH^- ion is exchanged for the tartrate anions (and other anions.) This lowers the tartrate content of the wine. By passing the wine through both cation (H^+ form) and anion (OH^- form) exchange resin, one exchanges H^+ and OH^- ions for potassium and tartrate ions. Thus the net result is the exchange of bitartrate for water.

Method 3 Contact Process

Grape juice and or wine can be considered as a supersaturated solution of KHT. Under certain conditions such as low temperature storage, the dissolved KHT becomes insoluble

and small crystals settle to the bottom in the form of sediment. In the contact process of stabilization, powdered KHT (Potassium hydrogen tartrate) crystals are added. These crystals serve as seed crystals and the crystals grow. The addition of approx 4g/L of KHT is sufficient to stabilize the wine. Chilling the wine helps the process go more quickly. The wine, once reaching saturation and crystallization, then requires filtration (another cost) to the treatment.

Method 4 Metatartaric Acid

Metatartaric acid is produced by heating tartaric acid. Heat causes the transformation of tartaric acid to metatartaric acid. The changes include dehydration, esterification and polymerization. When added to the wine, metatartaric acid retards crystal growth and inhibits the precipitation of KHT. However, this inhibitory effect is NOT permanent. The property is lost with time as metatartaric acid rehydrates to tartaric acid. The change from metatartaric to tartaric acid is influenced by storage Temperature. Rankine (1989) reported that in wine stored at 10 degrees C, the effectiveness of metatartaric acid lasted for 18 months, whereas at 25 degrees C, it lasted for only a few months. This suggests that metatartaric acid could be used to achieve (short term) stability, but it comes with a cost.

Method 5 CMC (Carboxymethyl cellulose)

Sodium carboxymethyl cellulose is a water soluble polymer derived from cellulose. It is more stable than metatartaric acid and is very effective in inhibiting tartrate precipitation, by acting as a protective colloid, which attaches to the surface of dissolved potassium hydrogen tartrate and thus prevents crystal growth. It is very effective against Potassium HT, but has limited effect on calcium tartrate. It is used in a dilute solution and mixed into wine, prior to filtration and bottling. No cooling is required. This has significant environmental benefits.

2. Information to enable identification of the additive

Chemical name: Cellulose, carboxymethyl ether, sodium salt
 CAS Nr 9004-32-4
 IUPAC no: acetic acid; 2,3,4,5,6 pentahydroxyhexanal
 Molecular Formula:
 Structural formula:

See attachment: Resolution OIV/Oeno 366/2009 Monograph on carboxymethylcellulose (Cellulose Gum)

Common Names: Carboxymethylcellulose, sodium salt
 Sodium Carboxymethyl cellulose
 CMC
 Cellulose GUM
 E466 or INS 466


Marketing Name: "Vinostab" from Erbsloeh (there are also many other marketing names as this is a non-proprietary product)

Carboxymethylcellulose (CMC: 466) is a derivative of cellulose formed by its reaction with alkali and chloroacetic acid.

Sodium carboxymethyl cellulose, was considered by the JECFA in its evaluations of modified celluloses at its fifth, seventh, tenth, thirteenth, seventeenth, twenty-sixth, twenty-

seventh, thirtieth and thirty-fifth meetings and of ethyl cellulose and ethylhydroxyethyl cellulose at the twenty-sixth and twenty-seventh meetings. At its thirty-fifth meeting, the Committee reviewed new data on seven modified celluloses including sodium carboxymethyl cellulose.

JECFA specification is available as below:

<i>Additive</i>	Sodium Carboxymethyl Cellulose
<i>Synonym(s)</i>	Cellulose gum CMC Na CMC Sodium CMC Sodium cellulose glycolate
<i>Specification</i>	Monograph 1 (2006) 
<i>Codex GSFA Online</i>	INS number: 466

I understand at the Fifty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) the ADI 'not specified' remained in place for sodium carboxymethyl cellulose. I have no additional information on this.

3. Information on the chemical and physical properties of the additive

CMC's are known as thickening agent 466. CMC's is a cellulose derivative, which is formed by a chemical conversion reaction from native cellulose. Wood or cotton dissolved in Sodium hydroxide solution and subsequently undergoes ether synthesis, constitute the raw material. The Na-CMC obtained by drying is a clear and is completely soluble in water and wine. CMC's are used in many foodstuffs as a thickening agent and is highly resistant even in the weakly acidic medium of wine. Recommended max dosage is 100g for 100L. CMC is stable in wine over long storage periods. Their major function is to inhibit crystal precipitation (i.e. that of Potassium tartrate and Tartaric acid).

