Winemakers' Federation of Australia

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Dear Standards Liaison Officer

Submission on Proposal P298—BENZOATE AND SULPHITE PERMISSIONS IN FOOD

I am writing on behalf of the Winemakers' Federation of Australia to provide comments on Proposal P298—Benzoate and Sulphite Permissions in Food. The Winemakers' Federation of Australia is the peak industry body representing Australia's wine producers. The issue of sulphite permissions is an important one for the industry and changes to the current regulatory regime may have significant impacts on Australia's trade flows.

I am happy to provide further comments as required. [redacted].

Yours sincerely

[redacted]

TONY BATTAGLENE
Director International & Regulatory Affairs
Winemakers' Federation of Australia

Enclosure/s: Submission

Submission on Proposal P298—BENZOATE AND SULPHITE PERMISSIONS IN FOOD

Technical information prepared by [redacted], Health and Regulatory Information Manager, The Australian Wine Research Institute

(a) The amount of benzoates and sulphites in Australian wine. Has it changed significantly from that used in April- May 2003 (as reflected in the products collected and analysed in the 21st ATDS)?;

Benzoates are not permitted additives in winemaking.

The Australia New Zealand Food Standards Code in Standards 2.7.4 (Wine and wine product) and 4.5.1 [Wine production standards (Australia only)] specifies that "Wine, sparkling wine and fortified wine must contain no more than 250 mg/L in total of sulfur dioxide in the case of products containing less than 35 g/L of sugars, or 300 mg/L in total of sulfur dioxide in the case of other products". In 2004, the mean concentration of total sulfur dioxide in 140 red wines was approximately 55 mg/L, and in 573 dry white wines was approximately 125 mg/L (Godden and Gishen 2005 [n press]). In the 21st Australian Total Diet Survey, the mean concentration of sulfur dioxide in 15 red wines was 55 mg/L and in 15 dry and sweet white wines was 123 mg/L.

(b) Market share data.

N/A

(c) The proportion of any food category that may contain the preservatives.

All wines contain naturally a small amount (approx. 10–50 mg/L) of sulfur dioxide. Approximately 10 to 50 mg/L of sulfur dioxide is formed during fermentation by the yeast although it is usually bound to acetaldehyde on formation (Eschenbruch 1974, Dott et al. 1976, Dittrich 1987); some yeast strains, however, can produce 100 to 150 mg/L sulfur dioxide, and one strain has even been observed to produce 225 mg/L (Eschenbruch 1974, Delteil 2003). This is the reason why the majority of certified organic wines in the marketplace are labelled 'no preservatives added' rather than 'preservative free'. The sulfur dioxide maximum permitted limit for certified organic wine is 125 mg/L in Australia, and 100 mg/L in the EU and USA. There are at least 82 certified organic winemakers in Australia while there are approximately 1,899 'non-organic' winemakers in Australia. It is generally recommended that certified organic wines should be consumed sooner than traditionally produced wine (for example, within 12 months of bottling and purchase) because the quality of the wine will diminish with age as they are more likely to become oxidised and consequently have a less desirable aroma and flavour. The antioxidant effect of sulfur dioxide and other antioxidants is primarily observed during the cellaring/storage of wine as distinct from during winemaking, as active oxidases such as laccase and to a lesser extent tyrosinase remain in the wine after clarification and the depletion of free sulfur dioxide (Simpson 1980, Somers et al. 1983, Gotegs and Geisenheim 1986, Carnevale 1988). Oxidation is initiated by the reaction of phenolic material with dissolved oxygen (Chapen and Chapon 1979, Wildenbrandt and Singleton 1974), and the oxidation of phenolic and other material induces colour changes in the wine and the formation of acrid and bitter substances (Peynaud 1984), which are generally unacceptable to, and unwanted by, the consumer.

(d) Whether there are certain parts of a food category for which preservatives are never used. For example, cola soft drinks versus non-cola soft drinks or intense sweetened soft drinks versus sugar sweetened soft drinks;

N/A

(e) Whether there are any food categories for which permissions exist but where the preservatives are never used;

N/A

(f) What categories of foods have these preservatives added, but not at the maximum permitted level?

Approximately 20–200 mg/L of sulfur dioxide may be added during winemaking (Ough 1986) and approximately 10–50 mg/L is formed by the yeast during fermentation, which is usually bound to acetaldehyde on formation. Therefore, when wine is analysed for the concentration of total sulfur dioxide, a small amount will always be measured regardless of whether sulfur dioxide was added during the course of winemaking. In addition to seeking sufficient antimicrobial and antioxidant activity, the style of wine produced and whether the wine is intended for short, medium or long-term storage will also influence the amount that will be added during winemaking (Rankine 1989, Robinson and Godden 2003).

