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

29 June 2016
[16-16]

Draft Assessment Report (Abandonment) – Proposal P298

Benzoate & Sulphite Permissions in Food

Food Standards Australia New Zealand (FSANZ) prepared a Proposal to consider the current permissions in the *Australia New Zealand Food Standards* Code for the food additives, benzoates and sulphites.

On 3 August 2005, FSANZ sought submissions on an Initial Assessment Report and received 24 submissions.

FSANZ has decided to abandon the Proposal pursuant to paragraph 15B(b) of the *Food Standards Australia New Zealand Act 1991* as was in force on 1 July 2007. Information on the reasons for FSANZ's decision is contained in this Report.

This decision is not reviewable under section 63 of the FSANZ Act (as was in force prior to 1 July 2007).

Table of Contents

Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at
http://www.foodstandards.gov.au/code/proposals/Pages/proposalp298benzoate2973.aspx

SD1 Risk and Technical Assessment Report

SD2 A Review of Sulphites in Raw Meat Sausages, prepared by the South Australian Research and Development Institute (SARDI)

Executive summary

In 2005, the 21st Australian Total Diet Study (ATDS) indicated that estimated dietary exposures to the preservatives benzoates and sulphites for some groups in the Australian population were potentially exceeding the relevant health-based guidance value (HBGV). This was also supported by a dietary exposure assessment carried out in New Zealand. For these preservatives, the relevant HBGVs are the acceptable daily intake (ADI) developed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

P298 was prepared in response to these surveys to consider permissions in the Code for benzoates and sulphites.

Benzoates and sulphites are permitted food additives in the *Australia New Zealand Food Standards Code* (the Code). Each preservative has a different maximum permitted level (MPL) for various food types based on the demonstrated technical need.

Following further surveys and dietary exposure assessments FSANZ concluded there was no public health and safety concern for benzoates. However, more work was identified for sulphites. An updated dietary exposure assessment for sulphites indicated that Australian children aged 2–5 years and New Zealand boys aged 5–12 years who were high consumers of products containing sulphites may be exceeding the ADI for sulphites.

FSANZ's risk assessment, based on the best available scientific evidence currently available, is that the ADI has been set too low.

This assessment recognises that the ADI for sulphites established by JECFA in 1974 and on which permissions are set in the Code, suffered from significant flaws in design and implementation. These flaws had the effect of undermining confidence in the extent of the risk posed by children whose dietary exposure was above the HBGV. On this basis, the risk characterization conclusion is that current levels of dietary sulphite exposure in Australia and New Zealand are therefore unlikely to pose a risk for consumers, including children.

This view is supported by a Scientific Opinion on sulphites issued by the European Food Safety Authority (EFSA) in April 2016. It concludes that the current toxicological database for sulphites is inadequate to support the current JECFA ADI. The European Union relies on the same ADI for sulphites. EFSA has recommended that that ADI be considered temporary pending the provision and evaluation of new toxicological data. Once new toxicological data is published, it will be possible to establish a new ADI. It is likely that JECFA will be asked to reconsider the group ADI for sulphites at that time as well.

In light of the risk assessment, amendment of the Code is not considered to be warranted at this time. Existing risk management measures in the Code are considered appropriate. Code requirements can be further reviewed in light of the outcomes of the above and any other international evaluations, when available.

For these reasons, FSANZ decided to abandon the Proposal.

1 Introduction

Benzoates and sulphites are used as preservatives in a wide range of foods to limit microbial spoilage. The permissions for these substances in the *Australia New Zealand Food Standards Code* (the Code) are similar to those in the Codex Alimentarius General Standards for Food Additives (GSFA)[1], established by JECFA in 1974.

The 21st Australian Total Diet Study (ATDS) [2] identified a potential public health and safety concern for benzoates and sulphites with estimated dietary exposures indicating some age groups may have been exceeding the relevant health-based guidance value (HBGV).

