



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

11 November 2008
[19-08]

DRAFT ASSESSMENT REPORT

APPLICATION A588

VOLUNTARY ADDITION OF FLUORIDE TO PACKAGED WATER

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 23 December 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 sought an amendment to the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of fluoride to packaged water². Since Initial Assessment, the Applicant has amended their request to seek permission to voluntarily add fluoride to packaged water within a narrower range of 0.6-1 mg/L (total of naturally occurring and added fluoride). Additionally, for product identification purposes, the Applicant is seeking permission to label packaged water as containing added fluoride.

Currently, the Code does not permit the voluntary addition of fluoride to 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 reticulated water,³ or as a source of fluoride for those who do not have access to fluoridated reticulated water.

The specific objectives in consideration 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 reticulated 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.

FSANZ's Approach to Assessment

At Draft Assessment, FSANZ has undertaken a robust and extensive assessment of the public health and safety implications of this Application. A summary of the key risk assessment findings and risk management issues are detailed below.

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 reticulated water.

Risk Assessment

The Risk Assessment of this Application has included an evaluation of whether fluoridated packaged water is nutritionally equivalent to fluoridated reticulated water. The history of safe use of fluoride in drinking water has also been investigated. Dietary intakes of fluoride have been estimated to determine baseline intakes and to determine if there is a risk to any population group from fluoride intakes.

¹ Australian Beverages Council Limited 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 (non-carbonated) or bulk 'bottled' water for coolers or dispensers.

³ For the purposes of this Application, the term 'fluoridated reticulated water' refers to drinking water from fluoridated municipal water supplies but not tank water.

This is the first time FSANZ has estimated dietary intakes of fluoride. The safety for potentially vulnerable population groups and the potential for any adverse effects has also been examined.

In summary, the Risk Assessment findings are as follows:

- packaged water is nutritionally equivalent to reticulated water when both are fortified with fluoride;
- the forms of fluoride to be added to packaged water are the same as those permitted in reticulated water and hence have similar bioavailability;
- there is a history of safe use of fluoride in reticulated drinking water at the same levels as in the amended Application;
- it is estimated that dietary intakes for a proportion of children up to 8 years could exceed the upper level of intake (UL) when optimally fluoridated water (0.6-1 mg/L) is consumed;
- the official Australian and New Zealand UL for children up to 8 years was based on the absence of moderate dental fluorosis and was set from dietary intakes estimated using model diets from the 1940s. These diets do not match current estimated dietary intakes for Australians using actual food consumption data, which are more positively skewed. Therefore, FSANZ considers that the UL is likely to be currently underestimated;
- there is evidence of very mild and mild dental fluorosis⁴, which are not adverse outcomes, in the Australian and New Zealand populations. However, there is no evidence to suggest a prevalence of moderate fluorosis which would be considered to be an adverse outcome. Therefore, the exceedance is considered to be not a cause for concern;
- there is no evidence of any other adverse effects or risk for any vulnerable sub-population groups from current levels of water fluoridation or dietary intakes in Australia or New Zealand; and
- any potential adverse risks from the consumption of fluoridated packaged water containing 0.6-1 mg/L of fluoride would be the same as from the consumption of fluoridated reticulated water, for all population groups.

The key risk assessment issues are discussed in Section 10 of this Report. Additional information is provided at Supporting Document 2 – Nutrition Risk Assessment Report, Supporting Document 3 – Dietary Intake Assessment Report and Supporting Document 4 – Derivation of the Upper Level for Fluoride Intake Report.

⁴ Very mild and mild forms of dental fluorosis are considered to be ‘good’ or ‘beneficial’ (i.e., fluoride incorporated into teeth) in comparison to moderate or severe dental fluorosis which is of aesthetic concern and could be deemed to be an adverse health effect. (Committee on Fluoride in Drinking Water, National Research Council (2006) *Fluoride in Drinking Water: A Scientific Review of EPA’s Standards*. National Academy of Sciences.)

Risk Management

This Draft Assessment Report considers, in the context of the findings from the Risk Assessment, a number of issues relevant to the regulation of the voluntary addition of fluoride to packaged water. The key strategies to help mitigate any potential risks include:

- the adoption of a range of fluoride (0.6–1 mg/L) which generally aligns with the recommended target range in fluoridated reticulated water in Australia and New Zealand so as to achieve nutritional equivalence;
- the adoption of compositional requirements for packaged water with added fluoride to clarify the intent of the permission;
- the adoption of mandatory labelling for food identification to inform consumers as to the presence of added fluoride to enable informed choice; and
- the adoption of consequential amendments to Standard 1.3.3 and the table to Standard 2.6.2 to clarify the permissions relating to packaged water.

In addition, other issues raised by submitters in response to the Initial Assessment Report have been addressed in this Report. A summary of submissions to the Initial Assessment Report is at Attachment 2.

Preferred Approach

The preferred regulatory option is to amend Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks to permit the addition of fluoride to non-carbonated packaged water to between 0.6 and 1 mg/L (total of naturally occurring and added fluoride) and to require mandatory labelling to indicate that fluoride has been added.

In addition, to make consequential amendments to Standard 1.3.3 and Standard 2.6.2 for clarification of permission for the addition of fluoride to packaged water.

Reasons for Preferred Approach

FSANZ supports the preferred regulatory approach to permit the voluntary addition of fluoride to packaged water as it:

- is nutritionally equivalent to fluoridated reticulated water and provides consumers with an alternative source of fluoridated water.
- does not raise any public health or safety concerns for consumers of packaged water with added fluoride or the general population;
- is consistent with FSANZ’s statutory objectives including Ministerial policy guidance on voluntary fortification;
- supports industry innovation;

- provides consumers with adequate information on the product label to make an informed choice and to prevent them from being misled; and
- provides a net benefit to affected parties.

The proposed draft variations are provided at Attachment 1.

Consultation

FSANZ received a total of 55 submissions on the Initial Assessment Report during the public consultation period from 19 March 2008 to 30 April 2008. The majority of government stakeholders, public health professionals and industry submitters indicated support for the Application. Most of the consumer submissions were opposed to the addition of fluoride to packaged water, citing safety concerns regarding water fluoridation in general and potential adverse health impacts as a result of increasing the fluoride content of the food supply.

Several stakeholders expressed concern regarding the risk of vulnerable groups to exceed the UL, especially infants drinking formulas reconstituted with fluoridated packaged water. Most submitters acknowledged the need for effective labelling to enable consumers to make an informed choice.

FSANZ also conducted targeted consultations with jurisdictions, the National Health and Medical Research Council (NHMRC), its Water Quality Advisory Committee, the New Zealand Ministry of Health, dental experts and professional dental associations regarding the risk assessment results, exceedances above the UL, basis of the UL and the prevalence of dental caries and dental fluorosis in Australia and New Zealand. These groups have expressed in principle support for FSANZ's risk assessment summary and for the proposed level of fluoride to be added to packaged water.

FSANZ is seeking comment on this Draft Assessment Report from all interested parties, particularly in relation to the expected impact(s) of the preferred regulatory approach. Comments received will assist in the preparation of a Final Assessment, including a recommended regulatory approach for the voluntary addition of fluoride to packaged water.

Implementation and Review

Following the consultation period, a Final Assessment of this Application will be completed and considered for approval by the FSANZ Board. If a draft variation to the Code is approved, FSANZ will notify that decision to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

Subject to any request for review by the Ministerial Council, the proposed draft variation permitting the voluntary addition of fluoride to packaged water is expected to come into effect upon gazettal.

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SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Draft Assessment Report, are available on the FSANZ website at

<http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa588volun3872.cfm>.

SD1 Policy Guideline Fortification of Food with Vitamins and Minerals

SD2 Nutrition Risk Assessment Report

SD3 Dietary Intake Assessment Report

SD4 Derivation of the Upper Level for Fluoride Intake Report

INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation/s to the Code 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. 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

Submissions need to be received by FSANZ by 6pm (Canberra time) 23 December 2008.

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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
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INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd⁵ (Australian Beverages) on 23 August 2006. The Application seeks to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of fluoride to packaged water⁶. The Application is supported by the Australasian Bottled Water Institute Inc. (ABWI).⁷

This Draft Assessment Report discusses issues relevant to the voluntary addition of fluoride to packaged water, addresses issues raised in submissions to the Initial Assessment Report, and proposes a preferred regulatory approach.

FSANZ is seeking comment on this Draft Assessment Report from all interested parties, particularly in relation to the expected impact(s) of the preferred regulatory approach.

1. Nature of the Application

1.1 Basis of the Application

The Applicant has requested permission to allow the voluntary addition of fluoride to packaged water to provide an alternative source of fluoride for consumers. This would provide an alternative for those who do not wish to drink fluoridated (reticulated (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 reticulated water. The Applicant has requested amendments to Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks 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 2005⁸, 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.

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 in part to the increasing consumption of non-fluoridated packaged water.

1.2 Scope of the Application

This Application only applies to still (non-carbonated) ‘packaged water’. ‘Packaged water’ is water presented in packaged form. Examples of packaged water include:

⁵ 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.

⁶ For the purposes of this Application, the term ‘packaged’ water will be used to describe water presented in packaged form including single serve (non-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).

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

1.3 Amendments to the Original Application

The original Application requested 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 using a reference quantity of 600 mL. The Application also sought 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’.

Since Initial Assessment, the Applicant subsequently amended their Application to seek permission to:

- voluntarily add fluoride to packaged water within a range of 0.6-1 mg/L;
- use sodium fluoride, sodium fluorosilicate (sodium silicofluoride) and hydrofluorosilicic acid (fluorosilicic acid) as the permitted forms of fluoride; and
- make a labelling statement to the effect that the product contains added fluoride for food identification purposes.

The Applicant is no longer seeking permission for nutrient content claims and has advised that permission is not being sought for addition of fluoride to carbonated packaged water.

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

⁹ NHMRC and NZMoH (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.

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 UL¹² have been set for various age groups (Table 1). The AI is used when an Estimated Average Requirement (EAR)¹³ cannot be determined and reflects average daily intakes based on observed or experimental studies for healthy populations assumed to be adequate. The fluoride NRVs were adopted by the NHMRC and NZMoH from the US/Canadian Dietary Reference Intakes (DRIs) which were assigned based on the best data available at the time.

Table 1: Fluoride NRVs for Australian and New Zealand Populations

Population Subgroup	Adequate Intake (mg/day)		UL (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

The Institute of Medicine in the USA stated that populations with access to water fluoridation at 1 mg/L in the USA had the lowest incidence of caries and a mean dietary fluoride intake of around 0.05 mg/kg body weight/day.¹⁴ It was noted that this level protects against caries with no adverse health effects.

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.

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.

The NHMRC and NZMoH adopted the reference body weights used for the US/Canadian DRIs, given their similarities to Australian and New Zealand values, for each population subgroup to obtain the NRVs for all population groups 7 months and above.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 AIs for fluoride for infants and children up to 8 years vary from 1 mg/day or less. The AI for infants up to 6 months of age is based on intakes from breast fed infants. The AI for adult males is 4 mg/day and for females is 3 mg/day. These AIs were based on equivalence with the fluoride intakes of populations that have access to fluoridated water supplies.

An UL was established at 10 mg/day for children aged 9 years and above and adults. For children aged 8 years of age and below the UL varies from 2.2 mg/day or less. The UL for fluoride for children up to 8 years was set on the basis of the presence of the clinical sign of moderate dental fluorosis¹⁶ whereas the UL for the population 9 years and above was based on skeletal fluorosis. The rationale for the latter appears to be based on i) by 9 years of age, dental maturation is considered to be complete and past the phase where excessive fluoride intake would be likely to lead to dental fluorosis and ii) that the development of skeletal fluorosis requires exposure for a considerable period before the clinical signs become apparent.

2.1.2 Additional 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 of age. 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 The 2007 ADA Policy Statement states that supplements should only be used when recommended by a dental professional. There are no similar recommendations relating to fluoride supplementation for infants and young children in New Zealand in their Food and Nutrition Guidelines.¹⁹

¹⁵ NHMRC and NZMoH (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. Very mild and mild forms of dental fluorosis are considered to be 'good' or 'beneficial' (i.e., fluoride incorporated into teeth) in comparison to moderate or severe dental fluorosis which is of aesthetic concern and could be deemed to be an adverse health effect. (Committee on Fluoride in Drinking Water, National Research Council (2006) *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*. National Academy of Sciences.)

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).

¹⁹ Ministry of Health (2008) *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A background paper*. 4th Edition. Ministry of Health, Wellington.

Recent guidelines²⁰ and the ADA Policy Statement 2007 advises that children between the age of 6 to 17 months should have their teeth cleaned, but with no toothpaste, and children between 18 months and 5 years should use toothpaste with lower levels of added fluoride (around 400-500 mg/kg fluoride).

2.1.3 Fluoride Recommendations for Pregnant Women

The average intakes and upper levels of intake for pregnant and lactating women from the NRVs are the same as for women in the general adult population (AI 3 mg/day; UL 10 mg/day). There is no evidence that there are increased requirements and no data that show an increased susceptibility to fluoride to warrant establishing different NRVs for these population groups²¹.

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, the preparation of beverages or the manufacture of other foods and beverages. There are some foods that have high concentrations of fluoride including many fish (canned sardines, mullet, salmon) and some dairy foods (ice cream, cheese). Tea leaves are naturally high in fluoride and when combined with fluoridated water can be a significant dietary source. Most other foods appear to contain low levels of fluoride, including fruit, vegetables, fats and oils and cereal based products. 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. Natural spring water is permitted to contain a maximum of 2 mg/L of fluoride, although how much is in any particular brand depends on the source of the spring water.

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)²² 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).

In March 2007, the Australian Bureau of Statistics conducted a survey on water supplies and use which showed that 93% of Australian households were connected to mains/town water supplies (either fluoridated or non-fluoridated)²³. This was slightly lower for households outside capital cities at 85%.

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

²¹ NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Canberra, ACT.

²² NHMRC (2004) *Australian Drinking Water Guidelines*. NHMRC Canberra ACT. Available from http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf.

²³ Australian Bureau of Statistics (2007) *Environmental Issues: People's Views and Practices*. ABS Catalogue Number 4602.0. Australian Bureau of Statistics, Canberra.

Eighty-one per cent of households reported that mains/town water was their main source of water for drinking. This was the highest in the ACT (95%) and lowest in South Australia (64%). In capital cities, 89% of households use mains/town water as their main source of water for drinking compared to 66% outside capital cities. Nineteen per cent of Australian households are choosing other sources of water as their main source of drinking water, despite being connected to mains/town water. Of this, 10% is rain water and 8% was reported as 'bottled' water. Less than one per cent use bore or well water as the main source of drinking water.

In 2007, 19% of households reported purchasing 'bottled' water, which was down from 21% in 2004. Except for Queensland and South Australia, 'bottled' water was purchased in greater proportion outside capital cities.

The majority of households (77%) were satisfied with the mains/town water supply, with 19% not satisfied and 4% not drinking the mains/town water. South Australia had the highest proportion who were not satisfied (26%) and that did not drink the mains/town water (9%). Across Australia, the main reason for dissatisfaction was taste (52%). Chemicals in the water (other than chlorine) was a reason for dissatisfaction in 4% of households as was a preference for another water source.

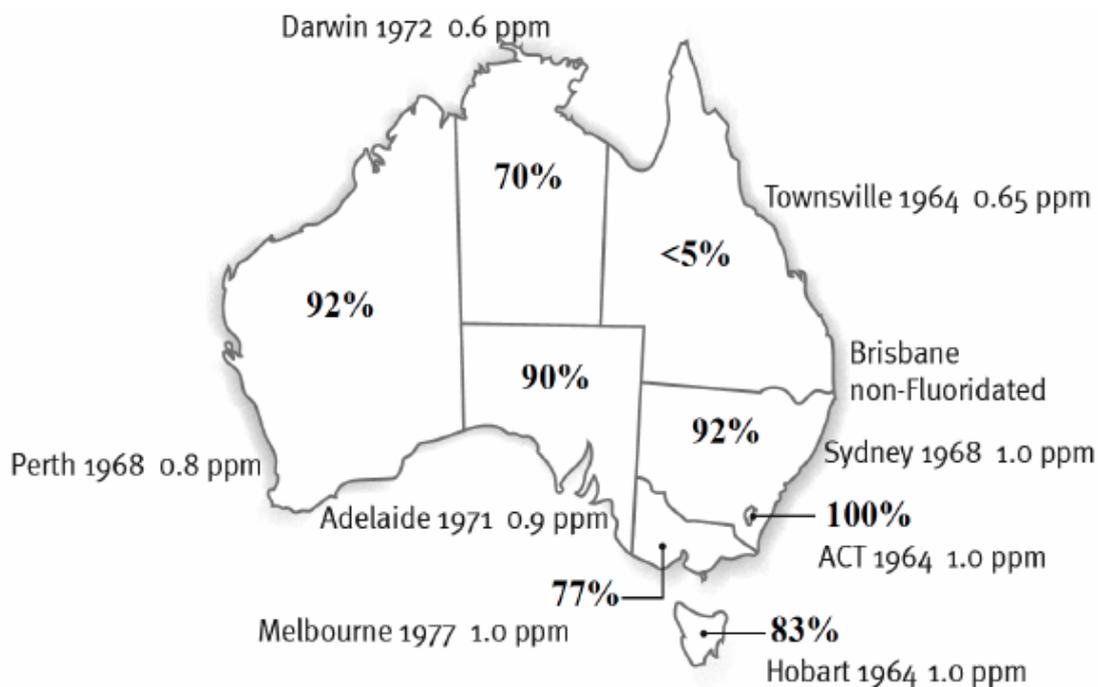
2.2.1.1 Fluoridation in Australia

Approximately 76% of Australians currently have access to fluoridated water supplies. Figure 1 highlights current access to fluoridated water in Australia. The lowest coverage of fluoridation is in Queensland with less than 5% of the population having access to a fluoridated water supply. However, by 2010, 83% of Queensland residents will have access to fluoridated water, increasing to 95% by 2012²⁴ with fluoridation of South-East Queensland water supplies to commence in late 2008. Nominal target fluoride levels vary according to climate and local water needs but the NHMRC recommended target fluoride concentration is between 0.6 and 1.1 mg/L.²⁵ 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. Currently, Queensland has a prescribed level of a minimum of 0.5 mg/L of fluoride to a maximum of 0.9 mg/L of fluoride depending on average maximum air temperatures under the *Fluoridation of Public Water Supplies Regulation 1998*. However, this legislation is presently under review and the proposed fluoride range will be 0.6-0.8 mg/L depending on the local average maximum air temperature.²⁶

²⁴ Timeline for water fluoridation in Queensland. Available from <http://www.health.qld.gov.au/fluoride/timeline.asp>

²⁵ NHMRC Public Statement *The Efficacy and Safety of Fluoridation 2007* Available from: http://www.nhmrc.gov.au/media/media/rel07/_files/Fluoride_Flyer.pdf

²⁶ Personal Communication with G Bielby, Queensland Health, October 2008.



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: Year of introduction of water fluoridation to Australian capital cities and percentage of the population in each State who have access to fluoridated water^{27,28}

The health guideline value (i.e. maximum permitted level) for monitoring of fluoride in drinking water as stated in the *Australian Drinking Water Guidelines*, is 1.5 mg/L. The NHMRC public statement on the *Efficacy and Safety of Fluoridation 2007*²⁹ recommends 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 2007 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’.

FSANZ collected information on actual water fluoride content of reticulated water in Australia. This information was primarily from water quality reports from various states and territories. Mean water fluoride concentrations in non-fluoridated areas were around 0.1-0.2 mg/L and between 0.7-1 mg/L in fluoridated areas, with lower levels in some places in the Northern Territory (around 0.5 mg/L). These data correspond with those reported by the NHMRC (Figure 1).

²⁷ Fluoridation measured as ppm (parts per million), which is equivalent to mg/L.

²⁸ Fluoridation of South-east Queensland water supplies will commence in late 2008 and more than 95% of Queenslanders will have access to fluoridated water by 2012.

²⁹ NHMRC Public Statement *The Efficacy and Safety of Fluoridation 2007* Available from: http://www.nhmrc.gov.au/media/media/rel07/_files/Fluoride_Flyer.pdf.

2.2.1.2 Fluoridation in 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* includes a maximum acceptable value for fluoride of 1.5 mg/L and recommends a target fluoride range of 0.7-1 mg/L for oral health reasons.³⁰

Approximately 89% of the New Zealand population has access to a community water supply of which approximately 58% receive fluoridated drinking water.³¹ Therefore, approximately 52% of the New Zealand population has access to a fluoridated water supply. Larger centres currently without fluoridated water supplies include Whangarei, Tauranga, Wanganui, Napier, Nelson, Blenheim, Christchurch, Timaru and Oamaru.

Actual concentrations of fluoride in reticulated water in New Zealand average around 0.8-0.9 mg/L in fluoridated areas and around 0.15 mg/L in non-fluoridated areas.³²

2.2.2 Fluoride Content of Packaged Water

Water from different sources (non-fluoridated spring and fluoridated or non-fluoridated reticulated 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. A recent analytical survey³³ of 9 brands of packaged spring and filtered water determined that all brands had concentrations of below 0.08 mg/L. One brand of rain water included in the study had a 'not detected' concentration (<0.03 mg/L).

2.2.3 Processed Foods and Beverages

Fluoride may be carried over into processed foods and beverages as a result of using water from reticulated water supplies during manufacturing. This general phenomenon for 'beneficial' components is often referred to as the 'halo effect'. FSANZ contacted the food industry to try and determine the extent that fluoridated reticulated water supplies are used in the manufacture of primarily fluid-based foods and the fluoride content of these foods and beverages. This information showed that the water used for manufacturing beverages is generally obtained from the reticulated water supplies from the area of the manufacturing plant. Therefore, if these plants are in areas where fluoridated reticulated water is available, the beverages would contain fluoride. The amount of remaining fluoride in these beverages may be affected by filtering and processing equipment. FSANZ analytical data indicate beverages such as soft drinks, fruit drinks and beer contain between 0.4 and 0.8 mg/L of fluoride.

³⁰ Ministry of Health. *Drinking-water Standards for New Zealand 2005*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz>.

³¹ Personal communication with Paul Prendergast, NZ Ministry of Health, January 2008.

³² Watercare Services Limited (2007) Annual Water Quality Report 2007. Auckland.

³³ Cochrane, N.J., Saranathan, S., Morgan, M.V. and Dashper, S.G. (2006) Fluoride content of still bottled water in Australia. *Australian Dental Journal* 51(3):242-244.

2.2.4 Fluoride Containing Dental Products

Fluoride can also be provided by dental products such as toothpaste, mouthwashes and topical applications. Levels of fluoride in toothpastes range from 400-500 mg/kg in those marketed towards children (between 18 months up to 6 years of age) and up to around 1000 mg/kg for adult toothpastes. Levels in mouth rinses range between 200 and 900 mg/kg which are for daily and weekly use respectively. Topical products (e.g. gels and solutions) are more commonly used and applied by dental professionals and contain up to 24000 mg/kg.

2.2.5 Fluoride Supplements

Fluoride supplements are available in the form of tablets. The chewable variety contains 0.25 mg per tablet. The recommended dose per day depends on age and level of water fluoridation in the area of residence and recommendations by dental professionals. The ADA recommends that tablets and drops should not be taken directly, but instead mixed in with water and consumed in that way.

The use of fluoride supplements is uncommon, however is more common in non-fluoridated areas. For example, for Western Australian children aged 12 years in 1989/1990, the use of fluoride tablets from birth to four years was rare (12%)³⁴; in 1990/1991 5% of 6 year olds reported taking a fluoride supplement³⁵; and 7% of 10 year olds in 2000³⁶.

2.2.6 Sources of Fluoride for Infants

The concentration of fluoride in breast milk is low irrespective of whether the mother consumes fluoridated or non-fluoridated water.³⁷ Levels in breast milk are around 0.007-0.011 mg/L³⁸. Powdered infant formulas in Australia and New Zealand contain low levels of fluoride.³⁹ Historically, the levels of fluoride in formula powder were there as a result of the water used to prepare the powder. In 1996, the levels of fluoride in the powdered milk-based formula in Australia were 0.23-3.71 mg/kg and soy based formula 1.08-2.86 mg/kg. When prepared using non-fluoridated water the concentration fell to 0.03-0.53 mg/kg⁴⁰. In 1997 in New Zealand, the levels in prepared infant formula made with non-fluoridated water were 0.13 mg/kg for milk based formula and 0.20 mg/kg for soy-based formula⁴¹.

³⁴ Riordan, P.J. and Banks, J.A. (1991) Dental Fluorosis and Fluoride Exposure in Western Australia. *Journal of Dental Research* 70(7):1022-1028.

³⁵ Riordan, P.J. (1993) Dental Fluorosis, Dental Caries and Fluoride Exposure among 7-Year-Olds. *Caries Research* 27:71-77.

³⁶ Riordan, P.J. (2002) Dental fluorosis decline after changes to supplement and toothpaste regimens. *Community Dentistry and Oral Epidemiology* 30(3):233-240.

³⁷ Ministry of Health (2008) *Food and Nutrition Guidelines for Healthy Infants and Toddlers (aged 0-2. A Background Paper. 4th Edition*. Ministry of Health, Wellington. Available from [http://www.moh.govt.nz/moh.nsf/pagesmh/7756/\\$File/0-2-food-and-nutrition-guidelines-may08.pdf](http://www.moh.govt.nz/moh.nsf/pagesmh/7756/$File/0-2-food-and-nutrition-guidelines-may08.pdf).

³⁸ Institute of Medicine. (1997) *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. National Academy of Sciences, Washington.

³⁹ Australian Research Centre for Population Oral Health, 2006. *The Use of Fluorides in Australia: guidelines*. *The Australian Dental Journal* 51 (2): 195-199.

⁴⁰ Silva, M. and Reynolds, E.C. (1996) Fluoride content of infant formulae in Australia. *Australian Dental Journal* 41 (1): 37-42.

⁴¹ Vannoort, R. W. and Cressey, P. J. (1997) Assessment of selected pesticides and the elements cadmium, lead, time, iodine and fluoride in infant formulae and weaning foods. A report for the Ministry of Health. Institute of Environmental Science and Research Limited (ESR), Christchurch.

The NHMRC Systematic Review of Water Fluoridation (2007) noted that the levels of fluoride in infant formula powder have been decreasing over time. The major source of fluoride in infant formulas is fluoridated water used to reconstitute the powdered formula. The levels in pre-prepared ready to drink formulas are generally very low, at or below the level of non-fluoridated water (manufacturer information).

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 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.⁴² 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 i.e. as contaminants.

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

Standard 1.2.4 – Labelling of Ingredients sets out specific requirements for the labelling and naming of ingredients and compound ingredients.

Standard 1.2.8 – Nutrition Information Requirements sets out nutrition information requirements that is required to be labelled and food exempt from these labelling requirements. It also prescribes when nutritional information must be provided, and the presentation format of this information.

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) as a processing aid that may be present in packaged water or in water used in manufacturing is 1.5 mg/kg⁴³ (equivalent to 1.5 mg/L). The maximum amount of Hydrofluorosilicic acid which may be present as a processing aid is established by good manufacturing practice (GMP).

3.2 Overseas and International Regulations

Currently, the regulation of packaged water differs between countries in Europe, Asia and the United States of America (USA). While some countries have separate standards for mineral or spring water and other packaged water, as is the case in Australia and New Zealand, other countries do not differentiate between different types of packaged water.

⁴² Standard 2.6.2 defines ‘mineral water or spring water’ as *ground water obtained from subterranean water-bearing strata that, in its natural state, contains soluble matter.*

⁴³ Note that mg/kg is equivalent to mg/L.

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 to 2 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’⁴⁴. The addition of fluoride to natural mineral water is not permitted.

At its meeting in February 2008, 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*⁴⁵. the WHO-recommended Guideline Value for naturally occurring fluoride in drinking water is 1.5 mg/L.

The Committee agreed 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’.⁴⁶ This new threshold, which has been reduced from the previous level of 2.0 mg/L, aligns with the WHO Guideline Value. The Committee proposed an Amendment of Sections 3.2 and 6.3.2 of the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981 (N12-2007))⁴⁷ which was adopted by the Codex Alimentarius Commission at its 31st meeting in July 2008.

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’.⁴⁸ 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.

⁴⁴ CODEX STAN 108-1981, Rev-1997, Amend.2001) is available from http://www.codexalimentarius.net/download/standards/223/CXS_108e.pdf.

⁴⁵ 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.

⁴⁶ 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).

⁴⁷ CODEX Alinorm 08/31/20 Appendix II

⁴⁸ CODEX STAN 227-2001 is available from http://www.codexalimentarius.net/download/standards/369/CXS_227e.pdf.

3.2.2 *European Union*

Most European countries have regulations that align with the European Union (EU) Commission Directive⁴⁹ 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 EU Commission Directive 98/83/EC of 3 November 1998⁵⁰ 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 Union members.⁵¹

3.2.3 *United States of America*

In the USA, packaged water is regulated by the US Food and Drug Administration (USFDA) in accordance with the Code of Federal Regulations⁵². 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 in imported bottled water with added fluoride must be less than 0.8 mg/L.

3.2.4 *Canada*

Canada’s Food and Drugs legislation⁵³ 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 mg/L). The principal display panel of the label must state that fluoride has been added and the total fluoride content.

⁴⁹ 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.

⁵⁰ Available from <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1998/L/01998L0083-20031120-en.pdf>

⁵¹ Personal communication from Mr Jean-François Roche, Administrator, Health and Consumer Protection Directorate General, European Commission.

⁵² Code of Federal Regulations (CFR165.110) Available from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?CFRPart=165>.

⁵³ 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.

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.

3.3 Interrelationships with other FSANZ Work

3.3.1 Application A611 – Labelling of Fluoridated & Non-fluoridated Water in Ingredients List

Application A611 – Labelling of Fluoridated & Non-fluoridated Water in Ingredients List is seeking to amend labelling requirements in Standard 1.2.4 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 non-fluoridated or artificially fluoridated. This Application has been included on the FSANZ Work Plan with commencement of the assessment process due in late 2008.

3.3.2 Proposal P293 – Nutrition, Health & Related Claims

The regulation of nutrition, health and related claims is being reviewed by Proposal P293 – Nutrition, Health & Related Claims. Draft Standard 1.2.7 sets out the criteria and conditions for making content claims, health claims and related claims.

In June 2008, FSANZ received a Review request from the Ministerial Council for Proposal P293. The response to the Review request is expected to be notified to the Ministerial Council in May 2009. If a Second Review is not requested, the Standard would be gazetted soon after. There will be a transition period of two years 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. In response to the release of the revised Nutrient Reference Values (NRVs),⁵⁴ FSANZ plans to commence a scoping exercise to determine how best to incorporate the new and revised values into the Code. FSANZ expects to consult on the proposed approach in 2009.

