



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

19 March 2008
[4-08]

INITIAL ASSESSMENT REPORT

APPLICATION A588

VOLUNTARY ADDITION OF FLUORIDE TO PACKAGED WATER

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 30 April 2008

SUBMISSIONS RECEIVED AFTER THIS DEADLINE

WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd¹ (Australian Beverages) on 23 August 2006. The Application proposes an amendment to Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of fluoride to packaged water,² as a claimable nutrient. The Applicant is seeking permission to voluntarily add sodium fluoride and sodium fluorosilicate (also called sodium silicofluoride) to packaged water up to a maximum claimable amount of 1.5 mg fluoride/L. Given that this amount is greater than the current level of fluoridation in tap water in Australia and New Zealand (0.6-1.0 mg/L), the Assessment will consider the level of fluoride to be used by manufacturers.

Currently, the Code does not permit the voluntary addition of fluoride to packaged water nor a nutrient claim to be made on the presence of fluoride in packaged water. The Applicant advises that permission to voluntarily add fluoride to packaged water would enable bottlers to offer fluoridated packaged water to consumers as an alternative to fluoridated tap water,³ or as a source of fluoride for those who do not have access to fluoridated tap water.

The specific objectives of this Application are:

- to protect the public health and safety of consumers in relation to the proposed voluntary addition of fluoride to packaged water as an alternative to fluoridated tap water; and
- to provide consumers with adequate information to enable informed choice and to ensure that they are not misled concerning the voluntary addition of fluoride to packaged water.

Purpose of Paper

The purpose of this Initial Assessment Report is to: provide relevant information, including that supplied by the Applicant; to outline relevant issues necessary to evaluate the Application; and to assist in identifying affected parties.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (as was in force prior to 1 July 2007), FSANZ has decided to accept this Application for the following reasons:

- The Applicant seeks approval to permit the voluntary addition of fluoride to packaged water as an alternative to fluoridated tap water, and to allow bottlers to make nutrient claims.

¹ ABCL is an industry association representing the interests of water and juice based, non-alcoholic beverage manufacturers, distributors and franchisees and their suppliers.

² For the purposes of this Application, the term ‘packaged’ water will be used to describe water presented in packaged form including single serve (still or carbonated) or bulk ‘bottled’ water for coolers or dispensers.

³ Note: The term ‘fluoridated tap water’ refers to drinking water from fluoridated reticulated or municipal water supplies but not tank water.

- There is currently no permission in the Code to voluntarily add fluoride to packaged water as a claimable nutrient.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.3.2. that could achieve the same end.
- At this stage no other relevant matters are apparent.

FSANZ’s Proposed Approach to Assessment

In assessing this Application, FSANZ must have regard to Ministerial Council policy guidance, which details the conditions under which the voluntary addition of vitamins and minerals may be permitted. A copy of the Policy Guideline on *Fortification of Food with Vitamins and Minerals* (2006) is included at Attachment 1. FSANZ considers that this Application can be assessed on the basis of nutritional equivalence because fluoridated packaged water can be considered a substitute beverage for fluoridated tap water.

Regulatory Options

FSANZ is currently considering two options for addressing this Application:

Option 1 – Maintain status quo

Maintain the *status quo* by not amending the Code to allow the voluntary addition of fluoride to packaged water; and

Option 2 – Amend Standard 1.3.2 to permit the voluntary addition of fluoride to packaged water up to a maximum claimable amount of 1.5 mg/L

Option 2 would allow the voluntary addition of fluoride as a claimable nutrient to packaged water under Standard 1.3.2 of the Code, up to a maximum claimable amount of 1.5 mg/L.

FSANZ will undertake a full impact analysis at Draft Assessment; however preliminary consideration of the impacts of these two options is included under Section 14 of this Initial Assessment Report.

Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist the assessment of this Application and is particularly interested in receiving further information on the questions asked throughout this Report, which are also presented at Attachment 2.

Responses to this Initial Assessment Report will assist with the development of the next stage of the Application and preparation of a Draft Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment 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 of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act (the new FSANZ Act, as in place from 1 October 2007). 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 confidential commercial information. Section 114 of the new 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) 30 April 2008.

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 standards.management@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.

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd⁴ (Australian Beverages) on 23 August 2006. The Application seeks to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of fluoride to packaged water,⁵ as a claimable nutrient. The Applicant is requesting permission for sodium fluoride and sodium fluorosilicate (also called sodium silicofluoride) to be voluntarily added to packaged water⁶ up to a maximum claimable amount of 1.5 mg fluoride/L. The Application is supported by the Australasian Bottled Water Institute Inc. (ABWI).⁷

This Initial Assessment Report discusses the issues to be considered in the Application and seeks comments from stakeholders, particularly in relation to expected regulatory impact(s), to assist FSANZ in making an assessment of this Application.

1. Nature of the Application

1.1 Basis of the Application

The Applicant is requesting permission to allow the voluntary addition of fluoride to packaged water as a claimable nutrient up to a maximum claimable amount of 1.5 mg/L. The Applicant is also requesting a reference quantity of 600 ml, which equates to a maximum claimable amount of 0.9 mg fluoride per 600 ml reference quantity. This permission would provide an alternative for those who do not wish to drink fluoridated tap water but who still want to consume fluoridated water. It would also provide a source of fluoride for those who do not have access to fluoridated tap water.

The Applicant also seeks clarification of the labelling requirements for packaged water with added fluoride. Specifically, for such products to use statements such as ‘Premium spring water with added fluoride’ or ‘Mineral water plus fluoride’. Therefore, the Applicant requests consequential amendments to Standard 2.6.2 and Standard 1.1.1 and other such Standards as required.

The Applicant advises that peak public health and dental authorities, including the NSW Upper House Committee hearing into dental services in 2005,⁸ support the addition of fluoride to packaged water. They also advise that the packaged water industry has received an increasing number of calls from health professionals for packaged water to be fluoridated.

⁴ Australian Beverages Council Ltd is an industry association representing the interests of water and juice based, non-alcoholic beverage manufacturers, distributors and franchisees and their suppliers.

⁵ Note: The term ‘fluoridated tap water’ refers to drinking water from fluoridated reticulated or municipal water supplies but not tank water.

⁶ For the purposes of this Application, the term ‘packaged’ water will be used to describe water presented in packaged form including single serve (still or carbonated) or bulk ‘bottled’ water for coolers or dispensers.

⁷ ABWI represents the interests of packaged water fillers and their suppliers.

⁸ NSW Parliament Legislative Council Standing Committee on Social Issues (2006) Dental services in NSW: Standing Committee on Social Issues. Sydney. Available from [http://www.parliament.nsw.gov.au/prod/PARLMENT/Committee.nsf/0/4fa2d0149b588095ca25714200077d20/\\$FILE/FINAL-%20COMPILED%2030%20MARCH.pdf](http://www.parliament.nsw.gov.au/prod/PARLMENT/Committee.nsf/0/4fa2d0149b588095ca25714200077d20/$FILE/FINAL-%20COMPILED%2030%20MARCH.pdf).

The Australian Dental Association (ADA) has provided a letter in support of this Application. The ADA strongly supports the Application and considers this permission would assist to redress the increasing incidence of dental caries which it believes could be attributable to the increasing consumption of unfluoridated packaged water.

1.2 Scope of the Application

This Application only applies to ‘packaged water’. Although ‘packaged water’ is not specifically defined in the Code, the term is used to describe all water presented in packaged form. Examples of packaged water include:

- single serve ‘bottled’ water (carbonated or still); or
- bulk water for home/office water coolers or dispensers.

2. Background

2.1 Nutritional Role of Fluoride

Fluoride is a natural constituent of the body involved in the mineralisation of teeth and bones. Approximately 99% of the fluoride in the human body is bound to calcified tissues, especially in bone and teeth. Fluoride intake is a significant factor in the maintenance of dental health, as it not only maintains tooth integrity but prevents tooth deterioration. Because of its role in dental health, fluoride is considered an essential nutrient by the National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (NZMoH) (2006).⁹

In its review of chronic disease and diet, the World Health Organization states that there is convincing evidence that both locally applied (i.e. direct contact with teeth) and systemic fluoride (from fluoride that has been ingested) are preventive for dental caries.¹⁰

Because of the low natural level of fluoride in some water supplies and high levels of dental caries, many authorities world wide, including Australia and New Zealand, have permitted fluoridation of water supplies.⁹ The aim of water fluoridation is the adjustment of the natural fluoride concentration in fluoride-deficient water to that recommended for optimal dental health.

2.1.1 Nutrient Reference Values for Australia and New Zealand for Fluoride

The NHMRC and NZMoH (2006) have established nutrient reference values (NRVs) for a wide variety of nutrients for Australian and New Zealand populations. For fluoride, an Adequate Intake (AI)¹¹ and an Upper Level of Intake (UL)¹² have been set for various age groups (Table 1). The AI is used when an Estimated Average Requirement (EAR)¹³ cannot be determined.

⁹ NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Canberra, ACT.

¹⁰ World Health Organization (2003) *Diet, nutrition and the prevention of chronic disease*. WHO Technical Report Series 196. Report of a joint WHO/FAO Expert Consultation. WHO, Geneva.