After the findings of the 21st ATDS were released, the then New Zealand Food Safety Authority (NZFSA) commissioned a targeted survey of key preservative-containing foods on sale in New Zealand and conducted its own safety assessment. This study by NZFSA indicated that there was an exceedance of the HBGV for sulphites for boys aged 5-12 years.

P298 was prepared in response to these surveys to consider permissions in the Code for benzoates and sulphites.

The Initial Assessment Report (IAR) mainly considered what foods could have lower levels of sulphites, or use replacement preservatives. Since the release in 2005 of the IAR, FSANZ has undertaken a number of activities to help assess this Proposal including:

- collecting and analysing additional food samples in Australia for foods that make a major contribution to sulphite dietary exposure
- measuring and comparing sulphite levels with declared remaining shelf life of dried apricots and raw meat sausages
- commissioning a report from the South Australian Research and Development Institute (SARDI) on the use of and alternatives to sulphites in raw meat sausages
- updating the dietary modelling to include the most recent Australian and New Zealand children's consumption data
- extensive consultation with the industry sectors that could be impacted by this Proposal
- commissioning a report into the cost of possible adverse outcomes arising from an exceedance of the acceptable daily intake (ADI)
- the funding of a dose range finding study to gain greater clarity around the current ADI for sulphites in food.

FSANZ identified sausages and dried fruit as the food products where reductions in levels would make the most significant contribution to reducing sulphite exposure for young children. Therefore, FSANZ focussed on these foods.

1.1 The proposal

FSANZ prepared this Proposal to:

- consider the potential public health and safety risks associated with exceedance of the relevant HBGV for benzoates and sulphites for some population sub-groups.
- where appropriate, develop risk management strategies to manage these risks, including the consideration of a need for amended food regulatory measures in the Code.

[1] http://www.foodstandards.gov.au/publications/Pages/21staustraliantotald2963.aspx
[2] 21st Australian Total Diet Study (ATDS) was published by FSANZ in August 2005.

1.2 The current standards

Standards 1.1.1 and 1.3.1 and Schedule 15 together provide the current permissions for the use of benzoates and sulphites as food additives.

In Schedule 15, under the table to section S15—5, benzoates and sulphites are permitted in a wide range of foods at differing concentration levels based on the food matrix, packaging type, distribution and storage conditions and required shelf-life pre- and post-purchase. These permissions are listed in Appendix 1 of the Risk and Technical Assessment Report (SD1).

Overall, permissions in the Code are generally consistent with those published in the Codex GSFA and are based on the maximum permitted level (MPL) needed at the time of manufacture to achieve the technological purpose.

1.3 International permissions for sulphites in food

The Codex GSFA permissions for the addition of benzoates (1000 mg/kg for fruit juices, concentrates and nectars) are higher than the current permissions in the Code (400 mg/kg for fruit juices and fruit juice products), while all other benzoate permissions are similar.

In Canada and the European Union, sulphites are permitted in sausages at a level similar to the MPL in the Code (500 mg/kg). In a number of countries, including the UK and Ireland, the production, manufacturing and distribution systems for sausages are similar to that in Australia and New Zealand. Their use of sulphites is at a similar level and for the same purpose as in Australia and New Zealand. JECFA has found that the ADI of 0.7mg/kg bw is exceeded for mean intake in the three Member States that submitted data.

In the USA, sulphites are not permitted in raw meat sausages. The USA industry comprises predominantly high-volume manufacturers with small butcher shops being less prominent. The product shelf life is typically 12 days achieved primarily by the use of modified atmosphere packaging (MAP), with colour being maintained through the use of other ingredients or additives such as butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT). In some cases, frozen distribution is used.

The Codex GSFA limit for sulphites in dried apricots is 2000 mg/kg, while the Code MPL is 3000 mg/kg. With respect to sulphites in other dried fruits, the Codex GSFA limit for bleached raisins is 1500 mg/kg and 1000 mg/kg in all other dried fruits, while in the Code, dried fruits, including raisins have a MPL of 3000 mg/kg. For more information refer to section 2.2 of SD1.