Sulfur dioxide is generally as potassium metabisulphite, a liquefied gas or as a solution made by dissolving sulfur dioxide in water (Beech *et al.* 1979, Ough *et al.* 1986). At the normal pH of juice or wine, 3.0–3.8, molecular sulfur dioxide undergoes ionisation to the bisulfite anion and sulfite anion. The primary antimicrobial form of sulfur dioxide is the unionised molecular form, followed by the bisulfite and sulfite forms, which have minimal antimicrobial activity (Ough *et al*. 1983). The unionised molecular form penetrates the yeast cell membrane by diffusion and subsequently inactivates the intracellular constituents (Stratford and Rose 1986). In the yeast cell, sulfur dioxide activates adenosine triphosphate (ATPase) and the ATP-hydrolysing enzyme, which decreases the concentration of ATP. Furthermore, once sulfur dioxide has entered the yeast cell, it is ionised in response to the difference between the pH of the grape juice and that of the cell and becomes trapped. The bisulfite and sulfite ions then react with the cellular constituents. The combined effect of ATP depletion and cellular activity leads to inactivation and eventual death of the yeast cell (Beech and Thomas 1985, Stratford and Rose 1986). The pH of juice and wine influences the equilibrium of the ionisation and consequently the proportion of the three forms of sulfur dioxide present. Increasing acidity increases the concentration of unionised molecular sulfur dioxide. At pH 3.0–3.6, however, approximately 94–98% of the added sulfur dioxide exists as the bisulfite form and only approximately 1.8–5.5% exists as the primary antimicrobial form (King *et al.* 1981).

The total concentration of sulfur dioxide in juice or wine, therefore, consists of free molecular sulfur dioxide, free ionic forms and ionic forms bound to juice or wine constituents. Consequently, it is necessary to add sufficient sulfur dioxide during winemaking to obtain an adequate concentration of the free molecular form to inhibit microbial activity, but not so much as to have an excess of the bisulphite form, which can adversely affect the sensory attributes or characteristics of the wine. Research undertaken by Beech *et al.* (1979) in a model wine indicated that 0.825 mg/L of molecular sulfur dioxide is necessary to control the growth of wine yeasts and bacteria. Subsequently, oenologists have generally accepted and adopted this concentration of molecular sufur dioxide to control growth in juice and wine, although some researchers advocate a higher concentration is necessary (Rankine *et al.* 1989, Margalit 1990, Boulton *et al*. 1996).

(g) Information on where a mixture of preservatives may be used in a food in preference to a single preservative and resultant additive levels of use;

There has been great interest in the development of products or techniques to replace or minimise sulfur dioxide addition. Some products reinforce its action, for example, sorbic acid and dimethyl dicarbonate (DMDC) exercise a complementary action on yeasts, lysosyme on bacteria and ascorbic and erythorbic acids reinforce the antioxidant protection properties. These products, however, are efficient only so long as they are used in conjunction with sulfur dioxide. In addition, certain practices, including conscientious winery sanitation, heating or pasteurisation and refrigeration of the juice and wine, which decrease the probability but do not eliminate the possibility of microbial growth during production, should also be used in conjunction with an antimicrobial agent.

(h) Any analytical data for foods with added sulphites or benzoates that have been analysed as prepared or ready to consume; and

The mean concentration of total sulfur dioxide observed in 9477 white wines and 18421 red wines analysed at The Australian Wine Research Institute from 1990 to 2001 was 121 mg/L and 33.5 mg/L, respectively (AWRI, unpublished data).

In 2004, the mean concentration of total sulfur dioxide in red wine was approximately 55 mg/L**;** it increased steadily from 40 mg/L in 1987 to 58 mg/L in 2001 and has subsequently stabilised. The mean concentration of free sulfur dioxide in red wine has also increased steadily from 1986 and in 2004 was 25 mg/L; it is the free form of sulfur dioxide that has the major antimicrobial and antioxidant activity. As total sulfur dioxide is the sum of free and bound sulfur dioxide, a consequent decrease in the concentration of bound sulfur dioxide in red wine has correspondingly occurred, and in 2004 was 35 mg/L. The ratio of free to total sulfur dioxide in red wine has thus increased, relatively steadily, from 1987 to 2004 (AWRI, unpublished data).