4. Current Market

4.1 Water Consumption Behaviours and Motivations

There are limited population data available on consumption patterns of packaged water products, and fluoridated reticulated water in Australia and New Zealand. FSANZ has explored available datasets to investigate proportions of consumers across Australia and New Zealand who consume packaged and reticulated water, to determine who consumes these beverages, and motivations for consumption. Study findings are discussed below.

⁵⁴ NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Canberra, ACT.

The success of bottled water is shaping the dynamics of the drinks market and is due to three main factors: convenience, maintenance of fluid balance and fashion and culture, as reported by the British Nutrition Foundation⁵⁵. 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.⁵⁶

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 people⁵⁷. 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 occasion⁵⁸. There are no data for consumption of packaged water by infants and very young children.

4.2 Australian Market

The Food Magazine E-Newsletter reports that the packaged water segment⁵⁹ is one of the fastest growing sectors within Australia's beverage industry with a 12% increase in revenue during 2006-2007 totalling \$AUD627 million⁶⁰. This represents approximately 5% of Australia's total beverage manufacturing revenue.

According to ACNielsen Australia Scan Track data published in the Australian Beverages Year Book 2008,⁶¹ still water constitutes 9.9% of sales for the non-alcoholic ready-to-drink (NARTD) market, up from 9.6% for the previous year. Along with tea, sports drinks and energy drinks, still water is gaining share of the NARTD market at the expense of soft drinks and fruit juices and drinks.

⁵⁵ Bedford, A.M. *Beverages and Health*. Available at:

<http://www.nutrition.org.uk/home.asp?siteId=43§ionId=1440&subSubSectionId=1419&subSectionId=336&parentSection=302&which=4> British Nutrition Foundation conference, 4th Dec 2001. Accessed: 12 June 2008.

⁵⁶ ABWI website: accessible from <http://www.bottledwater.org.au/scripts/cgiip.exe/WService=ASP0003/ccms.r>

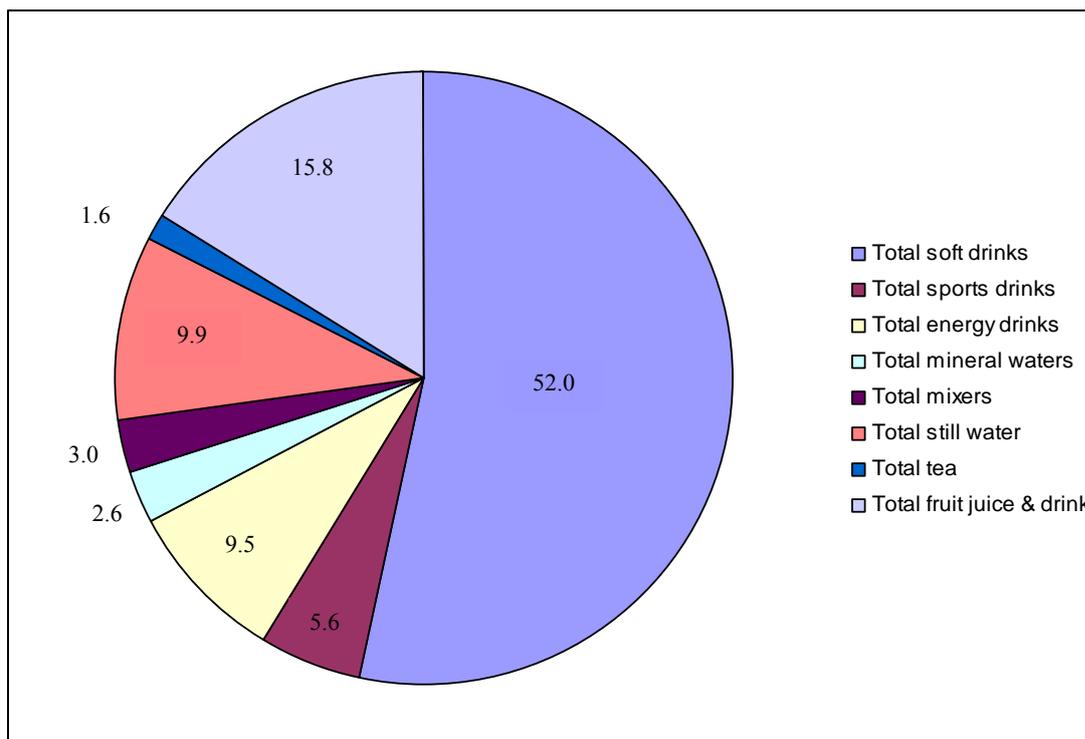
⁵⁷ Levy, G & Tapsell, L. (2007). Shifts in purchasing patterns of non-alcoholic water-based beverages in Australia, 1997-2006. *Nutrition and Dietetics*, 64, 268-279.

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

⁵⁹ Includes natural spring water and purified water.

⁶⁰ 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.

⁶¹ Australian Beverages, ABWI and Australian Fruit Juice Association (2008) Australian Beverages YearBook 2008 Melbourne, Vic.



Source: ACNielsen Australia Scan Track

Figure 2: Market Share of Non-alcoholic Ready to Drink Products in Australia (% Sales at April 2008)

According to a study by Levy and Tapsell⁶² on trends in purchasing patterns of non-alcoholic, water-based beverages in Australia from 1997 to 2006, sales of still water increased from 107 to 279 million litres, an increase of 162% over 10 years. This represents an increase from 23 (in 1997) to 46 L per person per year (in 2006).

The trend towards increasing consumption of still packaged water is in line with increasing consumption of non-sugar carbonated soft drinks. During the same period, sales of carbonated sugar-sweetened soft drinks fell by 5%.

4.3 New Zealand Market

The New Zealand population drinks approximately 10 litres of packaged water per head per year⁶³.

Packaged water (still water and carbonated water) generated retail sales totalling \$NZ136 million in 2007⁶⁴. Industry data⁶⁵ showed that total packaged water sales increased by 9.4% in 2007, with still water sales increasing by 9% over this period.

⁶² 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.

⁶³ Banham, S. (2008) Data sourced from Zenith International.

⁶⁴ Personal communication Vincent Meron, Technical Director, Frucor Beverages Limited.

⁶⁵ Personal Communication: based on AC Nielsen Scan Track Data (total supermarkets and service stations two year trading), February 2008.

Still water accounted for 7.8% of NARTD market in 2007. Still water has shown growth over the last 3 years, with increases of 22.7% from 2004 to 2005, 3.6% in 2006 and 9.0% in 2007.

4.4 Overseas 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 USA have added fluoride.⁶⁶

Growth in the packaged water market is occurring globally. In May 2008, it was reported⁶⁷ that global packaged water consumption has doubled in the past 10 years, from 15 to 29 litres (average) per person per annum. Western Europe and North America currently have the highest per capita consumption with 116 and 101 litres per person per annum respectively, while Australians drank 46 litres per person per annum in 2007.

In 2007, total USA volume of packaged water exceeded 33.3 billion litres, an increase of 6.9% over the 2006 level. Apart from carbonated soft drinks, USA consumers drink more bottled water annually than any other beverage⁶⁸.

4.5 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 products⁶⁹.

5. Ministerial Policy Guidance

The Ministerial Council endorsed a Policy Guideline *Fortification of Foods with Vitamins and Minerals* (the Policy Guideline) in May 2004. 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 Supporting Document 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.

⁶⁶ Informal figures from the IBWA provided in the Application.

⁶⁷ Banham S (2008) Data sourced from Zenith International

⁶⁸ Adapted from the Beverage Marketing Corporation's 2008 Market Report Findings. Available from the IBWA website: http://www.bottledwater.org/public/BWfactsHome_main.htm

⁶⁹ Based on an assessment of current market patterns by the ABWI.

5.1 FSANZ's Fortification Implementation Framework

FSANZ's *Fortification Implementation Framework – Addition of Vitamins and Minerals to Food* (2005)⁷⁰ (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. Currently it is not permitted to add fluoride to packaged water.

FSANZ's role is to: identify any risks associated with the voluntary addition of fluoride to packaged water as an alternative to fluoridated water; design 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 has assessed 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;
- 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;

⁷⁰ FSANZ's *Fortification Implementation Framework - Addition of Vitamins and Minerals to Food* (2005) Available from FSANZ on request.

- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objectives in consideration 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 reticulated 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 reticulated 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 Principles⁷¹. FSANZ considers fluoridated packaged water to be a substitute beverage in terms of appearance and use and that it is nutritionally equivalent to fluoridated reticulated water. (See also Sections 10.1.2 and 12.1 of this Report.)

⁷¹ 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.

FSANZ considers that inadequate fluoride intakes at a population level are unlikely due to the high prevalence of fluoridated reticulated water in Australia and New Zealand.

The prevalence of dental caries, particularly in children, is used as a crude indicator of low or inadequate 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.

The benefit of fluoride to dental health is well established. If fluoridated packaged water is considered to be nutritionally equivalent to fluoridated reticulated water, then both beverages will provide similar health benefits.

9. Key Assessment Questions

The key assessment questions addressed at Draft Assessment are:

9.1 Health and Safety Issues

- What is the history of safe use of fluoridated water?
- Is packaged water with added fluoride nutritionally equivalent to fluoridated reticulated water?
- Is there any evidence that the substitution of fluoridated packaged water for fluoridated reticulated 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?

9.2 Technological Issues

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

RISK ASSESSMENT

10. Approach to 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 determine if fluoridated packaged water is nutritionally equivalent to fluoridated reticulated water. The origin and derivation of the NRVs, particularly the ULs, with respect to dental outcomes (caries and fluorosis) were investigated in detail to determine their appropriateness for the risk characterisation. A dietary intake assessment was undertaken to obtain baseline estimates of dietary intake of fluoride which were compared to the UL. Submissions suggested that fluoride contributed to adverse outcomes including fluorosis, therefore these outcomes were assessed.

Any other adverse effects on potential vulnerable groups, including infants and young children, were also assessed.

The risk assessment considered the information provided by the Applicant. FSANZ also obtained other available information from the scientific literature, independent scientists and experts, other regulatory and government agencies, international agencies, the general community and general technical information.

FSANZ also:

- sought advice from Australian and New Zealand dental experts and professional associations regarding trends in the rates of dental caries and dental fluorosis and the possible causes;
- liaised with the NHMRC and NZMoH regarding the dietary intake assessment results and their implications for water fluoridation policy and nutrient reference values (NRVs); and
- liaised with other government agencies regarding the dietary intake assessment results.

10.1 Risk Assessment Issues

10.1.1 History of safe use

Fluoridation of water supplies to reduce the incidence of dental caries has been utilised in Australia, New Zealand and other countries for over 50 years. The benefits of water fluoridation on dental health are widely accepted. 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 National Health and Medical Research Council, the World Health Organization and the US Centers for Disease Control and Prevention. FSANZ concurs with these statements that there is a history of safe use of fluoride in reticulated water supplies in Australia, New Zealand and overseas. Thus, a comprehensive safety assessment was not undertaken on this issue.

The Applicant is requesting permission to use sodium fluoride, sodium fluorosilicate (also called sodium silicofluoride) and hydrofluorosilicic acid (fluorosilicic acid). It was raised in submissions that the safety of silicofluorides has never been tested. Silicofluorides are commonly used in fluoridating water supplies⁷², for which there is a history of safe use as stated above.

10.1.2 Assessment of nutritional equivalence

FSANZ assessed the nutritional equivalence of fluoridated reticulated water and packaged water with added fluoride. There are many similarities in nutrient content between packaged water and reticulated water in Australia and New Zealand, whether fluoridated or not. The macronutrient content is equivalent between the two types of waters with zero concentrations for energy, fat, protein, carbohydrates, fibre and alcohol.

⁷² NHMRC (2007) *Systematic Review of the Efficacy and Safety of Fluoridation*. Commonwealth of Australia, Canberra.

This is also the case for a range of vitamins which also have zero concentrations. There are some very minor differences between some minerals in ‘reticulated’ compared to ‘bottled’ water (e.g. iodine, sodium, magnesium). This is expected given the natural variation in water from different regions. However, the intake of minerals would not differ considerably as a result of substituting reticulated water with packaged water. For more information on the assessment of nutritional equivalence, see the Nutrition Risk Assessment Report at Supporting Document 2.

The forms of fluoride requested to be added to packaged water by the Applicant are the same as those added to fluoridated reticulated water, therefore the different types of water would be equivalent in relation in this respect. These forms are highly bioavailable from the water. Fluoride is slightly less bioavailable (by around 10-25%) from foods containing other cations, including calcium, and therefore less available from foods such as infant formula and milk. However, the bioavailability would not differ from infant formula prepared using fluoridated reticulated water compared to fluoridated packaged water.

FSANZ concludes that packaged water which does not have added fluoride is nutritionally equivalent to non-fluoridated reticulated water. Should packaged water be permitted to contain between 0.6 to 1 mg/L, then it would be nutritionally equivalent to fluoridated reticulated water supplies in Australian and New Zealand. FSANZ notes that the Application is for a voluntary permission to add fluoride. The Applicant estimates that only 15% of packaged water would contain added fluoride if the permission was granted.

10.1.3 Fluoride Upper Level

The current Australian and New Zealand UL values for fluoride were adopted without change from the US/Canadian values estimated by the Food and Nutrition Board: Institute of Medicine (USA) in 1997. The US/Canadian ULs were based on fluoride intakes estimated using model diets in the 1940s and the prevalence and severity of dental fluorosis in children who resided in areas with differing levels of fluoride in their drinking water supplies in the 1930s-1940s in the USA (FNB:IOM, 1997). As indicated in Table 1, the Australian/New Zealand ULs are 0.7 mg/day for 0-6 months of age, 0.9 mg/day for 7-12 months, 1.3 mg/day for 1-3 years, 2.2 mg/day for 4-8 years and 10 mg/day for 9 years and above.

FSANZ noted that as the ULs were assigned based on using model diets, it was now possible to perform a similar fluoride intake analysis utilising the actual consumption data from the Australian and New Zealand NNSs (1995 Australia; 1997 New Zealand) to confirm that the current levels of fluoride intake in Australian and New Zealand population groups were below the UL. The intake analysis revealed that when fluoride intakes were calculated using actual dietary data that apparent exceedances were noted for 2-3 year olds and 4-8 year olds (below and Supporting Document 3). However, these apparent exceedances by these 2 age groups were considered to be a function of the use of actual fluoride intake data rather than model intake data that were used to develop the UL.

A detailed examination of the basis of the UL led to the conclusion that the UL values adopted by the NHMRC & NZMoH (2006) were based upon the best available information at the time (Supporting Document 4). The absence of any increase in moderate fluorosis (see further details below) indicates that this revision is not urgent and the apparent exceedances of the existing UL do not indicate a safety concern.

The apparent discordance between the intake estimates without a corresponding increase in prevalence of dental fluorosis indicates that the existing UL will need to be revised.

10.1.4 *The Impact of Permitting the Voluntary Addition of Fluoride to Packaged Water*

10.1.4.1 Dietary Intake Assessment

In preparing the Draft Assessment Report for A588, FSANZ undertook a dietary intake assessment to:

1. establish baseline fluoride intakes; and
2. determine whether approving the application is likely to pose a risk to any vulnerable groups.

This is the first time that FSANZ has estimated fluoride intakes from the total diet for Australia and New Zealand. FSANZ combined data on food and water consumption patterns, fluoride composition data for foods and beverages and other relevant information to conduct the dietary intake assessment. See Supporting Document 3 for further details.

In the Code, a voluntary permission is one which allows manufacturers to add the substance, or not, as they wish as opposed to a mandatory permission which means that manufacturers must add the substance. The current Application is for a voluntary permission to add fluoride within a specified concentration range. Despite this, FSANZ took a conservative approach to the dietary modelling and assumed that all packaged water and reticulated water would be fluoridated. Because non-fluoridated packaged water would still be widely available, this approach would overestimate intakes of those who choose to purchase this product.

Scenarios for three different levels of fluoride in water were assessed: 0.1 mg/L (non-fluoridated); 0.6 and 1 mg/L, (within the target range for fluoridated reticulated water in Australia⁷³ and New Zealand⁷⁴), which is also the range requested by the Applicant. The range of actual concentrations of fluoride in reticulated water in Australia and New Zealand also lies between 0.6-1 mg/L, and therefore reflects the 'nutritional equivalence' approach used in this Assessment.

Intake estimates for Australian population groups aged 2 years and above were derived using food consumption data from the 1995 Australian National Nutrition Survey (NNS) (1995). Intakes were estimated for New Zealanders aged 15 years and above from the latest New Zealand NNS (1997). A second day adjustment methodology was used to better estimate longer term intakes for these population groups. For infants (3 months solely formula-fed) and young children (9-month olds Australia; 6-12 month olds New Zealand), model diets were used to estimate dietary intakes for those who do not always substitute fluoridated reticulated water with fluoridated packaged water.

A new food composition dataset was compiled using recent analytical results for the fluoride content of Australian foods, imputed values for mixed foods and some data from overseas food composition tables, including data from New Zealand.

⁷³ NHMRC Public Statement *The Efficacy and Safety of Fluoridation 2007* Available from: http://www.nhmrc.gov.au/media/media/rel07/_files/Fluoride_Flyer.pdf.

⁷⁴ Ministry of Health. *Drinking-water Standards for New Zealand 2005*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz>.

When constructing the dataset it was assumed that water used to prepare beverages such as tea, coffee and cordial, and water absorbed by foods such as rice and pasta, contained the level of fluoride specified for each scenario. Commercially-made beverages (e.g. fruit juices and drinks, soft drink) contain the level of fluoride in the reticulated water from where they are manufactured. Therefore, national average concentrations for these beverages were used in the composition dataset and these values did not change across scenarios.

Recent evidence suggests that sales of bottled water have increased since the NNSs were conducted. It was assumed in the dietary intake assessment that total water consumption has not changed over time, i.e. that bottled water has displaced reticulated water. Therefore, assigning the same fluoride concentration to both reticulated and bottled water in the NNS for each scenario means that possible changes in source of water are allowed for in the modelling. People might not always buy fluoridated packaged water in the future, therefore this approach could overestimate fluoride intake under the two fluoridation scenarios.

The intake estimates were based on total dietary intake (water and food) and did not include potential additional intakes from sources such as swallowed toothpaste or supplements. Mean dietary intakes were compared with the AI and the distribution of dietary intakes was used to estimate the proportion that exceeded the UL.

10.1.4.2 Estimated Dietary Intakes

The estimated mean dietary intakes for fluoride for a range of population groups in Australia and New Zealand are shown in Table 2. Estimated dietary intakes were less than 0.01 mg/day for breast fed infants (aged 3 months) and 0.2 mg/day for infant formula fed infants (aged 3 months) when non-fluoridated water was used to prepare the formula and between 0.7-1 mg/day when optimally fluoridated water was used to prepare the formula. For infants between 6 and 12 months of age who consume a diet of solid foods and infant formula mean dietary intakes are 0.4 mg/day when non-fluoridated water was used and between 0.6–1.3 mg/day when optimally fluoridated water (0.6-1 mg/L) was consumed.

For Australian population groups 2 years or over, mean dietary intakes were between 0.5 and 1 mg/day when non-fluoridated water was consumed and between 1 and 2.4 mg/day when optimally fluoridated water was consumed. For New Zealand population groups 15 years and over, mean dietary intakes were between 1 and 1.5 mg/day when non-fluoridated water was consumed and between 1.5 and 2.8 mg/day when optimally fluoridated water was consumed.

Table 2: Estimated mean dietary intakes of fluoride (mg/day) for various population groups

Country	Population Group	Estimated mean dietary fluoride intake (mg/day)			Adequate Intake [#] (mg/day)	
		Water – 0.1 mg/L	Water – 0.6 mg/L	Water – 1 mg/L	Males	Females
Aust / NZ	3 months breast fed	0.002-0.008*			0.01	0.01
Aust / NZ	3 months formula fed	0.2	0.7	1.0	0.01	0.01
Australia	9 months	0.4	1.0	1.3	0.5	0.5
	2-3 years	0.5	0.9	1.0	0.7	0.7
	4-8 years	0.6	1.0	1.2	1.0	1.0
	9-13 years	0.7	1.3	1.6	2.0	2.0
	14-18 years	1.0	1.7	2.1	3.0	3.0
	19-29 years	1.0	1.9	2.4	4.0	3.0
	30-49 years	1.0	1.9	2.4	4.0	3.0
	50-69 years	0.9	1.7	2.1	4.0	3.0
	70 years & above	0.8	1.4	1.7	4.0	3.0
New Zealand	2 years & above	0.9	1.7	2.1		
	6-12 months	0.4	0.6	0.9	0.5	0.5
	15-18 years	1.0	1.5	2.0	3.0	3.0
	19-29 years	1.1	1.7	2.3	4.0	3.0
	30-49 years	1.4	2.2	2.7	4.0	3.0
	50-69 years	1.5	2.2	2.8	4.0	3.0
	70 years & above	1.4	2.1	2.6	4.0	3.0
15 years & above	1.4	2.1	2.6	4.0	3.0	

* Water fluoride concentration irrelevant.

As would be expected, the major and only contributor to fluoride intakes for infants aged 0-6 months is breast milk or formula. Follow on formula is the major contributor (>5%) between the ages of 6-12 months, even in non-fluoridated areas. Where water is not fluoridated the major contributor is fruit and vegetable based drinks for Australian children 2-3 years (the majority of which comes from fruit drinks), soft drinks for Australian children 4-8 years, beer for Australian adults and tea for New Zealand adults. When water is optimally fluoridated, the major contributor for all population groups is drinking water (either plain or made up with cordial in the case of children, coffee in Australian adults or tea in New Zealand adults). Tea contains fluoride that is leached out from the leaves in addition to fluoride in the water.

For more details on the dietary intakes assessment see Supporting Document 3.

10.1.4.3 Effects on Dietary Fluoride Intake due to Beverage Substitution

If non-fluoridated water was replaced with optimally fluoridated water, mean dietary intakes could increase between 90-130% for Australians aged 2 years and above and between 50-90% for New Zealanders aged 15 years and above. Increases could be up to 400% for 3 month olds and between 50 and 230% for 6-12 month olds.

The results presented above discuss the substitution of non-fluoridated water with fluoridated water. However, water might be replaced by non-water beverages. An Australian study⁷⁵ indicates that sales of packaged water, non-sugar 'diet' soft drinks, sweetened sports drinks, energy drinks and iced tea have all increased, and sugar soft drinks have decreased. If it is assumed that total beverage consumption has remained the same and one beverage is substituted for another, the impact of substituting beverages such as fruit drinks and soft drinks for optimally fluoridated water (0.6-1 mg/L), would be minimal. This is because fruit drinks and soft drinks contain around 0.4-0.7 mg/L of fluoride (analysed values).

The summary of the main findings of the 2007 Australian Children's Nutrition and Physical Activity Survey were released on 3 October 2008⁷⁶, shortly prior to the release of this Draft Assessment Report. The summary showed that mean consumption of non-alcoholic beverages, which includes water, was lower in 2007 than 1995 for children up to 8 years. This would indicate that fluoride intakes might be lower for young children than described in this Report. These results also support the assumption that packaged water and other drinks are substituted for reticulated water rather than consumed in addition to reticulated water. As the details of the survey are not yet available, FSANZ is unable to assess this issue further. This issue will be considered further when more data become available to FSANZ.

10.1.4.4 Estimated Intakes from Other Sources

The Australian Dental Association recommends that children 17 months and under should not use toothpaste and should brush erupted teeth twice per day. Children 18 months-5 years should use a 'pea sized' amount of low fluoride ('child strength') toothpastes, which have a concentration of 400-500 mg/kg fluoride, and should brush twice per day. From 6 years of age, an adult strength toothpaste (~1000 mg/kg) can be used and teeth should be brushed twice per day.

The NZMoH advises that the New Zealand population use an adult strength toothpaste (1000 mg/kg). However, a 'smear' of toothpaste should be used for younger children, who should also be discouraged from swallowing or eating toothpaste.

Fluoride intake for young children from using a pea-sized amount (assumed to be 0.5 g) of child's toothpaste is likely to be around 0.1-0.3 mg/day.

⁷⁵ Levy.G. and Tapsell, L. (2007) Shifts in purchasing patterns of non-alcoholic, water-based beverages in Australia, 1997-2006. *Nutrition and Dietetics* 64:268-279.

⁷⁶ CSIRO (2008) 2007 Australian National Children's Nutrition and Physical Activity Survey. Main Findings. <http://www.health.gov.au/internet/main/publishing.nsf/Content/phd-nutrition-childrens-survey>.

This assumes one brushing per day and that half or all of the toothpaste is swallowed respectively, as young children have a poor swallow reflex and are known to swallow toothpaste.⁷⁷ This could be doubled if the recommendation of two brushings per day was adhered to. These estimated intakes from toothpaste may increase intakes for children by around 10% for those consuming fluoridated water and around 50% for those consuming non-fluoridated water as they have lower intakes to begin with. Fluoride intake for people aged 6 years and over from using a gram of adult toothpaste per day with minimal swallowing (up to around 10% in adults⁷⁷) would be 0.1 mg/day. This would increase intakes for this group between 4-10% in optimally fluoridated areas.

Fluoride supplements (tablets or drops) are no longer generally recommended and even in non-fluoridated areas should only be taken when advised by a dental professional. They are available in 0.25 mg fluoride tablets so would add this amount of fluoride to intakes if one tablet were taken per day. Recommended dose/day would depend on the recommendation of the dental professional.

A new pesticide containing fluoride (sulfuryl fluoride) has recently been approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and is currently being considered by FSANZ for inclusion in the Code under Proposal M1002⁷⁸. The pesticide has been approved for use on four commodities (Maximum Residue Limits: cereal grains 0.05 mg/kg; dried fruit 0.07 mg/kg; peanuts 7 mg/kg; tree nuts 7 mg/kg). Some submitters questioned the amount of fluoride that approval of this pesticide would add to dietary intakes.

A dietary intake assessment was included in Proposal M1002. It showed that likely residues would increase mean dietary intakes of the fluoride ion by around 0.14 mg/day for children 2-6 years and by 0.23 mg/day for the population 7 years and above. This increase equated to up to 10% of the upper levels of intake for these groups. However, this is likely to be an overestimate because it assumes the pesticide residue is found on all foods within each commodity group, which is unlikely. In addition, the analysed fluoride concentration in the food will include fluoride from the pesticide residue and will also include naturally occurring fluoride, which can not be distinguished from each other, therefore producing a greater overestimate in this calculation.

10.1.5 Risks to any Population or Vulnerable Groups including Infants and Young Children

10.1.5.1 Estimated Dietary Intakes in Relation to the UL

The possibility of excessive dietary intake from infant formula prepared using fluoridated reticulated water has been raised in the literature and in submissions to the Initial Assessment Report. Model diets were used to estimate dietary intakes for infants up to 12 months. The mean intakes were calculated and the 90th percentile intakes were estimated based on a simple calculation of two times the mean (see Supporting Document 3 for more details). As there were no distributions of dietary intakes for infants, the proportion of these population groups exceeding the UL could not be estimated. Instead, the mean and 90th percentile intakes were calculated as a per cent of the respective UL. These results are shown in Table 3.

⁷⁷ Institute of Medicine. (1997) *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. National Academy of Sciences, Washington.

⁷⁸ FSANZ (2008) *Proposal M1002. Maximum Residue Limits (January, February, March 2008). Assessment Report*. 6 August 2008. FSANZ, Canberra.

Table 3: Estimated dietary intakes as a per cent (%) of the UL for children up to 12 months of age for various water fluoridation scenarios

Population Group	Scenario water fluoride concentration (mg/L)					
	0.1		0.6		1	
	Mean	P90	Mean	P90	Mean	P90
3 months Formula fed	30	70	100	200	140	270
6-12 months New Zealand	45	80	65	140	100	190
9 months Australia	45	80	110	210	140	300

For infants who are solely breast fed, the mean and 90th percentile estimated dietary intakes of fluoride are 2% of the UL or less. For 3 month old formula-fed infants, where non-fluoridated water is used, mean and 90th percentile intakes are at 70% of the UL or less. When water fluoridated at 0.6 mg/L is used to prepare infant formula, mean intakes are equal to the UL and 90th percentile intakes above the UL (200%). When fluoridated water at 1 mg/L is used to prepare formula, mean and 90th percentile dietary intakes exceed the UL (140 and 270% respectively). Even though the levels of fluoride in infant formula powders have decreased following recommendations were made to do so in the early 1990s, these estimates indicate that infant formula prepared using optimally fluoridated water could result in dietary intakes at or above the UL for 0-6 month olds. This is primarily due to the water used to prepare the formula.

For infants between 6 and 12 months of age, the estimated mean and 90th percentile dietary intakes were below the UL for both Australia and New Zealand when non-fluoridated water is consumed. When optimally fluoridated water is consumed, mean and 90th percentile intakes for Australian 9 month olds exceed the UL between 110% and 300%. For New Zealand children aged 6-12 months, mean intakes are at or below the UL and 90th percentile intakes exceed the UL (140-190%).

No young children aged 2-8 years exceeded the UL when non-fluoridated water was consumed. When water is fluoridated at between 0.6 mg/L and 1 mg/L, between 5% and 22% of 2-3 year olds, and between <1% and 5% of 4-8 year olds, in the Australian population may currently exceed the UL for fluoride (see Table 4). Additional intakes from sources such as toothpaste or supplements would result in more children exceeding the UL. It is estimated that the fluoride from toothpaste may increase intakes for children by around 10% (for those consuming fluoridated water) and around 50% (for those consuming non-fluoridated water) (see Dietary Intake Assessment at Supporting Document 3).

Table 4: Estimated proportion (%) of Australian children 2 to 8 years with dietary intakes over UL for various water fluoridation scenarios

Age Group	Scenario water fluoride concentration (mg/L)		
	0.1	0.6	1
2-3	0	5	22
4-8	0	<1	5

Less than 1% of all population groups in Australia and New Zealand aged 9 years or above exceeded the UL when non-fluoridated or optimally fluoridated water was consumed.

10.1.5.2 High Consumers of Water

It was raised in submissions that some groups of the population may consume larger amounts of water than others and therefore are at increased risk of high fluoride intakes. These groups were identified as elite or endurance athletes, and people living or working in hotter climates.

Elite or endurance athletes cannot be identified in national nutrition surveys to perform a separate analysis. The amount of water required or consumed by elite or endurance athletes depends on the sport, intensity, duration, climate (temperature and humidity) during the event/training and sweat losses. No data were found on actual amounts of water consumed by elite athletes, or information about how long high consumption might be sustained.

However, information on sweat losses that need to be replaced following exercise indicates that most athletes lose around one litre of fluid per hour, which needs to be replaced with 1.5 litres of fluid following exercise. Athletes undertaking high intensity exercise in hot conditions can lose 2-3 litres of water per hour⁷⁹. This could lead to water and food consumption resulting in dietary intakes of fluoride around 10 mg/day (equivalent to the UL for people aged 9 years and over). Elite and endurance athletes would most likely be people above 9 years of age. The UL for this age group is based on skeletal fluorosis, a condition which requires daily intake of 10 mg/day or higher over a period of 10 years or more⁸⁰. It is unlikely that even elite or endurance athletes would maintain their elite/endurance status, and consequently such dietary intakes, for this period of time. Therefore, it is unlikely for adverse effects to occur for this population group.

