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

10/03
16 July 2003

INITIAL/DRAFT ASSESSMENT REPORT
(Section 36)

APPLICATION A463

COPPER CITRATE AS A PROCESSING AID IN WINE

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
27 August 2003
(See "Invitation for Public Submissions" for details)

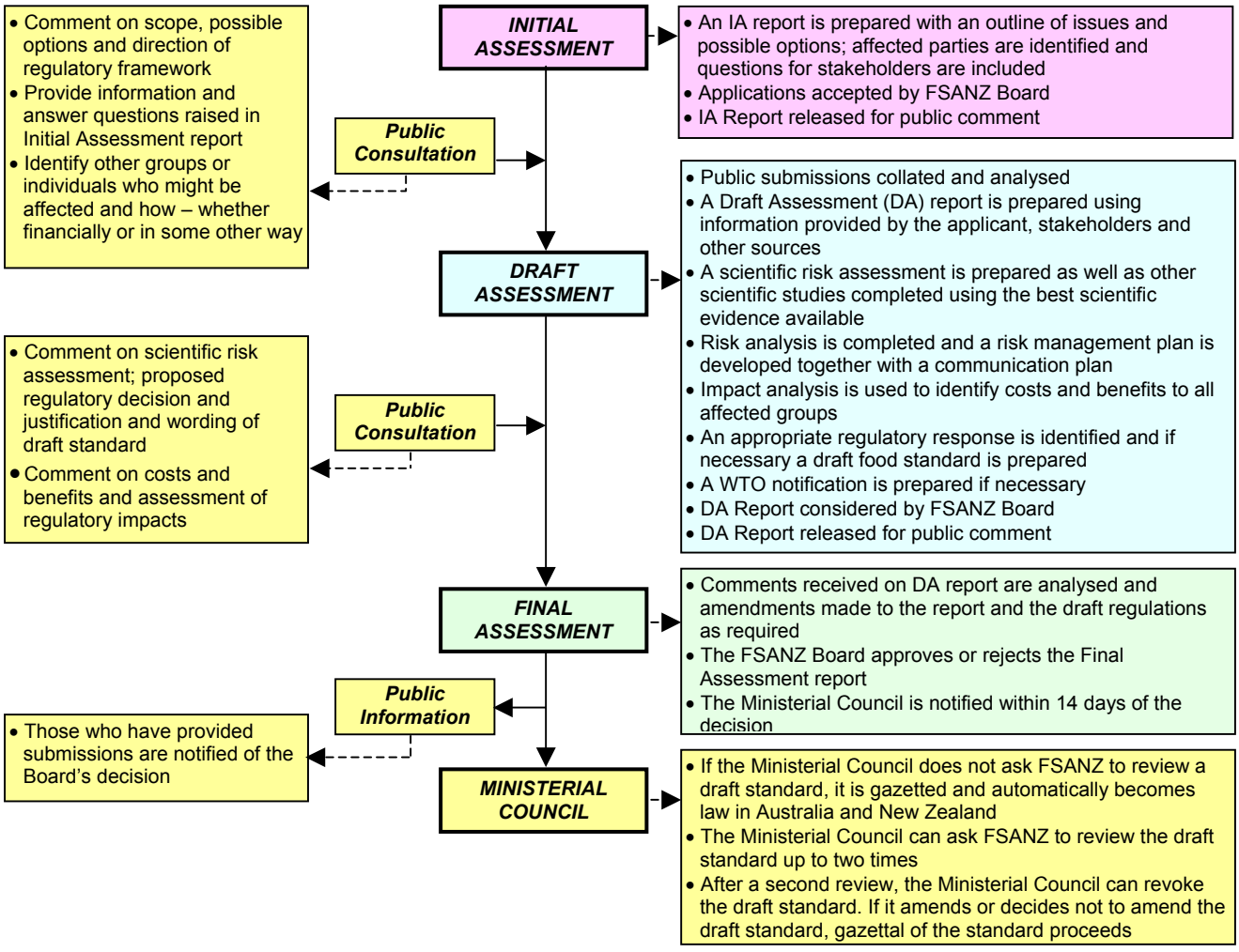
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial/Draft Assessment Report of Application A463, which includes a Draft Assessment and draft variations to the *Australia New Zealand Food Standards Code.*