2 Summary of the assessment

2.1 Risk assessment

2.1.1 Use of benzoates and sulphites

‘Sulphites’ and ‘benzoates’ refer to classes of food preservatives that have a long history of use in food in Australia and New Zealand. There are a range of specific permissions for their addition to certain foods, up to a MPL, contained in Schedule 15 in the Code.

In Australia and New Zealand, the typical levels of benzoates at manufacture were shown to be less than the MPL and were consistent with GMP i.e. they are added at a level necessary to accomplish the desired effect in the specific food. Generally, the addition level of sulphites at the point of manufacture is at a lower level than the MPL in the Code and is consistent with good manufacturing practice (GMP). However, there may be occasions where industry considers that addition at the MPL is required. In all cases, the average level of sulphites and benzoates in the product as consumed is less than that added at the point of manufacture due to natural degradation during storage, after opening or during preparation and cooking (Table A3.1 of SD1).

For raw meat sausages (and other sulphite-containing smallgoods), the sulphite level is linked to the type of sausage, choice of raw materials, packaging system and finished product supply chains (A Review of Sulphites in Raw Meat Sausages, prepared by the South Australian Research and Development Institute (SD2)). There are now limited ranges of preservative-free speciality sausages in Australia, with sulphite-free sausages being more common in New Zealand.

2.1.2 Health-based guidance values

The appropriate health based guidance value (HBGV)[3] for sulphites and benzoates, is an acceptable daily intake (ADI)[4]. The ADI values used by FSANZ for benzoates (0-5 mg/kg bw/day) and initially for sulphites (0-0.7 mg/kg bw/day) for dietary risk assessment purposes were those established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2.1.3 Dietary exposure estimates

In 2005, a potential public health and safety concern was identified in the 21st Australian Total Diet Study (ATDS) due to estimated dietary exposures to benzoates and sulphites for some groups in the Australian population potentially exceeding the relevant health-based guidance values. Updated dietary exposure assessments (DEAs)[5] were conducted for Australia and New Zealand[6] using the most recent food consumption data and updated sulphites analytical concentration data for those foods previously identified as being important contributors to total estimated dietary exposure.

The updated DEAs indicated that estimated dietary exposure to benzoates for Australian and New Zealand consumers of foods containing this additive were below the ADI for all populations assessed at both the mean and 90th percentile of benzoate exposures. The conclusion of the risk and technical assessment for benzoates (SD1) is that there is no public health and safety concern for the Australian and New Zealand populations arising from the consumption of foods containing benzoates.

[3] A numerical value reflecting the level of a chemical that can be ingested over a defined time period (e.g. a day, weekly, monthly or lifetime) without appreciable health risk. Most health based guidance values are expressed on a per kilogram bodyweight basis.

[4] An acceptable daily intake (ADI) is an estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis that, on the basis of all the known facts at the time of the evaluation, can be ingested daily over a lifetime without appreciable health risk to the consumer.

[5] A dietary exposure assessment is the process of estimating how much of a food chemical a population, or population sub group, may be exposed to from the diet.

[6] The dietary exposure assessment for sulphites and benzoates for New Zealand was commissioned by the then New Zealand Food Safety Authority, and published in 2009 by the New Zealand Institute of Environmental Science and Research Ltd (ESR), and is summarised in this report.

For consumers of foods containing sulphites, mean estimated dietary exposures were below the group ADI for all Australian and New Zealand population groups assessed. For high consumers, 90th percentile exposures to sulphites were also below the group ADI for all Australian and New Zealand population groups, except for Australian children aged 2–5 years and New Zealand boys aged 5–12 years, estimated at 130% and 110% of the ADI, respectively. It is considered likely that younger New Zealand children, aged 2–4 years, would also exceed the group ADI at the 90th percentile of exposure, similar to Australian children aged 2–5 years. Whilst the level of exposure for Australian children is above the group ADI, it does show a distinct reduction for the same age groups, compared with the previous Australian dietary exposure assessment, reported in the 21st ATDS.

