

**2-04**  
**17 March 2004**

## **FINAL ASSESSMENT REPORT**

### **APPLICATION A485**

# **EXTENSION OF STOCK-IN-TRADE PROVISIONS FOR BOTTLED WINE LABELLED WITH A 2002 VINTAGE DATE OR EARLIER**

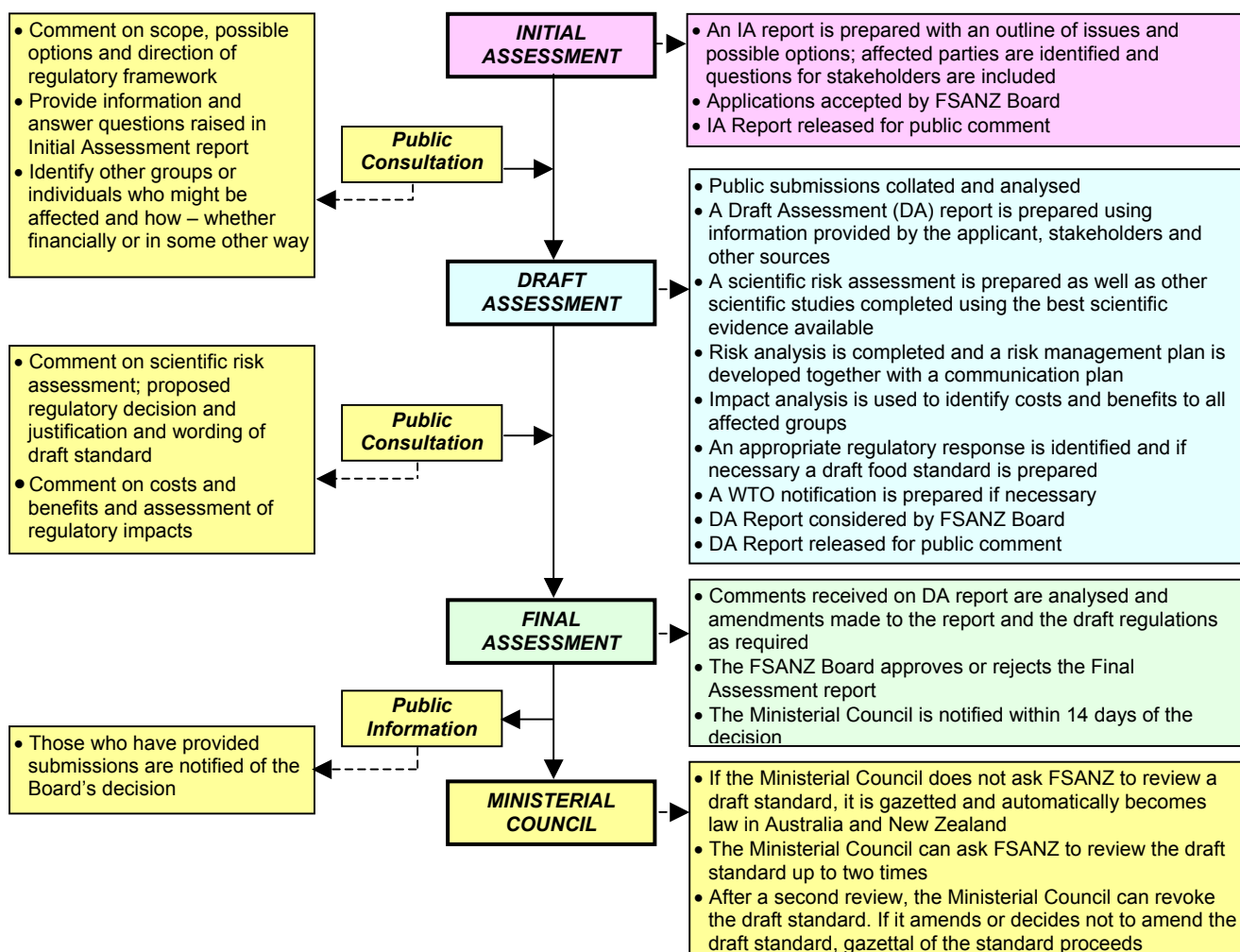
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



## **Final Assessment Stage**

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

## **Further Information**

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at 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](http://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](http://www.foodstandards.govt.nz)**

Assessment reports are available for viewing and downloading from the FSANZ website [www.foodstandards.gov.au](http://www.foodstandards.gov.au) or alternatively paper copies of reports can be requested from FSANZ's Information Officer at [info@foodstandards.gov.au](mailto: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. One of these provisions allow food with a shelf life of more than 12 months and 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 wines that have a very long shelf life and can remain in circulation for many years.

In accordance with Standard 1.1.1 – Preliminary provisions – application, interpretation and general prohibitions, in the Code, products with a long shelf life (shelf life of more than 12 months), 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-in-trade provisions will cease to have effect and 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 wines labelled with a vintage date of 2002 or earlier in order to enable these products to be legally sold after the expiration of the long shelf life stock-in-trade provisions on 20 December 2004. With acceptance of the Application, tannin derived from chestnuts and fining agents derived from egg, fish and milk would not be required to be declared when present in bottled wine labelled with a vintage date of 2002 or earlier.

### **Objectives**

The specific objectives in assessing Application A485 are to examine the extent of possible effects on public health and safety with the indefinite extension of stock-in-trade provisions for bottled wines labelled with a vintage date of 2002 or earlier; and to ensure that the labelling requirements that may result from an indefinite extension of the stock-in-trade provisions of bottled wines labelled with a vintage date of 2002 or earlier do not adversely affect the ability of consumers to make informed choices.

### **Regulatory Options**

The following regulatory options were posed in the Draft Assessment Report;

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

At Draft Assessment, FSANZ proposed that under Option 2 a fact sheet outlining the differing labelling requirements for those wines covered by the Application be developed and provided to the wine industry and health professionals involved in the care of allergy and asthma sufferers.

## **Consultation**

In response to the Draft Assessment Report a total of six submissions, primarily from industry, were received. Generally submitters were in support of the Application and the proposed draft variation to Standard 1.1.1. However, the New Zealand Food Safety Authority, Allergy New Zealand and Anaphylaxis Australia consider that a mandatory requirement to provide information at the point of sale on the different labelling requirements for wine bottled prior to 20 December 2002, is necessary.

## **Preferred option**

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

To assist consumers to manage any potential risk associated with the proposed extension of the stock-in-trade provisions for those wines, which are covered by Application A485, FSANZ proposes to provide a consumer fact sheet to the wine industry, allergen support groups and health professionals, providing information regarding the differing allergen labelling requirements. FSANZ also proposes to provide an industry fact sheet to the wine industry.

