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DRAFT ASSESSMENT REPORT

APPLICATION A485

EXTENSION OF STOCK-IN-TRADE PROVISIONS FOR VINTAGE WINE

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter: 19 November 2003

(See 'Invitation for Public Submissions' for details)

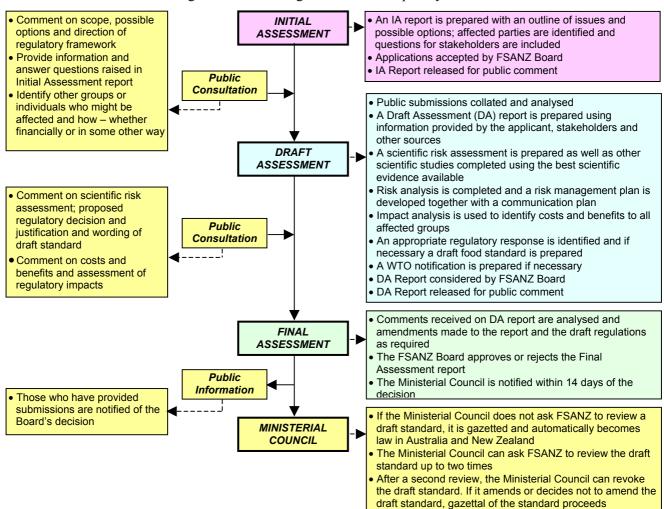
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

FSANZ has prepared a Draft Assessment Report of Application A485; and prepared a draft variation to the *Australian New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat inconfidence, 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 FSANZ by 19 November 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 <u>Standards Development</u> tab and then through <u>Documents for Public Comment</u>. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing <u>slo@foodstandards.gov.au</u>.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

Food Standards Australia New Zealand Food Standards Australia New Zealand

PO Box 7186 PO Box 10559

Canberra BC ACT 2610 The Terrace WELLINGTON 6036

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www.foodstandards.gov.nz www.foodstandards.govt.nz

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

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Executive Summary and Statement of Reasons

Current Regulations

FSANZ introduced stock-in-trade provisions in the *Australia New Zealand Food Standards Code* (the Code) in September 2002. These provisions allow food with a shelf-life of more than 12 months, manufactured and packaged prior to 20 December 2002 in compliance with applicable food standards at the time, to be lawfully sold until 20 December 2004.

While the intent of the long shelf-life stock-in-trade provisions is to allow the continued sale of long shelf-life food products manufactured and packaged, and legally produced during and prior to the transition period, consideration was not given to products such as bottled and labelled vintage wines that have a very long shelf-life and can remain in circulation for many years.

In accordance with Standard 1.1.1 in the Code, products with a long shelf-life, manufactured and packaged prior to 20 December 2002 in compliance with the applicable food standards at that time can only continue to be sold until 20 December 2004, as from this date the stock-intrade provisions will cease to have effect. Unless relabelled these products will become illegal.

The Winemakers Federation of Australia, the New Zealand Winegrowers' Association and the Australian Wine and Brandy Corporation have therefore applied to indefinitely extend the stock-in-trade provisions for vintage wines in order for these products to be legally sold after the expiration of the long shelf-life stock-in-trade provisions on 20 December 2004. If the draft variation to Standard 1.1.1 is approved, tannin derived from chestnuts, fining agents derived from egg, fish and milk and added sulphites in concentrations of 10 mg/kg to 25 mg/kg will not be required to be declared when present in vintage wine bottled prior to 20 December 2002.

Objectives

The specific objectives in assessing Application A485 are to examine the extent of possible effects on public health and safety should the stock-in-trade provisions for vintage wines bottled prior to 20 December 2002, be indefinitely extended; and to ensure that the labelling requirements that may result from an indefinite extension of the stock-in-trade provisions for vintage wines bottled prior to 20 December 2002 do not adversely affect the ability of consumers to make informed choices.

Regulatory Options

There are two options for progressing the Application;

- 1. Maintain the status quo and retain the prohibition on the sale after 20 December 2004 of all long shelf-life products, including vintage wines, not compliant with the Code, or
- 2. Amend Standard 1.1.1 to allow the indefinite sale of vintage wines bottled prior to 20 December 2002 in compliance with the applicable food standards at that time.

Consultation

In response to the Initial Assessment a total of eight submissions, primarily from industry, were received. Generally submitters were in support of the Application. However, the New Zealand Food Safety Authority, Allergy New Zealand and Anaphylaxis Australia considered the proposed amendments did not adequately address public health and safety concerns.

Preferred option

The impact analysis indicates that Option 2, to amend Standard 1.1.1 to allow the indefinite sale of vintage wine (including table wine, sparkling wine and fortified wine) labelled with a vintage date and bottled prior to 20 December 2002 in compliance with the applicable food standards of the time, is the preferred and most appropriate option.

Statement of reasons

- Under option 2, the proposed extension of the long shelf-life stock-in-trade provisions is limited to vintage wine bottled prior to 20 December 2002. Affected products will be clearly labelled with a vintage date of 2002 or earlier. All other alcoholic beverages sold after the expiration of the stock-in-trade provisions on 20 December 2004 will be labelled in accordance with the new Code, including the new allergen labelling requirements in Standard 1.2.3, where these are applicable.
- Wine bottled and labelled prior to 20 December 2002, which is currently available for sale, is not required to declare the presence of allergens, other than for the presence of sulphur dioxide in concentrations of 25 mg/kg or more. Consequently, an indefinite extension of the stock-in-trade provisions for vintage wines bottled prior to 20 December 2002 will not expose consumers of wine to any greater health and safety risk than currently exists.
- While there may be a low-level health and safety risk in the proposed extension of the stock-in-trade provisions for vintage wine, consumers will be able to clearly identify affected wines by using the vintage date on the label. Where consumers are concerned about a potential adverse reaction to allergens present in vintage wine, avoiding wines with a vintage date of 2002 or earlier will eliminate the risk.
- Over time, vintage wines bottled prior to 20 December 2002 will be removed from circulation. Consequently, any potential health and safety risk will reduce over time as stocks of affected vintage wines are used up.
- To assist consumers to manage any potential risk associated with the proposed extension of the stock-in-trade provisions for vintage wines, FSANZ proposes to develop a fact sheet, which will advise consumers of the differing allergen labelling requirements for those vintage wines, which are covered by Application A485.
- It is proposed that the fact sheet will be provided to the wine industry and health professionals involved in the care of allergy and asthma sufferers. This will enable health professions to advise allergy sufferers of the different labelling requirements of vintage wines bottled prior to 20 December 2002. The fact sheet may also assist the wine industry in developing their own fact sheet, which could be provided to retail associations.

