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

1-07
21 March 2007

DRAFT ASSESSMENT REPORT

APPLICATION A562

COPPER CITRATE AS A PROCESSING AID FOR WINE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 2 May 2007
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.

As a result of the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), Australia and New Zealand independently and separately develop food regulatory measures for the production of wine. Therefore any amendment to Standard 4.5.1 is only relevant to Australia. 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 along with any insoluble copper sulphides formed 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.

The Draft Assessment Report concludes that copper citrate fulfils a specific technological purpose consistent with that of a processing aid and that it raises no public health and safety concerns. Copper citrate is comparable in safety with already permitted forms of copper used as processing aids (namely copper sulphate and copper citrate when used on a bentonite base).

The regulatory impact analysis has concluded that the option to approve copper citrate may have advantages for consumers and for industry. There are no identified disadvantages to the approval of copper citrate.

Preferred Approach

Approval is proposed for cupric citrate as a processing aid in wine production without it being restricted to a bentonite base. This permission would be achieved by replacing 'Cupric citrate on a bentonite base' with 'Cupric citrate' in the Table to Clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia only) and in the Table to Clause 14 of Standard 1.3.3 – Processing Aids.

Reasons for Preferred Approach

Approval is proposed for cupric citrate as a processing aid in wine production without it being restricted to a bentonite base for the following reasons:

- There are no public health and safety concerns associated with the use of copper citrate under the proposed conditions of use. This conclusion is based on FSANZ's assessment of the safety of copper and its subsequent compounds **(Attachment 2)**; copper citrate would be an alternative to the currently permitted processing aids for wine treatment, these being copper sulphate and copper citrate on a bentonite base; and also that dietary exposure to copper via wine will be limited due to low residues of copper citrate in the wine.

- The use of copper citrate is technologically justified. In particular, its use is to remove unpleasant sulphur containing compounds from wine, and in performing this function has certain advantages over copper sulphate.

- Standard 4.5.1 – Wine Production Requirements is an 'Australia only' Standard which is designed to support the 1994 *Agreement between Australia and the European Community on Trade in Wine, and Protocol*[1]. This Standard contains a separate list of approved processing aids, which can be used for wine production in Australia. It does not relate to wine produced in New Zealand or wine imported into Australia or New Zealand. 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, and wine imported into Australia or New Zealand.

- The current restriction to cupric citrate on a bentonite base as the only permissible form is unnecessarily restrictive.

- The proposed draft variation to the Code is consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), in particular, it does not raise any public health and safety concerns, it is based on risk analysis using the best available scientific evidence, and helps promote an efficient and internationally competitive food industry.

- The regulatory impact statement concludes that there are potential benefits for both consumers and industry in using copper citrate and no specifically identified costs.

Consultation

Public comment on the Initial Assessment Report was sought from 4 October 2006 to 15 November 2006. A total of 8 submissions were received during this period and a summary of these can be found in **Attachment 4**. Specific issues raised relating to copper citrate use in winemaking has been addressed in this report.

[1] http://beta.austlii.edu.au/au/other/dfat/treaties/1994/6.html. Accessed on 11 January 2007.

Three submissions supported the Application, and five supported progression of the Application to the Draft Assessment stage. The majority of submitters stated that they would reserve their full comments until the release of the Safety Assessment Report addressing health and safety concerns.

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

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Draft 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 Final 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) 2 May 2007.

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

1. Introduction

1.1 Nature of Application

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 be modified to permit the use of forms of copper citrate, other than on a bentonite base, as processing aids in wine manufacture. Currently, cupric citrate on a bentonite base is the only form of copper citrate permitted for use as a processing aid in wine manufacture. 'Copper citrate' is used synonymously with 'cupric citrate', and as a more familiar term will be mainly used in this report, except when referring to legal drafting. The use of copper citrate is considered technically superior to the use of copper sulphate, which is also permitted and commonly used to eliminate hydrogen sulphide odours in wine.

1.2 Summary of proposed Amendments

The Applicant has proposed that:

- the Table to Clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia Only) and;

- the Table to Clause 14 of Standard 1.3.3 – Processing Aids, be amended to remove the words 'on a bentonite base' from the current entry 'Cupric citrate on a bentonite base', to remove the restriction that cupric citrate may only be used as a processing aid for wine if the cupric citrate is on a bentonite base.

2. Background

2.1 Current Regulations on processing aids in wine manufacture.

Standards 1.3.3 and 4.5.1 of the 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. As a result of the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), Australia and New Zealand independently and separately develop food regulatory measures for the production of wine.

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 Australia EC Wine Agreement.

There are currently no permissions in the Code for the use of copper citrate except on a bentonite base for wine production. However, copper sulphate is approved as a generally permitted food additive and is listed in Schedule 2 of Standard 1.3.1 - Food Additives (cupric sulphate, INS 519) and in the Table to clause 4 of Standard 4.5.1 as a permitted processing aid.

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).

2.2 Historical background

The current permission for the use of copper citrate as a processing aid in wine was considered as part of Application A463 – Copper Citrate as a Processing Aid in Wine. This Application concerned a product called Kupzit ® which consists of copper citrate at 2% on a bentonite base. 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. This was on the basis that:

- the Applicant sought specific permission for copper citrate (2% on a bentonite base);
- the data that was submitted in support of the Application demonstrated lower residual levels of copper in wine following the use of copper citrate on a bentonite base, compared to the residue levels following the use of the currently permitted processing aid copper sulphate;
- FSANZ examined this data and concluded from the data that, copper citrate at 2% on the carrier matrix bentonite led to greater affinity to remove sulphide odours in treated wine;
- there was no other data submitted by the Applicant and/or other submitters or available in the literature (from research conducted by FSANZ) that suggested that another base would be equally adequate in functionality, and result in low copper residues; and
- it was noted that an insoluble bentonite base allows the solid to be readily removed leading to less residual copper dissolved in the treated wine

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

2.3 Approval in other countries

The use of copper citrate on a bentonite base has been approved for use in wine manufacture within Austria, Switzerland, South Africa, Chile and Argentina, and used in all eastern European countries. FSANZ is not aware of the approval or rejection of other forms of copper citrate.