The proposed drafting for the amendment to Standard 1.1.1 is at Attachment 1.

## **Statement of Reasons**

- Under Option 2, the proposed extension of the long shelf life stock-in-trade provisions is limited to wine, including sparkling wine and fortified wine, bottled prior to 20 December 2002 and 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 required to be labelled in accordance with the new Code, including the new allergen labelling requirements in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, 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 certain substances that may cause adverse reactions in sensitive individuals. Consequently, an indefinite extension of the stock-in-trade provisions for bottled wines labelled with a vintage date of 2002 or earlier, will not expose consumers of wine to any greater health and safety risk than currently exists.
- The costs associated with Option 1 to recall, re-label and test affected wines and the resulting disruption to the wine trade, outweigh the benefits of declaring the presence of certain substances with the potential to cause an adverse reaction, particularly given that the likelihood of an adverse reaction occurring is very low.

- While there may be a low-level health and safety risk with the proposed extension of the stock-in-trade provisions for bottled wine labelled with a vintage date of 2002 or earlier, 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, wines with a vintage date of 2002 or earlier will be removed from circulation. Consequently, any potential health and safety risk will reduce over time as stocks of affected vintage wines are consumed.
- FSANZ will provide the allergen support groups and health professionals involved in the care of allergy and asthma sufferers with a consumer fact sheet outlining the different labelling requirements for wines covered by the Application. This will enable health professionals and allergen support groups to advise allergy sufferers of the different labelling requirements of wines bottled with a vintage date of 2002 or earlier. The consumer fact sheet will also be provided to the wine industry which may assist them in developing their own fact sheet, which could be provided to retail associations to disseminate to wine retail outlets. FSANZ will also provide the wine industry with an industry fact sheet to inform wine producers of their labelling obligations. The fact sheets will be placed on the FSANZ website.
- FSANZ considered a proposal by the New Zealand Food Safety Authority and Allergy New Zealand and Anaphylaxis Australia that the provision of information regarding the different labelling requirements for bottled wine with a 2002 vintage or earlier, be made mandatory. In the interest of minimum effective regulation, FSANZ is of the view that the provision of such information does not warrant legislation. A mandatory requirement would be costly, onerous and impractical for retailers and government enforcement agencies, with little consumer benefit. In addition, provisions exist in the Australian States and Territory Food Acts which prohibit a food business or person from supplying food by way of sale if it is not of the nature or substance demanded by the purchaser. This provision provides consumers with the confidence to obtain the information they require to make an informed decision.
- On balance, FSANZ considers that the proposed extension of the stock-in-trade provisions for bottled wines labelled with a vintage date of 2002 or earlier, 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 these wines will provide certainty for manufacturers and retailers and minimise any disruption to the 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 – Wine and wine product), 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 response to this request, 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 wine including sparkling wine and fortified wine bottled prior to 20 December 2002 and labelled with a vintage date. Such wines would need to be labelled with a vintage date of 2002 or earlier.

In their submission in response to the Initial Assessment Report in June 2003, the Winemakers' Federation of Australia and the New Zealand Winegrowers' Association requested a broadening of the scope of the Application to extend the stock-in-trade provisions to a small number of bottled fortified (tawny ports) and sparkling wines, both of which would not be labelled with a vintage date. Without a vintage date, it would be impossible for enforcement officers to ensure compliance and consumers would be unable to identify those products which would not be subject to the new allergen labelling requirements in the Code.

FSANZ therefore proposed that the scope of the Application not be broadened. At Draft Assessment, the wine industry was advised that the two-year long shelf life stock-in-trade provisions do not expire until 20 December 2004, thus allowing the wine industry fifteen months from that time 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 proposed draft variation to Standard 1.1.1, this should allow sufficient time for the majority of these stocks be consumed.



On this basis, FSANZ considers that Application A485 is limited to wine, including sparkling wine and fortified wine, bottled<sup>1</sup> prior to 20 December 2002 and labelled with a vintage date<sup>2</sup> of 2002 or earlier.

## **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.

## **2. Regulatory Problem**

### **2.1 Labelling Requirements of Wine and Wine Products**

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

Under the Code, certain 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. Substances listed in the Table to Clause 4 of Standard 1.2.3 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.

Sulphur dioxide is present in bottled white wine in concentrations of 100-140 mg/L and in bottled red wine in concentrations of 50-100 mg/L. Consequently, in the concentrations that sulphur dioxide is present in bottled wine, a declaration of its presence is required in accordance with the current Code and with the former food regulations.

In the wine production process, substances derived from egg, fish and milk may be used as fining agents. 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. Wine and wine products bottled after 20 December 2002 produced in accordance with the Code, are required to declare these substances on the label when present.

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. This means that all products including wine produced under the former regulations cannot be legally sold after 20 December 2004 unless they fully comply with the Code.

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<sup>1</sup> Bottled refers to wine bottled but not necessarily labelled.

<sup>2</sup> The vintage date is the year in which the grapes were harvested.

## 2.2 Public health risks

In developing and reviewing food standards the role of FSANZ is to protect public health and safety while facilitating industry innovation in the market, and improve 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, the mandatory declaration of the presence of certain substances in food that may cause severe adverse reactions was considered to be justified on the basis of protecting the health and safety of people who are sensitive to these substances. 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.

With an indefinite extension of the stock-in-trade provisions for bottled wine labelled with a vintage date of 2002 or earlier, tannin derived from chestnuts or fining agents derived from egg, fish and milk would not need to be declared. While fining agents are removed through filtration, very small residual amounts may be present in the final product.

No clinical or published evidence has been provided by submitters that fining agents derived from egg, fish or milk or tannin derived from chestnuts when present in wine are associated with adverse reactions.

## 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 with the indefinite extension of stock-in-trade provisions for bottled wine labelled with a 2002 vintage date or earlier; and

- to ensure that the labelling requirements that may result from an indefinite extension of the stock-in-trade provisions for bottled wine labelled with a 2002 vintage date or earlier, do not adversely affect the ability of consumers to make informed choices.

The objectives of this Application 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 long period of 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 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 wine, including sparkling wine and fortified wine, bottled prior to 20 December 2002 and labelled with a vintage date of 2002 or earlier. 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 or wine products that do not possess 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**

For wine, the only labelling requirements that differ between the Code and the former regulations in Australia and New Zealand are the additional labelling requirements for certain substances that may cause severe adverse reactions in sensitive individuals, in accordance with Clause 4 of Standard 1.2.3 of the Code. With acceptance of the Application, the source of fining agents derived from egg, fish and milk as well as tannin derived from chestnuts (sometimes used as a wine additive) will not be required to be declared if present in bottled wine labelled with a vintage date of 2002 or earlier. In the concentrations that sulphur dioxide is present in bottled wine, it is currently required to be declared in accordance with the Code and was previously required to be declared in accordance with the former food regulations.

