



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

7-06

4 October 2006

INITIAL ASSESSMENT REPORT

APPLICATION A562

COPPER CITRATE AS A PROCESSING AID FOR WINE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 15 November 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

This Application (A562) seeks to amend Standard 1.3.3 – Processing Aids and Standard 4.5.1 – Wine Production Requirements (Australia Only) of the *Australia New Zealand Food Standards Code* (the Code). It is an Application from the Winemakers’ Federation of Australia, to allow the use of cupric citrate other than on a bentonite base. The use of cupric citrate on a bentonite base is currently permitted. ‘Copper citrate’ is used synonymously with ‘cupric citrate’ in this report.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), excluded primary production standards from the joint Australia New Zealand food standards setting system. Australia and New Zealand independently and separately develop food regulatory measures for the production of wine. However, the Application also relates to amendments to Standard 1.3.3 – Processing Aids, which would be applicable to wine produced or sold in New Zealand.

The Applicant is specifically applying for permission for use of copper citrate as a processing aid in Standard 1.3.3-Processing Aids, and Standard 4.5.1-Wine Production Requirements (Australia only). Processing aids are required to undergo a pre-market safety assessment through an application to FSANZ before being offered for sale in Australia and New Zealand.

The purpose of copper citrate is to remove sulphides, particularly hydrogen sulphide from wine, after which the copper citrate is filtered out of the wine. There would be low levels of residual copper in the wine, and copper citrate would not perform a technological function in the final product. The Applicant has requested no specific maximum permissions for use of copper citrate; rather, Good Manufacturing Practice (GMP) would ensure appropriate use of the processing aid.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standard Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to use copper citrate other than on a bentonite base, as a processing aid during the wine production process. Such an approval would warrant a variation to Standard 4.5.1 and Standard 1.3.3 of the Code.
- There is currently no permission in the Code for allowing copper citrate other than on a bentonite base, to be added to wine during the wine production process.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 4.5.1 and Standard 1.3.3 of the Code that could achieve the same end.
- At this stage no other relevant matters are apparent.

Consultation

Public submissions are now invited on this Initial Assessment Report. Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of the Draft Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report 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 preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 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 and provide justification for treating it as commercial-in-confidence. Section 39 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. 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
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 15 November 2006.

Submissions received after this date will not be considered, unless 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.

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 Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

FSANZ received an Application (A562) on 28 April 2005 submitted by the Winemakers' Federation of Australia, seeking amendments to Standard 1.3.3 – Processing Aids, and Standard 4.5.1 – Wine Production Requirements (Australia only), of the *Australia New Zealand Food Standards Code* (the Code).

It is proposed that these Standards will be modified to permit the use of all forms of copper citrate as processing aids in wine manufacture. Currently, only cupric citrate on a bentonite base is permitted for use as a processing aid in wine manufacture. 'Copper citrate' is used synonymously with 'cupric citrate', and will be the term mainly used in this report, except when referring to legal drafting.

1. Background

1.1 Current Regulations on processing aids in wine manufacture.

Standards 1.3.3 and 4.5.1 of the *Australia New Zealand Food Standards Code* regulate the use of processing aids in wine manufacture. A processing aid is defined in Standard 1.3.3 as:

a substance used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food.

Clause 14 of Standard 1.3.3 currently permits the use of cupric citrate on a bentonite base for the purpose of removing sulphide compounds from wine. Standard 1.3.3 applies to both Australia and New Zealand, and the wine sold to these markets.

However, wine produced in Australia must also comply with Standard 4.5.1, an 'Australia Only' standard, which does not apply to New Zealand wines. This standard underpins the 1994 *Agreement between Australia and the European Community on Trade in Wine, and Protocol*¹ and repeats the permission to use cupric citrate on a bentonite base as a processing aid for wine.

There are currently no permissions in the Code for the use of copper citrate except on a bentonite base for wine production.

1.2 Historical background

The current permissions for the use of copper citrate as a processing aid in wine, were considered as part of Application A463 – Copper Citrate as a Processing Aid in Wine. Amendments to Standards 1.3.3 and 4.5.1 were gazetted on 29 April 2004, which permitted the use of cupric citrate on a bentonite base as a processing aid.

Bentonite is an inert insoluble material that acts as a support to which copper citrate is attached. Once the product had performed its function, the bentonite carrying the copper citrate, is filtered out of the treated wine.

¹ <http://beta.austlii.edu.au/au/other/dfat/treaties/1994/6.html>. Accessed on 25 August 2006.