It works as a protective colloid against crystal growth. It is stable through temperature changes.

It has been approved with the International Oenological Codex (OIV Resolution 2/2008) (copy attached).

It is Non GMO, non-Allergenic, and is neutral in taste and smell.

There are reduced costs – no chilling, no seeding of Cream of Tartar (Potassium hydrogen Tartrate), no filtration and no crystal waste to dispose of.

I have attached the JECFA specification prepared at the 28th JECFA in 1984 and revised in 2000 (Attachment 7). I have also been advised that a further revision was undertaken in 2006 and I have attached the link for your reference <http://www.fao.org/ag/agn/jecfa-additives/details.html?id=388> .

4. Information on the impurity profile

As per spec sheet (Attachment 5), and Resolution OIV/Oeno 366/2009 **Monograph on carboxymethylcellulose (Cellulose Gum)** (Reference attached). **Attachment 4**. I have also been advised that a further JECFA revision was undertaken in 2006 and I have

attached the link for your reference <http://www.fao.org/ag/agn/jecfa-additives/details.html?id=388> .

Appearance: clear viscous liquid
 Smell: very slight SO₂ smell (SO₂ used to prevent microrobes)
 Solid matter: >7.5%
 pH-value: 4.5 +-0.3

5. Manufacturing process

I have attached a production flow diagram supplied by one manufacturer of the product (Attachment 6).

6. Specification for identity and purity

I have attached the OIV specification. CMC also meets the specifications published in the Food Chemicals Codex.

7. Information for food labelling

Carboxymethylcellulose, sodium salt
 Sodium Carboxymethyl cellulose
 CMC
 Cellulose GUM

E466 or INS 466
 Stabilizer

8. Analytical method for detection

See Attached Mongraphs.

C. Information related to the safety of the food additive

Carboxymethylcellulose was first evaluated by JECFA in 1960. Its CAS number is 9000-11-7 with functional classes as a stabilizer and thickener. The report reference is NMRS 29/TRS 220-JECFA 5/26.).

From the WHO website, we obtained the following information:

Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

SODIUM CARBOXYMETHYL CELLULOSE

General Information

Synonyms: CELLULOSE GUM, CMC, Na CMC, SODIUM CELLULOSE GLYCOLATE, SODIUM CMC

Chemical Names: SODIUM SALT OF CARBOXYMETHYL ETHER OF CELLULOSE

CAS number: 9004-32-4

INS: 466

Functional Class:

- Food Additives
 - EMULSIFIER
 - STABILIZER
 - THICKENER

Evaluations

Evaluation year: 1989

ADI: NOT SPECIFIED

Comments: Group ADI for modified celluloses: ethyl cellulose, ethyl hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, methyl ethyl cellulose, and sodium carboxymethyl cellulose

Meeting: 35

Specs Code: S

Report: TRS 789-JECFA 35/24

Tox: FAS 26-JECFA 35/104

Monograph:

Specification: COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/68 (METALS LIMITS) (2004). R; FAO JECFA Monographs 1 vol.3/315

Previous Years: 1984, FNP 31/2-JECFA 28/103, COMPENDIUM/1325. R
1981, FNP 19-JECFA 25/191. R
1975, FAS 9/NMRS 55B-JECFA 19/80. R
1973, NMRS 53/TRS 539-JECFA 17/21, FNP 4-JECFA 17/48, FAS 5/NMRS 53A-JECFA 17/301. 0-25 (AS THE SUM OF TOTAL MODIFIED CELLULOSES; THE ADI M

We know of no additional health and safety information outside JECFA of relevance to this additive. CMC is also listed as a food additive in schedule 2 of Standard 1.3.1 at GMP. We assume that this means FSANZ is in possession of any later JECFA information.

D. Information related to the dietary exposure to the food additive

1. CMC is also listed as a food additive in schedule 2 of Standard 1.3.1 at GMP. The purpose in this application is to seek permission to include CMC for use with 14.2.2 Wine, sparkling wine and fortified wine.
2. We believe that the level should be at GMP or at least consistent with Commission Regulation EC 606/2009 which was adopted on 10 July 2009 which permitted the

addition of carboxymethylcellulose (cellulose gums) to ensure tartaric stabilisation at a level of no more than 100g/ml.