- The costs associated with Option 1 to recall, relabel and test affected vintage wines and the resulting disruption to the wine trade appear to outweigh the benefits of declaring substances with the potential to cause an adverse reaction, particularly given that the likelihood of an adverse reaction occurring is very low.
- On balance, FSANZ considers that the proposed extension of the stock-in-trade provisions for vintage wines bottled prior to 20 December 2002, is the most appropriate approach. Any potential risk to public health and safety can be managed by an avoidance of wines with a vintage date of 2002 or earlier. An extension of the stock-in-trade provisions for vintage wine will provide certainty for manufacturers and retailers and minimise any disruption to the vintage wine trade post 20 December 2004.

1. Introduction

1.1 Nature of Application

On 4 November 2002, the Winemakers Federation of Australia, the New Zealand Winegrowers' Association and the Australian Wine and Brandy Corporation submitted an application to FSANZ seeking an amendment to sub-clause 1(4) of Standard 1.1.1-Preliminary Provisions – Application, Interpretation and General Prohibitions, to indefinitely extend the two-year, long shelf-life stock-in-trade provisions, to wine and wine products (as defined in Standard 2.7.4), bottled prior to the 2003 vintage and labelled with a vintage date.

In January 2003, FSANZ sought clarification from the Applicant regarding certain aspects of the requested amendment to Standard 1.1.1. In respect of the requested clarification, the Applicant advised that:

- the extension would **not** apply to wine and wine products bottled and labelled after 20 December 2002;
- the extension would **not** apply to wine and wine products without a vintage date, such as bag-in-box products, non vintage sparkling wine and non vintage port; and
- the extension would **not** apply to other alcoholic beverages matured in large quantities and bottled and labelled after maturation, such as spirits.

Although the Applicant originally requested an extension to the stock-in-trade provisions for wine and wine products, when asked to clarify the scope of the extension the Applicant advised that it would be limited to vintage table wines, vintage sparkling wines and vintage fortified wines.

On this basis, FSANZ considers that Application A485 is limited to table wine, sparkling wine and fortified wine, bottled¹ prior to 20 December 2002 and labelled with a vintage date².

1.2 Current Regulations

FSANZ introduced stock-in-trade provisions in September 2002. Sub-clause 1(4) of Standard 1.1.1 provides that food with a shelf life of more than 12 months (long shelf-life food products), that were manufactured and packaged prior to 20 December 2002 in compliance with applicable food standards at the time, can continue to be lawfully sold until 20 December 2004.

A Draft Assessment of the Application has been completed and public comment is now being sought to assist in the Final Assessment of the Application.

2. Regulatory Problem

2.1 Labelling Requirements of Wine and Wine Products

The only labelling requirements that differ between the Code and the former food regulations in Australia and New Zealand, in relation to wine and wine products are the additional labelling requirements for substances that may cause severe adverse reactions in sensitive individuals.

¹ Bottled refers to wine bottled but not necessarily labelled.

² The vintage date is the year in which the grapes were harvested.

Under the Code substances that may cause severe adverse reactions in sensitive individuals must be declared in accordance with Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. These substances include cereals containing gluten and their products, crustacea and their products, egg and egg products, fish and fish products, milk and milk products, tree nuts and sesame seeds and their products, peanuts and soybeans and their products as well as added sulphites in concentrations of 10 mg/kg or more. Under the former regulations only sulphur dioxide in a proportion exceeding 25 mg/kg due to the presence of sulphur dioxide in an ingredient, was required to be declared.

In the wine production process, substances derived from egg, fish and milk may be used as a fining agent. While these products are largely removed through filtration, very small residual amounts may be present in the final product. Additionally, tannin derived from chestnuts is sometimes used as a wine additive, as is sulphur dioxide and its derivatives. These substances pose a public health risk to those individuals who are allergic to them. For wine and wine products produced under the Code, these substances are required to be declared on the label when present in the final food.

In accordance with the stock-in-trade provisions in Standard 1.1.1, wine and wine products with a long-shelf life manufactured and packaged prior to 20 December 2002 in compliance with the applicable food standards at the time may continue to be sold until 20 December 2004. From this date however, the stock-in-trade provisions will cease to have effect, which means that vintage wine and wine products produced under the former regulations cannot be legally sold after 20 December 2004 unless they fully comply with the Code.

2.2 Public health risks

The policies underpinning the Code aim to protect public health and safety while facilitating industry innovation in the market, and hence improving consumer choice. The aim when developing the Code was to create new standards that reduce the regulatory burden on industry and reflect the advances in scientific knowledge in areas such as nutrition, toxicology and allergenicity.

During the development of joint standards in Australia and New Zealand it was confirmed that the mandatory declaration of the presence of substances in food that may cause severe adverse reactions was justified on the basis of protecting the health and safety of people who are sensitive to these foods. Even where an exemption from ingredient labelling applies, the allergen labelling requirements in the Code must be complied with. Alcoholic beverages standardised in Part 2.7 of the Code are exempt from ingredient labelling.