The Authority invites public comment on this Initial/Draft Assessment Report based on regulation impact principles and the draft variation to the *Australia New Zealand Food Standards Code* for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority 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 should be received by the Authority **by 27 August 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. 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 Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application (A463) from Swift and Company Ltd seeking approval of copper citrate (2% on a calcium bentonite base[1]) as a processing aid in the production of wine. This application was received on the 7 February 2002 and commenced on 31 March 2003 under Workplan Group 2. The product containing copper citrate is commercially known as Kupzit ®.

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 4.1.1-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 Application is considered to raise issues of minor significance or complexity only and will be progressed under section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Copper citrate is to be used to remove hydrogen sulphide from wine and is then filtered out of the wine. Therefore, there would be low levels of residual copper in the wine and copper citrate would not fulfil 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) will ensure appropriate use of the processing aid.

The Initial/Draft Assessment Report concludes that copper citrate fulfils a specific technological purpose consistent with that of a processing aid and that it is safe by virtue of the previous extensive toxicological evaluation undertaken on copper under the review of the *Australia New Zealand Food Standards Code*. The use of copper citrate raises no additional safety concerns and is comparable in safety with already permitted forms of copper used as processing aids (eg copper sulphate).

No ingredient labelling of processing aids is required in the *Australia New Zealand Food Standards Code* and the regulatory impact analysis has concluded that the option to approve copper citrate has advantages for consumers and for industry. There are no identified disadvantages to the approval of copper citrate.

[1] Any reference to copper citrate in this Report refers to 2% copper citrate on a bentonite (clay) base

Statement of Reasons

The draft variation to Standards 1.3.3-Processing Aids and Standard 4.1.1-Wine Production Requirements (Australia only), giving approval for the use of copper citrate is recommended 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;

- the use of copper citrate is technologically justified;

- Standard 4.1.1 – Wine Production Requirements is an Australia only standard which has been written to ensure Australia's Agreement with the EU on trade in wine is maintained. This Standard contains a separate positive 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.

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act; and

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

1. Introduction

FSANZ received an Application (A463) from Swift and Company Ltd seeking approval of copper citrate as a processing aid in the production of wine under Standard P4[2]-Wine, Sparkling Wine and Fortified Wine of the *Australian Food Standards Code* and Standard 1.3.3-Processing Aids of the *Australia New Zealand Food Standards Code*.

Upon clarification with the Applicant it was ascertained that they are specifically applying for permission for use of copper citrate (2% on a calcium bentonite base) as a processing aid in Standard 1.3.3-Processing Aids and Standard 4.1.1-Wine Production Requirements (Australia only).

This application was received on the 7 February 2002 and commenced on 31 March 2003 under Workplan Group 2. The product containing copper citrate is known as Kupzit ® consists of copper citrate (2% on a calcium bentonite base).

2. Regulatory Problem

Swift and Company Ltd are seeking approval of copper citrate as a processing aid in the production of wine as there are currently no permissions in the *Australia New Zealand Food Standards Code* and the use of copper citrate is considered technically superior to the use of copper sulphate, which is currently used to eliminate hydrogen sulphide odours in wine.

Standards 1.3.3 and 4.1.1 of the *Australia New Zealand Food Standards Code* regulate the use of processing aids in wine manufacture. A processing aid is 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.

All wine sold in Australia must comply with Standard 2.7.4 – Wine and Wine Product. Standard 2.7.4 sets definitional standards for wine and wine product and provides permissions for the addition of certain specified foods during the production of wine.

However, all wine produced in Australia must also comply with Standard 4.1.1-Wine Production Requirements (Australia only). Standard 4.1.1 underpins Australia's 1994 Agreement with the European Community (EC) on trade in wine, which relies on Australian wine being recognised as wine of designated quality and origin (e.g. *appellation controllé,* DOC, *qualitätswein* etc).

