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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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FINAL ASSESSMENT REPORT

APPLICATION A588

VOLUNTARY ADDITION OF FLUORIDE TO PACKAGED WATER

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 (ABCL) 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 0.6-1.0 micrograms/Litre (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 water³, 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
- 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

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.

This Application was assessed on the basis of nutritional equivalence because fluoridated packaged water can be considered a substitute beverage for fluoridated reticulated water.

Risk Assessment

At Draft Assessment, FSANZ conducted a risk assessment to determine if fluoridated packaged water is nutritionally equivalent to fluoridated reticulated water. The Risk Assessment considered the information provided by the Applicant, as well as other available information from the scientific literature, scientific experts, other regulatory and government agencies, international agencies, the general community and general technical information.

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

² For the purposes of this Application, the term 'packaged water' will be used to describe water presented in packaged form including single serve (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.

Submissions to the Draft Assessment raised a number of issues that were directed at the findings of the risk assessment. The Risk Assessment has therefore been revised at Final Assessment where appropriate to reflect the issues raised by submitters.

In summary, the Risk Assessment findings at Final Assessment are as follows:

- Packaged water is nutritionally equivalent to reticulated water when both are fortified with fluoride at a level of 0.6-1.0 mg/L.
- There is a history of safe use of fluoride in reticulated water supplies, including for the forms requested by the Applicant.
- Packaged water that may have a low pH (including those with added fluoride) are likely to have a negligible effect on the potential for tooth enamel erosion due to a low buffering capacity.
- FSANZ's dietary intake assessment is based on data that includes individual, seasonal and geographic variations. All potential adverse risks from the consumption of fluoridated packaged water thus apply equally to all members of a population sub-group, including all high consumers of water including those living in hot climates.
- FSANZ estimates that a proportion of children up to 8 years could exceed the upper level (UL) of intake when fluoridated water (0.6-1.0 mg/L) from any source is consumed. However the upper level is based on moderate dental fluorosis and current prevalence data shows it is a rare condition in Australia and New Zealand. FSANZ is of the view that the exceedance is a consequence of the way that the UL was established, and so does not represent a safety concern.

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.

Risk Management

This Final Assessment Report also 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 permitted range of fluoride addition (0.6-1.0 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;
- specific compositional requirements for packaged water with added fluoride;
- mandatory labelling for food identification to inform consumers as to the presence of added fluoride to enable informed choice; and

- consequential amendments to Standard 1.3.3 and the table to Standard 2.6.2 to clarify the permissions relating to packaged water

Decision

FSANZ approves amendment of 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 1.0 mg/L (total of naturally occurring and added fluoride) and to require mandatory labelling for food identification purposes 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 Decision

FSANZ approves permitting 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 approved draft variations to the Code are provided at Attachment 1.

Consultation

FSANZ received a total of 36 submissions in response to the Draft Assessment Report during the public consultation period from 11 November 2008 to 23 December 2008. Two submissions were received from industry, six from government, five from public health organisations, and 23 from consumer organisations and individuals. In general, government, public health and industry submitters indicated support for the Application, FSANZ's Risk Assessment conclusions and the need for a review of the UL for fluoride in the future. Two submitters requested specifying pH levels for fluoridated packaged water. One jurisdiction recommended reducing the maximum fluoride concentration to take account of higher water consumption by populations living in hot climates.

All submissions from consumer groups and individual consumers opposed the addition of fluoride to packaged water, citing safety concerns with water fluoridation in general and potential adverse health impacts as a result of increasing the fluoride content of the food supply.

Several stakeholders continued to express concern regarding the risk to vulnerable groups of exceeding 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.

Issues raised by submitters in response to the Draft Assessment Report have been addressed in this Report. A summary of submissions to the Draft Assessment Report is at Attachment 2.

Implementation and Review

FSANZ will notify the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of the approved draft variations to the Code.

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

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SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Final Assessment Report, are available on the FSANZ website as indicated:

SD1 Policy Guideline Fortification of Food with Vitamins and Minerals

(<http://www.foodstandards.gov.au/standardsdevelopment/ministerialcouncilpolicyguidelines/policyguidelineonthe4132.cfm>)

SD2 Nutrition Risk Assessment Report

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

SD3 Dietary Intake Assessment Report

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

SD4 Derivation of the Upper Level for Fluoride Intake Report

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

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd⁴ (ABCL) 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 water⁵. The Application is supported by the Australasian Bottled Water Institute Inc. (ABWI)⁶.

This Final Assessment Report discusses issues, including those issues raised following public consultation, relevant to the voluntary addition of fluoride to packaged water.

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 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 2005⁷, 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.

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

⁵ 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.

⁶ Australasian Bottled Water Institute Inc. (ABWI) represents the interests of packaged water fillers and suppliers.

⁷ 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).

Examples of packaged water include:

- 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’.

At Draft Assessment, the Applicant amended their Application to seek permission to:

- voluntarily add fluoride to packaged water within a range of 0.6-1.0 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)⁸.

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 caries⁹.

⁸ NHMRC and NZMoH (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Canberra, ACT.

⁹ 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 supplies⁹. 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)¹⁰ and an Upper Level (UL)¹¹ have been set for various age groups (Table 1). The AI is used when an Estimated Average Requirement (EAR)¹² 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 1.0 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/day¹³. It was noted that this level protects against caries with no adverse health effects.

¹⁰ An Adequate Intake (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.

¹¹ The Upper Level (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.

¹² An Estimated Average Requirement (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).

¹³ 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 United States/ 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 above⁸. 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 fluorosis¹⁴ 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)¹⁵ 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 recommended¹⁶. The 2007 ADA Policy Statement¹⁷ 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 Guidelines¹⁸.

¹⁴ 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.)

¹⁵NHMRC (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.

¹⁶ 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).

¹⁷ Australian Dental Association Inc. (2007) *Policy Statement 1.2.1. Community Oral Health Promotion. Fluoride Use* available at: <http://www.ada.org.au/About/policies.aspx>.

¹⁸ 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 guidelines¹⁹ and the 2007 ADA Policy Statement¹⁷ 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 groups⁸.

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 fluoride²⁰, although how much is present 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)²¹ while water from deeper wells may have quite high fluoride concentrations (1-10 mg/L) if the rock formations are fluoride rich. In general, the naturally-occurring fluoride levels in 'drinking water' are very low (<0.1 mg/L).

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)²². This was slightly lower for households outside capital cities at 85%.

¹⁹ Australian Research Centre for Population Oral Health. (2006) The Use of Fluorides in Australia: Guidelines. *Australian Dental Journal* 51(2):195-199.

²⁰ Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks of the *Australia New Zealand Food Standards Code*

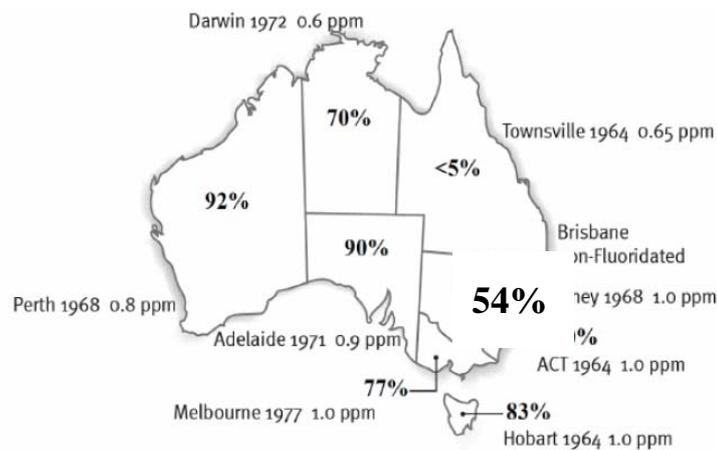
²¹ NHMRC (2004) *Australian Drinking Water Guidelines*. NHMRC Canberra ACT. Available from http://www.nhmrc.gov.au/publications/synopses/files/adwg_11_06.pdf.

²² 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.

2.2.1.1 Fluoridation in Australia

Up until December 2008, approximately 76% of Australians had access to fluoridated water supplies. Figure 1 highlights current access to fluoridated water in Australia. Since the roll out of water fluoridation in south east Queensland was commenced in 2008, 54% of Queenslanders are now receiving fluoridated water²³. By 2010, 83% of Queensland residents will have access to fluoridated water, increasing to 95% by 2012. Nominal target fluoride levels vary across Australia according to climate and local water needs but the NHMRC recommended target fluoride concentration is between 0.6 and 1.1 mg/L²⁴. 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. The *Water Fluoridation Regulation 2008*²⁵ prescribes the fluoridation concentrations for various local government areas in Queensland. These levels vary from 0.6-0.8 mg/L based on average daily maximum air temperatures using Australian Bureau of Meteorology data²⁶.



Source: Water fluoridation information for health professionals, State of Queensland, Queensland Health 2005.

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}

²³ Timeline for water fluoridation in Queensland. Available from <http://www.health.qld.gov.au/fluoride/document/timeline.pdf>

²⁴ NHMRC Public Statement *The Efficacy and Safety of Fluoridation 2007* Available from http://www.nhmrc.gov.au/media/media/rel07/_files/Fluoride_Flyer.pdf

²⁵ <http://www.legislation.qld.gov.au/LEGISLTN/SLS/2008/08SL394.pdf>

²⁶ Personal communication from G Bielby, Queensland Health, January 2009.

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

The health guideline value (i.e. maximum permitted level) for fluoride in drinking water as stated in the Australian drinking water guidelines, is 1.5 mg/L²¹. 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 2007 ADA Policy Statement states that ‘water fluoridation continues to be the most cost-effective, equitable and safe means to provide protection from dental caries and has been successfully utilised in Australia for over 50 years’¹⁷.

FSANZ has 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 Queensland Health (Figure 1).

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* (Revised 2008) includes a maximum acceptable value for fluoride of 1.5 mg/L and recommends a target fluoride range of 0.7-1.0 mg/L for oral health reasons³⁰.

Approximately 89% of the New Zealand population has access to a community water supply of which approximately 58% receive fluoridated drinking water³¹. 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 areas³².

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 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.

²⁸ Fluoridation of South-east Queensland water supplies commenced in late 2008 and approximately 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.

³⁰ Ministry of Health. *Drinking-water Standards for New Zealand 2005 (Revised 2008)*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz/moh.nsf/pagesmh/8534>

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

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

A recent analytical survey³³ of nine 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 *pH of packaged water*

The pH of water used in the manufacture of packaged water products varies according to the water source, and its composition. Industry data indicates that the pH of packaged water in Australia varies from 4.1-7.9³⁴ and from 6.5-7.5³⁵ in New Zealand. The ABWI Model Code 2005³⁶, which provides guidance on the composition of bottled water, recommends a pH range of 3.5-8.5 for these products. The guideline range for pH in reticulated water in the *Australian Drinking Water Guidelines* is 6.5-8.5²¹ and 7-8 in the *Drinking-water Guidelines for New Zealand 2005 (Revised 2008)*³⁰. These Guideline ranges are to optimise the efficacy of disinfection using chlorine, and reduce corrosion and encrustation in pipes and fittings.

2.2.4 *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.

2.2.5 *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.

2.2.6 *Fluoride supplements*

Fluoride supplements are defined by the ADA as *products that seek to achieve a similar effect on the individual as fluoridation of the water supply* and are limited to tablets and drops.

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.

³⁴ Australian Beverages Council Limited, March 2009.

³⁵ Personal communication with V Meron, Frucor Ltd, January 2009.

³⁶ ABWI Model Code is available at http://www.australianbeverages.org/lib/pdf/ABWIModelCode_Mar06.pdf

The ADA suggests supplement use in those areas not optimally fluoridated to promote a reduction in dental caries.

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 added to non-fluoridated water to mimic community water fluoridation¹⁷.

2.2.7 Sources of fluoride for infants

The concentration of fluoride in breast milk is low irrespective of whether the mother consumes fluoridated or non-fluoridated water¹⁸. Levels in breast milk are around 0.007-0.011 mg/L³⁷. Powdered infant formulas in Australia and New Zealand contain low levels of fluoride¹⁹. 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/kg³⁸. 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 formula³⁹. 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 water⁴⁰. 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.

³⁷ Institute of Medicine. (1997) *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. National Academy of Sciences, Washington.

³⁸ Silva, M. and Reynolds, E.C. (1996) Fluoride content of infant formulae in Australia. *Australian Dental Journal* 41 (1): 37-42.

³⁹ 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.

⁴⁰ 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*.

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/kg⁴¹ (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. 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’⁴². 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*⁴³. 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 and retain current labelling provisions where products with more than 1 mg/L of fluoride are labelled ‘contains fluoride’.

⁴¹ Note that mg/kg is equivalent to mg/L.

⁴² CODEX STAN 108-1981, Rev-1997, Amend.2001) is available from http://www.codexalimentarius.net/download/standards/223/CXS_108e.pdf.

⁴³ 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.

The Committee also agreed to 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’⁴⁴. 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))⁴⁵ 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’⁴⁶. Under this Standard, all packaged water must comply with the health-related requirements in the WHO *Guidelines for Drinking-water Quality*⁴³. 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. Neither Codex nor the WHO Guidelines propose a health-based guideline for the pH of water. However, the WHO Guidelines indicate an optimal pH range to balance effectiveness of chlorination and minimisation of pipe corrosion.

3.2.2 European Union

Most European countries have regulations that align with the European Union (EU) Commission Directive⁴⁷ 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 1998⁴⁸ 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*⁴³. 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 members⁴⁹.

⁴⁴ 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).

⁴⁵ CODEX Alinorm 08/31/20 Appendix II

⁴⁶ CODEX STAN 227-2001 is available from

http://www.codexalimentarius.net/download/standards/369/CXS_227e.pdf

⁴⁷ 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

⁴⁸ Available from <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1998/L/01998L0083-20031120-en.pdf>

⁴⁹ Personal communication from Mr Jean-François Roche, Administrator, Health and Consumer Protection Directorate General, European Commission.

