

INITIAL ASSESSMENT REPORT

APPLICATION A487

BROMATE LEVELS IN PACKAGED WATER

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
11 February 2004
(See 'Invitation for Public Submissions' for details)

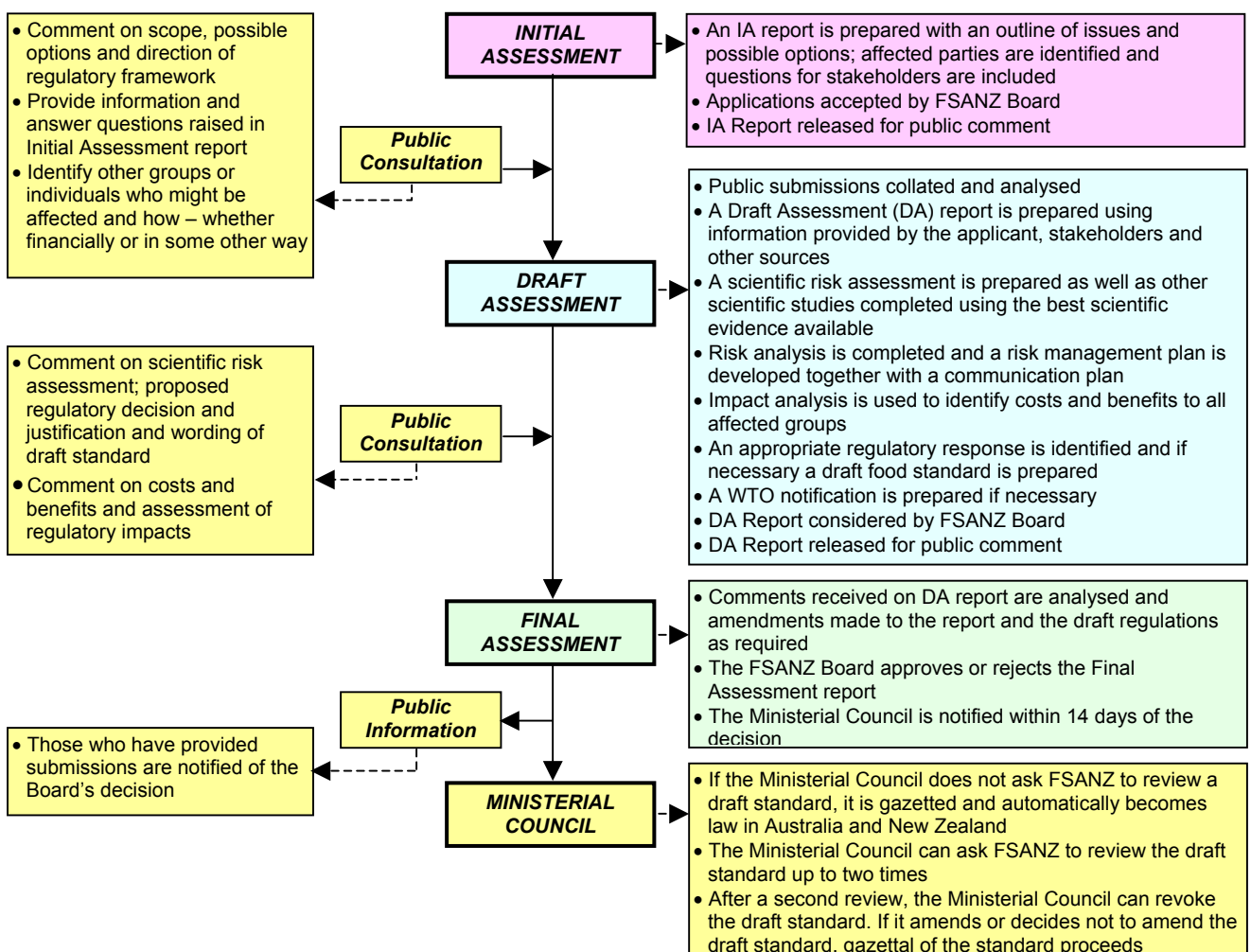
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Application A487, 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 Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat 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 should be received by FSANZ **by 11 FEBRUARY 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the 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 Liaison 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

FSANZ received an Application on 22 October 2002 from the Australasian Soft Drink Association Ltd (ASDA) to amend the *Australia New Zealand Food Standards Code* (the Code) to include a maximum limit for bromate in package water in Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks. Work commenced on this WorkGroup 2 Application on 13 October 2003.