Standard 4.1.1 does not permit the use of copper citrate as a processing aid. Therefore a variation will be required to Standard 4.1.1 in order to permit copper citrate as processing aids for wine produced in Australia.

Considering that the application appears to raise only minor technical issues in respect of safety and technological need/efficacy of copper citrate in wine products, approval of copper citrate is considered a minor amendment to the *Australia New Zealand Food Standards Code* and will be progressed under Section 36 of the *Australia New Zealand Food Standards Code.*

[2] Standard P4 was replicated by Standard 4.1.1 Wine Production requirements which apply in Australia only.

3. Objective

To determine whether the food standards should be changed to permit the sale of copper citrate as a processing aid. Such an amendment would need to be consistent with the section 10 objectives of the FSANZ Act.

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 *Food Standards Australia New Zealand Act 1991*. 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 objectives in assessing this application are:

- to protect the public health and safety of the community in their consumption of copper citrate as a processing aid in wine; and
- to determine whether a technological need exists for use of copper citrate in wine.

4. Background

Workplan Classification

FSANZ's preliminary assessment of this application for placement on the Workplan was Group 2, Category 3 (see FSANZ website for further information about the workplan and the different groups and categories). The initial/draft assessment confirms that this grouping is appropriate.

4.1 Properties of copper citrate

The product Kupzit ℞ consists of copper citrate (2% on a calcium bentonite base) and is to be used to remove hydrogen sulphide from wine and is then filtered out of the wine. Bentonite is permitted as a processing aid in the Table to clause 4 of Standard 4.4.1-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 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).

The Applicant has requested no specific maximum permissions for use of copper citrate; rather, Good Manufacturing Practice (GMP) will ensure appropriate use of the processing aid and there would be limited residues of copper in the wine and copper citrate would not fulfil a technological function in the final product.

The Applicant has stated that copper citrate offers the following features in the product Kupzit ℝ:

- has a higher affinity for hydrogen sulphide and thus greater potential to reduce sulphide off-flavours in wine;
- less copper is dissolved in wine;
- easy product to handle; and
- no reduction of residual copper levels with potassium hexacyanoferrate (II) (referred to as blue fining) is necessary in most cases; and
- copper citrate is considered superior to copper sulphate which is a currently permitted processing aid in Standard 1.3.3-Processing Aids of the *Australia New Zealand Food Standards Code*.

The Applicant supplied letters of support following their evaluation from several wineries in Australia and New Zealand supporting the use of copper citrate.

4.2 Approval in other countries

Kupzit ℝ has been approved for use in Austria, Switzerland and South Africa.

The product is currently being considered for approval for use in the EU.

5. Issues Relevant to this Application

5.1 Safety of copper citrate

The Applicant supplied a material safety data sheet (MSDS) on copper citrate, which detailed the acute effects of copper citrate and indicated that no subchronic, long-term studies, reproductive/developmental, genotoxicity studies were available with the main toxicological consideration being the inherent toxicity of copper. The LD_{50} was 1580 mg/kg bw/day indicating that copper citrate was of very low acute toxicity. There is no new data on the safety of copper citrate in the scientific literature in searches conducted to date by FSANZ.

However, during the review of the *Australia New Zealand Food Standards Code* an assessment of the safety of copper and its subsequent compounds was undertaken (**Attachment 2**). Copper is actively absorbed from the gastrointestinal tract, however, most mammals, including humans, have the capacity to maintain copper homeostasis by a combination of decreased absorption and increased excretion. This is reflected by the range of adult oral intake that can be ingested without any apparent detrimental health effect (between 1 and 13mg/day). Furthermore, as copper rarely occurs at high levels in foods other than liver, its potential to cause toxicity in healthy populations is probably limited.

Based on the previous evaluation of copper (**see Safety Assessment Report, Summary and conclusions in Attachment 2**), and that copper citrate will be used to replace currently

permitted copper sulphate (which from the previous toxicological evaluation suggested that they both have similar toxicity profiles) the use of copper citrate in wine raises no specific public health and safety problems. Dietary exposure via wine would also be limited due to the low residues of copper citrate in the final product.