If the Application is accepted, to provide an indefinite extension of the stock-trade-provisions for vintage wine bottled prior to 20 December 2002, allergens present in vintage wine would not be declared on the label. This could pose a risk to those individuals who may experience an adverse reaction to either the tannin derived from chestnuts or the fining agents derived from egg, fish and milk if present in the wine. While, the fining agents are removed through filtration, very small residual amounts may be present in the final product.

Additionally, added sulphites in concentrations of 10 mg/kg to 25 mg/kg may not be declared on vintage wine bottled prior to 20 December 2002. However, anecdotal evidence provided by the wine industry suggests that the majority of wine produced prior to the 2003 vintage (with added sulphites present at these concentrations) will actually have sulphur dioxide declared on the label in order to comply with export regulations. The wine industry have also indicated that where bottled wines prior to the 2003 vintage do not have sulphur dioxide declared on the label, the actual presence of sulphur dioxide is likely to be below 10mg/kg as the concentration of sulphur dioxide reduces with the age of the wine.

3. Objective

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 for this Application are:

- to examine the extent of possible effects on public health and safety should the stock-in-trade provisions for vintage wine bottled prior to 20 December 2002, be indefinitely extended.
- to ensure that the labelling requirements that may result from an indefinite extension of the stock-in-trade provisions for vintage wine bottled prior to 20 December 2002 do not adversely affect the ability of consumers to make informed choices.

The objectives of this Application will also have specific regard to the desirability of an efficient and internationally competitive food industry.

4. Background

4.1 Nature of wine production

Wine can remain in circulation for a very long time. Wineries may age red wines (and to a lesser extent white wines) for a period of up to five years before release. The wine can then be held at the retail level for a period of two to three years before being sold to the public at a premium. There is also a very strong secondary market for wine, which can be resold for a long period of time after production, for example at private auctions.

4.2 Current stock-in-trade arrangements

The stock-in-trade arrangements came into effect following advice from the food industry that it was considered necessary to include a provision in the Code, which had the effect of allowing the continued sale of 'stock-in-trade' manufactured and packaged during the transition period. The transition period commenced on 20 December 2000 and finished on 19 December 2002.

On 28 June 2002, prior to the end of the transition period, Ministers endorsed a 12-month stock-in-trade provision for all general food products and a 24-month stock-in-trade provision for long shelf-life food products that were manufactured and packaged and legally produced prior to 20 December 2002. In accordance with the current stock-in-trade provisions, long shelf-life wine and wine products, legally produced prior to 20 December 2002, do not need to comply with the Code until 20 December 2004 as specified in sub-clause 1(4) of Standard 1.1.1.

The intent of the long shelf-life stock-in-trade provisions contained in Standard 1.1.1 is to allow the continued sale of long shelf-life food products manufactured and packaged, and legally produced during and prior to the transition period. However, in developing the stock-in-trade provisions consideration was not given to products such as bottled and labelled vintage wines that have a very long shelf-life, which can remain in circulation for many years. In many cases these wines improve with age and therefore can be considered unique in this regard.

5. Relevant Issues

5.1 Food products likely to be affected

Food products covered by the Application are limited to table wine, sparkling wine and fortified wine, bottled prior to 20 December 2002, which are labelled with a vintage date. If the draft variation to Standard 1.1.1 is approved, the labelled vintage date will ensure enforcement officers can clearly differentiate between those products subject to the indefinite extension of the stock-in-trade provisions and other wines. The Application does not include other alcoholic beverages that are either:

- non-vintage wine products that do not posses a vintage date, such as bag-in-box products;
- non-vintage sparkling wine;
- non-vintage port; and
- other alcoholic beverages that are matured in large quantities and are bottled and labelled after maturation, such as spirits.

5.2 Differing labelling requirements upon acceptance of the Application

As mentioned the only labelling requirements that differ between the new Code and the former regulations in Australia and New Zealand are the additional labelling requirements for substances that may cause severe adverse reactions in sensitive individuals in accordance with Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations of the Code. If the draft variation to Standard 1.1.1 is approved, the source of fining agents derived from egg, fish and milk as well as tannin derived from chestnuts (sometimes used as a wine additive) and sulphites added in concentrations of 10 mg/kg to 25 mg/kg will not be required to be declared if present in vintage wine bottled prior to 20 December 2002.

5.3 Risk Assessment

Risk assessment is the process of using available information to identify, characterise and quantify adverse risks. In terms of the FSANZ objectives, risk assessment involves:

- scientific assessment to ascertain risks to public health and safety; and
- assessment of social and economic factors leading to the achievement of consumer protection objectives, such as providing adequate information and preventing misleading or deceptive conduct. An assessment of economic and social factors will help to determine the degree to which a market failure will occur.

Risk management decisions, in terms of labelling, must be evidence-based to ensure that appropriate labelling outcomes are achieved. The risk management framework should tie the degree of risk to a specific labelling requirement. The greater the degree of risk, the more prescriptive the labelling requirement is likely to be.

Any labelling action taken to control or minimise a risk will need to address the nature of the problem; the likelihood of the problem occurring and the consequences of the problem occurring; the need for flexibility or certainty in regulatory arrangements; and the costs and benefits of any regulatory action.

5.4 Recent developments in the European Union

The European Commission is in the process of amending the food labelling Directive 2000/13/EC to require the mandatory labelling of all ingredients including sub-ingredients of compound ingredients. Previously sub-ingredients that were part of a compound ingredient that made up less than 25% of the product did not require ingredient labelling. The new labelling requirements are intended to ensure that compound ingredient labelling does not hide the presence of allergens.

