



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

5-05

3 August 2005

INITIAL ASSESSMENT REPORT

PROPOSAL P298

BENZOATE AND SULPHITE PERMISSIONS IN FOOD

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 14 September 2005

SUBMISSIONS RECEIVED AFTER THIS DEADLINE

WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

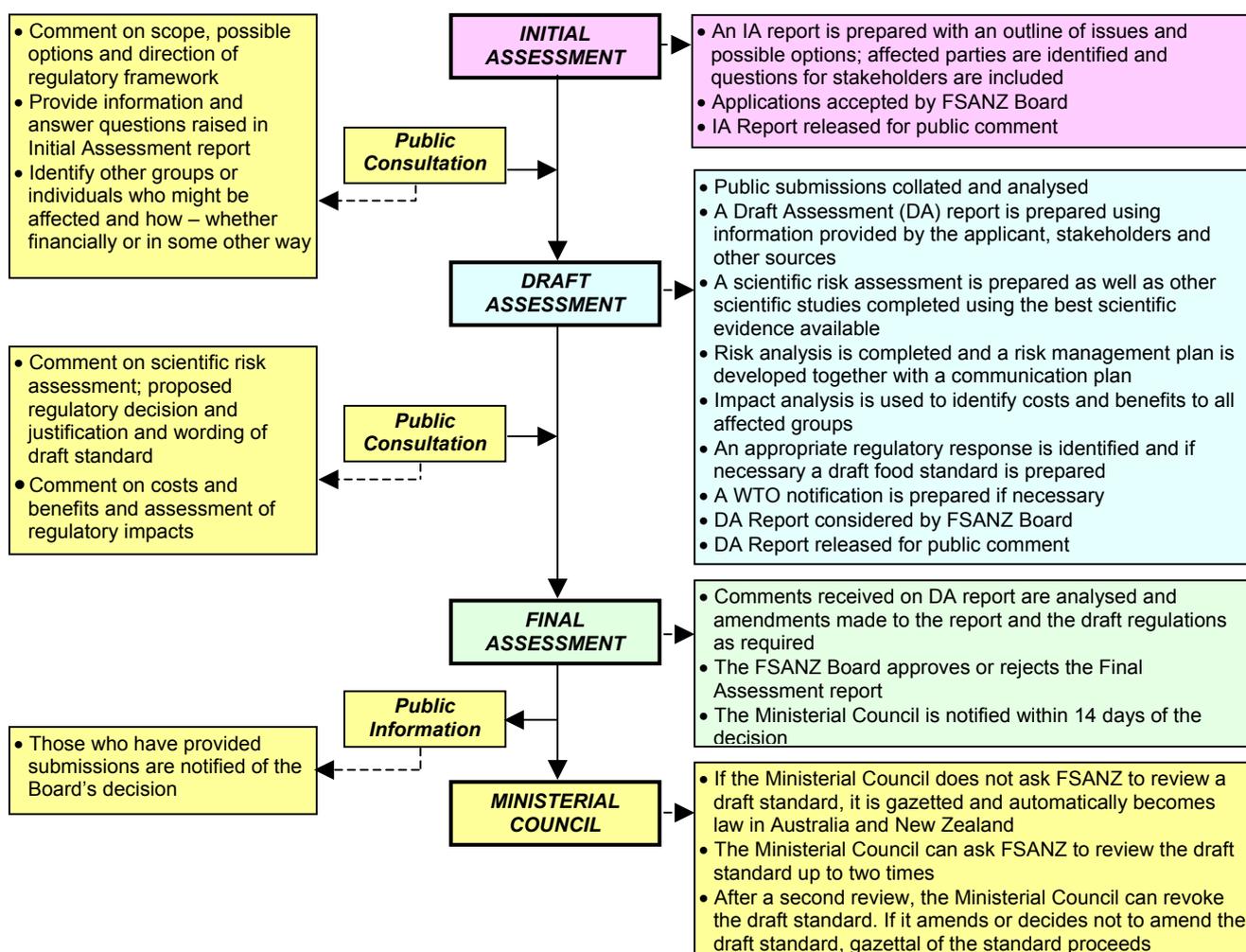
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Proposal P298, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 14 September 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

Proposal P298 has been prepared to consider the current permissions in the *Australia New Zealand Food Standards Code* (the Code) for the food additives, benzoates and sulphites. Both sulphites and benzoates are widely used food preservatives.

