

**11 November 2008**  
**[19-08]**

**DRAFT ASSESSMENT**

**APPLICATION A588**

**VOLUNTARY ADDITION OF FLUORIDE TO  
PACKAGED WATER**

**SUPPORTING DOCUMENT 2**

**NUTRITION RISK ASSESSMENT REPORT**

## **SUMMARY**

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd in 2006 seeking to permit the voluntary addition of fluoride to packaged water. The Applicant is seeking permission to voluntarily add sodium fluoride, sodium fluorosilicate (also called sodium silicofluoride) and hydrofluorosilicic acid to packaged water up to a range of 0.6 – 1.0 mg fluoride/litre.

FSANZ has not undertaken a nutrition risk assessment of fluoride added to food or beverages previously. The Application is being assessed on the basis of nutritional equivalence, according to the Ministerial Policy Guidelines. As nutritional need is not the approach being taken by FSANZ to assess this Application, a comprehensive nutritional risk assessment has not been undertaken. The purpose of the nutrition risk assessment is to establish if packaged water is nutritionally equivalent to fluoridated reticulated water. The bioavailability of the permitted forms was also assessed. The benefits and risks associated with fluoride exposure were assessed in relation to rates and trends for dental caries and dental fluorosis and potential associations with other conditions. FSANZ has reviewed key reports, position statements and scientific papers in conducting the nutrition risk assessment.

Overall, FSANZ found that:

- Packaged water is nutritionally equivalent to reticulated water in relation to nutrients other than fluoride. If fluoride is added to packaged water between 0.6-1.0 mg/litre, then it will be nutritionally equivalent to fluoridated reticulated water supplies in Australia and New Zealand.
- The requested forms of fluoride have been added to community water supplies in Australia and New Zealand for many years, some forms of which are also used in dental products such as toothpaste.
- The requested forms of fluoride are highly bioavailable when added to water.

Water fluoridation is performed at a level that provides a balance between the prevention of dental caries and the risk of developing dental fluorosis. There is both a systemic effect from fluoride before teeth have erupted and a topical effect following tooth eruption. The pre-eruptive exposure seems to have a greater influence on the development of dental fluorosis.

The benefit of fluoride on dental caries has long been established and therefore was not assessed in detail. Dental caries in adults have decreased over the last few decades due to the natural attrition of older generations with higher rates of dental caries and since the introduction of water fluoridation. Dental caries in Australia children and younger New Zealand children have been increasing since around 1996. The main causes of dental caries have been attributed to carbohydrates (fermentable carbohydrates, dietary sugars), acidic foods and drinks, inadequate fluoride exposure and deficiencies in natural protection from saliva. There has also been a suggestion that increased consumption of non-fluoridated bottled water may also play a role, but no robust evidence is available to demonstrate a direct correlation. Lower rates of dental caries are observed in people who reside in areas with fluoridated water compared to non-fluoridated areas for both Australia and New Zealand.

Dental fluorosis is generally recognised as an irreversible condition, particularly in relation to severe forms. Very mild and mild dental fluorosis are observed in around 10-25% of Australian and New Zealand children but these signs are not considered to be a health concern.

The prevalence has been decreasing since the early 1990s due to policy changes around the use of fluorides, particularly around dental products and decreases in concentrations in infant formula. Moderate dental fluorosis, which is the basis for the Upper Level and is of clinical concern, is rarely seen in Australia and New Zealand. Dental fluorosis has been associated with exposure from several sources, both individually or collectively, including fluoridated water, toothpaste, other dental products and supplement use. The prevalence of fluorosis is usually higher in fluoridated compared to non-fluoridated areas. There is no evidence of skeletal fluorosis that is attributable to water supply sources in Australia or New Zealand.

There is no evidence of any other adverse effects, such as cancer, from current levels of water fluoridation or dietary intakes in Australia or New Zealand.

The benefit of fluoridating water on dental caries needs to be weighed up with the occurrence of mild dental fluorosis. There appears to be a narrow margin between the amount of fluoride that is protective against dental caries and that which causes dental fluorosis. Water fluoridation is the most cost effective and socially equitable means of achieving broad exposure to the caries preventative benefits of fluoride. In order to decrease the prevalence of fluorosis, dental experts recommend that reducing exposures through sources such as dental products (toothpastes, mouth washes, dental gels) and supplements would have a greater impact compared to removing or lowering levels of water fluoridation. This would also retain the beneficial effect for the community on dental caries.

# CONTENTS

<b>SUMMARY .....</b>	<b>II</b>
<b>1. INTRODUCTION.....</b>	<b>1</b>
<b>2. NUTRITION RISK ASSESSMENT .....</b>	<b>1</b>
2.1 SCOPE OF ASSESSMENT .....	1
2.2 LITERATURE REVIEWED.....	1
<b>3. NUTRITIONAL EQUIVALENCE .....</b>	<b>2</b>
3.1 COMPOSITION OF RETICULATED AND PACKAGED WATER .....	2
3.1.1 Australian data.....	2
3.1.2 New Zealand data .....	4
3.2 FLUORIDE CONCENTRATIONS .....	4
3.3 EVALUATION OF NUTRITIONAL EQUIVALENCE .....	5
<b>4. PERMITTED FORMS .....</b>	<b>6</b>
<b>5. BIOAVAILABILITY .....</b>	<b>7</b>
5.1 BIOAVAILABILITY FROM FOOD AND WATER .....	7
5.2 BIOAVAILABILITY FROM DENTAL PRODUCTS AND SUPPLEMENTS .....	8
<b>6. HEALTH BENEFITS.....</b>	<b>8</b>
6.1 NUTRITIONAL ROLE FOR BONES .....	8
6.2 NUTRITIONAL ROLE FOR TEETH.....	8
6.2.1 Topical action of fluoride.....	10
6.2.2 Rates of dental caries.....	10
<b>7. HEALTH RISKS .....</b>	<b>17</b>
7.1 DENTAL FLUOROSIS .....	17
7.1.1 Rates of dental fluorosis.....	19
7.2 SKELETAL EFFECTS, INCLUDING FLUOROSIS.....	22
7.3 CANCER .....	23
7.4 VULNERABLE SUB-POPULATION GROUPS .....	23
7.4.1 Infants .....	23
7.4.2 Other at risk groups.....	24
7.5 OTHER HEALTH RISKS .....	24
7.6 CONCLUSION REGARDING HEALTH RISKS .....	24
<b>8. RISK VERSUS BENEFIT .....</b>	<b>24</b>
<b>9. CONCLUSION FROM THE NUTRITION RISK ASSESSMENT .....</b>	<b>26</b>
<b>REFERENCES.....</b>	<b>27</b>
<b>APPENDIX 1 – NEW ZEALAND DATA ON DENTAL CARIES FOR CHILDREN...31</b>	
<b>APPENDIX 2 – COMMON RATING SCALES FOR DENTAL FLUOROSIS .....</b>	<b>32</b>

## **1. INTRODUCTION**

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd on 23 August 2006 seeking to permit the voluntary addition of fluoride to packaged water. The Applicant requested permission for sodium fluoride, sodium fluorosilicate (also called sodium silicofluoride) and hydrofluorosilicic acid to be voluntarily added to packaged water to a level of between 0.6-1.0 mg fluoride/L. Current levels of water fluoridation in Australia and New Zealand range between 0.6 and 1.0 mg/L.

Fluoride is the ionic form of fluorine (F). Fluoride is ubiquitous in the environment and is a natural constituent of the body involved in the mineralisation of teeth and bones. About 99% of the body's fluoride is found in calcified tissues (such as bone and teeth), to which it is strongly but not irreversibly bound. This function is discussed later in this document.

## **2. NUTRITION RISK ASSESSMENT**

### **2.1 Scope of Assessment**

In accordance with the Ministerial Policy Guideline *Fortification of Foods with Vitamins and Minerals*, the application is being assessed on the basis of nutritional equivalence because fluoridated packaged water can be considered a substitute beverage for fluoridated reticulated (tap) water.

The purpose of the nutrition risk assessment is to establish if packaged water is nutritionally equivalent to fluoridated reticulated water. The bioavailability of the proposed permitted forms was also assessed. The benefits and risks associated with fluoride exposure were assessed in relation to rates and trends for dental caries and dental fluorosis and potential association with other conditions. This nutrition assessment does not examine all aspects of fluoride chemistry or biochemistry. FSANZ has not undertaken a nutritional risk assessment of fluoride added to food or beverages previously.

An assessment of the risks of fluoride (e.g. dental fluorosis) will be included to assist with the risk characterisation and to address concerns raised in submissions to the Initial Assessment Report. A brief evaluation of the benefits of fluoride on dental caries will also be included as this was raised in submissions. Other potential risks mentioned in submissions were also evaluated.

Food technology and safety considerations of adding fluoride to packaged water are discussed in the Draft Assessment Report and Supporting Document 4.

### **2.2 Literature Reviewed**

The nutrition assessment included consideration of the information provided by the Applicant in relation to nutritional issues but also had regard to other available information, including from the scientific literature, general technical information, key reports, position statements, independent scientists and experts, other regulatory agencies and international agencies and the general community. Information from reliable websites was also used.

Some relevant references included in submissions were also reviewed. The reference lists of the papers reviewed were assessed for further relevant information.

A literature search was conducted using the internet and in particular, PubMed. Topics searched included dental caries and fluorosis, bioavailability of fluoride and other adverse effects. The search for evidence for dental caries and fluorosis was primarily restricted to articles from Australia and New Zealand. However, international studies were reviewed where relevant. Dental experts in Australia and New Zealand also highlighted key papers for review.

The majority of the studies reviewed on dental evidence were cross sectional studies, with some case-control studies. Some systematic reviews on water fluoridation were also reviewed.

Many of the studies examining the evidence of dental caries and dental fluorosis had some limitations which included one or more of the following:

- no national data for Australia or New Zealand;
- reviewed different adverse effects;
- used different scales for rating adverse effects;
- the concentration of fluoride in the water the subjects have consumed and the level of dietary intake are not reported, not investigated or are unknown;
- participants move residence during their lives therefore have varying exposure to different levels of fluoride from water and the diet and different exposure times at different levels of intake; and
- were older studies prior to changes in dental policies in Australia.

The first limitation is partially accounted for by several studies being available for consideration for different areas of each country. The second and third limitations meant it was sometimes difficult to compare studies. Not knowing the fluoride intakes, and only knowing the fluoride content in the water, made it difficult to determine what levels of intake are directly associated with development of dental fluorosis. The age of the studies were considered and greater emphasis placed on more recent data when assessing current prevalence of dental caries and fluorosis.

### **3. NUTRITIONAL EQUIVALENCE**

This application is being assessed on the basis of nutritional equivalence. Nutritional equivalence in the context of this assessment is between fluoridated reticulated water and fluoridated packaged water. Similarities in nutrient content between packaged water and reticulated water in Australia and New Zealand, whether fluoridated or not, were assessed in order to determine their comparability as equivalent beverages. This included an evaluation of whether the contribution to the diet of other nutrients in water would be affected by substituting reticulated water with packaged water. FSANZ also considered the fluoride content of the waters.