Bentonite is permitted as a processing aid in the Table to clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia Only) and can currently be used at a level necessary to achieve a specific function in the processing of food. Bentonite is also approved as a generally permitted food additive listed in Schedule 2 of Standard 1.3.1, so it has approval as a generally permitted processing aid (via subclause 3(b) of Standard 1.3.3).

Prior to Application A463, the only permission to use copper as a processing aid was for copper sulphate at a level commensurate with Good Manufacturing Practice (GMP).

1.3 Approval in other countries

The use of copper citrate on a bentonite base has been approved for use in wine manufacture within Austria, Switzerland and South Africa, and approval for use is currently being considered in the European Union. No overseas jurisdictions have approved the use of copper citrate which is not on a bentonite base.

The treaty between the European Community and Australia currently only allows for the use of copper sulphate in wine, to remove hydrogen sulphide and other sulphide compounds which produce objectionable odours in wine. In particular, the European Union requires residual copper levels in wine to remain below 1 mg/L.

1.4 Properties of copper citrate

Copper citrate presented as Kupzit, which is copper citrate on a bentonite base, is considered to offer the following benefits when used in the removal of sulphide compounds during wine manufacture:

- a higher affinity than copper sulphate for hydrogen sulphide and thus greater potential to reduce sulphide off-flavours in wine;
- less copper is dissolved in wine compared to copper sulphate;
- is easy to handle; and
- in the majority of copper citrate applications it is unnecessary to add potassium hexacyanoferrate (II) to reduce residual copper levels (referred to as blue fining).

2. The Regulatory Problem

The Applicant is seeking an amendment to the Code to change permissions for the use of ‘copper citrate on a bentonite base’ in wine manufacture to ‘copper citrate’. It is claimed that the bentonite base is an inert carrier for copper citrate, and restricts the current permissions to a proprietary product only (trademark: Kupzit). Permissions for a wider range of copper citrate forms may give wine manufacturers access to a greater variety of products to remove sulphide compounds from their products.

Copper citrate as a processing aid in wine must therefore be assessed, and if approved, added to the Table to clause 14 of Standard 1.3.3 and the Table to clause 4 of Standard 4.5.1.

3. Objectives

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

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

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

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

FSANZ will ensure the protection of public health and safety and that the risk analysis will use the best available scientific evidence by undertaking an assessment of this application.

4. Key Assessment Questions

The question FSANZ will consider in assessing this application is:

- Does the use of copper citrate as a processing aid in wine manufacture, when the form of copper citrate does not have a bentonite base, pose any risk to public health and safety?

RISK ASSESSMENT

5. Safety Assessment

The safety of copper citrate on a bentonite base was assessed by FSANZ as part of Application A463. The bentonite base acts as an inert carrier for copper citrate, therefore the use of copper citrate without a bentonite base may present an altered safety profile. FSANZ will assess the safety of copper citrate, in particular what effect the use of copper citrate might have in regard to the potential for copper residues to remain in the final product. An evaluation of the safety data for copper citrate will be presented in the Draft Assessment Report.

RISK MANAGEMENT

6. Options

There are two regulatory options available for Application A562:

6.1 Option 1: Not approve the use of copper citrate as a processing aid in wine manufacture, if it is not on a bentonite base.

Under this option, the *status quo* would be maintained and there would be no changes to the Code.

6.2 Option 2: Approve the use of copper citrate in forms additional to copper citrate on a bentonite base.

This option would require an amendment to the Code, to permit the use of copper citrate other than on a bentonite base, as a processing aid in wine manufacture.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this Application are: **consumers** of wine and wine products in Australia and New Zealand; **industry** being those sectors of the wine industry intending to use copper citrate in wine manufacture, or currently using copper citrate on a bentonite base in wine manufacture; and the **governments** of Australia and New Zealand.

7.2 Benefit Cost Analysis

7.2.1 Option 1: Not approve the use of copper citrate as a processing aid in wine manufacture, if it is not on a bentonite base.

7.2.1.1 Consumers

It is likely that maintaining the *status quo* will have minimal impact on consumers of wine and wine products. Consumers will continue to have access to quality wines, as sulphide compounds can be readily removed with the current range of processing aids (e.g. copper sulphate or copper citrate on a bentonite base).

7.2.1.2 Industry

For industry, maintaining the *status quo* has disadvantages by the potential loss of cost savings that would occur with greater competition in the range of processing aids. Also, as copper citrate is deemed to have superior technological features over other processing aids, manufacturers that cannot, or choose not to use copper citrate on a bentonite base may be unable to produce higher quality wines. This may limit the potential financial returns they could receive on their products (in both local and overseas markets).