Results from the recent 21st Australian Total Diet Study (ATDS) conducted by FSANZ on exposure to benzoates and sulphites in Australia, indicate that while mean dietary exposure to both food additives for all consumers (2 years and above) are estimated to be below the Acceptable Daily Intake (ADI), some high level consumers may exceed the ADI at high (95th percentile) levels of dietary exposure. This exposure was greater for sulphites than for benzoates compared to the respective ADIs.

The high level consumers of sulphites exceeded the ADI for most population groups assessed; 2-5 year old boys were estimated to have the highest levels of exposure (approximately 280% of the ADI). The major contributors to sulphite exposure were sausages, dried apricots and cordial, in the case of children, and white wine, sausages and dried apricots for adults.

The population group which most notably exceeded the ADI for benzoates was also 2-5 year old boys (by approximately 140%), however all other population groups were well below the ADI for high level consumers of benzoates. The major foods contributing to benzoate exposure for children were cordial, non-cola soft drinks and orange juice.

This Initial Assessment Report is not intended to be a detailed assessment of Proposal P298. The Report summarises relevant information from the 21st ATDS, to be published in 2005, and has been written to assist in identifying the affected parties and to outline relevant issues to be addressed.

As part of the Proposal, FSANZ will be undertaking a full risk assessment, including a more refined dietary exposure assessment and consideration of any new safety data, in order to fully characterise the public health and safety risks. FSANZ will consider appropriate risk management strategies to limit exposure to benzoates and sulphites for specific population groups where necessary. FSANZ will be seeking the input of key stakeholders in industry, government agencies and consumers in the development of this risk management strategy. A number of regulatory and non-regulatory options for considering exposures to sulphites and benzoates are proposed in this Initial Assessment Report and will be further considered at Draft Assessment, once the full risk assessment has been undertaken, and public comments have been received.

FSANZ now seeks public comment on this Initial Assessment Report in order to proceed to the Draft Assessment stage.

1. Introduction

Over the past century there has been an increasing reliance upon the use of food preservatives in our food supply. Not only do these preservatives serve a primary function in improving microbiological safety, they also preserve the nutritional quality, palatability and attractiveness of foodstuffs to the consumer. The recent 21st Australian Total Diet Study (ATDS)¹ found that while the mean dietary exposure to two preservatives, namely, sulphites and benzoates for the population group representing all consumers (2 years and above) was below the relevant acceptable daily intakes (ADIs), the 95th percentile dietary exposure to benzoates and sulphites for some population groups (particularly children) exceeded the relevant ADIs.

This Initial Assessment Report discusses the ATDS findings, examines some of the issues raised by these findings and outlines possible regulatory and non-regulatory options to address the issues raised and manage any potential public health and safety risks.

2. Regulatory Problem

2.1 Current Standard

Current permissions for benzoates and sulphites in the Code under Standard 1.3.1 – Food Additives, cover a broad range of foods and beverages which are detailed in Appendix 1.

The reference health standard used for food additives is the ADI. This is the amount of food additive that can be ingested daily over an entire lifetime without any appreciable risk to health and is expressed in units of milligrams per kilogram of bodyweight per day (mg/kg bw/day). The group ADI for benzoates, confirmed in 1998 by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is 0-5 mg/kg bw/day and the group ADI for sulphites confirmed in 1998 by JECFA, is 0-0.7 mg/kg bw/day.