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. The European Community requires residual copper levels in wine to remain below 1 mg/L.

2.4 Properties of copper citrate

Copper citrate presented as Kupzit R, 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).

The Applicant has requested no specific maximum permission levels for use of copper citrate and has indicated that GMP would ensure appropriate use of the processing aid and there would be limited residues of copper in the wine. The Applicant states that good manufacturing practice for winemaking indicates that a maximum of 0.5 mg/l of copper should be used for the purposes of reducing unpleasant sulphide compounds from the wine. Higher levels of copper can produce reddish brown haze and potential precipitates so it is important for wine manufacturers not to over treat with copper. Copper citrate would not fulfil a technological function in the final product, since it would be removed from the treated wine.

3. The Regulatory Problem

The Applicant is seeking an amendment to the Code to change permissions for the use of ‘cupric citrate on a bentonite base’ in wine manufacture to ‘cupric 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.

4. 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.

The specific objective in assessing this Application is to assess the safety of copper citrate as a processing aid in wine manufacture, when the form of copper citrate is not on a bentonite base.

5. 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 is not on a bentonite base, pose any risk to public health and safety? Given that any other base or excipient used with copper citrate is approved in the Code and for that purpose.

RISK ASSESSMENT

6. Safety Assessment

6.1 Safety Assessment

The key issue in regard to the safety of wine treated with cupric citrate is the potential for dissolved copper to remain in the final food product. No information on the likely concentration of copper dissolved in wine following treatment with cupric citrate was submitted in this application, nor was there data available from Australian winemakers, internationally, or in the literature on the use of cupric citrate (without a bentonite base) in wine. Therefore, the chemistry by which hydrogen sulphide and other sulphur compounds are removed from solution by cupric citrate was reviewed in order to determine whether more dissolved copper was likely to be present relative to permitted processing aids.

Cupric citrate reacts with hydrogen sulphide in wine to form insoluble cupric sulphide. Cupric sulphide is also produced when the permitted processing aids cupric sulphate and cupric citrate on a bentonite base are used. Cupric citrate also reacts with other sulphur compounds in wine e.g. thiols. Cupric sulphide readily precipitates out of solution and is removed by decanting, filtering and/or fining[2].

Therefore, it was concluded that the use of cupric citrate as a processing aid in wine will pose no risk to public health and safety as the residue levels of copper in the final wine product are expected to be similar to residues produced using other approved processing aids that incorporate copper.

6.2 Technological need for copper citrate

Copper citrate in the hydrated form consists of light blue/green granules, which have a neutral smell, and are slightly soluble in water. A common method used in the wine industry to treat wine containing unpleasant volatile sulphur odours is to add copper sulphate which irreversibly binds up with hydrogen sulphide and simple thiols to form insoluble precipitates of copper compounds. These precipitates are subsequently removed from the wine and so remove the objectionable sulphur compounds and their unpleasant odours from the wine. Copper citrate on a bentonite base is used as an alternative to copper sulphate to remove unpleasant sulphur containing compounds from wine. This Application assumes other forms of copper citrate would be used for a similar purpose.

It has been ascertained that copper citrate has the following advantages over currently permitted copper sulphate when treating wine for removal of sulphide off-odours:

- it has greater reactivity towards sulphide compounds;
- there is less residual copper left in the treated wine; and
- less residual copper means less, or maybe no subsequent treatment with potassium ferrocyanide (blue finings) is necessary to limit residual copper.

It is concluded that the use of copper citrate as a processing aid for wine to remove unpleasant sulphide off-odours is technologically justified. The applicant considers the current restriction to cupric citrate on a bentonite base as the only permissible form is unnecessarily restrictive and that permission for copper citrate *per se* would be more appropriate. This is further discussed in the Food Technology Report **(Attachment 3).**

RISK MANAGEMENT

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

There are no options other than a variation to Standard 1.3.3 and Standard 4.5.1 for this Application. Therefore the regulatory options available for this Application are:

[2] Fining involves introducing a protein (fining agent, e.g. egg albumin, casein or isinglass) into wine, which flocculates, gathering particles that cause turbidity in the wine. Fining has a clarifying and stabilizing effect.

7.1 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.

7.2 Option 2: Approve the use of copper citrate in other forms which may include 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. By broadening the permission accordingly, the current Standard 'Cupric citrate on a bentonite base' would be replaced by 'Cupric citrate'.

8. Impact Analysis

8.1 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.

8.2 Benefit Cost Analysis

In developing food standards for Australia and New Zealand, FSANZ is required to consider the impact of all options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, including the likely health, economic and social impacts.

This Draft Assessment has considered the potential costs and benefits of the two regulatory options on the parties identified as being affected by the regulatory decision. This has been based on information on copper citrate supplied by the applicant, information gained from submissions to the Initial Assessment Report, and on knowledge gained from the previous safety assessment on copper under the review of the *Australia New Zealand Food Standards Code*.

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

<u>8.2.1.1 Consumers</u>

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).

8.2.1.2 Industry

For industry, maintaining the *status quo* has disadvantages by the loss of cost savings that could potentially occur with greater variety and competition in the range of copper citrate processing aids. This may limit the potential financial returns they could receive on their products.

8.2.1.3 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.

8.2.2 Option 2: Approve the use of copper citrate in other forms which may include copper citrate on a bentonite base.

8.2.2.1 Consumers

The use of a wider variety of copper citrate forms as processing aids could give wine manufacturers greater scope to produce wines of higher quality, and therefore allow consumers to have increased access to quality wine products. There may also be additional cost savings for consumers should any financial benefits for wine producers be passed on.

8.2.2.2 Industry

An amendment that broadens the permitted forms of copper citrate used in wine manufacture could have substantial benefits for industry due to the availability of alternative processing aid(s) for quality wines.