2.1.4 Chemical hazard assessment

A full hazard assessment for sulphites is presented in SD1. In 1973, JECFA established a group ADI for sulphites of 0–0.7mg/kg based on a 2-year rat study (Til, *et al.* 1972). Dietary exposure to sulphites resulted in gastric mucosal lesions. However, the presence of gastric mucosal lesions in rat and pig studies of metabisulphites is not a consistent finding across a number of studies and is not reproducible in laboratories other than the laboratory in which it was first reported. On the basis that this endpoint and study may not be appropriate for the setting of an ADI, FSANZ considered whether other studies would be more appropriate to base an ADI on. Limited evidence suggests that selection of a more reproducible adverse effect, such as impaired bodyweight gain or decreased haematocrit, would result in a higher NOAEL and therefore a higher ADI. There is no evidence that sulphites are developmental or reproductive toxicants, and although sulphites are genotoxic *in vitro*, there is no evidence that they are carcinogenic *in vivo*. Human toxicity is limited to hypersensitivity reactions in limited subpopulations. This uncertainty around the most relevant toxicological endpoint to establish a suitable HBGV can only be overcome if a robust long-term repeat dose study is completed.

Owing to these limitations in the available toxicological studies, in 2015, FSANZ commissioned a short-term toxicological study in rats. This showed no evidence of acute gastric irritation at much higher doses of sulphites than the NOAEL on which the current ADI was set by JECFA (Dalefield and Mueller, submitted). The highest dose at which no effects were found in the FSANZ study is more than five times greater than the NOAEL in the 1972 study (Til, *et al*.1972). A dose-range finding study – such as that commissioned by FSANZ - is not suitable to establish an ADI because of its short duration, small group sizes and the absence of a full range of measured toxicological endpoints. However, while the FSANZ study was of much shorter duration than the older studies, the supposed mechanism of gastric toxicity of $Na_2S_2O_5$ is direct irritation and it is difficult to account for the findings of chronic irritation in chronic studies when there was a lack of evidence of acute irritation in the 7-day study.

The FSANZ 7-day dose-range finding study and 1990 study (Til *et al*.1992) from the same investigators who performed the long term study on which the current ADI is based suggest that gastric lesions are not reproducibly observed at levels above the NOAEL established in the Til *et al* (1972) study. This suggests that the current ADI is probably much higher than it would be if based on robust evidence from a definitive study conducted to modern experimental standards. A longer-term study (e.g. ≥90 days) conforming to contemporary animal testing guidelines is required to establish a new ADI. Despite the uncertainty on the true value of the ADI, FSANZ is of the opinion that the existing ADI is too low and that current levels of dietary exposure are unlikely to pose a risk for any consumer.

2.1.5 Uncertainties and assumptions in the hazard characterisation

The current JECFA ADI is based on a NOAEL for gastric lesions in rats, but these findings are not consistently reproducible and this means that there is great uncertainty about the dose at which adverse findings are likely to occur.

2.1.6 Risk characterisation

The conclusion of the risk and technical assessment for benzoates from the updated DEA is that there is no public health and safety concern for the Australian and New Zealand populations arising from consumption of foods containing benzoates.

Due to new data suggesting the ADI for sulphites is not robust, and in light of a reduction in sulphite intake identified through the most recent exposure assessments, FSANZ has concluded the existing ADI is too low and current exposure levels are unlikely to pose a risk for any population group.

FSANZ has concluded that robust evidence from a definitive study conducted to modern experimental standards would be necessary to derive a revised group ADI, but it is likely that a revised group ADI would be higher than the current group ADI (A7.1 of SD1).

2.1.7 EFSA Scientific Opinion on Sulphites

In April 2016, the EFSA ANS Panel reviewing sulphites released its Scientific Opinion on the re-evaluation of sulphites. The Panel concluded that the current group ADI of 0.7 mg SO_2 equivalent/kg bw per day would remain adequate, but should be considered temporary while the database was improved. The EFSA ANS Panel further concluded that exposure estimates for European populations to sulphur dioxide and sulphites were higher than the group ADI of 0.7 mg SO_2 equivalent/kg bw per day for all population groups.