#### **3.1 Composition of reticulated and packaged water**

##### **3.1.1 Australian data**

The current publicly available food composition data for Australia, NUTTAB 2006, contains information on the nutritional composition of both 'tap' and 'bottled' water. This information is shown in Table 1 excluding fluoride.

**Table 1: The nutritional composition of tap and bottled water in Australia**

Nutrient	Value per 100 g	
	Tap water	Bottled water
Energy	0 kJ	0 kJ
Moisture	100 g	100 g
Nitrogen	0 g	0 g
Protein	0 g	0 g
Fat*	0 g	0 g
Sugars, total	0 g	0 g
Starch	0 g	0 g
Total dietary fibre	0 g	0 g
Alcohol	0 g	0 g
Calcium	1 mg	1 mg
Iodine	<b>0.7 µg</b>	<b>0.2 µg</b>
Iron	0 mg	0 mg
Magnesium	<b>1 mg</b>	<b>5 mg</b>
Phosphorus	0 mg	0 mg
Potassium	0 mg	0 mg
Sodium	<b>0 mg</b>	<b>1 mg</b>
Thiamin	0 mg	0 mg
Riboflavin	0 mg	0 mg
Niacin	0 mg	0 mg
Niacin derived from Tryptophan or Protein	0 mg	0 mg
Niacin equivalents	0 mg	0 mg
Folate	0 µg	0 µg
Dietary Folate Equivalents	0 µg	0 µg
Vitamin C	0 mg	0 mg
Beta Carotene	0 µg	0 µg
Beta Carotene Equivalents	0 µg	0 µg
Retinol	0 µg	0 µg
Retinol Equivalents	0 µg	0 µg
Alpha Tocopherol	0 mg	0 mg
Vitamin E	0 mg	0 mg

Source: (FSANZ, 2006)

Notes: kJ = kilojoules, g = grams, mg = milligrams, µg = micrograms

\* All lipids when reported separately, including saturated, monounsaturated, polyunsaturated, cholesterol, long chain Omega 3 etc, were also all zero concentrations.

Only nutrients where the information was available for both types of water have been included in the table. The composition data for manganese was left out of the table due to the unreliability of the data (as indicated by the FSANZ food composition team). The values represent average, or the most likely values, as natural variation occurs in the range of tap and bottled waters available for consumption.

Only three nutrients (shown in bold in the Table) had a slightly different concentration between 'tap' and 'bottled' water. These nutrients were iodine, magnesium and sodium.

### 3.1.2 New Zealand data

The latest publically available nutrient composition data for New Zealand (Athar *et al.*, 2006) were also used to assess the nutritional equivalence of ‘tap’ water compared to ‘bottled’ water. Table 2 shows the nutrient profile for these two waters for nutrients other than fluoride. Only one nutrient (shown in bold in the Table) showed a slight difference in concentration between ‘tap’ and ‘bottled’ water, which was sodium.

**Table 2: The nutritional composition of tap and bottled water in New Zealand**

Nutrient	Value per 100 g	
	Tap water	Bottled water
Energy	0 kJ	0 kJ
Water	100 g	100 g
Protein	0 g	0 g
Fat*	0 g	0 g
Sugars, total	0 g	0 g
Starch	0 g	0 g
Total dietary fibre	0 g	0 g
Calcium	2 mg	2 mg
Iron	Trace	Trace
Potassium	2 mg	Trace
Selenium	Trace	Trace
Sodium	<b>1 mg</b>	<b>3 mg</b>
Zinc	0 mg	Trace
Thiamin	0 mg	0 mg
Riboflavin	0 mg	0 mg
Total Niacin Equivalents	0 mg	0 mg
Folate, Total	0 µg	0 µg
Vitamin B6	0 mg	0 mg
Vitamin B12	0 µg	0 µg
Vitamin C	0 mg	0 mg
Beta Carotene Equivalents	0 µg	0 µg
Total Vitamin A Equivalents	0 µg	0 µg

Source: (Athar *et al.*, 2006)

Notes: kJ = kilojoules, g = grams, mg = milligrams, µg = micrograms

\* All lipids when reported separately, including saturated, monounsaturated, polyunsaturated, cholesterol, were also all zero concentrations.

### 3.2 Fluoride concentrations

At present, packaged water is not permitted to contain added fluoride. A recent analytical survey (Cochrane *et al.*, 2006) assessed nine brands of packaged spring and filtered water in Australia and determined that all brands had fluoride concentrations of below 0.08 mg/L.

The mean fluoride content in reticulated water supplies in Australia are between 0.6-1.0 mg/L in fluoridated areas, with lower levels in some places in the Northern Territory at around 0.5 mg/L. These data correspond with the target range in the National Health and Medical Research Council (NHMRC) Public Statement (NHMRC, 2007a) on water fluoridation of 0.6-1.1 mg/litre. Actual concentrations of fluoride in reticulated water in New Zealand averages around 0.8-0.9 mg/L in fluoridated areas (Water Care Services Limited, 2007).

This corresponds with the target range in *Drinking-water standards for New Zealand 2005* of 0.7–1.0 mg/L (Ministry of Health, 2005).

### 3.3 Evaluation of nutritional equivalence

The macronutrient content is equivalent between the two types of waters with zero concentrations for energy, fat, protein, carbohydrates, fibre and alcohol. This is also the case for a range of vitamins which also have zero concentrations.

There are some very minor differences between some minerals in ‘tap’ compared to ‘bottled’ water as outlined above. This is expected given the natural variation of nutrients in foods, beverages and water. The natural variation in mineral content in water can be influenced by time of year, the region where the product originated and any effects of processing. Variation in reported nutrient content can also be attributable to the analytical method used to measure mineral levels. In relation to differences in the concentration of iodine for example, the area from which the water was collected can strongly influence the concentrations in water, therefore, this variation could be attributed to the different sources of the samples.

While there are minor differences for the small number of minerals indicated, the results are still similar and generally in the same order of magnitude. Therefore, the intake of these minerals would not be expected to differ considerably as a result of substituting reticulated water with packaged water. To demonstrate this, a simple calculation to determine the variation in dietary intake was undertaken based on a mean consumption of water. The estimated intake was compared to the Recommended Dietary Intake (RDI) or Adequate Intake (AI) to determine if the variation in nutrient intakes due to the different concentrations would be important considering normal daily dietary requirements (see Table 3). For magnesium for example, the estimated intakes from both ‘tap’ and ‘bottled’ water are well within the RDI for adults of 310-420 mg/day (NHMRC and NZ MoH, 2006). This is also seen with the other nutrients

**Table 3: Estimated variation in intake of certain minerals for adults aged 19 years and over for tap and bottled water based**

Country	Mineral	Concentration (units/100 mL)		Intake (units/day) <sup>#</sup>		RDI* (units/day)	AI** (units/day)
		Tap	Bottled	Tap	Bottled		
Australia	Iodine	0.7 µg	0.2 µg	6.0 µg	1.7 µg	150 µg	
	Magnesium	1 mg	5 mg	8.5 mg	42.5 mg	310-420 mg	
	Sodium	0 mg	1 mg	0 mg	8.5 mg		460-920 mg
New Zealand	Sodium	1 mg	3 mg	8.5 mg	25.5 mg		460-920 mg

<sup>#</sup> Based on mean consumption of 850 ml/per person/day for *Mineral Waters and Water* aged 19 years and over from the 1995 Australian National Nutrition Survey (McLennan and Podger, 1999).

\* Range for magnesium is females to males.

\*\*Range for sodium is the range for both males and females.

Overall it is considered by FSANZ that the variation in mineral content from either type of water would be well within daily variation in dietary intake. Additionally, over time, different sources of water would be consumed with varying levels of the same minerals which would average out to similar dietary intakes over time.

The forms of fluoride requested to be added to packaged water by the Applicant are the same as those added to fluoridated reticulated water, therefore reticulated and packaged water would be nutritionally equivalent in relation in this respect.

FSANZ concludes that packaged water which does not have added fluoride is nutritionally equivalent to non-fluoridated reticulated water. Should packaged water be permitted to contain between 0.6 to 1.0 mg/L of fluoride, then it would be nutritionally equivalent to fluoridated reticulated water supplies in Australian and New Zealand.

#### **4. PERMITTED FORMS**

The requested permitted forms of fluoride are commonly used for fortifying water and dental products.

The Applicant is seeking permission to voluntarily add sodium fluoride (NaF), sodium fluorosilicate ( $\text{Na}_2\text{SiF}_6$ ) (also called sodium silicofluoride) and hydrofluorosilicic acid ( $\text{H}_2\text{SiF}_6$ ) to packaged water. The Applicant indicated that these forms of fluoride are the same as those added to fluoridated tap water.

There are currently no permitted forms of fluoride specified in the Schedule to Standard 1.1.1 in the Food Standards Code (the Code) where permissions to add vitamins and minerals are specified.

Several forms of fluoride are permitted in Standard 1.3.3 – Processing Aids in packaged water and in water used as an ingredient in other foods. This is to account for reticulated water supplies being used in the manufacturing of processed foods and beverages. The Table to Clause 11 specifies that the maximum permitted amount of sodium fluoride or sodium fluorosilicate (sodium silicofluoride) that may be present in packaged water or in water used in manufacturing is 1.5 mg/kg (1.5 mg/L) and hydrofluorosilicic acid is permitted to Good Manufacturing Practice (GMP).

The three requested permitted forms of fluoride are used commonly internationally for fluoridating drinking water (World Health Organization, 2002). The Australian Drinking Water Guidelines (NHMRC and NRMCC, 2004) permits the use of both sodium fluoride and sodium fluorosilicate for the purposes of fluoridation. Both of these forms are commonly used for fluoridating water in Australia and New Zealand, and have been used for over 50 years (NHMRC, 2007b), though sodium fluoride is used less commonly. Hydrofluorosilicic acid is also permitted and used for this purpose. These three forms are also used in New Zealand for water fluoridation (Ministry of Health, 2007). Sodium fluoride (a colourless to white solid) and sodium silicofluoride (a colourless solid) are moderately soluble in water, whereas fluorosilicic acid (a colourless solid) is highly soluble in water (World Health Organization, 2002).

There are several forms used in toothpastes available in the current market in Australia and New Zealand. These are sodium fluoride, sodium monofluorophosphate and stannous fluoride. Concentrations in toothpastes (around 1000 mg/kg fluoride for adult toothpastes and between 400-500 mg/kg for child toothpastes) are well above levels found in food and fluoridated water (up to around 1.0 mg/litre).

Commonly available mouthwashes contain sodium fluoride with concentrations of fluoride between 200 and 1000 mg/kg.

Professional products including dental solutions and gels use sodium fluoride and hydrofluoric acid. Concentrations in these products can be up to 24,000 mg/kg (NHMRC, 2007b).

Fluoride is used in supplements that come in tablets or drops. Chewable fluoride tablets use sodium fluoride and contain 0.25 mg fluoride per tablet.