The 1995 NNS was conducted from February 1995 to March 1996 and therefore covered summer. The 1995 NNS was conducted in all parts of Australia, including the Northern Territory, and so fluid consumption in hot climates and at hot times of the year were included as part of the fluoride intake distribution previously described.

Queensland and the Northern Territory are considered to be hotter parts of Australia whereas Tasmania is one of the cooler parts. The small population in the Northern Territory, and consequently small number of survey respondents, means that no separate assessment can be made for that jurisdiction. In the 1995 NNS, the mean intake of NNS food group *Mineral waters and water* was 1135 g/person/day in Queensland, followed by 982 g/person/day in Western Australia and only 538 g/person/day in Tasmania. The Australian population average was 852 g/person/day. In addition, the proportion of people reporting consumption of beverages in the *Mineral water and waters* group was highest in Queensland (87.8%) and lowest in Tasmania (68.0%). The national average was 79.8%⁸¹. This shows that people in hotter climates do drink more water.

FSANZ calculated indicative amounts of water that could be consumed at different levels of fluoridation before the UL would be exceeded. This was by taking into account current dietary intakes of fluoride (see dietary intake assessment report at Supporting Document 3 for more details).

⁷⁹ Sports Dietitians Australia. *Fact Sheet. Fuelling Fitness for the Future. Fluids in Sport*. www.sportsdietitians.com (accessed 2008).

⁸⁰ Institute of Medicine. (1997) *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. National Academy of Sciences, Washington.

⁸¹ McLennan, W and Podger, A. (1999) National Nutrition Survey. Foods Eaten. Australia. 1995. ABS Catalogue No. 4804.0. Commonwealth of Australia, Canberra.

Therefore, the results indicate the amount of water that needs to be consumed in addition to current diet and water consumption. The last column in Table 5 shows these results. For children up to 8 years the extra amount of optimally fluoridated water that could be consumed before exceeding the UL ranged from zero to 1.7 litres per day, depending on the age group. For the population aged 9 years and above, between 8-14 litres of additional optimally fluoridated water per day can be consumed before the UL is exceeded.

FSANZ compared these indicative amounts to amounts of water that high consumers consumed in the most recent nutrition surveys to determine if anyone is likely to consume volumes of water that would result in them exceeding the UL. The 95th percentile water consumption amounts are compared with the indicative amounts in Table 5.

The NNS data were used to determine how much water ‘high consumers’ consume irrespective of which state the respondent lived in or which season of the year they were reported in. High consumers of water (95th percentile) for the population aged 2 to 8 years consume around 1.4 litres per day and respondents aged 9 years and above consume between 2.0-3.0 litres per day (see Table 5).

It is evident that current patterns of consumption for children up to 8 years could result in intakes above the UL if fluoridated water is consumed. This is consistent with the findings of the dietary intake assessment discussed previously. The interpretation of the exceedance of the UL for this population group is discussed further below. Population groups aged 9 years and over consume water at amounts well below the additional water required to exceed the UL. It is unlikely that the estimated indicative amounts would be consumed daily on a long term basis. Therefore FSANZ concludes that people living and/or working in hotter climates are not at risk of adverse effects from consuming optimally fluoridated water.

Table 5: Actual water consumption and indicative water consumption required to exceed the UL (in addition to current water consumption)

Age Group	95 th percentile water consumption (Litres) Aust / NZ	Indicative consumption optimally fluoridated water before exceeding UL (Litres)
0-6 months	NA	0.7-1.2
7-12 months	NA	0-0
1-3 years	*1.3 / NA	0.3-0.5
4-8 years	1.5 / NA	1.0-1.7
9-13 years	2.1 / NA	8.0-14.0
14-18 years	2.5 / 2.4 [#]	8.0-13.0
19 years and above	2.7 / 2.5	8.0-13.0

* 2-3 years

[#] 15 - 18 years New Zealand

NA = Not available

10.1.5.3 Other Adverse Effects

Some literature and submitters suggest that fluoride exposure is related to cancer and several other adverse conditions or effects.

These other effects included bone disease including fracture, thyroid diseases, brain disease, neurological damage, kidney failure, cell toxicity, Parkinson's disease, Alzheimer's dementia, goitre, Down's syndrome, arthritis, high blood lead levels, and lowered IQ in children. Population sub-groups suggested to be at greater risk included the iodine deficient, diabetics and those with impaired kidney function.

From the evidence evaluated, including from recent systematic reviews, FSANZ concludes that there is a lack of evidence showing any association with cancer or any other adverse effects, and that water fluoridation at current levels in Australia and New Zealand would not contribute to any such adverse effects. Further details of this assessment can be found in the Nutrition Risk Assessment at Supporting Document 2.

10.2 Risk Characterisation

The dietary intake assessment for Australian children up to 8 years indicated that a significant proportion of those children may currently exceed the existing UL for fluoride. Therefore, FSANZ considered these results with the information on the basis of the UL (discussed above) and evidence of dental effects (discussed below) to establish whether this exceedance was a cause for concern to public health and safety.

FSANZ notes that the NHMRC recommended target range for water fluoridation provides a balance between reduction of dental caries and occurrence of dental fluorosis. There is a narrow margin between the level of intake required to obtain a beneficial effect for dental caries and the level at which the severity and incidence of dental fluorosis becomes unacceptable (see Figure 1 in Supporting Document 4).

The prevalence of dental caries has been increasing in Australian and New Zealand children since around 1996. Possible explanations for the rise in dental caries in children include the availability of lower fluoride toothpastes for children, increased consumption of non-fluoridated bottled and rain water, a reduction in the number of fissure sealants and changes in the diets of children in relation to sugar and fermentable carbohydrate intake. This supports the need for continuing water fluoridation.

If exceedance of the UL is a health risk, then dental surveys should report the existence of a certain level of moderate fluorosis in Australia and New Zealand. It is accepted that in areas with optimal water fluoridation, there will be a prevalence of around 10-12 % of very mild to mild dental fluorosis, which is not considered to be an adverse outcome. Recent studies in Australia (in the last decade) show a prevalence of fluorosis ranging between around 10 to 20%, but this includes very mild and mild fluorosis. There were usually only a few per cent with higher fluorosis rating scores, which were generally considered to be a lower level of fluorosis than 'moderate', the critical point which was used to set the UL. Dental fluorosis is seen both in areas with and without water fluoridation. Research suggests that the majority of mild fluorosis seen in Australia at present is not generally perceived as cosmetically adverse.

In New Zealand, dental groups collect data as 'enamel defects' rather than as 'fluorosis'. The enamel defects observed are consistent with mild dental fluorosis, however these defects may or may not be attributed to fluoride. The prevalence of enamel defects in New Zealand children has not increased since the 1980s. Severe enamel defects have decreased since that time. There was no significant difference in enamel defects between fluoridated and non-fluoridated areas.

Research suggests that fluorosis is commonly attributed to the use of dental products. Dental Associations and the literature state that because water fluoridation is the most effective and socially equitable means of minimising dental caries, the control of additional fluoride sources (e.g. toothpaste, supplements etc) should be undertaken to reduce levels of dental fluorosis, and not the reduction or removal of fluoride from drinking water. While the dietary intake assessment conducted by FSANZ showed that infants consuming infant formula could exceed the UL, experts who recently met in Australia found that there is no association between the consumption of infant formula prepared with fluoridated water and levels of dental fluorosis. Thus FSANZ considers that it is safe for infants to consume formula prepared with either fluoridated or non-fluoridated water.

For more details on the dental evidence see the Nutrition Risk Assessment report (Supporting Document 2).

Fluorosis was the only adverse effect identified in relation to risk of excess fluoride intake. Dental fluorosis, and not skeletal fluorosis, is the only clinical sign reported in Australian and New Zealand. The very mild and mild forms of dental fluorosis are considered to be ‘good’ or ‘beneficial’ (i.e., fluoride incorporated into teeth) in comparison to moderate or severe dental fluorosis which is of aesthetic concern and could be deemed to be an adverse health effect⁸². The development of skeletal fluorosis only occurs when dietary intakes are above 10 mg/day for over 10 years. This level of intake is much higher than the dietary intakes estimated for Australians and New Zealanders and is unlikely to be based on the current fluoride content of reticulated water.

The estimated proportions of children exceeding the UL does not correspond to the observation that moderate dental fluorosis in Australia and New Zealand, is rarely seen. Therefore FSANZ believes that the UL value may need to be revised to reflect actual intake levels of fluoride rather than hypothetical levels based on a model diet.

10.3 Risk Assessment Conclusions

There is a history of safe use of fluoride in reticulated water supplies, including for the forms requested by the Applicant to be added to packaged water. Fluoride is bioavailable in the forms added to drinking water, either reticulated or packaged.

Packaged water is nutritionally equivalent to reticulated water in relation to nutrients other than fluoride. Should the concentration of fluoride in packaged water be permitted at a level up to the target range of 0.6 to 1 mg/L as in reticulated water supplies, then any packaged water with added fluoride would be equivalent to actual concentrations in fluoridated reticulated water supplies in Australia and New Zealand.

The dietary intake assessment results showed that 5-22% of children up to 8 years currently exceed the UL which was set using a model diet based on the fluoride level of water associated with a low prevalence of moderate dental fluorosis. However, the dietary assessment results do not match the evidence for the minimal prevalence of moderate fluorosis in Australia. FSANZ concludes that the exceedance is a consequence of the way that the UL was established.

⁸² Committee on Fluoride in Drinking Water, National Research Council (2006) *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*. National Academy of Sciences.

Therefore, substitution of fluoridated reticulated water with packaged water containing fluoride at the same concentration is not considered to be a cause for concern. No other sub-population groups in Australia or New Zealand are considered to be at risk of adverse effects from consuming optimally fluoridated water.

Should the NRVs be reviewed in the future, FSANZ could provide estimated dietary intakes based on recent food consumption data for Australia and New Zealand to the NHMRC and NZMoH to re-define the upper safe levels of intake for fluoride.

11. Food Technology Considerations

The Applicant has sought permission to add sodium fluoride, sodium fluorosilicate (also called sodium silicofluoride) and hydrofluorosilicic acid (fluorosilicic acid) (noting the incorrect spelling in the Table to clause 11 of Standard 1.3.3 which will be corrected) to packaged water. These chemicals are currently widely used to add fluoride to reticulated water supplies in Australia and New Zealand (and throughout the world). Their use for this purpose is therefore well known. Also the quality and purity of the chemicals is known and readily available.

Sodium fluoride is either clear/colourless crystals or a white powder. Sodium fluoride is very soluble in water (the solubility being 4.0 g/100 ml at 15°C and 4.3 g/100 ml at 25°C). Sodium fluorosilicate is a white granular powder and reasonably soluble in water (solubility being 0.67 g/100 ml in cold water)⁸³. Hydrofluorosilicic acid is a colourless to pale yellow liquid⁸⁴.

Fluorine can be added to water by either adding a slurry of sodium fluorosilicate, a solution of hydrofluorosilicic acid or less commonly a saturated solution of sodium fluoride. These solutions are added using a metering dosing solution to ensure accurate addition of fluoride into the water flow.

These compounds are the preferred forms of fluoride that are currently used to supplement reticulated water supplies with fluoride due to adequate solubility, low cost and history of safe use. It is anticipated that the fluoridation process for packaged water would be similar to a fluoridation program for reticulated water treatment.

Sodium fluoride is often used by smaller water treatment facilities due to its ease of handling. Sodium fluorosilicate may be favoured by larger facilities because its lower cost can be used to offset the cost of setting up the specialised handling facilities required for this chemical. When sodium fluorosilicate is added to water it rapidly dissociates into sodium ions, fluoride ions, hydrogen gas and hydrated silica⁸⁵.

Chapter 8 (Drinking water treatment chemicals) of the *Australian Drinking Water Guidelines* (2004)³¹ contains relevant information about the chemicals approved for fluoridation of water. This section also addresses the quality and purity of these chemicals.

⁸³ *The Merck Index*, 14th Edition, Merck and Co. Ltd Whitehouse Station, N.J. (2006)

⁸⁴ Australian Drinking Water Guidelines 2004

http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf (assessed 12 September 2008)

⁸⁵ Pollick, H.F. (2004) Water fluoridation and the environment: Current perspectives in the United States. *Int. J. Occup. Envir. Health*, 10:343-350 (Abstract), at www.waterquality.crc.org.au/hsarch/HS35b_2.htm (accessed on 12 September 2008).

Bottled water producers would be expected and required to ensure the quality and purity of the added chemicals are equivalent to those used for reticulated fluoridation systems. The purity standards ensure that the chemicals are not contaminated by heavy metals from the production process. A number of submitters to the Initial Assessment Report for this Application have indicated concern about the purity of the chemicals used to fluoridate water. Some expressed concern that the fluoride chemicals are contaminated with heavy metals from aluminium or fertiliser production during the production process of these chemicals.

Scientists in the USA Environmental Protection Agency and epidemiologists from the Centers for Disease Control and Prevention (CDC)⁸⁶ in the US have investigated these claims and concluded that they are not credible⁸⁷.

11.1 Analytical Procedures

11.1.1 Current Practice

The Applicant has advised FSANZ that regulatory authorities could use standard laboratory methodology to test the level of fluoride in packaged water. ABWI 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.

11.1.2 Technical Feasibility of Proposed Approach

FSANZ understands that it is technically feasible to add fluoride to packaged water to achieve a total amount of naturally occurring and added fluoride within the proposed range of 0.6-1 mg/L. Members of the bottled water industry have advised that the proposed range is achievable and that they do not foresee any technical difficulties with this process.

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.

ABWI has indicated that it plans to amend its Model Code if this Application is successful, to include good manufacturing practices and quality assurance procedures for the addition of fluoride to bottled water. The Model Code is publicly available from the ABWI Website⁸⁸.

⁸⁶ Fact sheet on questions about bottled water and fluoridation Centers for Disease Control and Prevention, USA.

http://www.cdc.gov/Fluoridation/fact_sheets/engineering/wfadditives.htm (accessed 18 September 2008)

⁸⁷ The manufacture of the fluoride chemicals, September 2000, Thomas Reeves, Centers for Disease Control and prevention <http://www.cdphe.state.co.us/pp/oralhealth/fluoridation/fl-143.pdf> (accessed 12 September 2008)

⁸⁸ ABWI Model Code accessed on 29/09/08 from:
http://www.australianbeverages.org/lib/pdf/ABWIModelCode_Mar06.pdf

The Australian Food and Grocery Council indicated in its submission on the Initial Assessment Report that fluoride could be added to packaged water with a high level of precision and under good quality control. It claims that the addition of fluoride to packaged water will be delivered with greater consistency than can be achieved for reticulated water supplies.

RISK MANAGEMENT

12. Risk Management Issues

On the basis of FSANZ's Risk Assessment, the following sections discuss approaches to managing any identified public health and safety risks and other broader issues requiring consideration in the development of regulations for the voluntary addition of fluoride to packaged water.

12.1 Permission to Fortify on the Basis of Nutritional Equivalence

The voluntary addition of fluoride to packaged water is not currently permitted under Standard 2.6.2 which regulates the composition of packaged water. At Initial Assessment, FSANZ proposed that this Application could be assessed on the basis of nutritional equivalence because fluoridated packaged water could be considered a substitute beverage for fluoridated reticulated water.

The majority of government and public health submissions to the Initial Assessment supported using a nutritional equivalence approach to the Assessment of this Application. However, many of these submitters expressed concern that the level of fluoride originally requested by the Applicant (maximum claimable amount of 1.5 mg/L) was too high and could not be considered to be nutritionally equivalent to fluoridated reticulated water which is between 0.6 and 1.1 mg/L.

A majority of the private submitters were opposed to fluoridation in general while others considered that fluoride should only be permitted following identification of a clinical deficiency or a health benefit.

FSANZ's Risk Assessment has concluded that packaged water is nutritionally equivalent to reticulated water in relation to nutrients other than fluoride. Therefore, should the concentration of fluoride in packaged water be permitted in a target range similar to reticulated water supplies, then the packaged water can be considered to be nutritionally equivalent to reticulated water supplies in Australia and New Zealand.

12.2 Permitted Level of Fluoride

In accordance with a 'nutritional equivalence' approach, the majority of submitters considered that the requested maximum claimable amount of fluoride should be reduced to align with the recommended target range of fluoride in the *Australian Drinking Water Guidelines*⁸⁹ and the *Drinking-water Standards for New Zealand*⁹⁰.

⁸⁹ NHMRC (2004) *Australian Drinking Water Guidelines*. NHMRC Canberra ACT. Available from http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf.

⁹⁰ Ministry of Health. *Drinking-water Standards for New Zealand 2005*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz>.

Since Initial Assessment, the Applicant has amended their Application to seek permission to voluntarily add fluoride to packaged water within a range of 0.6 and 1 mg/L which reflects the *Australian Drinking Water Guidelines*⁸⁹ and the *Drinking-water standards for New Zealand*⁹⁰. On this basis FSANZ supports this amendment to the Application and proposes to permit the voluntary addition of fluoride to packaged water in a range between 0.6-1 mg/L.

12.3 Permitted Forms of Fluoride

The Applicant originally requested permission to add sodium fluoride and sodium fluorosilicate to packaged water. Since Initial Assessment, they have requested permission to add a third form of fluoride, hydrofluorosilicic acid to packaged water. These three forms of fluoride are currently permitted to be added to packaged water as processing aids in Standard 1.3.3 and have a history of safe use in water fluoridation over many decades. Further information on these forms of fluoride can be found in Section 11 of this Report.

Therefore, FSANZ proposes to permit the voluntary addition of sodium fluoride, sodium fluorosilicate and hydrofluorosilicic acid to packaged water.

12.4 Composition of Packaged Water

Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks sets out the compositional requirements for packaged water, including permission to 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 as contaminants, including fluoride.

At Initial Assessment, submitters supported limiting the addition of fluoride to water to which no other food or additives can be added.

The Codex General Standard for Bottled/Packaged Drinking Waters (other than natural mineral waters)⁹¹ defines packaged waters, other than natural mineral waters, as ‘waters for human consumption and may contain minerals, naturally occurring or intentionally added; may contain carbon dioxide, naturally occurring or intentionally added; but shall not contain sugars, sweeteners, flavourings or other foodstuffs.’

A number of jurisdictions also expressed concern that carbonated water should be excluded from the definition of packaged water on the basis that it is not equivalent to reticulated water and has a lower pH which could increase the risk of dental caries. Since Initial Assessment, the Applicant has advised that they do not seek permission to add fluoride to carbonated packaged water.

Therefore, consistent with Codex and to reflect the intention of this Application, FSANZ is proposing to limit the composition of packaged water to which fluoride is permitted to be added, to packaged water which does not contain sugars, sweeteners, flavourings or other food. FSANZ also proposes that fluoride may only be added to packaged water that is not carbonated.

⁹¹ Codex General Standard for Bottled/Packaged Drinking Waters (other than Natural Mineral Waters) Codex Stan 227-2001 is available from http://www.codexalimentarius.net/download/standards/369/CXS_227e.pdf

12.5 Consumer Issues

12.5.1 Proposed Target Market

The Applicant noted that consumers who have access to fluoridated water and are willing to consume reticulated water are unlikely to purchase these products. They have advised that fluoridated packaged water will be targeted to, and consumed by a niche market as an alternative to fluoridated reticulated water. The identified target groups for these beverages are:

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

It is assumed that these target consumers will ‘self-select’ on the basis of the product distinction (as distinguished by the label) and will make an informed choice (based on some knowledge) to purchase fluoridated packaged water with a premium price, assumingly substituting fluoridated reticulated water, or non-fluoridated reticulated or rain water, for fluoridated packaged water.

Sales data collected from 2004 to 2006⁹², provided by the Australian Beverages Council, suggest a degree of substitution may occur between similar beverages. Data reflect increases in purchases of non-sugar carbonated soft drinks (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’.

It remains uncertain whether consumers of fluoridated packaged water will substitute fluoridated packaged water products for reticulated water (fluoridated or non-fluoridated), other packaged water products (e.g. non-fluoridated packaged water), or other purchased products. However, it is a voluntary permission and FSANZ considers that mandatory labelling provisions will assist consumers to make an informed choice regarding purchasing these products.

12.5.2 Vulnerable Groups

A number of submitters expressed concern about safety aspects of fluoridated packaged water, and infants and young children exceeding the UL for fluoride. Of particular concern was the risk for infants consuming infant formula reconstituted with fluoridated packaged water with a concentration up to 1.5 mg/L.

Based on a history of safe use of fluoride in many countries over the last 60 years, FSANZ has assessed the potential risks and adverse effects of fluoride in relation to this Application for the whole population. No adverse conditions associated with the consumption of optimally fluoridated water were identified in any population group, including infants and young children.

⁹² 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.

As discussed in detail in Section 10.1.4.2 of this Report, the results of the dietary intake assessment showed that a significant proportion of infants and young children exceeded the upper level of fluoride when water is fluoridated at 0.6 and 1 mg/L. However, based on the information on the origin of the UL and the lack of evidence of dental fluorosis, FSANZ concluded that the exceedance of the UL was not of cause for concern.

FSANZ has contacted infant formula manufacturers who confirmed that the concentration of fluoride in infant formula products available in Australia (powdered and ready-to-drink products) is low. Powdered infant formula available in New Zealand also contains negligible amounts of fluoride.

The major source of fluoride in infant formula is from the water used to reconstitute the powdered formula (provided it is fluoridated water). There is no evidence that the fluoride derived from water used to reconstitute the formula has any harmful effects in areas where the fluoride concentration is no more than 1 mg/L⁹³.

As the Applicant has amended the Application to reflect the level of fluoride in reticulated water, FSANZ has concluded that there is no public health or safety risk for infants who consume formulas whether they are prepared using fluoridated or non-fluoridated water.

12.5.3 Potential to Mislead Consumers

At Initial Assessment, a number of submitters expressed the concern that consumers may be misled to pay a premium price for fluoridated packaged water if they may perceive fluoridated packaged water to be nutritionally superior to fluoridated reticulated water. This goes to two issues: a) consumer attitudes and understanding of fluoride as a mineral, and b) the labelling provisions on the packaged water (discussed in Section 12.6 below).

12.5.3.1 Consumer Understanding of Fluoride

There is limited consumer research data on the awareness and understanding of fluoride as a mineral. Where data exists, findings indicate that most communities and the general public have limited understanding and are not concerned about fluoride in water. International research indicating low levels of consumer understanding and misunderstanding of micronutrients includes findings from an Irish study that reveal a high level of misunderstanding about the purpose and function of fluoride and its specific benefits. It was often confused and perceived as a purifying agent⁹⁴. In addition, Scottish studies from 1991-1999 also reveal there is also a lack of knowledge of the aesthetic impairment associated with dental fluorosis⁹⁵. Furthermore, in terms of the influence on purchase and consumption behaviours of the presence of fluoride as denoted by the label, micronutrients (vitamins and minerals) have been found to be of little relative importance to general consumers, compared to other macronutrients (e.g. fat, sugar)^{96,97,98,99,100}.

⁹³ Ministry of Health (2008) *Food and Nutrition Guidelines for Healthy Infants and Toddlers (aged 0-2. A Background Paper. 4th Edition*. Ministry of Health, Wellington. Available from [http://www.moh.govt.nz/moh.nsf/pagesmh/7756/\\$File/0-2-food-and-nutrition-guidelines-may08.pdf](http://www.moh.govt.nz/moh.nsf/pagesmh/7756/$File/0-2-food-and-nutrition-guidelines-may08.pdf).

⁹⁴ Levallois, P., Grondin, J. & Gingras, S. (1998). Knowledge, perception and behavior of the general public concerning the addition of fluoride to drinking water. *Canadian Journal of Public Health*, 89:162-165.

⁹⁵ Pitts, N.B., Nugent, Z. & Smith, P. (1999). Scottish Health Board's Dental Epidemiological Programme – Report of the 1998/99 Survey of 14 year old children, Dundee, University of Dundee.

⁹⁶ 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.

Studies from Australia and New Zealand show a low consumer *understanding* of micronutrients overall. For example, around three quarters of South Australians reported they do not know the roles of several micronutrients¹⁰¹. The majority of Australians (95%) claimed to have heard of minerals; however, 93% were rated as having extremely poor to average knowledge about minerals. Almost a quarter of Australians could not give any examples of minerals¹⁰². In terms of relative importance of micronutrients, studies from Australia and New Zealand find that minerals are looked for between 18% and 20% of the time, by around 25% of consumers,^{103,104} suggesting other factors are of higher importance to look for on food labels.

Consumer research around the influence of *claims* about fluoride is extremely limited. The available research (discussion above) suggests low relative importance to consumers of most micronutrients^{105,106}.

FSANZ research into macronutrient nutrition content claims (of higher relative importance) reveals findings suggesting label elements such as content claims do not enhance consumer purchase intentions to a greater degree than other information on food labels¹⁰⁷. In addition, qualitative FSANZ research on vitamin and mineral supplementation of food revealed most consumers held neutral views towards vitamin and mineral nutrition content claims, reporting claims such as these make little to no difference to their purchase decisions¹⁰⁸. FSANZ has recently commissioned additional research on vitamin and mineral content claims that may add further evidence at Final Assessment.

Recent research¹⁰⁹ into the consumer mechanisms involved in general food purchase decisions highlights the importance of *convenience*, *cost*, and *taste*, which have been found to play a more extensive role than labelling elements.

⁹⁷ Scott, V. & Worsley, A. (1997). Consumer views on nutrition labels in New Zealand. *Australian Journal of Nutrition and Dietetics*, 54, 6-13.

⁹⁸ Paterson D, Zappelli R & Chalmers A. (2001) *Food Labelling Issues – consumer qualitative research*. Donovan Research, ed. Canberra: Australia and New Zealand Food Authority.

⁹⁹ Food Standards Australia New Zealand. (2007). *Consumer Attitudes Survey*. FSANZ, Canberra.

¹⁰⁰ ACNielsen. (2005). Fat content of most concern to US consumers when shopping for food, according to ACNielsen, July 27. <http://us.acnielsen.com/news/20050727.shtml>

¹⁰¹ Baghurst, K. I., Baghurst, P. A., & Record, S. J. (1992). Public perceptions of the role of dietary and other environmental factors in cancer causation or prevention. *Journal of Epidemiology and Community Health*, 46, 120–126.

¹⁰² Cox, D. N. & Bastiaans, K. (2005). Understanding Australian consumers perceptions of selenium and motivations to consume selenium enriched foods. *Food Quality and Preference*.

¹⁰³ Food Standards Australia New Zealand. (2007). *Consumer Attitudes Survey*. FSANZ, Canberra.

¹⁰⁴ Scott, V. & Worsley, A. (1997). Consumer views on nutrition labels in New Zealand. *Australian Journal of Nutrition and Dietetics*, 54, 6-13.

¹⁰⁵ 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.

¹⁰⁶ Paterson D, Zappelli R & Chalmers A. (2001) *Food Labelling Issues – consumer qualitative research*. Donovan Research, ed. Canberra: Australia and New Zealand Food Authority.

¹⁰⁷ Food Standards Australia New Zealand. (2008). An investigation into the impact of nutrition content claims on packaging in relation to consumer purchase intention, nutrition attitude and health benefits. FSANZ, Canberra.

¹⁰⁸ Food Standards Australia New Zealand. (2003b). Food labelling issues: A Qualitative consumer study related to nutrient content claims on food labels. Evaluation Report Series No. 6. FSANZ, Canberra.

¹⁰⁹ Drewnowski, A. (2002). Taste, Genetics and Food Choices. In H Anderson; J Blundell; M Chiva (eds) *Food Selection: from Genes to Culture*. Danone Institute.

Hence, consumers are likely to make purchases giving substantial regard to their assessments of these factors, as well as the emerging importance of *health* in purchase decisions relating to beverage choice, discussed above. This occurs within the complex framework of a purchase decision.

It can therefore be argued that limited consumer attention to vitamins and minerals and vitamin and mineral nutrition content claims, limits the capacity for nutrition content claims about fluoride (or other labelling provisions discussed in section 12.6) to mislead consumers in purchase decisions.

In addition, target consumers identified by the Applicant who are restricted in their consumption of fluoridated reticulated water by taste and access, are expected to ‘self-select’ fluoridated packaged water based on their knowledge and product identification. This voluntary permission to add fluoride to packaged water, and label according to the provisions specified in Section 12.6 (below) will allow consumers to exercise choice to buy fluoridated packaged water products.

12.6 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 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 Australian and New Zealand fair trading legislation regarding potential misleading or deceptive conduct in relation to a food or beverage.

In the Initial Assessment Report, FSANZ raised a number of issues around labelling, and in addition questioned whether any further specific labelling requirements for fluoridated packaged water should be considered. The following issues were noted.

12.6.1 Food Identification Requirements

The Applicant originally requested that fluoridated packaged water be permitted to carry nutrition claims as such claims about fluoride are currently not expressly permitted by the Code (See Section 12.6.4). The Applicant provided sample labelling and claim statements and sought clarification on the permission to include these on a label. Specifically, the statements included ‘Premium spring water with added fluoride’, ‘Mineral water plus fluoride’ and ‘Fluoridated spring water’. Since the Initial Assessment, the Applicant has amended their Application and is now seeking permission to require a statement, for food identification purposes, to the effect that the product contains added fluoride. This replaces their initial request for permission to make nutrition claims about fluoride.

A significant number of submitters suggested the presence and/or concentration of fluoride in the packaged water be clearly labelled. A smaller number of submitters also suggested labelling should distinguish between naturally occurring and added fluoride.

FSANZ proposes that a mandatory statement be included on the label of packaged water containing added fluoride to the effect that fluoride has been added. This is consistent with what is being sought by the applicant, as noted above. At present, references to fluoride on a food label, including in the name of the food, could be construed to be nutrition claims (refer to Standard 1.2.8 – Nutrition Information Requirements), rather than reference to the nature of the food (refer to Standard 1.2.2 – Food Identification Requirements). The proposed mandatory wording will ensure the product is labelled sufficiently to indicate the true nature of the food i.e. that the water contains added fluoride, as required under Standard 1.2.2, and provide clarity regarding the permission to refer to fluoride in the name or description of packaged water, without the potential for it to be seen as a nutrition claim.

The labelling statement will also ensure the consumer is able to differentiate between packaged water to which fluoride has been added, and packaged water not containing added fluoride, providing an opportunity for informed consumer choice when purchasing packaged water.

Through Application A588, FSANZ proposes to separate the permissions in Standard 1.3.3, for the use of fluoride substances to treat water used in packaged water, as opposed to water used as an ingredient in other foods (as discussed in section 12.9). Consequently, any packaged water containing fluoride added in the course of manufacture, including packaged reticulated water, will be required to be labelled to the effect that fluoride has been added. The rationale is detailed in the preceding paragraph. Permissions for fluoride added to water used as an ingredient in other foods will remain in Standard 1.3.3, and not be subject to the proposed labelling requirement.