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

8.2.2.3 Government

No significant impact on government is anticipated by the approval of non-bentonite forms of copper citrate

8.3 Comparison of Options

Industry stakeholders are the group most impacted by the regulatory options. Option 1 appears to be unnecessarily restrictive and there are potential benefits for the industry under Option 2. Such benefits are most likely to be derived from improvements in access to copper citrate products and competition between copper citrate manufacturers.

The benefits to industry may also flow on to benefit consumers by way of possible cost savings and increased availability of quality wines, although it is feasible that this impact will be small.

It is anticipated the regulatory options for amending the use of copper citrate as a processing aid will have very little impact on government stakeholders.

No significant adverse costs have been associated with either option for consumer and government stakeholders.

If the Application is accepted FSANZ proposes to replace ‘Cupric citrate on a bentonite base’ with ‘Cupric citrate’ into the Table to Clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia Only) and into the Table to Clause 14 of Standard 1.3.3 – Processing Aids. Copper citrate on a bentonite base will continue to be an approved processing aid, in that it will be encompassed by the proposed general permission for copper citrate.

The proposed draft variations are in **Attachment 1**.

To further 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?
- Are there any perceived costs or benefits for consumers in relation to public health and safety, or consumer information?
- 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?

More specifically, FSANZ seeks information as to:

- Use, approvals or potential development of new products in relation to copper citrate not on a bentonite base.
- Please provide as much data as possible on the form and use of such processing aid(s).

COMMUNICATION

9. Communication and Consultation Strategy

This is a standard FSANZ Application with two rounds of public consultation calling for submissions to assist FSANZ toward a Final 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.

10. Consultation

10.1 Public Consultation at Initial Assessment

The Initial Assessment was advertised for public comment between 4 October 2006 and 15 November 2006.

Eight submissions were received during this period and a summary of the submissions is included in **Attachment 4** to this Report.

FSANZ has taken the submitters comments into account in preparing the Draft Assessment of this Application. The majority of submitters expressed a keen interest in the health and safety aspects of copper residues in wine. A safety assessment report and a food technology report on copper citrate are located at **Attachments 2 and 3** respectively. Other specific issues raised in submissions are discussed below.

10.1.1 Copper residue limit

The Food Technology Association of Victoria, the NSW Food Authority and the Department of Human Services of Victoria have all indicated that a maximum limit for copper in wine should be established. The New Zealand Food Safety Authority is also interested in residue levels of copper in wine.

<u>10.1.1.1 FSANZ's Response</u>

The Applicant has stated that the application rate of copper citrate to wine is self limiting due to haze formation in the event of excess copper citrate. The Applicant states that haze can form with as little as 0.3 ppm (0.3 mg/L) residual copper, although if the wine has been successfully protein-fined, and sulphur dioxide is not excessive, wines should not be at risk.

10.1.2 Trade restrictions

The Food Technology Association of Victoria raised the question of whether the proposed amendment would lead to trade restrictions.

<u>10.1.2.1 FSANZ's Response</u>

The proposed amendment seeks to expand permissions. It does not seek to delete any currently existing permission, in that copper citrate on a bentonite base would be encompassed by the general permission for copper citrate, and thus trade would not be affected. However it should also be noted, copper citrate *per se* is not listed as an approved processing aid in the current Australia EC Wine Agreement, therefore Australian and New Zealand wine manufacturers producing wine for export to Europe would not be able to use it.

Copper residues in wine resulting from the use of different forms of copper citrate i.e. compared to copper sulphate or copper citrate on a bentonite base, are unlikely to be different. The current Australia EC Wine Agreement specifies a 1 mg/L maximum residue of copper in the final product.

10.1.3 Costs or benefits to Government

The NSW Food Authority has made the comment that there does not appear to be any evident costs or benefits to government with respect to administration and enforcement.

10.1.3.1 FSANZ's Response

FSANZ agrees there is no apparent impact on government by approving copper citrate.

10.2 Public Consultation at Draft Assessment

FSANZ now invites written submissions for the purpose of the Final Assessment under paragraph 17(3)(c) of the FSANZ Act and will have regard to any submissions received. Comments on the questions raised in the impact analysis (refer section 8 above) would be appreciated.

10.3 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 as Standard 4.5.1 does not apply to imported wine. However, Standard 1.3.3 does apply to imported wine, and there may be trade implications due to a liberalising of the use of copper citrate in winemaking. Therefore, notification of the proposed changes to the Code will be made to the WTO in accordance with the WTO Technical Barriers to Trade Agreement (TBT). This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

11. Conclusion and Preferred Approach

The Draft Assessment Report is based on information provided by the Applicant and submissions received in response to the Initial Assessment. Having regard to the requirements for Draft Assessment as prescribed in section 15 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to use copper citrate not 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 Draft Assessment Report will be used to develop the next stage of the Application and the preparation of the Final Assessment Report.

Preferred Approach

Approval is proposed for cupric citrate as a processing aid in wine production without it being restricted to a bentonite base. This permission would be achieved by replacing 'Cupric citrate on a bentonite base' with 'Cupric citrate' in the Table to Clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia only) and in the Table to Clause 14 of Standard 1.3.3 – Processing Aids.

11.1 Reasons for Preferred Approach

Approval is proposed for cupric citrate as a processing aid in wine production without it being restricted to a bentonite base for the following reasons:

- There are no public health and safety concerns associated with the use of copper citrate under the proposed conditions of use. This conclusion is based on FSANZ's assessment of the safety of copper and its subsequent compounds **(Attachment 2)**; copper citrate would be an alternative to the currently permitted processing aids for wine treatment, these being copper sulphate and copper citrate on a bentonite base; and also that dietary exposure to copper via wine will be limited due to low residues of copper citrate in the wine.

- The use of copper citrate is technologically justified. In particular, its use is to remove unpleasant sulphur containing compounds from wine, and in performing this function has certain advantages over copper sulphate.

