

EXPLANATORY STATEMENT

APPLICATION A562

COPPER CITRATE AS A PROCESSING AID FOR WINE

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 and Standard 4.5.1. 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. This is comparable with that permitted for alternatives, copper sulphate and copper citrate on a bentonite base which are both permitted at GMP.

The Final 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.

Decision

Approve 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 Decision

Approval for the use of cupric citrate as a processing aid in wine production without it being restricted to a bentonite base is proposed 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 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, this 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 variations to the Code are consistent with the section 18 objectives of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), in particular, it does not raise any public health and safety concerns 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 there are 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 eight submissions were received during this period. The Draft Assessment Report was advertised for public comment from 21 March 2007 to 2 May 2007. Four submissions were received during this period, with one late submission received after the closing date for public comment.

¹ <http://beta.austlii.edu.au/au/other/dfat/treaties/1994/6.html>. Accessed on 6 June 2007.

At **Attachment 4** is a summary of the submissions received during the first and second round of public comment. FSANZ has taken the submitters' comments into account in preparing the Final Assessment of this Application.

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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'. The use of copper citrate is considered technically superior to the use of copper sulphate, which is also permitted and commonly used to eliminate unpleasant sulphide (including hydrogen sulphide) odours in wine.

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.

1.2 Summary of Proposed Amendments

The Applicant has proposed that the following Standards are amended 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:

- 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.

2. Background

2.1 Current Regulations on Processing Aids in Wine Manufacture.

Standards 1.3.3 and 4.5.1 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 *Agreement between Australia and the European Community on Trade in Wine, and Protocol* (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 as it 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.

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 the product Kupzit® which consists of 2% copper citrate 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 and can currently be used at a level necessary to achieve a specific function (as an adsorbent agent) 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 Australia EC Wine Agreement 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.

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 18 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.

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

In assessing this Application, FSANZ considered the following question:

- 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?

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 were 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 fining².

The Safety Assessment Report (**Attachment 2**) 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.

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.

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.

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:

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 Final 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 and Draft Assessment Reports, and on knowledge gained from the previous safety assessment on copper during the review of food standards in Australia and New Zealand.

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.

8.2.1.1 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).

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.

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.

Use of copper citrate other than on a bentonite base as a processing aid in the manufacture of wine does not impose any additional/discernable costs to the industry. This is reflected in the Business Cost Calculator Report, in accordance with the Office of Best Practice Regulation (OBPR) guidelines which is found at **Attachment 5**.

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.

No significant adverse costs have been identified 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 and into the Table to clause 14 of Standard 1.3.3. 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, and since bentonite is a generally permitted processing aid.

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

COMMUNICATION

9. Communication and Consultation Strategy

FSANZ has applied a basic communication strategy to Application A562. This involved advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. The Applicant, individuals and organisations that made submissions on this Application were notified at each stage of the Application. If the FSANZ Board approves the Final Assessment Report, FSANZ will notify the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazettal changes to the Code in the national press and on the website.

10. Consultation

10.1 Public Consultation at Initial and Draft Assessments

The Initial Assessment was advertised for public comment between 4 October 2006 and 15 November 2006. Eight submissions were received during this period.

The Draft Assessment Report was advertised for public comment from 21 March 2007 to 2 May 2007. Four submissions were received during this period, with one late submission received after the closing date for public comment. All submitters supported the Application, noting that there are no public health and safety concerns associated with the use of copper citrate under the proposed conditions of use and that the potential benefits for consumers and industry outweigh any costs.

At **Attachment 4** is a summary of the submissions received during the first and second round of public comment. FSANZ has taken the submitters' comments into account in preparing the Final Assessment of this Application. While the comments received after the closing date cannot be considered and taken into account as a submission on the Draft Assessment of this Application, they have been considered in this report as 'other relevant material' under the *Food Standards Australia New Zealand Act 1991*. The major issues raised at Initial and Draft Assessments are discussed below.