## **5. BIOAVAILABILITY**

The bioavailability of fluoride, particularly of the requested permitted forms in drinking water, was evaluated. Some submitters at Initial Assessment suggested that different forms have different bioavailabilities.

### **5.1 Bioavailability from food and water**

Fluoride is absorbed by the body by passive diffusion, primarily from the stomach (the mechanism and rate of which is affected by gastric acidity) and the intestine (World Health Organization, 2002). Fifty per cent of orally ingested fluoride is absorbed from the gastrointestinal tract after approximately 30 minutes. Fluoride binds to calcium, magnesium, aluminium, iron and other cations forming insoluble and poorly absorbed compounds, therefore reducing its bioavailability (Institute of Medicine, 1997; NHMRC and NZ MoH, 2006). In the absence of calcium and other cations, absorption may be as high as 80% (Institute of Medicine, 1997). If fluoride is ingested with milk, infant formula or solid foods the bioavailability may be reduced to 10 to 25% (Institute of Medicine, 1997; NHMRC, 2007b). However, the bioavailability would not be expected to differ from infant formula prepared using fluoridated reticulated water compared to fluoridated packaged water.

The addition of fluoride to water supplies has been used as a public health measure in part due to the high bioavailability of fluoride obtained from this source.

Water soluble forms of fluoride such as sodium fluoride and fluorosilicic acid, which are both used for water fluoridation, are nearly completely absorbed from the intestine and utilised by the human body (World Health Organization, 2002; Maguire *et al.*, 2005; NHMRC and NZ MoH, 2006).

Less soluble forms of fluoride (e.g. calcium fluoride, magnesium fluoride and aluminium fluoride) are poorly absorbed (World Health Organization, 2002), however, these forms are not usually added to drinking water.

Children tend to absorb more fluoride due to development of the skeleton and teeth, with around 90% of ingested fluoride being absorbed (World Health Organization, 2002). Children may retain up to 80% of fluoride ingested, whereas young and middle aged adults may retain only 50% (Institute of Medicine, 1997).

In terms of chemistry and bioavailability, there is no difference between added and naturally occurring fluoride in drinking water and the effect of cations (calcium, magnesium) in water, even packaged water, on the bioavailability is very small (Jackson *et al.*, 2002). These were *in vitro* studies. Maguire *et al* (2005) conducted a human study using naturally and artificially fluoridated water with fluoride close to 1 mg/Litre, and a reference water.

There were no statistically significant differences in absorption between the naturally versus artificially fluoridated or reference water. There was more difference between and within individual subjects.

The 'hardness' of the water is characterised by the amount of calcium and magnesium in the water. The higher the levels of these elements, the harder the water. It has been found that the hardness of the water does not affect the bioavailability of the fluoride (Jackson *et al.*, 2002; Maguire *et al.*, 2005).

The evidence suggesting caffeine increases the bioavailability of fluoride is contradictory (Institute of Medicine, 1997).

In conclusion, the requested forms of fluoride are highly bioavailable when added to drinking water.

## **5.2 Bioavailability from dental products and supplements**

If toothpaste is ingested, whether it contains sodium monofluorophosphate or sodium fluoride, the fluoride is almost 100% absorbed (Institute of Medicine, 1997; Riordan, 2002). Sodium fluoride from tablets is rapidly absorbed as is fluoride from other dental products if swallowed, however if supplements are taken with milk or food, the bioavailability is decreased by around 30-40% (World Health Organization, 2002).

## **6. HEALTH BENEFITS**

This application is being assessed on nutritional equivalence, not in relation to health benefit. However fluoride is well recognised for its dental health benefits in relation to preventing dental caries. In requesting permission for the addition of fluoride to packaged water, the Applicant touched on a number of public health issues relating to the population intake of fluoride and methods for maintaining dental health through sufficient access to fluoride. Additionally, submissions to the Initial Assessment Report commented on this health benefit of fluoride. This issue is discussed briefly below however, as the benefits of fluoride on dental caries have long been recognised (WHO, 2002; NHMRC, 2007b, Fawell *et al.*, 2006), a full assessment of the benefit will not be considered in detail.

### **6.1 Nutritional role for bones**

Fluoride has the ability to stimulate the formation of new bone (Institute of Medicine, 1997). As with teeth, an increased fluoride intake has the potential to improve the structural integrity of bone through the promotion of bone mineralisation. However the evidence on the relationship between fluoride intake and bone mineral density is too variable to demonstrate any positive health outcome (NHMRC, 1999).

### **6.2 Nutritional role for teeth**

Dental caries is a condition defined as a destructive process causing decalcification of the tooth enamel and leading to continued destruction of enamel and dentin, and cavity formation in the tooth (W.B. Saunders Company, 1995).

Dental caries begin when some of the enamel is destroyed by acid. The acid is produced by bacteria that grow on the surfaces of teeth to form plaque. When teeth are exposed to foods or drinks containing sugars, the bacteria rapidly convert some of the sugars into acid. The plaque can hold the acid in contact with the tooth surface for up to two hours before it is neutralised by saliva. Acid exposure causes a loss of calcium and phosphate minerals from the tooth surface (demineralisation). Once the plaque acids have been neutralised the minerals can return to enamel via the saliva (remineralisation).

Fluoride intake is a significant factor in the maintenance of dental health, as it not only maintains tooth integrity but prevents tooth deterioration. Fluoride protects tooth enamel by:

- promoting repair of early damage to teeth;
- improving the chemical structure of tooth enamel making it more resistant to acid attack; and
- reducing the ability of plaque to produce acid.

The relationship between fluoride intake and dental caries is an inverse one (Institute of Medicine, 1997). However, as dental caries is a multi-factorial condition, an increase in fluoride intake by itself may not necessarily prevent dental caries formation. For example, prolonged exposure to dietary sugars and starches may also have an impact, as can many factors that affect saliva quality such as smoking, substance abuse, some medications, ageing and radiation therapy (Australian Dental Association, 2007).

Some submissions stated that there is insufficient evidence to suggest a benefit from fluoride. However, there is a very large body of evidence demonstrating that increased fluoride intake can decrease the prevalence of dental caries. The World Health Organization has classified the strength of this evidence as ‘convincing’ (World Health Organization, 2003). Water fluoridation and its contribution to the reduction of dental caries has also been described as one of the top 10 best public health measures in the United States in the twentieth century (Centres for Disease Control and Prevention, 1999). There are many studies from Australia and New Zealand in the published literature showing lower rates of dental caries in areas where water is fluoridated. Some of these studies are outlined below.

Due to its role in dental health, fluoride is considered an essential nutrient by the NHMRC and the New Zealand Ministry of Health (NZMoH) (NHMRC and NZ MoH, 2006).

Due to the low natural level of fluoride in some water supplies and high levels of dental caries, many authorities world wide, including Australia and New Zealand, have permitted fluoridation of water supplies (World Health Organization, 2003). The aim of water fluoridation is the adjustment of the natural fluoride concentration in fluoride-deficient water to that recommended for optimal dental health (NHMRC and NZ MoH, 2006).

The NHMRC state the optimal level for Australia is between 0.6 mg/L and 1.1 mg/L (NHMRC, 2007a) where as the NZMoH recommend between 0.7 mg/L to 1.0 mg/L (Ministry of Health, 2005). The American Dental Association reports that the optimal level of water fluoridation for preventing tooth decay is 0.7-1.2 mg/L. The ADA state that the optimal level will normally be in the range of 0.5 to 1.0 mg/L, however, this should take into account climactic conditions. In hotter climates, more water may be consumed, therefore a lower level of fluoridation may be appropriate.

### **6.2.1 Topical action of fluoride**

There are some conflicting views regarding the timing of fluoride exposure (i.e. before or after tooth eruption) on the beneficial effect on dental caries. Review articles have attributed the anticariogenic effects of fluoride to be mostly topical, however, a pre-eruptive role continues to be suggested. Products such as toothpastes are designed to provide post-eruptive exposure to fluoride through a topical action (Singh *et al.*, 2003).

Some reports indicate that there is convincing evidence that both locally applied (i.e. direct contact with teeth) and systemic fluoride (from fluoride that has been ingested) prevent dental caries (World Health Organization, 2003; Singh *et al.*, 2003). Systemic fluoride from birth is thought to build fluoride ions directly into the developing enamel (Singh *et al.*, 2003). Early exposure to fluoride, during the pre-eruptive stage, can protect the newly erupting deciduous teeth (Institute of Medicine, 1997; Do and Spencer, 2007b). There is also a beneficial post eruptive effect from fluoride contained in saliva and dental plaque due to reduced acid production by plaque bacteria and increased mineralisation (Institute of Medicine, 1997). The Australian Dental Association Inc (ADA) report that the effect of fluoride added to water is predominantly topical, with some systemic influence in children (Australian Dental Association Inc, 2007).

An Australian study (Singh *et al.*, 2003) examined the topical effects of water fluoridation on caries in permanent molars of children aged 6-15 years. Subjects were classified into groups according to the proportion of their life exposures to different levels of water fluoridation and the level of exposure both pre- and post tooth eruption. There was an exposure-response relationship that showed significantly lower level of dental caries among the groups that had the highest pre-eruption exposure. Exposure to fluoridated water post-eruption did not result in significantly lower rates of dental caries, which was the case for pre-exposure alone. The most preventative effect was shown by both pre- and post-eruption exposure.

### **6.2.2 Rates of dental caries**

Dental caries are often categorised or analysed collectively and are given a 'dmft' (decayed, missing and filled teeth) score (sometimes referred to as 'dmfs' (decayed, missing and filled surfaces)). The acronym is usually lower case when referring to deciduous (baby or first) teeth and upper case when referring to permanent (adult or second) teeth. This score represents a person's dental caries experience over a lifetime. Another good measure of oral health status is the percent of a population group that is caries free. It is recognised that if there are dental caries in deciduous teeth, the person is more likely to get dental caries in permanent teeth (Broadbent *et al.*, 2005).

The evidence for the rates and trends of dental caries in Australia and New Zealand were reviewed. This information is described below.

#### **6.2.2.1 Adults**

The overall trend for adults is that the prevalence of dental caries is lower now compared to decades ago.

The 2004-2006 National Survey of Adult Oral Health in Australia assessed 15-97 year olds by interview (n=14123) and dental examination (n=5505). Over 95% of the population born before 1970 had dental decay, whereas for those born after 1970 only 76% had dental decay. Across all adults, the DMFT was 12.8. This was lower for the 1970-1990 generation at 4.5 compared to the pre-1930s generation at 24.3 (Roberts-Thomson and Do, 2007). In 1973 the DMFT for adults 35-44 years was 19 (Spencer *et al.*, 1996).

Trends in caries were also examined between the 2004-06 survey and the 1987-88 national survey (Slade and Sanders, 2007). On a national basis across all ages, the DMFT decreased by 16% in the 17 years between the surveys from 14.9 DMFT in 1987-88. This reduction was influenced by the passing of older generations who had poorer dental health with higher rates of decay and tooth loss, and the emergence of the 'fluoride generation' with access to fluoridated water and toothpaste. Those born after the introduction of fluoridation had half the dental caries of those of the same age born pre-fluoridation (Spencer *et al.*, 2007).