- Standard 4.5.1 – Wine Production Requirements is an 'Australia only' Standard which is designed to support the Australia EC Wine Agreement. This Standard contains a separate list of approved processing aids, which can be used for wine production in Australia. It does not relate to wine produced in New Zealand or wine imported into Australia or New Zealand. 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, and wine imported into Australia or New Zealand.

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act, in particular, it does not raise any public health and safety concerns, it is based on risk analysis using the best available scientific evidence, and helps promote an efficient and internationally competitive food industry.

- The regulatory impact statement concludes that there are potential benefits for both consumers and industry in using copper citrate which outweigh any perceived costs.

12. Implementation and review

If the draft variation was adopted then it would come into effect upon gazettal.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3. Food Technology Report
4. Summary of issues raised in public submissions.

Attachment 1

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

To commence: on gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by omitting from the* Table to clause 14, cupric citrate on a bentonite base, *substituting* –

Cupric citrate	Removal of sulphide compounds from wine	GMP

[2] ***Standard 4.5.1*** *of the Australia New Zealand Food Standards Code is varied by omitting* from the Table to clause 4, cupric citrate on a bentonite base, *substituting* –

Cupric citrate

Attachment 2

Safety Assessment Report

Introduction

The Winemakers' Federation of Australia is seeking approval for the use of cupric citrate (copper (II) citrate, $Cu_2C_6H_4O_7$) as a processing aid in wine. As such, a pre-market assessment and amendment 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) would be required.

Currently cupric sulphate and cupric citrate on a bentonite base are the only permitted forms of copper for use in wine processing. Therefore, FSANZ is required to assess the risk to public health and safety from the use of cupric citrate as a processing aid in wine.

The key issue in regard to the safety of cupric citrate in wine is the potential for dissolved copper to remain in the final food product. During the review of metals and contaminants in food (Proposal P157), wine was not identified as a food that makes a major contribution to the dietary intake of copper for Australia or New Zealand consumers (ANZFA, 1999). At this time, the maximum level for copper in a range of foods was deleted from the Code due to the low public health and safety risk of copper in foods.

No data on the residues of copper in wine treated with cupric citrate were submitted in this Application, nor were there data available from Australian wine makers, internationally, or in the literature on the use of cupric citrate (without a bentonite base) in wine. Therefore, the chemistry by which hydrogen sulphide and other sulphur compounds are removed from solution by cupric citrate was reviewed in order to determine whether more dissolved copper (ions) would be present relative to permitted processing aids.

Risk assessment of copper

A risk assessment of copper was most recently undertaken by FSANZ (at that time as ANZFA) as part of the Review of Metal and Contaminants in Food (Proposal P157) of the Code (ANZFA, 1999). The following is the summary and conclusion of the toxicological evaluation.

Copper is an essential trace element. This essentiality results from its role as a cofactor in many fundamental redox reactions essential for cellular respiration, free radical defence, neurotransmitter function, connective tissue biosynthesis and cellular iron metabolism.

Copper is found as a natural component of food and this source can account for nearly 90% of the copper intake if the water supply is low in copper. Most foods in Australia and New Zealand contain between 1–5 mg/kg with the highest levels found in liver (up to 237 mg/kg) and more intermediate levels (8–24 mg/kg) found in nuts, seeds, bran and oysters. The most recent WHO recommendation on the estimated safe and adequate daily dietary intakes (ESADDI) for copper is 1.15–1.35 mg for adults, 0.75–1.15 mg for adolescents, 0.56–0.75 mg for children and 0.33–0.62 mg for infants. Estimated oral intakes for copper in Australia are about 2 mg/day for adults, 1.5 mg/day for children, and 0.6 mg/day for infants. In New Zealand, the estimated oral intake for adults is 2–3 mg/day.

These intakes are approximately twice the mean reported global intakes (0.93–1.24 mg/day) and twice the calculated essential level indicating that, in general, the copper status of Australian and New Zealand populations is good.

The level of copper in the body is subject to homeostatic control principally by absorption and excretion. Copper is actively absorbed, primarily in the intestine. The amount absorbed ranges from 55–75% for adults, depending on other dietary components present. In adults, the proportion of copper absorbed decreases as copper intake increases. This appears to be in contrast to infants, where the relationship between absorption and intake of copper is linear, i.e. the absorption is non–saturable. Once absorbed, copper (complexed principally with albumin) is transported via the portal blood to the liver, where it is partitioned either for excretion or distribution to other tissues. The distribution of copper to other tissues is mediated by caeruloplasmin. Excretion of copper occurs primarily via the bile and appears to be the main process for maintaining copper homeostasis.

The toxicity of copper derives from its direct effects on the structure and function of biomolecules such as DNA, membranes and proteins or from oxygen radical mechanisms. Excess copper intake also has the potential to adversely affect the absorption or bioavailability of other metals and may lead to nutritional deficiency, especially that of zinc and iron. Establishment of a No Observed Effect Level (NOEL) or Lowest Observed Effect level (LOEL) for these effects is complicated by the fact that the level of copper required to produce such signs will vary depending on the levels of copper, and other factors in the diet. Therefore, it has not been possible to define a level of copper intake that is associated with this endpoint.

Studies with acute exposure in animals have shown that the acute toxicity of a single dose of copper can vary widely depending on its chemical form.

In general, the more soluble the compound the more toxic it tends to be. These studies have also shown that the degree of toxicity can vary with the species of animal tested (e.g. copper sulphate is about 50 times more toxic to sheep than to rats).

The majority of animal studies have focussed on short–term and sub–chronic exposure of rodents to copper sulphate. These studies have shown that, in general, rats are more susceptible than mice to the toxic effects of copper. Overt toxic signs are generally manifest as a dose–related reduction in growth, seen at high doses in rats (194 mg/kg bw/day). The principal target organs for toxicity are the liver and kidney with effects noted from doses of 67 mg/kg bw/day. Forestomach effects are also seen at lower doses but this toxic endpoint may be of less relevance to humans. Some haematological changes have also been noted at doses of 34 mg/kg bw/day.