3. We believe that the majority of Australian white wine will switch to using this additive because of the environmental and cost advantages it possesses. Anecdotal evidence suggests that the majority of winemakers in Germany have now adopted this (Personal Communication, Prof. Dr. Monika Christmann, Head of department for Enology and Winetechnology, Geisenheim Research Center.
4. I have attached some information prepared by Dr Robert Konitz and presented to the OIV Expert Group of Oenology in March 2010 (unpublished) relating to CMC use.

8.0 References

- European Commission (2009) **COMMISSION REGULATION (EC) No 606/2009 of 10 July 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**, Official Journal of the European Union L 193/1, 24.7.2009. *Attachment 9*.
- Dharmadhikari, M (2002) **Methods for Tartrate Stabilization of Wine**, Publication of Grape and Wine Advisory Program Department of Fruit Science, Southwest Missouri State University Volume 18(2). *Attachment 1*
- Rankine, B (1989) **Making good wine: a Manual of Winemaking Practice for Australia and New Zealand**, The Macmillan company of Australia, Sydney.(p.169). *Attachment 2*
- Resolution OIV/Oeno 2/2008 (2008) **Wine treatment with (Cellulose Gums) carboxymethylcellulose** (Reference attached (*Attachment 3*))
- Resolution OIV/Oeno 366/2009 **Monograph on carboxymethylcellulose (Cellulose Gum)** (Reference attached). (*Attachment 4*)
- ERBSLOH (2009) **Product Specification Vinostab** (*Attachment 5*)
- ERBSLOH (2009) **Product of Vinostab Flowchart** (*Attachment 6*)
- JECFA (2006) Monograph 1 , <http://www.fao.org/ag/agn/jecfa-additives/details.html?id=388> (*Attachment 7* and full monograph available at web address)
- Robert Koenitz (2010) PowerPoint presentation to OIV Expert Group on oenology **"CMC an alternative to crystal stabilization"** and Draft Article by Robert Koenitz **"Carboxymethylcellulose for crystal stabilization – Recommendations for practical use** (unpublished) (*Attachment 8*)

Annex 1: International Organisations of relevance to 3.1.3

1. Australia – European Community Agreement on Trade in Wine

The *Australia – European Community Agreement on Trade in Wine* signed in Brussels on 1 December 2008 is a formal international agreement that regulates the trade in wine between Australia and the European Community. The agreement guarantees and improves access for Australian wine producers to our largest wine export market – Europe.

The new agreement replaces the *Australia - European Community Agreement on Trade in Wine* which came into force in 1994. The new agreement can be found at <http://www.daff.gov.au/agriculture-food/hort-wine/wine-policy>.

Under the EC/Australia Bilateral Wine Agreement, which came into effect on 1 March 1994, Australia gained improved access to the EC market through the lowering of technical barriers to Australia's wines in return for the Australian wine industry phasing out its use of European geographical indications. The use of some names such as Hock and White Bordeaux is being phased out and further negotiations will be held to establish phase-out arrangements for European names in widespread use in Australia such as Chablis and Champagne.

The Australian industry will in future use varietal, regional and brand names to market its wines. There will also be a need to develop replacement names where protected EC names have entered into common use, such as Sherry.

In effect, the Agreement is the finalisation of negotiations on outstanding issues from the initial Agreement, especially on GIs and traditional expressions (TEs). The main changes arising from the Agreement are:

- European recognition of an additional 16 Australian winemaking techniques
- simpler arrangements for approving winemaking techniques that may be developed in the future
- simplified labelling requirements
- protection within Europe for Australia's 112 registered GIs
- wholesalers will have five years to sell stock labelled with an EC GI and retailers will be able to sell all their stock and
- defined use of a number of quality terms used in the presentation and description of wine.
- Australian protection of more than 2,500 registered European GIs; including from member states who have joined the EC since 1994;
- Australian protection of 12 sensitive European GIs that have previously been used to describe Australian wines
- Prohibition on Australian producers from using a range of European TEs in the language specified in the agreement and to phase out the use of the term "Tokay" to describe Australian fortified wines within 10 years.

The Australian Wine and Brandy Corporation is the body responsible for implanting the Wine Agreement. The implementing legislation is scheduled to be introduced into the Australian parliament on 12 May. The Treaty will take effect around 28 days after the Bill receives Royal Assent. There is a threefold purpose to the *Australian Wine and Brandy Corporation Amendment Bill 2010* (the Bill):

1. to bring into force the Australia – European Community (EC) Agreement on Trade in Wine (the Agreement)
2. to further protect Australia's reputation for the production of wines of quality and integrity by strengthening the Australian Wine and Brandy Corporation's (AWBC) Label Integrity Program (LIP) and
3. to correct a number of weaknesses with the compliance provisions of the *Australian Wine and Brandy Corporation Act 1980* (the AWBC Act).