A study on oral health specifically in South Australia (Ellershaw *et al.*, 2005) assessed the prevalence of dental caries in young adults (20-24 years). The survey showed that oral health deteriorates significantly after leaving school and the School Dental Service. Young adults have an average of 3.68 decayed teeth. Only one in five were free of decay.

National oral health surveys were conducted in New Zealand in 1976 and 1988, however the results from these surveys are not publicly available. A national oral health survey is planned for New Zealand for 2008 which will include both adults and children (NZ MoH, 2008). One study stated that dental caries in New Zealand have decreased over the 40 years prior to the late 1990's (de Liefde, 1998).

As adults get older, their dental health deteriorates and there is an increase in caries (Thomson, 2004; Broadbent *et al.*, 2006). From the Australian Adult Oral Health Study, when assessing the same population group between 1987-88 and 2004-06, dental decay increased for both those born after the 1930's and for those in the 'fluoride generation'. For example, for those born between 1916-32 the DMFT was 22.9 in 1987-88 and 24.3 in 2004-06 and for those born 1967-83 the DMFT was 2.5 in 1987-88 and 6.4 in 2004-06. These data show the success of water fluoridation on the generation exposed who had lower rates of dental caries into adulthood. One New Zealand study (Broadbent *et al.*, 2006) showed that for the same cohort at age 26, 94.9% had dental caries and at 32 years, 96.8% had caries. Tooth loss was also higher at the older age.

#### **6.2.2.2 Children**

The data reviewed for Australian children indicate that the prevalence of dental caries is increasing. This is also the case for younger children in New Zealand. The data are summarised in Table 4.

The prevalence of dental caries in Australian children decreased until about the mid-1990's after which it increased. An annual Child Dental Health Survey is conducted in Australia by the Australian Institute of Health and Welfare (AIHW) Dental Statistics and Research Unit (DSRU), which is located in the Australian Research Centre for Population Oral Health (ARCPOH) at the University of Adelaide. The latest data from 2002 (which exclude NSW due to methodological reasons) show that around half of the six year olds and 40% of 12 year olds had some experience of dental decay.

The mean dmft for 5-12 year olds was 1.68 with and the mean DMFT was 0.49. The proportion of 5-12 year olds who were caries free was 60%. Children from Queensland had the highest decay experience in deciduous teeth, while for permanent teeth it was Tasmania (Australian Institute of Health and Welfare, 2007). Higher rates of caries in Queensland can be attributed to a greater proportion of residents in the state not having access to fluoridated water.

A national time series shows that there has been an increase in dental caries among children since 1996 for deciduous teeth and since 1998/99 for permanent teeth (see Figure 1). The data are adjusted for under-reporting in the NSW data which occurred between 1996-2000 due to changes in the methodology used to obtain the data.

Other studies have shown that between 1977 and 1998 dmft scores decreased in Australian children from over three in deciduous teeth to around 1.6 and DMFT scores from 4.8 to 0.89 respectively (Armfield and Spencer, 2008). Low rates of caries (DMFT 0.13) in the 1990/1991 study of Perth children can be attributed to the majority of children having lived in fluoridated areas and the short time since the eruption of the teeth examined (Riordan, 1993).

A study on oral health specifically in South Australia (Ellershaw *et al.*, 2005) has also highlighted the increase in dental caries in children since the late 1990's. For example, 6-7 year olds had an average of 1.44 decayed deciduous teeth in 1999 and 1.83 in 2002. For children aged 14-15 years, there was an average of 1.12 decayed permanent teeth in 1999 and 1.53 in 2000.

Socioeconomic status has been shown to have an impact on caries experience. Children from lower socioeconomic backgrounds have a significantly higher incidence of dental caries for both fluoridated and non-fluoridated areas, however, this was not as strong in permanent dentition (11-12 year olds) compared to deciduous dentition (5-6 year olds) (Armfield, 2005).

**Table 4: Summary of data for the prevalence of dental caries in Children**

Year	dmft/DMFT	%Caries free	Region	Age (years)	Fluoridation (mg/L in the water)	Study
2002	dmft 1.68 DMFT 0.49	60	Australia, National (excluding NSW)	5-12		AIHW, 2007
2002	dmft 1.83 DMFT 1.53		South Australia	dmft 6-7	NS	Ellershaw <i>et al.</i> , 2005
1999	dmft 1.44 DMFT 1.12			DMFT 14-15		
2002	dmfs 4.4 DMFS 1.05  F area dmfs 3.42 DMFT 0.70  Non-F area dmfs 5.11 DMFT 1.22	Deciduous 33 Permanent 57	Southland, New Zealand	Mean 9.8		Mackay & Thomson, 2005

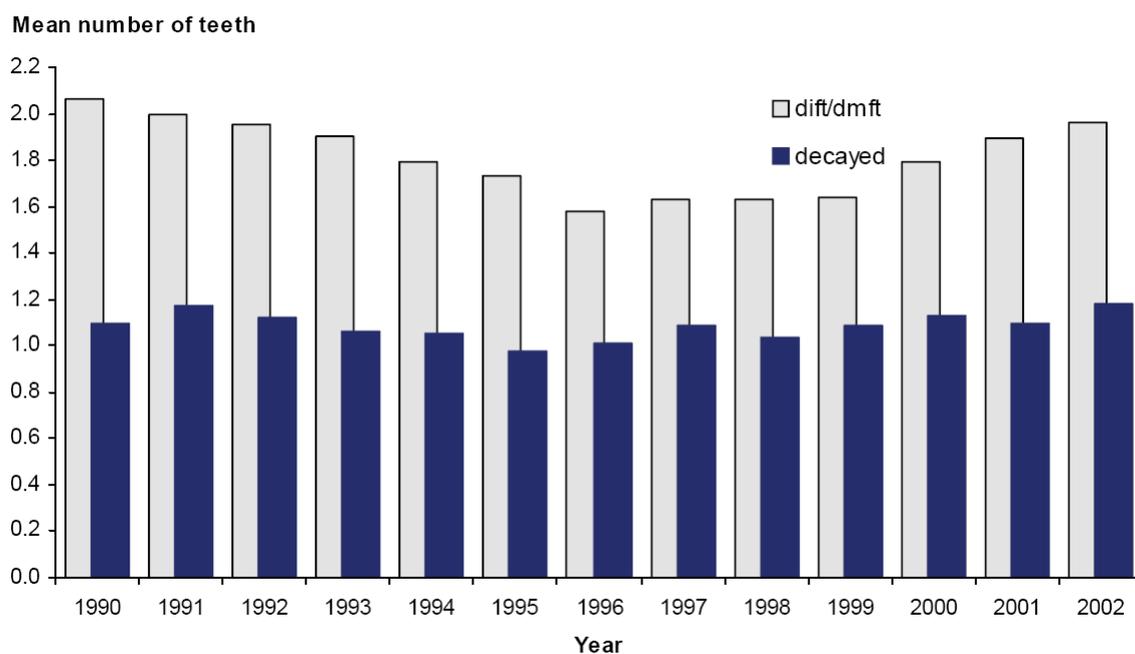
Year	dmft/DMFT	% Caries free	Region	Age (years)	Fluoridation (mg/L in the water)	Study
2000	DMFT 0.3 overall DMFT 0.31 F area DMFT 0.28 NF area	83*	Perth, Bunbury, WA	10	F area 0.85 NF area 0.2-0.3	Riordan, 2002
1998	dmft 1.6 DMFT 0.89		Australia			Armfield & Spencer, 2008
1977	dmft >3 DMFT 4.8					
1996	F area dmfs 2.63 NonF area dmfs 3.8  F area DMFS 1.39 NonF area dmfs 2.37		New Zealand	5 12		Lee & Dennison, 2004
1990/ 1991	DMFT 0.13	90	Perth, WA	7 years		Riordan, 1993
1989/ 1990	DMFT 0.89 F area DMFT 1.57 NF area		Perth, Bunbury, WA	12	F area 0.85 NF area 0.2-0.3	Riordan, 2002

Notes: F area = fluoridated area 0.8-0.85 mg/L, NF area = non-fluoridated area <0.2-0.3 mg/L.

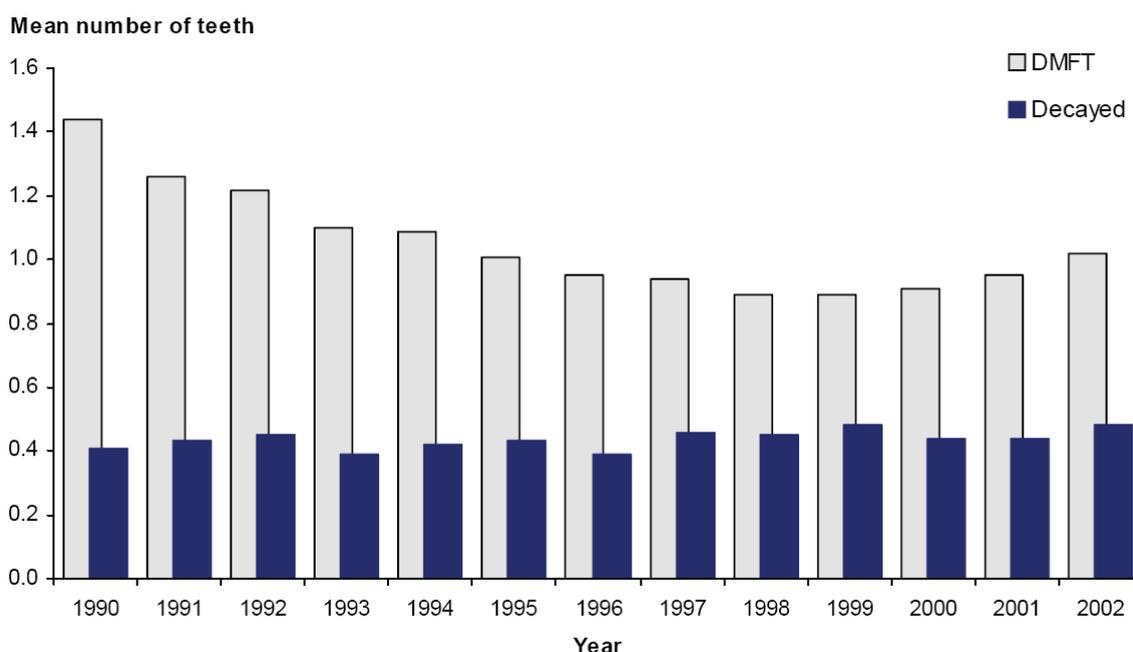
\* No significant different between fluoridated and non-fluoridated areas.

NS = not specified.

### a. 6 year old children



## b. 12 year old children



Source: (Armfield *et al.*, 2007)

\* Adjusted for under-reporting in NSW between 1996-2000.