¹¹ AI is defined as the average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.

Table 1: Fluoride NRVs for Australian and New Zealand Populations

Population Subgroup	Adequate Intake (mg/day)		Upper levels of intake (mg/day)	
	Males	Females	Males	Females
Infants 0-6 months	0.01		0.7	
Infants 7-12 months	0.5		0.9	
1-3 years	0.7		1.3	
4-8 years	1.0		2.2	
9-13 years	2.0		10.0	
14-18 years	3.0		10.0	
Adults 19+ years (including pregnant/lactating women)	4.0	3.0	10.0	10.0

These values have been determined on the basis of available epidemiological data. The Institute of Medicine in the USA established that populations with access to water fluoridation at 1.0 mg/L in the USA had the lowest incidence of caries and a mean fluoride intake from all sources of 0.05 mg/kg body weight/day.¹⁴ The NHMRC and NZMoH applied this value to Australian and New Zealand reference body weights for each population subgroup to obtain the AI values.¹⁵ For example, the reference body weight for adult men, 76 kg, was multiplied by 0.05 to yield a value of 3.8 mg which was rounded up to 4.0 as the AI. The UL for fluoride was set on the basis of moderate dental fluorosis.¹⁶

2.1.2 Fluoride Recommendations for Infants and Young Children

In addition to the 2006 NRV recommendations, the Australian *Infant Feeding Guidelines for Health Workers* (2003)¹⁷ also advocates that fluoride supplementation is not suitable for infants less than six months. However, for children aged from six months to two years who live in areas where the household water is not fluoridated, daily supplementation with 0.25 mg of fluoride may be recommended.¹⁸

¹² The UL is defined as the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

¹³ An EAR is defined as the daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group. The EAR is used to derive the Recommended Dietary Intake (RDI).

¹⁴ Institute of Medicine (IOM). *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride* (1997) Washington DC. Available from http://books.nap.edu/openbook.php?record_id=5776&page=R1.

¹⁵ NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Canberra, ACT.

¹⁶ Dental fluorosis is mottling of teeth due to over-exposure to fluoride.

¹⁷ NHMRC (2003) *Dietary Guidelines for Children and Adolescents in Australia incorporating the Infant Feeding Guidelines for Health Workers*. Available from http://www.nhmrc.gov.au/publications/synopses/_files/n34.pdf.

¹⁸ Recommendation was based on the National Research Council (1989) *Recommended Dietary Allowances 10th Edition* Washington DC. Recommendation existed before the development of the NHMRC NRVs for fluoride (AI for infants aged 7 months to 3 years is 0.5-0.7mg/day).

There are no similar recommendations relating to fluoride supplementation for infants and young children in New Zealand.

2.2 Sources of Fluoride

Fluoride is ubiquitous in the environment and consequently is a natural component of food and water, and is also present in particulate matter in the air. The major dietary source of fluoride is fluoridated water, and fluoridated water used in cooking or the manufacture of other foods and beverages. Some fish, e.g. canned sardines, contain fluoride. Most other foods appear to contain low levels of fluoride. Ingestion of fluoride may also occur by taking fluoride supplements and inadvertent ingestion can occur through the use of fluoridated toothpastes and other topical dental treatment products.

The concentration of fluoride in breast milk is low irrespective of whether the mother consumes fluoridated or unfluoridated water.¹⁹ Powdered infant formulas in Australia and New Zealand contain low levels of fluoride.^{19,20} The major source of fluoride in infant formulas is fluoridated water used to reconstitute the powdered formula.

2.2.1 Australian and New Zealand Water Supplies

Naturally-occurring fluoride levels in 'drinking water' vary, depending on the type of soil and rock through which water drains. Generally, concentrations in surface water are relatively low (0.1-0.5 mg/L)²¹ while water from deeper wells may have quite high fluoride concentrations (1-10 mg/L) if the rock formations are fluoride rich. In general, the naturally-occurring fluoride levels in 'drinking water' are very low (<0.1 mg/L).

2.2.1.1 Australia

Approximately 76% of Australians currently have access to fluoridated water supplies. The lowest coverage of fluoridation is in Queensland with less than 5% of the population having access to a fluoridated water supply. However, within two years, 80% of Queenslanders will have access to fluoridated water, increasing to more than 90% by 2012²². Nominal target fluoride levels vary according to climate and local water needs but the target fluoride concentration is between 0.7 to 1.0 mg/L.²³ To take account of higher water consumption in warmer climatic conditions, fluoridation levels are lower in hot and humid areas, e.g. Darwin, and higher in temperate zones, e.g. Hobart. Figure 1 highlights current access to fluoridated water in Australia. It is suggested that the optimal level of water fluoridation in Queensland is 0.6-0.7 mg/L.²⁴

¹⁹ Draft New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (aged 0-2)* (2007) Available from [http://www.moh.govt.nz/moh.nsf/pagesmh/6400/\\$File/food-nutrition-guidelines-infants-toddlers-consultation-draft-jun07.pdf](http://www.moh.govt.nz/moh.nsf/pagesmh/6400/$File/food-nutrition-guidelines-infants-toddlers-consultation-draft-jun07.pdf).

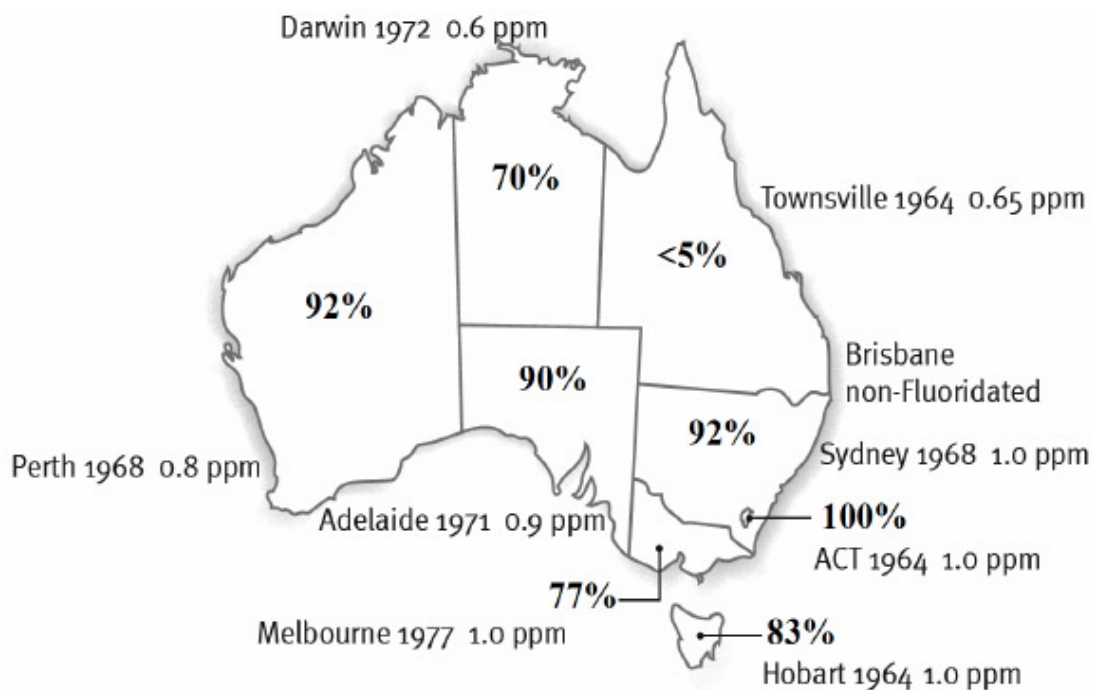
²⁰ Australian Research Centre for Population Oral Health, 2006. *The Use of Fluorides in Australia: guidelines*. *The Australian Dental Journal* 51 (2): 195–199.

²¹ NHMRC (2004) *Australian Drinking Water Guidelines*. NHMRC Canberra ACT. Available from http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf.

²² Ministerial Statement on water fluoridation. Available from <http://www.health.qld.gov.au/fluoride/default.asp>

²³ NHMRC (2004) *Australian Drinking Water Guidelines*. NHMRC Canberra ACT. Available from http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf.

²⁴ Australian Dental Association (Queensland Branch) Website on Fluoridation in Queensland: <http://www.fluoridationqld.com/index.htm>.



Source: Water fluoridation information for health professionals, State of Queensland, Queensland Health 2005.
 Percentages confirmed from personal communication with State/Territory offices in September 2007.

Figure 1: Dates of introduction of water fluoridation to Australian capital cities and percentage of the population in each State who have access to fluoridated water^{25,26}

The NHMRC review of the Efficacy and Safety of Fluoridation (2007)²⁷ recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis. The Australian Dental Association Policy Statement states that ‘water fluoridation continues to be the most cost-effective, equitable and safe means to provide protection from dental caries and has been successfully utilised in Australia for over 50 years’.

2.2.1.2 New Zealand

The New Zealand Ministry of Health has recommended fluoridation of water supplies since the 1950s as an effective and efficient way to prevent dental caries. The *Drinking-water standards for New Zealand 2005* recommends a fluoride level of 0.7–1 mg/L.²⁸

Approximately 89% of the New Zealand population has access to a community water supply of which approximately 58% receive fluoridated drinking water.²⁹ Therefore, approximately 52% of the New Zealand population has access to a fluoridated water supply.