Australian Wine and Brandy Corporation

The Australian Wine and Brandy Corporation (AWBC) is a statutory authority established under the *Australian Wine and Brandy Corporation Act 1980* (as amended) (the AWBC Act). It was formed in 1981, succeeding the Australian Wine Board which was originally set up in 1929.

The objectives of the Australian Wine and Brandy Corporation (AWBC) are set out in Section 3 of the *Australian Wine and Brandy Corporation Act 1980* (as amended).

(1) The objects of this Act are:

- a) to promote and control the export of grape products from Australia; and
- b) to promote and control the sale and distribution, after export, of Australian grape products; and
- c) to promote trade and commerce in grape products among the States, between States and Territories and within territories; and
- d) to improve the production of grape products and encourage the consumption of grape products, in the Territories; and
- e) to enable Australia to fulfil its obligations under prescribed wine-trading agreements; and
- f) for the purpose of achieving any of the objects set out in the preceding paragraphs:
 - to determine the boundaries of the various regions and localities in Australia in which wine is produced; and
 - to give identifying names to each of those regions and localities; and
 - to determine the varieties of grapes that may be used in the manufacture of wine in Australia.

The AWBC has a specific responsibility for controlling labeling (including presentation, description and advertising as related to label claims for vintage, variety and region). These include mandatory country of origin declarations for the origin of the grapes.

Label Integrity Program

The wine industry LIP was introduced in the *Australian Wine and Brandy Corporation Amendment Act 1989*. The LIP has its origins in the first (1981–82) and second Annual General Meetings of the AWBC. At these forums, the wine industry gave the AWBC permission to recommend to the Minister that legislation be enacted for an industry wide system of record keeping to substantiate label claims in respect of vintage, variety and region of origin. The permission and subsequent recommendation stemmed from concerns within the industry over a number of scandals in New South Wales involving wine additives and the potential effect that further scandals could have on wine exports.

The regulations covering the LIP require winemakers to keep records to substantiate label claims and are set out in the AWBC Act (Part VIA, sections 39A - 39ZL).

The LIP was introduced for the 1990 vintage and is now the basis of the Australian label-claim system in respect of vintage, variety and geographical indication. Winemakers are not required to make a label claim about the wine vintage, (grape) variety or region of origin of the grapes, but must keep an audit trail if they do. The LIP prescribes what events must be recorded, but not how records must be kept.

A "label claim" includes claims made on a wine label, in a commercial document or in an advertisement, about the vintage, variety or geographical indication of wine goods or of the wine goods from which they were manufactured. Generic name wines, such as Moselle, Claret, Dry Red, Dry White etc., which make no reference in a label statement as to vintage, variety or geographical indication, are not included.

The Corporation's auditors monitor the industry for compliance with the LIP provisions of the AWBC Act through an audit program. Under the *Australian Wine and Brandy Corporation Amendment Bill*

2010, the Government expects that the proposed changes will achieve that objective by requiring all those involved in the production, distribution and sale of wine and grapes used to make wine, to record the specified information to ensure a traceable trail throughout the wine production process.

2. World Wine Trade Group

The WWTG is an informal grouping of wine sector representatives from wine producing countries. Founded in 1998, the group aims to share information, collaborates on a variety of international issues and endeavours to create an environment for the free trade in wine. Meetings are attended by both the Government and Industry sectors. The joint participation of government and industry representatives at meetings is designed to ensure a free exchange of information between sectors and a better understanding of issues being discussed.

The Group is an informal one with a rotating Chair. Membership of the group includes Australia, Argentina, Canada, Chile, New Zealand, South Africa, and the United States. Georgia is currently being considered for membership and observers from Brazil, Uruguay and Mexico have also participated in the group.

Amongst the major achievements of the World Wine Trade Group have been two treaty level agreements with implications and obligations relating to wine labelling:

Mutual Acceptance Agreement on Oenological Practices

Early discussions at the World Wine Trade Group identified the possible threats to trade that arose from differing national rules on oenological practices. At the first Zurich meeting it was agreed that such differences should not be a basis for erecting technical barriers to trade.

From this point it was agreed to develop a Mutual Acceptance Agreement on Oenological Practices. The text of the Agreement was first discussed in Santiago, Chile in October 1999 and was further refined at the subsequent meetings.