If the permission to add fluoride to packaged water is included in Standard 2.6.2, under clause 2 of Standard 1.2.4 – Ingredient Labelling, an ingredient list would ordinarily be a mandatory requirement. However, FSANZ proposes to provide an exemption from the requirement for an ingredient list under Standard 1.2.4 on the basis that the mandated labelling statement about added fluoride will provide similar information to that provided by an ingredient list. This approach is consistent with the current exemption in the Code from including fluoride in ingredient lists on foods containing fluoridated water and aligns with the practice of minimum effective regulation.

12.6.2 Information around Fluoride Concentration and Nutritional Equivalence.

In response to the Initial Assessment Report, some submitters also suggested that the concentration of added fluoride should be included on product labels. If the addition of fluoride is approved within the range of 0.6 to 1 mg/L, equivalent to fluoridated reticulated water supplies, FSANZ considers mandating the labelling of concentration unnecessary. However, noting that many manufacturers choose to voluntarily label packaged water with a typical analysis table (see Section 12.6.3), it is anticipated that fluoride concentration could also be declared within this table, thereby providing further information for consumers.

Submissions were received suggesting labelling should inform consumers of the nutritional equivalence of fluoridated packaged water when compared to fluoridated reticulated water. However, FSANZ does not consider this necessary on the basis of consumer research findings, as detailed in Section 12.5.3, which suggest that labelling statements indicating the presence of fluoride (i.e. ‘contains fluoride’) would not enhance purchasing behaviour.

This is due to low relative importance to consumers of vitamins and minerals in general, limited consumer use of claims about vitamins and minerals, and the low importance of these factors in their overall purchase decisions. FSANZ has recently commissioned additional research on vitamin and mineral content claims that may add further evidence at Final Assessment. Thus, mandating labelling with an additional statement regarding nutritional equivalence would not be warranted.

12.6.3 Typical Analysis Labelling

Currently, the majority of manufacturers voluntarily label packaged water with a typical analysis of the product's mineral composition. This aligns with international practice. However, the voluntary declaration of certain minerals could be seen to be nutrition claims about the presence of those minerals, some of which are not permitted under clause 6 of Standard 1.3.2 – Vitamins and Minerals (see section 12.6.4), including fluoride. FSANZ therefore proposes that Standard 2.6.2 specifies that any naturally occurring compound in packaged water and any naturally-occurring or added fluoride may be included in a typical analysis table, and that the information included in such a table is not considered to be a nutrition claim for the purposes of Standard 1.2.8.

12.6.4 Nutrition and Health Claims

Nutrition and health claims about fluoride are currently not expressly permitted by the Code. Standard 1.3.2 regulates the claims which can be made about the vitamin and mineral content of foods. Claim permissions are underpinned by the list of vitamins and minerals in the Schedule to Standard 1.1.1 (for 'claimable foods'), or any other specific permissions within the Code.

As fluoride is currently not listed in the Schedule to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions, nor is an express permission provided in Standard 2.6.2, nutrition claims about fluoride are currently not permitted.

In addition, under clause 3(d) of Standard 1.1A2 – Transitional Standard for Health Claims, unless otherwise expressly permitted in the Code, the label on or attached to a package containing or any advertisement is prohibited from containing the name or a reference to any disease or physiological condition.

Several submitters at Initial Assessment commented on the possible eligibility for fluoridated packaged water to make nutrition and health claims. A number of submitters suggested permission for claims may mislead the consumer in the belief that packaged water offers additional benefits over reticulated water. However, other submitters supported the permission of claims if they could be scientifically supported, and on the basis that such labelling information would allow the consumer to be adequately informed.

As noted in Section 12.6.3, the mandatory labelling statement proposed by FSANZ will not be considered a nutrition claim, and therefore, will not trigger requirements under Standard 1.2.8. FSANZ does not propose to provide permission for nutrition and/or health claims within the context of this Application. The regulation of nutrition, health and related claims is currently under review by FSANZ as part of Proposal P293.

In the Final Assessment Report for Proposal P293, draft Standard 1.2.7 did not contain permissions for nutrition or health claims about fluoride, by virtue of the fact fluoride is not listed in the schedule to Standard 1.1.1. However, FSANZ plans to commence a scoping exercise to determine how best to incorporate the Revised 2006 NRVs for Australia and New Zealand into the Code, including Schedule 1.1.1. Consideration of vitamins and minerals, including fluoride will be part of this process.

12.6.5 Mandatory Warning and/or Advisory Statements

A number of submitters suggested in response to the Initial Assessment Report that mandatory warning and/or advisory statements should be included on the labels of packaged water containing added fluoride, with regard to a) use of fluoridated water in infant formula, b) for vulnerable groups, c) for people living in warmer climates where intake of fluoride from packaged water could exceed the upper limit; and d) indicating the potential for toxicity.

On the basis of the Risk Assessment, mandatory advisory statements such as those suggested above, regarding the addition of fluoride to packaged water are not considered necessary. It is FSANZ's view there is minimal risk to public health and safety, given the voluntary addition of fluoride to packaged water will be equivalent to reticulated water supplies where there is a history of safe use. In addition, the Risk Assessment demonstrates that population groups, such as those above, are not considered to be at risk of adverse effects; and whilst mild fluorosis has been identified, no other conditions were associated with the consumption of optimally fluoridated water. Therefore, the proposed mandatory labelling statement of the addition of fluoride will provide sufficient information for consumers to make an informed decision, whilst meeting the needs of industry and enforcement agencies.

12.6.6 Labelling Summary

Labelling provisions for the voluntary permission to add fluoride to packaged water should provide adequate information to the consumer to facilitate informed purchasing decisions and prevent misleading or deceptive conduct. As such, under this Application, FSANZ proposes to apply the following labelling provisions:

- Mandatory labelling be included on the label of packaged water containing added fluoride to the effect that fluoride has been added.
- Fluoridated packaged water will be exempt from the requirement of an ingredients list under Standard 1.2.4 – Labelling of Ingredients.
- Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks will specify that any naturally occurring mineral in packaged water and any naturally occurring or added fluoride may be included in a voluntary typical analysis table. The proposed drafting will further clarify that the information included in a voluntary typical analysis table will not be considered a nutrition claim for the purposes of Standard 1.2.8 – Nutrition Information Requirements.

- Nutrition and health claims about fluoride are currently not expressly permitted by the Code, and in the Final Assessment Report of Proposal P293, draft Standard 1.2.7 – Nutrition, Health and Related Claims did not allow for nutrition or health claims about fluoride, primarily on the basis that a reference value for fluoride is not provided by the Schedule to Standard 1.1.1.

12.7 Compliance and Enforcement

The Australian and New Zealand packaged water industries have indicated that they do not anticipate any problems adding fluoride to packaged water within the proposed range. The industry has advised that end stage monitoring of fluoride will be used to confirm the accuracy of the process as part of normal quality control procedures. As analytical testing for fluoride has been undertaken in reticulated water supplies for many years, FSANZ understands that there will be no issues with analytical testing for compliance and enforcement.

The Applicant has also advised that ABWI Model Code¹¹⁰ will be updated to include current information and quality assurance procedures for implementing and complying with the proposed Standard. Access to the Model Code will be generally available via the ABWI website.

12.8 Monitoring

A number of submitters considered that monitoring the uptake of these products is important to assess the impact on overall dietary fluoride intake. The Applicant has advised that they anticipate a small uptake with fluoridated packaged water constituting less than 10% of the packaged water market within 5 years of approval of the permission. The uptake of this permission would be part of FSANZ monitoring program for voluntary fortification permissions. Changes in dietary intake of fluoride could be assessed through the Total Diet Surveys or available ‘Single Source’ data on consumers’ use of packaged water. However, it may be difficult to account for intakes from supplements and non-dietary sources such as toothpaste and topical applications. As a start, FSANZ has included fluoride in the 23rd Total Diet Survey. In addition, the recently released results of the 2007 Australian National Children’s Nutrition and Physical Activity Survey, provide useful data for monitoring any changes in fluoride intake for the age groups targeted in the survey. This survey also reports on the use of dietary supplements.

12.9 Consequential Amendments to the Code

12.9.1 Standard 1.3.3 – Processing Aids

Standard 1.3.3 contains permissions for three fluoride substances as processing aids within the Table to clause 11 (permitted processing aids used in packaged water and in water used as an ingredient in other foods). These substances are hydrofluorosilicic acid permitted at good manufacturing practice (GMP), sodium fluoride and sodium fluorosilicate both permitted to a maximum level of 1.5 mg/kg.

¹¹⁰ ABWI Model Code is available from
http://www.australianbeverages.org/lib/pdf/ABWIModelCode_Mar06.pdf

These entries are listed in this Table to allow fluoridated water (from reticulated water treatment sources) to contain levels of fluoride that can then be used in packaged water and as an ingredient in other foods. FSANZ's Proposal P277 – Review of Processing Aids (other than Enzymes)) investigated these entries and the maximum permitted levels as part of this Review which was finalised in December 2006.

It was agreed in this Review that the use of these chemicals for the purpose of fluoridating reticulated water do not fully meet the requirements of processing aids, however no better solution could be found to enable water that had been fluoridated to contain fluoride so their entries were retained.

Under Proposal P277, the maximum permitted levels for two (sodium fluoride and sodium fluorosilicate) but not hydrofluorosilicic acid (which was an oversight) were amended from GMP to 1.5 mg/kg to be consistent with both the Australian and New Zealand Drinking Water Guidelines. Hydrofluorosilicic acid (fluorosilicic acid) is also misspelt in the Table to clause 11. It is incorrectly listed as hydrofluorosilic acid (fluorosilic acid). It makes sense to correct that oversight during the assessment of this Application, so the maximum permitted level for hydrofluorosilicic acid will be changed from GMP to also be 1.5 mg/kg, along with the correct spelling.

The Table to clause 11 in Standard 1.3.3 contains permissions for use of the three fluoride substances to treat water to be used in both packaged water and also for water used as an ingredient in other foods. Because the current Application is seeking a voluntary permission to add fluoride substances only to packaged water it was thought appropriate to separate out the fluoride permissions for the two separate uses. The specific permissions for adding fluoride to packaged water will be provided within Standard 2.6.2. The permissions for treating water with fluoride as a processing aid in the Table to clause 11 will be limited to apply only when the water is used as an ingredient in other foods.

12.9.2 Standard 2.6.2 – Non-alcoholic Beverages

Clause 2 (Composition of packaged water) of Standard 2.6.2 contains some requirements around packaged water. The Table to subclause 2(2) lists a number of contaminant levels that packaged water must not exceed. One of these entries relates to fluoride where the level in the packaged water must not exceed 2 mg/L (calculated as FI). It is important to note that this level refers to contaminants and it would be the natural level of fluoride found in natural sources presented as packaged water. This level differs from what has been proposed to be the maximum limit of fluoride that can be added to packaged water, which is the purpose of this Application. Proposed amendments to Standard 2.6.2 will clarify the permission for the addition of fluoride to packaged water.

FSANZ considers that a change to the permitted level of substances listed in the Table to subclause 2(2) of Standard 2.6.2 is outside the scope of this current Application.

12.10 Summary of Risk Management Issues

A number of potential risks and issues arising from this Application for the voluntary addition of fluoride to packaged water have been identified. These include public health and safety risks as well as social, technical and economic issues.

FSANZ has considered the totality of these issues and has devised the following strategies to help mitigate any potential risks:

- the adoption of a range of fluoride (0.6–1 mg/L) which generally aligns with the recommended target range in fluoridated reticulated water in Australia and New Zealand so as to achieve nutritional equivalence;
- the adoption of compositional requirements for packaged water with added fluoride to clarify the intent of the permission;
- the adoption of mandatory labelling for food identification to inform consumers as to the presence of added fluoride to enable informed choice; and
- the adoption of consequential amendments to Standard 1.3.3 and the Table to subclause 2(2) of Standard 2.6.2 to clarify the permissions relating to packaged water.

13. Regulatory Options

FSANZ is currently considering two options for addressing this Application:

13.1 Option 1 – Reject Application, thus maintaining the *status quo*

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

13.2 Option 2 – Amend Standard 2.6.2 to permit the voluntary addition of fluoride to non-carbonated packaged water to between 0.6 and 1 mg/L (total of naturally occurring and added fluoride)

Option 2 would allow the voluntary addition of fluoride to non-carbonated packaged water under Standard 2.6.2, to a total of naturally-occurring and added fluoride between 0.6 and 1 mg/L. Mandatory labelling would be required to indicate that the packaged water contains added fluoride. A consequential amendment to Standard 1.3.3 and Standard 2.6.2 would clarify permissions for the addition of fluoride to packaged water.

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 Australian States/Territories and New Zealand.

14.2 Benefit Cost Analysis

14.2.1 Consumers

The voluntary addition of fluoride to packaged water would benefit consumers with an alternative 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. There may be a niche market of consumers who are willing to pay a price premium for fluoridated packaged water for any additional benefits or perceived value.

A private submitter expressed concern that individuals who are fluoride-sensitive may incur additional costs in avoiding fluoridated packaged water, or health-related costs as a consequence of ingesting fluoride, due to cross-contamination in plants that produce both fluoridated and non-fluoridated packaged water. However, the Risk Assessment has established that fluoridated packaged water is nutritionally equivalent to that of fluoridated reticulated water. The consumers of fluoridated packaged water are at no greater risk than people drinking fluoridated reticulated water. Therefore there are no public health and safety concerns for fluoridated packaged water. Moreover, consumers will always have a choice and product labelling could be relied on to distinguish packaged water from fluoridated packaged 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. The permission would allow producers of packaged water to expand their market and potentially benefit from increased sales. As the addition of fluoride to packaged water would be a voluntary permission, there should not be additional barriers to trade.

One submitter expressed concern that should the outcome of the application (if approved) require all packaged water manufacturers to quantify or declare the amount of fluoride in their product; and/or label 'no added fluoride' for packaged water that does not contain any fluoride it will adversely affect the industry and impose cost burden on those producers who do not wish to add fluoride to their packaged water products. However, FSANZ does not intend to stipulate any labelling requirements above and beyond what is currently required for producers who do not wish to add fluoride to packaged water. Another submission raised that the Applicant would incur additional costs of transportation, handling and storage of materials involved in adding fluoride to packaged waters. A private submitter also expressed a concern that cross contamination with fluoride in non-fluoridated packaged water would be difficult to avoid without incurring further costs to the producer.

FSANZ acknowledges that while there would be a cost to manufacturers to add fluoride to packaged water, any such costs would be voluntary and 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 fluoride. If this permission is given, they have requested the ability, for food identification purposes, to note the presence of fluoride clearly on the label. They have stated that they expect these products will be purchased by a small niche market of consumers who are aware of the benefit of fluoride and who would be willing to pay a premium price.

14.2.3 Government

A government agency has reported as with any category of food, there would be a need for additional surveillance activities and possibly some enforcement activities. Significant resources may be required if any legal action was initiated. However, it is difficult to anticipate the resource implications and quantitative cost estimates for this agency. Overall it is expected that there would be minimal impact for Government for either regulatory option.

14.3 Comparison of Options

Analysis of costs and benefits for each option indicates that there are no public health and safety implications for fluoridated packaged water as it is nutritionally equivalent to fluoridated reticulated water. Consumers will benefit from choice of purchasing fluoridated packaged water, especially those who do not have access to fluoridated reticulated water. Finally there could be market growth opportunities and innovation for industry if fluoride was permitted to be added in packaged water.

Therefore, at Draft Assessment, the addition of fluoride to packaged water delivers benefits over and above the *status quo* of not permitting fluoridated packaged water.

COMMUNICATION AND CONSULTATION

15. Communication

A number of communication challenges arise from this Application. These include the need to ensure that FSANZ's risk management decisions are adequately informed by scientific and medical/dental evidence, and that appropriate authorities are alerted to the results of FSANZ's dietary modelling studies on the current level of exposure of the population to fluoride through reticulated water supplies.

The Application is for the voluntary addition of fluoride to packaged water. It does not address a public health issue, requiring mandatory action. Rather, it is a 'consumer choice' issue for those choosing not to drink reticulated water, people without access to fluoridated water supplies, or as a replacement for non-fluoridated packaged water. Packaged water with added fluoride would be a niche product and mandatory labelling would inform consumer choice.

FSANZ's communication approach, therefore, will be to focus on the consumer-choice benefits of the product. At the levels of added fluoride being considered for approval, FSANZ would have no public health or safety concerns, even for young children.

There may be dental benefits arising from consumption of the product, but FSANZ is not in a position to assess those benefits. FSANZ is working with the NHMRC and the NZMoH to ensure consistent messages on fluoride.

16. Consultation

16.1 Public Consultation

FSANZ received a total of 55 submissions on the Initial Assessment Report for Application A588 during the public consultation period from 19 March 2008 to 30 April 2008. Seven responses were from government, three from industry, 12 from public health professionals and two from consumer organisations and 31 from private submitters. The key issues raised in submissions are addressed in the relevant sections of this Report.

The majority of government stakeholders, public health professionals and industry submitters indicated support for the Application. Most of the consumer submissions were opposed to the addition of fluoride to packaged water, citing safety concerns regarding water fluoridation in general and potential adverse health impacts as a result of increasing the fluoride content of the food supply. Some consumers misunderstood what was being requested and thought that all packaged water would be fluoridated. The Application is to permit the voluntary (optional) addition of fluoride to packaged water. The Applicant has projected that most packaged water would not be fluoridated.

Many of the government and public health stakeholders supported FSANZ's approach to assessment on the basis of nutritional equivalence. However, the majority of these submitters expressed concern that the previously proposed maximum claimable amount of 1.5 mg/L was too high and was not aligned with the target for water fluoridation in Australia and New Zealand which is generally between 0.6 and 1.1 mg/L^{111,112}.

Several stakeholders questioned the increasing range of topical and ingested fluoride supplements and sources available and expressed concern regarding the risk of vulnerable groups to exceed the UL, especially infants drinking formulas reconstituted with fluoridated packaged water. Most submitters acknowledged the need for effective labelling to enable consumers to make an informed choice.

16.2 Targeted Consultation

To ensure the robustness of the risk assessment for this Application, FSANZ liaised with key dental experts and professional dental organisations in Australia and New Zealand. Groups including the Australian Research Centre for Population Oral Health, Paediatric Dental Faculty at Otago University, and the Australian Dental Association have expressed in principle support for FSANZ's risk assessment summary and for the proposed level of fluoride to be added to packaged water.

¹¹¹ NHMRC Public Statement *The Efficacy and Safety of Fluoridation 2007* Available from: http://www.nhmrc.gov.au/media/media/rel07/_files/Fluoride_Flyer.pdf

¹¹² Ministry of Health. *Drinking-water Standards for New Zealand 2005*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz>.

Additionally, FSANZ has liaised with the NHMRC, its Water Quality Advisory Committee and the NZMoH regarding the risk assessment results, exceedances above the UL, basis of the UL and the prevalence of dental caries and dental fluorosis in Australia and New Zealand. Both the NHMRC and the NZMoH have provided in principle support for FSANZ's findings and the proposed level of fluoride of 0.6-1 mg/L.

NZMoH advised that an independent Report on the Estimated Dietary Fluoride Intake for New Zealanders showed similar results to FSANZ's assessment with respect to young children exceeding the UL and the prevalence of dental caries and dental fluorosis.

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.

Amending the Code to allow the addition of fluoride to packaged water is unlikely to have a significant effect on international trade as the proposed permission will be voluntary and similar products are marketed internationally. However, FSANZ considers the proposed amendments to the Code regarding the composition and labelling requirements of packaged water with added fluoride could restrict the import of some fluoridated packaged water products.

Therefore at Draft Assessment, FSANZ considers it necessary to notify WTO member nations of the proposed amendment to allow the addition of fluoride to packaged water, under the Technical Barriers to Trade Agreement.

CONCLUSION

17. Conclusion and Preferred Approach

Preferred Approach

The preferred regulatory option is to amend Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks to permit the addition of fluoride to non-carbonated packaged water to between 0.6 and 1 mg/L (total of naturally occurring and added fluoride) and to require mandatory labelling to indicate that fluoride has been added.

In addition, to make consequential amendments to Standard 1.3.3 and Standard 2.6.2 for clarification of permission for the addition of fluoride to packaged water.

17.1 Reasons for Preferred Approach

FSANZ supports the preferred regulatory approach to permit the voluntary addition of fluoride to packaged water as it:

- is nutritionally equivalent to fluoridated reticulated water and provides consumers with an alternative source of fluoridated water.

- does not raise any public health or safety concerns for consumers of packaged water with added fluoride or the general population;
- is consistent with FSANZ’s statutory objectives including Ministerial policy guidance on voluntary fortification;
- supports industry innovation;
- provides consumers with adequate information on the product label to make an informed choice and to prevent them from being misled; and
- provides a net benefit to affected parties.

The proposed draft variations are provided at Attachment 1.

18. Implementation and Review

Following the consultation period, a Final Assessment of this Application will be completed and considered for approval by the FSANZ Board. If a draft variation to the Code is approved, FSANZ will notify that decision to the Ministerial Council.

Subject to any request for review by the Ministerial Council, the proposed draft variation permitting the addition of fluoride to packaged water is expected to come into effect upon gazettal.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions to the Initial Assessment Report

SUPPORTING DOCUMENTS

- SD1. Australia and New Zealand Food Regulation Ministerial Council Policy Guideline *Fortification of Foods with Vitamins and Minerals*
- SD2. Nutrition Risk Assessment Report
- SD3. Dietary Intake Assessment Report
- SD4. Derivation of the Upper Level for Fluoride Intake Report

Draft variation to the *Australia New Zealand Food Standards Code*

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act 2003 and are not subject to disallowance or sunseting.

To commence: On gazettal

[1] **Standard 1.2.4** of the *Australia New Zealand Food Standards Code* is varied by inserting after paragraph 2(a) –

- (aa) the food is water presented in packaged form as standardised in Standard 2.6.2;

[2] **Standard 1.3.3** of the *Australia New Zealand Food Standards Code* is varied by –

[2.1] *omitting clause 11, substituting –*

11 Permitted processing aids used in packaged water and in water used as an ingredient in other foods

Subject to any qualifications in the Table to this clause, the processing aids listed in the Table may be used in the course of manufacture of packaged water and in water used as an ingredient in other foods provided the final food contains no more than the corresponding maximum permitted level specified in the Table.

[2.2] *omitting from the Table to clause 11 –*

Hydrofluorosilic acid (fluorosilic acid)	GMP
Sodium fluoride	1.5
Sodium fluorosilicate (Sodium silicofluoride)	1.5

substituting –

Hydrofluorosilicic acid (fluorosilicic acid) (only in water used as an ingredient in other foods)	1.5
Sodium fluoride (only in water used as an ingredient in other foods)	1.5
Sodium fluorosilicate (Sodium silicofluoride) (only in water used as an ingredient in other foods)	1.5

[2.3] *inserting after the Table to clause 11 –*

Editorial note:

This clause contains the permissions for fluoride to be used in water that is used as an ingredient in other foods, but not in water presented in packaged form. Standard 2.6.2 contains a voluntary permission to add fluoride to water presented in packaged form.

[3] **Standard 2.6.2** of the *Australia New Zealand Food Standards Code* is varied by –

[3.1] *omitting the Purpose, substituting –*

This Standard deals with packaged waters and water-based beverages which contain food additives and in certain cases, nutritive substances. The Standard defines a number of products and sets certain compositional requirements for packaged water, electrolyte drinks, brewed soft drinks and formulated beverages. The Standard also permits the voluntary addition of fluoride to water presented in packaged form.

Labelling requirements specific to electrolyte drinks and water presented in packaged form are included in this Standard. This Standard also prohibits the labelling or presentation of non-alcoholic beverages in such a way as to suggest the product is an alcoholic beverage.

[3.2] *omitting the entry for Fluoride from the Table to subclause 2(2), substituting –*

Fluoride (naturally occurring)	2.0 (calculated as F-)
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[3.3] *inserting after clause 2 –*

2A Addition of fluoride to packaged water

(1) In this clause, **water suitable for added fluoride** means water presented in packaged form which –

- (a) does not contain sugars, sweeteners, flavourings or other food; and
- (b) is not carbonated.

(2) Fluoride must not be added to water presented in packaged form except in accordance with this clause.

(3) Fluoride may be added to water suitable for added fluoride provided that –

- (a) the total amount of the naturally occurring and any added fluoride is no less than 0.6 mg/L and no more than 1 mg/L; and
- (b) the form of fluoride added is –
 - (i) hydrofluorosilicic acid (fluorosilicic acid);
 - (ii) sodium fluoride; or
 - (iii) sodium fluorosilicate (sodium silicofluoride).

2B Labelling of packaged water

(1) The label on water presented in packaged form with added fluoride must contain a statement to the effect that the product contains added fluoride.

(2) Subject to subclause (3), the label on water presented in packaged form may include a typical analysis which lists the total concentration of any naturally occurring compound expressed in either mg/L or parts per million.

(3) A typical analysis may also include added fluoride provided that only the total amount of the naturally occurring and added fluoride is specified.

(4) A typical analysis which complies with subclauses (2) and (3) is not a nutrition claim for the purposes of Standard 1.2.8.

Summary of Submissions to the Initial Assessment Report

In April 2008, FSANZ received **55** submissions in response to the Initial Assessment Report for Application A588 – Voluntary Addition of Fluoride to Packaged Water. A summary of submitter comments is provided in the table below.

The two options proposed at Initial Assessment included:

Option 1 – Reject the Application, thus maintaining the *status quo*; 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.

SUBMITTER	SUBMISSION COMMENTS
Public Health Groups and Individuals	
Auckland Regional Public Health Service (ARPHS) Monica Briggs New Zealand	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p>ARPHS believed that permitting voluntary addition of fluoride up to 1 mg/L to packaged water would have a positive effect on oral health in specific groups within the Auckland region.</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Supported the NZ Ministry of Health’s recommendation and believed that 1 mg/L is a more appropriate maximum claimable amount if the intention is to promote oral health. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Noted that there is vast evidence demonstrating the effectiveness and safety of fluoridated water in preventing tooth decay. For instance, the lifetime benefit from drinking fluoridated water is estimated to be the prevention of 2.4-12.0 decayed, missing or filled teeth per person^{1,2}. Considered that there is evidence of a dose dependent increase in dental fluorosis (mottling teeth) which may occur at a prevalence of 12-33% at drinking-water concentrations between 0.9 and 1.2 mg/L^{3,4}. Some opponents of water fluoridation have argued that fluoride consumption can result in a number of adverse health effects such as cancer, damaged bones, and thyroid and brain disease. Recent reports by the Public Health Commission, National Health Medical Research Council of Australia and the World Health Organisation have addressed these concerns and found that many of the articles that raise fears about water fluoridation lack substance or repeat previous statements already shown to be without scientific validity^{2,5,6}. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Stated that children from low socioeconomic positions, particularly those of Maori and Pacific ethnicity, are disproportionately suffering from poorer oral health status⁷. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Considered that consumers should be informed that fluoridated packed water is regarded as equivalent to tap water and both offer similar oral health benefits.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered it is unlikely that those from low socio-economic position will benefit from this Application due to cost. The applicant assumed that consumers will pay a premium price for this product. According to AC Nielsen’s Panorama team ‘Bottled water drinkers tend to be under 40. They are more likely to be female, (...) their attitudes reflect a youthful, social group - they like to dine out, they like music, and shopping. They are more likely to play sport and exercise than the total population, with activities such as walking, cycling, going to the gym and swimming. They visit the cinema and use the Internet more than average and read a lot of magazines.’⁸ • Expressed concern that the consumer could be misled into thinking that fluoridated packed water has more benefit than tap water. Reported the results of a marketing survey which showed that more than twice as many consumers valued packaged water over milk as the beverage most associated with a healthy lifestyle⁸. <p><i>References</i></p> <ol style="list-style-type: none"> 1. National Advisory committee on Health and Disability (2003) <i>Improving Child Oral Health and Reducing Child Oral Health Inequalities</i>. Wellington: Author 2. Public Health Commission. (1994) <i>Water Fluoridation in New Zealand</i>. Wellington: Author. 3. McDonagh M, Whiting P, Bradley M, Cooper J, Sutton A, Chestnutt I, Misso K, Wilson P, Treasure E, Kleijnen J (2000) <i>A systematic review of public water fluoridation</i>. University of York, 243 pg 4. Ministry of Health (2005) <i>The Guidelines for Drinking-water Quality Management for New Zealand</i>. Wellington: Author 5. National Health and Medical Research Council of Australia. (2007). <i>A Systematic Review of the Efficacy and Safety of Fluoridation</i>. Canberra: Author. 6. World Health Organisation. (2006). <i>Fluoride in drinking water</i>. Geneva: Author. 7. Auckland Regional Public Health Service (2006) <i>Improving Health and Wellbeing: A Public Health Perspective for Local Authorities in the Auckland Region</i>. Auckland: Author. 8. Cited at: http://www.themarketingguy.co.nz/Latest/THE-WATER-STORY.html. On 21/04/08
<p>Australian Dental Association John Matthews Australia</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 0.6-1 mg/L fluoride)</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Supported packaged water being fluoridated to the same concentrations as public drinking water, in the range of 0.6-1 parts per million (ppm¹¹³). However, the ADA Policy Statement on Community Oral Health Promotion – Fluoride use recommends that ‘Manufacturers and producers of packaged water should be encouraged to ensure that their products contain fluoride at approximately 1 mg/L and that the fluoride content is included in labelling.’ (Policy statement is attached to the Submission) <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Stated that there is clear, solid, scientific evidence that water fluoridation has proven to be an efficient, effective and an equitable public health measure for reducing the prevalence of dental decay in all age groups. Cited the Australia’s National Oral Health Plan 2004-2013, signed off by all Australian Government Health Ministers.