²⁵ Fluoridation measured as ppm (parts per million), which is equivalent to mg/L.

²⁶ Fluoridation of South-east Queensland water supplies will commence in 2008 and more than 90% of Queenslanders will have access to fluoridated water by 2012.

²⁷ NHMRC (2007) Systematic Review of the Efficacy and Safety of Fluoridation. NHMRC, Canberra ACT Available from <http://www.nhmrc.gov.au/publications/synopses/eh41syn.htm>.

²⁸ Ministry of Health. *Drinking-water Standards for New Zealand 2005*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz>.

²⁹ Personal communication with Paul Prendergast, NZ Ministry of Health, January 2008.

Larger centres currently without fluoridated water supplies include Whangarei, Tauranga, Wanganui, Napier, Nelson, Blenheim, Christchurch, Timaru and Oamaru.

2.2.2 *Fluoride Content of Packaged Water*

Water from different sources (unfluoridated spring and fluoridated or unfluoridated municipal water supplies) is used to manufacture still water, carbonated mineral water and other packaged water products in Australia. Industry data from two large Australian beverage manufacturers indicates that the current level of fluoride in packaged water products ranges from <0.1-1.1 mg/L.

3. **Current Standards**

3.1 **Domestic Regulations**

3.1.1 *Australia and New Zealand*

Standards in the Code relevant to consideration of this Application include:

Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions sets out preliminary provisions which apply generally to the Code. Clause 9 of Standard 1.1.1 prohibits the addition of nutritive substances to food unless expressly permitted in the Code. The Schedule to Standard 1.1.1 lists the permitted forms, recommended dietary intakes (RDIs) or estimated safe and adequate daily dietary intakes (ESADDIs) for vitamins and minerals that may be added to foods. There is currently no RDI or ESADDI for fluoride in Standard 1.1.1.

Standard 1.3.2 – Vitamins and Minerals regulates the addition of vitamins and minerals to foods generally, as well as claims that can be made about the vitamin and mineral content of foods. Currently, Standard 1.3.2 permits the voluntary addition of a range of vitamins and minerals to certain foods such as breakfast cereals, most dairy products, some biscuits, fruit and vegetable juices/drinks, and soups. However, there is no permission for the voluntary addition of fluoride to any food or drink.

Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks regulates packaged water and water-based beverages which contain food additives and in certain cases, nutritive substances. The Standard sets the compositional requirements for packaged water and defines mineral water and spring water.³⁰ Packaged water may contain added carbon dioxide. The Table to subclause 2 (2) of Standard 2.6.2 provides maximum limits on the presence of certain substances in packaged water, including fluoride.

Standard 1.2.2 – Food Identification Requirements specifies the information which must be included on the label to identify the food in question.

The label on a package of food must include –

- (a) *the prescribed name of the food, where the name of a food is declared in this Code to be a prescribed name; and*

³⁰ *Mineral water or spring water means ground water obtained from subterranean water-bearing strata that, in its natural state, contains soluble matter.*

- (b) *in any other case, a name or a description of the food sufficient to indicate the true nature of the food.*

Other labelling standards which may be affected include: Standards 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, 1.2.4 – Labelling of Ingredients and 1.2.8 – Nutrition Information Requirements. These are discussed under Section 12 of this Report.

Standard 1.3.3 – Processing Aids includes permitted processing aids used in packaged water and in water used as an ingredient in other foods. The Table to clause 11 specifies that the maximum permitted amount of sodium fluoride or sodium fluorosilicate (sodium silicofluoride) that may be present in packaged water or in water used in manufacturing is 1.5 mg/kg³¹ (1.5 mg/L).

Standard 2.9.1 – Infant Formula Products regulates the compositional, and labelling requirements for infant formula products. Clause 19 of the Standard specifies the level of fluoride in powdered and concentrated infant formulas and ‘ready to drink’ products which triggers a labelling statement on the product advising its potential to cause dental fluorosis. The label also recommends that the risk be discussed with a medical practitioner or other health professional.

3.2 Overseas and International Regulations

Currently, the regulation of packaged water differs between countries in Europe, Asia and the US. While some countries have separate standards for mineral or spring water and other packaged water, other countries including Australia and New Zealand, do not differentiate between different types of packaged water. Many countries do not have specific legislation for the *addition* of fluoride to packaged water and simply have a limit on *total* fluoride which includes natural and added fluoride. Generally, the range of fluoride permitted in packaged water is 1.0 to 2.0 mg/L, although permitted levels of naturally occurring fluoride in some natural mineral water may be as high as 5 mg/L in some countries.

3.2.1 Codex Alimentarius

Codex has separate standards for natural mineral water and other packaged water. Natural mineral water is defined as ‘a water clearly distinguishable from ordinary drinking water because it is characterised by its content of certain mineral salts and their relative proportions and the presence of trace elements or of other constituents’.³² The addition of fluoride to natural mineral water is not permitted. If the product contains more than 1 mg/L of fluoride then the label should state ‘contains fluoride’. If the product contains more than 2 mg/L fluoride the label should state: ‘The product is not suitable for infants and children under the age of seven years’.

³¹ Note that mg/L is equivalent to ml/L.

³² CODEX STAN 108-1981, Rev-1997, Amend.2001) is available from http://www.codexalimentarius.net/download/standards/223/CXS_108e.pdf.

At its recent meeting, the Codex Committee on Natural Mineral Water reviewed the Natural Mineral Water Standard to consider aligning the limits for certain health-related substances, including fluoride, with the revised WHO *Guidelines for Drinking-water Quality*.³³ The WHO recommended Guideline Value for naturally occurring fluoride in drinking water is 1.5 mg/L. The Committee agreed at step 5/8 of the standards development process to: not set a maximum limit for fluoride in natural mineral water as per the current Standard; retain current labelling provisions where products with more than 1 mg/L of fluoride are labelled 'contains fluoride'; and amend the labelling provisions to require products with more than 1.5 mg/L to be labelled as 'not suitable for children under seven years'.³⁴ This new threshold, which has been reduced from the previous level of 2 mg/L, aligns with the WHO Guideline Value.

The Codex standard for bottled/package water (other than natural mineral water) describes packaged water as 'waters for human consumption and may contain minerals, naturally occurring or intentionally added, and may contain carbon dioxide, naturally occurring or added, but shall not contain sugars, sweeteners, flavourings or other foodstuffs'.³⁵ Under this standard, all packaged water must comply with the health related requirements in the WHO *Guidelines for Drinking-water Quality*. The addition of minerals to water before packaging must comply with the provisions in this and other Codex standards related to food additives and essential nutrients.

3.2.2 European Commission (EC)

Most European countries have regulations that align with the European Union (EU) Commission Directive³⁶ which establishes the list of constituents, concentration limits and labelling requirements for natural mineral water. The Directive states that the constituents must be naturally occurring and may not result from contamination at the source. If the fluoride content is above 1.5 mg/L, the label must state 'contains more than 1.5 mg/L of fluoride: not suitable for regular consumption by infants and children under 7 years of age'. The actual fluoride content must also be included on the label. The maximum permissible level of naturally occurring fluoride in natural mineral water is 5 mg/L.

The European Commission Directive 98/83/EC of 3 November 1998³⁷ regulates the quality of water intended for human consumption (other than natural mineral water), including water for sale in bottles or containers. The permitted level of fluoride specified in Annexe 1 of the Directive is 1.5 mg/L, which is based on the WHO *Guidelines for Drinking-Water Quality*. While the Directive permits the addition of fluoride to water for sale in packaged form, the permitted level of addition is regulated by individual European Commission members.³⁸

³³ WHO 2006. Guidelines for drinking-water quality [electronic resource]: incorporating first addendum. Vol. 1, Recommendations. – 3rd ed. Available at http://www.who.int/water_sanitation_health/dwq/gdwq3rev/en/index.html.

³⁴ Codex Committee on Natural Mineral Waters. February 2008 Report of the Eighth Session of the Codex Committee on Natural Mineral Waters (Alinorm 08/31/20).

³⁵ CODEX STAN 227-2001 is available from http://www.codexalimentarius.net/download/standards/369/CXS_227e.pdf.

³⁶ Commission Directive 2003/40/EC of 16 May 2003 which is available from http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_126/l_12620030522en00340039.pdf.

³⁷ Available from <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1998/L/01998L0083-20031120-en.pdf>

³⁸ Personal communication from Mr Jean-François Roche, Administrator, Health and Consumer Protection Directorate General, European Commission.

3.2.3 *United States of America (US)*

In the US, packaged water is regulated by the US Food and Drug Administration (USFDA) in accordance with the Code of Federal Regulations.³⁹ The Code defines different types of packaged water such as ‘spring water’ and ‘mineral water’. No minerals, including fluoride, may be added to packaged water defined as ‘mineral water’. Fluoride concentration ranging from 1.4 to 2.4 mg/L (temperature dependent) is permitted for **naturally occurring fluoride** and the fluoride content need not be indicated on the label. A maximum concentration of 1.4 mg/L of naturally occurring fluoride is permitted in imported packaged water with no fluoride added.