The EFSA ANS Panel made several recommendations including the need to update the database and to re-evaluate the temporary group ADI using more robust data, and to require product labels to provide information on the amount of SO_2 equivalent present in solid foods and beverages. They noted that the recommended studies could require 5 years for completion.

2.2 Risk management

2.2.1 General approach to risk management of food additives

The FSANZ risk management approach for food additives follows that of the Codex GSFA, where the preamble states[7]:

> *The primary objective of establishing maximum use levels for food additives in various food groups is to ensure that the intake of an additive from all its uses does not exceed the HBGV (the ADI).*

Risk assessments in Australia and New Zealand and internationally are undertaken with the goal of assessing whether estimated exposure to a given chemical from the total diet exceeds the relevant reference health standard, in this case the ADI. The ADI, the amount that can be ingested on a daily basis over a lifetime without an appreciable health risk, has been established following international protocols.

[7] http://www.codexalimentarius.net/gsfaonline/index.html?lang=en

Once the ADI is routinely exceeded it is no longer possible to be sure that there is no appreciable health risk.

2.2.2 Risk management approach for benzoates

At the time P298 was prepared following the publication of the 21st ATDS, the estimated dietary exposure for benzoates did raise some concerns. However, since the updated DEA for benzoates for high consumers was not above the ADI for any population group assessed in Australia and New Zealand, it was concluded that no additional risk management measures are needed for benzoates.

2.2.3 Risk management considerations for sulphites

Before finalising the 7-day dose range finding study, FSANZ was of the view that risk management measures were needed to reduce children's exposure to sulphites. A variety of measures were evaluated to reduce the MPL at point of retail sale for sausages and dried fruit including education and industry voluntary measures. However, in view of the updated risk characterisation, the current risk management considerations are:

- The risk assessment, based on the best scientific evidence currently available, is that there is a negligible likelihood of health and safety risks for the Australian and New Zealand populations, including children, arising from the consumption of foods containing sulphites and benzoates. See SD1.

- Updated DEA information regarding a reduction in children's exposure to sulphites since 2003.

- While there is some evidence that some sectors of the sausage industry (e.g. smaller manufactures such as butchers) could use lower levels of sulphites to achieve their technological function, amendment of the Code (e.g. change to MPL) is not considered to be cost effective as compared to targeted communication and education to improve the adherence to GMP.

- The recent release of the EFSA Scientific Opinion on the re-evaluation of sulphites and potential future activities in Europe will permit a re-evaluation of this issue in around five years.

In view of these considerations, FSANZ is of the opinion that an amendment of current risk management measures (i.e. amending MPLs and requiring sulphites to be used at levels which are consistent with GMP) is no longer considered necessary at this point in time.

2.2.4 Summary of issues raised in submissions

On 3 August 2005, FSANZ sought submissions on an Initial Assessment Report. The Initial Assessment Report asked a number of questions relating to:

- dietary exposure
- food products using benzoates and sulphites
- technologically required levels of benzoates and sulphites
- alternatives to benzoates and sulphites.

In total, 24 submissions were received: 17 from the food industry, four from regulators, two from interested associations and one private.

Some of the submissions contained detailed information relating to the questions in the IAR and supporting possible risk management options. In particular, information was provided on current use levels, the availability of alternative technologies, the necessity of using sulphites as a preservative for particular food types and costing information. Although these submissions were relevant to FSANZ consideration at the time of which foods could be identified where lower levels of these preservatives were technologically feasible and cost effective to reduce consumer exposure, they are no longer relevant since FSANZ no longer considers it necessary to amend the current risk management measure.

2.2.5 Decision

After having regard to the risk management considerations above and to the statutory requirements outlined below, FSANZ decided to abandon P298. The reasons for the decision are as outlined above in section 2.2.3 i.e. FSANZ now considers the likelihood of health and safety risks arising from the consumption of foods containing sulphites and benzoates negligible, taking into account the new evidence from the evaluation of various animal studies on sulphites, including a dose-range finding study commissioned by FSANZ and the updated DEA.