In 2004, the mean concentration of total sulfur dioxide in white wine was approximately 125 mg/L; it has been relatively constant since 1987. As with red wine, the mean concentration of free sulfur dioxide in white wine increased steadily from 1987 to 2001, and in 2004 was approximately 29 mg/L. The mean concentration of bound sulfur dioxide in white wine has thus decreased since 1987, and in 2004 was 100 mg/L. There has been, however, no significant increase in the ratio of free to total sulfur dioxide in white wine (AWRI, unpublished data).

(i) Data relating to changes in levels of benzoates and sulphites during storage and food preparation.

N/A

(j) What are the technologically required levels of benzoates and sulphites in foods where use is permitted?

Sulfur dioxide has been added during winemaking since the 17th century when Dutch winemakers began burning elemental sulfur in empty wine barrels to enable their reuse without spoiling the stored wine (Blackburn 1988), and when Bordeaux winemakers found that the sulfur dioxide gas produced from burning elemental sulfur also protected the stored wine from spoilage. Thus sulfur dioxide has been primarily added to grapes, juice, must and wine to restrict the growth of indigenous microflora, such as yeast, mould and bacteria, the latter being the most sensitive to sulfur dioxide (Cruess 1912, Kunkee and Amerine 1970, Ough *et al*. 1983).

Research undertaken by Beech et al (1979) in a model wine indicated that 0.825 mg/L of molecular sulfur dioxide is necessary to control the growth of wine yeasts and bacteria. Subsequently, oenologists have generally accepted and adopted this concentration of molecular sufur dioxide to control growth in juice and wine, although some researchers advocate a higher concentration is necessary (Rankine *et al.* 1989, Margalit 1990, Boulton *et al.* 1996). While bacteria are considered to be more sensitive to sulfur dioxide than yeast and moulds (Ough *et al.* 1983), the growth of moulds, such as *Botrytis cinerea*, on grapes, can be restricted by addition of sulfur dioxide to freshly harvested grapes prior to crushing. A higher concentration of sulfur dioxide should also be added to juice prepared from *Botrytis*-infected grapes, because such juice contains significant amounts of laccase (polyphenol oxidase) enzyme, which is a catalyst for oxidation and hence increases the need for sulfur dioxide, and aldehydes, which will bind a greater amount of the added sulfur dioxide (Ribéreau-Gayon *et al.* 1976).

In addition to antimicrobial activity, sulfur dioxide also protects the phenolic compounds in the must from enzymic oxidation by laccase and tyrosinase (phenol- and polyphenol-oxidase) prior to fermentation. Tyrosinase catalyses the hydroxylation of monophenols into diphenols and the oxidation of orthodiphenols into quinones, and laccase catalyses the oxidation of not only mono- and ortho-diphenols but also meta- and para-phenols, diamines and ascorbic acid as well as degrading the major phenolic compounds which impart colour—the anthocyanins and procyanidins (Ribéreau-Gayon *et al.* 1977, Somers *et al.* 1983). The minimum concentration of sulfur dioxide required to inhibit the activity of tyrosinase is influenced by factors such as grape cultivar, clarity and temperature of the must as well as the concentration of phenolic compounds in the must (Dubernet and Ribéreau-Gayon 1973, Traverso-Rueda and Singleton 1973, White and Ough 1973, Amano *et al.* 1979, Hooper *et al.* 1985, Ough 1985). A higher concentration of sulfur dioxide (100 mg/L) is necessary to modify, and not necessarily inhibit, laccase activity (Ribéreau-Gayon *et al.* 1977, Somers *et al.* 1983), such that the antioxidants ascorbic and erythorbic acid are generally added as an adjunct to a lower concentration of sulfur dioxide.

(k) What are the alternatives, if any, to the use of benzoates and sulphites for all their various uses in the food supply?