¹¹³ Fluoridation is often measured as ppm (parts per million), which is equivalent to mg/L.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Highlighted several published Australian research/studies which support water fluoridation. The studies provide evidence of better dental health outcomes for children living in areas with water fluoridation, regardless of whether children lived in the least or most socioeconomically disadvantaged areas. Marked differences were found in the average number of decayed, missing or filled teeth (DMFT) across all age groups. The submission also noted that water fluoridation is associated with better dental health for adults¹⁻⁵. • Noted that tooth decay in children in Queensland is higher than the national average⁶ with 6-11 year olds having 30% more decay in their baby teeth, with a similar result for permanent teeth in 12 year olds. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Acknowledged that increasing use of packaged water is a possible contributing factor for the growing rate of dental decay amongst children. Recognised that other contributing factors including poor diet, and a reduced fluoride intake since dentists have been advocating low fluoride toothpastes for children, must also be taken into consideration. • Noted that the most recent fluoride guidelines make it clear that using fluoridated water to reconstitute baby milk formula is safe in Australia and NZ (also included in the Policy Statement). <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considered that the fluoride content of packaged water should be clearly stated on the label. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered that fluoridated packaged water would provide choice for consumers with no access to fluoridated tap water. In those regions, fluoridated packaged water would be consumed instead of non-fluoridated tap water. <p><i>Benefit cost analysis</i></p> <ul style="list-style-type: none"> • Noted that tooth decay ranks as one of Queensland's most expensive health problems. <p><i>Other comments</i></p> <ul style="list-style-type: none"> • Suggested that FSANZ change its terminology to 'adjusting' rather than 'adding' to take account of pre-existing fluoride content in packaged water products. • Refuted concerns by some consumers who are opposed to water fluoridation⁷. <p><i>References</i></p> <ol style="list-style-type: none"> 1. Armfield, JM., Slade, GD. and Spencer, AJ (2007) <i>Water fluoridation and children's dental health – The Child Dental Health Survey, Australia 2002</i>, AIHW Cat. No. DEN 170, Dental Statistics and Research Series No. 36. 2. National Health and Medical Research Council (2007) <i>A Systematic Review of the Efficacy and Safety of Fluoridation</i>, Australian Government. 3. Australian Institute of Health and Welfare. Slade GD, Spencer AJ, Roberts-Thomson KF (2007) <i>Australia's dental generations — The National Survey of Adult Oral Health 2004-06</i>, DSRS No. 34. 4. Armfield, J (2005) <i>Public water fluoridation and dental health in New South Wales</i>, ARCPOH, Australian and New Zealand Journal of Public Health, Vol. 29. No. 5. p 477.

SUBMITTER	SUBMISSION COMMENTS
	<p>5. Hopcraft, M and Morgan MV. (2005) <i>Dental caries experience in Australian Army recruits 2002-2003</i>, Australian Dental Journal, 50(1), p 16.</p> <p>6. Robertson 2006a in AIHW in Slade GD, Spencer AJ, Roberts-Thomson KF (2007) <i>Australia's dental generations — The National Survey of Adult Oral Health 2004-06</i>, Australian Institute of Health and Welfare, DSRS No. 34, p 58.</p> <p>7. Armfield J (2007) <i>When public action undermines public health: a critical examination of antfluoridationist literature</i>, Australia and New Zealand Health Policy, 4:25.</p>
<p>Canterbury District Health Board</p> <p>Sue McEwan</p> <p>New Zealand</p>	<p>Supported Option 2</p> <p>Supported access to fluoridated water whether is in a packaged form or through reticulated supplies. Noted that for most people in the region, fluoridated packaged water would currently be the only means by which they could access the benefits of fluoridated water.</p> <p><i>FSANZ's approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> Supported amendment of Standard 1.3.2 to allow the voluntary addition of fluoride to packaged water and agree with the nutritional equivalence approach. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Preferred a maximum permitted amount of fluoride/L. While a manufacturer may be able to claim up to 1.5 mg/L of fluoride, this did not prevent them from adding more. Believed that there may be a wide variance between claimed amounts of nutrients added to foods and the actual amount present (based on Thompson ESR Client report to NZFSA FW0536, FW0637, FW0745 – these reports are due to be posted on the NZFSA web site and FSANZ is referred to NZFSA for these reports). Furthermore, noted having a cap would set clear boundaries for both manufacturers and enforcers and would provide some assurance to the public of the safety of the product. Believed the maximum permitted amount should be set in the standard related to this product. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Advised that the higher level of dental caries in communities without fluoridated water compared to communities with fluoridated water is of great concern to their District Health Board. Noted that the higher incidence of dental caries applied across all socioeconomic groups communities with non-fluoridated water supplies, but is much more marked in poorer, Pacific and Maori people. Methven township and Burnham Military Camp have the only fluoridated water supplies in their region.
<p>Dental Health Services, Dept of Health (WA)</p> <p>Peter Jarman</p> <p>Australia</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p>DHS provided dental health care for about 90% of primary school children and a lower proportion of high school students up to 17 years of age in WA. Approx 200,000 children attend for examination and treatment per year.</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Supported a maximum concentration of fluoride in packaged water of 1 mg/L (equivalent to maximum concentration in fluoridated reticulated water), but considered that this fluoride is unlikely to affect children's oral health negatively or positively, given the many other sources of fluoride to which most children are exposed e.g. water, toothpaste, the 'halo' effect of fluoride getting into foods and beverages.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Noted that, while the maximum acceptable concentration of fluoride in drinking water in the WHO and NHMRC guidelines is 1.5 mg/L, this upper limit allows some rural and remote water supplies to be used for drinking purposes when the expense involved in removal of fluoride would be crippling for the populations concerned. <p><i>Safety</i></p> <ul style="list-style-type: none"> • Noted that the principal sources of ingested fluoride in Australia are drinking water and toothpaste, especially by young children. • Noted that in the past, fluoride supplements were recommended for children who lived in areas with low water fluoride concentrations and applications of concentrated fluoride products were undertaken by dental professionals. However, because of a rising prevalence of dental fluorosis and a lack of proven efficacy, the use of fluoride supplements has generally been discontinued in recent years and no consequent increase in the prevalence of dental caries has been seen. After implementation of policies aimed at reducing children's fluoride intake, the current prevalence of mild fluorosis in Australian children is probably in the region of 10-30% (down from around 50% in the early 1990s)¹⁻⁴. <p><i>Nutrient reference value for fluoride</i></p> <ul style="list-style-type: none"> • Considered that the dental caries preventive role of fluoride did not qualify that substance as a nutrient (or food)^{6,7}. Acknowledged that fluoride is beneficial in appropriate quantities, but harmful if used in excess. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted that there is little research on the influences of packaged water on dental caries, although an Adelaide group has made an attempt⁸. • Identified that a fluoride concentration of 1.5 mg/L would entail a real risk of causing dental fluorosis, particularly in very young children, and water with such a high concentration of fluoride, if used to make up infant formula, would almost certainly cause some dental fluorosis⁹⁻¹¹. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considered that the addition of fluoride should not be used in marketing the packaged water and no health benefits should be permitted as it would be misleading. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Noted that there is considerable evidence of an increase in the prevalence and severity of dental caries in children of lower socio-economic backgrounds who are less likely to purchase or benefit from packaged water with added fluoride. <p><i>Other comment</i></p> <ul style="list-style-type: none"> • Noted that a similar proposal was put to the former National Food Authority¹¹⁴ in 1995 to import the Swedish packaged water, Ramlösa, which has a fluoride concentration of about 2.0 mg/L. Because this exceeds the drinking water guidelines, the importer sought a dispensation from the guidelines to allow importation of the product.

¹¹⁴ National Food Authority was a predecessor of FSANZ.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>References</i></p> <ol style="list-style-type: none"> 1. Burt BA, Keels MA, Heller KE. <i>The effect of a break in water fluoridation in the development of dental caries and fluorosis</i>. Journal of Dental Research. 2000;79:761-9. 2. Riordan PJ, Banks JA. <i>Dental fluorosis and fluoride exposure in Western Australia</i>. Journal of Dental Research. 1991;70:1022-1028. 3. Riordan PJ. <i>Dental fluorosis decline after changes to supplement and toothpaste regimens</i>. Community Dentistry and Oral Epidemiology. 2002;30:233-240. 4. Do LG, Spencer AJ. <i>Decline in the prevalence of dental fluorosis among South Australian children</i>. Community Dent Oral Epidemiol. 2007;35:282-291. 5. Balmer RC, Laskey D, Mahoney E, Toumba KJ. <i>Prevalence of enamel defects and MIH in nonfluoridated and fluoridated communities</i>. Eur J Paediatr Dent. 2005;6:209-212. 6. National Academy of Sciences. (1989). <i>Recommended Dietary Allowances: 10th Edition</i>. Commission on Life Sciences, National Research Council, National Academy Press. Washington DC, p. 235. 7. National Research Council (1993). <i>Health Effects of Ingested Fluoride</i>. National Academy Press, Washington DC. p. 30. 8. Armfield JM, Spencer AJ. <i>Consumption of nonpublic water: implications for children's caries experience</i>. Community Dent Oral Epidemiol. 2004;32:283-296. 9. Buzalaf MA, Granjeiro JM, Damante CA, de Ornelas F. <i>Fluoride content of infant formulas prepared with deionized, bottled mineral and fluoridated drinking water</i>. ASDC J Dent Child. 2001;68:37-41, 10. 10. Ekstrand J. <i>Fluoride intake in early infancy</i>. Journal of Nutrition. 1989;119:1856-1860. 11. Marshall TA, Levy SM, Warren JJ, Broffitt B, Eichenberger-Gilmore JM, Stumbo PJ. <i>Associations between Intakes of fluoride from beverages during infancy and dental fluorosis of primary teeth</i>. Journal of the American College of Nutrition. 2004;23:108-116.
<p>Dietitians Association of Australia Annette Byron Australia</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p><i>FSANZ Approach/Nutritional equivalence/</i></p> <ul style="list-style-type: none"> • Noted that this Application is being assessed on the basis of nutritional equivalence. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Believed the <i>Australian Drinking Water Guidelines</i> (ADWG) ¹ target level of 1 mg/L should guide the maximum claimable amount, rather than the guideline value. <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> • Supported the specification of ‘packaged water’ in the Code, consistent with Codex, to specifically exclude sugars, sweeteners, flavourings or other foodstuffs. <p><i>pH of packaged water</i></p> <ul style="list-style-type: none"> • Considered that pH of packaged fluoridated water should be between 6.5 – 8.5 as specified in the ADWG. Many carbonated waters have a lower pH, are not nutritionally equivalent to those with a pH in the range of 6.5-8.5 and are detrimental to oral health. Recommended that carbonated water be excluded from the Standard. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Supported dietary intake assessment by FSANZ to identify if any population groups, including high consumers in hot climates or 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.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Supported labelling packaged water so consumers are not misled into thinking that fluoridated packaged water is better than tap water. <p><i>Reference</i></p> <ol style="list-style-type: none"> National Health and Medical Research Council & Natural Resource Management Ministerial Council. 2004. <i>Australian Drinking Water Guidelines</i>. Canberra: Commonwealth of Australia
<p>Private Erin Mahoney New Zealand</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L)</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Supported maximum claimable amount of 1 mg/L fluoride. <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> Did not support addition of fluoride to carbonated water.
<p>New Zealand Dental Association David Crum New Zealand</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Recommended that the maximum claimable amount of fluoride should be equivalent to tap water i.e. 1 mg/L as there will be no impact on actual intake levels of fluoride. <p><i>Safety</i></p> <ul style="list-style-type: none"> Noted that reducing the maximum claimable amount of fluoride to 1 mg/L would address the risk of young children exceeding the UL. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Considered that labelling should not infer that packaged water is superior to, or has any additional benefits to, tap water.
<p>New Zealand Dietetic Association Jan Milne New Zealand</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Noted that this Application is being assessed on the basis of nutritional equivalence and believed the NZ Drinking Water Guidelines (NZDWS) target level of 1 mg/L should guide the maximum claimable amount in Standard 1.3.2., rather than the 1.5 mg/L maximum level set in the NZDWS. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Supported dietary intake assessment by FSANZ to identify if any population groups, including high consumers in hot climates or 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. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Supported the labelling of packaged water with fluoride to the same level permitted in tap water so consumers can make informed choices and are not misled as to the nutritional quality of water.

SUBMITTER	SUBMISSION COMMENTS
<p>New Zealand Nutrition Foundation (NZNF) Kelsey Woodcock New Zealand</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p><i>FSANZ's approach</i></p> <ul style="list-style-type: none"> Supported FSANZ's approach based on nutritional equivalence. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Considered that the maximum claimable amount should be consistent with the 'Drinking-water standards for NZ 2005' of 0.7-1 mg/L, rather than 1.5 mg/L. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Considered that a reduced maximum claimable amount would reduce the risk of dental fluorosis to high risk consumers as well as infants and toddlers. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Supported fluoridated packaged water being permitted to carry a nutrition claim, enabling consumers to make an informed choice. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Considered that the risk of consumers being misled about the nutritional equivalence of fluoridated packaged water versus other fluoridated water sources would be reduced if both contain the same maximum amount of 1 mg/L, and if packaged water is clearly labelled.
<p>Public Health South, NZ Marion Poore New Zealand</p>	<p>Supported Option 2</p> <p><i>Efficacy</i></p> <ul style="list-style-type: none"> Advised that NZ had naturally low levels of fluoride in water. Noted it was only by optimising the amount of fluoride in drinking water supplies that people in NZ can receive the well documented public health benefits of water fluoridation, namely reduced levels of dental caries and better oral health. Advised that currently fluoridated water in drinking water supplies is available to just over 50% of the NZ population¹. Cited NZ and international studies that showed that with optimal levels of fluoride in drinking water there are about 15% more children with no dental decay than in areas where the water supply is not fluoridated. Furthermore decay levels are 30-40% lower in children who use water with optimal levels of fluoride^{2,3}. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Cited Public Health Advisory Committee recommendation that <i>Alternatives to water fluoridation need to be considered in small communities where water fluoridation is not feasible</i>. This report also noted that fluoridated water is an important way of reducing child oral health inequalities⁴. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Noted packaged water is becoming increasingly popular. Packaged water with added fluoride will provide people living in areas without fluoridated water supplies the opportunity to make a healthy choice.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>References</i></p> <ol style="list-style-type: none"> 1. Ministry of Health. <i>Register of Community Drinking – water supplies in New Zealand</i>. Wellington 2007. 2. McDonagh M, Whiting P, Wilson P et al. 2000 <i>Systematic review of water fluoridation</i> British Medical Journal 321: 855 – 9. 3. Lee M, Dennison PJ. 2004 <i>Water fluoridation and dental caries in 5 and 12 year old children from Canterbury and Wellington</i>. New Zealand Dental Journal 100(1): 10 – 15. 4. National Health Committee. <i>Improving child oral health and reducing child oral health inequalities</i>. Report to the Minister of Health from Public Health Advisory Committee. Wellington. 2003.
<p>Paul Riordan Private Australia</p>	<p>Supported Option 1</p> <p>However, if it goes ahead, supported a maximum claimable amount of 1 mg/L fluoride.</p> <p>The submitter has undertaken substantial research on the health effects of ingested fluoride since the late 1980s.</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Considered that a fluoride concentration of 1.5 mg/L would entail a real risk of causing dental fluorosis, particularly in very young children, and water with such a high concentration of fluoride, if used to make up infant formula, would almost certainly cause some dental fluorosis¹⁻³. Supported a maximum concentration of fluoride in packaged water of 1 mg/L (equivalent to maximum concentration in fluoridated reticulated water), but considered that this fluoride is unlikely to affect children’s oral health negatively or positively, given the many other sources of fluoride to which most children are exposed e.g. (water, toothpaste, the ‘halo’ effect of fluoride getting into foods and beverages). • Noted that, while the maximum acceptable concentration of fluoride in drinking water in the WHO and NHMRC guidelines is 1.5 mg/L, this upper limit allows some rural and remote water supplies to be used for drinking purposes when the expense involved in removal of fluoride would be crippling for the populations concerned. <p><i>Safety</i></p> <ul style="list-style-type: none"> • Noted that the principal sources of ingested fluoride in Australia are drinking water and toothpaste, especially by young children. • Also noted that in the past, fluoride supplements were recommended for children who lived in areas with low water fluoride concentrations and applications of concentrated fluoride products were undertaken by dental professionals. However, because of a rising prevalence of dental fluorosis and a lack of proven efficacy, the use of fluoride supplements has generally been discontinued in recent years and no consequent increase in the prevalence of dental caries has been seen. After implementation of several policies aimed at reducing children’s fluoride intake, the current prevalence of mild fluorosis in Australian children is probably in the region of 10-30% (down from around 50% in the early 1990s).⁴⁻⁷ <p><i>Reference value for fluoride</i></p> <ul style="list-style-type: none"> • Considered that the dental caries preventive role of fluoride did not qualify that substance as a nutrient (or food).^{8,9} Expressed concern regarding possible community perception that, if fluoride is a nutrient, more is better. Acknowledged that fluoride is beneficial (caries prevention) in appropriate quantities, but harmful (dental fluorosis) if used in excess.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Considered that a fluoride concentration of 1.5 mg/L would entail a real risk of causing dental fluorosis, particularly in very young children, and water with such a high concentration of fluoride, if used to make up infant formula, would almost certainly cause some dental fluorosis.¹⁻³ <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Considered that the addition of fluoride did not augment the nutritional quality of water. Such a claim would be misleading and should not be permitted. <p><i>Other comment</i></p> <ul style="list-style-type: none"> Noted that a similar proposal was put to the National Food Authority in 1995 to import the Swedish packaged water, Ramlösa, which has a fluoride concentration of about 2.0 mg/L. Because this exceeds the drinking water guidelines, the importer sought a dispensation from the guidelines to allow importation of the product. <p><i>References</i></p> <ol style="list-style-type: none"> Buzalaf MA, Granjeiro JM, Damante CA, de Ornelas F. <i>Fluoride content of infant formulas prepared with deionized, bottled mineral and fluoridated drinking water</i>. ASDC J Dent Child. 2001;68:37-41, 10. Ekstrand J. <i>Fluoride intake in early infancy</i>. Journal of Nutrition. 1989;119:1856-1860. Marshall TA, Levy SM, Warren JJ, Broffitt B, Eichenberger-Gilmore JM, Stumbo PJ. <i>Associations between Intakes of fluoride from beverages during infancy and dental fluorosis of primary teeth</i>. Journal of the American College of Nutrition. 2004;23:108-116. Riordan PJ, Banks JA. <i>Dental fluorosis and fluoride exposure in Western Australia</i>. Journal of Dental Research. 1991;70:1022-1028. Riordan PJ. <i>Dental fluorosis decline after changes to supplement and toothpaste regimens</i>. Community Dentistry and Oral Epidemiology. 2002;30:233-240. Do LG, Spencer AJ. <i>Decline in the prevalence of dental fluorosis among South Australian children</i>. Community Dent Oral Epidemiol. 2007;35:282-291. Balmer RC, Laskey D, Mahoney E, Toumba KJ. <i>Prevalence of enamel defects and MIH in nonfluoridated and fluoridated communities</i>. Eur J Paediatr Dent. 2005;6:209-212. National Academy of Sciences. (1989). <i>Recommended Dietary Allowances: 10th Edition</i>. Commission on Life Sciences, National Research Council, National Academy Press. Washington DC, p. 235. National Research Council (1993). <i>Health Effects of Ingested Fluoride</i>. National Academy Press, Washington DC. p. 30.
<p>University of Otago School of Dentistry</p> <p>Bernadette Drummond</p> <p>New Zealand</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 1 mg/L fluoride)</p> <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> Considered that fluoride should only be allowed to be added to still water with no other additives such as sugars, artificial sweeteners, fruit juices or other ingredients. This is important because carbonated beverages with or without sugar may cause significant dental erosion because of the acidity and consumers should not think that they are equivalent to still water. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Recommended that the maximum claimable amount of fluoride should be equivalent to tap water i.e. 1 mg/L as there will be no impact on actual intake levels of fluoride.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Noted that reducing the maximum claimable amount of fluoride to 1 mg/L would address the risk of young children exceeding the UL. Supported the addition of fluoride to packaged water to give some protection and to decrease the risk of dental caries, as a significant number of NZers do not have access to fluoridated tap water. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Considered that labelling should not infer that packaged water is superior to or has any addition benefits to tap water.
Consumer Organisations and Individuals	
<p>Sabina Bacchus Private New Zealand</p>	<p>Supported Option 1</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Argued the maximum claimable amount is too high. Noted if fluoride is to be added it should not be higher than the maximum amount added to tap water of 1 mg/L. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Unconvinced that fluoride is protective against dental caries. Unconvinced that fluoride did not have any toxicological effects at the concentrations added to the municipal water supply. Requested a comprehensive safety assessment to review and reassess the safety of fluoridated water before consideration of the addition of fluoride to packaged water. Referenced a US National Research Council report¹ cited on the NZ Ministry of Health website² that indicated infants may get too much fluoride if their formula is made with fluoridated water. Also highlighted the main findings of the report which led to a recommendation that no fluoride should be added to municipal water supplies. Noted that there are a multitude of published scientific papers demonstrating the harmful effects of fluoride at concentrations lower than the proposed maximum level of 1.5 mg. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Believed that consumers are unlikely to be aware of the fact that the concentration is higher than in tap water and would therefore not be aware that they would be at higher risk of excessive consumption of fluoride. Concerned about the impact on consumers who use packaged water to avoid fluoridated water particularly if fluoridated packaged water becomes more easily available. Suggested that if companies who supply water to their employees via water coolers were only or more easily able to source fluoridated water this would remove the choice of employees to avoid fluoridated water while at work. Noted that some consumers may be under the erroneous impression that as fluoride is good for teeth, more is better than less. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Concerned for formula fed infants if fluoridated water is used to prepare formula as levels can reach twice the upper limit (0.9 mg/d). Provided an example of a 4-6 month old infant having 1250 mL of formula/day which would equate to 1.875 mg/day of fluoride. Also noted that the water intake of infants is three times greater than that of adults (per kg body weight) which puts them at greater risk from substances in water which have the potential to be toxic³.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Recommended additional labelling requirements should be considered including warnings on <ul style="list-style-type: none"> • the use of fluoridated water for infant formula; • products sold in warmer areas to inform consumers of the upper limit and how many bottles/cups this equated to; and • the potential toxicity of fluoride. <p><i>References</i></p> <ol style="list-style-type: none"> 1. Manz, F. Hydration in children Journal of the American College of Nutrition 2007; 26:562S-569S 2. See http://www.moh.govt.nz/moh.nsf/indexmh/fluoridation-infantformula 3. Carton, RJ. Review of the 2006 United States National Research Council report: Fluoride in drinking water Fluoride 2006;39:163-172.
<p>Pamela Beardmore Private Australia</p>	<p>Supported Option 1</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> • Concerned that fluoride has been banned in Scandinavia, Europe and other medically advanced nations. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted many mothers with babies use bottled water when they are out for convenience and that any mineral additive given to babies and toddlers is not good for them. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Strongly objected to the choice being taken from consumers as to whether they wanted this aluminium derivate added to their water.
<p>Keith Boyden Private Australia</p>	<p>Supported Option 1</p> <ul style="list-style-type: none"> • Let science, not politics, prevail when deciding whether or not to allow Application to add artificial fluorides that are listed on Poisons Schedules as ‘6’, and which are almost certainly industrial grade from either aluminium smelting or phosphate fertiliser production. • Take note of the difficulty of marketing fluoridated packaged water to suit the target range of 0.6 to 1.0 mg/L as now used in Australia’s potable water. <p><i>FSANZ approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> • Considered fluoride is not a nutrient and provided references to support this position¹⁻³. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considered that there would be a failure of duty of care on FSANZ's part if it were to ignore the potential for impaired thyroid function from consuming packaged water with added fluoride (most especially water fluoridated at 1.5 mg/L) particularly if consumers were iodine-deficient.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Quoted from the NRC report regarding the effects on thyroid function associated with fluoride exposures of 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine was inadequate ⁴. ● Provided evidence to support the statement that ‘a 10-kg iodine-deficient infant has the potential to have thyroid impairment from consuming daily no more than 100-300 ml’ of water that has had fluoride added at the 'optimal' recommended rate of 1 mg/L - which is one-third lower than the rate of 1.5 mg/L proposed by ABC. ● Also provided extrapolated evidence to show that even iodine adequate or iodine deficient adults have the potential to experience 'thyroid effects' from fluoridated drinking water. ● Advised that the DHHS 1991 estimates of adult fluoride consumption ‘taken conservatively, the daily rate of fluoride ingestion from all sources (1.58-6.6 mg/day) now overlaps the clinical dose of fluoride which is administered to lower thyroid function (2.3-4.5 mg/day)’ ⁵. ● Argued that when estimating adult fluoride intakes, DHHS 1991 would not have been taking into account extremely high water intakes and increased fluoride consumption from increasing levels of fluoride from all sources e.g. the fumigant Sulfuryl Fluoride. ● Noted an increasing fluoride consumption in the CDC released NHANES 2005, which is the findings of a study conducted during the years 1999- 2002 by the (US) National Health and Nutrition Examination Survey. The NHANES survey found an overall dental fluorosis (DF) rate of 32% among (all) US school children aged 6 to 19-years of age.⁶ This is an increase of 9.2% in visible fluoride toxicity in US school children since the DF incidence was reported as 22.8% in the previous national survey of fluorosis, conducted by the National Institute of Dental Research (NIDR) in 1986-87.⁶ ● Noted that the rate of DF is expected to rise in Australia and the US owing to the approval of the use of Sulfuryl Fluoride as a gas fumigant on food. ● Noted that fluoride consumption could increase dramatically since the US EPA and the Australian Pesticide and Veterinary Medicines Authority approved the use of the gas fumigant Sulfuryl Fluoride (Profume, etc) on food for which there are now permitted fluoride residue levels to maximums of 130 mg/L (wheat, milled, by-products, postharvest) 900 mg/L (dried eggs) in the US and 30 mg/L in Australia and with no apparent regulatory requirement for monitoring (at least in Australia) of fluoride residues. ● Concerned that with much food being imported into Australia, food with extremely high fluoride residue levels will make its way into this country from the US. The US EPA has permitted fluoride residue on literally hundreds of foods ⁷. ● Considered that fluoride affects the structure and appearance of tooth enamel <i>Dental fluorosis is a disease which affects the structure and appearance of enamel</i> and the more severe the effects: <i>Teeth so affected are prone to attrition and, thus early loss</i>⁸. ● Reported that <i>...fluoride's predominant effect is post eruptive (after the tooth has come into the mouth) and topical (surface application only)...</i>⁹ ● Provided evidence which showed that the use of drinking water containing as little as 1.2 to 3 mg/L of fluoride will cause such developmental disturbances as osteosclerosis, spondylosis and osteopetrosis, as well as goitre ¹⁰. ● Considered fluoride is more poisonous than lead and slightly less poisonous than arsenic.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Provides information on the deaths of two young children due to fluoride poisoning. <p><i>Reference value for fluoride</i></p> <ul style="list-style-type: none"> ● Considered that NHMRC's endorsed Upper Level Intake for fluoride for children 9 years and upward through adulthood (10 mg) exceeds the intake (5 mg/day) WHO 2002 noted will probably pose a significant risk of skeletal fluorosis¹¹. Believed that the NHMRC based virtually all of its AIs and ULs on dental decay status and did not take into account any other health effects. ● Noted that the NHMRC endorsed the 10 mg UL for fluoride, for ages 9 years and upward through adulthood, prior to the release of NRC 2006. ● Considered that the NHMRC 2007 brushed off the significant 500-page publication of NRC 2006 in two sentences. ● Considered that the NHMRC's Upper Level Intake of 10 mg/day for ages 9 years and upward through adulthood has only made allowances for the perceived measurement of 10-20 mg/day causing crippling skeletal fluorosis (having not taken into account the painful phases of stage one and stage two of skeletal fluorosis). <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> ● Advised that the American Dental Association and the CDC have issued advisories to the effect that formula for infants under 1 year should be mixed with 'low or no' fluoride water. ● Concerned that misinformed sub-groups (iodine-deficient; diabetics; kidney impaired; allergic, poorly nourished; outdoor workers etc) of the Australian population will unwittingly self-harm by choosing fluoridated packaged water instead of non-fluoridated packaged water. ● Advised of one person for whom fluoride intake from fluoridated water is life-threatening. <p><i>References</i></p> <ol style="list-style-type: none"> 1. US National Academy of Sciences. (1989). 'Recommended Dietary Allowances', 10th Edition. Commission on Life Sciences, National Research Council, National Academy Press. p.235. 2. US National Research Council (1993). 'Health Effects of Ingested Fluoride', National Academy Press, Washington DC. p.30. 3. Alberts B, Shine K. (1998). Letter from Bruce Alberts, President, National Academy of Sciences, and Kenneth Shine, President, Institute of Medicine to Dr Albert Burgstahler. November 18, 1998. 4. NRC 2006 (p218 of 467 pdf) 5. DHHS 1991. 'US Health and Human Services Review of Fluorine Benefits and Risks'. 6. See http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5403a1.htm 'National Health and Nutrition Examination Survey' 7. See http://www.fluoridealert.org/pesticides/fluoride.tols.july.2005.html ('TABLE 1. Fluoride pesticide residue tolerances approved by US EPA as of July 15, 2005') 8. H.S. Horowitz <i>et al</i>, American Journal of Public Health, vol. 54 page 1895, 1964. 9. (CDC, 'Weekly Morbidity and Mortality Report', 17/08/01, p. 4, 4th paragraph) 10. Editorial: Journal of the American Dental Association, 1944 11. Fluorides - 13. Previous Evaluations by International Bodies, Environmental Health Criteria 227, WHO 2002

SUBMITTER	SUBMISSION COMMENTS
<p>Diana Buckland Private Australia</p>	<p>Supported Option 1</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> • Considered credible evidence from around the world is being ignored and that adding even more toxic chemicals is harmful, negligent and arrogant. Furthermore, argued that the precautionary principle must be applied given there is a definite lack of integrity in science in some areas and serious conflicts of interest. • Concerned that with fluoride intake/exposure from numerous sources, no one can estimate how much a person has/will have. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Argued there was a massive world problem with chemical pollution which would be added to by this Application. • Provided additional supporting evidence with submission.
<p>James Chalmers Private Australia</p>	<p>Supported Option 1</p> <p>Preferred the Application be rejected, or if accepted, requested a severe reduction in the unit quantity together with clear labelling obligations.</p> <p><i>FSANZ Approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> • Argued fluoride was not a nutrient, nor has it been fully proven as a necessary element to human growth. Consequently, there should be no need for it to be added. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Considered the level proposed to be about 50% higher than what would be expected or permitted from town water supplies. • Suggested the level of fluoride be significantly lower than that permitted in town water. <p><i>Safety</i></p> <ul style="list-style-type: none"> • Argued fluoride has no proven benefit for adults and older people and may be detrimental to the nervous system of the latter¹. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Argued fluoride in the proposed proportion is detrimental to infant children up to six months or one year of age. Also suggested it would be difficult to avoid excessive doses if parents only have access to fluoridated bottled water on hot days or occasions. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Recommended that any water bottled with fluoride must be clearly labelled and marked with the unit quantity so persons who do not wish to ingest it can avoid it. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Noted bottled water has historically come from underground springs and tested for purity. Commented that this may mean bottlers are proposing to bottle already fluoridated town water.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>References</i></p> <p>1. National Research Council (2006) <i>Fluoride in Drinking Water: A Scientific Review of EPA's</i>.</p>
<p>Althea Deeley Private Australia</p>	<p>Supported Option 1</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> • Stated that China had long known that fluoride caused thyroid cancer in humans and has moved populations away from areas where the natural fluoride in water caused damage to health even in low concentrations.
<p>Xiaolan Deng Private New Zealand</p>	<p>Supported Option 2</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believed that addition of fluoride in water was an effective way to prevent dental problems. • Provided evidence of benefit of fluoride ingestion from World Health Organization (WHO)¹ and from a review about the efficacy of water fluoridation in Australia, Britain, Canada, Ireland, NZ and the United States². • Noted NZ research shows that dental decay levels are 30-40% lower in areas with optimal levels of fluoride in the water³. • Advised the results of the Southland study⁴ which showed that the dental decay level among 10-year old children who had never lived in a community with fluoridated water was twice the tooth decay level of those living in fluoridated community. • An evaluation of the epidemiological evidence concluded that there was no clear evidence of adverse effects associated with optimal fluoridation of water supplies⁵. • Noted that the prevalence of enamel fluorosis in NZ had remained constant since 1980s⁶. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Suggested that information about the potential effect of fluorosis in children could be included in labelling. • Also suggested the need to give warning to the vulnerable groups such as infants, young children and people with liver damage, impaired kidney function. • Noted that fluoridated packaged water in the US has between 0.8-1.7 mg/L fluoride, which is a wider range⁶. From 2006, packaged water may carry a claim to the effect that fluoridated water can possibly reduce the risk of dental cavities or tooth decay⁷. • Recommended including information about health claim and regulation of safe packaged water can be added on the bottles or packages, because these are the most frequently asked questions by general population⁸. <p><i>Enforcement</i></p> <ul style="list-style-type: none"> • Raised the importance of monitoring the food supply by NZ Food Safety Authority (NZFSA) and FSANZ.