The chronic toxicity of copper compounds is less well studied and NOELs or LOELs for such exposure have not been established. The effects in animals from chronic exposure to copper compounds are similar to the short–term and sub–chronic studies and include growth retardation, effects on the liver, kidney and forestomach. Increased mortality has also been observed. The dose at which these effects first appear vary with the species of animal tested and the copper compound tested, but in general are evident at doses greater than 10 mg/kg bw/day.

In humans there is limited evidence that acute ingestion of copper at very high doses can be toxic, in some cases leading to coma and death. Ingestion of copper at such doses, however, is usually the result of the contamination of beverages (primarily drinking water) or from accidental or deliberate ingestion of large quantities of copper salts. Effects on the gastrointestinal tract, such as nausea, vomiting and diarrhoea, occur at lower copper levels. The doses reported to induce such effects range from 2 to 32 mg/day in drinking water. This contrasts with the fact that up to 13 mg/day can be ingested via food without any apparent adverse effect on human health and suggests that the ionic form of copper may have a bearing on its toxicity.

The level of 13 mg/day was therefore been used by a Joint FAO/IAEA/WHO Expert Consultation in 1996 to establish an upper limit to the safe range of population intakes for adults of 0.2 mg/kg bw/day based on the limited data available for humans (WHO 1996). This level can be regarded as a NOEL.

Liver failure in an adult male has been associated with the chronic ingestion of about 30 mg/day, as copper supplements. While this level was obtained from a study of a single individual, and its relevance to copper intake via food may be questionable, it does give some indication of a level of chronic exposure that may be toxic in humans. This level of intake is approximately twice the upper safe limit for exposure via food.

Studies with rats have shown that copper may induce reproductive effects (reduced weights and/or abnormal histology of testes, seminal vesicles, uterus or ovaries) although these effects were not reproducible in mice at even higher doses of copper. The significance of this is uncertain and as a whole, these studies are inadequate for assessing the reproductive toxicity of copper compounds.

More extensive studies have been done on the developmental toxicity of copper in rodents and these show evidence in mice of foetotoxicity at doses of 80 mg/kg bw/day and malformations at doses >159 mg/kg bw/day. In mink, increased mortality in offspring was observed at the much lower dose of 12 mg/kg bw/day. The significance of this species difference is not clear. The information available for humans is very limited and therefore inadequate to assess the potential for reproductive and development toxicity.

Copper sulphate is not mutagenic in bacterial assays. In mammalian cells, dose–related increases in unscheduled DNA synthesis, mutation frequency and sister chromatid exchanges have been seen. *In vivo* studies using the mouse micronucleus assay, however, have given contradictory results. At levels occurring in the diet, there is no evidence that copper containing salts cause cancer.

In 1999, FSANZ adopted a provisional maximum tolerable daily intake (PTDI) of 0.2 mg/kg bw/day. This is set at the same level as the upper limit to the safe range of population intakes established by the Joint FAO/IAEA/WHO Expert Consultation in 1996.

More recently, the National Health and Medical Research Council (NHMRC) considered the essentiality and safety of copper and set an Upper Level of Intake (UL) for copper of 10 mg/day for adults aged 19 and above (NHMRC, 2006). This was based on a NOAEL of 10 mg/day in a twelve-week, double-blind study in seven adults. An uncertainty factor of one was applied as there is no evidence from large international databases of any adverse effects at 10-12 mg/day (NHMRC, 2006). The UL value is of similar magnitude to the PTDI.

Comparison of cupric citrate with permitted copper-based processing aids

Currently, depending on the amount of hydrogen sulphide in the wine, cupric sulphate ($CuSO_4$) may be used in wine at levels up to 1 mg copper/L to react with hydrogen sulphide and thereby remove unpleasant sulphide odours. Cupric citrate on a bentonite base is used in a similar manner. It is anticipated by the Applicant that cupric citrate may be added at any time during red or white wine making from the commencement of fermentation until prior to bottling, whenever sulphide odours occur.

Cupric citrate is only slightly soluble compared to cupric sulphate. Both compounds will react with hydrogen sulphide in solution to form insoluble cupric sulphide (CuS) and either citric acid or sulphuric acid (from cupric citrate and cupric sulphate respectively). However, only dissociated ionic salts can undergo reaction in solution. The dissociation of cupric citrate in solution occurs slowly and will be driven by the removal of the free copper ions from solution by reaction with sulphide to form insoluble cupric sulphide. Cupric citrate in excess of what is required to remove sulphur chemicals from solution, being only slightly soluble, can be removed from solution readily. That is, once the sulphur chemicals are removed from solution by the copper ions, any remaining cupric citrate will not dissolve to any great extent. On the other hand, cupric sulphate dissolves easily and provides a greater amount of copper ions available to react with sulphur containing compounds. However a greater amount of copper ions may remain in solution even after sulphur groups have essentially been removed from solution, compared to when cupric citrate is used.

Cupric sulphide, the reaction product, has a solubility product constant (K_s) of 6×10^{-36}, and is therefore practically insoluble (Aylward and Findlay, 1974; Merck Index, 2001). It is expected to precipitate out of the wine and take no further part in any reaction. The insoluble cupric sulphide deposits on the bottom of the tank or vessel and can be removed by decanting, fining[3] and/or filtering. The use of cupric citrate is expected to lead to similar residual levels of copper ions in solution in wine as the currently permitted cupric citrate on a bentonite base. Residual copper ion levels are expected to be lower than in wine treated with cupric sulphate.

During the review of metals and contaminants in food (Proposal P157), wine was not identified as a food that makes a major contribution to the dietary intake of copper for Australia or New Zealand consumers (ANZFA, 1999). Copper is found naturally in a range of foods including wine, and is an essential element for health. Even at the levels at which it is initially introduced into wine to remove sulphur containing chemicals (around 1 mg copper/L wine, most of which is later removed as mentioned above) and moderate consumption of wine, exposure would not approach anywhere close to the UL for adults of 10 mg/day.