Currently in the Europe Union (EU), alcoholic beverages are exempt from ingredient labelling. The proposed amendment will require alcoholic beverages to be labelled with those ingredients that are on the EU allergen list. The list of allergenic ingredients that may be present in wine include: eggs and products thereof, fish and fish products thereof, milk and dairy products (including lactose), nuts and nut products and sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or mg/litre.

Recently, however, the European Parliament adopted further amendments to the proposed changes to the labelling Directive 2000/13/EC. In July 2003, the European Parliament agreed that labelling declarations should be restricted to substances present in food in amounts that 'scientific research has shown will cause an allergic reaction'. Furthermore, they agreed that an indication of processing aids used in the manufacture of alcoholic beverages would not be required.

The European Commission intends to consult the European Food Safety Authority regarding a provisional list of products, which although derived from a potential allergen, should not be considered allergenic. It is anticipated that the provisional list will be adopted on or before 1 January 2004.

There is currently a bi-lateral agreement between the European Union and Australia regarding the trade of wine. In order for Australian wine to be exported to the European Union, it must comply with the European Union labelling requirements.

6. Regulatory Options

The following two regulatory options have been identified.

Option 1. Maintain the status quo and retain the prohibition on the sale after 20 December 2004 of all long shelf-life products, including vintage wine, not compliant with the Code.

Under this option, vintage wine bottled prior to 20 December 2002 in compliance with the applicable food standards at the time, will not be able to be legally sold after 20 December 2004 unless compliant with the Code.

Option 2. Amend Standard 1.1.1 to allow the indefinite sale of vintage wine bottled prior to 20 December 2002 in compliance with the applicable food standards of the time.

Under this option, table wine, sparkling wine and fortified wine bottled prior to 20 December 2002 in compliance with the applicable food standards of the time and labelled with a vintage date will be able to be legally sold after the long shelf-life stock-in-trade provisions cease on 20 December 2004.

The following section summarises comments from submitters in response to the two regulatory options proposed in the IAR.

6.1 Issues raised by submitters

6.1.1 Option 1. Maintain the status quo and retain the prohibition of the sale after 20 December 2004 of all long-shelf life products not compliant with the Code.

6.1.1.1 Costs associated with option 1

At Initial Assessment it was determined that under this option the wine industry would be required to recall and relabel all their affected products in order to comply with the Code and would undoubtedly incur significant costs. Wine outlets, including restaurants and function centres that have purchased vintage wine bottled prior to 20 December 2002, would be unable to sell these products unless the bottles were relabelled.

There was consensus amongst those who commented on this issue that it would be a costly process. The **Australian Food and Grocery Council** consider testing for allergens and relabelling would not only be required by winemakers but would also be required throughout the marketing chain, including restaurants and function centres. They believe that this would impose severe practical difficulties and significant cost and because of the practical difficulties, labelling would be incomplete. The **Winemakers' Federation of Australia** and the **New Zealand Winegrowers' Association** expressed concern that there are no accurate tests to determine the presence of allergens in wine and as a consequence retailers would have to return stocks, which could have devastating impacts on small companies.

While the **New Zealand Food Safety Authority** do not support the option to extend the stock-in-trade provisions for vintage wine, they recognise the concern of the Applicant that not to do so would impose significant cost and raise serious issues for the wine industry in terms of supply and public image.

6.1.1.2 Determining the presence of allergens in wine

At Initial Assessment it was noted that the Winemakers Federation of Australia consider that Option 1 is not a practical solution, as the ingredients and processing aids including those used as fining agents, will be unknown for many older vintages and it will be impossible to relabel these products legally under the Code without analysis of the contents.

The Winemakers' Federation of Australia and the New Zealand Winegrowers' Association restated in their submission that as many wines, particularly red wines, have a long shelf life and may not be released for some years after production, there is unlikely to be accurate records of processing aids used in production, and added that there are no accurate tests to determine presence. It appears that in most cases it would not be possible to determine the presence of potential allergens.

6.1.1.3 Community awareness of potential allergens in wine

Community awareness of potential allergens in wine and wine products and whether consumers are likely to use the additional labelling information that is required under Option 1 was questioned at Initial Assessment.

There was some difference of opinion from submitters in relation to the community awareness of potential allergens in wine. Allergy New Zealand and Anaphylaxis Australia Inc consider it not widely known by allergy sufferers that allergenic substances may be present in wine and wine products. They also consider allergy sufferers would use the additional labelling information required with Option 1, and those individuals with sensitivities to the substances declared on a label, would not purchase the wine. The Australian Food and Grocery Council on the other hand commented that any person with an allergy to a substance present in wine would be aware of the allergy and would know to avoid consumption.

6.1.1.4 Consumer investors

At Initial Assessment it was noted that there is likely to be consumer concern regarding a recall, which may affect the image of wine and future sales. Consumers expect to be able to purchase vintage wine and it is therefore vital that trade continues for these products. Additionally, the costs of recalling and relabelling affected wine are likely to be passed on to consumers.

It was noted that many vintage wines are purchased as an investment and these products will not be able to be legally resold unless they are relabelled. Any relabelling may negatively affect the value of these wine stocks. Therefore, there is likely to be strong public interest among wine investors to ensure these products do not become illegal and retain their value.

The **Western Australia Food Advisory Committee** consider that to require all wines to be allergy labelled regardless of the year of vintage could compromise consumers that have invested in vintage wines.

6.1.2 Option 2. Amend Standard 1.1.1 to allow the indefinite sale of table wine, sparkling wine and fortified wine that were bottled prior to 20 December 2002 in compliance with the applicable food standards of the time and are labelled with a vintage date.

6.1.2.1 Scope of the Application

The Winemakers Federation of Australia, the New Zealand Winegrowers' Association and the Australian Wine and Brandy Corporation have sought to amend sub-clause 1(4) of Standard 1.1.1- Preliminary Provisions – Application, Interpretation and General Prohibitions, to indefinitely extend the two-year, long shelf-life stock-in-trade provisions, for table wine, sparkling wine and fortified wine that were bottled prior to the 2003 vintage and are labelled with a vintage date.