The text of the Agreement, which has full treaty status, was signed in Toronto, Canada in December of 2001 by Australia, Canada, Chile, New Zealand, and the United States. Argentina became a signatory in December of 2002.

The text of the agreement is available in English, French and Spanish. The US Government is the repository for the Agreement which can be found on the following website:
<http://www.ita.doc.gov/td/ocg/wwwtg.htm>

The Agreement is a landmark in the development of international trade. It is the first plural-lateral Mutual Acceptance Agreement, in any field, fully compliant with the WTO's Technical Barriers to Trade Agreement.

In simple terms the Agreement accepts that there are historical differences in national rules governing oenological practices, but signatory countries accept that wine made in another signatory country should be allowed to be sold in its market, despite these differences in oenological practices. Market access is, however, conditional on compliance with the WTO obligations to protect the health and safety of consumers and to prevent deception of consumers. The Agreement is founded on WTO principles, and exceptions to the generally permitted access are WTO consistent.

Labelling Agreement

On January 23, 2007 the World Wine Trade Group (WWTG) participants welcomed the signing of their Agreement on the Requirements for Wine Labelling in Canberra, Australia.

This far-reaching Agreement enables wine exporters to sell wine into WWTG markets without having to redesign their labels for each individual market. It allows the placement of four items of mandatory information (country of origin, product name, net contents and alcohol content) anywhere on a wine bottle label provided they are presented in a single field of vision.

The Agreement reduces costs relating to the production, application and warehousing of labels. Savings achieved by this Agreement provide a competitive advantage and opportunities for further export growth to WWTG participants. The Agreement also brings benefits to consumers who are able to easily locate important items of information on the bottle in a single field of vision, allowing them better to compare between wines and brands.

The US Government is the repository for the Agreement which can be found on the following website: <http://www.ita.doc.gov/td/ocg/wwtg.htm>.

3. Codex Alimentarius Commission

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of this Program are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

There is no specific wine standard within Codex, but horizontal standards are of course relevant. The OIV is an observer of CODEX.

4. OIML

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The two main categories of OIML publications are:

- 1) International Recommendations (OIML R), which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;
- 2) International Documents (OIML D), which are informative in nature and intended to improve the work of the metrological services.

OIML Draft Recommendations and Documents are developed by technical committees or subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis.

Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

Labeling requirements for pre-packaged goods (including food) are developed by the OIML Technical Committee TC 6 Pre-packaged products and sanctioned by the International Conference of Legal Metrology. This publication – reference OIML R 79, LABELLING REQUIREMENTS FOR PREPACKAGED PRODUCTS makes recommendations on the size and placement of the 'volume' statement.

The treaty to which Australia is a signatory does not making binding recommendations, and Australia currently exempts certain products from the requirements of R79.

The recommendations in R79 are inconsistent with the Codex Alimentarius Commission labeling standard and more trade restrictive. OIML has recognised this and in recent times has reviewed R79 and has placed the issues on the agenda of the Codex Alimentarius Commission food Labeling committee (CCFL). However, due to the internal review in OIML, this item was removed from the agenda of the CCFL meeting scheduled for May 2010.

Trade measurement in Australia

The objectives of the OIML Convention, taken from Chapter 1 Article 1 *Purpose of the Organisation* from the Convention establishing OIML, do not oblige Australia to automatically adopt OIML recommendations. The emphasis is on cooperation and coordination.

The National Measurement Act (NMA) clearly states the role of the OIML with respect to Australian law. The National Measurement Act No.64 of 1960 (as amended) states:

The National Standards Commission must:

..... (d) Consult and cooperate with the International Organisation of Legal Metrology and other appropriate international organisations on matters relating to metrology.

However, its role is limited to examination and approval of patterns of measuring instruments.

Australia is not required to and has not agreed to mandatory adoption of the OIML Standards, nor does the Convention state OIML standards must be adopted by signatory nations.

The National Measurement Act also goes on to state that:

(7) Before the Governor-General makes a regulation for the purposes of subsection (1), the Minister must also either:

(a) Be satisfied that the regulation is not inconsistent with a specification published by the International Organisation of Legal Metrology regarding the examination and approval of patterns of measuring instrument; or

(b) If the regulation is inconsistent with a specification – be satisfied that:

(i) The inconsistency is in the national interest; or

(ii) It is not practicable to comply with the specification because of particular circumstances applying to Australia.

The national interest argument would therefore suggest that, even if the regulation is inconsistent, the Minister still has the capacity to make the regulation.