The Applicant states that the purpose of the Application is to ensure public health and safety, by prescribing a maximum limit for bromate in packaged water. The safety of bromate has been reviewed by a number of international agencies and has been classified by the International Agency for Research on Cancer as a Group 2B (possible human) carcinogen.

This Initial Assessment Report is not a detailed assessment of the merits of the Application but rather an assessment of whether the Application should undergo further consideration according to criteria laid down in the FSANZ Act. This Application has been assessed against the requirements of section 13 of the FSANZ Act, and it is recommended that this Application be accepted and progressed to Draft Assessment for the following reasons:

- The Application seeks a maximum level for bromate in packaged water to ensure public health and safety.
- The composition of packaged water is contained in Standard 2.6.2 of the Code. There is currently no limit for bromate.
- Therefore, the Application relates to a matter that warrants a variation to Standard 2.6.2, if further assessment supports such a variation.
- The Application is not so similar to any previous application that it ought not be accepted.
- At this stage of the assessment, there is no reason to believe that costs arising from such a variation to impose a limit on bromate in packaged water would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- FSANZ believes a variation to limit bromate levels in packaged water is the only measure available to ensure public health and safety.

This Initial Assessment Report includes a summary of the information supplied in the Application with relevant issues identified so that interested parties can make submissions to assist in completing the assessment.

The composition of packaged water is regulated under clause 2 and specifically the Table to subclause 2(2) of Standard 2.6.2 of the Code. There is currently no maximum limit for bromate in this Table. The Applicant proposes a maximum limit of 0.02 mg/L for bromate in packaged water.

Bromate in packaged water can be formed by the action of ozone, used as a water disinfection agent, on the naturally occurring bromide found in water. Bromate is formed as a by-product of the commonly used water disinfection process.

Public submissions are now invited on this Initial Assessment Report. Comments of specific interest for this Application relate to the justification for the proposed limits, the appropriateness of the proposed limit, the possible costs to industry and issues such as the availability of methods of analysis to ensure compliance.

1. Introduction

FSANZ received an Application on 22 October 2002, from the Australasian Soft Drink Association Ltd (ASDA) to amend the Code to add a maximum limit for bromate in packaged water in Standard 2.6.2. Work commenced on this Application on 13 October 2003.

1.1 Nature of Application

The ASDA members are manufacturers and importers of water based non-alcoholic beverages and fruit juices. The stated purpose behind this Application is to ensure public health and safety, by providing limits on the bromate levels in packaged water. Bromate has been classified by International Agency for Cancer Research (IARC) as a Group 2B (possible human) carcinogen. International agencies and national governments have set maximum levels for bromate in various drinking water and packaged water standards or guidelines. The Australian National Health and Medical Research Council (NHMRC) set a guideline value of 0.02 mg/L for bromate in drinking water other than packaged water. This Application is to provide a requirement that packaged waters also comply with this level and to reassure consumers that bromate levels are regulated at a safe level.

2. Regulatory Problem

Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks of the Code deals with packaged waters and water-based beverages. Water-based beverages may contain food additives and in certain cases, nutritive substances. This Application relates specifically to packaged water. The composition of packaged water is covered by clause 2 of Standard 2.6.2. The Table to subclause 2(2) lists the substances that must not be contained in packaged water at greater than prescribed maximum levels. There is no entry for bromate in this Table.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to have a prescribed maximum concentration for bromate in packaged waters, and if so, what that maximum should be.

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 Historical Background

Ozonation (treatment of water with ozone, O₃) of packaged water is a very effective and common disinfection treatment. Ozone is a strong oxidant and disinfects water by oxidising and destroying water-borne pathogens. Naturally occurring bromide in the water can be converted (oxidised) to bromate by the action of ozone. Bromate is therefore formed as a by-product of a commonly used packaged water disinfection process.

There are various processes employed by packaged water bottlers (and drinking water authorities) to limit the formation and/or reduce the concentration of bromate in drinking water. A number of these are summarised below.