7.2.1.3 Government

The impact of maintaining the *status quo* on the Australian and New Zealand governments is likely to be minimal, with respect to monitoring and enforcement of the processing aids used in wine manufacture.

7.2.2 *Option 2: Approve the use of copper citrate in forms additional to copper citrate on a bentonite base.*

7.2.2.1 Consumers

The use of a wider variety of copper citrate forms as processing aids will give wine manufacturers greater scope to produce wines of higher quality, and will therefore allow consumers to have increased access to quality wine products. However, from a consumer's perspective this change is unlikely to have a significant impact on their overall rate of wine consumption, as quality wines can already be manufactured using the current processing aid permissions. There may be additional cost savings passed onto consumers though, should the manufacture of wine be made more efficient through improvements in the removal of sulphide compounds.

7.2.2.2 Industry

An amendment that widens the permissions to use copper citrate in wine manufacture will have substantial benefits for industry. Industry will benefit from using an alternative processing aid in the production of wine products in Australia and New Zealand. Copper citrate as an alternative will provide increased flexibility to manage the removal of sulphide compounds, and therefore increase the industry's capability to produce quality wines.

There is the potential for cost savings in the manufacture of wine, due to greater competition in the market for the sale of processing aids to wine producers.

The proposed amendment may widen trade opportunities for export producers, as the more flexible use of copper citrate in wine manufacture will expand opportunities to improve the control over residual copper levels in wine. In particular, the European Union requires residual copper levels in wine to remain below 1 mg/L. Therefore, an increased availability to use a copper-based processing aid that produces lower residual copper levels, such as copper citrate, will have advantages for wine producers exporting wine to Europe.

7.2.2.3 Government

There is no direct impact on government in approving non-bentonite forms of copper citrate. Copper citrate can replace the use of copper sulphate or copper citrate on a bentonite base already permitted for wine, and therefore would not significantly affect enforcement costs.

7.3 Comparison of Options

The regulatory options for amending the use of copper citrate as a processing aid have very little impact on consumer and government stakeholders. Under either option, consumers and government agencies are unlikely to experience many changes in the way they view or interact with the wine market. However, consumers may have access to a wider range of higher quality and potentially lower cost wines under Option 2, although it is expected that this impact will be small. No significant adverse costs have been associated with either option for consumer and government stakeholders.

Industry stakeholders are the most impacted by the regulatory options. There are noticeable benefits for the industry under Option 2. An expansion in the range of available copper citrate products will increase the ability to control wine sulphide levels while producing lower residual copper levels. However, it should be recognised that copper citrate is already permitted for use in wine manufacture (on a bentonite base), and as such the benefits are more likely to be derived from improvements in access to copper citrate products and competition between copper citrate manufacturers. Under Option 1, industry stakeholders will still receive benefits from the current permission to use copper citrate, although to a lesser degree.

To develop the analysis of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?
- Are there any implications with the proposed change for international wine trade for Australian wines?
- Is copper citrate used elsewhere in the world to treat wine? If so, what is the process for treating wines with copper citrate?

COMMUNICATION

8. Communication and Consultation Strategy

This is a standard FSANZ Application with two rounds of public consultation calling for submissions to assist FSANZ toward a Draft Assessment. FSANZ will ensure that relevant stakeholders and other interested parties are made aware of the Application, and their comments sought, particularly those of wine producers and jurisdictions which enforce the Code.

9. Consultation

9.1 Public Consultation

FSANZ now invites written submissions to assist in the development of the Draft Assessment, and will have regard to any submissions received. Comments on, but not limited to, the following would be useful:

- Are there any safety issues with the use of copper citrate as a processing aid when it is not on a bentonite base?
- Are there any food technology issues associated with the use of copper citrate when it is not on a bentonite base?
- What potential impacts on stakeholders would result from the use of copper citrate in wine production when it is not on a bentonite base?

9.2 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.

While there are relevant international standards for the production of wine, amending the Code as proposed is unlikely to have a significant effect on international trade. This issue will be further considered at Draft Assessment and if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

10. Conclusion and Preferred Option

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standard Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to use copper citrate other than on a bentonite base, as a processing aid during the wine production process. Such an approval would warrant a variation to Standard 4.5.1 and Standard 1.3.3 of the Code.
- There is currently no permission in the Code for allowing copper citrate other than on a bentonite base, to be added to wine during the wine production process.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 4.5.1 and 1.3.3 of the Code that could achieve the same end.
- At this stage no other relevant matters are apparent.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of the Draft Assessment Report.