3.2.3 *United States*

In the United States, packaged water is regulated by the US Food and Drug Administration (USFDA) in accordance with the Code of Federal Regulations⁵⁰. 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 legislation⁵¹ permits the addition of fluoride to mineral water, spring and packaged water provided that the total fluoride concentration does not exceed 1 part per million (1 mg/L). The principal display panel of the label for mineral and spring water must state that fluoride has been added and the total fluoride content. For other bottled water containing fluoride (either naturally occurring or added), bottlers must state the total fluoride content and list any added fluoride as an ingredient on the principal display panel of the label.

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. The assessment of this Application commenced in January 2009.

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 First Review request from the Ministerial Council for Proposal P293. The response to the Review request is expected to be notified to the

⁵⁰ Code of Federal Regulations (CFR165.110) Available from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?CFRPart=165>.

⁵¹ 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.

Ministerial Council in March 2010. If accepted the Standard will be gazetted mid 2010 with provision for a two year transition period.

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

There is currently no NRV for fluoride in the Code. FSANZ plans to review vitamin and mineral provisions within the Code in light of the revised NRVs for Australia and New Zealand⁸ and anticipates consulting with stakeholders 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.

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 Foundation⁵². 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.⁵³

Data from a commissioned study comprising 34,000 interviews shows that the proportions of males and females consuming plain still water 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 people⁵⁴.

However, data exists showing contrasting results. Data from the Roy Morgan Single Source database (involving surveys with approximately 50,000 people over 14 years of age per annum and follow-up self-completion surveys of 25,000 people per annum) shows a slight decrease in consumption of spring water⁵⁵ from 2007 (19.4% in Australia; 28.6% in New Zealand) to 2008 (17.6% in Australia; 26.7% in New Zealand)⁵⁶.

⁵² 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.

⁵³ ABWI website: accessible from <http://www.bottledwater.org.au/scripts/cgiip.exe/WService=ASP0003/ccms.r>

⁵⁴ 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.

⁵⁵ 'Spring water' refers to all still bottled water.

⁵⁶ Roy Morgan Research. Single Source database. Accessed February 2009.

4.1.1 Snapshot of the bottled water consumer

Tables 2 and 3 present data of spring water consumers for January-December 2007 and January-June 2008. Findings show that in the first half of 2008, 18% of Australians and 27% of New Zealanders consumed spring water in the past seven days. In general, more women consumed spring water compared to men, and the age group with the highest proportion of spring water consumers was the 18-24 year age group for Australia and New Zealand. Across the Australian states (and city Darwin), the proportion of people aged 14 years and over consuming spring water, ranged from 16% (Queensland) to 27% (Darwin). Across the regions of New Zealand, proportions of people consuming spring water ranged from 24% (Southern region and South Island total) to 29% (Northern region total). (Data on spring water consumption was not collected prior to 2007.)

Table 2: Spring water consumption across Australia, over 2007-08(weighted data)

		2007 (% population)	2008 (% population)
Total		19.4	17.6
Gender	Male	15.6	14.3
	Female	23.1	20.8
Age groups	14-17 yrs	27.5	22.9
	18-24 yrs	31.4	30.2
	25-34 yrs	25.8	24.0
	35-49 yrs	19.5	18.2
	50-64 yrs	14.6	13.2
	65+ yrs	6.9	4.6
State	NSW	19.9	18.1
	Victoria	17.0	16.9
	Queensland	19.6	16.3
	South Australia	23.5	19.0
	Western Australia	20.7	18.6
	Tasmania	18.9	16.8
	Darwin	14.7	26.7

Table 3: Spring water consumption across New Zealand, over 2007-08(weighted data)

		2007 (% population)	2008 (% population)
Total		28.6	26.7
Gender	Male	22.9	21.1
	Female	33.8	31.9
Age groups	14-17 yrs	35.2	34.4
	18-24 yrs	41.1	33.0
	25-34 yrs	34.7	32.6
	35-49 yrs	30.2	31.1
	50-64 yrs	23.4	21.0
	65+ yrs	12.0	11.0
Region	Northern region	30.9	28.9
	Central region	27.5	25.2
	North Island	29.9	27.7
	Southern	24.7	23.6
	South Island	24.7	23.6

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 occasion⁵⁷. 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 segment⁵⁸ is one of the fastest growing sectors within Australia's beverage industry with a 12% increase in revenue during 2006-2007 totalling \$AUD627 million⁵⁹. 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 2008,⁶⁰ still water constitutes 9.9% of sales for the non-alcoholic ready-to-drink (NARTD) market, up from 9.6% for the previous year.

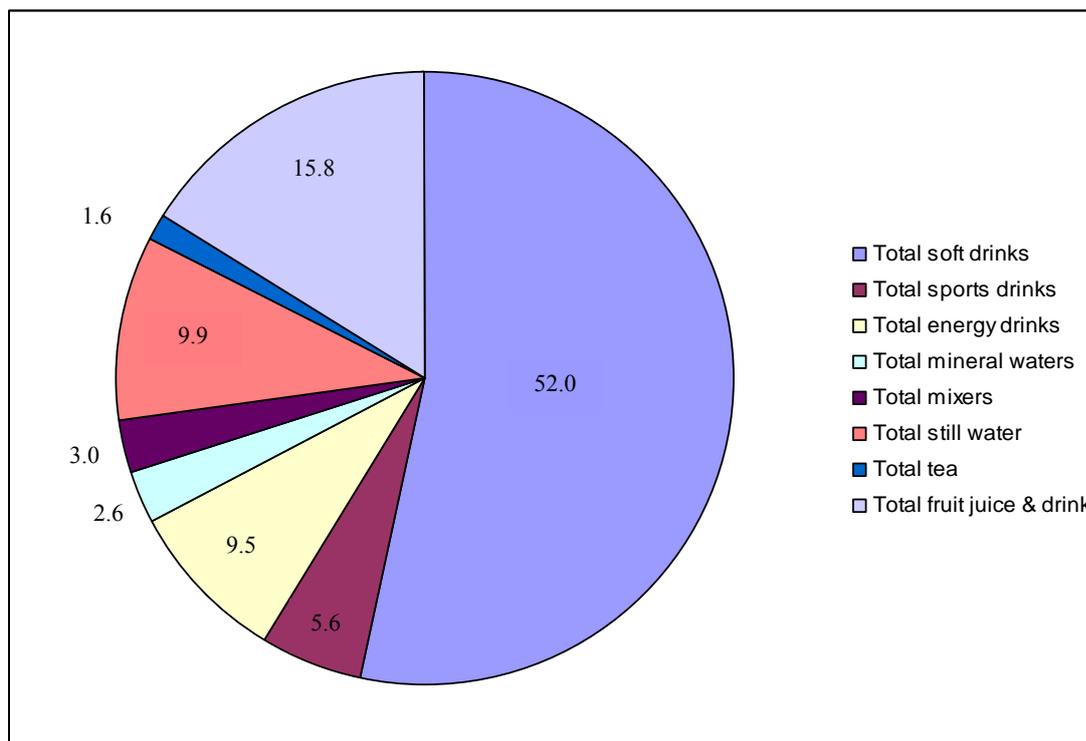
⁵⁷ Roy Morgan Research. (2008). *Bottled Water: Consumption among children aged 6-13*. Prepared for ABWI by Roy Morgan Research Pty Ltd.

⁵⁸ Includes natural spring water and purified water.

⁵⁹ 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.

⁶⁰ Australian Beverages, ABWI and Australian Fruit Juice Association (2008) Australian Beverages YearBook 2008 Melbourne, Vic.

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.



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 Tapsell⁵⁴ 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 approximately six litres per person (in 1997) to approximately 14 litres per person per year (in 2006). This data is based predominantly on supermarket sales data, but includes an estimate of food service, dining and convenience markets. However, it may be an underestimate of the total packaged water market which includes bulk water for coolers.

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 year⁶¹.

Packaged water (still water and carbonated water) generated retail sales totalling \$NZ136 million in 2007⁶². Industry data⁶³ showed that total packaged water sales increased by 9.4% in 2007, with still water sales increasing by 9% over this period.

⁶¹ Banham, S. (2008) Data sourced from Zenith International.

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.⁶⁴

Growth in the packaged water market is occurring globally. In May 2008, it was reported⁶¹ 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. This data includes water coolers and other channels⁶⁵ in addition to supermarket sales information⁶¹. The data also represents the total production of packaged water for Australia taking import and export figures into account.

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 beverage.

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 products⁶⁶.

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.

⁶² Personal communication Vincent Meron, Technical Director, Frucor Beverages Limited.

⁶⁵ Personal communication based on AC Nielsen Scan Track Data (total supermarkets and service stations to year trading), February 2008

⁶⁴ Informal figures from the ABWI provided in the Application.

⁶⁵ Includes petrol forecourts, or convenience, horeca (pubs, clubs & restaurants) and food service (delis, sandwich shops, fast food, ice cream shops, etc).

⁶⁶ Based on an assessment of current market patterns by the ABWI.

The ‘Specific Order’ Policy Principles for voluntary fortification include certain conditions for which the voluntary addition of vitamins and minerals may be permitted.

5.1 FSANZ’s Fortification Implementation Framework

FSANZ’s *Fortification Implementation Framework – Addition of Vitamins and Minerals to Food* (2005)⁶⁷ (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; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

⁶⁷ FSANZ’s *Fortification Implementation Framework - Addition of Vitamins and Minerals to Food* (2005) Available from FSANZ on request.

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

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

The specific objectives 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).*

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 Principles⁶⁸.

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.)

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

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

At Draft Assessment, FSANZ conducted a risk assessment to determine if fluoridated packaged water is nutritionally equivalent to fluoridated reticulated water. The Risk

⁶⁸ 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.

Assessment considered the information provided by the Applicant, as well as other available information from the scientific literature, scientific experts, other regulatory and government agencies, international agencies, the general community and general technical information.

The full details of the Risk Assessment are provided in Supporting Documents 2, 3 and 4.

Submissions to the Draft Assessment have raised a number of issues that were directed at the findings of the risk assessment. The following sections are a summary of the findings of the risk assessment, and where appropriate these have been revised to reflect the issues raised by submitters.

10.1 Risk Assessment issues

10.1.1 History of safe use

The Applicant is requesting permission to use sodium fluoride, sodium fluorosilicate (also called sodium silicofluoride) and hydrofluorosilicic acid (fluorosilicic acid) in bottled water. It was raised in submissions to the Draft Assessment that the safety of silicofluorides has never been tested.

FSANZ notes that silicofluorides are commonly used in fluoridating water supplies⁶⁹, for which there is a history of safe use in Australia, New Zealand and other countries for over 50 years. Further, the NHMRC has published the *Australian Drinking Water Guidelines*²¹, which give approval for the use of sodium fluoride, sodium silicofluoride, and fluorosilicic (hydrofluorosilicic acid) acid in the fluoridation of reticulated water supplies. A chemical is approved for use in the Guidelines only if it is non-toxic when ingested at the concentrations present in treated water.

An extensive number of Australian and New Zealand authoritative bodies have also evaluated the available scientific evidence and have concluded that water fluoridation is a safe and effective public health measure^{17,70,71,72}.

10.1.2 Assessment of nutritional equivalence

FSANZ has assessed the nutritional equivalence of fluoridated reticulated water and packaged water with added fluoride. As stated previously in Section 8 of this report, nutritional equivalence is a key requirement for this Application because fluoridated packaged water can be considered a substitute beverage for fluoridated reticulated water.

FSANZ has identified that there are many similarities in nutrient content between packaged water and reticulated water in Australia and New Zealand, whether fluoridated or not, with only very minor differences between some minerals (e.g. iodine, sodium, magnesium). However this is expected given the natural variation in water from different regions.

⁶⁹ NHMRC (2007) *Systematic Review of the Efficacy and Safety of Fluoridation*. Commonwealth of Australia, Canberra.

⁷⁰ NHMRC (2007) *NHMRC Public Statement. The Efficacy and Safety of Fluoridation 2007*. NHMRC.

⁷¹ Public Health Association of Australia (2006) *Oral Health Policy*.

⁷² Public Health Association of New Zealand (2003) *Water Fluoridation Policy*.

The three 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 this respect.

All three forms are highly bioavailable from the water^{73,74} and the presence of other cations (such as calcium and magnesium) do not have a significant effect on this bioavailability.

FSANZ therefore concludes that packaged water without added fluoride is nutritionally equivalent to non-fluoridated reticulated water. Should packaged water be permitted to contain fluoride between 0.6 to 1.0 mg/L, then it would be nutritionally equivalent to fluoridated reticulated water supplies in Australia and New Zealand.

For more information on the assessment of nutritional equivalence, see the Nutrition Risk Assessment Report at Supporting Document 2.

10.1.3 The health risks associated with the fluoridation of packaged water

10.1.3.1 Fluorosis

Fluorosis is a term that refers to the effects associated with excess fluoride intake. It manifests in two forms: dental and skeletal fluorosis, of which the former is more common. Dental fluorosis involves the incorporation of fluoride into the enamel of the teeth^{75,76}. The ‘very mild’ and ‘mild’ forms of dental fluorosis, although irreversible, are aesthetic in nature (making teeth stronger and whiter only) and are not considered to be a risk to population health⁷⁷. ‘Moderate’ and ‘severe’ forms of dental fluorosis are of greater clinical concern (the Upper Level is based on moderate dental fluorosis). Skeletal fluorosis is a serious medical condition, and can lead to significant bone degradation and adverse neurological manifestations.

Two submitters to the Draft Assessment were of the view that moderate to severe dental fluorosis is already occurring in New Zealand and Australia, and that FSANZ was incorrect in concluding otherwise at Draft Assessment.

However in reviewing this issue, FSANZ maintains the view that although there is evidence on the prevalence of very mild and mild fluorosis, the more severe forms of dental fluorosis are rarely seen in Australia and New Zealand. This view is based on the current Australian and New Zealand prevalence rate data for fluorosis (see Table 6 of Supporting Document 2 for more detail on the prevalence rates).

In summary, very mild and mild dental fluorosis are observed in around 10-25% of Australian and New Zealand children. The mild forms of dental fluorosis have been

⁷³ World Health Organization (2002) *Fluorides. Environmental Health Criteria 227*. World Health Organization, Geneva.

⁷⁴ Maguire, A., Zohouri, F.V., Mathers, J.C., Steen, I.N., Hindmarch, P.N. and Moynihan, P.J. (2005) Bioavailability of Fluoride in Drinking Water: a Human Experimental Study. *Journal of Dental Research* 84(11):989-993.