- Control and limit the ozone treatment which is used for water disinfection accurately so as to limit the oxidation of naturally occurring bromide to bromate.
- Reduce the concentrations of bromide by using reverse osmosis water treatment before ozonation. The reverse osmosis filtration units removes ions, such as bromide, from the water so reducing their concentration.
- Use activated carbon filters to remove bromate from ozone treated water, or to remove bromide before ozone treatment.
- Use alternative water disinfection treatments involving other agents such as chlorine or chlorine dioxide.

FSANZ requests further information about alternative water treatments to limit the bromate concentrations and whether there are problems with meeting the proposed limit.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 2 (level of complexity) and placed in Group 2 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Safety Considerations

The safety of bromate has been evaluated by the World Health Organisation (WHO)¹, the Joint FAO/WHO Expert Committee on Food Additives (JECFA)², the IARC³, the US Environmental Protection Agency (EPA)⁴ and Health Canada⁵.

The US EPA (2001) has classified bromate as B2 (probable human carcinogen) under the 1986 EPA Guidelines for Carcinogen Risk Assessment by the oral route of exposure on the basis of adequate evidence of carcinogenicity in male and female rats. The IARC evaluated potassium bromate in 1986 and again in 1999. In 1999, the IARC concluded that: there is inadequate evidence in humans for the carcinogenicity of potassium bromate; although there is sufficient evidence in experimental animals for the carcinogenicity of potassium bromate. Potassium bromate was classified as a Group 2B carcinogen, that is, possibly carcinogenic to humans. Health Canada (1999) has classified bromate as probably carcinogenic to humans (sufficient evidence in animals; no data in humans). Bromate is mutagenic both *in vitro* and *in vivo*. There is not sufficient evidence to conclude the mode of carcinogenic action for potassium bromate. JECFA concluded, on the basis of long-term toxicity and carcinogenicity studies and mutagenicity studies, that potassium bromate is a genotoxic carcinogen and it was recommended that the use of potassium bromate as a flour treatment agent is not acceptable.

Guidelines levels for bromate in drinking water have been determined based on safety studies and technological feasibility, i.e. available analytical and treatment methods. Specifically, either a no observable adverse effect level (NOAEL) or a lowest observable adverse effect level (LOAEL), is combined with an uncertainty factor (to account for inter- and intra-species variation and possible carcinogenicity) and an allocation of the contribution of drinking water (2L/day for a 60 kg person) as being 20% of the total daily intake, to estimate an acceptable value for bromate in drinking water.

The Application contains a “Final Range-Finding Report: Immunotoxicity of Sodium Bromate in female B6C3F1 Mice, undertaken by the US National Toxicology Program (NTP) (NTP Study number: IMM98004). This dose-range finding study was performed in order to establish the potential effects of sodium bromate on the immune system and to determine the doses that could be used in a full immunotoxicology study. Also summarised in the Application is a study of the short-term reproductive and developmental toxicity screen of sodium bromate on rats, Study number: RDGT94007 (NTIS# PB96-190640). No other safety studies have been provided.

The safety of bromate and the appropriateness of a maximum level of bromate in packaged water will be considered in more detail at Draft Assessment.

¹ WHO. World Health Organisation. Guidelines for Drinking Water Quality, 3rd edition, 2003, sourced from http://www.who.int/water_sanitation_health/dwq/guidelines3rd/en/; WHO. World Health Organisation. Environmental Health Criteria: 216 Disinfectants and Disinfectant by-products. World Health Organisation, Geneva. International Programme on Chemical Safety (IPCS), 2000.

² WHO. World Health Organisation. WHO Food Additive Series 18, 24 and 30.

³ IARC monographs (Volumes 40 and 73), sourced from <http://monographs.iarc.fr/htdocs/monographs>

⁴ U.S. EPA. Environmental Protection Agency, 2001. Toxicological review of bromate. In support of Integrated Risk Information System (IRIS). Washington, DC. Sourced from <http://www.epa.gov/iris/>

⁵ Sourced from: www.hc-sc.gc.ca/hecs-sesc/water/pdf/bromate.pdf

5.2 International Regulatory Standards

Relevant international regulations or guidelines for bromate in drinking and packaged water are listed below (some of which were provided by the Applicant).