2.2 Results of the 21st ATDS.

2.2.1 Dietary exposure estimates for sulphites and benzoates from the ATDS

Representative foods thought to contain sulphites and benzoates were sampled and prepared to a ‘table-ready’ state before analysis, in order to provide estimates of the amounts of preservatives in the food as consumed.

The estimated dietary intakes for benzoates and sulphites were found to exceed the ADI for some high (95th percentile) consumers, particularly children. Children have higher exposures per kilogram of body weight and therefore greater exposures as a percentage of the ADI. This is primarily due to their higher food consumption per kilogram of body weight compared to adults, and their lower body weights.

The results of the 21st ATDS indicate that there may be concerns with levels of benzoates and sulphites in certain populations consuming high levels of particular foods, and that this issue may need to be addressed through changes in the Code.

¹ 21st Australian Total Diet Survey (ATDS) to be published by FSANZ mid 2005

3. Objective

The objective of this Proposal is to re-examine, in light of the 21st ATDS findings, the permissions for benzoates and sulphites in the Code to ensure that the consumption of foods containing these substances does not pose a public health and safety risk.

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 FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Background to the 21st ATDS

Previous ATDSs undertaken by FSANZ have consistently shown that Australian dietary exposures to pesticide residues and contaminants were well below relevant reference health standards, such as the ADI, and therefore did not represent a public health and safety risk.

In 2003, FSANZ decided, in consultation with State and Territory Government food agencies, that the scope and format of the ATDS should change to consider a wider range of food chemicals, including additives and nutrients, with smaller surveys being conducted more frequently.

This has enabled FSANZ greater flexibility in focusing the study on food chemicals for which there may be concern that dietary exposures could exceed the reference health standard for some population groups, or where significant data gaps exist on chemicals in foods.

The review of the food additive permissions undertaken by FSANZ in 1999, as part of the review of the Australian *Food Standards Code* and the *New Zealand Food Regulations 1984*, to produce the *Australia New Zealand Food Standards Code*, identified a number of food additives, including the preservatives sulphites and benzoates, where the dietary exposure to these food additives had the potential to exceed the ADI for the whole population or specific sub-population groups. This may be as a result of changes in product availability and consumption creating altered dietary patterns; for example, in the past decade there has been a considerable increase in the range of non-cola soft drinks and refrigerated fruit juices on the market, which often utilise benzoate a preservative.

Similar changes have also occurred in dietary patterns in relation to sulphite-containing foods, leading to intakes equal to, or exceeding the ADI. The 1998 JECFA report on sulphites² indicated that eating regular (100g) portions of foods with sulphite levels above 400 mg/kg, would result in an intake equal to the ADI. Thus, consuming foods and beverages with relatively high sulphite levels, may lead to intake levels above the ADI.

The review therefore recommended that sulphite and benzoate concentrations in foods be monitored and that dietary exposure from these foods be assessed, hence their inclusion in the 21st ATDS.

4.2 Key overall findings of the 21st ATDS

Fifty-nine types of foods sampled during April and May 2003 were tested for key food preservatives including sulphites and benzoates. Food types included mainly processed foods for which there are permissions to contain preservatives in the Code. Foods were sampled in each State and Territory in Australia.

Dietary exposures to sulphites and benzoates were estimated for a range of age–gender groups. These age-gender groups were girls aged 2-5 years, boys aged 2-5 years, girls aged 6-12 years, boys aged 6-12 years, girls aged 13-18 years, boys aged 13-18 years, adult females aged 19 years and over and males aged 19 years and over.

In addition, dietary exposure was estimated for the entire female and male population aged two years and over being representative of a lifetime of exposure. The estimated dietary exposure to each chemical from the Australian diet was then compared to appropriate reference health standards, in this case the ADI.

Summary of key findings from the ATDS:

4.2.1 Overall

- the mean dietary exposure to both benzoates and sulphites for all consumers (2 years and above) was below the relevant ADI.
- high level exposure for some consumers was greater for sulphites than for benzoates compared to each ADI.