10.1.1 Copper Residue Limit

At Initial Assessment, several submitters indicated that a maximum limit (ML) for copper in wine should be established in conjunction with this Application. This issue was again raised at Draft Assessment by one submitter who noted the following concerns:

- Data has not been provided to support the claim that addition of cupric citrate to wine without a bentonite base will not lead to undesirably high copper residues/compounds in wine or will not promote the production of undesirable side products in the wine (e.g. reactions with thiol compounds).
- It will be difficult to determine whether copper citrate is being added to wine to improve the quality of raw materials or to mask poor manufacturing practices. Therefore, a maximum copper limit should be set at 0.3 mg/L, in line with the Applicant's comment that haze begins to form in wine at concentrations greater than this.

- The Applicant contends that overuse of copper citrate will be self-regulated through the formation of reddish brown hazes and precipitates in wine. However, in red wines it will be problematic for consumers to detect these formations prior to purchase.

10.1.1.1 FSANZ's Response

The key principle when considering establishment of an ML for a substance in food (e.g. food additive, processing aid or a contaminant) is whether that substance presents a significant risk to public health and safety and makes a significant contribution to total dietary exposure of that substance. In addition, the levels used in food should only be used in an amount necessary to achieve the desired technological need.

FSANZ acknowledges that it has been unable to obtain data from Australian or international winemakers or from the literature, on the likely concentration of copper dissolved in wine following treatment with cupric citrate. Therefore, the safety assessment for this Application focussed on the function of cupric citrate as a processing aid in removing hydrogen sulphide and other sulphur compounds (e.g. simple thiols) from wine, in comparison with other permitted copper-based processing aids in the Code, namely, cupric sulphate and cupric citrate on a bentonite base. These processing aids are permitted to be added at GMP levels.

The Safety Assessment Report (**Attachment 2**) concluded that the use of cupric citrate at GMP levels as a processing aid in wine does not pose a risk to public health or safety. The residue levels of copper in the final wine product are expected to be low and similar to residues produced using other permitted copper-based processing aids which are currently permitted at GMP levels. Furthermore, the review of metals and contaminants in food (Proposal P157) did not identify wine as being a major contributor to the dietary intake of copper for Australian and New Zealand consumers. For these reasons, this Application does not raise any public health and safety concerns.

In the absence of an established ML for copper residues in wine in conjunction with this Application, it is acknowledged that there is scope for the manufacturer to add copper citrate at a level greater than that required to achieve the required technological function. This argument can also be made for copper sulphate and copper citrate on a bentonite base which do not have maximum copper limits established in the Code and are currently approved at GMP. However, FSANZ notes that the application rate of copper citrate to wine is self-limiting due to the formation of haze and ultimately, precipitates, in the event that excess copper citrate is added. While a haze may not be visible in red wines, it is expected that any resulting precipitate would be apparent in both red and white wines, and should therefore discourage excess use. It should also be noted that excess copper citrate in wine can be removed from solution by the use of potassium ferrocyanide as discussed below. For these reasons, FSANZ considers that it is not necessary to establish an ML for copper in wine in conjunction with this Application.

10.1.2 Removal of Excess Copper Citrate

At Draft Assessment, one submitter commented that the mechanisms by which excess copper citrate in wine will be removed from solution have not been identified, noting that the major advantage of binding copper sulphate and copper citrate to a bentonite base was the ease of removal from solution.

10.1.2.1 FSANZ's Response

As outlined in the Food Technology Report at **Attachment 3**, excess copper in solution is removed by the use of blue finings (potassium ferrocyanide), which produces an insoluble precipitant of $\text{Fe}(\text{CN})_6\text{Cu}_2$ and is removed from the wine by filtration. This process is also used to remove excess copper in solution from wine where copper sulphate is used as a processing aid.

Potassium ferrocyanide is an approved processing aid in the Table to clause 6 in Standard 1.3.3 and in the Table to clause 4 in Standard 4.5.1. It should also be pointed out that copper sulphate is not used bound to a bentonite base when it is used to treat wine.

10.1.3 Trade Restrictions

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

10.1.3.1 FSANZ's Response

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 (although the updated agreement which includes copper citrate was initialled on 6 June 2007), 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, which is also the limit for wine imported into Europe.