K.1. Sorbic acid

Sorbic acid is a naturally occurring, legal alternative additive to sulfur dioxide. Sorbic acid may be used as an antimicrobial agent to prevent the growth of spoilage yeast following fermentation, particularly pre-bottling. Several mechanisms for the inhibitory effect of sorbate on yeast have been proposed, but the mechanism has not been completely elucidated. It is postulated to inhibit the dehydrogenase system of the yeast cell (Desrosier and Desrosier, 1977). The antimicrobial activity of this compound is pH-dependent, as it is inhibitory to yeast growth when in an undissociated form. To interfere with microbial metabolism, it is necessary for the sorbate to pass through the cell membrane. The cell membranes of yeasts and moulds are ionically charged and do not permit the transfer of negatively charged molecules. At neutral or near neutral pH, sorbic acid molecules are almost completely ionised and cannot be transported across the cell membrane; they are effectively inactive. As the pH decreases, the concentration of the un-ionised form increases and hence the antimicrobial activity of the acids increases (Schmidt, 1987). Sorbic acid (an unsaturated fatty acid) is permitted in wines at a concentration up to 300 mg/l according to the country (200 mg/l in the EC and Australia, and 300 mg/l in the USA), but it is generally added at the lower concentration of 100-200mg/l (Kunkee and Goswell, 1977; De Rosa *et al.,* 1982; Splittstoesser, 1982). It is generally added as potassium sorbate. Like sulfur dioxide sorbic acid is most active in the un-ionised form or at lower wine pH values (Amerine and Ough, 1980). Indeed, an advantage of sorbic acid is that the undissociated form is present in the greatest concentration (93-98%) at the normal wine pH of 3.0-3.8 (Sofos and Busta, 1981,1983). Above pH 3.8, a dose of 200 mg/L may be inadequate. Sorbic acid is most effective when used in conjunction with approximately 30-50 mg/L of sulfur dioxide (Amerine and Joslyn, 1970). When added alone, these acids have minimal effect on yeast growth *per se* below a concentration of 300 mg/L; the yeast species *S. bailii* is resistant to sorbic acid (Rankine, 1989), and the resistance of yeast species to this acid varies according to the pH of the medium (Pitt, 1974). In addition, unlike sulfur dioxide, this compound does not inhibit the growth of bacteria and they do not have antioxidant properties. Another potential problem with the addition of sorbic acid is the development of unpleasant odours resulting from bacterial attack. Lactic acid bacteria may reduce the acid to 2,4-hexadienol, an unsaturated alcohol, which reacts with ethanol to produce 2-ethoxy-3,5-hexadiene, imparting a geranium-like odour to the wine (Amerine et al., 1980; Sofos and Busta, 1983; Edinger and Splittstoesser, 1986).

K.2. Diethyldicarbonate and Dimethyldicarbonate

In 1959, several alkyl esters of pyrocarbonic acid were identified and subsequently tested for their effectiveness as fungicides (Figs 7.8 and 7.9; Henning, 1959, 1960). Diethyldicarbonate (DEDC) was originally approved as an additive in 1963 in the USA, and later in Australia. It inhibits the growth of bacteria, moulds and yeasts (Ough, 1983). On addition to wine it readily hydro*l*yses to ethanol and carbon dioxide (CO_2), which are normal constituents of wine; however, DEDC also produces ethyl carbonate by reaction with ammonia, which has been observed to be carcinogenic. Hence, the legislation for its use as an additive in food and beverages was rescinded by the Food and Drug Administration of the United States in 1972 and later in Australia and New Zealand (Ough, 1983). While currently not a permitted additive in wine in Australia, Canada or the EC (although it may be added to soft drinks), an alternative to DEDC is the analogue dimethyldicarbonate (DMDC), which is observed to have antimicrobial properties similar to

DEDC (Genth, 1979, 1980) without the production of ethyl carbamate (Ough, 1983). DMDC also readily hydrolyses on addition to wine, and although methanol is a by-product, the amount produced, approximately 36-116 mg/L, is not significant toxicologically. The rate of hydrolysis and antimicrobial activity is observed to be related to temperature and the concentration of ethanol in the wine (Ough, 1983), and is pH-dependent. Porter and Ough (1982) observed that ethanol increased the efficacy of DMDC and that 20°C was the optimum temperature for use. Accordingly, the amount recommended for addition to wine ranges from 50-250 mg/L. Its effectiveness is enhanced when used with sulfur dioxide. These compounds are generally added to wine post-fermentation/pre-bottling either as a substitute for sulfur dioxide or an adjunct to sulfur dioxide thereby reducing the concentration of sulfur dioxide necessarily added to the wine; however, DEDC and DMDC have no antioxidant role.

K.3. Lysosyme

In 1992, an FAO/WHO Commission, which was formed to revise food labelling, authorised the use of lysosyme in food processing. Lysozyme is a class I enzyme (protein) that consists of 129 amino acids cross-linked by four disulfide bridges (EC 3.2.1.17). The European Commission Decision 96/657/EC of 12 November 1996 then authorised the experimental use of lysosyme in winemaking in order to limit the use of sulfur dioxide. Lysosyme has since been adopted into the list of authorised oenological practices and processes for Australia, EU, South Africa and USA; however, it has not been authorised for use in winemaking by other countries.