Therefore there is no public health and safety risk from the use of cupric citrate at GMP as a processing aid in wine.

[3] Fining involves introducing a protein (fining agent, e.g. egg albumin, casein and isinglass) into wine, which flocculates, gathering particles that cause turbidity in the wine. Fining has a clarifying and stabilizing effect.

Conclusions

Wine is not a significant contributor to dietary copper intakes. The use of cupric citrate as a processing aid in wine will pose no risk to public health and safety as the residue levels of copper in the final wine product are expected to be similar to, or less than, residues produced using other approved processing aids. The use of Good Manufacturing Practise should keep copper residues to a minimum.

References

ANZFA (1999) Contaminants in Foods – Metals: Full Assessment Report, Proposal P157, Australia New Zealand Food Safety Authority, Canberra

Aylward G.H. and Findley T.J.V. (1974) SI chemical data. John Wiley and Sons Australasia Pty. Ltd. Sydney

Merck Index, 13th edition, (2001) Merck and Co. Ltd. Whitehouse Station, N.J

NHMRC (2006) Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes. Australian Government http://www.nhmrc.gov.au/publications/synopses/n35syn.htm Accessed 19 January 2007.

WHO (1996). Copper In: *Trace elements in human nutrition and health*, WHO, Geneva, pp 123–143

Attachment 3

Food Technology Report

A562 – COPPER CITRATE AS A PROCESSING AID FOR WINE

Introduction

FSANZ received an Application from the Winemakers' Federation of Australia to amend the *Australia New Zealand Food Standards Code* (the Code) to approve the use of copper citrate other than on a bentonite base as a processing aid for wine. Currently cupric citrate on a bentonite base is a permitted processing aid for wine to remove sulphide compounds in the Table to clause 14 of Standard 1.3.3 – Processing Aids and the Table to clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia only). 'Copper citrate' is used synonymously with 'cupric citrate' in this report.

Background

A number of unpleasant volatile sulphur containing compounds can form in wine during fermentation, from the reduction of sulphur dioxide by yeast or from reactions of the sulphur containing amino acids such as methionine and cysteine, which have a deleterious impact on the quality and acceptance of the wine. These objectionable volatile sulphur compounds are mainly hydrogen sulphide (rotten egg gas), methanethiol and ethanethiol. There are some other sulphur compounds that are inherent in wine and have a positive role in the development of flavour.

There are a variety of causes for the formation of unpleasant volatile sulphur compounds during wine fermentation. Some of these are the yeast strain, incorrect or unusual fermentation, deficiencies of nutrients for the yeast (amino acids, vitamins), high concentrations of sulphate in the must and high concentration of sulphur-containing amino acids from the grapes.

A common method used in the wine industry to treat wine containing unpleasant volatile sulphur odours is to add copper sulphate which irreversibly binds up with hydrogen sulphide and simple thiols to form insoluble precipitates of copper compounds. These precipitates are subsequently removed from the wine and so remove the objectionable sulphur compounds and their unpleasant odours from the wine. Copper citrate is proposed as an alternative to copper sulphate to remove unpleasant sulphur containing compounds from wine.

Chemical Structure

Copper(II) citrate has:

- the CAS registry number of 866-82-0, for the anhydrous compound;
- while the hydrate has the molecular structure of $Cu_2C6H4O7\textbf{.}2.5\ H_2O$; and
- a molecular weight of 360 g/mol for the hydrated form.

Copper citrate, as the hydrate, (i.e. copper citrate**.**2.5 H_20) is light blue/green granules which have a neutral smell. It is only slightly soluble in water.