The Winemakers' Federation of Australia and the New Zealand Winegrowers' Association in their submission to A485 are seeking to extend the stock-in-trade provisions for wine and wine products to a small number of bottled fortified (tawny ports) and sparkling wines, both of which would not be labelled with a vintage date. The Winemakers' Federation of Australia and the New Zealand Winegrowers' Association explained that some of these products remain at the winery for longer than the two-year period allowed for stock-in-trade.

6.1.2.2 Perceived risk associated with option 2

Views were mixed amongst submitters in relation to the perceived risk associated with extending the stock-in-trade provisions for vintage wine products. The Winemakers' Federation of Australia and the New Zealand Winegrowers' Association and the Australian Food and Grocery Council consider that to the best of their knowledge there have been no reported cases of allergenic reactions to wine due the presence of allergens. In the absence of evidence, they support the application to extend the stock-in-trade provisions to these products. Allergy New Zealand and Anaphylaxis Australia Inc accept that there is some dispute over whether any residual allergenic protein remains in the product after filtration, however given the lack of minimum threshold data and regulatory allergen testing of products, consider the allergic substances should be declared on the label without exception. Additionally, the New Zealand Food Safety Authority acknowledge the argument that the public health and safety risk associated with allergens in wine is likely to be low, but consider the evidence in support of this argument seems to be largely anecdotal. They therefore do not support Option 2 to extend the stock-in-trade provisions for vintage wine.

While the **New Zealand Food Safety Authority's** policy is that all common food allergens must be declared to consumers, they consider that if an advisory statement is provided either on the label; displayed on or in connection with the display of the wine; or provided to the purchaser upon request, advising purchasers that the subject wines were manufactured and packaged before the allergen declaration requirement was developed, this would address the public health and safety issues associated with this option. **Allergy New Zealand** and **Anaphylaxis Australia Inc** also in principle do not support an extension of the stock-in-trade provisions. However they note that the products are unique and therefore would support an extension to the stock-in-trade provisions for the identified wines providing the extension and implications for allergy sufferers, is clearly and conspicuously communicated in media, point of sale material (eg. posters, flyers), wine publications and allergy/asthma publications and is also communicated in writing directly to medical and nutritional health professionals involved in the care of allergy and asthma sufferers, eg. allergy specialists, specialist physicians, dietitians.

7. Impact Analysis

7.1 Affected parties

Parties affected by this Application are:

- wine producers of vintage wines, particularly small business.
- retail outlets including restaurants, which sell vintage wines.
- consumers of vintage wines including investors and those that suffer from severe adverse reactions.
- government agencies responsible for enforcement of food standards.

7.2 Cost-benefit assessment of regulatory options

7.2.1 Option 1. Maintain the status quo and retain the prohibition of the sale after 20 December 2004 of all long shelf-life products, including vintage wine, not compliant with the Code.

Wine producers

There are likely to be considerable negative impacts on wine producers in Australia and New Zealand when the current long shelf-life stock-in-trade provisions expire. Under this option vintage wine bottled prior to 20 December 2002 that is not labelled in accordance with the Code will be required to be recalled and relabelled. Given that materials derived from egg, fish and milk are commonly used in order to remove phenolic compounds from wine, and tannin derived from nuts can be used as a wine additive, a considerable number of vintage wines bottled prior to 20 December 2002 will be affected. Not only will affected Australian and New Zealand vintage wines be required to be returned to the wine producer for relabelling, but affected wines that are imported may have to be returned to the country in which they were produced. This will be a very expensive process.

Relabelling may negatively affect the value of wine and consumer concern regarding a recall may affect public image and future sales.

The wine industry has indicated that the costs associated with a recall are likely to be greater for small and medium sized wineries. Small and medium sized wineries have lower turnover

rates and require longer cellaring times to produce premium wines and a greater proportion of the wine they sell is vintage.

Anecdotal evidence provided by the wine industry suggests that recalling and relabelling is not only a very expensive option but is also not practical as ingredients and processing aids including those used as fining agents will be unknown for many older vintages and it will be impossible to relabel without analysis of the contents. Therefore, if testing is also required, this will be a very costly process for the wine industry.

At Initial Assessment, FSANZ requested information, which would assist in estimating the costs of recalling, relabelling and testing affected vintage wines. FSANZ wishes to restate a request for any information, which would assist in quantifying these costs as part of the impact analysis.

Retail outlets

If the status quo is retained, retail outlets including restaurants and function centres will be forced to return all products not compliant with the Code. There has been a suggestion by the **Australian Food and Grocery Council** that allergen testing and relabelling would be required at each point throughout the marketing chain, however the wine industry has indicated that affected products would be returned to the wine producer for relabelling. Regardless of where the relabelling occurs, a recall will result in a significant disruption to the wine supply.

Consumers

The current requirements of the Code to declare the presence of egg and egg products; fish and fish products; milk and milk products; tree nuts and their products and added sulphites in concentrations of 10mg/kg or more when present in wine, provide some protection to consumers of wine who are sensitive to these substances. The declarations allow those who are susceptible to severe adverse reactions to identify a wine, which may pose a potential risk.

Under this option the requirement to relabel vintage wine sold after 20 December 2004 will be onerous and costly for manufacturers and retailers, which may result in some lack of compliance. As a result, there may be inconsistent labelling of vintage wines bottled prior to 20 December 2002. Therefore, this option may actually pose a greater risk to those consumers who are sensitive to allergic substances when present in wine, as they will expect that all products are correctly labelled and this may not necessarily be the case.

It is likely that some of the industry costs associated with recalling and relabelling will also be passed on to consumers.