Research had previously demonstrated that lysosyme, which is an enzyme present in hen egg white, had lytic activity against lactic acid bacteria and, hence, could control the secondary malolactic fermentation (MLF) in wine (Pitotti *et al.,* 1991; Amanti *et al.,* 1994). It is not necessary for all wines to undergo MLF, and depends upon the wine variety and desired wine style. In contrast to sulfur dioxide and sorbic acid, the antimicrobial activity of lysosyme is not pH-dependent, although the lytic activity of lysosyme is observed to increase with an increasing pH of the wine (Gerbaux *et al.,* 1997). The typical amount of lysosyme added to inhibit MLF in white wine is between 250-500mg/L (Gerbaux *et al.,* 1999), where optimal lytic activity is observed when lysosyme is added immediately after crushing and cold juice clarification. An addition of between 125-250 mg/L is required to stabilise a red wine post-MLF where a lesser amount of sulfur dioxide is correspondingly required. While the presence of lactic acid bacteria in wine is necessary for MLF, they are a source of spoilage post-MLF as subsequent metabolic activity may increase the volatile acidity of the wine as well as the concentration of acetic acid and biogenic amines in the wine. The lytic activity of lysosyme is significantly decreased by the concomitant addition of the fining agents bentonite and activated carbon to the wine, which adsorb the enzyme. The technical processes of centrifugation, filtration and refrigeration, however, have no significant effect on activity (Amanti *et al.,* 1996). The primary advantage of lysosyme is that it decreases the requirement for sulfur dioxide to microbiologically control or stabilise wine, while having no chemical and sensorial effects on wine. The disadvantages lysosyme, however, include a limited duration of lytic activity and a reduction of colour intensity in treated red wines, as well as having no antioxidant activity (Bamberger, 2000).

K.4. Ascorbic acid and erythorbic acids

Ascorbic acid has two asymmetric carbon atoms at C_5 and C_9 positions. The naturally occurring ascorbic acid is the L-ascorbic acid form, which is a diastereoisomer of D-isoascorbic acid (erythorbic acid). These diastereoisomers have similar, but not necessarily the same, physicochemical properties. While ascorbic acid is an accepted additive in Australia, Argentina, Canada, Chile, EU, Japan, Mercosur (Argentina, Brazil, Paraguay, Uruguay) and the USA, erythorbic acid and its sodium salt are not permitted in the EU, Chile or Mercosur for winemaking.

Ascorbic acid occurs naturally in grapes in amounts between 10 and 100mg/L, but may be rapidly oxidised after crushing and as a result of the associated aeration. Both ascorbic acid and erythorbic acid are strong reducing agents (oxygen accepting) due to their ene-diol moiety; they are equally effective antioxidants in foods and beverages (Ewart *et al.,* 1987). The reactivity of ascorbic and erythorbic acids towards dissolved oxygen in juice and wine is slightly greater than that of the more reactive phenolics in wine; therefore, these additives are capable of conferring some protection on the wine phenolics and can protect against oxidative pinking, even in the absence of sulfur dioxide although flavour changes may still occur (Simpson, 1980; Simpson *et al.,* 1983). To enhance the antioxidant capacity of sulfur dioxide in white must, ascorbic acid can be added in conjunction to protect against brown colour formation immediately after crushing in amounts in the range 30-100mg/L (Simpson, 1980; Day, 1981) and following fermentation at each wine transfer stage (Ewart *et al.,* 1987).

Ascorbic and erythorbic acids in vinification are less deleterious to the aroma of the resultant wine than sulfur dioxide (Ewart *et al.,* 1987). It is only when they are used in conjunction with sulfur dioxide, however, that protection against oxidation is assured. As in the absence of adequate levels of free sulfur dioxide some oxidative reactions are promoted by these additives (Peng *et al.,*1998). The mode of reaction is similar to that of the non-enzymic oxidation and therefore can lead to more rapid accumulation of hydrogen peroxide (Simpson, 1980). The roles of sulfur dioxide and ascorbic and erythorbic acids are complementary. Sulfur dioxide is not an effective oxygen scavenger, while the acids are not effective hydrogen peroxide scavengers. Consequently, the concurrent addition of sulfur dioxide (35mg/L free SO_2) (Ewart *et al.,* 1987) to juice and wine is also necessary to react with dehydroascorbic acid and hydrogen peroxide produced by these acids to minimise any detrimental effects on wine quality that result from these products. For example, sulfur dioxide reacts with the hydrogen bonds of dehydroascorbic acid to prevent further oxidation (Ough *et al.,* 1983). Furthermore, ascorbic and erythorbic acids convert the quinones produced by the oxidation of phenols back to phenols in the process being oxidised to dehydroascorbic acid (AlIen, 1983).

(I) If alternatives exist, what are the disadvantages and advantages of their use?

See answer to Question K.

(m) What are the potential costs or benefits of the proposed risk management options to you as a stakeholder? Would the benefits outweigh the costs?