The USFDA has set limits between 0.8 and 1.7 mg/L for **added fluoride** dependent on the annual average maximum daily temperatures of the locality where the packaged water will be sold. The fluoride concentration for imported bottled water with added fluoride must be less than 0.8 mg/L.

3.2.4 *Canada*

Canada’s Food and Drugs legislation⁴⁰ makes a regulatory distinction between mineral water, spring water and bottled water. Fluoride is a permitted addition to mineral water and spring water provided that the total fluoride concentration does not exceed 1 part per million (1.0 mg/L). The principal display panel of the label must state that fluoride has been added and the total fluoride content. For other bottled water and packaged ice, bottlers must state the total fluoride content on the principal display panel of the label. Mineral water, spring water and other bottled water must also list any added fluoride as an ingredient.

3.2.5 *Other Countries*

The Applicant has advised that the requested maximum claimable level of fluoride in packaged water (1.5 mg/L) is consistent with the drinking water guidelines set by the WHO and a number of other countries including Malaysia, Vietnam and India. They also noted that Singapore, China, Malaysia and India have adopted a limit of 2 mg/L of fluoride in natural mineral water.

3.3 **Interrelationships with other FSANZ Work**

3.3.1 *Application A611 – Unfluoridated and Fluoridated Water Labelling*

Application A611 is seeking to amend labelling requirements in Standard 1.2.4 of the Code for packaged foods containing water as an ingredient. It is proposed that water when used as an ingredient is labelled to indicate whether it is unfluoridated (UF) or artificially fluoridated (AF). This Application has been included on the FSANZ Work Plan with commencement of the assessment process due in late 2008.

³⁹ Code of Federal Regulations (CFR165.110) Available from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=165>.

⁴⁰ Food and Drugs Act (R.S., 1985, c. F-27) Part B Division 12 Prepackaged water and ice. Available from http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/fda-lad/index_e.html.

3.3.2 *Proposal P293 – Nutrition, Health and Related Claims*

The regulation of nutrition, health and related claims is being reviewed as part of Proposal P293 - Nutrition, Health and Related Claims. The proposed Standard 1.2.7 sets out the criteria and conditions for making content claims, health claims and related claims. Until such time as Proposal P293 is finalised, the existing requirements of the Code would apply to all foods, including, if approved, fluoridated packaged water.

Proposal P293 is expected to be notified to the Ministerial Council by mid 2008. If no review is requested, the Standard would be gazetted soon after. There will be a transition period before the Standard comes into effect.

3.3.3 *Consideration of Revised 2006 Nutrient Reference Values for Australia and New Zealand in the Code*

There is currently no reference value for fluoride in the Code. If permission is given for the voluntary addition of fluoride to packaged water, FSANZ will consider an appropriate reference value for fluoride in Standard 1.1.1. In response to the release of the revised Nutrient Reference Values (NRVs),⁴¹ FSANZ is currently undertaking a scoping exercise to determine how best to incorporate the revised values into the Code. Consideration of a suitable reference value for fluoride for the purposes of this Application will precede FSANZ's consideration more broadly of the incorporation of the revised NRVs into the Code.

4. Current Market

4.1 Domestic Market

4.1.1 Australia

The Food Magazine E-Newsletter reports that the packaged water segment⁴² is one of the fastest growing sectors within Australia's beverage industry with a 12% increase in revenue during 2006-2007 totalling \$627 million.⁴³ This represents approximately 5% of Australia's total beverage manufacturing revenue.

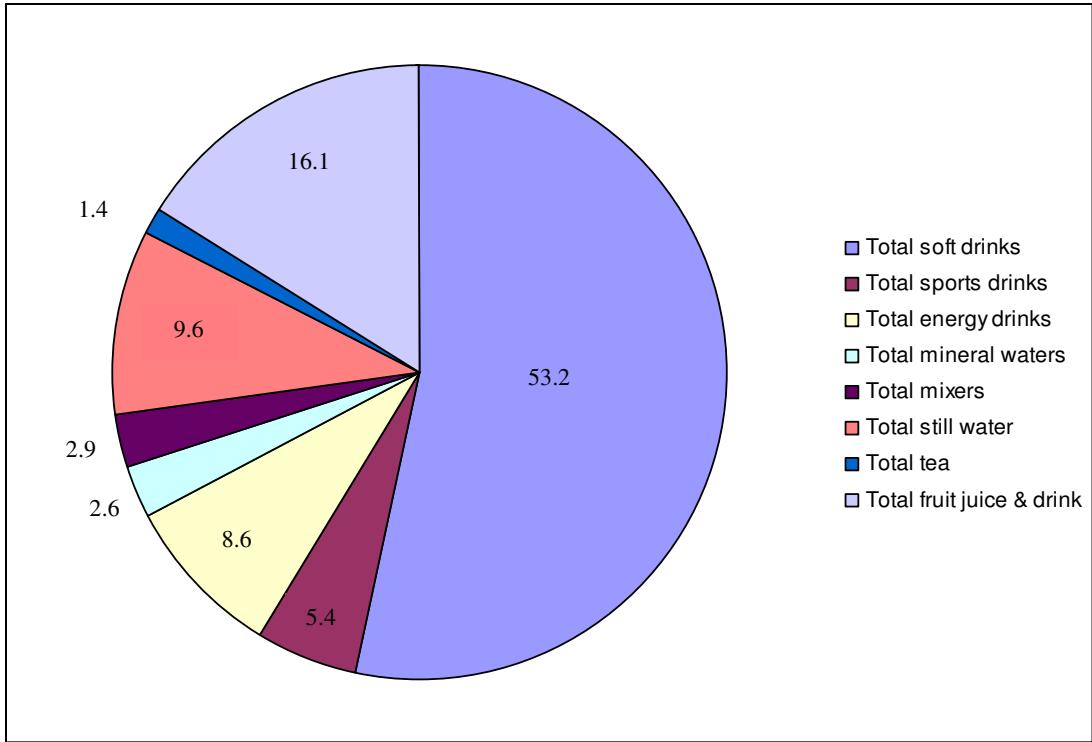
According to ACNielsen Australia Scan Track data published in the Australian Beverages YearBook 2007,⁴⁴ still water sales are growing at a faster rate than carbonated mineral water. As shown in the Figure 2 on the following page, still water constitutes 9.6% of the non-alcoholic ready-to-drink (NARTD) market while mineral water makes up 2.6%, a total of 12.2% for both still water and mineral water.

⁴¹ NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Canberra, ACT.

⁴² Includes natural spring water and purified water.

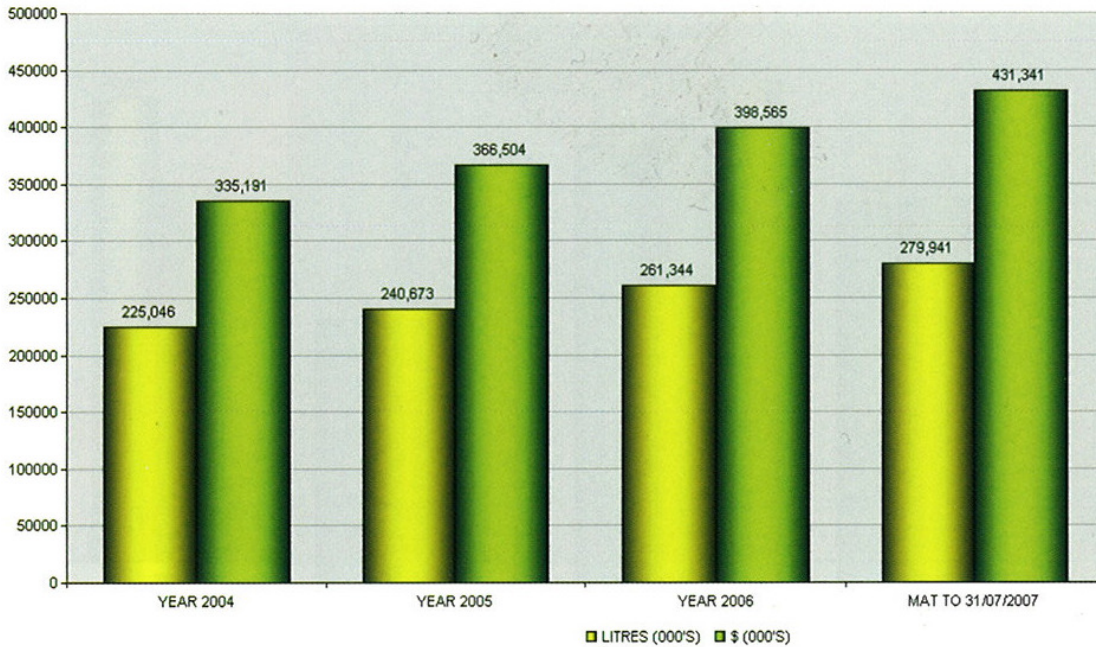
⁴³ Johnson, C. Industry update: future looks bright for bottled water. Food Magazine Weekly e newsletter. Available from Food Magazine website: http://www.foodmag.com.au/articles/Industry-update-future-looks-bright-for-bottled-water_z72492.htm.