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	<p><i>Communication</i></p> <ul style="list-style-type: none"> Recommended promotion of key messages relating to the safety and efficacy of fluoridated packaged water by the Ministry of Health, and health professionals, to increase knowledge about fluoridation and reduce public concern about safety issues. <p><i>References</i></p> <ol style="list-style-type: none"> World Health Organisation. Diet, nutrition and the prevention of chronic disease. WHO technical Report Series 196. Report of a joint WHO/FAO Expert Consultation. WHO, Geneva.2003. Newbrun E. Effectiveness of water fluoridation. J Publ Health Dent 1989 (Special Issue) 49: 279-89. Ministry of Health. Fluoridation in New Zealand. Wellington: Ministry of Health. Benefits of Water Fluoridation. Website: http://www.votefluoride.org.nz/K/benefits-fluoridation-water-health-improve-whyreason/_I.10 Bate M. Fluoridation of water supplies: an evaluation of the epidemiological Coleman P. Improving oral health care for the frail elderly: A review of widespread problems and best practices. Geriatric Nursing July 2002, 23 (4) 189-199 9. American Dental Association Applauds Health Claim for Fluoridated Bottled Water. website: http://www.ada.org/public/media/releases/0610_release01.asp Centres for disease control and prevention, Department of Health and Human Services. Fact Sheet on Questions About Bottled Water and Fluoride website: http://www.cdc.gov/FLUORIDATION/fact_sheets/bottled_water.htm
<p>Stacey Erbacher Private</p>	<p>Supported Option 1</p> <p><i>FSANZ Approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> Commented that fluoride was not a nutrient, rather it was a chemical, noting calcium fluoride occurred naturally in water and rocks, whereas sodium fluoride did not. Furthermore, stated that fluoride was not essential for healthy bones and teeth (a healthy diet and regular brushing of teeth with fluoridated water is sufficient). <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Believed the addition of fluoride to un-fluoridated bottled water supplies would limit personal choice. Considered FSANZ's Application negatively impacted on a consumers' choice. Suggested many people purchased bottled water because it did not contain fluoride. <p><i>Other issues</i></p> <ul style="list-style-type: none"> Suggested the addition of sodium fluoride to drinking water, whether bottled or tap, provided a convenient disposal of a phosphate industry by-product.
<p>Craig Felsman Private Australia</p>	<p>Supported Option 1</p> <ul style="list-style-type: none"> Provided additional supporting material with submission.

SUBMITTER	SUBMISSION COMMENTS
<p>Fluoride Action Network Mark Atkin New Zealand</p>	<p>Supported Option 1</p> <p>Argued that to allow this poison to be put in bottled water was not only nonsensical, it will expose manufacturers to law suits, which were already being prepared in the USA and are being investigated in Australia. Estimated water fluoridation would be banned within the foreseeable future, possibly within 5 years.</p> <p><i>FSANZ's approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> ● Opposed the proposal to allow the request on the basis of nutritional equivalence. ● Considered that, as the specific order principles are subject to the high order principles, assessment using a nutritional equivalence approach should only be applied where the need for the primary food has been established under one of the other principles. ● Considered that High Order Policy 1 (protection of public health) has not been established for artificially fluoridated water. Therefore, considered it would be inappropriate to use the equivalence provision. Also considered that the 'primary food' must be considered to be naturally-occurring unfluoridated water which is typically below 0.3 ppm in NZ, and commonly below 0.1 ppm. Considered that artificial fluoridation is an alteration of the true primary food, and artificially fluoridated water is therefore a secondary food. ● In addition, considered that, on the basis that should FSANZ consider artificially fluoridated water the primary food, it fails to meet the other specific principles: <ul style="list-style-type: none"> - has never been proven safe; - has never been established as necessary or beneficial; - in the case of silicofluorides, has never been tested for human health safety ¹; - is the most controversial public health issue in history; - has been demonstrated to pose unacceptable risks to a significant proportion of the population; - in light of current scientific evidence, is likely to be discontinued within the next 5 to 10 years. ● Argued that permission for the voluntary addition of fluoride to packaged water should not be permitted as the required conditions were not met. ● Provided supporting evidence that there can be no deficiency of a substance that is neither a vitamin nor an essential mineral. Advised that the current daily intake of fluoride is considered to be at least 3 mg. As the 'optimal intake' claimed by fluoridation promoters was determined to be 1-1.5 mg/day ², current intakes cannot be considered 'deficient'. Advised that this was supported by the move in NZ in the 1990s to reduce the levels in water from 1.0 to 0.08 mg/L due to overdosing. ³ ● Considered that changes in food habits will not reduce the intake of fluoride from naturally occurring levels. ● Noted that it is not generally accepted that increasing the intake of fluoride will deliver a health benefit. ● Advised that fluoridation is illegal in Sweden and Holland. Noted that the city of Basel, Switzerland, ceased fluoridation in 2003 after 41 years citing lack of evidence of benefit. ● Referred to a Systematic Review by York University ⁴ which found that the evidence of alleged benefit was of such poor quality that the Board considered that legitimate scientific controversy would remain until better quality studies were completed.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Advised that the rate of dental caries caused by tooth decay has dropped substantially both in countries which have added fluoride, such as Germany and Portugal, and those which have not, such as Austria and Sweden. • Noted the latest Australian study⁵ which demonstrated that any apparent benefit under the age of 12 was temporary. Considered that the results that showed zero benefit to the permanent teeth, and a small temporary difference up to the age of 12 that could not be attributed to fluoride, as there was no control for delayed tooth eruption. Advised that analysis of the figures indicated that those drinking water with up to 0.3 mg/L had less decay than those drinking water at 1 mg/L. • Provided supporting evidence and tables of official government figures from both NZ and Australia, as well as the USA, which showed no statistical difference in decay between fluoridated and unfluoridated communities and that dental health had improved equally in both types of community since the mid 1980s⁶. • Provided references supporting the view that there was no overall significant difference in rates of dental decay in children in fluoridated or unfluoridated cities, but children in the fluoridated city show significantly higher rates of dental fluorosis than children in the un-fluoridated city.⁷ • Also provided evidence which demonstrated no benefit after 30-40 years of fluoridation⁸. • Advised that Pre-European Maori had virtually no dental decay, with as little as 0.01 mg/L fluoride in the water⁹. • Advised that calcium fluoride was processed through the pancreas and excreted through the faeces, while silicofluorides and sodium fluoride are processed through the kidneys and excreted through urine. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Did not consider 1.5 mg/L an appropriate maximum claimable amount. Advised that the US National Research Council's 2006 report could find no lower limit of fluoride exposure that was protective of human health, and no safe limit in water. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believed that demonstrated adverse health effects of fluoride at levels above 0.7 mg/L are such that fluoridated water posed a significant health risk to humans. • Advised that <i>The Lancet</i> recently described fluoride as 'an emerging neurotoxic substance'. The American Medical Association described it similarly in 1943.¹⁰ • Argued that 'Even with DDT, you don't have the consistently strong data that the compound can cause cancer as you now have with fluoride.'¹¹ • Provided references which demonstrated the difference in bioavailability, and toxicity of the different forms of fluoride¹²⁻¹⁴. • Noted that the US Environmental Protection Agency (EPA) has acknowledged that silicofluorides have never been tested for human health safety, and requested such research in 2002. • Noted that the major source of fluoride is no longer fluoridated water, as in the 1940s. US fluoride exposure is up to 6 mg/day, and in NZ estimated at 3 mg/day. • Concerned with the potential increase in dental fluorosis from adding fluoride to packaged water.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Noted that large numbers of people in Japan, China, India, the Middle East, and Africa have been diagnosed with skeletal fluorosis from drinking naturally fluoridated water. In India alone, nearly a million people suffer from the affliction. • Noted that while only a dozen cases of skeletal fluorosis have been reported in the US, there may have been more cases of fluorosis – even crippling fluorosis – because most doctors in the US have not studied the disease and do not know how to diagnose it. Because some symptoms of skeletal fluorosis mimic those of arthritis, noted that the first two clinical phases of fluorosis can be easily misdiagnosed. • Advised that, according to the WHO, in combination with certain other factors (e.g. sub-optimal nutrition, kidney disease), chronic fluoride intake between 2.0-8.0 mg/day can produce pre-clinical skeletal fluorosis, a debilitating and/or crippling bone disease.⁵. These findings are consistent with those of the National Research Council’s findings, published in 2006. • Noted that some people drink more than two litres of water per day and the Institute of Medicine recently recommended that men over the age of 19 drink three litres of water per day (IOM 2004). • Considered that the NRC was misled over the Bassin osteosarcoma study¹⁶ which showed a 500% to 700% increase in osteosarcoma rates in adolescent boys who had consumed fluoridated water between the ages of six and ten specifically. • Considered that no claim of dental health benefit should be allowed as there is little benefit from ingestion of fluoride; any benefit is by topical application at concentrations of 2 mg/L or more (5 studies)¹⁷⁻²¹. • Quoted from a 2007 review of the literature²²: ‘The level of fluoride incorporated into enamel by systemic ingestion was proved to have no significant effect in preventing/reversing caries. Also advised that clinical/epidemiological data from fluoridation studies supported the current view that the cariostatic effect of fluoride is almost exclusively post-eruptive and the mechanism of action is topical’. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted that the US National Research Council (NRC) identified a number of population subgroups at greater than average risk from fluoride exposure including: <ul style="list-style-type: none"> - infants fed primarily on infant formula rather than breast milk - diabetics - anyone with impaired kidney function (generally) – specifically those on dialysis and the elderly - those with high water intake such as outdoor workers and sports people • Noted that these groups comprise at least 40% of the population in NZ and presumably a similar proportion in Australia. • Noted that both the American Dental Association (ADA) and the US Government’s Centers for Disease Control and Prevention (CDC) advised in November 2006 that bottle fed infants were at an increased risk if formula powder was reconstituted with water containing 0.7 mg/litre or more.²³ • Noted that the Standard 2.9.1, setting the limit of fluoride in formula powder which triggers a warning statement, was based on using fluoride-free water. Increased risk of dental fluorosis may occur above 0.5 mg/day. • Further noted that the ADA and CDC state that it is the fluoride in the water that poses the threat; not the formula powder.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Noted that it is internationally accepted that the heightened risk of fluorosis continues up to the age of 4 years, with the first 6-12 months being the most important. A recent study also established that even small changes in fluoride levels significantly affect the incidence of dental fluorosis. Hong Kong sequentially decreased fluoride levels from 1.0 in 1967 to 0.7 in 1978 and 0.5 mg/L in 1988. Between 600 and 700 12 year old children were studied from each year (1983, 1991, 2001). Enamel defect prevalence decreased from 92.1% to 55.8% to 35.2%.²⁴ ● Noted WHO findings which showed that, along with other factors (e.g. sub-optimal nutrition, kidney disease), a chronic fluoride intake of 2.0 to 8.0 mg/day can produce the pre-clinical stage of skeletal fluorosis, a debilitating and/or crippling bone disease¹⁵. Noted that these results are consistent with those of the NRC's findings, published in 2006. A further study by Mayo Clinic scientists (Johnson 1979), found strong evidence of skeletal fluorosis among people with kidney disease (not on dialysis) drinking water with just 1.7 to 2.0 mg/L. ● Noted up to 5% of the population had some level of hypersensitivity to fluoride as found in the Netherlands in the early 1970s. ● Referred FSANZ to documentation of a US family medically certified as allergic to fluoride, and provided with a free fluoride filter as a result.²⁵ <p><i>Reference value for fluoride</i></p> <ul style="list-style-type: none"> ● Noted that the latest review of Nutrient Reference Values for Australia and NZ increased the 'adequate daily dose' to the previous level classified as the maximum tolerable daily exposure. ● Questioned the accuracy and determination of the UL and provided information and references supporting the view that the claimed lowest observed adverse effect level (LOAEL) is incorrect. ● Believed that the increase in the adequate daily dose appeared to be purely a politically driven change across English-speaking countries with which NZ and Australia are politically aligned. ● Concerned that the safety factor of 2.5 was unacceptably low and cannot cover the full range of sensitivities in a human population, for example, those suffering from kidney impairment, or those exposed through infancy and the full duration of childhood. ● Also noted that as fluoride accumulates in bone, a smaller dose over a longer time would have the same effect as 10 mg/day for 20 years. ● Noted that the LOAEL was based on only one adverse health effect; skeletal fluorosis and advised other demonstrated adverse health effects, for example: <ul style="list-style-type: none"> - pineal Gland accumulation and melatonin production inhibition 26 - neurological damage 27 - links to Alzheimer's' Dementia 28 - increased rates of osteosarcoma in adolescent males 29 - disruption of cell communications 30 - lowered IQ among children. 31 - the first health study of children living in a fluoridated community found a statistically significant increase (13.5 versus 6.5%) in cortical bone defects in the fluoridated community (Newburgh, NY) compared with the unfluoridated community (Kingston, NY) after just ten years of fluoridation at 1 mg/L fluoride.³²

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> ● Considered that fluoride is not a nutrient or essential mineral and that no such claim be permitted on packaged water. ● Provided evidence and references to support this view. ● If the Application was approved, recommended the following be included on the label: <ul style="list-style-type: none"> <u>Products contain the following information:</u> <ul style="list-style-type: none"> - The fluoride level - The exact agent used <u>Products list the following warnings:</u> <ul style="list-style-type: none"> - Not suitable for children under 3. - Not suitable for reconstituting infant formula powder - May increase cancer risk in boys aged 6 – 10 years - Not suitable for diabetics - Not suitable for people on dialysis treatment - Do not consume if you have impaired kidney function - May not be suitable for the elderly - Determine your total daily fluoride intake before consuming this product - ‘Do not consume more than 1 bottle per day’ (if the reference package delivers 0.9 mg fluoride) or ‘Do not consume more than 900 ml per day’ on other package sizes. - If medical symptoms appear with regular use of this product, contact your medical professional. Symptoms may take several weeks to appear. ● Considered that if warnings and fluoride levels are required on packaged water, it would be inconsistent not to require the same information on other beverages with added fluoride or made with fluoridated public water. ● Noted that fluoride tablets designed to be dissolved in water carry the warning ‘do not give to children under 3’. Considered that labelling of packaged water should be consistent with this requirement. ● Noted that the US FDA had approved a claim that fluoridated water benefits teeth in spite of there being no credible evidence to support this claim⁷. Also noted that the FDA has refused to allow a claim that it benefits children’s teeth. ● In light of the Armfield and Spencer study, recommended that no claims of dental health benefit be allowed⁴. ● Recommended that, if allowed, standard packaging should carry the warning ‘Do not consume more than one bottle per day’. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> ● Considered that if the proposal was allowed, fluoride quality must be at least ‘food grade’. ● Considered that there should be no contamination of foods with lead or arsenic. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> ● Considered that consumers would inevitably be misled on this issue. ● Noted that while packaged water would be equivalent to artificially fluoridated public water, consumers could be misled into believing it was also equivalent to naturally occurring water with the same level of (calcium) fluoride, which is untrue.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Considered that this Application would in fact be a disservice to the packaged water industry, which would need to meet increased demand for unfluoridated packaged water from Qld and Vic in the short term, and will have invested in a product that will be unsaleable within the foreseeable future. ● Noted a number of unfluoridated communities listed in the Assessment Report either actively rejected or deliberately discontinued fluoridation, including Christchurch, Timaru, Tauranga, and Whangarei. ● Also noted communities that recently rejected fluoridation by public referenda included Ashburton, Hokitika, Greymouth, and Waitaki. ● Noted that Napier, the control city in the 'Hastings experiment' on which fluoridation of NZ was 'justified', still has less tooth decay, and has had decay reduce at the same rate, as fluoridated Hastings. Noted that both cities were demographically similar. Timaru, since discontinuing fluoridation 1985, had also shown continual improvement in dental health, and today had less decay (DMFT) than any fluoridated South Island community. ● Enclosed letters which noted cessation of fluoridation in Sweden and the Netherlands. <p><i>References</i></p> <ol style="list-style-type: none"> 1. US Environmental Association, 25 April 2002. 2. McClure, Frank J. (1943) <i>American Journal Diseases of Children</i>, 66:362. 3. <i>Water Fluoridation in New Zealand</i> Public Health Commission 1995. 4. McDonagh M, Whiting P, Bradley M et al (2000) A systematic review of public water fluoridation. NHS Centre for Reviews and Dissemination, University of York. 5. Jason M. Armfield and A. John Spencer, <i>Community Dentistry And Oral Epidemiology</i> Volume 32 Issue 4 Page 283 - August 2004. 6. de Liefde B, The decline of caries in New Zealand over the past 40 years, <i>NZ Dental Journal</i>, 1998 Sept 94 (417):109-13. 7. Recommendations for fluoride use in children. Kumar, J.V and Green, E.L. <i>New York State Dent. J.</i> (1998) 40-47. 8. Hunt Eldridge and Beck, 'Effect of Residence in a Fluoridated Community on the Incidence of Coronal and Root Caries in an older Population <i>Journal of Public Health Dentistry</i>, Vol 49, No. 3, Summer 1989, pp 118 - 141. 9. Weston A Price DDS, <i>Nutrition and Physical Degeneration</i>, 1937 10. <i>Journal of the American Medical Association</i>, September 18, 1943. 11. 'Fluoride water 'causes cancer',' by Bob Woffinden, June 12, 2005, The Observer http://observer.guardian.co.uk/uk_news/story/0,6903,1504672,00.html 12. Crosby NT; 'Equilibria of Fluosilicate Solutions with Special Reference to The Fluoridation of Public Water Supplies'; <i>J Appl Chem</i>; v19; pp 100-102, 1969. 13. Johannes Westendorf 'The Kinetics of Acetylcholinesterase Inhibition and the Influence of Fluoride and Fluoride Complexes on the Permeability of Erythrocyte Membranes' Dissertation to receive Ph.D. in Chemistry from the University of Hamburg, Germany, 1975. 14. Masters R , Coplan M. 'Water Treatment with Silicofluorides and Lead Toxicity,' <i>International Journal of Environmental Studies</i> (July-August 1999) 56: 435-449. 15. <i>Fluorides and Human Health</i>, 1970, pages 239-240. 16. Elise B. Bassin , David Wypij, Roger B. Davis, Murray A. Mittleman 'Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma (United States)' <i>Cancer Causes and Control</i> Volume 17, No. 4; May 2006.

SUBMITTER	SUBMISSION COMMENTS
	<p>17. Damato, F.A. (1990). 'Effect of fluoride concentration on remineralization of carious enamel.' <i>Caries Res.</i> 24(3):174-80.</p> <p>18. Cutress, T.W. (1995) 'Effects of fluoride-supplemented sucrose on experimental dental caries.' <i>Advances in Dental Research</i> 9(1).</p> <p>19. Arends, J, Christoffersen, J, Ruben, J & Jongebloed, WL (1989) 'Remineralisation of bovine dentine in vitro. The influence of the F content in solution on mineral distribution.' <i>Caries Res.</i> 23. 309-14.</p> <p>20. Pearce, E.I. (1992). Supplementation of domestic sugar (sucrose) with fluoride. <i>New Zealand Dent. J.</i> 88(393):84-8.</p> <p>21. Tanaka, M. (1993). 'Effect of fluoride incorporation into human dental enamel on its demineralization in vitro.' <i>Arch Oral Biol.</i> 38(10):863-9</p> <p>22. G. Pizzo : M. R. Piscopo : I. Pizzo : G. Giuliana; Department of Oral Sciences, University of Palermo 'Community Water Fluoridation and Caries Prevention: a Critical Review.' <i>Clin Oral Invest</i> DOI 10.1007/s00784-007-01 0111-61</p> <p>23. http://www.ada.org/prof/resources/positions/statements/fluoride_infants.asp?id=egram_061109 ; http://www.cdc.gov/fluoridation/safety/infant_formula.htm.</p> <p>24. Wong et al 'Association Between Developmental Defects of Enamel and Different water Concentrations of Fluoride in the Public water Supply' <i>Caries Research</i> 2006:40: 481-486.</p> <p>25. See San Antonio Express News (26 July 2002) at http://news.mysanantonio.com/story.cfm?xla=saen&xlc=768845 last accessed 3 August 2002.</p> <p>26. J Luke <i>The Effect of Fluoride on the Physiology of the Pineal Gland</i> (Ph.D. thesis, University of Surrey, 1997); J Luke 'Fluoride Deposition in the Aged Human Pineal Gland' (2001) 35 <i>Caries Res</i>128.</p> <p>27. Mullinex PJ, Dembesten PK, Schunior A, Kerman WJ 'Neurotoxicity of Sodium Fluoride in Rats' (1995) 17 (2) <i>Neurotoxicology and Teratology</i> 169; Guan et al, <i>Toxicology</i>, August 2004.</p> <p>28. Varner, J.A., Jensen, K.F., Horvath, W. And Isaacson, R.L. <i>Brain Research</i> 784 284-298 (1998).</p> <p>29. Elise B. Bassin , David Wypij, Roger B. Davis, Murray A. Mittleman 'Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma (United States)' <i>Cancer Causes and Control</i> Volume 17, No. 4; May 2006.</p> <p>30. <i>Physiological Research</i> 51(6):557-64; Strunecka A, Patocka J. (1999). 'Pharmacological and toxicological effects of aluminofluoride complexes.' <i>Fluoride</i> 32: 230-242.)</p> <p>31. Xiang Q, et al. (2003). Effect of fluoride in drinking water on children's intelligence. <i>Fluoride</i> 36: 84-94.</p> <p>32. Schlesinger ER, et al. (1956). Newburgh-Kingston caries-fluorine study XIII. Pediatric findings after ten years. <i>Journal of the American Dental Association</i> 52: 296.</p>
<p>Beverly Fogarty Private Australia</p>	<p>Supported Option 1</p> <p>Believed there would be a backlash against the beverage industry if this Application proceeds.</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> Argued there was plenty of evidence to support the claims that fluoride was deleterious to health over the longer term. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Concerned that the industry would 'push their products' with the end result of an increase in consumption and an increase in the harmful side effects. Questioned whether FSANZ was prepared to 'foist onto the unsuspecting public and particularly the smaller members of the public a known contaminated product'.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Enforcement and monitoring</i></p> <ul style="list-style-type: none"> Argued FSANZ had no way of monitoring this permission.
<p>Jack Forward Private Australia</p>	<p>Did not state a preferred option, but appears to support Option 1 as advised mass medication is wrong.</p> <p>Questioned whether fluoridating the bottled water supply would result in the public supply being restored to its natural condition for drinking i.e. fluoride-free public water supply.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Sought clarification regarding the addition of fluoride as a pharmaceutical or as a natural product extracted from rocks or hydrofluorocilicic acid produced by the phosphate fertiliser industry, which the US Centre for Disease Control warns should not be swallowed but used topically as it is a waste product which may contain lead, mercury, cadmium and arsenic. Questioned whether FSANZ will seek a report on the long-term effects of ‘dosing’ water with fluoride as is done before the release of prescription drugs for sale. Advised that China did not fluoridate because of the effect on behaviour. Also noted Belgium, Quebec and most European nations have abandoned the practice. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Questioned whether a warning label will have to be attached to relieve suppliers of legal action if consumers are adversely affected. <p><i>Other issues</i></p> <ul style="list-style-type: none"> Provided additional supporting evidence with submission.
<p>Astrid Gesche Private Australia</p>	<p>Supported Option 1</p> <p><i>FSANZ’s approach</i></p> <p>Recommended that the assessment should be based on an investigation of need for artificially fluoridised packaged drinking water rather than nutritional equivalence.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned that increasing use of fluoridated water in consumer products such as food technology implied that overall exposure becomes more significant in the future. Considered that evidence of toxicity or harm in some humans from fluoridated water arising from systemic exposure to fluoridated water cannot be dismissed ¹. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Consider that, for risk assessment purposes, evaluating existing exposure assessment methods may not be sufficient to determine the physiological and immunological responses to fluoride in vulnerable persons. For example whether fluoride can exacerbate pre-existing medical conditions or increase susceptibility to diseases, such as allergies. Concerned that cross contamination with fluoride in unfluoridated packaged water would expose susceptible people to substantial risk.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Concerned about the risk of enamel fluorosis during tooth development if fluoridated water is used to dilute formula or foods for infants one year and younger². • Concerned with the possibility of adverse effects, even at low concentration, for those with medical conditions such as thyroid function, kidney patients and diabetics who are at risk of consuming too much fluoride as they tend to drink more water than healthy individuals. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Concerned that, in a civilised society, access to affordable drinking water that is safe for all consumers is assumed to be a basic civil right. • Considered that the addition of fluoride to packaged water would restrict the choice for vulnerable sub-populations. On the other hand, individuals who lived in areas with unfluoridated tap water, would be able to economically, and, without undue risk to their health and lives, fluoridise their teeth by simple measures such as purchasing appropriate toothpastes or improving their dental hygiene. <p><i>Benefit cost analysis</i></p> <ul style="list-style-type: none"> • Concerned that cross-contamination with fluoride in unfluoridated packaged water would be difficult to avoid without incurring further costs to the producer. • Considered that susceptible individuals may incur additional costs to purify packaged water – an expense that should be regarded as inequitable, given that those households are generally already burdened with additional health costs and consumer spending costs. <p><i>References</i></p> <ol style="list-style-type: none"> 1. Fawell, J., Bailey K., Chilton J., Dahi, E., Fewtrell L. and Magara Y. 2006. <i>World Health Organization. Fluoride in Drinking-water</i>. Available from: http://www.who.int/water_sanitation_health/publications/fluoride_drinking_water_full.pdf; retrieved 29 April 2008. 2. American Dental Association (ADA). 2006. Interim guidance on fluoride intake for infants and young children. Available from: http://www.ada.org/prof/resources/positions/statements/fluoride_infants.asp?id=egram_061109, retrieved 29 April 2008.
<p>Brook Hinckley Private Australia</p>	<p>Did not state a preferred option, but appears to support Option 1 (Advised bottled water consumed to avoid fluoride).</p> <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considered it was essential that fluoridated packaged water be identified as ‘fluoridated water’ and that labels include the fluoride concentration. • Believed it would be beneficial if the fluoride source (i.e. calcium fluoride, sodium fluoride) be referenced on the label as ‘Fluoride: 1 ppm (from NaF or H₂SiF₆). • Recommended a warning should be included on the label against consumption by infants, those with high serum fluoride levels, those with hypothyroidism or those with impaired kidney function. Alternatively, suggested wording advising medical advice should be sought before drinking fluoridated water.

SUBMITTER	SUBMISSION COMMENTS
Anton Ingarfield Private Australia	<p>Did not state a preferred option but appeared to support Option 1</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considered there is overwhelming evidence that fluoridation of water is neither safe nor effective in reducing tooth decay nor medically ethical. • Suggested several US cities are ceasing fluoridation of their water supplies. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Recommended that FSANZ require full disclosure of the amount of fluoride present in the fluoridated packaged water. • Also recommended that the levels of contaminants in the fluorosilicate or other chemicals used to fluoridate the packaged water, including lead, arsenic and heavy metals, are also clearly stated on the package. • Considered that not to do so must be against the regulations of disclosure of constituents of beverages.
Jan Isaac Private Australia	<p>Did not state a preferred option but appeared to support Option 1</p> <p>Cautions that sodium fluoride has been ‘sold’ to Australians as a panacea for dental cavities.</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> • Concerned regarding sodium fluoride as a ‘toxic poison’. • Suggested calcium fluoride is what is needed, especially for children rather than sodium fluoride, which is used as an insecticide and pesticide, is poisonous and may be fatal. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Provided additional supporting evidence with submission.
I Jeray Private Australia	<p>Opposed the Application unless the voluntary addition of fluoride is clearly identified on the label</p>
Terry Kiernan Private Australia	<p>Appears to support Option 1 (Stated objection to Option 2)</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Referred to a peer reviewed report that suggested that fluoridation has little discernable dental benefit when compared to a comparable non-fluoridated area. (However, reference to report was not supplied.) • In view of the wide variation of fluoride concentration in the tested bottled waters, recommended the need for regulatory guidelines to control concentration in order to prevent dental fluorosis ¹. • Cited information on the chemical analysis of food stuffs in America from Jeff Green, Director of ‘Citizens for Safe Drinking Water’, which showed that a bowl of wheaties with full cream milk and orange juice could exceed the maximum allowable (adult) daily level of fluoride.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Stated that the fluoride compounds proposed to be voluntarily added to packaged water products are contaminated with a cocktail of heavy metals including Arsenic, Lead and Mercury.² <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered that as an industrial pollutant³, the proposed fluorides have documented health threats⁴ and, when ingested, these fluorides pose additional health risks to increasing sub-populations including diabetics, renal disease sufferers⁵ and infants fed reconstituted milk formula made on fluoridated water⁶. • Concerned that fluoridation increases blood lead levels in children and reduces their IQ levels^{7,8}. • Considered that, when prescribing supplements, dentists should be aware of the fluoride content of packaged waters used by paediatric patients, especially with concentrations higher than 0.3 mg/L fluoride¹. <p><i>Technological issues</i></p> <ul style="list-style-type: none"> • Stated that the fluoride compounds proposed to be voluntary added to packaged water products are contaminated with a cocktail of heavy metals including Arsenic, Lead and Mercury². <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Referred to an article titled ‘Fluoride content of bottled waters available in Northern Greece’, which noted that, the manufacturers’ labelling of fluoride concentrations may be inaccurate¹. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Referred to the <i>Hazardous Waste Act 1989</i> (Cth) which listed the fluoride compounds used in fluoridation as hazardous wastes and directs commercial disposal of these designated hazardous wastes in accordance with environmental regulations³. <p><i>References</i></p> <ol style="list-style-type: none"> 1. International Journal of Paediatric Dentistry, volume 16, issue 2, page 111/116 (March 2006) 2. tex.parliament.vic.gov.au/bin/texhtmlt?form=VicHansard.dumpall&db=hansard91&dodraft=0&speech=... 3. See <i>Hazardous Waste Act 1989</i> (Cth) 4. Health Concerns Index submitted to the Queensland Fluoride Debate 5. Liu JL, Xia T, Yu YY, Sun XZ, Zhu Q, He W, Zhang M, Wang A. (2005). [The dose-effect relationship of water fluoride levels and renal damage in children] <i>Wei Sheng Yan Jiu</i>. 34(3):287-8. See: http://tinyurl.com/7gv3h 6. www.council.Lithgow.com/pdfs/fluoride/correspondence_other.pdf 7. www.lead.org.au/lanv7n4/L74-11.html 8. www.johnston-independent.com/fluoride_fraud.html

SUBMITTER	SUBMISSION COMMENTS
<p>Tony La Spina Private Australia</p>	<p>Did not state a preferred option, but appeared to support Option 2, on condition that there was no fluoride added to town or city water supplies.</p> <p>Mandatory water fluoridation violated all scientific and democratic practices and the proposal to add fluoride to all packaged water will only add to this violation, while further reducing people's CHOICE as to what they consume.</p> <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted that some people claimed sensitivity to fluoride added to water. Also noted that some health practitioners estimated that about one person in one hundred developed visible signs of reaction to fluoride besides the more common one of dental fluorosis! <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Suggested that Councils who wished to make fluoride available could provide fluoridated packaged water free at child care centres, schools, hospitals etc. Different sized bottles could contain the daily recommended dose for each child according to age or weight. • Believed that this approach would safeguard the principle of CHOICE i.e. people who wished to consume fluoridated water in the belief that it would benefit their children's teeth could purchase it. Those who wished to avoid it could either use town water or purchase unfluoridated packaged water.
<p>Brett Laboo Private</p>	<p>Appears to support Option 1 (Stated objection to Option 2)</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considered that fluoride was harmful to human health at the levels added to public domestic potable water. • Believed that the NHMRC report (2007) ignored extant information about the detrimental effects of consuming fluoridated water. • Considered that there was already an overabundance of fluoride in the food chain. • Additionally, considered that ABC had not provided sufficient evidence; in the form of peer-reviewed long-term placebo controlled double-blind longitudinal studies into the complete safety of the human consumption of fluoride. • Considered that any claimed 'benefit' to teeth is from topical application only. • Also considered that there is no significant difference between the dental health of fluoridated and non-fluoridated communities. <p><i>Nutrient reference value for fluoride</i></p> <ul style="list-style-type: none"> • Considered that fluoride is not a nutrient. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered that fluoridated water should not be used to prepare infant formula.