## **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**

Directive 2000/13/EC which requires the mandatory labelling of all ingredients including sub-ingredients of compound ingredients, has been adopted in the European Union (EU). 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 obscure the presence of allergens.

In addition, the amendment will require alcoholic beverages to be labelled with those ingredients that are on the EU Annex IIIa allergen list. The list of allergenic ingredients that may be present in wine include: eggs and products thereof; fish and 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. Under the former regulations, alcoholic beverages were exempt from ingredient labelling.

Furthermore, Directive 2003/89/EC which provides further amendments to the proposed changes to the labelling Directive 2000/13/EC, was recently adopted by the European Parliament. This Directive allows an exemption from ingredient declaration where it has been scientifically established that these ingredients do not cause an allergic reaction. The Commission can be notified until 25 August 2004 of studies being undertaken to establish whether ingredients or substances, derived from ingredients listed in Annex IIIa are not likely, under specific circumstances to trigger adverse reactions. After consultation with the European Food Safety Authority, the Commission will then, not later than 25 November 2004, adopt a list of those ingredients or substances which will consequently be excluded from Annex IIIa. Consequently, the ingredients or substances in which studies are being undertaken will have a temporary waiver from declaration until the studies are complete and prove that the ingredients do not cause allergic reactions, or until 25 November 2007.

There is currently a bi-lateral agreement between the EU and Australia regarding the trade in wine. In order for Australian wine to be exported to the EU, it must comply with the EU labelling requirements. According to the Winemakers' Federation of Australia the EU Directive 2003/13/EC will have very little effect on exports of Australian wine as generally only post 2002 vintages are exported. Post 2002 vintages in compliance with Australian and New Zealand regulations will also comply with the new EU regulations. However, small quantities of rare, highly sought after wines such as Grange may be affected. It is likely that the Australian wine industry will notify the European Commission of research to determine whether the ingredients in wine trigger allergic reactions.

## **6. Regulatory Options**

At Draft Assessment, the following two regulatory options were 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 wine not compliant with the Code.**

Under this option, bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of 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 bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.**

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

In response to the public health and safety concerns raised by submitters, FSANZ proposed at Draft Assessment to develop a fact sheet outlining the differing labelling requirements for those wines covered by the Application. It was proposed that the fact sheet be provided to the wine industry and health professionals involved in the care of allergy and asthma sufferers.

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

## **6.1 Issues raised by submitters in relation to the regulatory options**

*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, including wine not compliant with the Code.*

### 6.1.1.1 Costs associated with option 1

Under this option the wine industry would be required to recall and relabel all their affected products in order to comply with the Code, which will undoubtedly be costly, onerous and impractical. 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 the ingredients and processing aids used in the production. Therefore it will be impossible to relabel these products without analysis of the contents. In addition, there are currently no accurate tests to detect the low levels at which some of the substances listed in the Table to Clause 4 of Standard 1.2.3 may be present in wine. Recall, testing and relabelling would not only be required by wine producers but would also be the responsibility of the proprietors of retail outlets where these wines are sold, including restaurants, function centres and auction houses.

The **Winemakers' Federation of Australia** considers that retail outlets for wine including restaurants and secondary markets will not be able to sell older vintages unless they have a manufacturer's declaration of what fining agents were used. Such information is unlikely to be available and each bottle of wine cannot be tested prior to drinking. The **Department of Agriculture, Fisheries and Forestry** considers that to require a recall and relabelling will be a costly burden on the wine industry with little additional consumer benefit.

### 6.1.1.2 Community awareness of potential allergens in wine

There are divergent views among submitters in relation to community awareness of potential allergens in wine and whether consumers are likely to use the allergen labelling information required under Option 1. The **Winemakers' Federation of Australia** believes that consumers with sensitivities to the substances listed in the Table to Clause 4 of Standard 1.2.3 are highly aware of the labelling requirements and are aware that allergen labelling is a new requirement. In addition, the **Department of Agriculture, Fisheries and Forestry** considers that consumers will be able to avoid wine bottled with a 2002 vintage or earlier if they face any potential allergen risks. The **Australian Food and Grocery Council** considers that consumers of bottled wines labelled with a vintage date of 2002 or earlier with sensitivities to allergenic substances, will generally have a limited number of brands that they consume on a regular basis and will have either rejected the wine due to a reaction or will have consumed the wine safely.

However, **Allergy New Zealand and Anaphylaxis Australia** maintains that the majority of food allergy sufferers are not aware that allergenic substances may be present in wine and consider that allergy sufferers would use the allergen labelling information required with Option 1 to avoid purchasing affected wine.

#### 6.1.1.3 Wine investors

There is likely to be consumer concern regarding a recall, which might affect the image of wine and future sales. Consumers expect to be able to purchase wines with a vintage date of 2002 or earlier and it is vital that trade continue in these products. Additionally, the costs of recalling and relabelling affected wine are likely to be passed on to consumers.

Many wines of a 2002 vintage and earlier 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. A recall will compromise consumers who have invested in wine and consequently, there is likely to be strong public interest among wine investors to ensure these products do not become illegal after December 2004 and retain their value.

*6.1.2 Option 2. Amend Standard 1.1.1 to allow the indefinite sale of bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.*

#### 6.1.2.1 Perceived risk associated with option 2

The **Australian Food and Grocery Council**, the **Food Technology Association of Victoria**, the **Department of Agriculture, Fisheries and Forestry** and the **Winemakers' Federation of Australia** support Option 2 to allow the indefinite sale of bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time. The **Australian Food and Grocery Council** agrees with the statement of reasons provided in the Draft Assessment Report and consider that Option 2 is consistent with the allergen requirements adopted by the EU. The **Department of Agriculture, Fisheries and Forestry**, consider that Option 2 will not pose any greater risk to the public after the transitional arrangements of 20 December 2004.

However, the **New Zealand Food Safety Authority** considers that to provide an indefinite extension will overlook an identified public health risk and therefore do not support the Application. In addition, the **New Zealand Food Safety Authority** consider that at some point affected consumers should be able to rely on having complete information on allergens available to them at the relevant time. **Allergy New Zealand and Anaphylaxis Australia** support option 2 only where the publication of the different labelling requirements for affected wine is made mandatory.