Option 1. Maintain the *status quo* by not altering permissions for benzoates and/or sulphites.
Option 1 is the preferred option for the Australian wine industry. It enables product quality to be maintained. The National Health and Medical Research Council's *Australian Alcohol Guidelines: health risks and benefits* (2001) recommend a maximum of four and two standard (approximately 100 mL) glasses of wine per day for men and women, respectively. Consumption of this amount of wine per day by men and women should limit the dietary intake of sulfites. Benefits outweigh costs.

Option 2. Review and reduce permissions for benzoates and/or sulphites for certain foods. In order to do this, detailed information from industry and food manufacturers regarding the use of benzoates and sulphites could be used to establish scenario dietary exposure assessments. In addition, FSANZ could consider reviewing consumer information, such as fact sheets.
Option 2 would require considerable research and has the potential to be detrimental to wine quality. Costs probably outweigh benefits.

Option 3. Review and partially replace the use of benzoates and/or sulphites with alternative preservatives, or consideration of altering the methods of preventing microbial spoilage.
Option 3 is not desirable as sulfites are the most effective as well as cost-efficient additive. Replacement of sulfites in winemaking is likely to have an adverse impact on product quality and consumer acceptance. In addition, replacement of sulfur dioxide would put Australia at odds with other country's winemaking regulations, potentially triggering non-tariff trade barriers and creating a possible breach of World Trade Organisation rules. Costs clearly exceed benefits.

Option 4. Encourage consumers to eat a balanced diet and not over-consume foods with high levels of benzoates and/or sulphites.
Irrespective of which option is chosen from 1, 2 or 3, option 4 should also be considered. The Australian wine industry is pro-active in encouraging the moderate consumption of alcohol as part of a healthy diet and lifestyle, and an inexpensive education campaign on sulfite consumption has merit.

(n) What are the costs or benefits for consumers of the proposed risk management options in terms of public health and safety? Do any identified health benefits for the targeted group of consumers outweigh any costs to non-target groups?

A relatively small amount of a food is needed to trigger an IgE-mediated food allergy. Symptoms attributed to the ingestion of sulfite compounds or sulfite-containing foods include asthma (bronchospasms and wheezing), urticaria and angioedema, nausea, abdominal pain and diarrhea, hypotension and anaphylactic shock, seizures and death, where symptoms may occur immediately or be delayed. The most common adverse reaction to sulfite compounds is asthma.

Foods and food additives, however, are not common triggers for asthma (National Asthma Council of Australia 2005). Furthermore, adverse reactions to sulfite compounds in non-asthmatic and non-sensitive individuals are rare (Bush *et al*. 1986).

Approximately thirty years ago it was purported that 1–3 mg sulfur dioxide released from wine and inhaled by a sulfite-sensitive individual may trigger an adverse reaction (Freedman 1977, Baker *et al*. 1981, Ough *et al.* 1983). It has since been clinically demonstrated, however, that sulfur dioxide will generally only precipitate an adverse reaction in sulfite-sensitive asthmatics, which comprise approximately 1.7% of all asthmatics. Steroid-dependent asthmatics are most at risk of an adverse reaction. The threshold for an adverse reaction varies between 5 to 200 mg sulfur dioxide (Taylor et al. 2002) where foods containing greater than 100 mg/L sulfur dioxide may elicit no reaction in some sulfite-sensitive individuals. Usually the minimum threshold is considered to be 10 mg/L (Hefle and Taylor 2002, Taylor *et al*. 2002), which reflects existing Australian and international legislation stipulating that "added sulphites in concentrations of 10 mg/kg or more" must be stated on the label of a food product such as wine. Indeed, adverse reactions elicited by additives and processing aids are relatively rare.

A recent study assessed the potential sensitivity of 16 individuals with asthma to red and white wines containing a low (3.7 and 18.9 mg/L), a high (290.7 mgL) concentration of total sulfur dioxide and model wine solutions containing no sulfur dioxide (Vally *et al.* 1999); the concentration of free sulfur dioxide in the wines was 1.9, 2.1 and 238.9 mg/L, respectively. These individuals had self-reported wine-induced asthma, and were initially subject to a double blind study of the low-sulfite containing wines, conducted between two and eight days apart, at the same time on each occasion; 175 mL was consumed over a period of three minutes, and measurements of lung function and asthmatic symptoms were subsequently made.