On 13 April 2007 the Council of Australian Governments formally agreed that the Commonwealth should assume responsibility for trade measurement. The transition period for the transfer of responsibility from the states and territories to the Commonwealth will be three years, with the new system commencing on 1 July 2010. The ***Error! Reference source not found.*** were passed on 7 September 2009 and under section 1.3 recognised the *World Wine Trade Group Agreement on Requirements for Wine Labelling* by exempting the position of a measurement marking for standard-sized wine containers.

5. International Organisation of Vine and Wine (OIV)

The International Organisation of Vine and Wine (OIV) replaced the International Vine and Wine Office was established by the Agreement of 3 April 2001.

The OIV is an intergovernmental scientific and technical organization with recognised competence for its works concerning vines, wine, wine-based beverages, table grapes, raisins and other vine-based products established in its current form in April 2001. It has a permanent secretariat located in Paris, and conducts its work through a structure co-ordinated by a scientific and technical committee and implemented by four commissions responsible for viticulture, oenology, and law and economy and health and safety.

The objectives of the OIV are:

- a) to inform its members of measures whereby the concerns of producers, consumers and other players in the vine and wine products sector may be taken into consideration;
- b) to assist other international organisations, both intergovernmental and non-governmental, especially those which carry out standardisation activities;
- c) to contribute to international harmonisation of existing practices and standards and, as necessary, to the preparation of new international standards in order to improve the conditions for producing and marketing vine and wine products, and to help ensure that the interests of consumers are taken into account.

These missions are laid out in a triennial strategic plan

To attain these objectives, the O.I.V's activities are:

- to promote and guide scientific and technical research and experimentation
- to draw up and frame recommendations and monitor implementation of such recommendations in liaison with its members, especially in the following areas: les conditions for grape production, oenological practices, definition and/or description of products, labelling and marketing conditions, methods for analysing and assessing vine products
- to submit to its members all proposals relating to: guaranteeing the authenticity of vine products, especially with regard to consumers, in particular in connection with the information provided on labels, protecting geographical indications, especially vine- and wine-growing areas and the related appellations of origin, whether designated by geographical names or not, insofar as they do not call into question international agreements relating to trade and intellectual property, improving scientific and technical criteria for recognising and protecting new vitivinicultural plant varieties
- to contribute to the harmonisation and adaptation of regulations by its members or, where relevant, to facilitate mutual recognition of practices within its field of activities
- to help protect the health of consumers and to contribute to food safety: by specialist scientific monitoring, making it possible to assess the specific characteristics of vine products, by promoting and guiding research into appropriate nutritional and health aspects, by extending the dissemination of information resulting from such research to the medical and healthcare profession.

The European Union takes into account OIV Resolutions relating to wine. There are currently 43 members including Australia and New Zealand.

PART 7 STATUTORY DECLARATION - AUSTRALIA

(as required by section 3.1.10 of the Application Handbook December 2008)

I, ANTHONY NICHOLAS BATTAGLIONE, do solemnly and sincerely declare that the information provided in this application fully sets out the matters required and that this information is true to the best of my knowledge and belief and that no information has been withheld which might prejudice this application.

And I make this solemn declaration by virtue of the *Statutory Declarations Act 1959* and subject to the penalties provided by that Act for the making of false statements in statutory declarations, conscientiously believing the statements contained in this declaration to be true in every particular.

Declared at CANBERRA

the 3rd day of MAY 2010

Signature 

before me* ANDREAS CLARK

Title: COMMISSIONER FOR TAKEN AFFIDAVITS

*a list of persons who may witness statutory declarations under the *Statutory Declaration Act 1959* is contained in the *Statutory Declarations Regulations 1993*, available online at <http://scaleplus.law.gov.au/>

ANNEX 4: CHECKLIST

CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.3.1-3.3.3 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

- x Form of application
- x Assessment procedure
- x Applicant details
- x Confidential Commercial Information
- x Purpose of the application
- x Exclusive Capturable Commercial Benefit
- x Justification for the application
- x International standards
- x Information to support the application
- x Statutory Declaration

Food Additives (3.3.1)

- x Support for the application
- x Analytical detection method
- x Nature and technological function information
- x Toxicokinetics and metabolism information
- x Identification information
- x Toxicity information
- x Chemical and physical properties
- x Safety assessments from international agencies
- x Impurity profile
- x List of foods likely to contain the food additive
- x Manufacturing process
- x Proposed levels in foods
- x Specifications ☐ ☐ Percentage of food group to contain the food additive
- x Food labelling
- x Use in other countries (if applicable)