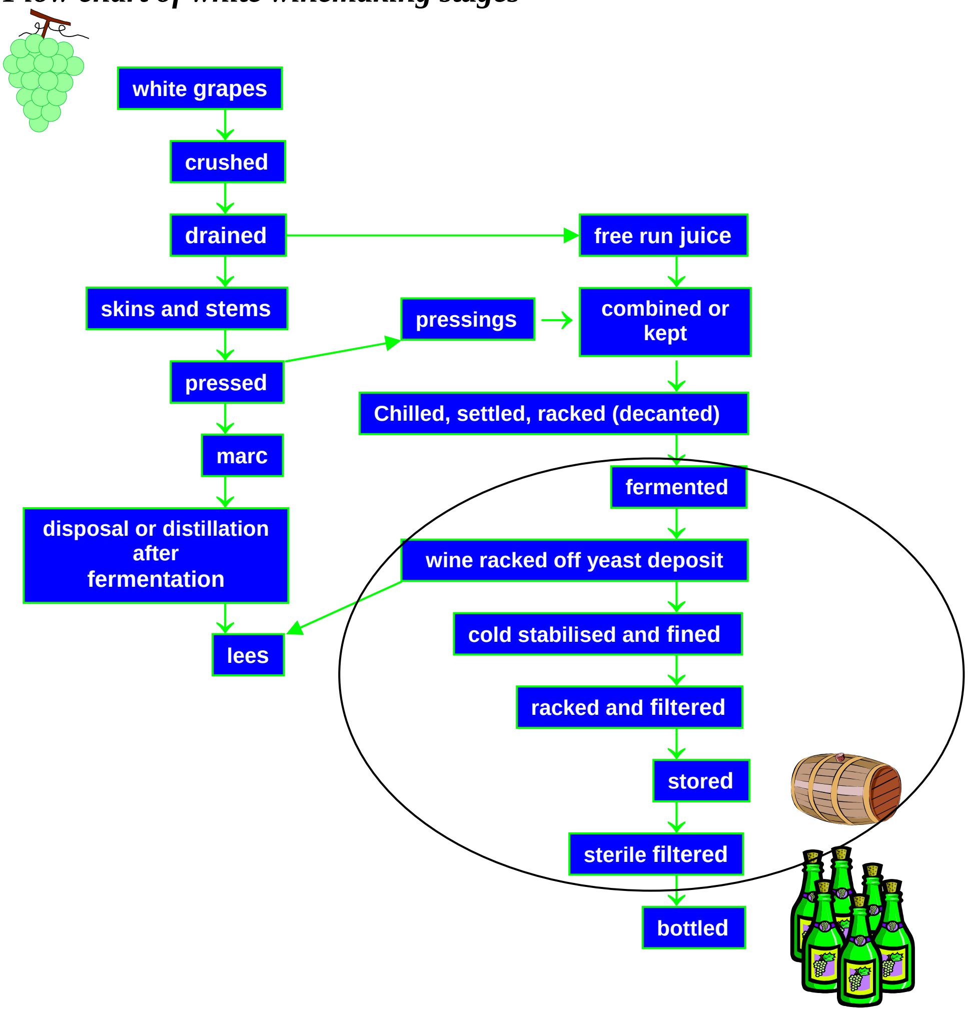
Technological Function

The use of copper compounds (sulphate and citrate) is to bind with unpleasant sulphide compounds from wine to produce precipitates which are subsequently removed before the wine is bottled. That is they are fulfilling a technological function relating to treatment or processing of the wine but do not have a technological function in the final bottled wine, as required for processing aids in subclause 1(a) of Standard 1.3.3.

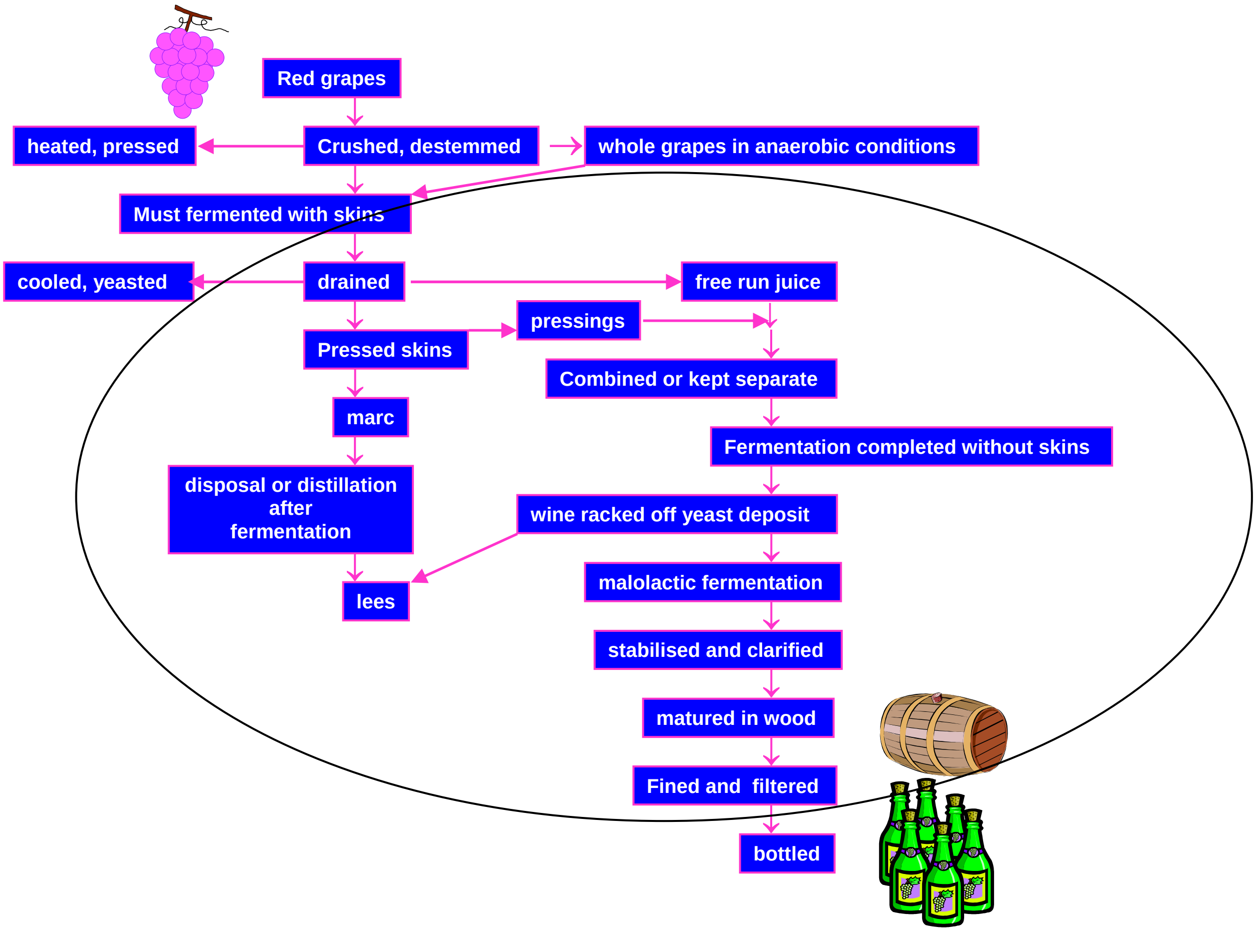
The Applicant supplied the information below explaining how copper citrate could be (and how copper sulphate currently is) used in wine treatment (both white and red wine).

Copper sulphate and if approved copper citrate could be added at any winemaking stage from the commencement of fermentation until prior to bottling whenever sulphide odours occur. The insoluble copper sulphide that is formed in the wine settles to the bottom of the tank/vessel as a fine brown deposit. The wine is then racked, that is, transferred or decanted from the deposit, and subsequently fined and/or filtered prior to bottling. The amount of copper remaining in the wine after it is fined and/or filtered is negligible.