- The International Bottled Water Association (IBWA) based in the USA has set a self-regulatory limit of 0.01 mg/L.
- The World Health Organization (WHO) have set a guideline value of 0.025 mg/L. However, this is under review and the proposed new guideline value is 0.01 mg/L.
- The US Environmental Protection Authority (EPA) set a maximum contaminant level of 0.01 mg/L for bromate in water.
- The UK Food Standards Agency is proposing to introduce new regulations on 25 December 2003 which will limit bromate levels in bottled water to 0.01 mg/L.
- Health Canada has set an interim maximum acceptable concentration for bromate in drinking water of 0.01 mg/L.

The 1996 Australian Drinking Water Guidelines set a limit for bromate in water of 0.02 mg/L and the Applicant is seeking the same limit for bottled water, while all aforementioned international guidelines or limits are (or are proposed to be) 0.01 mg/L.

5.3 Other Issues

There are no nutritional or dietary implications in this Application.

One issue that has been raised in the Application is that a number of water bottlers have questioned the ability of analytical laboratories to accurately determine the concentration of bromate in packaged water to the proposed maximum acceptable level of 0.02 mg/L.

The Applicant states that they support the current ion chromatography method employed by the Australian Government Analytical Laboratories (AGAL) to be able to perform this analysis down to the proposed maximum limit of 0.02 mg/L. The AGAL limit of reporting for their analytical method is 0.01 mg/L (which is the same level as some international guidelines or limits, as discussed above).

6. 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.

The following three regulatory options are available for this Application.

Option 1. Maintain the status quo and not require a maximum prescribed level for bromate in packaged water.

Option 2. Amend the Code to set a maximum permitted level of bromate for packaged water, as requested by the Applicant, and to set this as 0.02 mg/L.

Option 3. Amend the Code to set a maximum permitted level of bromate for packaged water and to set this as 0.01 mg/L, similar to other international authorities.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

- consumers of packaged water;
- manufacturers and importers of packaged water; and
- Australian Commonwealth, State, Territory and New Zealand government enforcement agencies.

7.2 Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

The regulatory impact of the proposed change will be assessed at Draft Assessment.

8. Consultation

8.1 Public Consultation

The Initial Assessment Report is not a detailed assessment of Application A487 but rather an assessment of whether the Application should undergo further consideration. FSANZ is seeking public comment in order to assist in assessing this Application at Draft Assessment. A further round of public comment will occur after the Draft Assessment Report is completed to assist in the Final Assessment.

FSANZ is seeking public comment to assist in assessing the Application. Comments on, but not limited to, the following would be useful.

- Is there agreement that there is a need to impose a maximum limit of bromate in packaged waters?
- Is the proposed limit the correct level?
- What are the likely costs and benefits to consumers in relation to public health and safety?

- What are the likely costs and benefits for industry to comply with this proposed amendment to the Code?
- Is the proposed maximum bromate limit a reasonable limit and are there any compliance issues for industry?
- Are there issues with respect to methods of analysis with being able to meet the proposed maximum bromate limit for industry and for enforcement agencies?

8.2 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.

There are relevant international standards and amending the Code to require a maximum level of bromate in packaged waters is unlikely to have a significant effect on international trade as there are already international guidelines and self-regulatory limits which are comparable if not lower. 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.

9. Conclusion and Recommendation

This Application has been assessed against the requirements of section 13 of the FSANZ Act and accepted for the following reasons:

- The Application seeks a maximum level for bromate in packaged water to ensure public health and safety.
- The composition of packaged water is contained in Standard 2.6.2 of the Code. There is currently no limit for bromate.
- Therefore, the Application relates to a matter that warrants a variation to Standard 2.6.2, if further assessment supports such a variation.
- The Application is not so similar to any previous application that it ought not be accepted.
- At this stage of the assessment, there is no reason to believe that costs arising from such a variation to impose a limit on bromate in packaged water would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- FSANZ believes a variation to limit bromate levels in packaged water is the only measure available to ensure public health and safety.

It is recommended that this Application now be progressed to Draft Assessment.