5.2 Technological justification for copper citrate

Copper citrate consists of light blue/green granules, which have a neutral smell, and are insoluble in water. In the current application copper citrate is added to wine as a 2 % copper citrate solution coated onto bentonite.

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.

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 may be no subsequent treatment with potassium ferrocyanide (blue finings) to limit residual copper (regulations require < 1 mg/L for export wine) is necessary.

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

5.3 Labelling of copper citrate

Processing aids are not currently required to appear in ingredient lists under general labelling provisions in the *Australia New Zealand Food Standards Code*.

6. Regulatory Options

There are two options available:

6.1 OPTION 1: Do not approve copper citrate

This option maintains the status quo, in that there is currently no permission to use copper citrate in food.

6.2 OPTION 2 Approve the use of copper citrate.

This option would require an amendment to the *Australia New Zealand Food Standards Code*, to permit the use of copper citrate use in wine.

7. Impact Analysis

7.1 Affected parties

- those sectors of the wine industry wishing to use copper citrate in wine;
- consumers; and
- state, territory and New Zealand governments

7.2 Impact of regulatory options

In developing regulations for adoption in 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 Initial/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, and on knowledge gained from the previous safety assessment on copper under the review of the *Australia New Zealand Food Standards Code*.

7.2.1 Option 1

In relation to consumers, there is a potential cost in terms of reduced access to a variety of quality wine products. There is a potential disadvantage to industry in restricting the use of copper citrate as a processing aid for wine as it offers benefits above currently permitted forms (eg copper sulphate). There is no identified impact on government in not permitting copper citrate in the food supply.

7.2.2 Option 2

There is a potential benefit to consumers in permitting copper citrate in terms of access to a variety of improved wine products. Industry will have the advantage of another processing aid in the production and retail sale of particular food products in Australia and New Zealand. Importers will not be adversely affected where a product that has been manufactured overseas contains copper citrate as a permitted processing aid. There is no direct impact on government in approving copper citrate as it may replace the use of copper sulphate in already specified foods and therefore would not significantly affect costs associated with enforcement of the Standard.

In order to complete the analysis of the costs and benefits associated with the two proposed options, the Authority seeks comments on the following:

- Are there any other potential costs and benefits to consumers, industry or government that have not been identified in this Initial/Draft Assessment?

- What are the costs and benefits of the regulatory options for consumers in terms of public health and safety, consumer information and labelling?

In addition, representatives of the Australian Wine and Brandy Corporation, Winemakers' Federation of Australia, and the Department of Agriculture, Fisheries and Forestry - Australia will be approached to specifically comment on the application, in particular, whether an amendment to Standard 4.1.1 will have an impact on the Australia EU wine Agreement.

Overall, the proposed changes to approve copper citrate in wine are not expected to significantly affect costs to the public, government or industry. There are no identifiable public health risks associated with the proposed approval of copper citrate and the amendment is considered to be of minor significance.

8. Consultation

8.1 Omission of one round of public consultation

Under section 36 of the FSANZ Act, the procedure for an application may be simplified if the Authority is satisfied that:

(a) omitting to do the thing will not have a significant adverse effect on the interests of anyone; or

(b) the application or proposal raises issues of minor significance or complexity only.

In this case, FSANZ considers that the application raises issues of minor public health and safety significance and is progressing this application as a matter of minor significance and complexity only, and in so doing has omitted the first round of public consultation. However, following Board agreement to this Initial/Draft Assessment Report, FSANZ will conduct one round of public consultation in accordance with general procedures.

8.2 World Trade Organization (WTO) Notification

As members of the WTO, Australia and New Zealand are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS agreement) and on Technical Barriers to Trade (TBT Agreements). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable member countries of the WTO to make comment.

The proposed amendments to the Code are considered to be minor in nature and without significant trade implications. The matter therefore will not be notified to the WTO under either the SPS or TBT Agreements.

9. Conclusion and Recommendation

The proposed draft variations contained in this report have been prepared to permit the use of copper citrate as a processing aid. No public health and safety concerns were raised in the assessment, its use is technologically justified and there are no labelling requirements needed.