Additionally, **Allergy New Zealand and Anaphylaxis Australia** considers that the lack of published information on allergic reactions to fining agents in wine is a concern and that without clinical studies, it is only possible to report anecdotal reactions. **Allergy New Zealand and Anaphylaxis Australia** provided anecdotal information from Dr Steve Taylor of the Food Allergy Research and Resource Program, the University of Nebraska regarding a person anaphylactically sensitive to egg who claimed to have suffered serious reactions from wine on half a dozen or more occasions. These reactions were not clinically validated.

## **6.2 Issues raised by submitters in relation to the provision of information regarding the labelling requirements for wines covered by the Application**

The **Department of Agriculture, Fisheries and Forestry** considers that FSANZ's proposal to develop a fact sheet to advise health professionals and the wine industry of the different labelling requirements for wine bottled prior to 20 December 2002 should address any consumer allergen concerns. However, the **New Zealand Food Safety Authority** considers that a non-mandatory fact sheet is not adequate to address this risk. The **New Zealand Food Safety Authority** believes there is a strong possibility that a non-mandatory requirement would result in consumers not receiving this information, and consequently consumers would incorrectly assume that all wine that does not bear an allergen declaration regardless of vintage date, is free of allergenic substances. The **New Zealand Food Safety Authority** considers that this possibility is likely to become stronger as more wines from post 2002 vintages appear on the market and consumers become accustomed to seeing and relying on this information.

At Draft Assessment, in response to the **New Zealand Food Safety Authority** proposal for a mandatory requirement, FSANZ considered that not to offer mandatory advice would not result in any greater risk than that already present before the new requirements came into force. The **New Zealand Food Safety Authority** considers that the FSANZ assessment should not be conclusive of the matter.

The **New Zealand Food Safety Authority's** proposal that the provision of information regarding the differing labelling requirements be made mandatory would, at a minimum require retailers upon request to inform consumers at the point of sale that wine bottled prior to 20 December 2002 is not required to declare the presence of allergens on the label. The **Winemakers' Federation of Australia** considers that such a requirement is likely to be expensive and impractical. The vast majority of older wines are not sold through large retailers as they generally clear out current vintage stocks much more quickly than specialty retailers and producers. The **Winemakers' Federation of Australia** therefore considers that there is little chance of compliance with such an onerous requirement.

**Allergy New Zealand** and **Anaphylaxis Australia** also consider that the provision of a fact sheet alone would not adequately inform adults with sensitivities to the substances listed in the Table to Clause 4 of Standard 1.2.3, of the differing labelling requirements for affected wines. **Allergy New Zealand** and **Anaphylaxis Australia** considers that these individuals do not consult their health professionals as regularly as do children. Therefore **Allergy New Zealand** and **Anaphylaxis Australia** consider that mandatory publication of the amendments should be required by the Applicant in as many publications as possible. **Allergy New Zealand** and **Anaphylaxis Australia** believe that a mandatory publication should be made in point of sale material, wine industry publications and allergy/anaphylaxis organisation publications (eg. *Allergy Today* (Allergy New Zealand newsletter) and the Anaphylaxis newsletter.)

## **6.3 Other comments**

The **New Zealand Food Safety Authority** suggests that as scientific research is currently being conducted in Australia and the EU on actual risks associated with the presence of allergens in wine, it may be worthwhile to ascertain whether the results of this research can be provided before the assessment of this Application is finalised.



## **7. Impact Analysis**

### **7.1 Affected parties**

Parties affected by this Application are:

- wine producers, particularly small business.
- retail outlets including restaurants, which sell bottled wines with a vintage date of 2002 or earlier.
- consumers of wine, including investors and those that are likely to 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 on the sale after 20 December 2004 of all long shelf life products, including wine not compliant with the Code.*

#### 7.2.1.1 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 bottled wine labelled with a vintage date of 2002 or earlier 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 wines bottled prior to 20 December 2002 will be affected. Not only will affected Australian and New Zealand 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 would be a very expensive process.

Re-labelling 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 re-label without analysis of the contents. Therefore, if testing is also required, this will be a very costly process for the wine industry.

#### 7.2.1.2 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. A recall would result in a significant disruption to the wine supply.

### 7.2.1.3 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, 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 Option 1 the requirement to re-label bottled wine labelled with a vintage date of 2002 or earlier after 20 December 2004 would 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 wines with a vintage date of 2002 or earlier. Therefore, this option may actually pose a greater risk to any consumers who may be sensitive to allergenic 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.

### 7.2.1.4 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 bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.*

#### 7.2.2.1 Wine producers

The adoption of this option would ensure the continued sale of bottled wines with a vintage date of 2002 or earlier, which will have a neutral impact on those sectors of the industry dealing in affected wines. Additionally, this option will avoid any negative impact on the image of the Australia and New Zealand wine industry.

#### 7.2.2.2 Retail outlets

A recall of bottled wine labelled with a vintage date of 2002 or earlier will not be required with this option and there will be no disruption to the supply of wine at retail outlets.

#### 7.2.2.3 Consumers

The **New Zealand Food Safety Authority** believes that at some point affected consumers should be able to rely on having complete information on allergens available to them. However, the supply of wine bottled prior to 20 December 2002 will diminish over time and therefore at some point Option 2 will provide complete information to affected consumers.

The lack of published information on allergic reactions to fining agents in wine is a concern to **Allergy New Zealand** and **Anaphylaxis Australia**. However, FSANZ considers that without clinical evidence it is not possible to conclude that reactions have resulted from substances derived from egg, fish, milk and nuts, present in wine.

FSANZ considers that consumers have lived with wine without allergen labelling for many years. In addition, 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.<sup>3</sup>

In fact, to allow an indefinite extension of long shelf life stock-in-trade provisions for bottled wine labelled with a vintage date of 2002 or earlier, provides more information on potential allergenic substances to consumers than the current EU requirements. The EU requirements have allowed a temporary waiver from allergen labelling where research is been undertaken to prove that substances present in wine do not cause allergic reactions. The temporary waiver will be provided until the studies are complete or until 25 November 2007. Consequently, post 2002 vintages in the EU may not necessarily have allergenic substances declared.

A risk associated with Option 1 is that there may be some lack of compliance, which could result in inconsistent labelling of affected wine. 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 affected wine is more likely to be accurate.

The requirements in the Code to declare the presence of certain 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. At Draft Assessment FSANZ considered that Option 2 would not provide a greater risk to sensitive individuals than that already present before the new requirements came into force and that sensitive consumers can choose not to purchase these wines.

The **New Zealand Food Safety Authority**, however, considers that as Option 2 would result in some wines bearing allergen declarations while others would not, this may confuse consumers. In addition, the **New Zealand Food Safety Authority** considers that consumers may incorrectly assume that wines that do not bear an allergen declaration do not contain any substances derived from egg, fish, milk and nuts. However, FSANZ considers that educating consumers about the different labelling requirements for wine bottled prior to 20 December 2002 via a fact sheet, should address any potential confusion.