² <http://www.inchem.org/documents/jecfa/jecmono/v042je25.htm>

4.2.2 *Benzoates*

- the 95th percentile estimated dietary exposure for benzoates exceeded the ADI for boys 2-5 years (approximately 140%), girls 2-5 years (approximately 120%) and was equivalent to the ADI for boys 6-12 years.
- all other population groups were below the ADI for 95th percentile exposures, including across all ages at approximately 60% for males two years and over, and approximately 50% for females two years and over.
- the major foods contributing to benzoate exposure for children (2-5 years and 6-12 years) were cordial, non-cola soft drinks and refrigerated orange juice.

4.2.3 *Sulphites*

- the 95th percentile estimated dietary exposure for sulphites exceeded the ADI for most population groups assessed; boys 2-5 years (approximately 280%), girls 2-5 years (approximately 210%), males and females 2+ years (approximately 130%).
- the major contributors to sulphite exposure for children (2-5 and 6-12 years) were sausages, dried apricots and cordial.
- the major contributors to sulphite exposure for adults (19 years and over) were white wine, sausages and dried apricots.

4.3 **Impact of the results from the 21st ATDS**

Although results from the 21st ATDS indicated that there may be some cause for concern regarding levels of benzoates and sulphites, the dietary modelling provided a conservative estimate of high-level exposure at the 95th percentile.

Exceedances of the ADI does not necessarily mean that there is a public health and safety issue, as ADIs incorporate substantial safety margins. The ADI relates to daily consumption over a lifetime, with a default uncertainty (or safety) factor value of 100.

A full risk assessment, including a more refined dietary exposure assessment and consideration of any new safety data, will be necessary before it is possible to fully characterise the public health and safety risks. This will be undertaken as part of the Draft Assessment.

5. Relevant Issues

5.1 Safety of benzoate and sulphite-containing food

5.1.1 *Benzoates*

In 1998, JECFA re-evaluated the group ADI for benzoates as 0-5-mg/kg bw/day, based on a long-term exposure study on rats³. The NOEL was established at the highest dose tested (500 mg/kg bodyweight per day) where no adverse effects were observed.

General signs of toxicity were observed in more recent short-term studies at higher dose levels. In establishing the ADI, a safety factor of 100 was applied to the NOEL to take into account species differences and individual human variation.

The 21st ATDS showed that the mean estimated dietary exposure to benzoates for all population groups was well below the ADI, indicating that for the majority of the population, there is no public health and safety risk from the consumption of a balanced diet, which includes foods containing benzoates.

5.1.2 *Sulphites*

In 1998, JECFA re-evaluated a group ADI for sulphites as 0-0.7 mg/kg bw/day. This ADI was based on studies conducted in rats and pigs⁴, where exposure to sulphites was found to cause gastric lesions in both short-term (3 month) and long-term (2 year) studies. The no-observed-effect level (NOEL) was 70 mg/kg bodyweight per day.

There was little evidence of toxicity in other organs, even at higher dose levels. In establishing the ADI, a safety factor of 100 was applied to the NOEL to take into account species differences and individual human variation.

JECFA also noted that the gastric effects arise from local irritation, and therefore the effects would be more dependent on concentration in the stomach, than on daily dose. Therefore, adverse effects are more likely to occur following regular on-going consumption of meals with foods that have high concentrations of sulphites, such as dried apricots and dried apples.

The 21st ATDS revealed that the mean estimated dietary exposure to sulphites for all population groups was well below the ADI, indicating that, for the majority of the population, there is no public health and safety risk from the consumption of a balanced diet, which includes foods containing sulphites.

FSANZ will re-examine the toxicological data in relation to benzoates and sulphites at Draft Assessment and carryout a more in-depth analysis of how the current ADI was derived and whether the end-points are relevant.

³ <http://www.inchem.org/documents/jecfa/jecmono/v042je22.htm>

⁴ <http://www.inchem.org/documents/jecfa/jecmono/v042je25.htm>

5.2 Dietary exposure

FSANZ will undertake a dietary exposure assessment, where necessary, to determine overall exposure to benzoates and sulphites for a range of populations, for example, for the New Zealand population, which was not covered in the 21st ATDS. FSANZ may be able to refine or qualify the dietary exposure assessment conducted in the 21st ATDS, should appropriate information be submitted.