⁷⁵ The grading for the severity of dental fluorosis is based on Dean’s index, which identifies six grades of clinical symptoms; none, questionable, very mild, mild, moderate and severe.

⁷⁶ Dean HT (1934) Classification of mottled enamel diagnosis. *J Am Dent Assoc* 21:1421-1426

⁷⁷ 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.

associated with exposure from several sources, both individually and collectively, including fluoridated water, toothpaste, other dental products and supplement use. The prevalence of very mild and mild fluorosis is usually higher in fluoridated compared to non-fluoridated areas.

FSANZ has not identified any evidence of more severe forms of fluorosis, including skeletal fluorosis, that are attributable to water supply sources in Australia or New Zealand.

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

10.1.3.2 The acidity of fluoridated packaged water

Two submissions to the Draft Assessment Report expressed concern that the fluoridation of packaged waters may create conditions that could promote dental erosion due to the potential for an increase in acidity of the final product (a reduction in pH). FSANZ has therefore conducted an additional review of available literature to further explore the process of dental erosion, and to determine how packaged waters may/may not contribute to this process, especially packaged waters with an acidic (low pH) profile. The full details of this review are provided in Supporting Document 2, with a summary provided below.

Available scientific literature cites the acidity of beverages as an important factor in the development of dental erosion. A low pH level of less than 5.5 is widely reported within scientific literature and through public health advice as the critical pH for the relationship between beverages and dental erosion.

However, FSANZ has been unable to identify any *in vivo* studies on the relationship between packaged water and dental erosion. The epidemiological evidence showing an association between acidic beverages and the development of dental erosion is based primarily on other beverages, such as juice and carbonated soft drinks.

Due to the limitations of the *in vivo* and epidemiological evidence, FSANZ has investigated the available *in vitro* studies. From this literature search, FSANZ identified three *in vitro* studies that assess the effect of non-fluoridated packaged water on dental erosion. These studies provide support for the findings on other acidic beverages (and acidic beverages in general) that as the pH of a beverage decreases, there is an increase in dental erosion outcomes. However, the three *in vitro* studies were insufficient to determine the effect of low pH water on dental erosion, as the pH of the test waters was too high (pH \geq 5.5).

Because of the limited direct evidence on packaged water, FSANZ undertook an additional step of investigating the chemical processes involved in dental erosion. An important aspect of the chemistry is the influence of a beverage's buffering capacity on the relationship of pH to dental erosion, where beverages with a high buffering capacity have a greater erosive potential than beverages with a lower buffering capacity at a similar pH. This is due to the protective role of saliva, which contains a wide range of buffering agents that can protect against the acidic challenges of beverages with a low buffering capacity.

The influence of buffering capacity is an important consideration for this Application, as compositional data on local packaged water shows that those waters with the lowest pH (as low as 4.1) are likely to have a very low buffering capacity, and a buffering capacity that is

much lower than higher pH water. It was also noted that the addition of the proposed fluoride compounds to low pH packaged water was unlikely to introduce a significantly greater amount of buffering ions, and thus is unlikely to substantially change the existing low buffering capacity of these water.

On the basis of the above information, FSANZ considers that low pH, low buffering capacity packaged water (including those with added fluoride) are likely to have a negligible effect on the potential for tooth enamel erosion.

10.1.3.3 Other health risks

Comments were received to the Draft Assessment stating that water fluoridation is associated with the development of several pathological conditions and/or illnesses, including kidney disease, thyroid function (especially in the iodine deficient), brain disease, heart disease, neurological conditions (e.g. Alzheimer's disease, lowered IQ in children, Parkinson's disease), behavioural changes in children, goitre, kidney failure, osteoporosis and arthritis.

FSANZ previously reviewed the available literature at Draft Assessment on the association between fluoride intake and the above conditions (see Supporting Document 2 in this report). No evidence of haematological, hepatic or renal effects had been found⁷⁸. Associations between fluoridated water and other effects (Down's syndrome, mortality, dementia, goitre, IQ) were not found in a systematic review of water fluoridation by McDonagh *et al.* (2000)⁷⁹. A systematic review conducted by the NHMRC⁶⁹ also concluded that there was no evidence for the contribution of fluoride to any adverse effects other than fluorosis.

FSANZ has conducted a further review of the literature since Draft Assessment, and has not identified any new material relating to the association between fluoridation and the above-mentioned adverse conditions.

10.1.4 The nutritional role and health benefits of fluoridation

In considering the addition of fluoride to packaged water at Draft Assessment, FSANZ described the positive health outcomes associated with fluoride intakes. However, six submitters to the Draft Assessment indicated that they did not consider fluoride to be a nutrient (with respect to this classification by the NHMRC and the New Zealand Ministry of Health⁸), that it is not essential for human health, and that there is no evidence of any benefit associated with fluoride intakes.

Fluoride is naturally present in the human body, and is one of the 19 nutrients for which the NHMRC and the New Zealand Ministry of Health have developed recommended intakes⁸.

In addition, FSANZ maintains the view that there is a very large body of evidence demonstrating that an increase in fluoride intakes across the population can decrease the prevalence of dental caries. This evidence is outlined in detail at Supporting Document 2. Of particular importance are the following two reviews:

⁷⁸ World Health Organization (2002) *Fluorides. Environmental Health Criteria 227*. World Health Organisation, Geneva.

⁷⁹ McDonagh, M.S., Whiting, P.F., Wilson, P.M., Sutton, A.J., Chestnutt, I., Cooper, J., Misso, K., Bradley, M., Treasure, E. and Kleijnen, J. (2000) Systematic review of water fluoridation. *British Medical Journal* 321:855-859.

- a review on diet and chronic diseases by the World Health Organization, which has classified the strength of evidence on the relationship between increased fluoride intakes and a decreased prevalence of dental caries as ‘convincing’⁹, and
- a recent (2007) systematic review of fluoridation by the NHMRC, which concluded that the evidence strongly suggests that water fluoridation is beneficial for reducing dental caries⁶⁹.

Two submitters also commented that decreases in the rates of dental caries can be explained by changes in other aspects of the environment, such as decreases in lead pollution. However, there is sufficient information to indicate that the relationship between fluoridation and dental caries is an inverse one, and is independent of other factors⁸⁰. This relationship is best demonstrated by data which consistently show that areas with access to fluoridated water have a lower prevalence of dental caries compared to areas with non-fluoridated water (see Supporting Document 2 for more detail).

10.2 Dietary Intake Assessment

The aim of the dietary intake assessment was to make as realistic an estimate of dietary fluoride intake as possible. Where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake.

This was the first time that FSANZ had estimated fluoride intakes from the total diet for Australia and New Zealand. FSANZ combined data on food and water consumption patterns, fluoride content of foods and beverages and other relevant information to conduct the dietary intake assessment.

See Supporting Document 3 for full details of the Dietary Intake Assessment.

10.2.1 Dietary modelling approach

The Application seeks a voluntary permission to add fluoride within a specified concentration range. However, to provide dietary intake estimates that incorporate high levels of fluoride consumption, FSANZ has assumed that all packaged water and reticulated water will be fluoridated.

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 New Zealand NNS (1997). 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.

The fluoride intake estimates were calculated under three scenarios, each using a different level of fluoride in water: 0.1 mg/L (all water is non-fluoridated); 0.6 mg/L and 1.0 mg/L, (within the upper and lower bounds of fluoridated reticulated water in Australia⁷⁰ and New

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

Zealand³⁰, which is also the range requested by the Applicant). The range of actual concentrations of fluoride in Australia and New Zealand fluoridated water supplies lies between 0.6-1.0 mg/L, and therefore reflects the 'nutritional equivalence' approach used in this Assessment (see Section 10.1.2 and Supporting Document 2 for more details on nutritional equivalence).

The estimated fluoride intakes for each of the three scenarios are detailed in Supporting Document 3.

10.2.2 Dietary sources of fluoride in Australia and New Zealand

The only contributor to fluoride intakes for infants aged 0-6 months was breast milk or formula. Follow-on formula was the major contributor between the ages of 6-12 months in Australia and New Zealand, even in non-fluoridated areas.

Where water is not fluoridated the major contributors were fruit-based 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 Australians (adult population) and tea for New Zealanders aged 15+ years. If water is fluoridated then the major contributor for all population groups is drinking water (either plain or made up with cordial in the case of children or made up with coffee or tea for Australian and New Zealand adults).

10.2.3 Other sources of fluoride in Australia and New Zealand

Fluoride intake of children aged five years or less from the recommended amount of low-fluoride children's toothpaste (assumed to be 0.5 g) is likely to be around 0.1-0.3 mg/day (via swallowing). Fluoride intake would be 0.1 mg/day for children aged 6 years or more and adults (approximately 0.1 g of regular toothpaste per day is swallowed by older age groups⁸⁰).

A new pesticide containing fluoride (sulfuryl fluoride) recently approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA) has been recommended for inclusion in the Code through Proposal M1002⁸¹. A dietary exposure assessment was included in Proposal M1002. It showed that residues of sulfuryl fluoride could increase mean dietary intakes of fluoride across the population by up to 10% of the upper levels of intake. However, FSANZ considers that the recommended permissions for sulfuryl fluoride do not significantly alter the results of the dietary intake assessment for this Application, as the dietary exposure assessment for M1002 used overestimates in its calculations to ensure that a protective outcome was produced.

10.2.4 Fluoride Upper Level

FSANZ has used the current Australian and New Zealand ULs for fluoride in its dietary intake assessment⁸. As indicated previously 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.

The Australian and New Zealand ULs were based on the severity of adverse health effects associated with each level of intake for the respective population groups. These intakes were

⁸¹ FSANZ (2008) *Proposal M1002. Maximum Residue Limits (January, February, March 2008). Approval Report. 11 November 2008.* FSANZ, Canberra. A copy of the report can be obtained from <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalM1002maximum3937.cfm>

identified from the process used by the Food and Nutrition Board: Institute of Medicine (US) in 1997 to establish US/Canadian UL values.

The US/Canadian ULs were based on the following for each age group:

- for children up to 8 years of age, fluoride intakes estimated using model diets from the 1940s, and the prevalence of moderate dental fluorosis in areas with differing levels of fluoride in their drinking water supplies in the 1930s-1940s; and
- for individuals 9 years or older, the intake identified with the development of skeletal fluorosis within the USA.

It is now possible to perform a fluoride intake analysis using estimates of actual consumption from the Australian and New Zealand NNSs (1995 Australia; 1997 New Zealand), to compare the current levels of fluoride intake in Australian and New Zealand populations with the UL. FSANZ's intake assessment has shown that when baseline fluoride intakes are calculated using actual dietary data, then apparent exceedances of the UL occur for 2-3 year olds and 4-8 year olds (see Table 5 in Section 10.2.5.2). However, the apparent exceedances are considered to be the result of comparing values based on actual consumption data for children up to 8 years of age to an UL that was originally based on model data for these ages (see Supporting Document 4 for more detail on this issue).

10.2.5 Analysis of excessive fluoride intakes

The following sections detail the estimated fluoride intakes of specific population groups against the UL for fluoride. For the general population in Australia and New Zealand aged 9 years or above, FSANZ has determined that less than 1% of all population groups will exceed the UL when fluoridated water is consumed.

10.2.5.1 Infants

Model diets were used to estimate dietary intakes for infants up to 12 months (see Table 4 below). The mean intakes were derived from the 50th weight percentile for infants, and the 90th percentile intakes were then estimated based on a calculation of two times this mean intake (see Supporting Document 3 for more detail).

Table 4: Estimated dietary intakes of fluoride 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

Even though the levels of fluoride in infant formula powders have decreased following recommendations in the early 1990s, the above estimates indicate that infant formula prepared using water fluoridated between 0.6-1.0 mg/L 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.

When water is fluoridated at 0.6-1.0 mg/L, mean and 90th percentile intakes for Australian 9 month olds apparently 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 apparently exceed the UL (140-190%).

10.2.5.2 Young children

When water is fluoridated at 0.6-1.0 mg/L, between 5% and 22% of 2-3 year olds, and between <1% and 5% of 4-8 year olds may apparently exceed the UL for fluoride (see Table 5). Additional intakes from sources such as toothpaste or supplements would result in more children apparently 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).

Table 5: Estimated proportion (%) of Australian children 2 to 8 years with dietary intakes over UL for fluoride 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

10.2.6 Comments received on the Dietary Intake Assessment at Draft Assessment

10.2.6.1 Calculation of high infant fluoride intakes

A submission to the Draft Assessment suggested that it would be more appropriate to calculate mean infant fluoride intakes using the weight of 97th percentile children on WHO growth charts (because energy requirements, and therefore formula intake, are related to an infant’s weight).

Dietary intake assessments are ‘estimates’ and FSANZ agrees that the suggested approach could be used as an alternative to estimating dietary intakes. As formula requirements are dependent on an infant’s weight, there are numerous ways that infant dietary intakes can be calculated. The approach used by FSANZ to estimate high (90th) percentile infant intakes (two times the formula intake at the 50th weight percentile) has been used for previous dietary intake assessments and is an internationally accepted practice.

Therefore, the methods used to calculate the mean and 90th percentile fluoride intakes of infants have been retained at Final Assessment.

10.2.6.2 High consumers of water

Five submissions to the Draft Assessment Report mentioned that at the proposed fluoridation range of 0.6-1.0 mg/L, people who consume more water (e.g. those living and/or working in hotter climates and elite athletes) would be exposed to excessive dietary fluoride intakes. It

was also commented that the fluoride level in packaged water should be kept at or below the fluoridation requirements for the reticulated water supply in each local region, as these requirements are set at levels that match the local water consumption rates (e.g. lower levels for hotter climates).

The dietary intake assessment was based on food consumption amounts for individuals, and thus included high consumers of water. The 1995 NNS was conducted from February 1995 to March 1996 and thus included the summer season. The 1995 NNS was conducted in all parts of Australia, including the Northern Territory and Queensland, and so fluid consumption in hot climates and at hot times of the year were included as part of the fluoride intake distribution calculated by FSANZ.

The results of the dietary intake assessment are therefore applicable across the different locations within Australia and New Zealand, as local variations have been taken into account. Any risks identified for high consumers of water can be considered as applying to all of these individuals, regardless of their place of residence.