Government agencies

There are not likely to be any direct impacts on government of retaining the current regulations.

7.2.2 Option 2. Amend Standard 1.1.1 to allow the indefinite sale of table wine, sparkling wine and fortified wine that were bottled prior to 20 December 2002 in compliance with the applicable food standards of the time and are labelled with a vintage date.

Wine producers

This option will ensure the continued sale of vintage wines, which will have a neutral impact on those sectors of the industry dealing in vintage wines. Additionally, this option will avoid any negative impact on the image of the Australia and New Zealand wine industry.

Retail outlets

A recall of vintage wine will not be required with this option and there will be no disruption to the supply of vintage wine at retail outlets, including restaurants and function centres.

Consumers

The requirements in the Code to declare the presence of substances in food that may cause severe adverse reactions was considered justified on the basis of protecting the health and safety of people who are sensitive to these foods. However, to allow the indefinite sale of vintage table wine, sparkling wine and fortified wine that were bottled prior to 20 December 2002 in compliance with the applicable food standards of the time, will not provide a greater risk to sensitive individuals than that already present before the new requirements came into force. Consumers can choose not to purchase wine with a vintage date of 2002 and earlier.

Additionally, the incidence of food allergies is greater amongst children who have less exposure to wine. In 1987, the worldwide prevalence of food allergy was estimated to be 4-6% in children and 1-2% in the adult population.³

As mentioned, a risk associated with Option 1 is that there maybe some lack of compliance, which could result in inconsistent labelling of affected vintage wine bottled prior to 20 December 2002. Therefore, Option 2 may actually pose less risk to consumers who suffer from severe adverse reactions from allergenic substances in food, as the labelling of vintage wine is more likely to be accurate.

Government agencies

There is likely to be an initial minor impact on government enforcement agencies if Option 2 is adopted. Enforcement agencies will have to differentiate between vintage wine bottled prior to 20 December 2002 and vintage wine produced post 20 December 2002, in order to ensure that the products are correctly labelled. A vintage date will be present on all table wine, sparkling wine and fortified wine where the extension of the stock-in-trade provisions apply. This will assist enforcement officers to determine compliance.

The impact on government enforcement agencies will decrease over time as the stocks of vintage wines produced prior to 20 December 2002 are consumed.

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³ Bock. S. A. 1987. Prospective appraisal of complaints of adverse reaction to foods in children during the first three years of life. *Pediatrics* 79:683-688.

8. Consultation

FSANZ is committed to actively engaging stakeholders in the review and development of food standards. The Community Involvement Protocol was developed to provide a framework of principles and guidelines for engaging the community on food standards issues to assist FSANZ in implementing its community involvement policy. The Application has been placed in Community Involvement Category Two on the basis that there is a low perceived risk to health and safety, little or no scientific evidence of health or safety risk, low but broad social or economic impact and low but broad public interest or relevance. For this reason an external advisory group has not been established. However, submissions are encouraged.

In response to the Initial Assessment Report, a total of eight submissions were received. These submissions were primarily from industry. There were three submissions from government and one from a consumer group.

The majority of submitters, including the Winemakers' Federation of Australia and the New Zealand Winegrowers' Association, the Australian Food and Grocery Council, Beringer Blass Wine Estates, the Food Technology Association of Victoria and the Western Australia Food Advisory Committee were generally in support of the application to amend Standard 1.1.1, to allow the indefinite sale of table wine, sparkling wine and fortified wine that were bottled prior to 20 December 2002 in compliance with applicable food standards of the time and are labelled with a vintage date.

The New Zealand Food Safety Authority, Allergy New Zealand and Anaphylaxis Australia Inc considered that the proposed amendments identified in the application, did not adequately address public health and safety concerns.

A full summary of submission is included at **Attachment 2**.

8.1 World Trade Organization (WTO)

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by Coalition of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory.

Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, FSANZ is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists). As Application A485 is seeking to extend an existing stock-intrade provision, there is no need to notify the WTO.

9. Conclusion and Recommendation

It is recommended that the most appropriate regulatory option with which to proceed is Option 2, that is to amend Standard 1.1.1 to allow the indefinite sale of vintage wine (including table wine, sparkling wine and fortified) wine bottled prior to 20 December 2002 in compliance with the applicable food standards of the time, which is labelled with a vintage date of 2002 or earlier

The costs associated with Option 1 to recall, relabel and test affected vintage wines and the resulting disruption to the wine trade appear to outweigh the benefits, of declaring the substances such as fining agents derived from egg, fish and milk as well as tannin derived from chestnuts and sulphites added in concentrations of 10 mg/kg to 25 mg/kg on the label, when present in these products.

Option 1 is not considered appropriate, as it will be very costly and resource intensive for the wine industry. Ingredients and processing aids including those used as fining agents will be unknown for many older vintages and it will be impossible to relabel without analysis of the contents. Because of this, there is a risk of some lack of compliance, which could result in inconsistent labelling of vintage wine bottled prior to 20 December 2002. Therefore this option may pose a greater risk to those consumers who are sensitive to allergic substances when present in vintage wine, as the substances may not always be declared on the label.

FSANZ is aware that there is some concern that to allow the indefinite sale of vintage wines bottled prior to 20 December 2002 may not adequately address potential risks to public health and safety. The **New Zealand Food Safety Authority** considered that providing an advisory statement to the effect that vintage wines were manufactured and packaged before the allergen declaration requirements were developed, would address public health and safety concerns. However, FSANZ is of the view that not to offer this information does not provide any greater risk than that already present before the new requirements came into force. Therefore FSANZ considers that the mandatory provision of this advice does not warrant legislating.

Allergy New Zealand and Anaphylaxis Australia believe that information on the extension and implications for allergy sufferers should be provided in the media, point of sale (eg. posters, flyers), wine publications and allergy/asthma publications and be communicated in writing directly to medical and nutritional health professionals involved in the care of allergy and asthma sufferers, eg. allergy specialists, specialist physicians and dietitians.