The draft variation to Standards 1.3.3-Processing Aids and Standard 4.1.1-Wine Production Requirements (Australia only), giving approval for the use of copper citrate is recommended 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;

- the use of copper citrate is technologically justified;

- Standard 4.1.1 – Wine Production Requirements is an Australia only standard which has been written to ensure Australia's Agreement with the EU on trade in wine is maintained. This Standard contains a separate positive 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.

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act; and

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

The proposed draft variations to the Code are at **Attachment 1**.

10. ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety assessment report
3. Food technology report

ATTACHMENT 1

Draft variation 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 inserting in the* Table to clause 14 –

Copper citrate on a bentonite base	Removal of sulphide compounds from wine	GMP

[2] ***Standard 4.1.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 4 –

Copper citrate on a bentonite base

ATTACHMENT 2

Safety assessment report

TOXICOLOGICAL EVALUATION OF COPPER

Summary and conclusions from the safety review of copper undertaken under the Review of Metal and Contaminants in Food (Proposal P57) of the Australia New Zealand Food Standards Code

Copper is an essential trace element. This essentiality results from its role as a co–factor 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 1–5mg/kg with the highest levels found in liver (up to 237mg/kg) and more intermediate levels (8–24mg/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 1.15–1.35mg for adults, 0.75–1.15mg for adolescents, 0.56–0.75mg for children and 0.33–0.62mg for infants. Estimated oral intakes for copper in Australia are about 2mg/day for adults, 1.5mg/day for children, and 0.6mg/day for infants. In New Zealand, the estimated oral intake for adults is 2–3mg/day. These intakes are approximately twice the mean reported global intakes (0.93–1.24mg/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 and the amount of copper that is actually ingested. 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, ie 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 ceruloplasmin. 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 (eg, 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. The chronic toxicity of copper compounds does not appear to have been well studied and NOELs or LOELs for such exposure have not been established. The short–term and sub–chronic 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 principle 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 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 10mg Cu/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 32mg/day in drinking water. This contrasts with the fact that up to 13mg/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.

In 1982, the Joint Expert Committee on Food Additives (JECFA) set a provisional mean tolerable daily intake (PMTDI) for copper of 0.5mg/kg bw/day based on the endpoint of reversible liver function abnormalities seen in dogs. However, the dog may not be an appropriate species from which to extrapolate to humans. The level of 13mg/day has therefore been used to establish an upper limit to the safe range of population intakes for adults of 0.2mg/kg bw/day (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 30mg Cu/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 80mg/kg bw/day and malformations at doses >159mg/kg bw/day. In mink, increased mortality in offspring was observed at the much lower dose of 12mg/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. On balance, these studies do not indicate significant concern that copper sulphate is genotoxic. On the basis of the available epidemiological and limited experimental data in animals there is no convincing evidence that copper plays any aetiological role in the development of cancer in humans.

In conclusion, the adverse effects associated with copper can be related to deficiency as well as to excess, therefore, any consideration of the toxicity of copper must also take into account its essentiality. Copper is actively absorbed from the gastrointestinal tract, however, most mammals, including humans, have the capacity to maintain copper homeostasis by a combination of decreased absorption and increased excretion. This is reflected by the range of adult oral intake that can be ingested without any apparent detrimental health effect (between 1 and 13mg/day). Furthermore, as copper rarely occurs at high levels in foods other than liver, its potential to cause toxicity in healthy populations is probably limited. It is recommended that the Authority adopt the upper safe limit for adults of 0.2mg/kg bw/day as a provisional maximum tolerable daily intake (PTDI).

ATTACHMENT 3

Food Technology report

A463 – COPPER CITRATE AS A PROCESSING AID IN WINE

Introduction

FSANZ received an application from Swift and Co. Ltd. to amend the *Australia New Zealand Food Standards Code* (the Code) to approve the use of copper citrate as a processing aid for wine.

Background

A number of unpleasant volatile sulphur containing compounds can occur in wine during fermentation 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;
- the molecular structure of $Cu_2C6H4O7.2.5\ H_2O$; and
- a molecular weight of 360 g/mol.