Finally, information on sweat losses that need to be replaced following exercise indicates that most elite athletes lose around one litre of fluid per hour, which needs to be replaced with 1.5 litres of fluid following exercise. Elite athletes undertaking high intensity exercise in hot conditions can lose 2-3 litres of water per hour⁸². 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 results from a daily intake exceeding 10 mg/day 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 fluoride intakes, consistently for this period of time. Therefore, it is unlikely that adverse effects will occur with this population group.

10.3 Risk Characterisation

The Dietary Intake Assessment for Australian children up to 8 years indicated that a significant proportion of those children may exceed the existing UL for fluoride at higher levels of fluoride (up to 1 mg/L). Therefore, FSANZ has considered these results in the context of the adverse health effects associated with exceeding the UL and evidence of beneficial dental outcomes to establish whether this exceedance is 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 decreased substantially across the population since the widespread introduction of water fluoridation in the 1960s and 1970s. There is, however, a small upwards trend in prevalence rates since 1996 for Australian and New Zealand children.

⁸² Sports Dietitians Australia. *Fact Sheet. Fuelling Fitness for the Future. Fluids in Sport*. www.sportsdietitians.com (accessed 2008).

Possible explanations for the recent upwards trend include the availability of lower fluoride toothpastes for children, increased consumption of non-fluoridated bottled and rain water, a reduction in the number children receiving preventative dental treatment, and changes in the diets of children in relation to sugar and fermentable carbohydrate intake^{83,84}. This supports the need for continuing water fluoridation and providing equitable access to fluoridated water.

Fluorosis was the only adverse effect identified in relation to risk of excess fluoride intake. Dental fluorosis, and not skeletal fluorosis, is the only type of fluorosis that has been reported in Australia and New Zealand. 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 estimated Australian and New Zealand dietary intakes, and is unlikely to occur with the current fluoride content of reticulated water or proposed addition of fluoride to bottled water.

The very mild and mild forms of dental fluorosis are considered to be ‘good’ or ‘beneficial’ (i.e. fluoride is incorporated into teeth) in comparison to the more clinically adverse conditions of moderate or severe dental fluorosis. The UL is based on the development of moderate forms of dental fluorosis. Moderate fluorosis is commonly attributed to the use of dental products and not water fluoridation⁸⁵.

A detailed examination by FSANZ of the UL for children aged 2-8 years has led to the conclusion that the UL values adopted by the NHMRC & NZMoH⁸ were based upon the best available information at the time (Supporting Document 4). However, the absence of any increase in moderate fluorosis in the current Australian and New Zealand population (Supporting Document 2) indicates that the apparent exceedances of the existing UL do not indicate a safety concern. Furthermore, 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 in infants⁸⁶.

The apparent disagreement between the intake estimates and the lack of a corresponding increase in prevalence of dental fluorosis also indicates that the existing UL will need to be reviewed.

Outside of considerations on fluorosis, the risk assessment has not identified any other health risks associated with the addition of fluoride to packaged water at a level of 0.6-1.0 mg/L.

⁸³ Ellershaw, A., Spencer, A.J. and Slade, G.D. (2005) *Oral Health in South Australia 2004. ARCPOH Population Oral Health Series No. 4*. Australian Institute of Health and Welfare, Canberra.

⁸⁴ Draper, G., Unwin, E., Serafino, S., Somerford, P. and Price, S. (2005) *Health Measures 2005. A report on the health of the people of Western Australia*. Department of Health WA, Perth.

⁸⁵ Riordan, P.J. (1993) Dental Fluorosis, Dental Caries and Fluoride Exposure among 7-Year-Olds. *Caries Research* 27:71-77.

⁸⁶ Australian Research Centre for Population Oral Health (2006) The use of fluorides in Australia: guidelines. *Australian Dental Journal* 51(2):195-199

10.4 Risk Assessment Conclusions

There is a history of safe use of fluoride in reticulated water supplies, including for the forms requested by the Applicant. 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 within 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 also showed that 5-22% of children up to 8 years currently exceed the UL. However, the Dietary Assessment results do not match the evidence showing that moderate fluorosis is a rare condition in Australia and New Zealand, which should not be the case given that the UL is based on the development of moderate fluorosis. FSANZ is of the view that the exceedance by children up to 8 years is a consequence of the way that the UL was established, and so does not represent a safety concern.

Therefore, provided fluoride is added within the proposed range of 0.6-1.0 mg/L, then the substitution of fluoridated reticulated water with packaged water containing fluoride is not considered to be a cause for concern. No sub-population groups in Australia or New Zealand are considered to be at risk of adverse effects from consuming fluoridated packaged water.

In respect to the UL for fluoride, FSANZ is consulting with the NHMRC to determine what future measures can be undertaken to increase the accuracy of these levels. FSANZ has access to dietary intakes based on recent food consumption data for Australia and New Zealand, and so may be able to assist in re-defining the upper safe levels in a review process.

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.

11.1 Forms of fluoride

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)⁸⁷. Hydrofluorosilicic acid is a colourless to pale yellow liquid²¹.

⁸⁷ *The Merck Index*, 14th Edition, Merck and Co. Ltd Whitehouse Station, N.J. (2006)

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 silica⁸⁸. Chapter 8 (Drinking water treatment chemicals) of the *Australian Drinking Water Guidelines*²¹ contains relevant information about the chemicals approved for fluoridation of water. This Section also addresses the quality and purity of these chemicals.

11.1.1 Potential lowering of pH due to addition of permitted forms of fluoride

Two submitters supported the Application however they recommended that the pH of the fluoridated packaged water be specified in the Code between 6.5 and 8.5 as recommended in the *Australian Drinking Water Guidelines*²¹. The reason for this suggestion was the concern that the addition of hydrofluorosilicic acid to water may reduce the pH of the water and so create conditions that promote dental enamel erosion. They were further concerned if the water is 'soft' (i.e. does not contain high mineral content, and therefore has low pH buffering capacity) it will not buffer the effect of pH lowering from the addition of hydrofluorosilicic acid.

Specifically, the Tasmanian Department of Health and Human Services provided information regarding the pH levels of one of Hobart's catchment and water treatment facilities. They indicate that this water is initially very pure with extremely low alkalinity (i.e. < 10 mg/L of calcium carbonate) so has low pH buffering capacity. The water is also initially slightly acidic, at times being as low as pH 6.2. The water is treated with chlorine gas which reduces the pH by 0.2 units. They found that using hydrofluorosilicic acid for fluoridation at 1 mg/L of fluoride can reduce the pH by 0.3 to 0.5 units. With both treatments, they indicated that an initial low pH of 6.2 can be reduced to 5.8.

FSANZ's investigation into this issue included receiving information from some municipal treatment agencies and data from bottled water manufacturers on the pH levels of their products. FSANZ received analytical data from ABCL that indicated some Australian packaged waters have pH ranges between 4.1 and 7.9. FSANZ established some low pH and low buffering capacity waters will have their pH further reduced after hydrofluorosilicic acid treatment.

⁸⁸ 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 12 September 2008).

FSANZ also investigated the literature on the possible effect of hydrofluorosilicic acid (and the other two permitted forms of fluoride addition, being sodium fluoride and sodium fluorosilicate) addition on pH levels, and in particular what pH lowering can be expected. The Fact Sheet for hydrofluorosilicic acid in the *Australian Drinking Water Guidelines*²¹ states that ‘despite its low pH of 1.2, it has little effect on the pH of highly alkaline water, because relatively low amounts are used. However, the pH effects can be significant with water of low alkalinity’. A number of other references were found supporting this view.

The pH of a saturated solution of sodium fluorosilicate is around 3.6. Its addition to initial low pH water with low buffering capacity can also reduce water pH, but to a lesser extent compared to hydrofluorosilicic acid. Sodium fluoride solutions are quite neutral (the pH of a 1% solution is 6.5 and a 4% solution is 7.6) and so its addition is not expected to affect the pH of the treated water.

Hydrofluorosilicic acid is diluted with water from the initial aqueous concentrate of about 23-24% by a factor of about 250,000 to 300,000 to produce the desired fluoridation levels of 0.7-1.2 mg/L (this compares very similarly to that proposed for packaged water for this Application, being 0.6-1.0 mg/L)⁸⁸. This indicates that a very large dilution is required, and also the level of added fluoride is very small, being in the range of parts per million (being 4.4-6.3 mg/L for a 20% solution to achieve 0.7-1.0 mg/L fluoride²⁰).

In conclusion, FSANZ understands that the very small amount of hydrofluorosilicic acid that is added to water to produce packaged water containing 0.6-1.0 mg/L of fluoride will normally have very little, if any, effect on the pH of the water. However, there are some specific waters that have initially low pH and low buffering capacity where treatment with hydrofluorosilicic acid may well lower the pH. Sodium fluorosilicate addition has less effect on pH compared to hydrofluorosilicic acid, while sodium fluoride is expected to have no effect. A discussion on the effect of fluoridated packaged water on dental erosion is provided at Section 10.1.3.2 and Supporting Document 2.

11.2 Quality and purity of fluoride

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 and Draft Assessment Reports 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)⁸⁹ in the US have investigated these claims and concluded that they are not credible⁹⁰.

⁸⁹ 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)

⁹⁰ 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)

11.2.1 Concerns regarding lead contamination of fluoridation chemicals

One submission that did not support the Application, considered any chemical used to fluoridate packaged water should be 'food grade' and of an appropriate standard to ensure no extra lead contamination via leaching from the chemical. The submission states that the Maximum Contaminant Level Goal for lead is zero and there can be no justification for adding extra lead to water when it could be removed from the fluoridating chemical.

FSANZ investigated this issue and found that the potential contamination of water with lead (and arsenic) by fluoridating chemicals has been well investigated and determined it was not a safety concern. This issue is the same whether the fluoridation occurs with municipal water treatment or fluoridation of packaged water. Currently the three fluoridating chemicals are already permitted as processing aids to treat water (essentially this relates to municipal water fluoridation treatments) within the Table to clause 11 of Standard 1.3.3 – Processing Aids.

The specifications for these chemicals are contained in the primary or secondary sources within clauses 2 and 3 respectively in Standard 1.3.4 – Identity and Purity. These same specifications will be relevant for the use of these chemicals for fluoridating packaged water, i.e. their use for this Application.

The contamination limit of lead in packaged water is 0.05 mg/L as required in the Table to subclause 2(2) of Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks. Bottled water manufacturers will need to ensure that their products meet this limit, from all sources of lead, as well as the other contamination limits of this table.

11.3 Analytical procedures

11.3.1 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.

11.3.2 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 0.6-1.0 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.

11.4 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.

The Australian Food and Grocery Council indicated in its submission to 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.

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 Website⁹¹.

RISK MANAGEMENT

12. Risk Management Issues

Based on FSANZ's Risk Assessment, the following sections discuss approaches to managing any identified public health and safety risks, other broader issues relevant to permitting the voluntary addition of fluoride to packaged water, and responds to issues raised in submissions.

Some issues raised by submitters were beyond the scope of this Application e.g. the ecological impact of an increase in the sale of plastic bottles through marketing packaged water products containing added fluoride. These concerns therefore have not been addressed in this Report. Additionally concerns about reticulated water fluoridation policies have not been further examined as the Risk Assessment has determined a history of safe use and that the proposed fortification does not pose any risk to public health and safety.

12.1 Consistency with the Ministerial Policy Guideline

The Ministerial Policy Guideline provides guidance on the voluntary addition of vitamins and minerals to food.

12.1.1 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. FSANZ has 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. In responding to the Initial Assessment Report, Government and public health submissions generally supported using a nutritional equivalence approach to the Assessment of this Application.

At Draft Assessment, FSANZ's Risk Assessment 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, it can be considered to be nutritionally equivalent to reticulated water supplies in Australia and New Zealand.

⁹¹ ABWI Model Code accessed on 29/09/08 from:
http://www.australianbeverages.org/lib/pdf/ABWIModelCode_Mar06.pdf

In response to the Draft Assessment Report, one consumer submitter stated that the Application is inconsistent with the Specific Order Policy Principles for Voluntary Fortification with respect to a need to increase the intake of fluoride. However the Application is being assessed on the basis of nutritional equivalence with fluoridated reticulated water not on the basis of an increased fluoride intake and is therefore consistent with policy guidance.

12.2 Permitted level of fluoride

At Initial Assessment, 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*²¹ and the *Drinking-water Standards for New Zealand*³⁰.

At Draft Assessment, in response to submitter concerns, the Applicant 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 and New Zealand drinking water guidelines.

12.2.1 Level of fluoride for hotter climates

Four consumer submitters to the Draft Assessment Report expressed concern that people who consume more water (those who live in hot climates and elite athletes) would be exposed to excessive dietary fluoride intakes. Additionally one jurisdiction while supporting the addition of fluoride to packaged water did not support the proposed level. They proposed the level should not exceed the maximum concentration permitted in its public water supplies, i.e.

0.6 mg/L, because of the risk of exceedance of the UL. In particular, due to dietary modelling limitations and uncertainty around fluoride values, they considered it is premature to underestimate the public health risk of exceedances of the upper limit.

To determine the safety of the proposed range for population groups living in hotter climates, FSANZ re-examined the dietary intake assessment results for population groups living in hot climates and at hot times of the year. FSANZ also sought advice from the NHMRC through its Water Quality Advisory Committee and conferred with Australian and New Zealand dental experts.

The dietary intake assessment generally used conservative assumptions to ensure that the dietary intake assessment did not underestimate intake. (See Sections 10.2 and 10.2.6.2 of this Report) As a means of incorporating high levels of fluoride consumption into dietary intake estimates, it was assumed that all packaged water and reticulated water was fluoridated at

1.0 mg/L. In addition, fluid consumption data from the 1995 NNS included fluid consumption in hot climates and at hot times of the year. The results showed that people in hot climates do drink more water. However, FSANZ’s risk assessment concluded that people living in hot climates are not at risk of exceeding the UL from consuming packaged water fluoridated at 0.6-1.0 mg/L.