In response to this and the concerns raised by the New Zealand Food Safety Authority, FSANZ proposes to develop a fact sheet outlining the different labelling requirements for those vintage wines covered by the Application. The fact sheet will be provided to the Winemakers Federation of Australia and the New Zealand Winegrowers' Association to use as they see fit. They may find it appropriate to develop their own fact sheet, which can be provided to retail associations to disseminate to wine retail outlets. FSANZ will also provide the fact sheet to the Australasian Society of Clinical Immunology and Allergy Inc, the Dietitians Association of Australia, the New Zealand Dietetic Association, the Australian Medical Association and the New Zealand Medical Association. This will enable health professions to advise allergy sufferers of the different labelling requirements for vintage wine products bottled prior to 20 December 2002.

FSANZ proposes not to broaden the scope of the Application to extend the stock-in-trade to a small number of bottled fortified (tawny ports) and sparkling wines, both of which would not be labelled with a vintage date, as requested by the **Winemakers' Federation of Australia** and the **New Zealand Winegrowers' Association** in their submission to the Initial Assessment. Given these products would not be labelled with a vintage date, it would be impossible for enforcement officers to ensure compliance of these products with the proposed extension to the stock-in-trade provisions and consumers would be unable to identify those products which would not be subject to the new allergen labelling requirements in the Code.

The two-year long shelf life stock-in-trade provisions do not expire until 20 December 2004. This allows the wine industry fifteen months to clear wine stocks where an extension does not apply. Given there are only a small number of bottled fortified and sparkling wines that are not captured by the draft variation to Standard 1.1.1, there should be sufficient time between now and December 2004 for the majority of these stocks be consumed.

On balance, FSANZ considers that the proposed extension of the stock-in-trade provisions for vintage wines bottled prior to 20 December 2002, is the most appropriate approach. Any potential risk to public health and safety can be managed by an avoidance of wines with a vintage date of 2002 or earlier. An extension of the stock-in-trade provisions for vintage wine will provide certainty for manufacturers and retailers and minimise any disruption to the vintage wine trade post 20 December 2004.

10. Implementation and review

Following the consultation period for this report, the Final Assessment of this Application will be completed. The Final Assessment Report is expected to be considered by the FSANZ Board in March 2004, following which, a notification will be made to the Ministerial Council. It is expected that this will be completed by mid 2004.

The variation to Standard 1.1.1 will take effect from the date of Gazettal.

ATTACHMENTS

- 1. Proposed drafting of Standard 1.1.1
- 2. Summary of submissions

Draft Variation to the Australia New Zealand Food Standards Code

To commence on gazettal

- [1] Standard 1.1.1. of the Australia New Zealand Food Standards Code is varied by omitting subclauses (4),(5) and (6), substituting –
- (4) Subject to subclause (5) and prior to 20 December 2004, subclause (1) does not apply to food products with a shelf life of more than 12 months
 - (a) manufactured and packaged prior to 20 December 2002; and
 - (b) which complied with all applicable food standards in the case of Australia and all applicable food standards or New Zealand *Food Regulations (1984)* in the case of New Zealand, as of the date of manufacture or packaging of the food product.
- (5) Subclause (1) does not apply to wine with a shelf life of more than 12 months
 - (a) bottled before 20 December 2002; and
 - (b) that complies with all food standards in the case of Australia and all food standards or New Zealand *Food Regulations (1984)* in the case of New Zealand, that would have applied on the date of bottling; and
 - (c) which is labelled with a 2002 vintage date or earlier.

Editorial note:

'Wine' includes sparkling wine and fortified wine.

- (6) For the purposes of a Standard in this Code for which a corresponding transitional Standard in Part 1.1A applies, the reference to 'commencement of the variation' in subclause 2 is a reference to the date when that corresponding Standard in Part 1.1A ceases to have effect.
- (7) Prior to 20 December 2003, Part 1.2, other than Standards 1.2.3, those parts of Standard 1.2.5 that refer to 'use-by dates', and 1.2.6, does not apply to food labelled on the premises for retail sale from which it is sold.

Summary of Submissions

Option 1. Maintain the status quo and retain the prohibition of the sale after 20 December 2004 of all long-shelf life products not compliant with the *Code*.

Wine producers

Submitter	Comments
Winemakers' Federation of Australia and the New Zealand Winegrower's Association	• states that as many wines, particularly red wines, have a long shelf life and may not be released for some years after production, there is unlikely to be accurate records of processing aids that were used in their production. Therefore it would not be possible to ascertain presence of potential allergens from records. Additionally, there are no accurate tests to determine the presence of many allergenic substances in wine. This may mean that retailers will not stock these wines or will demand that companies take them back, which could have devastating impacts on small companies.

Retail outlets and other industry bodies

Submitter	Comments
The Australian Food and Grocery Council	 states that if the products covered by the Application are required to be labelled in accordance with the <i>Food Standards Code</i>, it will impose extreme practical difficulties not only on wine makers but also throughout the marketing chain, including restaurants and function centres. Testing for likely allergens and the level of sulphur dioxide, as well as relabelling would be required at each point throughout the marketing chain. considers that any attempt to apply the current stock-in-trade provisions to these products would be subject to severe practical difficulties, would impose significant cost and because of the practical difficulties be incomplete.

Consumers

Submitter	Comments
Allergy New Zealand and	• considers it not widely known by allergy sufferers that these substances may be present in wine products.
Anaphylaxis Australia Inc	• considers allergy sufferers would use the additional labelling information required with option 1, and those allergic to these substances would not purchase the wine.

Government agencies

Submitter	Comments
Western Australia Food Advisory Committee	 considers that the current provisions could compromise consumers who for various reasons may have invested in select vintage wines.