FSANZ is seeking the following data for both Australia and New Zealand:

- (a) the amount of benzoates and sulphites used in a given food product. Has it changed significantly from that used in April- May 2003 (as reflected in the products collected and analysed in the 21st ATDS)?;**
- (b) market share data. For example, what is the proportion of the orange juice market for refrigerated versus shelf stable juices?;**
- (c) the proportion of any food category that may contain the preservatives. For example, what proportion of the orange juices would contain benzoates? What proportion of this juice is refrigerated?**
- (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;**
- (e) whether there are any food categories for which permissions exist but where the preservatives are never used;**
- (f) what categories of foods have these preservatives added, but not at the maximum permitted level ?**
- (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;**
- (h) any analytical data for foods with added sulphites or benzoates that have been analysed as prepared or ready to consume; and**
- (i) data relating to changes in levels of benzoates and sulphites during storage and food preparation.**

5.3 Technological justification for using benzoates and sulphites

Both sulphites and benzoates are widely used food preservatives which have a beneficial effect by their addition to processed foods to ensure treated food is safe to consume under normal storage and preparation conditions as provided on the label. Preservatives help maintain a safe food supply and extend shelf life of treated products.

Sulphites also have effect as antioxidants, which improve food quality and appearance as well as extending shelf life. Preparing food without benzoates or sulphites could have drastic effects on food quality and safety. There are limited alternatives for many foods to the use of benzoates and sulphites as food additives.

Benzoates are commonly used in products with low pH, such as mayonnaises, pickled vegetables, preserves, fruit preparations, fruit-based drinks, dessert sauces and syrups.

They are also commonly used in combination with sorbates since the mixture is more effective than each individually. Benzoates exert their antimicrobial activity upon yeasts and moulds, including aflatoxins-producing moulds, and some bacteria⁵.

Sulphites are important food antimicrobial preservatives, as well as reducing agents, enzyme inhibitors, bleaching agents, antioxidants and oxygen scavengers. Sulphites are effective against most bacteria and are used as antimicrobial agents in the production of certain meats, in fruit products such as dried fruit, certain fruit juices, potatoes, biscuit dough and alcoholic beverages (including wine and beer). Sulphites are not easy to replace in foods, so usually a combination of additives needs to be used if sulphite levels are reduced.⁴

FSANZ will undertake a food technology assessment as part of the Draft Assessment of this Proposal and seeks comment on the following:

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

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

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

5.4 Views of major interest groups/stakeholders

The results of the dietary exposure assessments conducted for the 21st ATDS are likely to be of particular interest to food manufacturers. Dried fruit, wine, cordial, and sausages are major contributors to estimated dietary exposures to sulphites. Non-cola soft drinks, orange juice and cordial are major contributors to estimated dietary exposure to benzoates.

In addition, consumer organisations are likely to be concerned that a proportion of high consumers of foods containing sulphites and benzoates may exceed the reference health standards.

FSANZ will contact key industry and consumer associations in regard to this Proposal, and will invite them to participate in providing comment throughout the stages of assessment.

5.5 Sulphite sensitivity

A small section of the population, mainly people who suffer from asthma, react to sulphites with allergy-like symptoms.

Such reactions can be symptoms of a sensitivity response such as skin rashes and irritations, as well as provocation of asthma. Sulphite sensitivity can also occur with non-food sources, for example sulphite can be used as a preservative in medicines. Sensitivity to sulphites in food is dependent on how much a person is exposed to all sources of sulphites.

⁵ Beales N. and Smith, J. (2004) Antimicrobial preservative-reduced foods. In: Smith, J. ed. *Technology of Reduced Additive Foods*, 2nd Edition, Blackwell Science, Oxford, UK, pp 84-105.