Figure 1: Decay experience in Australian children 1990-2002\*

It has also been shown that children living in rural and remote areas have a higher prevalence of caries and higher mean dmft/DMFT scores (AIHW Dental Statistics and Research Unit, 2006). The results are shown in Table 5. About 8-12% less children from metropolitan areas had dental caries experience in deciduous teeth. This was also the case for permanent teeth for 9 year olds and above. This trend remained the same after also adjusting for socioeconomic status.

**Table 5: Dental caries (dmft/DMFT) rates for children living in urban and rural areas**

Age (years)	Measure	Metropolitan	Rural	Remote
5-6	dmft	1.53	2.14	2.31
7-8	dmft	1.80	2.54	2.51
11-12	DMFT	0.65	0.84	0.85
13-14	DMFT	1.11	1.40	1.28

Source: (AIHW Dental Statistics and Research Unit, 2006)

A summary of data for New Zealand children from the School Dental Service (Ministry of Health, 2008) are provided in Figure 2 (and Table 1 in Appendix 1). The data for the 5 year olds show a slight increase in both the dmft and percent caries free parameters between 1990 and 2006. Over the last 10 years of data examined there appears to be an increase in the dmft and decrease in the proportion who are caries free. The data show that for 12 year olds, the DMFT has decreased between 1990 and 2006, while the proportion who are caries free has slightly increased. Both parameters for 12 year olds appear to have remained relatively stable over the last 10 years examined. These data are descriptive data only and have not been corrected for any factors (e.g. area of fluoridation, socioeconomic status etc) or statistically adjusted.

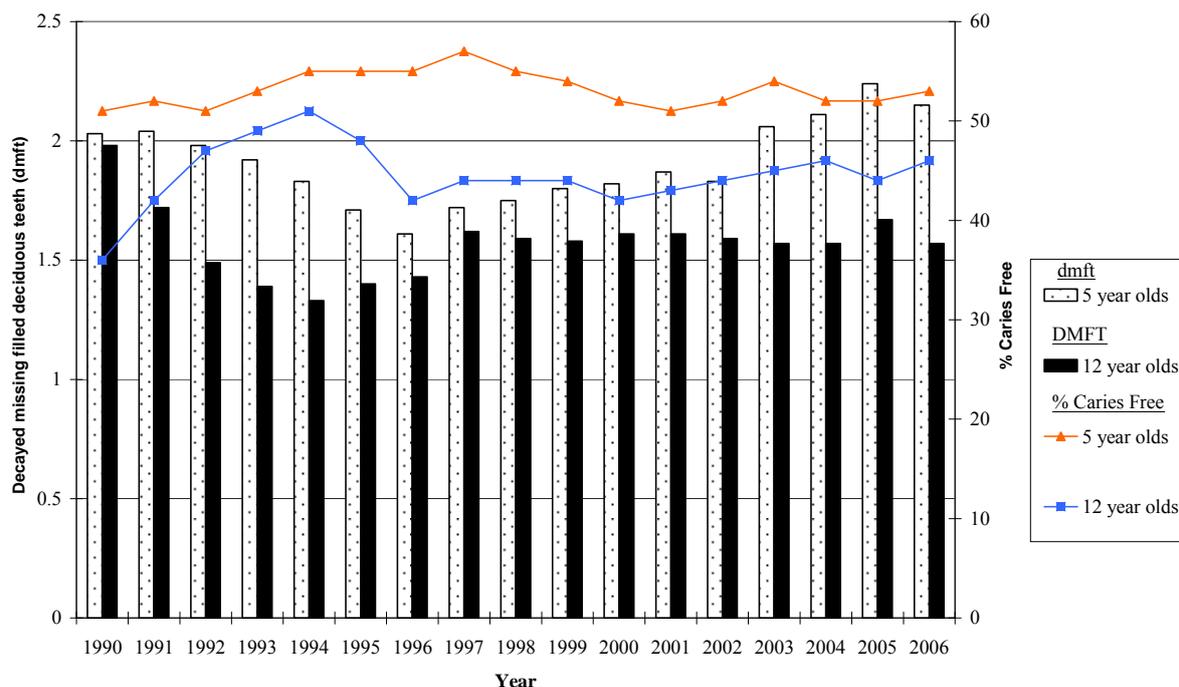


Figure 2: Dental Caries in New Zealand Children from School Dental Service data 1990-2006

Other data from New Zealand indicate that two thirds of Southland children in 2002 had caries in deciduous teeth with a mean dmfs of 4.4 (Mackay and Thomson, 2005).

Possible explanations for the rise in dental caries in children include the availability of lower fluoride toothpastes for children, increased consumption of bottled and rain water, a reduction in the number of fissure sealants and changes in the diets of children in relation to sugar and fermentable carbohydrate intake (Ellershaw *et al.*, 2005; Draper *et al.*, 2005).

### 6.2.2.3 Difference between fluoridated and non-fluoridated areas

It has been shown that children with exposure to fluoridated water have a lower prevalence of dental caries.

On a national basis, data from 2002 (Armfield *et al.*, 2007) show that children from areas with negligible fluoride in the water had poorer dental health (higher dmft/DMFT scores). This is shown in Figure 3. This difference remained when assessed by residential location and socioeconomic status.

A number of studies in Australia were reviewed assessing the difference in the rates of dental caries between fluoridated and non-fluoridated areas (Spencer *et al.*, 1996), including a study in Tamworth that evaluated dental caries before and after the implementation of water fluoridation. All studies showed a lower prevalence of caries due to water fluoridation.

One study on South Australian children (Armfield and Spencer, 2004) showed use of non-public water supplies (from bottles or rain water tanks) resulted in a significantly higher rate of dental caries in deciduous teeth but not permanent teeth. Another study on South Australian children (Do and Spencer, 2007b) evaluated rates of dental caries based on history of exposure to fluoridated water and toothpaste use.

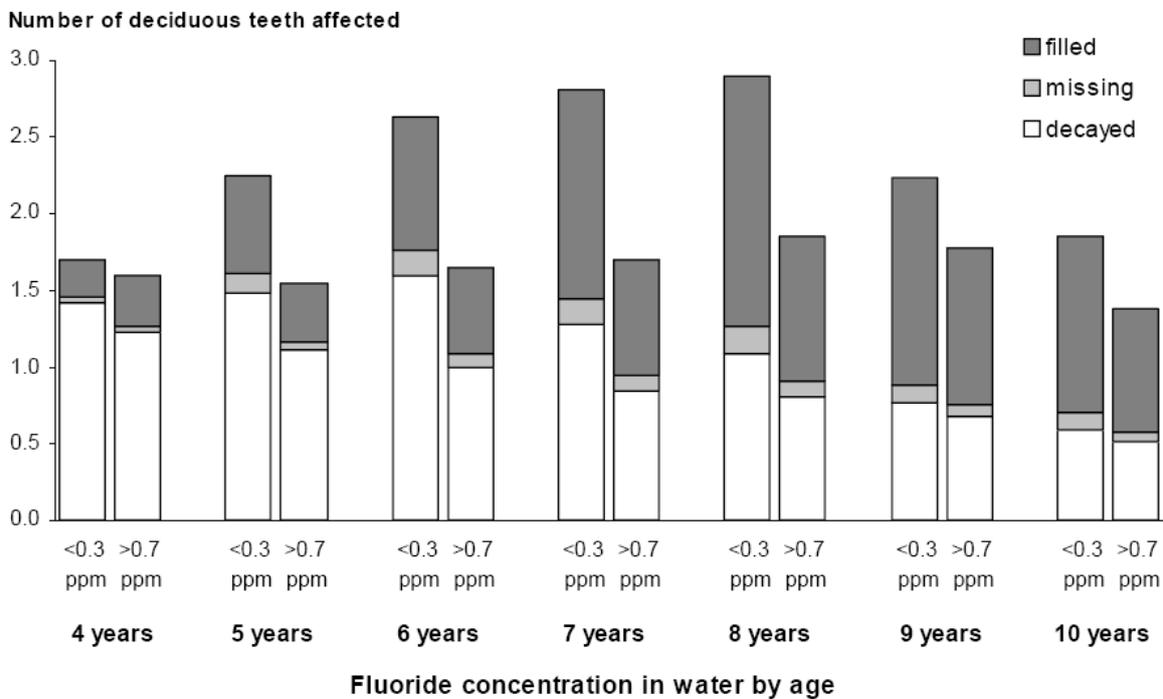
The authors found that subjects with no exposure to fluoridated water had significantly higher rates of dental caries. Commencing toothbrushing after 30 months of age was significantly associated with higher prevalence and severity of dental caries. The use of children's toothpaste (i.e. 400-500 ppm fluoride), swallowing brushing slurry and eating/licking toothpaste were not significantly associated with a lower rates of dental caries.

A study in South East Queensland (Teo *et al.*, 1997) showed mean DMFS were significantly lower in subjects who had fluoride from water in the first 12 years of life (14%) or those who had fluoride supplements (8%) compared to those with no form of fluoride (25%).

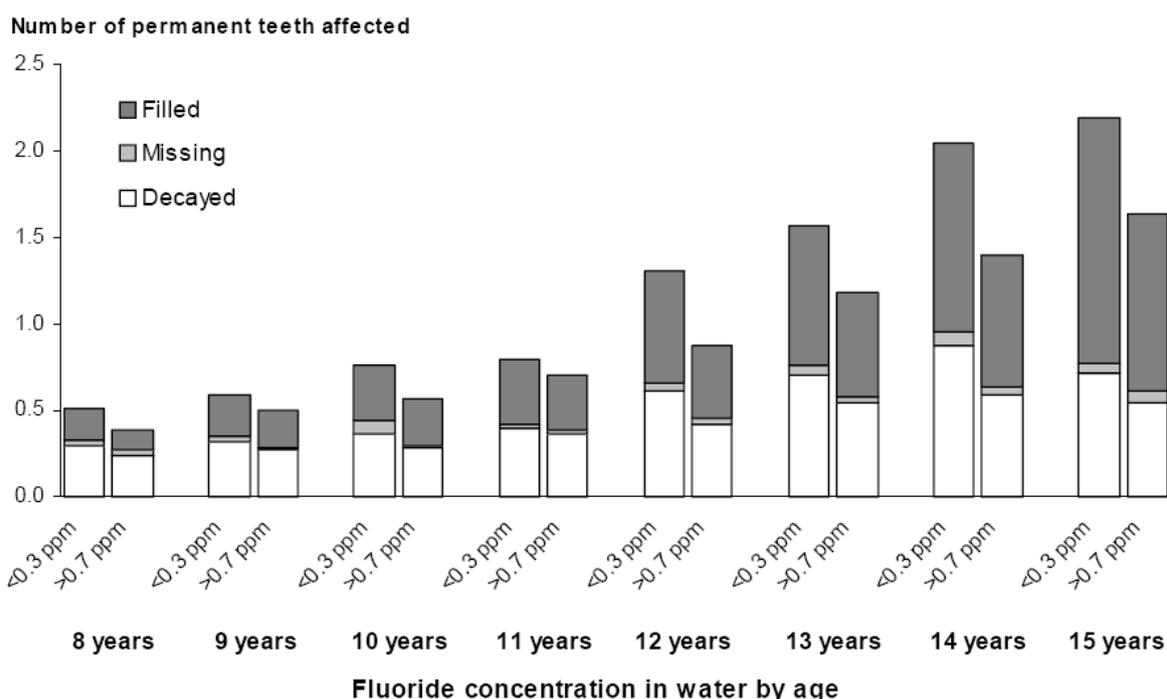
The difference in dental caries between fluoridated and non-fluoridated areas has been assessed for NSW children (Armfield, 2005). For 5-6 year olds, there were significantly higher dmft scores in six of the eight Area Health Service regions assessed. In only two regions were the dmft scores higher for fluoridated areas, but these differences were not significant. The same trend was seen for DMFT scores for 11-12 year olds where six of the 10 regions had higher scores in non-fluoridated areas and where this was the opposite, the results were again not significant.