Only three of the 16 asthmatic individuals experienced a rapid and significant change in lung function and worsened asthmatic symptoms—one subject to a low-sulfite containing wine, one to both low-sulfite containing wines and one placebo wine, and one to one low-sulfite containing wine and one placebo wine. The fact that two of the three individuals experienced an adverse reaction to both the low-sulfite containing wines and the placebo suggests that compounds other than sulfur dioxide may have also elicited an adverse reaction in these individuals. In addition, four other individuals, however, perceived a significant reaction to one or more of the wines without a change in lung function. Ten of these asthmatic individuals were then subject to a double blind study of the high-sulfite containing wines, and only two experienced an adverse reaction. This suggests that unless the asthmatic individuals were also sulfite-sensitive then even the maximum permissible concentration of sulfur dioxide wine, 300 mg/L, may not elicit an adverse reaction, although some individuals may only react adversely when their asthma is unstable or exacerbated by environmental condition, such as cigarette smoke (Dahl 1986).

An additional study then formally assessed sulfite reactivity in wine-sensitive asthmatics using medium- and high-sulfite containing wines (Vally and Thompson 2001). Wine containing 300 mg/L sulfur dioxide elicited a positive asthma challenge in 4 of 24 patients reporting wine-sensitive asthma but with no response to wines containing 20, 75 or 150 mg/L sulfur dioxide. The researchers concluded that only a small number of historically wine-sensitive asthmatic patients responded to a single dose challenge with sulfited wines under laboratory conditions.

These data suggest that the role of sulfur dioxide and/or wine in triggering asthmatic responses has been overestimated, or alternatively they suggested that cofactors or other components of wine may be important influences, although none of the asthma individuals assessed in either study by Vally *et al.* (1999, 2001) were also allergic to egg, fish, milk and nuts, which are the common food allergens used in winemaking.

According to the 21st Australian total diet survey, the rational for the risk management options proposed is primarily to reduce the dietary intake of sulfites, as in animal studies, where high doses of sulfites were consumed daily for a prolonged period, they were observed to cause gastric lesions. There is no evidence from human studies, however, to suggest that high dietary exposure to sulfites also causes gastric lesions in humans.

(o) What are the costs or benefits for business of the proposed risk management options—increased market opportunities both domestically and overseas, production costs, marketing costs including providing advice to consumers?

Option 1. Maintain the *status quo* by not altering permissions for benzoates and/or sulphites.
There are no increased costs or benefits from this option.

Option 2. Review and reduce permissions for benzoates and/or sulphites for certain foods. In order to do this, detailed information from industry and food manufacturers regarding the use of benzoates and sulphites could be used to establish scenario dietary exposure assessments. In addition, FSANZ could consider reviewing consumer information, such as fact sheets.
Option 2 has a potential negative impact on the quality of Australian wine and hence a potential reduction in market share, both in domestic and export markets, which could lead to reduced exports and reduced production of Australian wine resulting in reduced employment for Australians. This also creates the potential for non-tariff technical barriers to trade to be created and possible World Trade Organisation action from Australia's competitors.

Option 3. Review and partially replace the use of benzoates and/or sulphites with alternative preservatives, or consideration of altering the methods of preventing microbial spoilage.
Option 3 has the potential to increased production costs and also has a potential negative impact on the quality of Australian wine and hence a potential reduction in market share, both in domestic and export markets, which could lead to reduced exports and reduced production of Australian wine resulting in reduced employment for Australians. This also creates the potential for non-tariff technical barriers to trade to be created and possible World Trade Organisation action from Australia's competitors.

Option 4. Encourage consumers to eat a balanced diet and not over-consume foods with high levels of benzoates and/or sulphites.
Option 4 could become a part of responsible alcohol/wine drinking campaigns.

(p) What are the costs and benefits for government of the proposed risk management options–administrative, public health and safety?

Option 1. Maintain the *status quo* by not altering permissions for benzoates and/or sulphites.
The National Health and Medical Research Council's *Australian Alcohol Guidelines: health risks and benefits* (2001) recommend a maximum of four and two standard (approximately 100 mL) glasses of wine per day for men and women, respectively. There is no evidence of a risk to public health and safety from the current permitted maximum limits of sulphites for wine is wine is consumed as recommended.

Option 2. Review and reduce permissions for benzoates and/or sulphites for certain foods. In order to do this, detailed information from industry and food manufacturers regarding the use of benzoates and sulphites could be used to establish scenario dietary exposure assessments. In addition, FSANZ could consider reviewing consumer information, such as fact sheets.
Option 2 could impact negatively on winemakers due to a reduction in product quality and an increase in production costs.

Option 3. Review and partially replace the use of benzoates and/or sulphites with alternative preservatives, or consideration of altering the methods of preventing microbial spoilage.
Option 3 could impact negatively on winemakers due to a reduction in product quality and an increase in production costs.