10.1.4 Removal of Permission for Copper Citrate on a Bentonite Base

At Draft Assessment, one submitter questioned the removal of the permission for copper citrate bound to a bentonite base and suggested that the drafting be re-worded to indicate that permissions include copper citrate on a bentonite base.

10.1.4.1 FSANZ's Response

As discussed in the previous response, the existing permission for copper citrate on a bentonite base would be encompassed by the general permission for copper citrate. Both copper citrate and bentonite will be permitted processing aids. FSANZ does not consider that this needs to be clarified in the drafting.

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards for the production of wine. As Standard 1.3.3 applies to imported wine, amending the Code as proposed may have a significant effect on international trade, due to a liberalising of the use of copper citrate in winemaking. Therefore, notification of the proposed changes to the Code was made to the WTO in accordance with the WTO Sanitary and Phytosanitary Measures (SPS) Agreement. This enabled other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them. No comments were received by WTO member countries in response to these notifications.

CONCLUSION

11. Conclusion and Decision

FSANZ agrees to approve the use of 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 and in the Table to clause 14 of Standard 1.3.3.

Decision

Approve 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 Decision

Approval for the use of cupric citrate as a processing aid in wine production without it being restricted to a bentonite base is proposed 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 variations to the Code are consistent with the section 18 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 and there are no specifically identified costs.

12. Implementation and review

It is proposed that the draft variations come into effect on the date of gazettal.

ATTACHMENTS

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

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
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[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

Safety Assessment Report

Introduction

The Winemakers' Federation of Australia is seeking approval for the use of cupric citrate (copper (II) citrate, $\text{Cu}_2\text{C}_6\text{H}_4\text{O}_7$) 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 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, fining³ 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 Practice 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, pp123–143

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
- $\text{Cu}_2\text{C}_6\text{H}_4\text{O}_7 \cdot 2.5 \text{H}_2\text{O}$; and
- a molecular weight of 360 g/mol for the hydrated form.

Copper citrate, as the hydrate, (i.e. copper citrate.2.5 H₂O) is light blue/green granules which have a neutral smell. It is only slightly soluble in water.