A study on New Zealand children (Lee and Dennison, 2004) showed that caries were more prevalent in an area with no water fluoridation (Wellington) compared to an area with fluoridation (Canterbury). Five year olds in a fluoridated area had a dmfs of 2.63, and in a non-fluoridated area it was 3.8. Twelve year olds had a DMFS of 1.39 if a fluoridated area and a DMFS of 2.37 in a non-fluoridated area. Macaky and Thomson (2005) also showed this with a study in Southland children, with higher caries in non-fluoridated areas (dmfs 5.11; DMFT 1.22) compared to fluoridated areas (dmfs 3.42; DMFT 0.70).

**a. Deciduous teeth**



## b. Permanent teeth



Source: (Armfield *et al.*, 2007)

Figure 3: Decayed, missing and filled teeth by age and fluoride concentration in water for Australian children, 2002

New Zealand data from the School Dental Service (Ministry of Health 2008) also show that in fluoridated areas the mean dmft is lower and percent caries free higher compared to non-fluoridated areas.

Several of the studies reviewed for dental caries in children included a comparison between exposure to, and not to, fluoridated water. These studies show the success of water fluoridation in the reduction of dental caries. These data dispel the notion, as raised in submissions, that dental health in non-fluoridated areas can be better than those in fluoridated areas and provides evidence for the effectiveness of water fluoridation.

## **7. HEALTH RISKS**

Fluorosis is a term that refers to the effects associated with excess fluoride intake. It manifests in two forms: dental and skeletal fluorosis (United States Institute of Medicine, 1997), of which the former is more common.

### **7.1 Dental fluorosis**

Dental fluorosis refers to the incorporation of fluoride into the enamel of the teeth. It can range from a beneficial effect, making teeth stronger and whiter, to an adverse health effect. It varies from very thin, almost invisible, white patches or lines over the tooth surface or mottling, to significant areas of pitted enamel with brown stains arising from very high fluoride exposure. The milder forms are generally considered to be a cosmetic adverse effect.

Dental fluorosis is generally recognised as an irreversible condition, particularly in relation to moderate and severe forms. Mottling of teeth, as occurs in the mild form of fluorosis, can have numerous other causes (Australian Dental Association Inc, 2007). Instances of severe dental fluorosis are now rare in Australia (Australian Dental Association Inc, 2007).

While early exposure to fluoride can protect newly erupting teeth, it can also be a risk factor for fluorosis (Do and Spencer, 2007b). The pre-eruptive development period for teeth is considered to be the most vulnerable for the development of dental fluorosis (Institute of Medicine, 1997). Deciduous teeth erupt anywhere from 6 months (usually the central incisors) to 33 months (molars) (Dental Practice Education Research Unit, 2008). Permanent teeth develop around 3-4 months of age and erupt between 6-12 years of age (Department of Human Services Victoria, 2007). However, there is some uncertainty for the key exposure period with claims of 18-30 months of age (Puzio *et al.*, 1993), 0-6 years (Do and Spencer, 2007a), from 22 months to 36 months (Evans and Stamm, 1991) or after 12 months of age, or whether there are any post eruption influences. The NHMRC concluded that the critical time for exposure is after the first 12 months of life, therefore after infant formula consumption has ceased (NHMRC, 2007a). Mature enamel is not susceptible to the condition. Therefore, dental fluorosis only affects children up to around eight years.

Fluorosis development relates to both the time of exposure in relation to enamel formation and the cumulative duration of elevated fluoride intake (Hong *et al.*, 2006). One study suggests that it can take as little as four months to develop fluorosis (Evans and Stamm, 1991). Fluoride intake from a range of sources cumulates to produce fluorosis if ingestion occurs when the teeth are mineralising (Riordan, 2002). Fluorosis can be found on both the deciduous and permanent teeth.

Dental fluorosis has been associated with exposure from several sources, both individually or collectively, including fluoridated water (NHMRC, 1999), toothpaste, other dental products and supplement use. The Australian Drinking Water Guidelines says levels above 1.5 mg/L can cause dental fluorosis (NHMRC and NRMCC, 2004).

The clinical signs of very mild and mild dental fluorosis are not specific and can also be attributed to other enamel defects (e.g. enamel demineralisation disorders). Some of the studies assessing fluorosis may report figures that are slightly overestimated as enamel opacities not caused by fluoride may have been included according to the indices used to score fluorosis (McDonagh *et al.*, 2000). The degree of the overestimate is unknown and could be different for different studies depending on factors such as examiner training, examiner bias or poor examiner randomisation.

There are many rating scales for fluorosis. Some that are commonly referred to include Dean's Classification, the Thylstrup-Fejerskov (TF) Index, the Tooth surface index of fluorosis (TSIF) and the Fluorosis Risk Index (FRI). The most commonly used indexes seem to be Dean's, which was developed in the 1940's and in countries such as the United States of America, and the TF index, which is commonly used in Australian studies. The scales have different numbers of level of classification and it is difficult to match classifications in one scale to those in another. Appendix 2 shows the Dean's classification, TF index and the TSIF scale. There is also different reporting of fluorosis, from 'any' fluorosis to 'fluorosis of aesthetic concern' as well as terms such as 'mild' or 'moderate', which can be based on the rating scales mentioned above. All of these classification scales and descriptions of dental defects make it difficult to compare results between studies.

Apart from the Iowa Fluoride Study (Hong *et al.*, 2006), there is little information directly linking levels of dietary intake to rates of fluorosis. The Iowa study showed a strong significant positive relationship between total fluoride intakes (diet, water, dental products, supplements) and the prevalence of any fluorosis. Cumulative average daily intakes of more than 0.04 mg/kg bw/day results in a significantly higher prevalence of fluorosis. Intakes below 0.04 mg/kg bw had a less than 20% probability of developing any fluorosis, and the majority of the fluorosis was the mild form. The highest rates of fluorosis are associated with intakes >0.06 mg/kg bw/day. Intakes at 0.04 mg/kg bw/day have a low risk of developing any fluorosis, intakes at 0.04-0.06 have a significantly elevated risk and above 0.06 is a high risk.

FSANZ investigated the prevalence of dental fluorosis in Australia and New Zealand. The results are discussed below.

### **7.1.1 Rates of dental fluorosis**

There were no data found on the prevalence of dental fluorosis in Australian or New Zealand adults. Studies on dental fluorosis are generally done on children. Given that the condition is generally accepted to be irreversible, rates in adults should be the same as, or higher than, the rates for children. It is likely to be higher given that today's younger adults would have had higher exposures to fluoride as children before policy changes on the use of fluorides were implemented in the early 1990's (e.g. introduction of child strength toothpastes, decrease in fluoride in infant formulas). A summary of the data on the prevalence of fluorosis in children is shown in Table 6.

There are no national data on fluorosis for Australian or New Zealand children, but there is some information from some Australian states and for some different areas in New Zealand. It is accepted that in areas with optimal water fluoridation, there will be a prevalence of around 10-12 % of very mild to mild dental fluorosis. The more recent studies in Australia (in the last decade) show a prevalence of fluorosis ranging between around 10 to 20%, but which includes primarily very mild and mild fluorosis. The prevalence of diffuse opacities in New Zealand children, which is the marker assessed in New Zealand and is similar to the milder forms of fluorosis, is reported to be between 20 and 25%.

The prevalence of fluorosis in children is decreasing. Fluorosis in Australian children was more prevalent in the early 1990's (Riordan, 2002; Do and Spencer, 2007a). Following work in the early 1990s through the NHMRC, the levels in infant formula powders were reduced, low fluoride toothpastes for children and advice on using a 'pea sized' amount were introduced and new dosage schedules for supplement use in children were recommended. Therefore, children born after 1993 should have a lower prevalence of fluorosis.

A study was undertaken in South Australia to assess the difference in the prevalence of fluorosis across three birth cohorts: before (born 1989/1990); during (born 1991/1992); and after (born 1993/1994) policy changes (Do and Spencer, 2007a). The majority of the fluorosis in south Australian children was very mild to mild (see Table 6). Overall there was a decrease in the prevalence of fluorosis across the birth cohorts: TF 1 16% earliest cohort, 15% latest cohort; and TF 2+ 18% earliest cohort and 8% latest cohort. Both the whole sample and the analysis by birth cohort showed an association between fluorosis and starting toothbrushing before 2 years of age, eating/licking toothpaste, using high fluoride toothpaste (1000 mg/kg) and exposure to fluoridated water. Supplement use was not associated with the prevalence of fluorosis.

The strongest effect on the decrease in fluorosis was due to the increased use of lower fluoridated toothpastes. These results imply that the policy changes had a beneficial effect on decreasing the prevalence of fluorosis.

One study (Spencer and Do, 2008) stated a decline in fluorosis from 45% in 1992/1993 to 26% in 2002/2003 in South Australian children (using a TF score of 1+). The main reason for the decrease appears to be changes in policy from around 1990 and due primarily to the change in use of dental products.

Fluorosis has been associated with exposure from several sources, both individually or collectively, including fluoridated water, toothpaste, other dental products, supplement use and use of infant formula. At the same time, some studies may show no association from these sources, which may be due to factors such as the small number of people in the study taking supplements, for example (Riordan, 1993). Fluorosis prevalence is generally higher in children who had lived for longer periods of time in fluoridated areas (Riordan and Banks, 1991; Riordan, 1993; Riordan, 2002). Residence in a fluoridated area as a risk factor for mild fluorosis (TF $\geq$ 1) was not a significant risk factor for a more severe rating of fluorosis (TF $\geq$ 2) in one study, unlike swallowing toothpaste (Riordan, 1993), or optimal supplement use (Riordan and Banks, 1991). Even no exposure to fluoridated water or supplements can lead to fluorosis (11-17%) (Riordan and Banks, 1991; Riordan, 2002), suggesting other factors such as toothpaste as the cause. In one study, there was a fluorosis prevalence (TF $>$ 0) of 53% for persons who used supplements in accordance with directions (Riordan and Banks, 1991).