Option 2. Amend Standard 1.1.1 to allow the indefinite sale of wine and wine products covered by Application A485, that were produced prior to 20 December 2002 in compliance with the applicable food standards of the time.

Wine producers

Submitter	Comments
Winemakers' Federation of Australia and the New Zealand Winegrower's Association	 seeks an extension of the stock-in-trade provisions to an additional small number of bottled fortified wines (tawny ports) and non-vintage sparkling wines without a vintage date, as some of these products remain at the winery for longer than the two year period allowed for stock-in-trade. This could save expensive recall action, as small and medium wineries will not have the detailed record keeping process in place to assure retailers that their product is compliant. states that to the best of their knowledge there have been no reported cases of allergenic reactions to do with the consumption of wine due to the presence of fish, egg or milk products as processing aids.
Beringer Blass Wine Estates	• supports Option 2 – to amend Standard 1.1.1 to allow the indefinite sale of wine and wine products produced before 20 December 2002, in compliance with applicable food standards of the time. Due to the length of the maturation process required for premium wines, the two year stock-in-trade provision does not allow a sufficient time frame.

Retail outlets and other industry bodies

Submitter	Comments
The Australian Food and Grocery Council	 believes that FSANZ must produce strong evidence of a public health and safety risk, if it is to maintain the current stock-in-trade provisions. Part of this evidence would need to include a history of proven allergenic reactions from wine due to the presence of fining agents derived from egg, fish and milk and also any sensitivity to sulphur dioxide at levels below 25mg/kg. The AFGC is unaware of any such information. Without such evidence, the AFGC supports the Application to extend the stock-in-trade provisions to a limited number of wines – namely "table wine, sparkling wine and fortified wine that were bottled prior to the 2003 vintage and are labelled with a vintage date". believes that any person with an allergy to egg, fish or milk or sensitivity to sulphur dioxide at levels below 25mg/kg, who had

	experienced an allergenic reaction to these wines would already
	be aware of it and know to avoid their consumption.
Food	• supports Option 2 – to amend Standard 1.1.1 to allow the
Technology	indefinite sale of wine and wine products produced before 20
Association of	December 2002, in compliance with applicable food standards of
Victoria Inc	the time.

Consumers

Submitter	Comments
Allergy New Zealand and Anaphylaxis Australia Inc	 states that given the lack of minimum threshold data having full declaration of allergens labelled when present in a product is the ideal scenario for sensitive individuals. They accept that there is some dispute over whether any residual allergenic protein remains in the product after filtration. However, given the lack of regulatory allergen testing of all products containing these ingredients, they consider these substances must be declared on the label without exception. Therefore, in principle they do not support an extension to the stock-in-trade provision. However, they accept that vintage-date labelled table wine, sparkling wine and fortified wine are unique products and bear unique issues in maturation, storage, sale and investment. states that they therefore support an extension to the stock-in-trade provisions with the following conditions: that the stock-in-trade extension and implications for allergy sufferers, is clearly and conspicuously communicated in media, point of sale material (eg. posters, flyers), wine publications and allergy/asthma publications. that the stock-in-trade extension and implications for allergy sufferers be communicated in writing directly to medical and nutritional health professionals involved in the care of allergy and asthma sufferers, eg. allergy specialists, specialist physicians, dietitians.

Government agencies

Submitter	Comments
Department of Agriculture, Fisheries and Forestry - Australia	• states that the Australian Quarantine and Inspection Service (AQIS) will assess the regulatory impact of any proposed amendment to the <i>Code</i> on AQIS operations, after the draft assessment stage has been completed.
Western Australia Food Advisory Committee	• supports Option 2 – Amend Standard 1.1.1 to allow the indefinite sale of wine and wine products covered by Application A485 that were produced prior to 20 December 2002 in compliance with the applicable Food Standards of the time.
New Zealand Food Safety Authority	• states that their policy is that common food allergens must be declared to consumers. They therefore, can not support option 2 to allow the indefinite sale of wine and wine products covered by the Application, as this would require them to overlook identified public health risks.

states that the evidence that supports the argument that the public health and safety risk associated with allergens in wine is likely to be low, seems to be largely anecdotal. recognises the concern of the applicant that option 1 will impose significant cost and raise serious issues for the wine industry in terms of supply and public image. suggest that an advisory statement could be provided advising purchasers that the subject wines were manufactured and packaged before the allergen declaration requirement was developed. This advisory statement could be provided by the same means referred to in Standard 1.2.3, Clause 4(2)(b). For example, a subclause could be added under Clause 4, along the lines of (c) in the case of wine bearing a vintage date that was manufactured and packaged prior to 20 December 2002 in compliance with the applicable food standards of the time, an advisory statement must be provided – o on the label on a package of the wine; or o displayed on or in connection with the display of the wine; or o provided to the purchaser upon request to the effect that the wine was manufactured and packaged prior to the coming into force of the requirement to declare the presence of allergens on the label on a package of wine. believes this option would address the public health and safety issue while removing much of the deterrent involved with the recall and re-labelling of the subject wine and minimising the costs of compliance. in proposing this option, relies upon the fact that allergen declarations on current vintage wines will build public awareness of the presence of allergens in wine generally.

Other comments

Submitter	Comments
The Australian Food and Grocery Council	• notes that with regard to sulphur dioxide, under the old <i>Code</i> if present at more than 25mg/kg sulphur dioxide would be required to be declared; however, under the new <i>Code</i> this threshold has been reduced to 10mg/kg.
Food Technology Association of Victoria Inc	• questions whether the term "produced" actually refers to product packaged before 20 December 2002 or to product manufactured prior to this date but held in storage for maturation purposes, etc with the intention of subsequent packaging with a vintage date that may indicate '2002' or earlier.