Copper citrate is light blue/green granules which have a neutral smell and is insoluble in water. In the current application copper citrate is added to wine as a 2 % copper citrate solution coated onto bentonite.

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 Standard 1.3.3.

Evidence of Technological Need

The technological need claimed for this application is to be able to remove unpleasant sulphide odours from wine before bottling. The purpose of the chemical is to provide aid in food processing as well as improve 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.

A discussion of the two products, copper sulphate and copper citrate is provided below.

Copper sulphate

Copper sulphate (also called cupric sulphate) is approved for use under the Code as a processing aid for the wine industry to treat unpleasant sulphides contained in wine. However there are some drawbacks to its use. The copper sulphate needs to be carefully and accurately dosed to a level determined from tests on the wine. The level needs to be enough to eliminate the unacceptable sulphide odours but not too much to cause quality problems from having excess copper ions in the treated wine. There is also a legal requirement for exported wine that residual copper levels not exceed 1 mg/L. Excess residual copper, post sulphide treatment, is removed by adding another chemical, potassium ferrocyanide (commonly called blue finings or also potassium hexacyanoferrate II), which irreversibly binds the free copper ions in the wine. Excess copper ions in the treated wine have a negative impact on the wine quality. Excess copper causes a bitter taste, reduction in odour and may also cause cloudiness since the copper ion can complex with tannins in the wine. Copper bound with the blue finings forms a precipitate which is removed from the wine after cold storage via the usual methods (filtration, racking or centrifugation).

Copper citrate

Copper citrate is proposed as an alternative to using copper sulphate for the removal of unpleasant volatile sulphides from wine. Copper citrate can be coated to a mineral carrier matrix (for example bentonite). Bentonite is approved as a generally permitted food additive 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). It is also an approved processing aid (Table to clause 4) for wine produced in Australia (Standard 4.1.1 – Wine Production Requirements).

Trial results within the application using bentonite as the carrier matrix indicated that copper citrate has a greater affinity to remove sulphide odours in treated wine compared to the control copper sulphate treatment. Less residual copper ions remained in the treated wine, requiring less or no addition of potassium ferrocyanide. These trial results have been converted into a table to show the comparison between treatment with copper sulphate and copper citrate (see Table I). The copper citrate results relate to it being used on a bentonite support, while the copper sulphate results are when it is used by itself.

Table I
Comparison between copper sulphate and copper citrate treated wines

Initial wine sulphide odour	Copper sulphate treatment		Copper citrate treatment	
	dosage (g/100 l)	residual copper (mg/l)	dosage (g/100 l)	residual copper (mg/l)
slight	0.29	0.40	0.21	0.25
moderate	0.71	0.75	0.40	0.35
strong	1.08	1.77	0.60	0.50
extreme	2.38	3.83	1.08	0.94

Comparison between copper sulphate and copper citrate

As shown above in Table I copper citrate has the following advantages over 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 may be no subsequent treatment with potassium ferrocyanide (blue finings) to limit residual copper (regulations require < 1 mg/L for export wine)

Specifications of copper citrate bound to bentonite

The specifications of the copper citrate bound to bentonite are in Table II.

Table II
Specifications of copper citrate bound to bentonite

Analysis	Applicant Specification
Copper	7 ± 0.5 g/kg
Moisture	approx 6 –8 %
Bentonite analysis	
Loss on drying	≤ 8 %
Lead	≤ 40 ppm
Arsenic	≤ 5 ppm
Soluble matter in 1% tartaric acid	
Calcium	<0.40 %
Sodium	< 0.50 %
Iron	< 0.10 %
Arsenic	<2 ppm
Lead	<20 ppm

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.
'Impact of Volatile Sulfur Compounds on Wine Quality', Doris Rauhut, given at the 5th Workshop on Sulfur Transport and Assimilation, April 11-14 2002, Ensa Montpellier, France. Copy of paper found at the internet site:
http://www.rug-plfys.org/~grill/Rauhut_final-version.pdf