#### 7.2.2.4 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 wine bottled prior to 20 December 2002, in order to ensure that the products are correctly labelled. A vintage date of 2002 or earlier will be present on all bottled wine including sparkling wine and fortified wine where the extension of the stock-in-trade provisions apply, which will assist enforcement officers to determine compliance. The impact on government enforcement agencies will decrease over time as the stocks of vintage wines bottled prior to 20 December 2002 are consumed.

### **7.3 Cost-benefit assessment of a mandatory requirement for the provision of information regarding the labelling requirements for wines covered by the Application**

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<sup>3</sup> 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.

### 7.3.1 *Wine producers*

The mandatory provision of information regarding the different labelling requirements, as proposed by the **New Zealand Food Safety Authority** and **Allergy New Zealand** and **Anaphylaxis Australia** is likely to be expensive and impractical for those wine producers that sell affected wine directly to consumers.

### 7.3.2 *Retail outlets*

Retail sale is defined in Standard 1.2.1 as *sale to the public*. In addition, the definition of 'sale' under food legislation is very broad. Therefore where wine is sold to the public at auction houses, restaurants, wineries, small wine speciality shops, over the phone or online, or even where wine is given away at wine tastings, it is considered to be food for retail sale. According to the **Winemakers' Federation of Australia**, the majority of large retail outlets will not sell older vintages. It is likely that a significant number of bottled wines labelled with a vintage date of 2002 or earlier are sold at small speciality shops and on the secondary wine market, such as restaurants and auction houses, which represent a small proportion of the wine market. Consequently, a mandatory requirement as such is likely to be onerous, impractical and have a financial impost particularly on those sectors of the wine industry.

### 7.3.3 *Consumers*

If the provision of information regarding the different labelling requirements for wine bottled prior to 20 December 2002 is made mandatory, the costs incurred by wine retail outlets, wineries, restaurants and auction houses is likely to be passed onto consumers. While the **New Zealand Food Safety Authority**, **Allergy New Zealand** and **Anaphylaxis Australia** consider that a mandatory requirement for the provision of this information is necessary to address consumer risk, FSANZ is of the view that the same outcome can be achieved by a non-mandatory fact sheet.

A mandatory requirement that at a minimum would require retailers upon request to inform consumers at the point of sale that wine bottled prior to 20 December 2002 is not required to declare the presence of allergens on the label, as proposed by the **New Zealand Food Safety Authority**, relies on the consumer requesting information on the different labelling requirements. Consumers are unlikely to request this information unless they are aware of the different labelling requirements, and hence would have already been informed.

Secondly, if information about the different labelling provisions were required on the label of affected wine, the costs associated with such an approach will be similar to Option 1 and consequently there will be little chance of compliance. In addition, as many affected wines are sold at wine speciality stores, wineries, restaurants and auction houses, it does not seem practical to have a mandatory requirement for this information to be displayed on or in connection with the display of the wine, for example by way of a poster. Such a requirement is largely impractical at such locations and it will be difficult to enforce. There is likely to be little chance of compliance and consequently the information regarding the different labelling requirements will not be conveyed to affected consumers.

The Food Acts in Australian States and Territories have a general provision which prohibits a food business or person from supplying food by way of sale if it is not of the nature or substance demanded by the purchaser.

Consequently, in Australia if a consumer wants to know whether wine contains derivatives from egg, fish, milk or nuts, the onus is on the manufacturer to provide information about the product, which is not misleading or untruthful. This is a mechanism that enables the consumer to obtain the information regarding the composition of wine in order to make an informed purchasing decision.

#### *7.3.4 Government agencies*

There will be costs for Government agencies associated with the enforcement of a mandatory provision of information regarding the differing labelling requirements. In addition, as many wines bottled prior to 20 December 2002 are sold at wine speciality stores, wineries, restaurants and auction houses, the enforcement of a mandatory requirement for the provision of information regarding the different labelling requirements for these wines will be difficult. For example, with a mandatory requirement that at a minimum would require retailers upon request to inform consumers at the point of sale that wine bottled prior to 20 December 2002 is not required to declare the presence of allergens on the label, waiting staff will need to inform consumers of the different labelling requirements when this information is requested and enforcement of such a requirement will prove to be difficult. A similar outcome could be achieved by a non-mandatory requirement and without the costs and impracticalities associated with a mandatory requirement.

#### **7.4 Cost-benefit assessment of other comments**

In relation to the **New Zealand Food Safety Authority's** suggestion that it may be worthwhile to ascertain whether the results of scientific research currently being conducted in Australia and the EU on actual risks associated with the presence of allergens in wine can be obtained before this Application is finalised, it is likely this information will not be available for some time. The deadline to notify the European Commission of studies being undertaken is not until 24 August 2004 and ingredients or substances in which studies are being undertaken will have a temporary waiver from declaration until the studies are complete or until 25 November 2007. Therefore, studies are unlikely to be completed by 20 December 2004 when the long shelf life stock-in-trade provisions cease, and consequently FSANZ proposes to finalise this Application without waiting for the outcomes of these studies. It is possible however, that a requirement to allergen label bottled wines with a vintage date of 2002 or earlier can be revisited after the EU studies are complete.

### **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, two rounds of public comment have been carried out.

## 8.1 First round

The Initial Assessment Report for this Application was released for a six week consultation period from 21 May 2003. 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 bottled wine including sparkling wine and fortified wine labelled with a vintage date of 2002 or earlier.

However, 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.

## 8.2 Second round

The Draft Assessment Report for this Application was released for a six week consultation period from 8 October 2003. In response to the Draft Assessment Report, a total of six submissions were received. Three submissions were received from industry, two from government and one from a consumer group.

The majority of submitters including the **Australian Food and Grocery Council**, the **Winemakers' Federation of Australia**, the **Department of Agriculture, Fisheries and Forestry** and the **Food Technology Association of Victoria** supported the Application and the FSANZ proposal to provide the wine industry and health professionals involved in the care of allergy and asthma sufferers a fact sheet outlining the different labelling requirements for those wines covered by the Application.

**Allergy New Zealand** and **Anaphylaxis Australia Inc** consider that a mandatory requirement to provide information on the different labelling requirements for wine bottled prior to 20 December 2002 to affected consumers is necessary in order to safely extend the stock-in-trade provisions. The **New Zealand Food Safety Authority** did not support the Application and considered that a non-mandatory fact sheet would not be adequate to address risk associated with acceptance of the Application.

A full summary of submissions is included at Attachment 2.