2.3 FSANZ Act requirements

Proposal P298 was prepared in 2005. For this reason, it has to be assessed in accordance with the *Food Standards Australia New Zealand Act 1991* as was in force prior to 1 July 2007.

2.3.1 Section 15AA of the FSANZ Act

Subsection 15AA(2) (as was in force prior to 1 July 2007) of the previous FSANZ Act provides that FSANZ must have regard to certain matters when assessing a proposal. These are:

- Any submissions made to it within the specified period in response to a notice sent or published under section 14A of the FSANZ Act (as was in force prior to 1 July 2007).

  This is discussed in section 2.2.4 above

- The objectives and matters listed under section 10 of the FSANZ Act (as was in force prior to 1 July 2007) – these are addressed in section 2.4.2 of this report.

- Any relevant New Zealand standards – there are no relevant New Zealand Standards; the food additive standards are joint standards.

- Any other relevant matters – these are considered below.

2.3.2 Subsection 10(1) considerations

FSANZ considered the three objectives in subsection 10(1) (as was in force prior to 1 July 2007) during the assessment of this Proposal as follows.

2.3.2.1 Protection of public health and safety

FSANZ's assessment, based on the best scientific evidence currently available, is that there is a negligible likelihood of health and safety risks for the Australian and New Zealand populations, including children, arising from the consumption of foods containing sulphites and benzoates.

2.3.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

This objective is not relevant to this Proposal.

2.3.2.3 The prevention of misleading or deceptive conduct

This objective is not relevant to this Proposal

2.3.3 Subsection 10(2) considerations

FSANZ has also had regard to the objectives set out in subsection 10(2) (as was in force prior to 1 July 2007):

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's risk assessment (SD1) was based on the best scientific evidence currently available.

- **the promotion of consistency between domestic and international food standards**

No change is proposed to the relevant standards.

- **the desirability of an efficient and internationally competitive food industry**

As no regulatory changes are proposed, there is no further cost impost on industry which could arise due to a need to alter practices to address safety concerns.

- **the promotion of fair trading in food**

Not relevant in relation to this matter.

- **any written policy guidelines formulated by the then Ministerial Council**

FSANZ has had regard to the Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals.

3 Rights of review

Under section 63 of the FSANZ Act (as was in force prior to 1 July 2007), the decision is not reviewable by the Administrative Appeals Tribunal.

4 References

FSANZ (2005). *21st Australian Total Diet Study* .http://www.foodstandards.gov.au/publications/Pages/21staustraliantotald2963.aspx. Accessed July 2013.

Cressey P and Jones S (2009). Levels of preservatives (sulfite, sorbate and benzoate) in New Zealand foods and estimated dietary exposure. *Food Addit Contam* **26**:614-613.

Til HP, Feron VJ and de Groot AP (1972). The toxicity of sulphite. I. Long-term feeding and multigeneration studies in rats. *Food and Cosmetics Toxicology* **10**: 291-310

Dalefield R and Mueller U (2016). Gastric Mucosal Irritation following Sodium Metabisulphite Exposure: A Reproducible Effect?. *Submitted.*

Til HP and Feron VJ (1992). "Toxicology of sulphiting agents. I: Animal studies." Food Addit Contam 9(5): 587-595.

FSANZ (2008). *Survey shows levels of sulphites in dried apricots has decreased since 2003*. Food Surveillance News, Spring 2008. http://www.foodstandards.gov.au/science/monitoring/surveillance/Pages/news/spring2008.aspx. Accessed July 2013

EFSA (2016) Scientific Opinion on the re-evaluation of sulfur dioxide (E 220), sodium sulfite (E 221), sodium bisulfite (E 222), sodium metabisulfite (E 223), potassium metabisulfite (E 224), calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228) as food additives. EFSA Journal 14(4): 4438