⁴⁴ Australian Beverages and ABWI (2007) *Australian Beverages YearBook 2007* Melbourne, Vic.



Source: ACNielsen Australia Scan Track

Figure 2: Market Share of Non-alcoholic Ready to Drink Products in Australia (% Sales for 2007)



Source: ACNielsen Australia Scan Track

Figure 3: Still Water Market in Australia (Volume and Sales 2004-2007)

As shown in Figure 3 above, the still water market has grown consistently since 2004. Sales grew by 9.3% from 2004 to 2005 and by 8.7% from 2005 to 2006. At the same time the value of still water sales grew by 6.9% from 2004 to 2005, and by 8.6% from 2005 to 2006.

Sales of still water increased by 12.3% in 2007. In comparison, following a 7.6% increase from 2004 to 2005, the sales of carbonated mineral water remained steady until 2006. Sales of total mineral water increased by 4.8% in 2007.

4.1.2 New Zealand

Packaged water generated retail sales totalling \$NZ136m in 2007.⁴⁵ Industry data⁴⁶ show that total packaged water sales increased by 9.4% in 2007. Still water sales increased by 9%, while carbonated mineral water increased by 10.9%. This compares with carbonated soft drinks which increased by 4% in the same period.

Total water accounted for 9.4% of NARTD market in 2007. Still water constitutes 7.8% of the NARTD market while carbonated mineral water is 1.6%. Still water has shown growth over the last 3 years, with an increase of 22.7% from 2004 to 2005, slowing to 3.6% in 2006 and then 9.0% in 2007. Carbonated mineral water increased by 57.7% in 2005, 13.3% in 2006 and 10.9% in 2007.

4.2 US Market

The Applicant is unaware of any definitive survey on overseas consumption patterns of fluoridated packaged water. They advise that around 10% of current brands of bottled water available in the US have added fluoride.⁴⁷

In 2003, packaged water was the second largest commercial beverage category by volume in the US in 2003 and has continued to grow in 2006. This growth rate is occurring globally. In 2006, total US volume of packaged water exceeded 31.23 billion litres, an increase of 9.5% over the 2005 level. That equates to an average of 104.5 litres per person, which means apart from carbonated soft drinks, US consumers drink more bottled water annually than any other beverage.⁴⁸

4.3 Future Market Share Predictions

The Applicant has advised that if permission was approved for the voluntary addition of fluoride to packaged water, they would expect a small range of fluoridated products with limited impact on market shares. They suggest that fluoridated packaged water could amount to up to 10% of the total packaged water sales within 5 years of introduction of these products.⁴⁹

5. Ministerial Policy Guidance

The Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) endorsed a Policy Guideline *Fortification of Foods with Vitamins and Minerals* (the Policy Guideline) in May 2004.

⁴⁵ Source: Personal communication Vincent Meron, Technical Director, Frucor Beverages Limited.

⁴⁶ Personal Communication: based on AC Nielsen Scan Track Data (total supermarkets and service stations two year trading), February 2008.

⁴⁷ Informal figures from the IBWA provided in the Application.

⁴⁸ Adapted from the Beverage Marketing Corporation's 2007 Market Report Findings. Available from the IBWA website: http://www.bottledwater.org/public/BWFactsHome_main.htm

⁴⁹ Based on an assessment of current market patterns by the ABWI.

This Policy Guideline provides guidance on the addition of vitamins and minerals to food for both mandatory and voluntary fortification. In considering permissions for voluntary fortification, FSANZ must have regard to this policy guidance. The Policy Guideline is at Attachment 1.

The Policy Guideline provides ‘High Order’ as well as ‘Specific Order’ Policy Principles and additional policy guidance for voluntary fortification. The ‘High Order’ Policy Principles reflect FSANZ’s statutory objectives (see Section 7 of this Report) and therefore take precedence over the ‘Specific Order’ Policy Principles. The ‘Specific Order’ Policy Principles for voluntary fortification include certain conditions for which the voluntary addition of vitamins and minerals may be permitted.

5.1 FSANZ’s Fortification Implementation Framework

FSANZ’s *Fortification Implementation Framework – Addition of Vitamins and Minerals to Food* (2005)⁵⁰ (the Framework) was developed to provide a context for the work of FSANZ concerning the fortification of food with vitamins and minerals. The main function of the Framework is to provide guidance to FSANZ regarding assessment of the addition of vitamins and minerals to food for inclusion in the Code. In relation to voluntary fortification, the Framework provides direction on the assessment of the proposed fortification in relation to the relevant Ministerial Policy Principles.

Consideration of this Application with reference to the Policy Guideline and the Framework is discussed further in Section 8 of this Report.

6. The Issue

The Applicant is requesting permission to allow the voluntary addition of fluoride to packaged water as an alternative to fluoridated tap water and as a source of fluoride for those individuals who do not have access to fluoridated water.

However, in facilitating this choice, consumers will be unable to discern whether the addition of fluoride to packaged water is safe and nutritionally equivalent to currently available water sources of fluoride. Hence there is a role for FSANZ to: identify any risks associated with the voluntary addition of fluoride to packaged water as an alternative to fluoridated water; provide a regulatory mechanism for industry to provide fluoridated packaged water as an alternative to fluoridated tap water; and to ensure consumers are provided with adequate information to make informed choices. In addressing this problem, FSANZ will assess whether fluoridated packaged water can substitute for fluoridated tap water without compromising public health and safety.

7. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;

⁵⁰ FSANZ’s *Fortification Implementation Framework - Addition of Vitamins and Minerals to Food* (2005) Available from FSANZ on request.

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

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

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

The specific objectives of this Application are to:

- protect the public health and safety of consumers in relation to the proposed voluntary addition of fluoride to packaged water as an alternative to fluoridated tap water; and
- provide consumers with adequate information to enable informed choice and to ensure that they are not misled concerning the voluntary addition of fluoride to packaged water.

8. FSANZ's Approach to Assessment

As previously stated in Section 5 of this Report, FSANZ must have regard to ministerial policy guidance. The Policy Guideline sets out five specific conditions when voluntary fortification may be permitted. The following three conditions are relevant and could apply to this Application:

- *The voluntary addition of vitamins and minerals to food should be permitted only:*
 - *where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake;*
 - OR*
 - *where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit;*
 - OR*
 - *to enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).*

FSANZ considers that this Application can be assessed on the basis of nutritional equivalence (the third option) because fluoridated packaged water can be considered a substitute beverage for fluoridated tap water.

The Ministerial Policy Guideline does not explicitly define ‘substitute food’ (or beverage) or ‘nutritional equivalence’. FSANZ has defined a substitute food in the *Fortification Implementation Framework* as ‘a food which is designed to resemble a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles (i.e. reference food)’. This definition is based on the definition of a substitute food in the Codex General Principles.⁵¹ FSANZ considers fluoridated packaged water to be a substitute beverage in terms of appearance and use and that it is nutritionally equivalent to fluoridated tap water, although both of this issue will be explored further at Draft Assessment.

FSANZ considers fluoride deficiency at a population level is unlikely due to the prevalence of fluoridated tap water in Australia and New Zealand. In terms of inadequate intakes, the prevalence of dental caries, particularly in children, is used as a crude indicator of low levels of fluoride intake, however the use of fluoridated toothpaste, through its topical action, diet and dental hygiene also influence dental caries experience, thus diluting the contribution of fluoride intake from drinking water to dental health. While FSANZ acknowledges an increase in the prevalence of dental caries, it is difficult to attribute this to the increase in sales of packaged water.

While the benefit of fluoride to dental health is well established, if fluoridated packaged water is considered to be nutritionally equivalent to fluoridated tap water, then both beverages will provide similar health benefits.

Question for Submitters:

Do you agree with FSANZ’s approach to assessment based on nutritional equivalence?

9. Key Assessment Questions

The key assessment questions at Initial Assessment have been developed to address whether fluoridated packaged water is nutritionally equivalent to fluoridated tap water, and could therefore be used as a substitute food (or beverage, in this case). In keeping with FSANZ’s primary objectives, issues of safety will also be addressed.

The key assessment questions at Initial Assessment are:

- What is the history of safe use of fluoridated water?
- Is packaged water with added fluoride nutritionally equivalent to fluoridated tap water?
- Do consumers substitute packaged water for tap water?
- Is there any evidence that the substitution of fluoridated packaged water for fluoridated tap water is likely to pose a risk to any vulnerable groups e.g. infants and young children?
- What impact would permission to allow the voluntary addition of fluoride to packaged water have on the fluoride intakes of Australian and New Zealand populations?

⁵¹ Codex General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 09-1987 is available from http://www.codexalimentarius.net/download/standards/299/CXG_009e.pdf.

- Are there any technological issues related to the addition of sodium fluoride or sodium fluorosilicate to packaged water compared with their use in the fluoridation of water supplies?

RISK ASSESSMENT

10. Risk Assessment Issues

The risk assessment will consider the information provided by the Applicant in relation to risk assessment issues but will also have regard to other available information, including from the scientific literature, general technical information, from independent scientists, from other regulatory agencies and international bodies, and the general community. If required, FSANZ will seek additional information from the Applicant as well as medical and dental health experts.