The NHMRC has provided its support for this conclusion. The NHMRC has advised that the guideline value of 1.5 mg/L in the *Australian Drinking Water Guidelines* (2004)²¹ was set in

recognition that the concentration range between the beneficial and adverse effects is rather narrow. At a water consumption level of 2 L/day for an adult and 1 L/day for young children, it was considered that the guideline value provided adequate balance of benefits and risks.

The maximum level of fluoride of 1.0 mg/L proposed for packaged water provides an additional safety margin with respect to any potential dental fluorosis if consumption of packaged water in hot climates were to exceed 2 L per day as used in the *Australian Drinking Water Guidelines*²¹.

Dental experts in Australia and New Zealand also support the level of fluoride proposed by FSANZ. While acknowledging climatic variation across the country exists, they note that we live, work and sleep in 'micro-climates' which truncate the extremes. Therefore, the regional climates may not be as closely associated with water consumption as in the past. They support FSANZ's proposed approach to maintain the voluntary addition of fluoride to packaged water in a range between 0.6-1.0 mg/L and agree that this approach maintains an appropriate balance between safety, choice and practicality in the addition of fluoride to bottled water.

FSANZ proposes to approve the voluntary addition of fluoride to packaged water in a range between 0.6-1.0 mg/L.

12.3 Permitted forms of fluoride

The Applicant originally requested permission to add sodium fluoride and sodium fluorosilicate to packaged water. At Draft Assessment, the Applicant amended their Application to request 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.

12.4 pH of packaged water

Two submissions at Draft Assessment noted that the addition of hydrofluorosilicic acid to packaged water may reduce the pH and so create conditions that promote dental enamel erosion. These submitters suggested specifying the pH of fluoridated bottled water in the Code in line with the *Australian Drinking Water Guidelines*²¹.

As previously noted the very small amount of hydrofluorosilicic acid that is added to water to produce packaged water containing 0.6-1.0 mg/L will normally have very little, if any, effect on the pH of the water. However, there are some specific waters that have initially low pH and low buffering capacity where treatment with hydrofluorosilicic acid may well lower the pH. The bottled water industry has advised that hydrofluorosilicic acid is rarely used, if at all⁹². Sodium fluorosilicate addition has less effect on pH compared to hydrofluorosilicic acid, while sodium fluoride is expected to have no effect. Further information on the forms of fluoride can be found in Section 11 of this Report.

Additionally in considering this issue, FSANZ also sought information from the Applicant in relation to the pH values of packaged water. ABCL advised that many national packaged water manufacturers use water from more than one source and that the pH from each source

⁹² Personal communication with Lucy Pearson, Australian Beverages Council Ltd, 2 April 2009.

is varies based on both regional and environmental factors. A survey conducted among ABCL members of the pH range of their packaged water products reported a range of 4.1 - 7.9. This survey represented 20 manufacturers across 26 regional water sources.

Consequently FSANZ undertook further assessment and consulted with both government and industry water experts to identify the potential level of risk from consuming packaged water with a low pH.

FSANZ's Risk Assessment has concluded that low pH, low buffering capacity packaged water (including those with added fluoride) are likely to have a negligible effect on the potential for tooth enamel erosion (See Section 10.1.3.2). For this reason, no risk management response is required. As previously discussed, the guideline pH range of 6.5-8.5 within the Australian and New Zealand drinking water guidelines is to optimise the efficacy of disinfection using chlorine, and reduce corrosion and encrustation in pipes and fittings, rather than for health reasons (see Section 2.2.3).

12.5 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.

The Codex General Standard for Bottled/Packaged Drinking Waters (other than natural mineral waters)⁹³ 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.'

At Draft Assessment, FSANZ proposed 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 proposed that fluoride may only be added to packaged water that is not carbonated. All submitters who commented on this issue supported this approach.

12.6 Consumer issues

12.6.1 Proposed target market

The Applicant identified the following target groups for these beverages as:

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.

⁹³ 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

Consumers who have access to fluoridated water and are willing to consume reticulated water are unlikely to purchase these products, except for in cases of convenience. Fluoridated packaged water will be targeted to and consumed by a niche market as an alternative to fluoridated reticulated water.

In response to the Draft Assessment Report, several submissions commented that adding fluoride to packaged water as a voluntary option provides an alternative for the target groups stated above. In contrast, some submissions emphasised the need for a fluoride-free water alternatives to remain available to consumers at all times. As this Application is for a voluntary permission to add fluoride to packaged water, it is expected there will be non-fluoridated packaged water available to consumers. Industry has indicated that it is unlikely that more than 10% of packaged waters will contain added fluoride. Labelling provisions will assist consumers to make an informed choice regarding purchasing these products (See Section 12.7).

One submission proposed that most consumers buy bottled water to consciously avoid chemicals added to the water supply, including fluoride. Recent research shows that general food purchase decisions are motivated by *convenience*, *cost*, and *taste*⁹⁴. If this permission is approved, consumers will continue to have the choice to purchase packaged water without added fluoride.

12.6.2 Potential to mislead consumers

In response to the Draft Assessment Report, a number of submissions noted that there will be choice for consumers who do not wish to drink packaged water with added fluoride, and that labelling measures will provide sufficient information to enable consumers to make an informed choice without misleading them as to the nutritional quality of the packaged water.

12.6.2.1 Consumer understanding of fluoride

Evidence about consumer knowledge and understanding of fluoride is limited. Some research around consumer understanding of fluoride in relation to fluoridated municipal water supplies was found, mainly from opinion polls in the United Kingdom and the United States. In literature searches no additional Australian or New Zealand data were found regarding consumer understating of fluoride. The international findings are summarized below.

UK national opinion surveys suggest the general public has a limited to moderate knowledge about water fluoridation; most people do not realise fluoride is naturally-occurring in water supplies. Eight polls posed at least five different questions relating to the caries-preventive effectiveness of fluoride in general, or water fluoridation. Around half of each sample appeared to link fluoride to reduced tooth decay⁹⁵. Focus groups with people in fluoridated and non-fluoridated regions of NE England revealed variable knowledge of fluoride in relation to dental and general health. Although most group participants were aware of water fluoridation, there were misconceptions: for example, some people mistakenly thought that their water supplies were already fluoridated at the appropriate level when they were not. There was little detailed understanding of water fluoridation and confusion surrounding the

⁹⁴ Drewnowski, A. (2002). Taste, Genetics and Food Choices. In H Anderson; J Blundell; M Chiva (eds) *Food Selection: from Genes to Culture*. Danone Institute.

⁹⁵ Catleugh, M., Delves, A. & Bellaby, P. (2008). *A review of polls concerning water fluoridation carried out in the United Kingdom between 1977 and 2007*. North West Fluoridation Evaluation Group. United Kingdom.

benefits of fluoridation, even in an area where a formal publicity and consultation exercise had been undertaken^{96,97}.

About 73% of Ireland's inhabitants live in areas served by fluoridated water supplies, which have been fluoridated since the 1960s⁹⁸. Findings from an Irish study reveal a high level of misunderstanding about the purpose and function of fluoride and its specific benefits. Fluoride was often confused and perceived as a purifying agent, and dental benefits were not mentioned by the majority of respondents⁹⁹.

Water fluoridation has occurred increasingly in public water systems across the US since it was introduced in 1945. The national baseline fluoridation levels in 1989 and 1992 were 61% and 62%, respectively, for the US population served by community water systems that receive water^{100,101}.

The 1991 Gallup poll from the US showed that 94% of parents agreed fluoride is important to a child's dental health (58% very important; 36% somewhat important), yet most could only cite toothpaste as a source. The sample was taken across fluoridated and non-fluoridated communities in the US; however, proportions in these regions were not provided¹⁰². A Canadian telephone survey of 2000 people living in fluoridated and non-fluoridated municipalities in 1994 showed that in both areas, knowledge of the preventive benefits of fluoride was low¹⁰³.

Before water supplies in South Africa were required to fluoridate all main and drinking water, a South African study found that a substantial proportion of people surveyed about water fluoridation believed fluoride was linked somehow to health, and others believed it 'purifies water'. The study found that 62% of survey respondents were in favour of fluoride being added to drinking water; 9% were against it. Of those in favour, 30% mentioned the reason of reducing tooth decay; 30% mentioned 'health'; and 10% believed it 'purifies water'¹⁰⁴. Since this study, The Department of Health has legislated regulations indicating that water service providers are obliged to fluoridate water to a concentration level of up to 0.7 mg F⁻/ℓ as of September 2003¹⁰⁵.

⁹⁶ Hastings, G.B., Hughes, K., Lawther, S. & Lowry, R.J. (1998). The role of the public in water fluoridation: public health champions or anti-fluoridation freedom fighters? *British Dental Journal*, 184(1), 39-41.

⁹⁷ Lowry, R.L., Thompson, B. & Lennon, M.A. (2000). How much do the general public want to be involved in decisions on implementing water fluoridation? *British Dental Journal*, 188, 500-502.

⁹⁸ Clarkson, J., McLoughlin, J & O'Hickey, S. (2003). Water Fluoridation in Ireland: A Success Story. *Journal of Dental Research*, (82), 334-337.

⁹⁹ The Dental Health Foundation – Ireland. Accessed February 2009 at:

http://www.dentalhealth.ie/information/text_index.tml?secid=20020822160750&sub

¹⁰⁰ CDC. National Center for Prevention Services. Fluoridation census 1989 summary. Atlanta, Georgia: US Department of Health and Human Services, Public Health Service, CDC, 1991.

¹⁰¹ CDC. National Center for Prevention Services. Fluoridation census 1992 summary. Atlanta, Georgia: US Department of Health and Human Services, Public Health Service, CDC, 1993.

¹⁰² Gallup Organization, Inc. (1991). A Gallup study of parents' behaviour, knowledge and attitudes towards fluoride. Princeton, NJ: Gallup Organization, Inc.

¹⁰³ Levallois, P., Grondin, J. & Gingras, S. (1998). Knowledge, perception and behaviour of the general public concerning the addition of fluoride to drinking water. *Canadian Journal of Public Health*, 89(162-165).

¹⁰⁴ Chikte, U.M. & Brand, A.A. (2000). Attitudes to water fluoridation in South Africa 1998. Part III. An analysis of pro- and anti-fluoridation attitudes in South Africa. *SADJ*, 55(2), 70-76.

¹⁰⁵ Rand Water supplier website, accessed March 2009 at:

<http://www.randwater.co.za/ArticlesDetails.asp?ArticleId=2>

In summary, results show mixed findings about understanding of fluoride as a mineral. Most of the evidence suggests consumers have limited to moderate knowledge about water fluoridation, and the purposes and benefits of fluoride, but are in general aware of the link between the mineral fluoride and dental health, despite also linking fluoride to water purification. FSANZ assumes consumers in the target group for consumption of fluoridated packaged water products to have an adequate knowledge of the purpose of fluoride to be purchasing the product.

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

12.7.1 Food identification requirements

Following the Initial Assessment, the Applicant amended their Application and sought permission to require a statement, for food identification purposes, to the effect that the product contains added fluoride. This replaced their initial request for permission to make nutrition claims about fluoride.

At Draft Assessment, submitters suggested the presence of fluoride in the packaged water should be clearly labelled and supported FSANZ's proposed approach for a mandatory statement to be included on the label for food identification purposes to the effect that fluoride has been added. FSANZ is continuing with this approach. At present, references to fluoride on a food label, including in the name of the food, could be interpreted as nutrition claims (refer to Standard 1.2.8 – Nutrition Information Requirements), rather than a 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 regulatory status of the declaration. For example, 'spring water: Contains added fluoride.'

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 this Application A588, FSANZ is proposing to separate the permissions in Standard 1.3.3 – Processing Aids, 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 12.9.1). Consequently, any packaged water containing fluoride added in the course of its manufacture, including packaged reticulated water, will require labelling to the effect that fluoride has been added. However, permissions for fluoride added to water used as an

ingredient in other foods will remain in Standard 1.3.3 and will not be subject to the proposed labelling requirement.

One submission received in response to the Draft Assessment Report suggested provisions for labelling of naturally present fluoride in spring water should be included. This is beyond the scope of the current application, which considers added fluoride only and therefore will not be addressed at this time. Information about the presence and concentration of naturally occurring fluoride can currently be voluntarily included on the label of spring water in a typical analysis table (see Section 12.7.3) and this provision will remain.

If the proposed permission to add fluoride to packaged water is approved, under clause 2 of Standard 1.2.4 – Ingredient Labelling an ingredient list would 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 labelling statement will provide similar information to that provided by an ingredient list. This aligns with the practice of minimum effective regulation.

Some submitters to the Draft Assessment Report suggested the chemical form of the added fluoride be included on the label. In particular, one submitter commented that, given the scientific name of colourings (additives) are listed in the ingredients list by class name followed by a coded number in accordance with Schedule 1 and 2 of Standard 1.3.1 – Food Additives, it would be inconsistent not to adopt the same approach for fluoride. FSANZ considers this inappropriate on the basis that fluoride is not an additive, and the suggested approach would be inconsistent with requirements for the addition of vitamins and minerals, where under Clause 4 (a) of Standard 1.2.4 – Labelling of Ingredients, the vitamin or mineral may be listed by its common name rather than by its scientific name. We note that in addition, consumers may seek additional information from the manufacturer if desired.

12.7.2 Information around fluoride concentration and nutritional equivalence

At Draft Assessment, some submitters 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 1.0 mg/L, equivalent to fluoridated reticulated water supplies, FSANZ maintains that mandating the labelling of concentration is unnecessary. We note that manufacturers can choose to label packaged water with a typical analysis table (see Section 12.7.3), which would include information about the concentration of fluoride. This provision allows manufacturers to respond to consumer demand for specific information.

12.7.3 Typical analysis labelling

Currently, many manufacturers voluntarily label packaged water with a typical analysis of the product's mineral composition. This also 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 12.7.4), including fluoride. FSANZ therefore proposes that Standard 2.6.2 specifies that any naturally occurring mineral compound in packaged water including 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.

12.7.4 Nutrition and health claims

Nutrition and health claims about fluoride are currently not permitted by the Code. Standard 1.3.2 regulates 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 – Preliminary Provisions – Application, Interpretation and General Prohibitions (for ‘claimable foods’), or in some cases other specific permissions within the Code.

As fluoride is currently not listed in the Schedule to Standard 1.1.1, nor is an express permission provided in Standard 2.6.2, nutrition claims about fluoride are currently not permitted.