The issue of sulphite sensitivity has been previously addressed by FSANZ. Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires a mandatory declaration of sulphites on the label of the food when sulphites have been added to food in concentrations of 10 mg/kg or more. This is the case whether the sulphites have been added as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive, or a processing aid or component of a processing aid. A fact sheet “For asthma sufferers: The Facts About Sulphites in Food” is also provided on the FSANZ web site⁶.

The dietary exposure assessment and risk characterisation of sulphites conducted as part of the 21st ATDS considers only the longer-term health effects of dietary exposure by comparing estimated exposure with the ADI set by JECFA. The 21st ATDS does identify the high sulphite-containing foods, but does not specifically address the issue of sulphite-sensitivity. This Proposal will not specifically address the issue of sulphite-sensitivity, as consumers are made aware of sulphite-containing food through labelling. However, if the maximum permitted levels of sulphite in some foods are lowered, this may potentially impact on the occurrence of sulphite-induced sensitivity in the population.

6. Risk Management

In developing a meaningful and realistic risk management strategy to protect any groups considered at risk of excess dietary exposure to benzoates and sulphites from the food supply, FSANZ intends to raise the awareness of, negotiate with and seek input from key stakeholders in industry, government agencies and consumers.

A risk management strategy may involve identifying appropriate options to manage the risk of high dietary exposure to benzoates and sulphites for the whole population and/or specific sub-populations, which may include:

- (i) reviewing maximum limit permissions for benzoates and sulphites in foods;
- (ii) consideration of alternative preservatives, antioxidants or treatments which will need to match the technological function and efficacy of benzoates and sulphites; and
- (iii) advisory statements and public education to encourage a reduction in the consumption of high benzoate and sulphite containing foods

7. Regulatory and Non-Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles.

⁶<http://www.foodstandards.gov.au/mediareleasespublications/factsheets/factsheets2001/forasthmasufferersth1152.cfm>

The possible regulatory and non-regulatory options available for this Proposal are identified below:

Option 1. Maintain the *status quo* by not altering permissions for benzoates and/or sulphites.

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 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 4. Encourage consumers to eat a balanced diet and not over-consume foods with high levels of benzoates and/or sulphites.

To further develop the impact analysis in terms of the costs and benefits of the regulatory and non-regulatory options proposed, FSANZ seeks comment on the following:

Scientific aspects of the Proposal, in particular any information relevant to the safety assessment and/or dietary exposure assessment.

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

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?

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?

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

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

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?

8. Impact Analysis

Parties likely to be affected by the possible options as listed above are consumers, manufacturers and Australian, State/Territory and New Zealand Governments.

8.1 Affected Parties

Affected parties identified are:

- those sectors of the food industry wishing to retain the manufacturing of benzoates and sulphites and/or the marketing of benzoate and sulphite -containing food products in the foods identified, and in particular the effects on small business (if any);
- consumers who experience adverse health effects from food additives in the foods identified;
- consumers, in particular those who agree with the need for food additives who may be disadvantaged if regulatory measures were required that decreased availability of some products on the market; and
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food regulations.

9. Consultation

9.1 Public consultation

FSANZ is seeking public comment in order to assist in assessing this Proposal. There will also be a further round of public comment after the Draft Assessment Report is completed.

9.2 World Trade Organization (WTO)

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

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

10. Conclusion

The results of the 21st ATDS, which concluded that some high consumers of benzoate and sulphite containing products may exceed the ADI, indicate that there may be potential public health and safety concerns with the current permissions in the Code for the use of sulphites and benzoates.

FSANZ is therefore preparing a Proposal to more fully examine the potential public health and safety risks, and to explore possible risk management options to reduce exposures to sulphites and benzoates.

FSANZ now seeks public comment in order to make a Draft Assessment of the Proposal.