**Table 6: Summary of data for the prevalence of dental fluorosis in children**

Year	% with any fluorosis	Fluorosis index and score <sup>#</sup>	Region	Age (years)	Teeth examined	Reference
Recent <sup>##</sup>	19	Diffuse opacities	Auckland, New Zealand	9		Schluter et al, 2008
2003/2004	12 (TF=1) 11 (TF=2-3)  14 (>50% life F area) 11 (0-50% life F area) 3% (0% life F area)	TF  TF $\geq$ 2	South Australia	8-13	Maxillary central incisors	Do and Spencer, 2007b
2002/2003	15 (TF=1) 12 (TF=2-3)	TF	South Australia	8-14	Maxillary central incisors	Do & Spencer, 2007a
2002	24%	Diffuse opacities	Southland, New Zealand	Mean 9.8	check	Mackay & Thomson, 2005

Year	% with any fluorosis	Fluorosis index and score <sup>#</sup>	Region	Age (years)	Teeth examined	Reference
2000	18 (overall)  15 (TF=1) 3 (TF=2) <1 (TF=3)  22 F area* 11 NF area	TF>0	Perth (F area), Bunbury (NF area), WA	10	Not specified as to permanent or deciduous	Riordan, 2002
1992/1993	57 F area** 29 NF area  34 F area 19 NF area	TF ≥1  Deans ≥ very mild	South Australia	10-17		Puzio 1993
1990/1991	48 (overall)  31 (TF=1) 13 (TF=2) 5 (TF=3)	TF Any > 0 More severe ≥ 2	Perth, WA	7	Permanent	Riordan, 1993
1989/1990	40 F area (0.8) 33 NF area (0.2) (p>0.05)  27 (TF=1) 9 (TF≥2)	TF Any > 0	Perth (F area), Bunbury (NF area), WA	12	Permanent	Riordan and Banks, 1991

Notes: F area = fluoridated area, NF area = non-fluoridated area

\* Water fluoride concentration F area 0.85 mg/L, NF area <0.2-0.3 mg/L.

\*\* Water fluoride concentration F area 1.0 mg/L, NF area 0.3 mg/L. Same data classified using two different indexes of fluorosis.

# See Appendix 2 for index definitions.

##Exact year unknown, study still in press.

A study on South Australian children between 2003 and 2004 (Do and Spencer, 2007b) evaluated rates of fluorosis based on history of exposure to fluoridated water and toothpaste use. The authors found that exposure to fluoridated water from birth to three years was significantly associated with the prevalence of fluorosis whereas the group with no exposure to fluoridated water had significantly lower rates of fluorosis. Commencing toothbrushing after 30 months of age was not significantly associated with lower rates of fluorosis. The use of children's toothpaste (i.e. 400-500 ppm fluoride) was significantly associated with lower prevalence of fluorosis. Swallowing brushing slurry was associated with higher odds of fluorosis and eating/licking toothpaste was significantly associated with a higher risk of fluorosis.

For the two studies 10 years apart in two areas of Western Australia; Perth, a fluoridated area and Bunbury, a non-fluoridated area (Riordan and Banks, 1991; Riordan, 2002), a reduction of the prevalence of fluorosis occurred between 1990 and 2000. The author attributed a decline in fluorosis to changes in education. After 1989/1990, the School Dental Service discouraged fluoride supplements and promoted low fluoride toothpaste for children under 6 years. No increase in dental caries was recorded.

Different assessment methods are used in New Zealand. Australia assesses ‘dental fluorosis’, and New Zealand assesses ‘enamel defects’. The enamel defects observed are consistent with mild dental fluorosis, however these defects may or may not be attributed to fluoride. The prevalence of enamel defects in New Zealand children has not increased since the 1980s. The prevalence of diffuse opacities in New Zealand children has not increased in children who have lived their whole lives in fluoridated areas, and severe enamel defects have decreased (Mackay and Thomson, 2005). There was no significant difference in severe enamel defects between fluoridated and non-fluoridated areas. Preliminary data for a study in the Auckland region (Schluter et al, 2008) showed that children living continuously in fluoridated areas were four times more likely to have diffuse opacities compared to those living in non-fluoridated areas. Other studies have shown that enamel defects are higher in children in New Zealand from fluoridated areas compared to non fluoridated (Suckling and Pearce, 1984; Cutress *et al.*, 1985).

Different scales of rating fluorosis can result in different estimates of rates of fluorosis in the population groups being assessed. Table 6 shows one study where the same children were rated using two different scales (Deans and TF) (Puzio *et al.*, 1993) and resulted in rates of fluorosis that were higher using the TF index. The majority of studies also just report any fluorosis and do not distinguish between mild or moderate. Moderate fluorosis on the Dean scale was the basis of the Upper Level (UL) for children aged up to 8 years. Also, different teeth are examined (e.g. deciduous versus permanent; incisors versus molars), which can also influence the result. Permanent central maxillary incisors are reported to have a higher prevalence of fluorosis than first permanent molars (Hong *et al.*, 2006). Different individuals in the same exposure category have different susceptibilities to fluorosis (Hong *et al.*, 2006).

A study conducted in Perth in 1989-90 asked parents, dentists and student dentists to rate the appearance of children’s teeth. The majority (85-90%) were neutral or agreed that teeth with no fluorosis (TF scale=0) looked nice, approximately 80% had this opinion for teeth with barely discernable fluorosis (TF=1) and 65-80% for teeth graded as TF=2. However only 40-50% agreed or were neutral that teeth graded as TF=3 looked nice (Riordan, 1993b). Therefore, the majority of mild fluorosis seen in Australia at present is not generally perceived as cosmetically adverse.

## **7.2 Skeletal effects, including fluorosis**

Skeletal fluorosis is a serious medical condition, and can lead to significant bone degradation and neurological manifestations. Some submissions were concerned about adverse skeletal effects from fluoride. Skeletal fluorosis is, however, an extremely rare condition even with excessive fluoride intake. Only five cases have been diagnosed in the U.S. over the last 45 years. It is more common in India and Pakistan where natural fluoride levels in water may be as high as 18 mg/L. The rarity of skeletal fluorosis is due primarily to the need for continued chronic exposure to very high fluoride intakes (in the order of about 10 mg/day for >10 years to produce mild forms of skeletal fluorosis). The Australian Drinking water Guidelines says levels above 4 mg/L can cause skeletal fluorosis (NHMRC and NRMCC, 2004), but the maximum set in the Guidelines was 1.5 mg/L.

No evidence for occurrence of skeletal fluorosis in Australia or New Zealand was found. Levels of fluoride in drinking water in Australia and New Zealand are much lower than those attributed to the development of skeletal fluorosis.

An Australian review in 2001 assessing 33 individual studies concluded that fluoride at 1 mg/L does not have an adverse effect on bone strength, mineral density, or evidence of fractures. A systematic review of fluoridation in McDonagh *et al* (2000), followed by a subsequent systematic review by the NHMRC (2007b), also found no clear evidence of an association between any other adverse bone related conditions including fracture or bone development where water is fluoridated around 1 mg/litre. Optimally fluoridated water may be beneficial in decreasing fracture risk (NHMRC, 2007b).

### **7.3 Cancer**

It was raised in submissions that long-term exposure to levels of fluoride, even as low as those found in Australian water, may cause cancer, particularly bone cancer.

From a systematic review of the evidence for fluoridation, the studies assessing the relationship with cancer did not indicate that fluoride caused cancer (McDonagh *et al.*, 2000). Additional studies on cancer published after the McDonagh *et al* review were evaluated by the NHMRC as part of its systematic review (NHMRC, 2007b).. The NHMRC did not find any evidence to the contrary. The NHMRC concluded that the studies examining the association between fluoride and cancer provide insufficient evidence to reach a conclusion. These reviews included an assessment of the Bassin *et al* (2006) osteosarcoma study which is often used as evidence that shows an association between fluoride exposure and osteosarcoma in teenage boys but not teenage girls.

### **7.4 Vulnerable sub-population groups**

The issue of susceptible sub-population groups to intakes of fluoride was raised in submissions.

#### **7.4.1 Infants**

Infants, particularly those fed formula that is made up with fluoridated water, have often been described as an at risk group for exposure to fluoride. FSANZ included an evaluation of dietary intakes and risk for infants for this Application. See the Draft Assessment Report and Dietary Intake Assessment report at Supporting Document 3 for further details.

Being breast fed was not associated with lower levels of fluorosis in one study in Western Australian children and weaning before 9 months of age was a significant risk factor for fluorosis ( $TF \geq 1$ ) (Riordan, 1993). Being formula fed as an infant was not associated with the prevalence of fluorosis in a 2002/2003 study in South Australian Children (Do and Spencer, 2007a).

Guidelines on the use of fluorides (Australian Research Centre for Population Oral Health, 2006) noted that there was no evidence from Australian population based studies to indicate levels of dental fluorosis from the consumption of infant formulas made up with either fluoridated or unfluoridated water.

#### **7.4.2 Other at risk groups**

An evaluation of the risk to other potential at risk groups such as high consumers of water (elite or endurance athletes and those working and/or living in hotter climates) was considered as part of the Draft Assessment Report based on data included in the Dietary Intake Assessment (in Supporting Document 3).

Pregnant women are assigned the same Nutrient Reference Values for fluoride as non-pregnant women, as they are thought to not have increased requirements or be at any greater risk of skeletal fluorosis. Therefore this group was not evaluated further.

#### **7.5 Other health risks**

Many potential adverse conditions or risks associated with fluoride were highlighted in submissions. These included associations with kidney disease, thyroid function (especially in the iodine deficient), those with brain disease, heart disease, neurological conditions (e.g. Alzheimer's dementia, lowered IQ in children, Parkinson's disease), goitre, birth defects, Down's Syndrome, kidney failure, arthritis.

No evidence of haematological, hepatic or renal effects has been found (World Health Organization, 2002). An association between fluoridated water and other effects (Down's Syndrome, mortality, dementia, goitre, IQ) was not found in a recent systematic review of water fluoridation (McDonagh *et al.*, 2000). A similar conclusion was reached following the systematic review conducted by the NHMRC (NHMRC, 2007b), that there is no evidence for the contribution of fluoride to any adverse effects other than fluorosis.

#### **7.6 Conclusion regarding health risks**

The only observed adverse effect in Australia and New Zealand from exposure to fluoride is very mild and mild dental fluorosis in children.

Other effects have not been proven (cancer, birth defects) or only occur in areas of extremely high fluoride content of water over many years (e.g. skeletal fluorosis), which are well above the concentrations in Australian or New Zealand water supplies.

This evaluation concurs with a previous toxicological review and risk assessment of fluoride conducted by FSANZ in 1999 as part of Proposal P158 – A review of maximum permitted concentrations of non-metals in foods. The conclusion of this risk assessment was that there is no evidence of public health and safety concerns from current dietary exposures to fluoride.

### **8. RISK VERSUS BENEFIT**

Much of the literature indicates that it is generally accepted that levels of fluoridation of around 1 mg/L will result in some fluorosis, usually very mild to mild in nature, but that the benefit of water fluoridation on dental caries outweighs the risk of fluorosis. This is also reflected by government agencies and dental and health associations, see Table 7. Dental associations and experts also suggest the way to lower the incidence of fluorosis and retain beneficial effects on dental caries, is to reduce exposure to fluoride from sources other than water fluoridation (e.g. toothpaste, supplements).