With respect to health claims, 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 to the Initial Assessment Report 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 12.7.1, the mandatory labelling statement proposed by FSANZ will provide for informed choice, but 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 being considered by FSANZ as part of Proposal P293 – Nutrition Health and Related Claims.

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. We note that draft Standard 1.2.7 is currently subject to review in response to a request by the Ministerial Council. As a separate project, FSANZ plans to review the Code in light of the 2006 Nutrient Reference Values for Australia and New Zealand. This process will include consideration of the Schedule in Standard 1.1.1. Fluoride will be part of this process.

12.7.5 Mandatory warning and/or advisory statements

A number of submitters suggested in response to the Draft 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 normal consumption of optimally fluoridated water.

Taking the above factors into account, FSANZ considers 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.

12.7.6 Labelling summary

The proposed 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 continue with the approach as given in the Draft Assessment Report by applying the following labelling provisions:

- A mandatory declaration be included on the label of packaged water containing added fluoride to the effect that fluoride has been added.
- Fluoridated packaged water is exempt from the requirement to provide an ingredients list under Standard 1.2.4 – Labelling of Ingredients.
- Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks to specify that any naturally occurring mineral in packaged water including 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. Further considerations around such claims remain within the domain of Proposal P293 – Nutrition, Health and Related Claims.

12.8 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.

At Draft Assessment, a submitter suggested that packaged water manufacturers undergo the same testing procedure as water authorities. 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.

A submitter at Draft Assessment suggested that packaged water manufacturers should ensure that staff who transport, handle or use fluoride chemicals should undergo similar training as required for water authority staff involved in fluoridation of public water supplies. The Applicant has advised that ABWI Model Code¹⁰⁶ 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.

12.9 Monitoring

A number of submitters to the Draft Assessment Report 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 five 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.

12.10 Consequential amendments to the Code

12.10.1 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.

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.

¹⁰⁶ ABWI Model Code is available from
http://www.australianbeverages.org/lib/pdf/ABWIModelCode_Mar06.pdf

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 is practical 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. In addition, the inclusion of the statement (as fluoride) adjacent to the specified level will clarify that the amount refers to the fluoride component rather than the total fluoride chemical added.

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.

12.10.2 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 F⁻). 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.

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

- a permitted 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;
- specific compositional requirements for packaged water with added fluoride;

- mandatory labelling for food identification to inform consumers as to the presence of added fluoride to enable informed choice; and
- 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

There are two options in considering 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 1.0 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 1.0 mg/L. Mandatory labelling for food identification purposes 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 jurisdictions 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 premium price for fluoridated packaged water for any additional benefits or perceived value.

At Initial Assessment 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. Submissions at Draft Assessment also expressed concerns over safety, exposure and adverse effects of ingesting fluoride especially by vulnerable groups and non-target audience.

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

Permitting 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.

Submissions at Initial Assessment 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 a 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 suggested 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.

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. This additional cost will be voluntary since it will only apply to consumers who opt to purchase fluoridated water.

14.2.3 Jurisdictions

A government agency has reported as with any category of food, there may be a need for additional surveillance activities and possibly some enforcement activities. Some resources

may also be required if any legal action was initiated. It is difficult to anticipate the precise resource implications and make cost estimates.

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. Fluoridated packaged water is nutritionally equivalent to fluoridated reticulated water. Moreover consumers will benefit from the added choice of fluoridated packaged water, especially those who do not have access to fluoridated reticulated water. Finally there could be opportunities for further innovation and new markets that would benefit industry, if fluoride was permitted to be added in packaged water.

The addition of fluoride to packaged water will deliver benefits to consumers and industry.

COMMUNICATION AND CONSULTATION

15. Communication

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, has focussed on the consumer-choice benefits of the product. At the levels of added fluoride being considered for approval, FSANZ's risk assessment has found 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 has liaised with the NHMRC and the NZMoH to ensure consistent messages on fluoride.

FSANZ does not intend to undertake any specific communication strategies. Feedback via submissions indicated general support from government, public health professionals and the food industry for the proposed voluntary fortification. Any concerns raised by stakeholders have been assessed and risk management strategies identified, as required.

16. Consultation

16.1 Public consultation

16.1.1 Initial Assessment

The Initial Assessment Report for Application A588 was released for public comment from 19 March 2008 to 30 April 2008. FSANZ received a total of 55 submissions, with seven responses from government, three from industry, 12 from public health professionals, two from consumer organisations and 31 from private submitters.

While the majority of government stakeholders, public health professionals and industry submitters indicated support for the Application, 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^{107,108}. At Draft Assessment, the Applicant amended the Application to seek permission to voluntarily add fluoride to packaged water within a range of 0.6-1.0 mg/L which reflects the Australian and New Zealand drinking water guidelines^{21,30}. Most of the consumer submissions opposed the addition of fluoride to packaged water due to safety concerns.

16.1.2 Draft Assessment

FSANZ received a total of 36 submissions in response to the Draft Assessment Report during the public consultation period from 11 November 2008 to 23 December 2008. Two submissions were received from industry, six from government, five from public health organisations, and 23 from consumer organisations and individuals. In general, government, public health and industry submitters indicated support for the Application, FSANZ's Risk Assessment conclusions and the need for a review of the UL for fluoride in the future.

Two submitters requested specifying pH levels for fluoridated packaged water. One jurisdiction recommended reducing the maximum fluoride concentration to take account of higher water consumption by populations living in hot climates.

All the consumer groups and individual consumer submissions opposed the addition of fluoride to packaged water, citing safety concerns with water fluoridation in general and potential adverse health impacts as a result of increasing the fluoride content of the food supply.

Several stakeholders continued to express 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.

Issues raised by submitters in response to the Draft Assessment Report have been addressed in this Report. A summary of submissions to the Draft Assessment Report is at Attachment 2.

16.2 Targeted consultation

At Draft Assessment, 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 provided in principle support for FSANZ's risk assessment summary and for the proposed level of fluoride to be added to packaged water.

¹⁰⁷ NHMRC Public Statement *The Efficacy and Safety of Fluoridation 2007* Available from http://www.nhmrc.gov.au/media/media/rel07/_files/Fluoride_Flyer.pdf

¹⁰⁸ Ministry of Health. *Drinking-water Standards for New Zealand 2005*. Wellington: Ministry of Health. Available from <http://www.moh.govt.nz>.

In responding to issues raised during Initial and Draft Assessment consultations, FSANZ has liaised with the NHMRC through its Water Quality Advisory Committee and the NZMoH regarding the risk assessment results and proposed approach, 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 0.6-1.0 mg/L, even for those in hot climates.

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. The NZMoH has advised that the report is expected to be publicly available in 2009.

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 considered that 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, following the Board's decision at Draft Assessment, FSANZ notified WTO member nations under the Technical Barriers to Trade Agreement of the proposed amendments to the Code to allow the addition of fluoride to packaged water. No submissions were received.

CONCLUSION

17. Conclusion and Decision

Decision

FSANZ approves amendment of 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 1.0 mg/L (total of naturally occurring and added fluoride) and to require mandatory labelling for food identification purposes 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 decision

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 approved draft variations to the Code are at Attachment 1.

18. Implementation and Review

FSANZ will notify the Ministerial Council of the approved draft variations to the Code.

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

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions to the Draft 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 variations 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 (as fluoride)
Sodium fluoride (only in water used as an ingredient in other foods)	1.5 (as fluoride)
Sodium fluorosilicate (Sodium silicofluoride) (only in water used as an ingredient in other foods)	1.5 (as fluoride)

[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 Draft Assessment Report

In December 2008, FSANZ received **36** submissions in response to the Draft 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 Draft Assessment included:

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

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).

SUBMITTER	SUBMISSION COMMENTS
Public Health Groups and Individuals	
Auckland Regional Public Health Service (ARPHS) D Gomez Camelo New Zealand	<p>Supported Option 2</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Acknowledged FSANZ’s safety assessment results regarding lack of public health and safety concerns for consumers of packaged water or general population. • Noted nutritional equivalence of fluoridated packaged water with fluoridated reticulated water at fluoride concentration of 0.6-1.0 mg/L and similar potential adverse risks from consumption for all population groups. • Noted proposed forms of fluoride are used in reticulated water and hence have similar bioavailability. • Attached ARPHS position statement on water fluoridation which supports water fluoridation as the most cost-effective, population-based strategy for dental caries prevention. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Noted that adding fluoride to packaged water as a voluntary option provides an alternative for those who do not have access to fluoridated tap water.
Australian Dental Association N Hewson Australia	<p>Supported Option 2</p> <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.

SUBMITTER	SUBMISSION COMMENTS
<p>Australian Dental Association N Hewson Australia</p>	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Recognise fluoridation of water supplies has proven to be one of the most significant public health initiatives in Australia and the ADA has developed policies to reflect this. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Recommended that the fluoride content of packaged water 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. <p><i>Other comments</i></p> <ul style="list-style-type: none"> Noted the ADA has been a strong advocate of water fluoridation together with other reputable international and Australian organisations including: World Health Organisation, International Association for Dental Research, US Centers for Disease Control and Prevention, British National Health Service, NHMRC, AIHW, Public Health Association of Australia, and the Australian Medical Association.
<p>Dietitians Association of Australia (DAA) A Byron Australia</p>	<p>Supported Option 2, providing addition of fluoride will not result in a pH which increases the risk of dental erosion.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Noted that the Draft Assessment Report addressed some concerns raised in its previous submission regarding level of fluoride, exclusion of carbonation and other foodstuffs or additives and the need for a restricted dietary intake assessment. Noted that nutrient content claims are no longer being sought. Noted advice indicating that hydrofluorosilicic acid may lower pH of the water which could increase the risk of dental erosion. In fluoridated reticulated water, the pH is specified to prevent corrosion of the pipes. Hydrofluorosilicic acid does not appear to be a problem in hard water where minerals act as a buffer. However, this could be a problem in packaged water with a low mineral content. Considered a suitable pH threshold should be specified to reduce the risk of dental erosion.
<p>National Health and Medical Research Council (NHMRC) C Morris Australia</p>	<p>Did not state a preferred option, but comments appeared to support Option 2</p> <p><i>Level of fluoride</i></p> <ul style="list-style-type: none"> Noted that the proposed level of fluoride to be added to packaged water (0.6-1 mg/L) is within the range of the NHMRC recommendations for fluoridation of drinking water.

SUBMITTER	SUBMISSION COMMENTS
<p>National Health and Medical Research Council (NHMRC) C Morris Australia</p>	<p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered that packaged water containing fluoride will provide choice for consumers who do not have access to fluoridated water. • Noted that there will still be choice for consumers who do not wish to drink fluoridated packaged water as only a small proportion of packaged water will contain added fluoride.
<p>New Zealand Nurses Organisation (NZNO) M Head New Zealand</p>	<p>Supported Option 2</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considered that fluoridated packaged water could contribute to enhance health and reduce inequalities in New Zealand. • Considered that for 48% of New Zealanders without access to fluoridated public water supplies, bottled water offers a safer alternative than fluoride tablets which may impose a possible risk of dental fluorosis. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted that Pacific children are at particular risk from poor oral health due to high rate of rheumatic heart disease in Pacific communities: infection in the oral cavity for these children can have life-threatening sequelae (reference provided in submission). • Noted that unacceptable inequalities exist in the oral health of New Zealand children, especially among Maori and Pacific children, and those from low socio-economic groups, and though this measure cannot address them, it may help to raise the profile of the benefits of fluoridation.
<p>Public Health Association of Australia M Moore Australia</p>	<p>Supported Option 2</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Noted safety and dental health benefits of fluoridated water and considered fluoridated drinking water to be the most cost-effective and socially equitable means of achieving community-wide exposure to the caries prevention of fluoride. • Also noted compelling evidence form international and Australian research (references included in submission). <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered that fluoridated packaged water will give people a choice to access the proven dental caries prevention benefit of fluoride where fluoridated water is not available or when people do not wish to drink reticulated water.

Industry	
Food Technology Association of Australia T Zipper Australia	Supported Option 2
Table Top Spring Water Pty Ltd R Bratchell Australia	Did not state a preferred option, but comments appeared to support Option 2 <i>Technological issues</i> <ul style="list-style-type: none"> • Considered that to evaluate the effectiveness of the total solids in the water at any given time, the same percentages of fluoride in packaged water would result in a higher intake by consumers. • Recommended research to ensure fluoride content of packaged water is not higher than the standard for fluoridated reticulated drinking water in each state. <i>Labelling</i> <ul style="list-style-type: none"> • Noted there is no current requirement to label fluoride or other elements present in fluoridated reticulated water. • Considered the scope of the Application should be widened to include the provision for labelling natural spring water with fluoride. • Supported appropriate labelling for consumer choice at point of sale. <i>Other information</i> <ul style="list-style-type: none"> • Noted that the table to clause 2(2) of Standard 2.6.2 applies to natural spring water with fluoride. Considered there should be no minimum fluoride requirement and the maximum concentration of 2 mg/L should be maintained. Labelling would indicate the amount of fluoride present in the water.
Consumer Organisations	
Coffs Harbour Pure Water Association S Turner Australia	Supported Option 1 <i>Safety and efficacy</i> <ul style="list-style-type: none"> • Noted the forms of fluoride to be added to packaged water are by-products of fertiliser manufacture and have never been tested for safety for human consumption. Advised that these compounds are now listed for review by the US National Toxicology Program. • Noted that arsenic and beryllium found in fluoride used in water fluoridation are known human carcinogens.