10.1 History of safe use

Fluoridation of water supplies to reduce the incidence of dental caries has been utilised in Australia, New Zealand and other overseas countries for over 50 years. The Applicant cites support for water fluoridation as a safe and effective public health measure from an extensive list of authoritative bodies including the Australian Dental Association, the US Centers for Disease Control and Prevention, the World Health Organization, and the National Health and Medical Research Council. FSANZ concurs with these statements that there is a history of safe use of fluoride in municipal⁵² water supplies in Australia, New Zealand and overseas. Thus, a comprehensive safety assessment will not be undertaken but further information about the history of safe use will be provided at Draft Assessment.

10.2 Nutritional Equivalence

FSANZ will assess the nutritional equivalence of packaged water with added fluoride and fluoridated tap water.

The Applicant has indicated that the forms of fluoride proposed to be added to packaged water are the same as those added to fluoridated tap water. The bioavailability of these forms will be briefly described. Technological issues that may potentially affect their equivalent status will be discussed in food technology considerations (see Section 11). Similarities in nutrient content between packaged water and tap water in Australia and New Zealand, whether fluoridated or not, will be described to assess their comparability as equivalent beverages; in particular, whether the contribution to the diet of other minerals in water would be affected by substituting tap water with packaged water.

10.3 Dietary Intake Assessment Approach

As this Application is being assessed on the basis of nutritional equivalence a restricted dietary intake assessment will be undertaken by FSANZ at Draft Assessment. The focus will be on estimating if any population group, including infants fed infant formula reconstituted with fluoridated packaged water, is likely to exceed the UL for fluoride if they consume only packaged water with added fluoride at the maximum claimable amount of 1.5 mg/L.

⁵² Municipal water includes reticulated water and piped mains water supplies.

This will be the first time that FSANZ has estimated fluoride intakes from the total diet for Australia and New Zealand. Therefore, estimates of baseline fluoride intakes will be presented for Australian and New Zealand population groups. In order to conduct the dietary intake assessment, FSANZ will gather the relevant information on food consumption patterns, fluoride composition data for foods and beverages, and other relevant information as required.

10.4 Summary of Proposed Approach to the Risk Assessment

The objective of the risk assessment for this Application is to fully describe the history of safe use of fluoridated water and to establish if fluoridated packaged water is nutritionally equivalent to fluoridated tap water. A restricted dietary intake assessment will be undertaken to compare fluoride intakes against the UL, in particular complete substitution of fluoridated tap water with fluoridated packaged water.

If nutritional equivalence is not established at Draft Assessment, FSANZ will review the Ministerial Council's Policy Guideline to determine the appropriate approach to risk assessment.

11. Food Technology Considerations

Although there is a previous history of use of sodium fluoride and sodium fluorosilicate in the fluoridation of water supplies, FSANZ will consider any technological issues related to the addition of these forms of fluoride to packaged water.

11.1 Analytical Procedures

The Applicant has advised FSANZ that regulatory authorities use standard laboratory methodology to test the level of fluoride in packaged water. Australian Bottled Water Industry members currently test fluoride levels to ensure compliance with the maximum limit for naturally occurring fluoride specified in Standard 2.6.2. FSANZ understands that Australian laboratories are equipped to conduct these tests for a reasonable cost.

11.2 Manufacturing Process

The Applicant has advised that Australian manufacturers of packaged water currently implement good manufacturing practices which are subject to a number of third party audits and local health authority inspections to ensure that procedures and processes are in accordance with maximum limits set for health and safety and quality control purposes. Accuracy and confidence in the final product will be assured through regular quality control activities combined with external audits to validate the testing procedure.

RISK MANAGEMENT

12. Risk Management Issues

The following sections discuss issues relevant to the regulation of fluoridated packaged water. FSANZ will consider any other identified risks at Draft Assessment. Submitter comments received during the public consultation period will also be considered at Draft Assessment.

12.1 Permission to Fortify as a Substitute Food

The addition of fluoride to packaged water is not currently permitted under Standard 1.3.2, which regulates the addition of vitamins and minerals to foods. Fluoride is not listed as a nutrient in the Schedule to Standard 1.1.1 – Preliminary Provisions and there are no permitted forms of fluoride included.

The Applicant is seeking permission to voluntarily add fluoride to packaged water up to a maximum claimable amount of 1.5 mg/L which reflects the *Australian Drinking Water Guidelines*.⁵³ However, current levels of water fluoridation in Australia range between 0.6 and 1.0 mg/L. The maximum claimable amount relates to the maximum amount of naturally occurring and added quantity of the vitamin or mineral which can be claimed for a reference quantity of the specified food (or beverage).⁵⁴ However, the manufacturer may choose to add a lower level of fluoride to packaged water.

The Applicant has requested a reference quantity of 600 mL for packaged water, which is consistent with the most popular still water pack size sold through grocery, route and convenience stores.⁵⁵ If permission is given to permit the voluntary addition of fluoride up to a maximum claimable amount of 1.5 mg /L, this is equivalent to a maximum claimable amount of 0.9 mg fluoride per 600 ml reference quantity.

As part of the Assessment, FSANZ will consider whether fluoridated packaged water is an appropriate substitute for fluoridated tap water, and any issues raised by submitters regarding inclusion of fluoride as a nutrient in the Code and permitted forms of fluoride will also be addressed. FSANZ will also consider an appropriate reference quantity for packaged water.

Question for Submitters:

Do you consider 1.5 mg/L to be an appropriate maximum claimable amount for the voluntary addition of fluoride to packaged water?

12.2 Patterns of Consumption

12.2.1 Consumption Patterns of Packaged Water

There are limited population data available on consumption patterns of packaged water products, and fluoridated tap water in Australia and New Zealand. The available evidence for consumption of these waters in Australia is reported below.

A recent Australian study⁵⁶ found that household purchase patterns of non-alcoholic water-based beverages in Australia has increased, with more water-based beverages being purchased from 1997 until 2006, in particular packaged water and non-sugar carbonated soft drinks (CSDs). A key year for this change in trend was 2002 which observed marked decreased sales of sugar-sweetened CSDs.

⁵³ NHMRC (2004) *Australian Drinking Water Guidelines*. NHMRC Canberra ACT. Available from http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf.

⁵⁴ Reference quantity as defined in the Standard 1.3.2 of the Code. Available from: http://www.foodstandards.gov.au/srcfiles/Standard_1_3_2_Vits_&_Mins_v95.pdf.

⁵⁵ Australian Beverages and ABWI (2007) *Australian Beverages YearBook 2007* Melbourne, Vic.

⁵⁶ Levy, G & Tapsell, L. (2007). Shifts in purchasing patterns of non-alcoholic water-based beverages in Australia, 1997-2006. *Nutrition and Dietetics*, 64, 268-279.

The number of still packaged water drinkers has increased from 2004 to 2006 for each gender across most age groups; more females drink still packaged water than males, and more young people drink this water compared to older people.

In support of this, consumer research conducted on behalf of the Australasian Bottled Water Institute revealed that people of different ages and occupations consume packaged water across Australia, with the majority being younger single people and younger couples, particularly females aged between 14 and 35 years. This research also found that the consumption of packaged water was tied to health, wellbeing and social trend motivations.⁵⁷

A recent study of Australian children aged between 6 and 13 years demonstrated an increase in the proportion of children drinking packaged water (43%) compared to two years ago. However, these children reported drinking tap or dispenser water the majority of time (80%), even if consuming packaged water in addition to, or as a replacement for, a drinking occasion.⁵⁸

FSANZ is unaware of consumer research on consumption patterns of non-alcoholic water-based beverages in New Zealand.

12.2.2 Proposed Target Market

The Applicant has advised that fluoridated packaged water will be targeted to, and consumed by a niche market as an alternative to fluoridated tap water. The identified target groups for these beverages are:

1. Consumers who do not have fluoride added to their tap water, and
2. Consumers who do not like the taste of their tap water but still wish to consume fluoridated water.

12.2.3 Projected Purchasing and Consumption Behaviours

The Applicant noted that consumers who have access to fluoridated water and are willing to consume tap water are unlikely to purchase these products. The Applicant has assumed that consumers who choose to purchase fluoridated packaged water will pay a premium price with some basis/knowledge for this decision.

Sales data collected from 2004 to 2006,⁵⁹ provided by the Australian Beverages Council, suggest a degree of substitution may occur between similar beverages. Data reflect increases in purchases of non-sugar CSDs in addition to sugar-sweetened CSDs, which is suggestive that 'some of the sugar-sweetened drinking occasions were being replaced with non-sugar occasions'.

In light of this, it remains uncertain whether consumers of fluoridated packaged water will substitute this for tap water (fluoridated or unfluoridated), other packaged water products (e.g. unfluoridated packaged water), or other purchased products.

⁵⁷ ABWI website: accessible from <http://www.bottledwater.org.au/scripts/cgiip.exe/WService=ASP0003/ccms.r>

⁵⁸ Roy Morgan Research. (2008). *Bottled Water: Consumption among children aged 6-13*. Prepared for ABWI by Roy Morgan Research Pty Ltd.