## 8.3 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 seeks to extend an existing stock-in-trade provision, there was 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 bottled wine (including sparkling wine and fortified wine) labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.

Option 1 is not considered appropriate, as it would be very costly and resource intensive for the wine industry including, wine producers and small retail outlets where wines of the 2002 vintage and earlier are sold. 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. In addition, there are currently no accurate tests to detect the low levels at which some of the substances listed in the Table to Clause 4 of Standard 1.2.3 may be present in wine. Because of this, there is a risk of some lack of compliance, which could result in inconsistent labelling of wines of the 2002 vintage and earlier. Therefore this option may pose a greater risk to those consumers who may be sensitive to allergenic substances when present in wine, as the substances may not always be declared on the label.

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

FSANZ is aware that there is some concern that to allow the indefinite sale of bottled wines labelled with a vintage date of 2002 or earlier may not adequately address potential risks to public health and safety. To address these concerns, FSANZ has developed a consumer fact sheet at Attachment 3 and an industry fact sheet at Attachment 4, outlining the different labelling requirements for those wines covered by the Application.

FSANZ will provide the consumer fact sheet to the **Winemakers' Federation of Australia** and the **New Zealand Winegrowers' Association** to assist them in customising a fact sheet for wine retailers and consumers. The customised fact sheets could then be provided to retail associations to disseminate to wine retail outlets. FSANZ will also provide the consumer 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 professionals to advise allergy sufferers of the different labelling requirements for bottled wine labelled with a vintage date of 2002 or earlier. The consumer fact sheet will also be provided to the allergen support groups, **Allergy New Zealand** and **Anaphylaxis Australia** for publication in their newsletters. FSANZ will provide the industry fact sheet to the **Winemakers' Federation of Australia** and the **New Zealand Winegrowers' Association** to inform wine producers of their labelling requirements. In addition, the fact sheets will be placed on the FSANZ website.

FSANZ acknowledges concerns from submitters that a non-mandatory requirement will not adequately inform food allergic adults of the amendment to the Code. However, FSANZ considers that as there are no clinical or published cases of allergic reactions to tannin derived from chestnuts or fining agents derived from egg, fish and milk when present in wine, the risk to consumers who are sensitive to these substances is considerably small. In addition, FSANZ considers that the non-mandatory provision of information regarding the different labelling requirements for wine bottled prior to 20 December 2002 will not result in any greater risk than that already present before the new requirements came into force.

Bottled wines labelled with a vintage date of 2002 or earlier represent a small proportion of the wine market and many are likely to be sold at speciality wine outlets. From a retail and an enforcement perspective a mandatory requirement will be costly, onerous and impractical with little consumer benefit. Additionally, FSANZ is of the view that the same outcome can be achieved by a non-mandatory requirement. Consequently, FSANZ considers that in the interest of minimum effective regulation, the provision of this information does not warrant legislation.

In addition, the Food Acts in Australian States and Territories have a general provision which prohibits a food business or person from supplying food by way of sale if it is not of the nature or substance demanded by the purchaser. This places the onus on the manufacturer to provide information about the product, which is not misleading or untruthful and provides a mechanism which enables consumers to obtain information they require to make an informed decision.

In conclusion, FSANZ considers that the proposed extension of the stock-in-trade provisions for bottled wines labelled with a vintage date of 2002 or earlier, is the most appropriate approach. Any potential risk to public health and safety can be managed by avoidance of wines with a vintage date of 2002 or earlier. FSANZ has developed a consumer fact sheet (see Attachment 3) and an industry fact sheet (see Attachment 4) which outlines the differing labelling requirements for those wines covered by the Application to assist in informing affected consumers and the wine industry of the different labelling requirements. The consumer fact sheet will be provided to the wine industry, allergen support groups and health professionals involved in the care of allergy and asthma sufferers. The wine industry will also be provided with the industry fact sheet. An extension of the stock-in-trade provisions for bottled wine labelled with a vintage date of 2002 or earlier will provide certainty for manufacturers and retailers and minimise any disruption to the vintage wine trade, post 20 December 2004.

The proposed drafting for the amendment to Standard 1.1.1 is at Attachment 1.

## **10. Implementation and review**

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

### **ATTACHMENTS**

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Summary of submissions
3. Proposed consumer fact sheet
4. Proposed industry fact sheet



**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

### (First round)

#### 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 Winegrowers' Association	<ul style="list-style-type: none"> <li>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.</li> </ul>

##### *Retail outlets and other industry bodies*

Submitter	Comments
The Australian Food and Grocery Council	<ul style="list-style-type: none"> <li>states that if the products covered by the Application are required to be labelled in accordance with the Code, it will impose extreme practical difficulties not only on wine s 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.</li> <li>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.</li> </ul>

##### *Consumers*

Submitter	Comments
Allergy New Zealand and Anaphylaxis Australia Inc	<ul style="list-style-type: none"> <li>considers it not widely known by allergy sufferers that these substances may be present in wine products.</li> <li>considers allergy sufferers would use the additional labelling information required with option 1, and those allergic to these substances would not purchase the wine.</li> </ul>

##### *Government agencies*

Submitter	Comments
Western Australia Food Advisory Committee	<ul style="list-style-type: none"> <li>considers that the current provisions could compromise consumers who for various reasons may have invested in bottled wines labelled with a vintage date of 2002 or earlier.</li> </ul>

#### 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*

<b>Submitter</b>	<b>Comments</b>
Winemakers' Federation of Australia and the New Zealand Winegrowers' Association	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
Beringer Blass Wine Estates	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

### *Retail outlets and other industry bodies*

<b>Submitter</b>	<b>Comments</b>
The Australian Food and Grocery Council	<ul style="list-style-type: none"> <li>• 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 25 mg/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”.</li> <li>• believes that any person with an allergy to egg, fish or milk or sensitivity to sulphur dioxide at levels below 25 mg/kg, who had experienced an allergenic reaction to these wines would already be aware of it and know to avoid their consumption.</li> </ul>
Food Technology Association of Victoria Inc	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

### *Consumers*

<b>Submitter</b>	<b>Comments</b>
Allergy New Zealand and Anaphylaxis Australia Inc	<ul style="list-style-type: none"> <li>• 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 wine including sparkling wine and fortified wine are unique products and bear unique issues in maturation, storage, sale and investment.</li> <li>• states that they therefore support an extension to the stock-in-trade provisions with the following conditions: <ul style="list-style-type: none"> <li>○ 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.</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ 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.</li> </ul>
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### Government agencies