<p>Coffs Harbour Pure Water Association S Turner Australia</p>	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considered that there is already an overabundance of fluoride in food and drinks. • Noted a US Public Health Service report which stated the range in total daily fluoride from water, dental products, food and beverages exceeded 6.5 mg per day, greater than levels known to cause third stage of skeletal fluorosis. • Noted that UNICEF and NHMRC reports Australia as having one of the highest rates of dental fluorosis in the world. • Advised that the main benefit of fluoride in reducing tooth decay is topical rather than systemic. • Noted that tooth decay rates are higher in fluoridated areas (e.g. Sydney) than non-fluoridated rural areas. • Considered adding fluoride to packaged water will increase dental fluorosis, the risk of osteosarcoma in boys and skeletal fluorosis and/or brittle bones in the aged. • Noted there have not been any properly conducted, peer reviewed studies of the effects of fluoridation on other aspects of human health in NSW or Australia. Noted people whose health has been adversely affected by fluoridation include those with Parkinson’s disease, kidney disease, asthmatics, war veterans, and those with arthritic conditions. • Noted the 2004 Armfield and Spencer review which showed no significant difference in the decay rates of permanent teeth of children on the basis of access to fluoridated and unfluoridated drinking water. Considered the decline in dental caries in 12 year old Australian children from 1955 – 1975 fails to take account of the increased use of topical treatments during this period. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted American Dental Association and American Medical Association advice to parents to avoid using fluoridated water to reconstitute infant formulas due to risk of dental fluorosis. • Noted that many people need access to non-fluoridated water e.g those with an allergy to fluoride, and those with health problems requiring them to drink large amounts of water. • Noted studies by Professor Masters of Dartmouth College on the harmful side-effects of water treated with silicofluorides which warn of the uptake of lead into blood and effect on children’s behaviour. (studies not included) <p><i>Forms of fluoride</i></p> <ul style="list-style-type: none"> • Noted that forms of fluoride used in water fluoridation contain arsenic, lead, beryllium, cadmium, vanadium, mercury, silicon and radionuclides.
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<p>Coffs Harbour Pure Water Association S Turner Australia</p>	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considered if the Application proceeds, that it should be mandatory to list the fluoride content of all packaged water whether the fluoride is naturally occurring or added. • Also considered there should be clear and concise warnings on packages, similar to those on US toothpaste packaging. • Recommended warning parents not to reconstituted infant formulas using these products. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Advised that it is illegal to add fluoride to public drinking water supplies in Europe and the UK following the European Court of Justice ruling (2005) 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 regulation, licensing, sale and administration of medicines.’
<p>Queenslanders for Safe Water, Air and Food Inc M Haines Australia</p>	<p>Supported Option 1</p> <p>Considered that the Application would be in breach of the specific order policy principles for voluntary fortification with respect to a need to increase intake of fluoride as:</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 • There is evidence that some population groups are vulnerable to fluoride. <p>However, if the Application proceeds:</p> <ul style="list-style-type: none"> • No more than 0.6 mg/L fluoride • Clear labelling in large font with concentration and absolute amount of fluoride on bulk packaged water containers and individual bottles. • Warning for infants under 12 months not to consume regularly and warning for dental fluorosis. (For liability purposes, it must be acknowledged that fluoridated water can cause dental fluorosis.) <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Questioned FSANZ’s risk assessment conclusions, e.g. a history of safe use of fluoride, dental fluorosis, no adverse effects. • Considered that there is little evidence of a benefit of fluoride in preventing tooth decay, especially taking into account the delay in eruption as a result of fluoride exposure. Cited dental and oral health surveys and WHO data which compared results in fluoridated and non-fluoridated areas.

<p>Queenslanders for Safe Water, Air and Food Inc</p> <p>M Haines</p> <p>Australia</p>	<p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Cited epidemiological studies which showed that children are more likely to absorb lead in the environment where silicofluorides have been added to public water. E.g. children in Mt Isa who have high blood lead levels (reference included in submission). • Considered FSANZ has not taken into account the increased fluoride intake by vegetarians and vegans following recent approval of sulfuryl fluoride as a fumigant for use on grains, nuts and fruit. • Suggested awaiting the results of the Australian Total Diet Survey to determine extra fluoride sources. • Expressed concern regarding fluoride intake and the increasing incidence of dental fluorosis in infants fed infant formula reconstituted with fluoridated water. Noted a lack of data on fluorosis in Australia and cited a paper by Dr Kathleen Thiessen that demonstrates infants can exceed the UL consuming water with 0.8 mg/L fluoride (Copy of paper included with submission). Also included the American Dental Association Health alert which recommends that infants under 12 months should not consume fluoridated water. • Noted anecdotal evidence that elite athletes and outside workers can consume 10 L water or more per day. Also noted that Queensland children up to 8 years, living in a hot climate, can easily drink more than 1.4 L water and other liquids per day. • Questioned FSANZ's statement regarding lack of evidence showing any association with cancer or any other adverse effects and provided references showing an association of fluoride with cancer, thyroid dysfunction, kidney impairment, chemical sensitivities or allergies and osteoporosis. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considered the data in Supporting document 4 should reflect the increasing sources of fluoride in the diet e.g. few commercially prepared foods would be prepared using unfluoridated water. • Noted that FSANZ has not yet released an Australian total fluoride intake study, despite NHMRC and APVMA requests for such a study. • Noted the WHO has called for total fluoride studies to be done before any area is fluoridated. <p><i>Forms of fluoride</i></p> <ul style="list-style-type: none"> • Questioned why the Applicant has not applied to add calcium fluoride, a naturally occurring source of fluoride. • Questioned the quality of fluoride to be added to packaged water, whether pharmaceutical grade or industrial grade which may contain contaminants. • Recommended that water packaging company staff who transport, handle or use fluoride chemicals should undergo similar TAFE training as required for water authority staff involved in fluoridation.
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<p>Queenslanders for Safe Water, Air and Food Inc M Haines Australia</p>	<p><i>Forms of fluoride</i></p> <ul style="list-style-type: none"> • If the application is progressed, requested provision of toxicology studies of the forms of fluoride intended for use, a list of contaminants and concentrations of lead, mercury, cadmium, arsenic present, and any health studies on silicofluoride. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Noted if the Application proceeds, packaged water should be clearly labelled as containing fluoride in addition to the form and concentration. This includes both bulk and individual containers. • Recommended that labelling must include a warning for infants under 12 months as per the Center of Disease Control and Prevention advisory ‘Not recommended for regular consumption by infants under 12 months old’ and ‘May cause dental fluorosis’. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered the introduction of fluoridated packaged water would give a small minority an alternative source of fluoride. However, it could also reduce consumer choice for those who want to purchase unfluoridated packaged water, especially if there is limited refrigeration space. • Recommended that FSANZ arrange for an independent consumer survey to determine the proportion of people who want to purchase bottled water with added fluoride before progression of the Application. • Considered consumer choice seems a poor justification for application approval. <p><i>Monitoring and enforcement</i></p> <ul style="list-style-type: none"> • Recommended that packaged water manufacturers undergo the same testing procedures as water authorities and the results of testing and compliance are made publicly available. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Noted that water fluoridation had been introduced in Queensland since the release of the Draft Assessment Report which resulted in fewer Australians being without access to fluoridated water, one of the justifications for submitting the Application. • Questioned the accuracy of many statements in the Draft Assessment Report e.g. consumption of packaged water in Australia and New Zealand. • Considered that failure to adequately inform parents of the risk of dental fluorosis from regular consumption of fluoridated bottled water could be a future liability issue unless there are sizable warnings on labels. • Considered that encouraging more people to drink bottled water with the addition of fluoride as a marketing angle would be anti-environmental. • Questioned if carbon credits could be claimed if a waste product (fluoride) is disposed of to offset the ecological cost and carbon cost of plastic bottles? Requested advice regarding implications for gaining carbon credits if the Application proceeds.
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<p>Fluoride Action Network (FANNZ) G Atkin New Zealand</p>	<p>Supported Option 1</p> <p>Stated that FSANZ did not consider the US National Research Council Review (apart from claiming it considers lower levels of fluorosis beneficial) or the York Review in preparing its report, and also noted that the report’s findings are contrary to the findings of those reviews. Also considered that the report did not consider the procedural issues raised in relation to Objectives.</p> <p><i>Fluoride as an essential nutrient</i></p> <ul style="list-style-type: none"> • Suggested that fluoride is not an essential nutrient as a minimum daily intake, below which clinical symptoms appear, has not been determined. • Cited the US National Academy of Sciences as stating fluoride is neither a nutrient nor an essential mineral. Also noted WHO lists sodium fluoride as an allowable medicine but does not list silicofluorides. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Refuted the comment that there is a history of safe use of fluoride has no factual foundation and noted that neither the Australian nor the NZ governments monitor adverse effects (and doctors are not taught to look for any). • Suggested that the UL was derived from Hodge’s analysis of Roholm’s studies (0.05 mg/kg/day) (as acknowledged in the Dietary Reference Values document) and therefore the comment that the UL is likely to be underestimated is incorrect. • Refuted the comment that <i>there is no evidence to suggest a prevalence of moderate fluorosis which would be considered to be an adverse outcome</i> noting Dr J Colquhoun photographed moderate to severe fluorosis in Auckland in the 1980s and the FANNZ has observed individuals with 3mm fluorosis bands. • Commented that the NRC found evidence of harm at the current levels of water fluoridation and/or dietary intakes in Australia and NZ. • Highlighted an inaccuracy in relation to the footnote (No.82 NRC) accompanying the statement <i>very mild and mild forms of dental fluorosis are considered to be ‘good’ or ‘beneficial’</i> and advised the following NRC comment <i>There appears to be general acceptance in today’s dental literature that enamel fluorosis is a toxic effect of fluoride intake.</i> • Questioned the validity of the statement from the Institute of Medicine regarding populations with access to water fluoridated at 1 mg/L in the US had the lowest incidence of caries and a mean dietary fluoride intake around 0.5 mg/kg/day. • Noted this equated to 3.5 mg/day for a 70 kg person. Cited original work in the 1930s and 40s which identified 1-1.5 mg per day as optimal, beyond which adverse effects were expected. • Advised 0.05mg/kg/day was identified by Hodge as the level at which advanced skeletal fluorosis would occur after 20 years exposure.
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<p>Fluoride Action Network (FANNZ) G Atkin New Zealand</p>	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Refuted the statement that <i>dental associations and experts suggest the best way to lower the incidence of fluorosis and retain beneficial effects on dental caries is by reducing exposure to fluoride from sources other than water fluoridation (e.g. toothpaste, supplements)</i> • Disputed the explanation regarding the use of theoretical diets as the basis for derivation of the UL. Suggested the figure of 0.05 mg/kg/day was derived from Hodge’s analysis of Roholm’s work and stage 3 skeletal fluorosis as is internationally documented. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • If the Application proceeds, submitted that the fluoride content and chemical used should be clearly stated. This should apply to all other beverages with added fluoride or made with fluoridated public water. • Considered warning statements that the water should not be given to children under two or used for reconstituting infant formula should be mandatory. Not to do would be inconsistent with the FSANZ report (DAR page 93) and the labelling requirements of Std 2.9.1. <p><i>Food technology considerations</i></p> <ul style="list-style-type: none"> • Suggested any chemical used for fluoridating packaged water must be at least ‘food grade’ and an appropriate standard be developed and that fluoride should not be given special treatment.
<p>Consumer Individuals</p>	
<p>N Adsett Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Stated fluoride has no nutritional value and its addition could be considered mass medication. • Considered there is no conclusive evidence to prove fluoride is beneficial in reducing tooth decay. Furthermore noted early fluoridating countries are ceasing the practice because of known adverse health conditions. • Argued artificial fluorides are not safe for human consumption and the adverse effects with some people occur far quicker than with others. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Stated it would morally irresponsible and a breach of civil liberties and constitutional rights to remove the only other choice freely available for citizens who choose not to ingest fluoride. <p><i>Other comments</i></p> <ul style="list-style-type: none"> • Argued it is not fair or reasonable for FSANZ to make additions to products. Their aim is to test and ensure a product is safe. Also noted FSANZ should prevent population from being poisoned instead of being responsible for it.

<p>J Ashton Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Considered that the health risks associated with fluoridation have not been sufficiently appreciated. • Advised that 25-50 mg fluoride is highly toxic, causing vomiting, diarrhoea and central nervous system manifestations. (references included in submission) • Noted the effects of fluoride from industrial processes such as manufacture of phosphate fertilizers and aluminium production on agriculture and livestock. (references included in submission) • Noted Australian and overseas studies on the effectiveness of water fluoridation and concluded that there were serious inadequacies in the study design. (references included in submission) • Noted increasing fluoride sources due to fluoride toothpastes, gels and tablets. • Considered the ‘panacea’ has become a ‘poison’ and noted studies reporting dental fluorosis affecting 25-50% of children in fluoridated communities. (references included in submission) • Noted studies linking water fluoridation with cancer e.g. osteosarcomas in young males, ageing process, immune function, hip fracture, neurotoxicity. (references included in submission) • Noted that highly mineralised (hard) water e.g. Vichy water, contains higher concentrations of calcium and magnesium which binds fluoride as an insoluble form which is more easily excreted by the kidney than lower mineralised waters.(references provided in submission) • Noted a review of dental caries and periodontal disease which concluded that meticulous oral hygiene and cariostatic food additives were of limited benefit. Suggested instead a diet of unrefined, fibrous foods to increase mastication, and induce secretion of saliva of high buffering capacity to promote periodontal health and dental decay resistance. (reference provided in submission) • Noted a study of lead levels in Tasmanian children due to pesticide sprays and suggested a link between environmental lead and dental decay. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered athletes at risk of overconsumption of fluoride due to higher fluid consumption. • Noted evidence suggesting that fluoride, together with nutritional deficiencies, may contribute to fluoride toxicity, especially in infants and young children. (references included in submission).
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<p>J Ashton Australia</p>	<p><i>Other issues</i></p> <p>Noted that 96% of the world’s population has either discontinued fluoridation of drinking water or never commenced them. Advised that less than 50% of the US and less than 10% of England is currently fluoridated. Sweden, Holland, and West Germany have discontinued fluoridation. (references included in submission).</p>
<p>D Buckland Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Suggested the pre-cautionary principle must be applied to the issue. • Highlighted adverse health effects of individuals by ingestion of fluoride.
<p>K Chlebowczyk Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Argues that the Application violates section 51 (xxiiiA) of the Australian Constitution. • Recommended that the government must ensure that at all times there is a fluoride-free water alternative available to all consumers.
<p>R Crowe D Kerr Australia</p>	<p>Supported Option 1</p> <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Raised concerns that if larger manufacturers fluoridate bottled water and demand increases it may result in more fluoridated than non-fluoridated water being available given the monopoly on distribution channels such as petrol stations and food chains. Noted this would make it difficult for consumers to obtain non-fluoridated water.
<p>C Davis Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Noted that fluoridation is not permitted in most European and Asian countries. • Considered that good nutrition is a safer and more affordable way to address dental decay. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Noted 23 published human studies reported an association between exposure to high levels of fluoride and reduced IQ in children. (link to studies included in submission) <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Considered citizens have a right to freedom of choice regarding water fluoridation.