⁵⁹ Levy, G & Tapsell, L. (2007). Shifts in purchasing patterns of non-alcoholic water-based beverages in Australia, 1997-2006. *Nutrition and Dietetics*, 64, 268-279.

Questions for Submitters:

Are there any available data on consumption patterns in relation to fluoridated packaged water or packaged water in general?

Is there any evidence regarding consumers' likely substitution of fluoridated packaged water for tap water, unfluoridated packaged water, or other purchased beverages?

12.2.4 *Vulnerable Groups*

In addition to the target populations identified above, fluoridated packaged water products may be consumed by vulnerable populations, e.g. infants and young children.

Overconsumption of fluoridated water by some groups in the population may result in these groups exceeding the recommended upper limit for fluoride. For example, infant formula becomes a major source of fluoride if the powdered formula is reconstituted with fluoridated water. There are currently no definitive data in Australia regarding the use of fluoridated water in food and beverage manufacture, or the fluoride concentration of foods containing water.

The consumption data for packaged water discussed above suggest an overall increase in consumption of this product over the last decade across all age groups, due to motivations based on changing social conditions. The increasing proportions of young females (of childbearing age) and younger children consuming packaged still water may present possibilities for overconsumption of fluoride within vulnerable groups, assuming direct substitution of fluoridated packaged water for unfluoridated packaged water and fluoridated tap water.

As mentioned in Section 10.3 of this Report, FSANZ will conduct a restricted assessment of dietary intake including estimates of the potential for any population groups to exceed the UL if fluoridated packaged water is substituted for other drinking water.

Question for Submitters:

Are there any potential impacts of allowing the voluntary addition of fluoride to packaged water on any vulnerable sub-populations in the community e.g. infants or young children?

12.3 **Labelling of Fluoridated Packaged Water**

Labelling provisions are included within the Code as a means of achieving three main objectives: to protect public health and safety through the management of risk, to provide adequate information relating to food to the consumer to facilitate informed purchasing decisions, and to prevent misleading or deceptive conduct.

In addition to meeting the Code's requirements, fluoridated packaged water will need to comply with the respective Australian and New Zealand fair trading legislation regarding potential misleading or deceptive conduct in relation to a food or beverage.

The Applicant is seeking amendments to the Code to:

- (a) permit the voluntary addition of fluoride to packaged water up to a maximum claimable amount of 1.5 mg/L; and
- (b) allow bottlers to make nutrition claims on the fluoride present in packaged water.

The amendments proposed by the Applicant require consideration of the mandatory and voluntary labelling requirements set out in the following Standards:

- 1.2.2 – Food Identification Requirements;
- 1.2.3 – Mandatory Warning and Advisory Statements and Declarations;
- 1.2.4 – Labelling of Ingredients; and
- 1.2.8 – Nutrition Information Requirements.

This Application requires consideration of both mandatory and voluntary labelling information. Labelling elements such as the ingredients list, the Nutrition Information Panel (if a claim is made), the use of nutrition claims and the requirements of Standard 1.2.2 provide consumers with information to make informed choices when purchasing fluoridated packaged water. As part of its assessment of this Application, FSANZ will consider the need for any mandatory or voluntary labelling requirements for fluoridated packaged water if permission is given.

12.3.1 Mandatory Labelling Requirements –

12.3.1.1 Food Identification Requirements

As mentioned in Section 3.1.1 of this Report, unless otherwise exempt, foods must comply with the provisions of Standard 1.2.2 – Food Identification Requirements that require the label on a package of food to include –

- (a) *the prescribed name of the food, where the name of a food is declared in this Code to be a prescribed name; and*
- (b) *in any other case, a name or a description of the food sufficient to indicate the true nature of the food.*

The Applicant has provided sample statements and claims regarding the labelling of packaged water, such as ‘Premium spring water with added fluoride’, ‘Mineral water plus fluoride’ or ‘Fluoridated spring water’. In addition to the requirements of the Code, these statements and claims must comply with the *Trade Practices Act 1974* in Australia and *Fair Trading Act 1986* in New Zealand.

12.3.2 Voluntary Labelling Requirements

12.3.2.1 Typical Analysis Labelling

Currently, some manufacturers label packaged water with a typical analysis of the product’s mineral composition. The Code does not prohibit typical analysis labelling, which aligns, and is consistent, with international practices.

Such information is not mandated by the Code as manufacturers are likely to label packaged water with a typical analysis if this is information that consumers use to make purchasing decisions. Notably, typical analysis labelling is not a requirement of Standard 1.2.8.

12.3.2.2 Vitamin and Mineral Claims

Standard 1.3.2 regulates the claims which can be made about the vitamin and mineral content of foods. As fluoride is currently not listed in the Schedule to Standard 1.1.1, claims about fluoride are currently not permitted. The Table to clause 3 of Standard 1.3.2 specifies the vitamins or minerals that may be added to a particular food, the maximum amount of the vitamin or mineral (naturally occurring and added) that may be present in a reference quantity of the food, and/or the maximum amount of the vitamin or mineral which may be ‘claimed’ to be present in the reference quantity.

The Applicant has requested that fluoridated packaged water be permitted to carry nutrition claims. If the addition of fluoride to packaged water is permitted (by its inclusion in the Table to clause 3 of Standard 1.3.2) and a reference value is added to the Schedule in Standard 1.1.1, claims would be permitted under clause 6 of Standard 1.3.2.

As discussed in Section 3.3.2 of this Report, the regulation of nutrition, health and related claims is currently under review by FSANZ as part of Proposal P293. Any claims regarding fluoride in packaged water would need to comply with either the current requirements of Standard 1.3.2 or the new rules, depending on the outcome of Proposal P293 and the timing of the introduction of the new Standard in relation to permission to add fluoride to packaged water.

As part of its assessment, FSANZ will consider an appropriate reference value for fluoride for inclusion in Standard 1.1.1 for the purpose of permitting nutrition claims. FSANZ will also consider the likely impact of Proposal P293 on this Application and any specific labelling requirements for nutrition claims if permission is given for fluoride to be added to packaged water.

Question for Submitters:

In addition to current mandatory labelling requirements, should FSANZ consider any specific labelling requirements for fluoridated packaged water?

12.4 Potential to Mislead Consumers

As part of its assessment of this Application, FSANZ will examine the potential for consumers to be misled as to the nutritional quality of fluoridated packaged water compared with fluoridated tap water. This is in accordance with FSANZ’s second and third priority statutory objectives and the Specific Order Policy Principle for voluntary fortification which states that ‘the fortification of a food, and the amount of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food’.

Consumers may be misled by fluoridated packaged water as they may perceive fluoridated packaged water to be nutritionally superior. This may result in consumers purchasing a fluoridated packaged water when they could be satisfied with their existing tap water. However, some consumers may choose fluoridated packaged water for other reasons, for example preferring the taste.

As part of this assessment, FSANZ will consider labelling issues regarding fluoridated packaged water, including the potential for misleading or deceptive conduct in relation the Australian and New Zealand fair trading legislation.

Questions for Submitters:

Would consumers perceive packaged water with added fluoride to be nutritionally equivalent to fluoridated tap water?

Is there potential for consumers to be misled about the nutritional equivalence of fluoridated packaged water versus other fluoridated water sources?

13. Regulatory Options

FSANZ is currently considering two options for addressing this Application:

13.1 Option 1 – Maintain status quo

Maintain the *status quo* by not amending the Code to allow the voluntary addition of fluoride to packaged water; and

13.2 Option 2 – Amend Standard 1.3.2 to permit the voluntary addition of fluoride to packaged water up to a maximum claimable amount of 1.5 mg/L

Option 2 would allow the voluntary addition of fluoride as a claimable nutrient to packaged water under Standard 1.3.2 of the Code, up to a maximum claimable amount of 1.5 mg/L.

14. Impact Analysis

14.1 Affected Parties

The parties likely to be affected by this Application are:

- (a) **consumers** of packaged water;
- (b) Australian and New Zealand manufacturers and importers of packaged water (**industry**); and
- (c) the **government enforcement agencies** of Australia States/Territories and New Zealand.

14.2 Benefit Cost Analysis

Stakeholders are invited to provide information that will inform the analysis of the benefits and costs of this Application. This analysis provides a preliminary assessment of the potential impacts of the regulatory options on the affected parties. A full benefit cost analysis will be undertaken at Draft Assessment.

14.2.1 Consumers

Adding fluoride to packaged water would provide consumers with an additional source of fluoride in their diet. In addition, it would provide consumers with increased choice as beverages with and without added fluoride would be available for purchase.

Any additional costs incurred by the manufacturers of these beverages are expected to be passed on to consumers who choose to purchase fluoridated packaged water. It is unknown to what extent consumers will 'accept' this product. As this Application is being assessed on the basis of nutritional equivalence, FSANZ, will identify any public health and safety issues for consumers if fluoridated packaged water is substituted for fluoridated tap water.

14.2.2 Industry

A permission to permit the voluntary addition of fluoride to packaged water allows industry to be innovative and produce new products for the Australian and New Zealand markets, and potentially, international markets. As the addition of fluoride to packaged water would be a voluntary permission, there should not be additional barriers to trade. While there would be a cost to manufacturers to add fluoride to packaged water, it is expected that this cost will be passed on to consumers at the point of sale.