Submitter	Comments
Department of Agriculture, Fisheries and Forestry - Australia	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
Western Australia Food Advisory Committee	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
New Zealand Food Safety Authority	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• suggests 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 <ul style="list-style-type: none"> <li>• <i>(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 –</i> <ul style="list-style-type: none"> <li>○ <i>on the label on a package of the wine; or</i></li> <li>○ <i>displayed on or in connection with the display of the wine; or</i></li> <li>○ <i>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.</i></li> </ul> </li> </ul> </li> <li>• 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.</li> <li>• in proposing this option, relies upon the fact that allergen declarations on bottled wines with a vintage date of 2003 or later will build public awareness of the presence of allergens in wine generally.</li> </ul>

### Other comments

Submitter	Comments
The Australian Food and Grocery Council	<ul style="list-style-type: none"> <li>• notes that with regard to sulphur dioxide, under the old <i>Code</i> if present at more than 25 mg/kg sulphur dioxide would be required to be declared; however, under the new <i>Code</i> this threshold has been reduced to 10 mg/kg.</li> </ul>
Food Technology Association of Victoria Inc	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

**(Second round)**

**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*

<b>Submitter</b>	<b>Comments</b>
Winemakers' Federation of Australia	<ul style="list-style-type: none"><li>considers that under Option 1, the vast majority of small Australian producers will be met with a potentially crippling cost impost of having to re-label back vintages. Restaurants, retailers and secondary market will not be able to sell older vintages of wine unless they have a manufacturer declaration of what fining agents were used in this wine. Such information is unlikely to be available and each bottle of wine cannot be tested prior to drinking.</li></ul>

*Government agencies*

<b>Submitter</b>	<b>Comments</b>
Department of Agriculture, Fisheries and Forestry	<ul style="list-style-type: none"><li>considers to require a recall and relabelling will be a costly burden on producers, particularly small wineries with little additional consumer benefit.</li></ul>

**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*

<b>Submitter</b>	<b>Comments</b>
Winemakers' Federation of Australia	<ul style="list-style-type: none"><li>considers that consumers with sensitivities to these substances are highly aware of labelling requirements and are aware that allergen labelling is a new requirement.</li></ul>

*Retail outlets and other industry bodies*

<b>Submitter</b>	<b>Comments</b>
The Australian Food and Grocery Council	<ul style="list-style-type: none"><li>supports Option 2, to amend Standard 1.1.1 to allow the indefinite sale of bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.</li><li>agrees with the statement of reasons provided in the Draft Assessment Report and offers the additional reasons:<ul style="list-style-type: none"><li>Option 2 is consistent with the allergen requirements adopted by the EU.</li><li>Consumers of bottled wines labelled with a vintage date of 2002 or earlier, generally have a limited number of "favourite" brands which they consume on a regular basis. Any of these consumers who suffer from allergic reactions, will have either rejected the wine due to a reaction or will have consumed the wine safely.</li></ul></li></ul>
Food Technology Association of Victoria Inc	<ul style="list-style-type: none"><li>endorses the Technical Sub Committee preferred option - Option 2, to amend Standard 1.1.1 to allow the indefinite sale of bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.</li></ul>

## Consumers

Submitter	Comments
Allergy New Zealand and Anaphylaxis Australia Inc	<ul style="list-style-type: none"> <li>maintains that the majority of food allergy sufferers are not aware of the use of allergens in the production of wine, despite AFGC comments at Initial Assessment that any person with an allergy to a substance present in wine would be aware of the allergy and would know to avoid consumption.</li> <li>provides anecdotal evidence from Dr Steve Taylor of the Food Allergy Research and Resource Program, the University of Nebraska of a person anaphylactically sensitive to egg, who claimed to have suffered serious reactions from wine on half a dozen or more occasions.</li> <li>considers that the lack of published information on allergic reactions to fining agents in wine is a concern. Without clinical studies in egg/milk/fish allergic individuals, it is only possible to report anecdotal reactions.</li> </ul>

## Government agencies

Submitter	Comments
Department of Agriculture, Fisheries and Forestry	<ul style="list-style-type: none"> <li>supports option 2 to amend Standard 1.1.1 to allow the indefinite sale of bottled wine labelled with a vintage date of 2002 or earlier, in compliance with the applicable food standards of the time.</li> <li>notes that option 2 will pose no greater risk to the public after the transitional arrangements of 20 December 2004. The risk of similar wine which has yet to be released also poses very low risks to consumers.</li> <li>considers consumers will be able to avoid pre-2003 wines if they face any potential allergen risks.</li> </ul>
New Zealand Food Safety Authority	<ul style="list-style-type: none"> <li>does not support the Application to amend Standard 1.1.1, as to do so would overlook an identified public health risk.</li> <li>considers that at some point affected consumers should be able to rely on having complete information on allergens available to them at the relevant time.</li> <li>believes that the FSANZ assessment at Draft Assessment that “not to offer mandatory advice does not provide any greater risk than that already present before the new requirements came into force” in response to the NZFSA consideration that an advisory statement would address public health and safety concerns, should not be conclusive of this matter.</li> </ul>

## Provision of information in relation to the differing labelling requirements

### Wine producers

Submitter	Comments
Winemakers' Federation of Australia	<ul style="list-style-type: none"> <li>considers that a mandatory requirement which at a minimum would require retailers, upon request, to inform consumers at the point of retail sale that wine produced prior to 20 December 2002 is not required to declare the presence of allergens on the label, is likely to be expensive and impractical. The vast majority of older vintages are not sold through the big retailers who in general clear out current vintage stocks much quicker than specialty retailers and producers. There is little chance of compliance with such an onerous requirement.</li> </ul>

## Consumers

Submitter	Comments
Allergy New Zealand and Anaphylaxis Australia Inc	<ul style="list-style-type: none"> <li>believes that the provision of a fact sheet alone will not adequately inform food allergic adults of the amendment to the Code. Food allergic adults do not consult their health professionals as regularly as children.</li> <li>believes that the wine industry and FSANZ must ensure that as many consumers as possible have access to this information, by way of mandatory publication in as many appropriate publications as possible by those who made the Application.</li> <li>believes that mandatory publication be made in point of sale material, wine industry publications and allergy/anaphylaxis organisation publications (e.g. Allergy Today (Allergy New Zealand) and Anaphylaxis Australia's newsletter.)</li> </ul>