Flow chart of white winemaking stages



Flow chart of red winemaking stages



Evidence of Technological Need

The technological need for copper citrate in winemaking is to be able to remove unpleasant sulphide odours from wine before bottling. Copper citrate performs its function during food processing which leads to improvements in the organoleptic properties of the treated wine. The chemical does not have a technological function in the final food since it has performed its function during processing. Copper citrate binds irreversibly to sulphide chemicals and the resulting compounds are removed from the wine.

Technical results performed using copper citrate on a bentonite base indicated it had advantages over copper sulphate. Bentonite is an approved processing aid for wine manufacture in the Table to clause 4 of Standard 4.5.1. It is also a generally permitted processing aid since it is approved as a food additive with INS number 558 in Schedule 2 of Standard 1.3.1 – Food Additives (due to subclause 3(a) of Standard 1.3.3). Copper citrate has a greater reactivity to sulphide compounds than copper sulphate.

Concentration required for function, self limiting aspect

The Applicant states that Good Manufacturing Practice (GMP) for winemaking indicates that a maximum of 0.5 mg/l of copper should be used for the purposes of reducing unpleasant sulphide compounds from the wine.

Higher levels of copper can produce reddish brown haze and potential precipitates so it is important for wine manufacturers not to over treat with copper. The formation of this haze and ultimately precipitation is called copper casse (‘casse’ is a French word meaning ‘breakage’, Macquarie Dictionary 3rd Edition definition: ‘clouding of wine caused by the formation of colloidal complexes of metals’) and can occur with aged storage in the bottle, especially for white wines containing free sulphur dioxide and no air (minimum oxygen). This situation is the same whether copper is added as copper sulphate or copper citrate. The Code applies the limit of GMP for copper sulphate and cupric citrate on a bentonite base for the treatment of wine for sulphide compounds and this should be the limit listed for copper citrate. GMP requires that the minimum amount of the chemical is used to achieve the intended result.

Excess copper is removed by the use of blue finings (potassium ferrocyanide) which produces an insoluble precipitant of $Fe(CN)_6Cu_2$ which is removed from the wine by filtration. Potassium ferrocyanide is approved as a processing aid in the Table to clause 6 in Standard 1.3.3 and in the Table to clause 4 of Standard 4.5.1.

Specification

Copper citrate (listed as cupric citrate) is listed in the Merck Index, 13th edition (2001) which is one of the secondary sources for specifications listed in clause 3 of Standard 1.3.4 – Identity and Purity of the Code. Therefore no specification is required in Standard 1.3.4 for this Application if it is successful.

Conclusion

The use of copper citrate as a processing aid for wine to remove unpleasant sulphide off-odours is technologically justified.

References

Background article on sulphur compounds found in wine.
Rauhut, D. Impact of Volatile Sulfur Compounds on Wine Quality, *the 5th Workshop on Sulfur Transport and Assimilation*, April 11-14 2002, Ensa Montpellier, France, original copy taken from this web address but no longer available when checked 12/1/07
http://www.rug-plfys.org/~grill/Rauhut_final-version.pdf

Goertges, S. (2001) Wine treatment with copper citrate: A new careful way to eliminate hydrogen sulphide odours and similar sulphide off-odours in wine. *Australian Grapegrower and Winemaker*, **452**, 102-105.

Ribéreau-Gayon, P., Glories, Y., Maujean, A. and Dubourdieu, D. (2001) *Handbook of Enology, Volume 2 The Chemistry of Wine Stabilization and Treatments*, pages 91-94, John Wiley & Sons Ltd., Chichester, England

The Merck Index, 13th edition, (2001) Merck and Co. Ltd. Whitehouse Station, N.J..

Attachment 4

Summary of Public Submissions

Round one

Submitter organisation	Name
Food Technology Association of Victoria Inc.	David Gill
The New Zealand Food Safety Authority	Carole Inkster
Department of Human Services, Victoria	Victor Di Paola
Department of Health, SA	Joanne Cammans
NSW Food Authority	Bill Porter
Environmental Health Unit of Queensland Health	Chris Wold
Australian Food and Grocery Council	Kim Leighton
Department of Agriculture, Fisheries and Forestry	Scott Channing

Submitter	Position	Comments
Food Technology Association of Victoria Inc.	Supports	Supports Option 2, but raises the question whether the proposed amendment would lead to trade restrictions. FTA Vic. also states that a maximum limit for copper in wine should be established.
The New Zealand Food Safety Authority	Supports	Supports Option 2, and may comment further at Draft Assessment. Of particular interest will be the safety assessment and residue levels.
Department of Human Services, Victoria	Supports progression to Draft Assessment	Requests that at Draft Assessment FSANZ address copper concentration levels in the final wine product. They state that copper is soluble in acid, and therefore ask whether copper levels would generate a health risk, and should maximum levels of copper in wine be set.
Department of Health, SA	Supports progression to Draft Assessment	Offers tentative support subject to more detailed safety assessment at Draft Assessment.
NSW Food Authority	Supports progression to Draft Assessment	Notes the key assessment question raised by FSANZ in section 4 of the Initial Assessment Report. Agrees that approval of copper citrate is contingent on further assessment of health and safety risks to the public. Anticipates that the Draft Assessment Report would address mechanisms of removal of the processing aid from the finished product and the need to establish a maximum residue limit. There appears to be no evident administration/enforcement costs or benefits to Government.
Environmental Health Unit of Queensland Health	Reserve comments until the Draft Assessment Report	Will review the Draft Assessment Report upon its release and provide comment at that time.
Australian Food and Grocery Council	Supports	Supports Option 2, provided that the FSANZ risk assessment does not establish any safety concerns of copper citrate associated with its intended use. AFGC also notes that the current approval of copper citrate on a bentonite base is unnecessarily restrictive, limiting the current permissions to a proprietary product only. 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 wine.
Department of Agriculture, Fisheries and Forestry	Reserve comments until the Draft Assessment Report.	Awaits the outcome of the FSANZ safety report in the Draft Assessment Report, with respect to copper citrate use in wine without a bentonite base.