SUBMITTER	SUBMISSION COMMENTS
<p>Sookling Leong Private</p>	<p>Did not specify preferred option, but considered that adding fluoride to packaged water should only be approved when supported and justified by strong evidence that the benefits override the negative consequences.</p> <p><i>FSANZ approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> ● Considered fluoridated packaged water would be a substitute for fluoridated tap water. ● Recommended that the efficacy of additional fluoride in preventing dental caries and its risk for infants and children be considered. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> ● Reported a 2007 study which showed that fluoridated water has little benefit in preventing dental caries among adults¹. By comparing the cost of dental treatment, the study concluded that those living in the non-fluoridated water areas required less dental treatment compared with the population living in fluoridated water areas. ● Noted a cohort study in Iowa which monitored the prevalence of tooth caries among children from the age of five to adolescence. Results showed that there was no evidence of an association between fluoride in bottled water and tooth decay². The study concluded that although there was a lower level of fluoride intake, there was no evidence of an association between low levels of fluoride and an increase rate of tooth decay. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> ● Concerned that infants and young children are at risk of ingesting amounts that exceed the UL if fluoride is added to packaged water, especially at the optimal amount of 1.5 mg fluoride/L³. In a 2004 study, infants between one and twelve months are found to be susceptible to dental fluorosis when formulas were diluted with fluoridated packaged water⁴. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> ● Considered that, if the effectiveness of fluoride from tap water in preventing dental caries is questionable, adding fluoride to packaged water would be misleading to the consumer if the proposal is being approved. <p><i>References</i></p> <ol style="list-style-type: none"> 1. Maupome G, Gullion C, Peters D, Little SJ. A Comparison of dental treatment utilization and costs by HMO members living in fluoridated and nonfluoridated areas. <i>Journal of Public Health Dentistry</i>. 2007;67:224- 233. 2. Broffitt B, Levy SM, Warren JJ, Cavanaugh JE. An investigation of bottled water use and caries in the mixed dentition. <i>American Association of Public Health Dentistry</i>. 2007;67:151-158. 3. Food Standards Australia New Zealand. 19 March 2008. <i>Voluntary addition of fluoride to packaged water</i>. Retrieved 19 April 2008 from http://www.foodstandards.gov.au/. 4. Buzalaf M, Damante CA, Trevizani L, Granjeiro JM. Risk of fluorosis associated with infant formulas prepared with bottled water. <i>Journal Dent Child</i>. 2004;71:110-113.

SUBMITTER	SUBMISSION COMMENTS
<p>MFH Private (Name withheld for privacy reasons) Australia</p>	<p>Appeared to support Option 1 (Stated objection to Application)</p> <p>Recommended that FSANZ should not permit the addition of fluoride to packaged water as the specific guidelines would be breached considering that:</p> <ul style="list-style-type: none"> • fluoride cannot be proved to be a vitamin or mineral; • no fluoride deficiency state ever proved or demonstrated; • no evidence to prove a need in any population group; • no evidence to show a low intake and fluoride exposure is increasing; and • there is evidence that some population groups are vulnerable to fluoride. <p>However, if the Application progressed, the following recommendations were made:</p> <ul style="list-style-type: none"> • no more than 0.6 mg/L fluoride anywhere in Australia for transportable water; • clear labelling in large font with concentration and absolute amount of fluoride on bulk and individual packages; • fluoride was an ‘ingredient’, but not to be included in the nutrition panel or claimed as a nutrient; • warning for infants under 12 months not to consume regularly; and • warning for dental fluorosis (for liability purposes). <p><i>FSANZ’s approach/nutritional equivalence</i></p> <ul style="list-style-type: none"> • Did not agree with FSANZ’s approach to assessment based on nutritional equivalence. Considered that fluoride is not a nutrient, and there can be no nutritional equivalence. • Considered that the results of the Australian Children’s Dental Survey¹ (2002, published Dec 2007) showed that, despite less than 5% of the population drinking fluoridated water, by age 12, Qld children had less decay in their permanent teeth than children from the ACT (100 % fluoridated) who had consumed fluoridated water for 12 years, and almost the same as Tasmania (83 % fluoridated). The survey also showed that 75.1 % of Qld children aged 5-12 years had NO decay in their permanent teeth. This was similar to other states, with Qld rating higher than Tasmania and the ACT. Looking at the amount of clinically detected untreated decay in baby teeth combined with permanent teeth shows more Qld children had NO decay than do Vic or NT children. Looking at the breakdown of children who had one, two, three, four, five or more teeth with decay showed that Qld children are average across each category. In each state, whether heavily fluoridated or not, most of the decay burden is carried by a small number of children. • Considered that there would be no difference in decay found in both baby teeth and permanent if the delay in tooth eruption caused by fluoride in fluoridated areas is correctly accounted for in the NHMRC’s Review of Water Fluoridation and Fluoride Intake from Discretionary Fluoride Supplements (1999) which stated <i>It has been suggested that fluoride exposure may delay tooth eruption and therefore studies should be designed to allow for comparisons of children who are one year younger in non-fluoridated areas than the fluoridated area.</i> Considered that these studies had not been done by the Australian Research Centre for Population Oral Health, even though it gathers all the data for Australian Children’s Dental surveys.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Considered that, after fluoride in public drinking water has been consumed for 12 years and little, if any, difference in decay is seen, it would be difficult to justify adding fluoride to packaged drinking water for a dental benefit. Provided supporting information from three Qld Dental surveys (for 2002, 2001, 2000), a paper by Jason Armfield and A John Spencer (Community Dentistry and Oral Epidemiology 2004) a Children's Survey by Brunelle and Carlos USA (1990). <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> ● Considered that a maximum claimable amount of 1.5 mg/L is totally inappropriate. Water is fluoridated in Australia from 0.6 mg/L to 1.0 mg/L with the concentration allowed tied to average ambient temperatures. ● Fluoridated packaged water, if allowed, should never have a higher fluoride concentration than the concentration of the public water supply of the area that it is sold in, thus the absolute maximum for Tasmania would be 1.0 mg/L and the absolute maximum for the NT would be 0.6 mg/L. ● Recommended that unless FSANZ mandated labelling which shows which Australian states and the latitudes and longitudes where water containing higher than 0.6 mg/L can be sold, the allowable level of fluoride is an absolute maximum of 0.6 mg/L. ● The absolute maximum concentration in packaged water should be 0.6 mg/L to align with the planned variation in fluoride concentration between 0.6 and 0.9 in public water supplies proposed by the Qld Government. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> ● Noted that in hotter climates and with certain employments people can consume 10 to 12 litres a day. Lowering the concentration from 0.9 to 0.6 mg/L would not give protection to people drinking five or more times the average consumption of water. ● Considered that the Dental Association had not provided data or references to support the claim that dental decay is increasing because of consumption of packaged water. ● Considered the acids in these reconstituted juice concentrates, carbonated drinks and sports drinks could be contributing to increased decay, rather than the lack of fluoride or the drinking of plain unadulterated water. ● Noted that silicofluorides contain lead. Concerned that epidemiological studies show that, where these silicofluorides were added to public water, children are significantly more likely to absorb lead in their environment from lead paint in old houses, lead levels in water etc ^{2,3} e.g. in Gladstone and Esperance. ● Requested health and toxicology studies be undertaken if Application is progressed. Also requested a list and concentrations of any contaminants such as lead, mercury, cadmium, arsenic present in the chemicals intended for use. ● Noted there were limited data available on dental fluorosis in Australia. However, results from small studies in WA and SA showed that nearly 50 % of children in SA had dental fluorosis which led to the introduction of a children's toothpaste with half the quantity of fluoride of adult toothpaste to try and reduce the amount of fluoride ingested by children. Additionally, infant formula manufacturers reduced the amount of fluoride in powdered formula to reduce children's exposure to fluoride.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Concerned with the York University Review 2000 which estimated that 41% of people would have dental fluorosis at a concentration of 0.7 mg/L fluoride in drinking water. Also noted a letter in 2004 from Professor Trevor Sheldon, Chair of the York Review, which suggested that findings of the Review were misused by the British Fluoridation Society and the British Medical and Dental Associations e.g. that the review did not find water fluoridation to be safe and that the level of fluorosis was significant and <i>not just cosmetic</i>. ● Noted that no total fluoride intake studies have been done in Australia. Thus, it would be difficult to show that there is a low or significantly decreasing intake of fluoride. ● Considered that the population's exposure to fluoride to was believed to be steadily increasing. Many drugs, particularly anti-depressants were fluoridated and many agricultural chemicals contain fluoride, which could end up in foodstuffs. ● Advised that the Australian Pesticides and Veterinary Medicines Authority (APVMA) was considering an application by DOW AGROSCIENCES to be allowed to fumigate food handling and food storage facilities with the gas Sulfuryl Fluoride. APVMA was considering allowing foods such as whole nuts to contain fluoride residues of 30 ppm or 30 times what is allowable in water fluoridated at 1.0 ppm. If Sulfuryl Fluoride was approved a considerable amount of fluoride could end up in the food supply. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> ● Suggested that the incidence of tooth decay was more a function of socio-economic circumstance than any other factor and noted children from poorer areas usually had higher incidence of tooth decay. Considered that packaged water, was not commonly consumed by poorer children due to cost, and would be of no benefit to poorer children. ● Noted that since November 2006, the American Dental Association and the Centre for Disease Control and Prevention (CDC) had recommended that infants under the age of 12 months not consume fluoridated water. Based on the (US) 2006 National Research Council Report 'Fluoride in Drinking Water' which found that babies drinking optimally fluoridated water would be overdosed, getting 3 to 4 times the dose of adults. Only one adverse outcome was looked at, that of developing dental fluorosis, yet if a baby is overdosed there would be other systemic effects. ● Health conscious parents may choose to use only packaged water when reconstituting infant formula, not realising that the infant could be placed at risk unless there sizable warnings in labelling. ● Concern regarding potential harm from fluoride for people with various medical conditions including osteosarcoma (in boys), thyroid problems, kidney impairment, chemical sensitivities/allergies and osteoporosis. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> ● Considered, for the ABC to make claims as a nutrient, it must provide proof in the way of animal and or human studies that show a fluoride deficiency state did exist, and additionally, that fluoride is essential and vital for good oral health. It is believed that there are no such studies in existence. ● Recommended labelling of bulk and individual containers as 'FLUORIDATED (SPRING / MINERAL) WATER' with the concentration of fluoride and in the case of small individual containers, the amount of fluoride in each bottle. Additionally, labelling should state which chemical has been added, Sodium Fluoride or Sodium Fluorosilicate.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Recommended a warning statement for infants under 12 months as per the CDC advisory ‘Not recommended for regular consumption by infants under 12 months old’ and ‘May cause dental fluorosis’. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> ● Concerned with the source, purity or level of contaminants included in the sodium fluoride and sodium silicofluoride to be added to packaged water. Concerned that, as in water fluoridation schemes, industrial waste products of aluminium smelting or phosphate fertiliser manufacture would be intended for use in packaged water. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> ● Noted that soft drink consumption has fallen slightly in recent years and considered that consumption of packaged water in place of soft drink could provide a benefit to dental health. If this is the case, the claim that unfluoridated packaged water consumption is leading to increased tooth decay would seem hard to justify. ● Based on ABC consumption data, considered the claim that the small average volume of packaged water consumed per person is responsible for increasing tooth decay appears far-fetched. ● Recommended that an independently conducted consumer survey be undertaken to determine the proportion of people who would buy packaged water with fluoride before allowing this Application to progress. ● Considered that fluoridating packaged water to give people a choice of having fluoridated packaged water in addition to fluoridated tap water seems poor justification for approval of the application. Also considered that people who desire fluoride have plenty of choice already, with most public water supplies fluoridated artificially, and choices of fluoridated toothpastes, mouthwashes, tablets and drops. Noted the Dental Association advice, that the public can fluoridate their own water with fluoride tablets or fluoride drops available from chemists. <p><i>Enforcement</i></p> <ul style="list-style-type: none"> ● Recommended that packaged water undergo the same testing procedures as fluoridated water and the results of testing made available to the public. <p><i>Other issues</i></p> <ul style="list-style-type: none"> ● Recommended that staff involved in the transport, handling or use of fluoride chemicals undertake training similar to staff involved in water fluoridation. ● Noted the ecological cost of encouraging increased consumption of packaged water. ● Questioned if there is another agenda e.g. claiming carbon credits if waste product (fluoride) is disposed of to offset the ecological cost and carbon cost of plastic bottles. ● It would be restriction of trade to not allow free sales across the Australian States. There would be no way to stop packaged water manufacturers transporting their product across state lines. <p><i>References</i></p> <ol style="list-style-type: none"> 1. Australian Institute of Health and Welfare Dental Statistics and Research Unit: Armfield JM, Slade GD & Spencer AJ 2007. Water fluoridation and children’s dental health: The Child Dental Health Survey, Australia 2002. Cat. no. DEN 170. Dental statistics and research series no. 36. Canberra: Australian Institute of Health and Welfare. 2. Masters et al, (2000) Neurotoxicology 23:101

SUBMITTER	SUBMISSION COMMENTS
	3. Int. J. Env. Stud. (1999) 56:435.
<p>Lilian Malcolm Private Australia</p>	<p>Did not state a preferred option but appeared to support Option 1</p> <p>Based on her submission to the 1985 Federal Government’s Better Health Commission regarding fluoridation of tap water in Townsville, Qld.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> ● Considered that sodium fluoride is a lethal poison, is more hazardous to use, and has a longer effect in killing pests than Arsenic Pentoxide, Calcium Cyanide and Sodium Arsenite.Fluoride. ● Concerned with the role of fluoride as a vitamin antagonist and in inhibiting a range of enzyme functions in the body, and provided reference material supporting this concern¹. ● Concerned with the risk of cancer and other chronic diseases. ● Provided information sources linking fluoride to a range of medical conditions including, Parkinson’s Syndrome², Goitre³, and Arthritis⁴. ● Noted independent studies by Dr Lonel Rapaport, Psychiatric Institute, University of Wisconsin, on the relationship of Mongoloid births to fluoride levels in the drinking water which indicated that the number of such births was more than triple among mothers who resided in communities where the fluoride concentration in the water supply was 1.0 to 2.6 ppm (48 per 100,000) as compared to the number among those who lived where it was only 0.1 to 0.2 ppm (15 per 100,000). (These figures showed the highest degree of probability recognised by the Chi square formula used in statistical analysis)³. ● Noted that in 1968, the US FDA advised that fluoride containing tablets or drops should not be given to pregnant women. In Australia, fluorine tablets and drops are recommended in both fluoride and non-fluoride areas – Also noted that tablets and drops are recommended for expectant mothers.³ ● Reported that a number of deaths attributed to hydrofluorosis can be found in Fluoridation and Truth Decay pp. 258-262. Where people are prone to kidney ailments and unable to deal with the fluoride ingested by elimination, it can destroy the kidneys, and also poison other organs of the body. Fluoride has the same cumulative poisonous properties as lead, which once in the body cannot be eliminated. ● Noted that evidence had emerged ... showing a higher rate of hip fractures in fluoridated regions compared with unfluoridated areas reports Mark Diesendorf, professor of environmental science at Sydney’s University of Technology. ● Noted a range of symptoms of fluoride poisoning in non-lethal doses, some of which disappeared when fluoride ceases⁵. Symptoms included gastrointestinal problems, nausea, headaches, rashes, hair loss and lack of mental concentration. ● Concerned about mottling of teeth with associated damage to the organs within the body. In Qld, a dentist found widespread mottling among children attending the Proserpine Primary School. At least two of the children showed signs of chizzola maculae, which are small circular, bruise-like markings on the skin. ● Considered that a better program would be to provide free dental services to schools.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Considered that fluoridation of the Townsville water supply above suggests that fluoridation of the water supply has not reduced the number of doctors and dentists but has significantly increased the need for them. ● Advised that Dr Hallett, a leading dental researcher, found that only one out of 16 children that he examined at a Townsville school, had a healthy mouth (Townsville Bulletin 16/2/08). This was quoted in support of retaining the need for school dental services. ● Considered that there was a lack of research on fluoride poisoning, and the side effects of fluoridation. ● Also believed that there was no scientific explanation of the benefits of fluoride on teeth. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> ● Believed that it was morally wrong to forcibly medicate the whole population by the water supply. <p><i>References</i></p> <ol style="list-style-type: none"> 1. McLure F.J. A Review of Fluorine & its Physiological Effects. 2. Sullivan W.D., S.J. and Von Knobedorff A.J. <i>Broteria Serie de Ciencias Naturals</i>, Lisbon, 31 Vol 1962.1. 3. Caldwell and Zanfagna (Physicol. Review 13: pp. 243 July 1933) 4. Ibid pp.248. 5. Penthouse Magazine 1979. The compulsory poison p. 102
<p>Cathy Mifsud Private Australia</p>	<p>Did not state a preferred option but appeared to support Option 1</p> <ul style="list-style-type: none"> ● Considered that fluoride was not required by those who eat well and only drink pure water. ● Suggested adding fluoride to soft drink.
<p>Bo Ning Private New Zealand</p>	<p>Supported Option 1</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> ● If fluoridated packaged water is introduced to areas where fluoridated tap water was not available, recommended that the amount of fluoride added had to be reconsidered to a safe range, or it had to be clearly labelled to avoid infants and young children being fed purely by this water. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> ● Concerned with the risk of dental fluorosis, especially in developing teeth of infants and young children. ● Considered that fluoridation of water was not the only way to improve dental and medical health. Suggested that an explanation of the convergence of caries prevalence in fluoridated and non-fluoridated areas since the 1970s may require a re-assessment of the fluoride effect. This convergence, and the overall decline during the last decade without known additional fluoride supplementation, suggested that factors other than fluoride, such as food additives and antibiotics, may have contributed¹.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Provided information and a reference from NZ which indicated that, ‘levels of fluoride intake from foods and drinks alone as estimated by the duplicate-diet approach are much lower than previously estimated from food consumption tables or diet records. If all children in the low-fluoride areas were to take currently recommended dosages of fluoride tablets, which have been based on dietary surveys and diet records, then the total fluoride intake of some children in the low-fluoride areas would exceed that of their counterparts in the fluoridated areas.’ ● Advised that the fluoride from toothpaste contributed about a half of total fluoride intake in children aged 3 to 4 years. However, the mean fluoride intake from diet and toothpaste in the low-fluoride areas was still 30% lower than that in the fluoridated areas². <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> ● Provided information and a reference which showed that children living in a fluoridated area have significantly better oral health compared to those not in a fluoridated area. These differences were greater for Maori and Pacific children and children of low socio-economic status³. However, noted that water fluoridation contributed to increased fluoride availability in NZ teeth over the past 30 years, but this increase was compatible with exposure of the community to optimal rather than excessive levels of ingested fluoride⁴. ● Advised that practically all Norwegian children are users of fluoride tablets, fluoridated toothpaste or both and thereby have an elevated baseline intake of fluoride. Provided information on two studies in Norway which showed that uncontrolled groundwater with moderate to high fluoride content was the most important factor in the development of dental fluorosis among infants⁵ and children 5-18 years old⁶. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> ● Noted that packaged water with 1.5 mg/L fluoride will be labelled as ‘contains fluoride’ but not ‘the product is not suitable for infants and children under the age of seven years’. Considered this could mislead parents who might feed their infants or young children with this water and increase the risk of dental fluorosis. <p><i>References</i></p> <ol style="list-style-type: none"> 1. de Liefde B. The decline of caries in New Zealand over the past 40 years. [see comment]. New Zealand Dental Journal 1998;94:109-13. 2. Guha-Chowdhury N, Drummond BK, Smillie AC. Total fluoride intake in children aged 3 to 4 years--a longitudinal study. Journal of Dental Research 1996;75:1451-7. 3. Lee M, Dennison PJ, Lee M, Dennison PJ. Water fluoridation and dental caries in 5- and 12-year-old children from Canterbury and Wellington. New Zealand Dental Journal 2004;100:10-5. 4. Cutress TW, Coote GE, Shu M, Pearce EI. Fluoride content of the enamel and dentine of human premolars prior to and following the introduction of fluoridation in New Zealand. Caries Research 1996;30:204-12. 5. Bardsen A, Bjorvatn K. Risk periods in the development of dental fluorosis. Clinical Oral Investigations 1998;2:155-60. 6. Bardsen A, Klock KS, Bjorvatn K. Dental fluorosis among persons exposed to high- and low-fluoride drinking water in western Norway. Community Dentistry & Oral Epidemiology 1999;27:259-67.

SUBMITTER	SUBMISSION COMMENTS
Robina Reordan Private Australia	<p>Did not state a preferred option but appeared to support Option 1</p> <p>Has a sensitivity to fluoride that caused perioral dermatitis.</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> Recognised advantages of fluoride for children, but considered that addition of fluoride to packaged water has no advantages for adults and would aggravate her medical condition. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Considered that Australia had a ‘Nanny State’ mentality and should permit individuals to choose the type of water they want to consume.
June Shanahan Private Australia	<p>Did not state a preferred option but appeared to support Option 1</p> <p>Is allergic to fluoride and wheat. Advised that her health improved with packaged water.</p> <p>Concerned that the government is mass-medicating the community with toxic waste.</p> <p><i>Safety</i></p> <ul style="list-style-type: none"> Concerned that some in the community were allergic to fluoride in water supply. Did not agree that fluoride helps prevent tooth decay. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Considered that parents who wanted their children to have fluoride should give them a tablet.
Jennifer Sharp Private Australia	<p>Did not state a preferred option but appeared to support Option 1</p> <p><i>FSANZ Approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> Questioned whether the Ministerial Council Policy Guideline was appropriate, as ‘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 food through fortification, become like or are taken to be therapeutic goods.’ Noted the ‘General Exemptions’ in the Standards for the Uniform Scheduling of Drugs and Poisons (SUSDP) No 22, which exempt FOOD except: <ol style="list-style-type: none"> food additives before incorporation into food: or when used as a means of administering a poison for therapeutic use. Considered that the voluntary addition of fluoride to packaged water as a claimable nutrient is the adding of the S6 poison, either as sodium fluoride or sodium fluorosilicate, for therapeutic use namely dental decay prevention. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Considered that the voluntary addition of fluoride to packaged water as a claimable nutrient was the adding of the S6 poison, either sodium fluoride or sodium fluorosilicate, for therapeutic use namely dental decay prevention.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Some countries in European Union had not allowed the voluntary addition of fluoride to bottled water because it becomes a medication. • Provided information from the Cairns Fluoridation Workshop (November 2006), where Professor L. Walsh suggested that the action of fluoride is the inhibition of glycolysis in the bacteria. This meant that fluoride in water was supposed to select only the detrimental bacteria in the mouth ,but this is untrue. Advised that Prof Walsh helped develop a Mousse which faded the fluorosis produced by fluoride and need not contain fluoride. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Recommended that the total daily intake of fluoride from air, food, drugs and water should be calculated for each individual, which could only be done if all products are labelled. • Noted that under Schedule 2(b)(iv), a fluoridated dental product that was not for therapeutic use was to be labelled (A) Do not swallow; and (B) Do not use (this product /name of product) in children six years of age or less. The products in (b)(iv) should be listed in other schedule in the SUSDP for example hydrogen peroxide. <p><i>International</i></p> <ul style="list-style-type: none"> • Noted that some countries in European Union had not allowed the voluntary addition of fluoride to bottled water because it became a medication.
<p>Bill Silvester Private Australia</p>	<p>Did not state a preferred option but appeared to support Option 1</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Argued there was an abundance of evidence to show fluoride ‘did more harm than good’ and provided reference for information. • Noted the American Dental Association had advised fluoride ‘is not to be given to children under six years of age’. <p><i>References</i></p> <ul style="list-style-type: none"> • Barry Grove. (2001) Fluoride – Drinking ourselves to Death? Gill and Macmillan Ltd, West Dublin.
<p>Carol Skeggs Private Australia</p>	<p>Appeared to support Option 1 (Stated objection to Option 2)</p> <p>Daughter suffers from fluoride toxicity for last 10 years. Symptoms include fluorosis of teeth, arthritis, overgrowth of bone spurs requiring surgical removal and thyroid disruptions.</p> <p>Relies on unfluoridated packaged water for drinking and cooking.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • 1% of the population was expected to suffer adverse effects of fluoridation. 5 people living in Mackay, Qld (currently unfluoridated) suffer from fluoride toxicity with two suffering disabilities. • Considered that fluoride was a toxin used in psychiatric drugs and should not be used to mass medicate the community.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Provided WHO data (2004) on tooth decay trends in fluoridated versus unfluoridated countries. Considered that the results were insignificant. (Table attached to Submission.) ● Expressed concern regarding the lack of Australian database on fluoride content of foods and beverages in Qld. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> ● Concerned that food and drinks grown/manufactured in Qld would be contaminated with fluoride when water fluoridation went ahead. ● Advised that currently only two brands of fluoride-free packaged water available in local supermarket. ● Considered there were many forms available for those who wished to consume fluoride, but that there were few choices for those who suffer adverse reactions and wished to avoid fluoride. <p><i>Cost benefit analysis</i></p> <ul style="list-style-type: none"> ● Advised she was unable to purchase a reliable reverse osmosis water filter as rent took almost half her disability pension. ● Advised that legal action could happen in Australia as was occurring in the US.
Marilyn Vine Private Australia	<p>Appeared to support Option 1 (Stated objection to Option 2)</p> <p><i>Maximum amount of fluoride</i></p> <ul style="list-style-type: none"> ● Considered that the maximum amount of fluoride (1.5 mg/L) was far in excess of optimal levels of fluoridation recommended for specific areas of Australia (from 0.6 mg/L in Darwin to 1.0 mg/L in Sydney, Melbourne, ACT and Hobart.) <p><i>pH of packaged water</i></p> <ul style="list-style-type: none"> ● Expressed concern that packaged water may be acidic when tap water must be alkaline. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> ● Considered Australia had tried to brush under the carpet the ADA warning on using fluoride to make up bottled formulas for babies by saying that our formulas were in fact fluoride free. This was not the issue at all – it was the fluoride in the water that is the issue not the formula. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> ● Considered that fluoride was not a nutrient and should be shown as an additive and in fact as a poisonous additive (sodium fluorosilicate DEFINITELY MUST BE SHOWN AS A POISON as this product was a Class 7 poison and a number 8 Corrosive). <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> ● Bottled water was sometimes the only means that people who did not wish to be fluoridated had to obtain water.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Other issues</i></p> <ul style="list-style-type: none"> Expressed concern that this Application was to protect packaged water manufacturers who were using tap water and who wished to avoid the cost involved in removing fluoride from the water supply.
<p>Kazaf Wan Private New Zealand</p>	<p>Supported Option 2</p> <p><i>FSANZ approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> Suggested the assessment should be based on ‘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’ rather than on nutritional equivalence. Questioned the term ‘nutritional equivalence’ as being quite vague. Believed that ‘nutritional equivalence’ involved other nutritional components, while in this application only fluoride is considered. No matter whether fluoridated packaged water was ‘nutritionally equivalent’, packaged water was already partially replacing tap water^{1,2}. Argued that the problem lay with whether packaged water caused low level of fluoride intake and thus whether fortification of fluoride was justified, and therefore can be assessed by the suggested approach. Noted preliminary evidence from one study³ which suggested that drinking non-public water (including bottled water) resulted in a higher level of deciduous caries in young children in Australia. Believed that more evidence would justify fluoride fortification of packaged water. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Believed that regulations needed to be set to avoid marketers making an unsubstantiated claim of the fluoride content so as to differentiate their fluoridated products by misleading customers. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Provided reference to data from a global leading market database which supports the dramatic increase in consumption of packaged water. Packaged water was perceived as healthy, and with the ongoing focus on health, the consumption of packaged water was forecasted to increase further in the next five years in Australia and NZ^{1,2}. Noted that concentrations of fluoride in packaged water were proven to be low (other countries data)^{4,5}. Considered that the public is more likely to have inadequate intake of fluoride and that providing fluoride in packaged water which is likely to be a dominant non-alcoholic beverage in the future is valid measure to prevent future dental problems. Given the existing good perceptions of packaged water in consumers’ minds^{1,2,4,5} fluoridated water may be perceived as nutritionally superior to tap water due to an extra functional claimable ingredient. If Application was permitted, government may bear the cost to educate and inform the public about the fluoride content of packaged water so as to help them interpret the claim. <p><i>References</i></p> <ol style="list-style-type: none"> Euromonitor International. Country sector briefing: Bottled water – Australia. 2008; 10p. Euromonitor International. Country sector briefing: Bottled water – New Zealand. 2008; 9p.