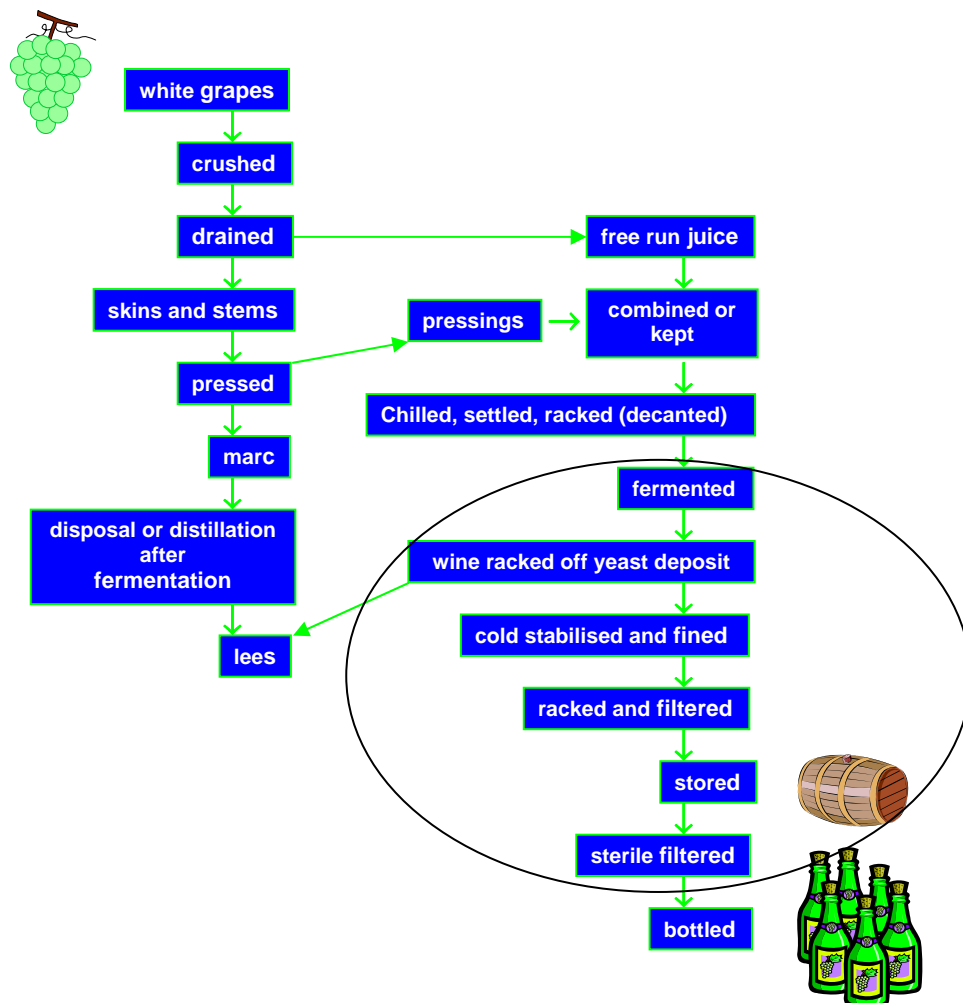
Technological Function

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.

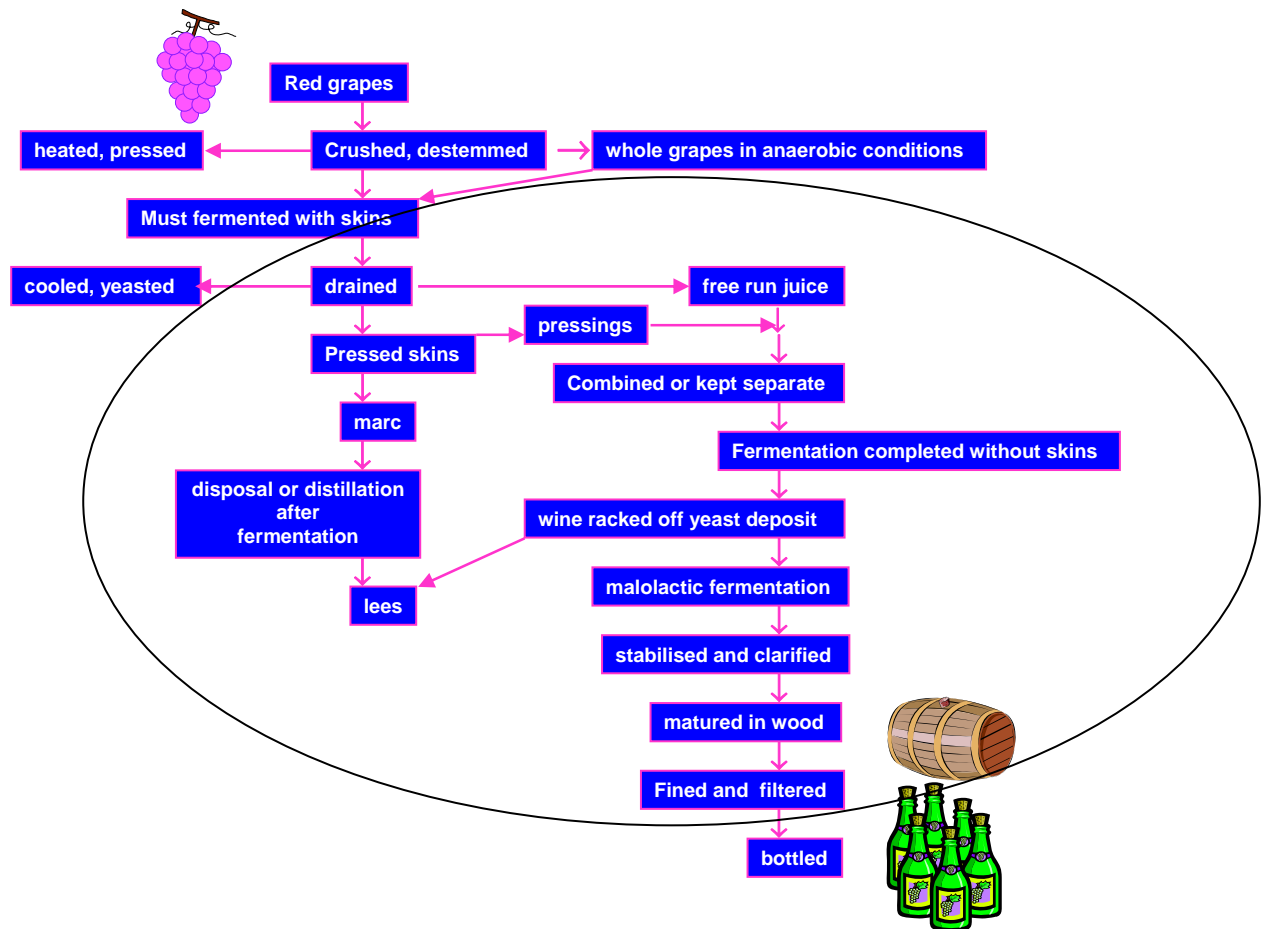
The Applicant supplied the information below explaining how copper citrate could be (and how copper sulphate currently is) used in wine treatment (both white and red wine).