The Applicant has indicated that the addition of fluoride to packaged water would incur additional expense including costs arising from the technical aspects of handling the fluoride. If this permission is given, they have requested the ability to claim the presence of fluoride clearly on the label. They have stated that the increased cost can only be met by showing consumers that this water, attracting a premium price, has the added benefit of fluoride.

Question for Submitters

What costs would be incurred by businesses adding fluoride to packaged water? Are these costs intended to be recovered from the market by higher prices?

14.2.3 Government

It is expected that there would be minimal impact for Government for either regulatory option.

Questions for Submitters

What changes to enforcement procedures, if any, do the jurisdictions believe may result from this Application?

What would be the resource implications of these changes?

14.3 Comparison of Options

At this Initial Assessment stage, no comparison of the identified regulatory options can be undertaken. Further information on the risk assessment and risk management aspects of these Applications is required before such a comparison can be made. A comparison of options will therefore be provided at Draft Assessment for this Application.

Question for Submitters

Please provide any additional relevant information regarding costs and benefits of this Application.

COMMUNICATION AND CONSULTATION**15. Communication**

FSANZ does not intend to undertake specific communication and consultation work outside the two statutory public consultation periods. FSANZ will however review the nature of the feedback received from submitters to the Initial Assessment, and determine whether additional communication strategies are required for Draft and Final Assessments.

16. Consultation**16.1 Public Consultation**

FSANZ is aware of diverse views among stakeholders in relation to the addition of fluoride to packaged water. A number of media articles and radio broadcasts in 2007 reported that consumer, health and industry groups are calling for the fortification of some packaged water with fluoride, to assist in fighting increased tooth decay in children and teenagers. However, FSANZ is also aware of other groups that are publicly opposed to fluoridation of water, arguing that it has harmful effects on human health. This issue is likely to continue to attract media attention.

This Initial Assessment Report is intended to seek early input on a range of specific issues on the likely regulatory impact of this Application. At this stage, FSANZ is seeking public comment to assist it in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this Report, which are also presented at Attachment 2.

Comments made by submitters during the consultation period will be reviewed and reported in the Draft Assessment Report.

16.2 Targeted Consultation

FSANZ has conducted preliminary consultations with jurisdictions to provide an overview of FSANZ's approach to the Assessment, which is based on nutritional equivalence and providing choice for consumers rather than addressing a public health problem. Targeted consultation on the safety of this Application may be conducted with experts in the field of dental and medical health. FSANZ will conduct other targeted consultation as necessary.

16.3 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 Barriers to Trade or Sanitary and Phytosanitary Measures Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (as was in force prior to 1 July 2007), FSANZ has decided to accept this Application for the following reasons:

- The Applicant seeks approval to permit the voluntary addition of fluoride to packaged water as an alternative to fluoridated tap water, and to allow bottlers to make nutrient claims.
- There is currently no permission in the Code to voluntarily add fluoride to packaged water as a claimable nutrient.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.3.2. that could achieve the same end.
- At this stage no other relevant matters are apparent.

ATTACHMENTS

1. Australia and New Zealand Food Regulation Ministerial Council Policy Guideline *Fortification of Foods with Vitamins and Minerals*
2. Initial Assessment Questions for Public Comment.

Policy Guideline Fortification⁶⁰ of Food with Vitamins and Minerals

This Policy Guideline provides guidance on development of permissions for the addition of vitamins and minerals to food.

The Policy Guideline does not apply to special purpose foods the formulation and presentation of which are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code).

The policy should only apply to new applications and proposals. There is no intention to review the current permissions.

The policy does not apply to products that should be or are regulated as therapeutic goods. This should not lead to a situation where generally recognised foods, through fortification, become like or are taken to be therapeutic goods.

The policy assumes the continuation of a requirement for an explicit permission for the addition of a particular vitamin or mineral to particular categories of foods to be included within the Food Standards Code. Currently the majority of permissions are contained in Standard 1.3.2 – Vitamins and Minerals.

Regard should be had to the policy in development of regulatory measures applying to the mixing of foods where one, or both of the foods may be fortified.

The policy for regulation of health and nutrition claims on fortified food is covered by the Policy Guideline on Nutrition, Health and Related Claims. Claims should be permitted on fortified foods, providing that all conditions for the claim are met in accordance with the relevant Standard.

‘High Order’ Policy Principles

The Food Standards Australia New Zealand Act 1991 (the Act) establishes a number of objectives for FSANZ in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - (a) the protection of public health and safety;
 - (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - (c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:

⁶⁰ Within the context of this policy ‘Fortification’ is to be taken to mean all additions of vitamins and minerals to food including for reasons of equivalence or restoration.

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food; and
- (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

These objectives apply to the development of standards regulating the addition of vitamins and minerals to food.

A number of other policies are also relevant to the development of food standards including the Council Of Australian Governments document ‘Principles and Guidelines for national Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies(1995, amended 1997)(Australia only), New Zealand Code of Good Regulatory Practice (November 1997), the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System and relevant World Trade Organisation agreements.

Specific Order Policy Principles - Mandatory Fortification

The mandatory addition of vitamins and minerals to food should:

1. Be required only in response to demonstrated significant population health need taking into account both the severity and the prevalence of the health problem to be addressed.
2. Be required only if it is assessed as the most effective public health strategy to address the health problem.
3. Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
4. Ensure that the added vitamins and minerals are present in the food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.
5. Ensure that the mandatory fortification delivers effective amounts of added vitamins and minerals with the specific effect to the target population to meet the health objective.

Additional Policy Guidance - Mandatory Fortification

The specified health objective of any mandatory fortification must be clearly articulated prior to any consideration of amendments to the Food Standards Code to require such mandatory fortification.

The Australian Health Ministers Advisory Council, or with respect to a specific New Zealand health issue, an appropriate alternative body, be asked to provide advice to the Australia and New Zealand Food Regulation Ministerial Council with respect to Specific Order Policy Principles 1 and 2, prior to requesting that Food Standards Australia New Zealand raise a proposal to consider mandatory fortification,

The assessment of public health strategies to address the stated health problem must be comprehensive and include an assessment of alternative strategies, such as voluntary fortification and education programs.

Consideration should be given, on a case by case basis, to a requirement to label foods that have been mandatorily fortified by including the information in the Nutrition Information Panel of the food label.

An agreement to require mandatory fortification also requires that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Specific order policy principles – Voluntary fortification

- The voluntary addition of vitamins and minerals to food should be permitted only:
 - Where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake.
 - or**
 - Where data indicates that deficiencies in the intake of a vitamin or mineral in one or more population groups are likely to develop because of changes taking place in food habits.
 - or**
 - Where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit.
 - or**
 - To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration⁶¹).
 - or**
 - To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).
- The permitted fortification has the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use.

⁶¹ The principle of Modified Restoration as derived from The FSANZ document *Regulatory principles for the addition of vitamins and minerals to foods*. (Canberra, 2002) is as follows:

Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% Recommended Dietary Intake (RDI) per reference quantity) to some foods providing that the vitamin or mineral is present in the nutrient profile, prior to processing, for a marker food in the food group to which the basic food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food. This regulatory principle is based on the restoration or higher fortification of the vitamin or mineral to at least pre-processed levels in order to improve the nutritional content of some commonly consumed basic foods.

- Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand.
- Permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.
- Fortification will not be permitted in alcoholic beverages.
- Permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which will not have the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.
- The fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.

Additional Policy Guidance - Voluntary Fortification

Labelling – There should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods. An added vitamin or mineral is required to be listed in the Nutrition Information Panel only if a claim is made about it and the vitamin or mineral is present at a level for which a claim would not be misleading. An added vitamin or mineral must be listed in the ingredient list under current labelling requirements.

Monitoring/Review - A permission to voluntarily fortify should require that it be monitored and formally reviewed in terms of adoption by industry and the impact on the general intake of the vitamin/mineral.

Initial Assessment Questions for Public Comment

- Do you agree with FSANZ's approach to Assessment based on nutritional equivalence?
- Do you consider 1.5 mg/L to be an appropriate maximum claimable amount for the voluntary addition of fluoride to packaged water?
- Are there any available data on consumption patterns in relation to fluoridated packaged water or packaged water in general?
- Is there any evidence regarding consumers' likely substitution of fluoridated packaged water for tap water, unfluoridated packaged water, or other purchased beverages?
- Are there any potential impacts of allowing the voluntary addition of fluoride to packaged water on any vulnerable sub-populations in the community e.g. infants or young children?
- In addition to current mandatory labelling requirements, should FSANZ consider any specific labelling requirements for fluoridated packaged water?
- Would consumers perceive packaged water with added fluoride to be nutritionally equivalent to fluoridated tap water?
- Is there potential for consumers to be misled about the nutritional equivalence of fluoridated packaged water versus other fluoridated water sources?
- What costs would be incurred by businesses adding fluoride to packaged water? Are these costs intended to be recovered from the market by higher prices?
- What changes to enforcement procedures, if any, do the jurisdictions believe may result from this Application?
- What would be the resource implications of these changes?
- Please provide any additional relevant information regarding costs and benefits of this Application.