SUBMITTER	SUBMISSION COMMENTS
	<p>3. Armfield JM, Spencer AJ. Consumption of nonpublic water: implications for children's caries experience. <i>Community Dental Oral Epidemiology</i> 2004; 32: 283-296.</p> <p>4. Johnson SA, DeBiase C. Concentration levels of fluoride in bottled drinking water. <i>The Journal of Dental Hygiene</i> 2003; 77: 161-167.</p> <p>5. Zohouri FV, Maguire A, Moynihan PJ. Fluoride content of still bottled waters available in the North-East of England, UK. <i>British Dental Journal</i> 2003; 195: 515-518.</p>
<p>Wyong Shire Ratepayers and Residents Association Inc Sylvia Turner Australia</p>	<p>Supported Option 1</p> <p>Supported comments made by the Australian Fluoridation Information Network.</p> <p>Expressed concern about the lack of democracy related to mandatory water fluoridation.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Noted that modern studies by several eminent researchers strongly suggested that fluoride worked primarily by topical means through direct action on the surface of the teeth via toothpaste, or gels used in dental treatments CDC 1999¹. • Provided information sources of fluoride in the food chain. ²⁻⁵. • Considered that forty years of fluoridation in Sydney had not been panacea for dental decay that was promoted and cited two media articles which reported that Sydney had higher rates of dental decay than other unfluoridated country regions • Noted that Health Canada, the US Food & Drug Administration and the US Environmental Protection Agency had not been able to find any chronic toxicological studies to demonstrate safety of the actual products used to add to water supplies for claimed dental benefits – after more than 60 years of artificial water fluoridation. • Also noted that the US National Review Council Toxicological review of Fluoride in Drinking Water (2006) – substantiated the harmfulness of fluoride at very low levels; such as those found in water fluoridated at the recommended ‘optimal’ level of 1 part per million⁶. • Provided links to summaries of emerging new evidence for potential serious harm from long-term fluoride ingestion ^{7,8}. • Considered that the findings of the NRC 2006 Review were not taken into account in the NHMRC Review into the efficacy and safety of fluoridation. Noted that the NRC Report cited a wide range of health problems, with bones and teeth being the foremost but not sole targets of concern. NRC 2006 noted a growing body of scientific research linking fluoride exposure to disruption of the nervous and endocrine systems, including the brain, thyroid and pineal gland. According to data presented in the NRC report, the doses of fluoride associated with thyroid disturbances were now exceeded by many Americans, particularly children, living in so-called ‘low fluoride’ (1 ppm) areas ⁶. • Noted that UNICEF reported Australia as being among the worst in the world for dental fluorosis. A warning about dental fluorosis through fluoridation exposure was also noted in the NHMRC Review 1999⁹. • Noted the European Court of Justice in 2005 ruled that ‘all ingestible substances are either foods or medicines, when fluoride – in ANY form – is added to water with the intent to medicate then that water becomes a medicine, and must comply with regulations relating to the regulation, licensing, sale and administration of medicines.’

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> ● Expressed concern regarding Studies on the Harmful Side-Effects of Water Treated with Silicofluorides by Prof. Roger Masters Dept. of Government, Dartmouth College which warned of the uptake of lead into the blood and its effects on children behaviour from the use of silicofluorides in water¹⁰. ● Reiterated concern regarding <i>The Sunday Telegraph</i> article on 27/04/8 ‘Cancer Explosion’ which referred to the increase in thyroid cancer. Suggested FSANZ consider the links to fluoride and thyroid dysfunction as raised in the NRC Review 2006. Provided information from a 2006 study by Bassin et al which appeared to link fluoride with osteosarcoma (bone cancer) in boys and young men. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> ● Noted recent American Dental Association (ADA) advice regarding use of ‘low or no fluoride’ for infant formula reconstitution for infants under one year. ‘<i>Interim Guidance on Reconstituted Formula</i>’¹¹. This ADA guidance was issued as a result of ‘recent developments’ that included: <ul style="list-style-type: none"> ● The release of NRC 2006, which raised the possibility that infants could receive too much fluoride from reconstituted infant formula⁶. ● The US Food and Drug Administration’s permission to allow bottlers to claim that fluoridated water could reduce the risk of dental decay, but the claim could not be used on water marketed for infants. ● Noted that fluoridators countered the ADA Interim Guidance with claims that it only referred to the US because it had a higher fluoride content in infant formula. However, considered this to be incorrect and provided information which suggested that <i>The issue isn't the infant formula itself, but the water it's reconstituted with..</i>¹². <p><i>Reference value for fluoride</i></p> <ul style="list-style-type: none"> ● Considered that fluoride was not an essential element and provided references and private material supporting this view¹³⁻¹⁵. ● Noted that the Adequate Intakes for fluoride for all age groups were endorsed by the National Health and Medical Research Council (NHMRC) on 9/9/2005, prior to the release of NRC 2006 by the National Academy of Sciences. (NRC 2006 consists of hundreds of pages of findings by a 12 member scientific panel that reviewed, over a 39 month period, <i>The Toxicological Risks of Fluoridated Water</i>⁶. ● Considered that in the <i>Nutrient Reference Values for Australia and New Zealand – Executive summary</i> it is obvious that Adequate Intakes (AIs) of fluoride for all age groups, except for infants 0-6 months, were based solely on data relating fluoride intake to dental caries status. It appeared that NHMRC did not give consideration to any health issue whatsoever related to any other part of the body¹⁶. ● The exception to NHMRC basing AIs on data relating fluoride intake to dental caries status can be noted in the above-mentioned NRV document - Executive Summary's wording i.e. <i>Adequate Intakes (AIs) only are set for infants aged 0-6 months based on the content of breast milk in healthy mothers assuming a breast milk volume of 780 ml/day and rounding where appropriate (reference body weight 7 kg).</i>¹⁶ ● NB: NHMRC’s AI for 0-6 months’ infants is 0.01 mg/F/day. Therefore, if infants 0-6 months were to ingest 780 mL per day of infant formula reconstituted with water fluoridated at 1 ppm, they would receive 0.78 mg of fluoride daily from formula alone, which is 78 times greater than NHMRC’s AI of 0.01 mg/F/day. Further, 0.78 mg/F/day would be 0.08 mg higher than the NHMRC-endorsed Upper Level Intake (UI) for 0-6 months’ infants of 0.70, without taking into account fluoride sourced from food. (1 litre of water fluoridated at 1 ppm contains 1 mg of fluoride)¹⁶.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling</i></p> <ul style="list-style-type: none"> • Considered that, due to the accumulation of fluoride in our environment and the use of water in food products, labelling on all food products should disclose whether they had been formulated with fluoridated water or if water from fluoridated sources has been added; where the fluoride was sourced and the levels of contaminants present in that water. Recommended placing a requirement on Australian Water Bottlers to include ALL ingredients in bottled water and where their water was sourced. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Expressed concern that parents who relied on packaged water without fluoride to reconstitute infant formula and other baby foods, and those whose immune systems are impaired, would have their choice of pure water severely reduced, risking their health and well-being. <p><i>References</i></p> <ol style="list-style-type: none"> 1. Centers for Disease Control {CDC} 1999 and 2001 See www.slweb.org/bibliography.html see: XIII, 'topical versus systemic effects' 2. 'US Department of Agriculture National Fluoride Data Base of Selected Beverages and Foods' (This lists fluoride content of foods (published October 2004 before high fluoride residues {up to 900 ppm} from the gas fumigant Sulfuryl Fluoride would have been on foodstuffs). See http://www.nal.usda.gov/fnic/foodcomp/Data/Fluoride/fluoride.pdf 3. See 'Fluoride sources'. See http://www.fluoridealert.org/f-sources.htm 4. 'Fluoride residue tolerances approved for food by US EPA as of July 15, 2005' See http://www.fluoridealert.org/pesticides/fluoride.tols.july.2005.html 5. See http://www.fluoridealert.org/press/epa-sf.htm (The US EPA approved fluoride residue levels on food that are five times higher for infants than adults) 6. National Research Council (2006) 'Fluoride in Drinking Water: A Scientific Review of EPA's 7. See www.fluoridealert.org/limeback.htm 8. See www.fluoridealert.org/50-reasons.htm 9. UNICEF (2001) 'Fluoride in water: an overview'. See http://www.unicef.org/wes/fluoride.pdf 10. See http://www.dartmouth.edu/~rmasters/AHABS 11. See http://www.ada.org/prof/resources/pubs/epubs/egram/egram_061109.pdf 12. Young A. (2007) 'Center for Disease Control, dental group warn of too much fluoride for babies' Atlanta Journal Constitution, February 7, 2007. 13. National Academy of Sciences. (1989). Recommended Dietary Allowances: 10th Edition. Commission on Life Sciences, National Research Council, National Academy Press. p. 235. 14. National Research Council (1993). Health Effects of Ingested Fluoride. National Academy Press, Washington DC. p. 30. 15. Alberts B, Shine K. (1998). Letter from Bruce Alberts, President, National Academy of Sciences, and Kenneth Shine, President, Institute of Medicine to Dr Albert Burgstahler. November 18, 1998. 16. NHMRC and NZ MoH (2006) <i>Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes</i>. Canberra, ACT.

SUBMITTER	SUBMISSION COMMENTS
Industry	
<p>Australian Food and Grocery Council</p> <p>Kim Leighton</p> <p>Australia</p>	<p>Supported Option 2</p> <p>Represents Australia’s packaged food, drink and grocery products industry.</p> <p><i>FSANZ’s approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> • Supported the Ministerial Council Policy Position that permits fortification of foods with vitamins or minerals where there was a need for increasing the intake of a vitamin or mineral in one or more population groups due to a demonstrated deficiency, and that the intended fortification has the potential to address the deficit or deliver the benefit. • Considered that the application meets FSANZ’s objectives and the Policy Guideline’s principles for voluntary fortification in that it addresses a public health need for access to fluoridated drinking water in some Australian communities which is not otherwise available, and that the voluntary fortification of packaged water provides industry opportunity to deliver the benefits of reduced dental caries and provide consumer choice. • Expressed concern with the statement ‘FSANZ considers fluoride deficiency at a population level is unlikely due to the prevalence of fluoridated tap water in Australia and NZ.’, given that a large section of the Australian population in Qld did not have access to a fluoridated water supply. The evidence presented demonstrates that there is an increase in the prevalence of dental caries in children, and irrespective of whether this is due to increase use of non-reticulated sources of drinking water, there was a clear public health need to increase the opportunity for consumers to access fluoridated water. • Considered that fluoride added to packaged water IS nutritionally equivalent to fluoride added to the reticulated water supply. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Noted that some consumers had concerns over drinking tap water because it had added fluoride and considered that clearly labelling packaged water as ‘Mineral water with added fluoride’ or ‘Fluoridated Spring Water’ was essential these consumers to ensure consumer choice is preserved. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> • Considered that fluoride added to packaged water would be added with a high level of precision and under quality control, whereas the fluoride added to the tap water was affected by the reticulated system with highly variable amounts of fluoride reaching consumers depending on how far the water has travelled and the type and age of reticulation pipe that the water passes through. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered that the increase in purchases of household water purifiers and use of bulk water coolers in offices and homes demonstrated that consumers currently had concerns with the reticulated water supply and may wish to have the choice of purchasing fluoridated packaged water. • Consider it is unlikely that there would be any significant shift away from the use of reticulated water supplies in the event that permission for voluntary addition of fluoride to packaged water was permitted. The most likely result would be a change within category for those consumers currently using packaged water.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Benefit cost analysis</i></p> <ul style="list-style-type: none"> • Considered that, if voluntary fortification of packaged water was permitted, industry would incur costs for installing equipment to manage the fluoridation process, and the development of quality control processes. Additional costs would be incurred in labelling and including a declaration of the fluoride content in the nutrition information panel. However, such costs were not considered relevant to a benefit cost analysis. • If a requirement to quantify the level of fluoride in all packaged water was introduced, or to label packaged water as ‘no added fluoride’, this would add significant costs and disadvantage manufacturers who did not wish to produce packaged water with added fluoride. • In contrast, if there was a degree of consumer confusion, or an opportunity for manufacturers to capitalise on an ‘all natural’ product, the additional costs of labelling and analysis would be done in conjunction with normal labelling changes and in product innovation and development. • Noted that would be no significant additional costs to enforcement agencies for the monitoring of fluoridated packaged water as they were already responsible for the administration, surveillance and enforcement of the requirements of Standard 2.6.2 which prescribed a maximum limit of fluoride that may be present in mineral water. There may even be less cost for enforcement agencies since they would be able to assess the quality control records of the packaging plant and determine whether there are adequate processing controls rather than relying on end product testing. Similarly, there were no significant additional costs on assessing the relevance of the nutritional content statement, since the declaration of the packaged water that has added fluoride can be verified against product records.
<p>Food Technology Association of Australia David Gill Australia</p>	<p>Supported Option 2</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • The total of 1.5mg/L fluoride present in the final ready-to-consume beverage should include the natural or base level of fluoride present prior to fortification and would depend on the source of the water.
<p>New Zealand Juice and Beverage Association John Robertson New Zealand</p>	<p>Supported Option 2</p> <p>Supported this Application as it was based on good science and meets consumer needs.</p> <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Supported the concept that science-based nutrition and health claims were highly desirable and had the potential to assist consumers in making informed decisions relating to their overall diet.
Government	
<p>Department of Health & Human Services Tasmania (DHHS) Jennifer Savenake Australia</p>	<p>Appeared to support a modified Option 2 (Maximum claimable amount of 1 mg/L)</p> <p><i>FSANZ’s approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> • Supported the progression of the application on the basis of nutritional equivalence. • Argued that if packaged water was considered a substitute for tap water, the levels of fluoride in the water should not exceed what was in tap water, where it was fluoridated.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Noted the <i>Australian Drinking Water Guidelines</i>¹ set a target level of 1.0 mg/L as the optimum fluoride concentration for caries prevention. The <i>Australian Drinking Water Guidelines</i> set 1.5 mg/L as a maximum level, (not optimal exposure) to protect against dental fluorosis amongst children. Advised that DHHS uses the <i>Australian Drinking Water Guidelines</i> in the fluoridation of water supplies in Tasmania. <p><i>Definition of 'packaged water'</i></p> <ul style="list-style-type: none"> Supported a definition of 'packaged water' for the voluntary addition of fluoride in the Code, consistent with Codex to specifically exclude: sugars (intense or artificial) sweeteners, flavourings or other foodstuffs. Supported fluoridated packaged water with a pH range of 6.5-8.5 which reflected the recommended range for drinking water specified by the <i>Australian Drinking Water Guidelines</i>. Recommended carbonated water was excluded from definition based on nutritional equivalence. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Advised that DHHS was aware that consumers with a high intake of packaged water for example those in hot climates, sports people or infants may be at risk of exceeding the upper level of intake for fluoride of 10.0 mg/day for adults and 0.7 mg/day for infants if the permitted level of fluoride is set at 1.5 mg/L (NHMRC 2006). <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Supported labelling of packaged water with fluoride to the same level permitted in fluoridated tap water to provide adequate information to enable consumers make an informed choice, without misleading consumers as to the nutritional quality of the water. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> Highlighted the low pH of many carbonated waters, and the impact on oral health of low pH drinks. <p><i>Reference</i></p> <p>1. National Health and Medical Research Council & Natural Resource Management Ministerial Council. 2004. <i>Australian Drinking Water Guidelines</i>. Canberra: Commonwealth of Australia.</p>
<p>Department of Health Western Australia (DOHWA) Sophe Williamson Australia</p>	<p>Supported Option 2</p> <p><i>FSANZ's approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> Concurred with FSANZ's approach to an assessment based on nutritional equivalence. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Noted Std 2.9.1 recommended that infant formula powder containing more than 17 µg F/100 kJ include a warning about dental fluorosis on the label. It was assumed that this condition was put in place based on the use of fluoridated tap water, which had a normal concentration of between 0.5-1.0 mg/L (in WA).

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • If packaged water manufacturers fluoridated water between 1.0-1.5 mg/L, then the infant formula standard may need to be reviewed. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted that where communities were provided with water that has nitrate levels above 50 mg/L but below 100 mg/L, water suppliers were required to provide packaged water to mothers of bottle fed infants up to three months of age. • Advised that should fluoridation of packaged water occur, DOH may direct that unfluoridated packaged water also be made available. <p><i>Labelling</i></p> <ul style="list-style-type: none"> • Suggested labelling requirements would require review to determine if the reconstitution of infant formula with packaged water containing more than 1 mg/L and up to 1.5 mg/L fluoride would exceed the suggested threshold for fluorosis avoidance. In the instances where the fluorosis avoidance threshold was exceeded, warnings should be printed on the labels of the infant formula and/or the packaged water. • Stated that consumers needed to be able to make an informed choice in regard to food purchases by being provided with appropriate information on the label. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Reported findings from public consultation conducted by DOHWA which had shown that some members of the public hold strong views both for and against fluoridation of water. Noted however the majority appeared to be ambivalent. <p><i>Benefit cost analysis</i></p> <ul style="list-style-type: none"> • Noted sodium fluoride and sodium fluorosilicate were considered hazardous material. Transportation, handling and storage of fluoride would incur additional cost to the Applicant. • Suggested increased costs were likely if regulators were required to increase monitoring. <p><i>Enforcement</i></p> <ul style="list-style-type: none"> • Noted stringent monitoring and competency assessment by enforcement agencies. • Stated that ABC would have to set up a continuous quality assurance system to ensure that overdosing did not occur. Recommended that any water quality monitoring system and maintenance program must be in accordance with appropriate guidelines and auditing procedures. Suggested Chapter 8 of the <i>Australian Drinking Water Guidelines</i> should be applied. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Expressed concern about the possible health ramifications associated with the handling of sodium fluoride or sodium fluorosilicate. Considered that industry practices must implement adequate measures to ensure that these substances are handled with caution.
<p>Department of Human Services Victoria (DHS)</p> <p>Fiona Jones</p> <p>Australia</p>	<p>Supported Modified Option 2 (Maximum claimable range of 0.6-1.1 mg/L fluoride)</p> <p><i>FSANZ's approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> • Noted the condition to permit the addition of fluoride to packaged water for nutritional equivalence was met in areas with fluoridated tap water.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • For those areas without access to fluoridated tap water, the Policy Guideline conditions on permitting the addition of a mineral where an increase in intake was associated with a health benefit and where low levels of intake occurred, applied. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Did not support the proposed maximum claimable amount of 1.5 mg/L for fluoride added to packaged water. Noted that the NHMRC reviewed the efficacy and safety of fluoridation and recommended that, ‘water should 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.’⁷¹ Currently no Australian state or Territory fluoridated water above 1 mg/L. Similarly, the <i>Drinking Water Standards</i> for NZ recommended a fluoride level of 0.7-1 mg/L. Stated that it was not clear why a level of 1.5 mg/L had been chosen over these recommendations. • Noted that the <i>Australian Drinking Water Guidelines</i> specify a maximum permissible level of 1.5 mg/L for naturally-occurring fluoride in water. This did not represent the optimal level of fluoridation for obtaining a health benefit. Where fluoride was added for the purpose of reducing dental caries, it should be added up to a total (added and naturally-occurring) level consistent with the NHMRC recommended range of 0.6-1.1 mg/L. This was the level that was deemed optimal to achieve the desired health benefit, whilst minimising adverse effects. This would ensure packaged water was nutritionally equivalent to fluoridated tap water. <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> • Noted it was unclear whether flavoured mineral waters would qualify for added fluoride under the proposed changes. • Did not consider flavoured, sweetened (natural or artificial) mineral waters or carbonated waters to be nutritionally equivalent to plain, still water and did not support their inclusion in the permissions. In addition to the lack of nutritional equivalence, both carbonated and flavoured beverages were known to contribute to dental caries development. Permitting the addition of fluoride (to protect against dental caries) to beverages that contribute to dental caries had the potential to provide misleading and conflicting messages to consumers. • Recommended that the permission to add fluoride to packaged water should specify still, unflavoured, unsweetened water only. • Suggested a pH of 6.5-8.5 as specified in the <i>Australian Drinking Water Guidelines</i>. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Suggested it would be useful to know if the majority of packaged water manufacturers were State/Territory-based or national, and whether fluoridation levels in packaged water would be aligned with the State levels of fluoridated tap water. If not, the dietary assessment should consider the impact of fluoride intake if fluoride levels in packaged water were higher than local tap water. The dietary assessment should also consider whether water naturally fluoridated above 1.1 mg/L existed and was routinely consumed. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered that given the majority of Vic had access to fluoridated tap water, the addition of fluoride to packaged water was unlikely to greatly increase fluoride consumption in this State, assuming that packaged water was fluoridated at the same level as tap water (i.e. 1 mg/L) and that only still, unflavoured water was fluoridated.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Cautioned that fluoridating above this level may result in some populations (predominantly infants and young children) routinely exceeding the Upper Level indicated for moderate fluorosis. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Advised that DHS did not have information on consumer attitudes to fluoridated packaged water. Noted that should fluoride be permitted to be added to carbonated and flavoured waters, then there was the potential for consumers to be misled. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> • Noted that ABC had advised that manufacturers of packaged water implement good manufacturing practices and that regular quality control activities and auditing assured the final product. Proposed that it be specified that the quality control guidelines, testing procedures and audits should be consistent with those used for fluoridating tap water. <p><i>Monitoring</i></p> <ul style="list-style-type: none"> • FSANZ should also discuss any monitoring that was being conducted on levels of fluorosis in the community to determine whether excessive intake of fluoride is an issue. <p><i>Reference</i></p> <ol style="list-style-type: none"> 1. NHMRC review of Efficacy and Safety of Fluoridation (2007)
<p>NSW Food Authority</p> <p>Bill Porter</p> <p>Australia</p>	<p>Supported Modified Option 2 (Maximum absolute permitted amount of 1 mg/L fluoride)</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Recommended the concentration of fluoride in packaged water not exceed 1.0 mg/L in order to protect against dental fluorosis. Noted this was consistent with the target dose for fluoridation of public water supplies in most states and territories. • Suggested an absolute maximum level rather than a maximum permitted claim, which would otherwise allow for imprecise addition and potential for higher levels to be present. • Noted the current maximum level for naturally-occurring fluoride at 2.0 mg/L in packaged water in standard 2.6.2. • Noted the <i>Guidelines on Use of Fluorides in Australia</i> recommended packaged water containing approximately 1.0 mg/L fluoride. <p><i>Definition of 'packaged water'</i></p> <ul style="list-style-type: none"> • Supported a definition of 'packaged water' for the voluntary addition of fluoride in the Code, consistent with Codex to specifically exclude: sugars, flavourings food acids or other foodstuffs. • Noted any permission should be restricted to water only. • Did not support the addition of fluoride to carbonated packaged water. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Requested particular attention is given to bulk water packages for water coolers or dispensers in offices and public areas where minimum labelling requirements may be insufficient to advise consumers under normal conditions of use.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> Noted the US Food and Drug Administration had allowed fluoridation of packaged water since 2006 to assist in the prevention of dental caries (cavities). Furthermore, packaged water containing between 0.6 and 1.0 mg/L total fluoride was eligible to bear the claim: ‘Drinking fluoridated water may reduce the risk of (dental caries or tooth decay)’. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> Highlighted concerns with the impact of added carbon dioxide on the pH of water, the impact on oral health of low pH drinks and the availability of fluoride.
<p>New Zealand Food Safety Authority (NZFSA)</p> <p>Carole Inkster</p> <p>New Zealand</p>	<p>Supported Modified Option 2 (Maximum claimable range of 0.7-1.0 mg/L fluoride)</p> <p><i>FSANZ’s approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> Agreed that nutritional equivalence was used as the basis for the assessment of the Application. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> Believed the limit should be equivalent to, and no greater than, the optimal level in fluoridated water (0.7-1.0 mg/L) given it would be available across all areas and should be equivalent to what can be obtained by using fluoridated tap water. Suggested this concentration should also be consistent with FSANZ’s nutritional equivalence approach. Acknowledged the requested maximum claimable amount is consistent with the maximum acceptable amount for fluoride in <i>The Drinking-water Standards for New Zealand 2005</i> (1.5 mg/L). However, believed consumers purchasing packaged drinking water with added fluoride should have access to water at the optimal level for the health benefit of reducing dental decay and minimising the potential for enamel developmental defects e.g. fluorosis. Advised that the level established in NZ was between 0.7 and 1.0 mg/L. Also noted that this level addressed the use of water for young children so that there was no potential to increase their present intake. <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> Recommended limiting the Application to still, plain, unadulterated mineral or spring water (as defined in Std 2.6.2). Recommended flavoured waters with added sugars were not permitted to add fluoride and make nutrient/health claims. Furthermore noted carbonated beverages with or without sugar may cause significant dental erosion because of the acidity. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Recognised that fluoride protects against dental caries, however highlight the World Health Organisation which reports ‘convincing’ evidence that excess fluoride is associated with enamel development defects¹. Recognised that the proposed compounds to add fluoride to water were both sodium-based and noted interest in the effect this may have on the sodium content of water and whether any significant difference to the sodium consumption would occur as a result of the Application.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Advised that any labelling should not infer that packaged water containing fluoride was superior or has any additional benefits to fluoridated tap water. • Recommended that all packaged water should be clearly labelled as to the level and whether it was added intentionally or naturally-present, to enable informed consumer choice. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Unclear whether individuals would substitute unfluoridated water with fluoridated water or further whether individuals would substitute fluoridated community water with packaged fluoridated water in the future. Highlighted that this was an important distinction when modelling exposure to dietary fluoride and considering public health and safety. • Remarked that the common public perception was that packaged water did not contain fluoride despite the fact it was naturally-occurring in some water sources or that some packaged water was sourced from fluoridated reticulated water supplies. <p><i>References</i></p> <ol style="list-style-type: none"> 1. World Health Organisation. Diet, Nutrition and the Prevention of Chronic Diseases: Report of a Joint WHO/FAO Expert Consultation. 2003;916.
<p>Queensland Health Gary Bielby Australia</p>	<p>Supported Modified Option 2 (Maximum claimable amount of 0.5 mg/L fluoride)</p> <p><i>FSANZ's approach/Nutritional equivalence</i></p> <ul style="list-style-type: none"> • Supported the voluntary addition of fluoride to packaged water. • Acknowledged 3 of the 5 specific conditions of the voluntary fortification Policy Guidelines could apply to the Application. • Supported progression of Application on basis of nutritional equivalence. • Requested consideration be given to assessing the Application on the basis of health benefit. However, understood there was paucity of evidence to show a direct correlation between fluoridated packaged water and improved dental health. <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Supported the voluntary addition of fluoride to packaged water at 0.5 mg/L. • Did not support a maximum claimable amount of 1.5 mg/L. Advised that this is more than twice the prescribed level for fluoridated water (0.6-0.7 mg/L) in most areas. • Noted that Qld allowed fluoride to be added to its public water supplies to levels governed by the average maximum air temperatures. Report there were 4 average maximum air temperature ranges listed in Qld legislation which meant public water supplies could be currently fluoridated to levels between 0.5-0.9 mg/L of fluoride. • Advised that Qld was currently reviewing fluoride levels for public water supplies. <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> • Believed the definition should be consistent with Codex specifically excluding sugars, sweeteners, flavourings or other foodstuffs.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Believed carbonated water needed to be excluded since many have a low pH which could be detrimental to oral health. Acknowledged the pH range for drinking water specified in the <i>Australian Drinking Water Guidelines</i> and supported a pH of 6.5-8.5. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Highlighted evidence noted by the NHMRC that many older infants and younger children were already ingesting 0.4-0.6 mg F/day from foods, beverages and toothpaste. Advised that this intake approached or exceeded the AI established by the NHMRC and NZ MOH for children under the age of 3 years. • Supported FSANZ's intention to conduct a restricted assessment of dietary intake including estimates of the potential for any population group to exceed the UL if fluoridated packaged water was substituted for other drinking water. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considered that if the Application proceeded, the amount of fluoride should be stated on all packaged water, irrespective of whether a health benefit is claimed to enable the public to make informed judgements about their purchases. Furthermore, a mandatory advisory statement should be displayed on labels to protect infants and young children. • Supported consideration of the impact of Proposal P293 on this Application and any specific labelling requirements for nutrition claims. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> • Recognised Std 2.6.2 allowed a maximum of 2 mg/L fluoride in packaged water which is taken to relate to naturally-occurring fluoride. Advised a consequential amendment would be required to remove any inconsistency with Std 2.6.2 of limits between naturally-occurring and added fluoride in packaged water should the permission be allowed. • Imperative that the quality of the fluoride compounds to be added to packaged water should meet appropriate specifications for identity and purity. • Suggested consideration may be given to Qld's Code of Practice for the Fluoridation of Public Water Supplies when addressing this issue. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Believed it was reasonable to assume that uptake is likely to be greater in higher socioeconomic groups, in view of the costs. Furthermore, this group was more likely to be aware of, and adopt, preventively orientated health behaviours. Suggested that as a strong inverse relationship exists between socioeconomic status and caries prevalence, it was probably that fluoridated packaged water will have only limited effect on overall caries prevalence in the population. • Advised recent research confirms that the consumption of soft drinks in Australia had increased significantly in recent years and unless packaged fluoridated water was able to be promoted to the same extent, it seemed unlikely many consumers would be aware of its availability. • Noted Australian consumers had been exposed to fluoridated drinking water for over 40 years with ample evidence of broad community acceptance of its safety and benefits. Advised there was no reason, provided the addition of fluoride to packaged water was properly regulated, that consumers would have concerns it was not essentially the same product.

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	<ul style="list-style-type: none"> • Believed there was no doubt that potential existed for consumers to be misled about the nutritional equivalence of fluoridated packaged water versus other fluoridated water sources. <p><i>Benefit cost analysis</i></p> <ul style="list-style-type: none"> • Stated it was difficult to estimate resource implications noting over time this would involve investigation work, label reviews and product testing. Also advised significant resources would be required if legal action is initiated. <p><i>Enforcement</i></p> <ul style="list-style-type: none"> • Noted as with any new category of food, the need for additional surveillance measures and possible enforcement activities.
<p>South Australian Department of Health (SADH)</p> <p>Elena Anear Australia</p>	<p>Did not state a preferred option, but appeared to support a modified Option 2 (noted that the maximum claimable amount of 1.5 mg/L fluoride exceeds the level in Australian tap water).</p> <p><i>Maximum claimable amount of fluoride</i></p> <ul style="list-style-type: none"> • Noted that the proposed maximum claimable amount of 1.5 mg/L fluoride exceeded the level of fluoride in Australian tap water. Requested more information on why the proposed level of 1.5 mg/L was higher than the target fluoride concentration for tap water. <p><i>Definition of packaged water</i></p> <ul style="list-style-type: none"> • Believed that a definition for ‘packaged water’ should be included in the Code. For the purposes of this Application, ‘packaged water’ should only include still water that did not contain sugar, flavourings or other ingredients. <p><i>Enforcement</i></p> <ul style="list-style-type: none"> • Inclusion of a definition was also important for enforcement purposes.