Option 4. Encourage consumers to eat a balanced diet and not over-consume foods with high levels of benzoates and/or sulphites.
Option 4 has the potential to increase public confidence in the government.

(q) What effects, if any, on international trade would occur if FSANZ decreased the benzoate and sulphite permissions in selected foods?

Sulfur dioxide is a permitted additive in winemaking in the at least the following countries: Argentina, Brazil, Canada, Chile, EU, Hong Kong, Japan, Mercosur (Argentina, Brazil, Paraguay, Uruguay), New Zealand, Norway, Poland, Russia, South Africa, Switzerland, Turkey and the USA.

1. The current maximum permitted concentration for sulfur dioxide in Argentina is:

- Dry red wine, 130 mg/L sulfur dioxide
- Dry white wine, 180 mg/L sulfur dioxide
- Dry rose wine, 180 mg/L sulfur dioxide
- Sweet red wine, 180 mg/L sulfur dioxide
- Sweet white wine, 210 mg/L sulfur dioxide
- Sweet rose wine, 210 mg/L sulfur dioxide

2. The current maximum permitted concentration for sulfur dioxide in Canada is:

- For wines with 35 g/L or more residual sugar, 400 mg/L total sulfur dioxide
- For wines with less than 35 g/L residual sugar, 300 mg/L total sulfur dioxide

3. The current maximum permitted concentration for sulfur dioxide in the EU is:

- For red wine less than or equal to 5 g/L sugar, 160 mg/L sulfur dioxide in the free and combined states;
- For red wine greater than 5 g/L sugar, 210 mg/L sulfur dioxide in the free and combined states;
- For white wine less than or equal to 5 g/L sugar, 210 mg/L sulfur dioxide in the free and combined states;
- For white wine greater than 5 g/L sugar, 260 mg/L sulfur dioxide in the free and combined states sulfur dioxide in the free and combined states;
- For sparkling wine, 235 mg/L sulfur dioxide in the free and combined states; and
- For botrytised-style wines, 350–400 mg/L [Council Regulation (EEC) No 822/87].

4. The current maximum permitted concentration for sulfur dioxide in Hong Kong is 450 mg/L.

5. The current maximum permitted concentration for sulfur dioxide in Japan is 350 mg/L.

6. The current maximum permitted concentration for sulfur dioxide in Norway is 300 mg/L.

7. The current maximum permitted concentration for sulfur dioxide in Poland is 260 mg/L.

8. The current maximum permitted concentration for sulfur dioxide in Russia is:

- All wines and treated materials, excluding semi dry and semi sweet, is 200 mg/L sulfur dioxide;
- Semi dry wines is 250 mg/L sulfur dioxide; and
- Semi sweet wines is 250 mg/L sulfur dioxide.

9. The current maximum permitted concentration for sulfur dioxide in South Africa is 200 mg/L.

10. The current maximum permitted concentration for sulfur dioxide in Switzerland is:

- For dry red wine, 160 mg/L sulfur dioxide;
- For sweet red wine (>5 g/L residual sugar), 210 mg/L sulfur dioxide;
- For dry white, rose and sparkling wine, 210 mg/L sulfur dioxide;
- For sweet white, rose and sparkling wine, 260 mg/L sulfur dioxide; and
- For naturally sweet or fortified wine, 400 mg/L sulfur dioxide.

11. The current maximum permitted concentration for sulfur dioxide in Turkey is:

- For white wine is 300 mg/L total sulfur dioxide; and

- For red wine is 200 mg/L total sulfur dioxide.

12. The current maximum permitted concentration for sulfur dioxide in the USA is:

- 350 mg/L for all wine [Bureau of Alcohol, Tobacco and Firearms 27 CFR 4.22(b)(1)].

If the maximum limit for total sulfur dioxide in wine is reduced in Australia from the current limit, then wine exported to Australia from countries with a greater limit made to conform with a limit that is lower than that prescribed for their domestic market, may be considered to be a technical barrier to trade.

(r) In particular, can food manufacturers specifically indicate the effect of reducing the permitted levels of benzoates and sulphites as food additives in foods, including, effects of continued use of benzoates and sulphites as food additives, use of other food additives to replace benzoates and sulphites, impact on the product range and magnitude of any change in costs and final prices to consumers?

Reducing the permitted level of sulfur dioxide in wine would increase the potential for microbial spoilage and oxidation, which would result in sensory defects, both aroma and palate, and a diminished shelf-life. This would negatively impact on the quality and hence image of Australian wine in both the domestic and international market place.

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