Attachments

1. Current benzoate and sulphite permissions

Current benzoate and sulphite permissions

Benzoates include the following food additives:

INS Number	Food additive name
210	Benzoic acid
211	Sodium benzoate
212	Potassium benzoate
213	Calcium benzoate

Sulphites include the following food additives:

INS Number	Food additive name
220	Sulphur dioxide
221	Sodium sulphite
222	Sodium bisulphite
223	Sodium metabisulphite
224	Potassium metabisulphite
225	Potassium sulphite
228	Potassium bisulphite

Benzoates (INS 210, 211, 212 and 213)

Food	Maximum permitted levels (mg/kg)
Preparations of food additives	1000
Rennetting enzymes	9000
Oil emulsions (<80% oil)	1000
Ice confection sold in liquid form	400
Mushrooms in brine or water and not commercially sterile	500
Preserved cherries (maraschino cherries, cocktail cherries or glace cherries)	1000
Fruits and vegetables in vinegar, oil, brine or alcohol	1000
Low joule chutneys, low joule jams and low joule spreads	1000
Fruit and vegetable preparations including pulp	1000
Chilli paste	3000
Other fruit and vegetable based products – imitation fruit	400
Icings and frostings	1000
Semi preserved fish and fish products	2500
Tabletop sweeteners – liquid preparation	GMP
Solid formulated supplementary sports foods	400
Liquid formulated supplementary sports foods	400
Fruit and vegetable juices and fruit and vegetable juice products	400; GMP principle precludes the use in juices represented as not preserved by chemical or heat treatment.
Coconut milk, coconut cream and coconut syrup	1000
Water based flavoured drinks	400
Fruit wine, vegetable wine and mead (including cider and perry)	400
Mixed alcoholic beverages.	400
Dairy and fat based desserts, dips and snacks	700
Sauces and toppings (including mayonnaises and salad dressings)	1000

Sulphites (INS 220, 221, 222, 223, 224, 225, 228)

Food	Maximum permitted levels (mg/kg)
Preparations of food additives	350
Cheese and cheese products	300
Ice confection sold in liquid form	25
Unprocessed fruits and vegetables - grapes packed with permeable envelopes	10
Unprocessed fruits and vegetables - Longans	10
Peeled and/or cut fruits and vegetables – products for manufacturing purposes; apples and potatoes only.	200
Peeled and/or cut fruits and vegetables – root and tuber vegetables	50
Frozen unprocessed fruits and vegetables – frozen avocado	300
Processed fruits and vegetables (ginger only)	20
Dried fruits and vegetables	3000
Desiccated coconut	50
Products made from bleached vegetables	750
Low joule chutneys, low joule jams and low joule spreads	285
Candied fruits and vegetables	2000
Fruit and vegetable preparations including pulp	350
Fruit and vegetable preparations for manufacturing purposes	1000
Other fruit and vegetable based products – imitation fruit	3000
Flour products (including noodles and pasta)	300
Biscuits, cakes and pastries	300
Processed comminuted meat, poultry and game products	500
Sausage and sausage meat containing raw, unprocessed meat	500
Edible casings	500
Unprocessed fish and fish fillets - uncooked crustacea	100
Processed fish and fish products – cooked crustacea	30
Fully preserved fish including canned fish products	30
Canned abalone (paua)	1000
Sugars and syrups	450
Vinegars and related products	100
Solid formulated supplementary sports foods	115; sulphur dioxide only
Liquid formulated supplementary sports foods	115; sulphur dioxide only
Fruit and vegetable juices and fruit and vegetable juice products	115; GMP principle precludes the use in juices represented as not preserved by chemical or heat treatment.
Water based flavoured drinks	115
Beer and related products	25
Wine, sparkling wine and fortified wine containing >35 g/L residual sugar	400
Wine, sparkling wine and fortified wine containing <35 g/L residual sugar	250
Fruit wine, vegetable wine and mead containing > 5 g/L residual sugar	300
Fruit wine, vegetable wine and mead containing < 5 g/L residual sugar	200
Mixed alcoholic beverages	250
Sauces and toppings (including mayonnaises and salad dressings)	350