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 in solution is removed by the use of blue finings (potassium ferrocyanide) which produces an insoluble precipitant of $\text{Fe}(\text{CN})_6\text{Cu}_2$ 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..

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	Reserves 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	Reserves 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.

Round Two

Submitter organisation	Name
Food Technology Association of Victoria Inc.	David Gill
The New Zealand Food Safety Authority	Carole Inkster
Queensland Health	Gary Bielby
Australian Food and Grocery Council	Kim Leighton

Submitter	Position	Comments
Food Technology Association of Victoria Inc.	Supports	Supports Option 2.
The New Zealand Food Safety Authority	Supports	Supports Option 2. Notes that the risk assessment carried out by FSANZ has not raised any public health or safety concerns for copper citrate associated with the proposed conditions of use.
Queensland Health	Supports	Supports Option 2. Notes that there are no public health or safety concerns associated with the use of copper citrate under the proposed conditions of use based on: FSANZ's assessment of the safety of copper and its subsequent compounds; copper citrate would be an alternative to the currently permitted processing aids for wine treatment i.e. copper sulphate and copper citrate on a bentonite base; and dietary exposure to copper via wine will be limited due to low residues of copper citrate in the wine. Acknowledges that the use of copper citrate is technologically justified and there are potential benefits for both consumer and industry in using copper citrate which outweigh any perceived costs.
Australian Food and Grocery Council	Supports	Supports Option 2. Notes the findings from the Draft Assessment Report that copper citrate fulfils a specific technological purpose consistent with that of a processing aid, it raises no public health and safety concerns and is comparable in safety with already permitted forms of copper used as processing aids. Supports FSANZ's assessment that approval of copper citrate may have advantages for consumers and industry, while there are no identified disadvantages.

Business Cost Calculator Report

Application A562 - Copper Citrate as a processing aid for wine

Problem: Current provisions of the Code restrict the scope of processing agents in wine manufacture to proprietary products only. The applicant is seeking an amendment to the Food Standards Code to allow copper citrate other than a bentonite base as a processing agent for manufacturing wine.

Objective: Assess and permit the use of copper citrate as a processing aid in wine manufacture, when the form of copper citrate is not on a bentonite base .

Policy Options

Option Name	Quickscan Result
Status Quo	FALSE
Approve the use of copper citrate in other forms as a processing aid for wine	FALSE

Compliance Cost Summary

Option Name:	Status Quo		
Businesses Affected:	N/A		
Type	Cost per Business	Total Cost of Regulation	
N/A	N/A	N/A	

Option Name:	Approve the use of copper citrate in other forms as a processing aid for wine		
Businesses Affected:	N/A		
Type	Cost per Business	Total Cost of Regulation	
N/A	N/A	N/A	

Caution should be used comparing options and interpreting results over time. The Business Cost Calculator does not estimate the future values of ongoing costs. Refer to the User Guidelines for further information.

This report contains summaries of compliance costs only. An assessment on the compliance cost in itself does not provide an answer to which policy option is the most effective and efficient one. Rather, it provides information which needs to be considered alongside other relevant factors and issues when deciding between alternative policy options.