<p>J Davis Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Suggested most consumers buy bottled water to consciously avoid chemicals added to the water supply including fluoride. • Believed the proposal offers little consumer choice with consumers having to ingest poisonous chemicals or purchase expensive filtration equipment to remove chemicals from their water. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Noted if the Application proceeds, packaged water should be labelled as containing fluoride.
<p>R Edyp Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Did not support FSANZ’s conclusion that there are no public health and safety concerns. • Noted overseas studies which show the incompatibility of fluoride with the human body over 50 years, especially for young children, babies and foetuses. (articles included in submission) • Provided scientific reports and other information highlighting the effects of fluoride on the brain, endocrine system (thyroid and insulin secretion), chromosomes, bones, immune system, gastrointestinal system, liver, kidneys and reproductive system. Also noted that fluoride is linked to cancer (articles provided in submission). • Noted that fluoride is absorbed through skin and effects are cumulative. • Considered that the hardening of teeth from exposure to fluoridated water is not preferable for prevention of tooth decay in the long run as hard teeth are less flexible and more likely to crack and become infected. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered there was a lack of evidence of the safety of fluoridated drinking water at 1 ppm for all population groups, especially babies, children under 12 years, pregnant and nursing women, the elderly and those who are unwell. • Considered kids’ dental health reflect our lifestyle with too much junk food, poor nutrition, insufficient exercise and lack of hygiene. <p><i>Forms of fluoride</i></p> <ul style="list-style-type: none"> • Considered that sodium fluoride (a poison) and naturally occurring organic calcium –fluoro-phosphate (needed by the body to build and strengthen bones and teeth) have different properties and bioavailability. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Noted choice in European countries where the government provides fluoride tablets to people who need it and are willing to take it.

<p>R Edyp Australia</p>	<p><i>Other issues</i></p> <ul style="list-style-type: none"> • Raised concern regarding the introduction of water fluoridation in Queensland rather than the addition of fluoride to packaged water. Considered fluoridation is mass ‘medication’.
<p>L Hutton Australia</p>	<p>Supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Noted many people are allergic to fluoride. Provided anecdotal information of allergic reactions to fluoride. • Noted that ‘legal’ fluoride compounds are class 6 or 7 poisons which may cause spasms and possible death. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered fluoridated bottled water provided a risk for those with asthma or men, women and children with allergies. • Noted that outside manual workers may drink 11-13 litres of water daily. <p><i>Food technology issues</i></p> <ul style="list-style-type: none"> • Considered that industrial grade fluoride from phosphate fertilizers added to bottled water would contain dangerous toxic chemicals. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered that the addition of fluoride to water is ‘medication’. • Considered that the addition of fluoride to bottled water removes the alternative to fluoridated drinking water being introduced in Queensland.
<p>T MacKenzie Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Recommended that FSANZ undertake further study to assess the safety of fluoridated packaged water. Considered FSANZ is relying on outdated data which is not supported by current studies. Advised that there are 23 studies showing the dangers to IQ levels due to the addition of fluoride to water – bottled or town supply (link to studies provided in submission). • Provided links to relevant current information regarding health and safety issues related to fluoridation. (links provided in submission) • Considered that there is no significant statistical difference between dental caries in fluoridated and unfluoridated areas in Australia, New Zealand, UK, USA and China. • Considered fluoridation chemicals are toxic waste residue from the phosphate fertilizer industry and contain other contaminants such as lead, cadmium, arsenic, radon, mercury and are classed as an S7 poison.

<p>T MacKenzie Australia</p>	<p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Advised that fluoride ingestion suppresses iodine uptake in the body and suggested a link between iodine status in children (and IQ) and water fluoridation. (links to Professor Cresswell’s report in submission) • Noted population sub-groups at risk from fluoridated water or beverages include people with allergies, chemical sensitivity, kidney impaired and diabetics. • Considered babies are at higher risk as they consume up to four times their body weight in fluids. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Considered that if Franklin Water, one of the cheapest packaged water products adds fluoride, it will reduce choice for poorer people. <p><i>Other information</i></p> <ul style="list-style-type: none"> • Noted that Europe is 99% fluoride free. • Considered water fluoridation is mass medication without monitoring dosage.
<p>C and N Mifsud Australia</p>	<p>Supported Option 1</p> <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Suggested consumers need choice of bottled water without added fluoride.
<p>L Parker Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Supported M Haines’ submission and highlighted scientific and actual evidence of toxicity of fluoride in drinking water. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered that babies, people with kidney disease, and people with thyroid imbalance are at risk as fluoride decreases the natural minerals that keep our thyroid in good health. • Noted that the Federal Government is adding iodine to bread to address iodine deficiency. Considered that the low rate of iodine deficiency in Queensland is due to a lack of water fluoridation. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Advised it is imperative that consumers have choice of a fluoride-free water option available as reverse osmosis is not an option for many due to the cost.

<p>C Poggioli Australia</p>	<p>Supported Option 1</p> <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Advised it is imperative citizens have a fluoride-free option available. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Noted if the Application proceeds, packaged water should be clearly labelled as containing fluoride in addition to the form and concentration.
<p>P Robertson Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Considered that Dr B Spittle’s review of side effects from fluoridated water is the most recent and comprehensive study of toxic reactions to fluoride (included copy of publication with submission). • Considered that FSANZ risk assessment conclusion that there is a history of safe use is untrue. • Noted case studies and information regarding severe reactions occurring with exposure to fluoride from sources including fluoridated water at 1 mg/L. Symptoms included joint and muscle pain, and swollen lymph glands (included article by Dr Waldbott in submission). • Noted case studies and information regarding skin reactions, asthma and other respiratory problems from fluoride exposure. Also noted that workers at Alcoa in Victoria were exposed to less fluoride than they would receive from a fluoridated water supply. • Considered that approximately 1% of the Australian population (over 200,000 people) may have a health reaction to fluoridated bottled water if there is no warning label. • Considered that the 1991 NHMRC recommendation to conduct testing for fluoride sensitivity has been ignored by state health departments and the Australian Dental Association and the Australian Medical Association. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Noted if the Application proceeds, that packaged water should carry a caution ‘not to be used by those sensitive to fluoride’ as occurs with some fluoride mouth rinses. <p><i>Monitoring</i></p> <ul style="list-style-type: none"> • Recommended the NHMRC conduct a proper evaluation to confirm if fluoridation is safe for every individual in Australia before FSANZ should assume to endorse it is safe and add it with no warnings. <p><i>Other information</i></p> <ul style="list-style-type: none"> • References and articles included with submission.

<p>J Ryan Australia</p>	<p>Supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Highlighted a published review article which included fluoride in the list of emerging neurotoxic substances (article included in submission). • Provided an article on the fluoride content of foods and beverages in the United States and noted an additional source of fluoride from gassing grains and nuts (article included in submission). • Referred to an article on the potential dangers of fluoride and aluminium in the body (article included in submission). • Noted concern regarding effect of fluoridated water on lead toxicity (article included in submission).
<p>J Sharp Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Noted that some countries in the European Union have not permitted the addition of fluoride to bottled water as it becomes a medication. <p><i>Labelling</i></p> <ul style="list-style-type: none"> • Considered that labelling should allow the total daily intake of fluoride from air, food, drugs and water to be calculated for each individual to avoid dental or skeletal fluorosis at any stage of their lives. Noted that there is no exposure, there is no risk, irrespective of how high the hazard rating is.
<p>J Tichborne Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> • Highlighted link between Alzheimer’s disease and fluoride. Also noted fluoride blocks calcium absorption which results in frail bones. • Argued there are three poisons which destroy sections of the body: fluoride, sugar and chlorine.
<p>I Watson Australia</p>	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considered that fluoridated water should not be consumed by young infants, those whose medical conditions would be exacerbated by fluoride, the elderly, and those who have concerns about the health consequences of fluoridated water. • Considered there are doubts in the medical profession about the safety of fluoride and reliable clinical evidence of any benefits.

I Watson Australia	<p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Stated that the community should have access to fluoride-free drinking water especially with the rollout of fluoridation of public water supplies.
B Wilson Australia	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> Noted strong reservations that industry would not add fluoride to bottled water in the maximum allowable quantity accurately. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Stated the community should be able to consumer clean, healthy fluoride-free water.
P Wraith Australia	<p>Did not state a preferred option, but comments strongly supported Option 1</p> <p><i>Safety and efficacy issues</i></p> <ul style="list-style-type: none"> Considered fluoride to be a toxic poison and provided anecdotal evidence of related illnesses including kidney stones. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> Stated surveys reveal fluoride is not wanted and individuals are preparing for a class action against fluoride in the water supply (in QLD).
Government	
Department of Health & Human Services Tasmania (DHHS) J Savenake Australia	<p>Supported Option 2</p> <ul style="list-style-type: none"> Noted the Australian Drinking Water Guidelines recommend a pH of between 6.5-8.5 for drinking water. Recommended the drafting specify pH levels for fluoridated packaged water. Noted packaged water with a high mineral content ‘hard water’ will buffer the addition of hydrofluorosilicic acid. However, noted that if the packaged water is not high in minerals, that is, soft or pure water, the pH of the water may drop with the addition of hydrofluorosilicic acid and create conditions which may promote dental erosion. The critical pH of dental enamel is approximately 5.5 (reference included in submission). <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Supported labelling of packaged water with fluoride to provide adequate information to enable consumers to make an informed choice without misleading them as to the nutritional quality of the water.

<p>Depart of Human Services Victoria (DHS) V Di Paola Australia</p>	<p>Supported Option 2</p> <ul style="list-style-type: none"> • Noted DHS is satisfied that issues raised at initial assessment have been adequately addressed in the DAR. • Supported the suggestion to redefine the UL should the nutrient reference values be reviewed in the future. • Noted the ABWI Code will be updated to specify quality assurance procedures for the addition of fluoride.
<p>New Zealand Food Safety Authority (NZFSA) and New Zealand Ministry of Health (MoH) J Reid New Zealand</p>	<p>Supported Option 2</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • In addition to other measures, MoH recommends drinking reticulated ‘tap’ water wherever safe supplies are available to decrease dental caries. • Noted that FSANZ’s risk assessment identified a theoretical risk of exceeding the UL by a proportion of children up to eight years. • Agreed with suggestions that the existing fluoride UL may need to be revised upwards. • Supported re-examination of the UL, particularly for children, using New Zealand Children’s Nutrition Survey and the 2008/09 New Zealand Adult Nutrition Survey when results become available in 2010/11. • Considered that current evidence does not indicate any increase in moderate dental fluorosis in New Zealand communities. • Therefore considered that the theoretical risk to children is not associated with elevated levels of fluorosis and that revision of the UL could be included in a strategic program of work, rather than as a high priority. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Noted NZFSA/MoH’s support for the preferred approach is conditional on labelling clearly stating that fluoride has been added. • Supported mandatory labelling whether the fluoride is added by the manufacturer or by the local council, in cases where fluoridated reticulated water is packaged, to ensure consumers are informed whenever fluoride is added to packaged water. <p><i>Consumer issues</i></p> <ul style="list-style-type: none"> • Noted that permission provides consumers with potential access to fluoridated water, at their cost. • Noted that as it is a voluntary permission, continuation of public health policy promoting fluoridation of reticulated water supplies is required. <p><i>Monitoring</i></p> <ul style="list-style-type: none"> • Considered monitoring the uptake of the permission, consumption patterns and potential harms may be required and should be discussed by appropriate jurisdictions.

<p>New South Wales Food Authority and New South Wales Health B Porter Australia</p>	<p>Supported Option 2</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Noted that the estimated dietary fluoride among 90th percentile is well above the UP for children consuming infant formula reconstituted with fluoridated water at 0.6-1.0 mg/L. Suggested that the basis for the calculations is incorrect and that it would be more appropriate to adopt the same method used to calculate the mean intake using weight of larger children from the WHO growth charts and calculating expected consumption of formula. Considered using infants on 97th percentile rather than the 90th percentile would result in a more reasonable level exceeding the UL.
<p>Queensland Health (Qld Health) G Bielby Australia</p>	<p>Supported Option 1 or Option 3 – permit fluoride addition to a maximum of 0.6 mg/L (total and naturally occurring)</p> <p><i>Level of fluoride</i></p> <ul style="list-style-type: none"> Noted Qld Health does not support Option 2 based on the legislative requirements of Queensland’s <i>Water Fluoridation Regulation 2008</i> which prescribes the fluoride concentration added to the water supply at a level of 0.6, 0.7 or 0.8 mg/L (total of naturally occurring and added fluoride). Considered there is a need for a lower maximum level of fluoride in water consumed by Queenslanders as a result their higher apparent consumption of water as reported in the Draft Assessment Report (p31). Considered the fluoride concentration of fluoridated packaged water should not exceed the concentration of public water supply of the area it is sold in. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Noted that the fluoride range was prescribed to address consumers who drink more water in a hotter climate. Acknowledged the issues around derivation of the UL for fluoride intake outlined in Attachment 4 of the DAR. However, considered it is premature to underestimate the public health risk of exceedances of the current UL until more robust data is available, given the limitations of the dietary modelling, assumptions regarding water intakes since the 1995/97 national nutrition surveys and uncertainty around fluoride values for some foods. Noted the percentage of infants and young children whose estimated dietary intakes exceeded the UL for various water fluoridation scenarios. Noted that there is a paucity of information regarding the use of fluoridated water in food and beverage manufacture and the concentration of fluoride in water-containing foods. Also noted the potential for overconsumption of fluoride by vulnerable groups e.g. young women of child-bearing age and younger children if fluoridated packaged water is substituted for unfluoridated packaged water and fluoridated tap water (p22 of the Initial Assessment Report).

Queensland Health (Qld Health) G Bielby Australia	<i>Labelling/claims</i> <ul style="list-style-type: none">• Considered if permission is given to enable the addition of fluoride to packaged water, there needs to be a mandatory advisory statement displayed on labels to protect infants and young children.
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