## Government agencies

Submitter	Comments
New Zealand Food Safety Authority	<ul style="list-style-type: none"> <li>considers that a non-mandatory fact sheet is not adequate to address this risk.</li> <li>considers there to be a strong possibility that a non-mandatory requirement for disclosure of information about the different labelling requirements for affected wines, would result in consumers not receiving this information and consequently consumers would incorrectly assume that all wine that does not bear an allergen declaration regardless of vintage date, is free of allergenic substances.</li> <li>considers that this possibility is likely to become stronger as more wines from post 2002 vintages appear on the market, consumers become accustomed to seeing and relying on this information and the 2002 changeover date becomes more distant from the minds of consumers.</li> </ul>
Department of Agriculture, Fisheries and Forestry	<ul style="list-style-type: none"> <li>notes that the proposal to prepare a fact sheet to advise health professions and the wine industry of the different labelling requirements for wine bottled before 20 December 2002 may further address any consumer allergen concerns.</li> </ul>

## Other comments

### European Union requirements

#### *Wine producers*

Submitter	Comments
Winemakers' Federation of Australia	<ul style="list-style-type: none"> <li>states that the EU directive will have very little effect on exports of Australian wine. By the time the directive is implemented into legislation the quantities of Australian wine of pre-2003 vintages exported would be virtually nil. However, small quantities of Grange and similar wines may be affected as the current vintage on sale is the 1998. It is likely that Australia will notify the European Commission of research to determine whether the ingredients in wine trigger allergic reactions.</li> </ul>

## Government agencies

Submitter	Comments
New Zealand Food Safety Authority	<ul style="list-style-type: none"> <li>suggests that as scientific research is currently being conducted in Australia and the European Union on actual risks associated with the presence of allergens in wine, it may be worthwhile to ascertain whether the results of this research can be provided before this assessment is finalised.</li> </ul>

**PROPOSED CONSUMER FACT SHEET**

**Bottled wine labelled with a vintage date of 2002 or earlier**

There are new allergen labelling requirements in the *Australia New Zealand Food Standards Code* (the Code) for all food including wine.

Despite these new allergen labelling requirements, bottled wine (including sparkling wine and fortified wine) labelled with a vintage date of 2002 or earlier will not have the presence of egg, fish, milk and nuts declared on the label.

Derivatives of egg, fish and milk may be used as fining agents in the wine production process. While these substances are largely removed through filtration, very small residual amounts may be present in the final product.

In addition, tannin derived from chestnuts is sometimes used as a wine additive.

These substances will not be declared on bottled wine labelled with a vintage date of 2002 or earlier, because bottled wines have a very long shelf life and can remain in circulation for many years and prior to the introduction of the Code in December 2002, manufacturers of wines were not required to label their presence.

Consequently, individuals who suffer from adverse reactions to egg, fish, milk and chestnuts should be aware that bottled wine (including sparkling wine and fortified wine) labelled with a vintage date of 2002 or earlier will not have these substances declared on the label, if present.

From 20 December 2004, bottled wine labelled with a vintage date of 2003 or later and all other alcoholic beverages must declare on the label derivatives of egg, fish, milk and nuts, when present.



## PROPOSED INDUSTRY FACT SHEET

### Wine and the labelling of certain substances that may cause adverse reactions

There are new allergen labelling requirements in the *Australia New Zealand Food Standards Code* (the Code) for all food including wine.

Derivatives of egg, fish and milk may be used as fining agents in the wine production process. While these substances are largely removed through filtration, very small residual amounts may be present in the final product. In addition, tannin derived from chestnuts is sometimes used as a wine additive.

Although there are new allergen labelling requirements for all food including wine, individuals who suffer from adverse reactions to egg, fish, milk and chestnuts should be aware that bottled wine labelled with a vintage date of 2002 or earlier will not have these substances declared on the label if present.

This is due to an indefinite extension to the long shelf life stock-in-trade provisions being granted for bottled wines, including sparkling wine and fortified wine labelled with a vintage date of 2002 or earlier. An indefinite extension has been granted as these wines have a very long shelf life and can remain in circulation for many years, long after the stock-in-trade date ends.

For an indefinite extension of the stock-in-trade provisions to apply, the wine **must** meet the following conditions:

- have been bottled before 20 December 2002;
- have been compliant with all applicable food standards at time of bottling; and
- be labelled with a 2002 vintage date or earlier.

The indefinite extension of the stock-in-trade provisions does not apply to:

- wine and wine products bottled and labelled after 20 December 2002;
- wine and wine products without a vintage date, such as bag-in-box products, non-vintage sparkling wine and non vintage port; and
- other alcoholic beverages matured in large quantities and bottled and labelled after maturation, such as spirits.

Bottled wine labelled with a vintage date of 2003 or later, must declare on the label derivatives of egg, fish, milk and nuts.

#### ***Existing Stock-in-trade provisions***

The Code came into effect in December 2000 with a two-year transition period ending 20 December 2002. During this transition period the pre-existing Australian Food Standards Code (the old Code) and the *New Zealand Food Regulations* (the NZ Regulations) remained in effect. Therefore, in Australia, manufacturers and importers could legally sell food if it complied with either the Code or the old Code. In New Zealand, food had to comply with the joint Code, the old Code or the NZ regulations.

This situation changed on 20 December 2002 when provisions in the old Code and the NZ Regulations were repealed. A 24 month stock-in-trade provision for long shelf life products, which includes wine, was introduced into the Code to allow foods with a shelf life of more than twelve months, that were manufactured and packaged prior to the 20 December 2002 and complied with all applicable food standards at that time to continue to be sold lawfully until 20 December 2004. These products included bottled wine, canned fruit, vegetables, meats, fish and packaged herbs, spices and sauces.

This provision also included foods in warehouses or storage, in transport (including being imported into Australia or New Zealand) or on supermarket shelves or for sale in other food outlets. **Standard 1.1.1 – Application, Interpretations and General Prohibitions of the Food Standards Code** deals with Stock-in-trade provisions.

### ***Further information***

Electronic versions of the *Australia New Zealand Food Standards Code*, User Guides and Fact Sheets can be obtained from the FSANZ website at [www.foodstandards.gov.au](http://www.foodstandards.gov.au) or [www.foodstandards.govt.nz](http://www.foodstandards.govt.nz)

Hard copies of the Code and the complete set of User Guides may also be purchased from Anstat on 03 9278 1144 . Hard copies of Fact Sheets are available from FSANZ's Information Officer in Australia on 02 6271 2241 or in New Zealand on 04 473 9942 .

Businesses may currently obtain guidance on standards in the Code through the Industry Advice Helpline on 1 300 652 166 (Australia) and 0 800 441 571 (New Zealand) or by e-mail at [advice@foodstandards.gov.au](mailto:advice@foodstandards.gov.au)

### **March 2004**

This document is intended as a guide only: legal requirements are contained in the *Australia New Zealand Food Standards Code*, other relevant food legislation and other applicable laws. The information in this document should not be relied upon as legal advice or used as a substitute for legal advice. You should exercise your own skill, care and judgment before relying on this information in any important matter.