The research literature also supports this (Riordan, 1993). Water fluoridation is seen as a cost effective measure (Wright *et al.*, 2001) in relation to dental caries and is socially equitable.

**Table 7: Statements in relation to the risks and benefits of fluoridation**

Agency	Statement	Reference
NHMRC public statement	‘Fluoridation of drinking water remains the most effective and socially equitable means of achieving community-wide exposure to the caries prevention effects of fluoride. It is recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis.’	(NHMRC, 2007a)
Australian Dental Association (ADA) Policy 2007	The ADA recommends: ‘Water fluoridation as the most effective, equitable and efficient measure for achieving reduction in dental caries incidence across a community.’ The ADA recommends that the control of additional fluoride sources (e.g. toothpaste, supplements etc) should be undertaken to reduce levels of fluorosis, and not the reduction or removal of fluoridating drinking water which is the preferred way to maintain the low incidence of dental caries.	(Australian Dental Association Inc, 2007)
Australian Dental Association Queensland (ADAQ) – Position statement	‘ADAQ acknowledges that all sources of fluoride availability (toothpastes, mouth rinses, tables and water fluoridation) have the potential to contribute to varying levels of incidence and severity of dental fluorosis, a white mottled specking of tooth enamel. This is a condition of aesthetic concern only and may occur in a small number of individuals as a result of inappropriate exposure to fluorides during the period of development of the secondary dentition.’ ‘ADAQ endorses optimal community water fluoridation is the safest, most effective and most equitable means of improving the oral health of Queenslanders regardless of age, educational level or socio-economic situation.’	(Australian Dental Association (Queensland Branch), 2007)
Public Health Association of Australia – Oral Health Policy (2006)	‘Fluoridation of reticulated water supplies is the most effective socially equitable and safe method of prevention of dental caries.’ Supports the National Oral Health Plan 2004-2013 that ‘The fluoridation of reticulated water supplies should be continued and extended to all communities across Australia of 1000 or more people.’	Public Health Association of Australia (2006)
Public Health Association of New Zealand – Water Fluoridation Policy (2003)	‘The adjustment of fluoride to between 0.7 and 1.0 ppm in drinking water is the most effective and efficient way of preventing dental caries in communities receiving a reticulated water supply.’	Public Health Association of New Zealand (2003)

## **9. CONCLUSION FROM THE NUTRITION RISK ASSESSMENT**

In summary it is concluded that reticulated and packaged water are nutritionally equivalent. The permitted forms have been used for many years and are highly bioavailable from drinking water.

Water fluoridation provides a balance between benefits in relation to the reduction of dental caries and the risk of developing dental fluorosis. The prevalence of dental caries in children in Australia and New Zealand is increasing, which highlights the importance of continuing water fluoridation, which could include the provision of fluoridated packaged water. It is generally accepted that optimally fluoridated water will result in some mild dental fluorosis. There is evidence showing mild forms of fluorosis in Australian and New Zealand children.

Water fluoridation at current levels in Australia and New Zealand is not associated with any non-dental adverse health effects.

## **REFERENCES**

- AIHW Dental Statistics and Research Unit (2006) *AIHW Dental Statistics and Research Unit Research Report Number 28. Urban and rural variations in child oral health. AIHW Catalogue number DEN 154.* AIHW Dental Statistics and Research Unit and ARCPOH School of Dentistry The University of Adelaide, Canberra.
- Armfield, J.M. (2005) Public water fluoridation and dental health in New South Wales. *Australian and New Zealand Journal of Public Health* 29(5):477-483.
- Armfield, J.M., Slade, G.D. and Spencer A.J. (2007) *Water fluoridation and children's dental health. Australia 2002. Catalogue number DEN170. Dental statistics and research series number 36.* Australian Institute of Health and Welfare, Canberra.
- Armfield, J.M. and Spencer, A.J. (2004) Consumption of nonpublic water: implications for children's caries experience. *Community Dentistry and Oral Epidemiology* 32:283-296.
- Armfield, J.M. and Spencer, A.J. (2008) Quarter of a century of change: caries experience in Australian children, 1977-2002. *Australian Dental Journal* 53:151-159.
- Athar, N., McLaughlin, J., Taylor, G. and Mishra, S. (2006) *The Concise New Zealand Food Composition Tables. 7th Edition.* New Zealand Institute for Crop & Food Research, Palmerston North.
- Australian Dental Association (Queensland Branch) (2007) *Australian Dental Association (Queensland Branch) Position Statement. Water Fluoridation in Queensland.* Australian Dental Association (Queensland Branch).
- Australian Dental Association Inc (2007) *Policy Statement 1.2.1. Community Oral Health Promotion. Fluoride Use.*
- Australian Institute of Health and Welfare (2007) *Dental Statistics and Research Series. Number 34. Australia's dental generations. The National Survey of Adult Oral Health 2004-06.* In: Slade, G.D., Spencer A.J., and Roberts-Thomson, K.F. eds. Australian Institute of Health and Welfare, Canberra.
- Australian Research Centre for Population Oral Health. (2006) The Use of Fluorides in Australia: Guidelines. *Australian Dental Journal* 51(2):195-199.
- Broadbent, J.M., Thomson, W.M. and Poulton, R. (2006) Progression of Dental Caries and Tooth Loss between the Third and Fourth Decades of Life: A Birth Cohort Study. *Caries Research* 40:459-465.
- Broadbent, J.M., Thomson, W.M. and Williams, S.M. (2005) Does Caries in Primary Teeth Predict Enamel Defects in Permanent Teeth? A Longitudinal Study. *Journal of Dental Research* 84(3):260-264.
- Cutress, T.W., Suckling, G.W., Pearce, E.I.F. and Ball, M.E. (1985) Defects of tooth enamel in children in fluoridated and non-fluoridated water areas of the Auckland Region. *New Zealand Dental Journal* 81:12-19.
- de Liefde, B. (1998) The decline of caries in New Zealand over the past 40 years. *New Zealand Dental Journal* 94:109-113.

- Dean, H.T. (1942) The investigation of physiological effects by the epidemiological method. In: Moulton, F.R. eds. *Fluorine and Dental Health*. American Association for the Advancement of Science, Washington DC, pp. 23-31.
- Dental Practice Education Research Unit. (2008) Patient Information Pamphlet No. 9. Early Childhood Decay. Protecting your baby or pre-schooler from decay problems. The University of Adelaide, <http://www.arcpoh.adelaide.edu.au/dperu/caries/pamphlets/>.
- Department of Human Services Victoria (2007) *Young infants, infant formula and fluoride exposure*. Department of Human Services, Victoria.
- Do, L.G. and Spencer, A.J. (2007a) Decline in the prevalence of dental fluorosis among South Australian children. *Community Dentistry and Oral Epidemiology* 35:282-291.
- Do, L.G. and Spencer, A.J. (2007b) Risk-Benefit Balance in the Use of Fluoride among Young Children. *Australian Dental Journal* 86(8):723-728.
- 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.
- 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.
- Evans, R.W. and Stamm, J.W. (1991) An Epidemiologic Estimate of the Critical Period during which Human Maxillary Central Incisors Are Most Susceptible to Fluorosis. *Journal of Public Health Dentistry* 51(4):251-259.
- FSANZ. (2006) NUTTAB 2006 Online Version. <http://www.foodstandards.gov.au/monitoringandsurveillance/nuttab2006/onlineversionintroduction/index.cfm>.
- Hong, L., Levy, S.M., Warren, J.J., Broffitt, B. and Cavanaugh, J. (2006) Fluoride Intake Levels in Relation to Fluorosis Development in Permanent Maxillary Central Incisors and First Molars. *Caries Research* 40:494-500.
- Institute of Medicine. (1997) *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. National Academy of Sciences, Washington.
- Jackson, P.J., Harvey, P.W. and Young, W.F. (2002) *Chemistry and Bioavailability Aspects of Fluoride in Drinking Water*.
- Lee, M. and Dennison, P.J. (2004) Water fluoridation and dental caries in 5- and 12-year old children from Canterbury and Wellington. *New Zealand Dental Journal* 100(1):10-15.
- Mackay, T.D. and Thomson, W.M. (2005) Enamel defects and dental caries among Southland children. *New Zealand Dental Journal* 101(2):35-43.
- 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.
- 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.

- McLennan, W. and Podger, A. (1999) *National Nutrition Survey. Foods Eaten. Australia. 1995. Catalogue number 4804.0*. Commonwealth of Australia, Canberra.
- Ministry of Health (2005) *Drinking-water Standards for New Zealand 2005*. Ministry of Health, Wellington.
- Ministry of Health (2007) *Fluoridation of water supplies*.
- Ministry of Health (2008) *Age 5 and Year 8 oral health data from the School Dental Services*. <http://www.moh.govt.nz/moh.nsf/indexmh/oralhealth-resources#statistics>. Accessed on
- NHMRC (1999) *Review of Water Fluoridation and Fluoride Intake from Discretionary Fluoride Supplements*. Australian Government Publishing Service, Canberra.
- NHMRC (2007a) *NHMRC Public Statement. The Efficacy and Safety of Fluoridation 2007*. NHMRC.
- NHMRC (2007b) *Systematic Review of the Efficacy and Safety of Fluoridation*. Commonwealth of Australia, Canberra.
- NHMRC and NRMCC (2004) *National Water Quality Management Strategy. Australian Drinking Water Guidelines 6. 2004. Endorsed by the NHMRC 10-11 April 2003*. NHMRC.
- NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand*. Commonwealth of Australia, Canberra.
- NZ MoH (2008) *2008 New Zealand Oral Health Survey*. <http://www.moh.govt.nz/moh.nsf/indexmh/phi-survey-oral-health-survey>. Accessed on 8 July 2008.
- Puzio, A., Spencer, A.J. and Brennan, D.S. (1993) Fluorosis and fluoride exposure in South Australian children. In: *Consensus Conference: Appropriate fluoride exposure for infants and children, Perth*.
- Riordan, P.J. (1993) Dental Fluorosis, Dental Caries and Fluoride Exposure among 7-Year-Olds. *Caries Research* 27:71-77.
- Riordan, P.J. (2002) Dental fluorosis decline after changes to supplement and toothpaste regimens. *Community Dentistry and Oral Epidemiology* 30(3):233-240.
- Riordan, P.J. and Banks, J.A. (1991) Dental Fluorosis and Fluoride Exposure in Western Australia. *Journal of Dental Research* 70(7):1022-1028.
- Roberts-Thomson, K. and Do, L. (2007) Oral Health Status. In: Slade, G.D., Spencer A.J., and Roberts-Thomson, K.F. eds. *Australia's dental generations. The National Survey of Adult Oral Health 2004-06*. Chapter 5. Australian Institute of Health and Welfare, Canberra.
- Singh, K.A., Spencer, A.J. and Armfield, J.M. (2003) Relative Effects of Pre- and Posteruption Water Fluoride on Caries Experience of Permanent First Molars. *Journal of Public Health Dentistry* 63(1):11-19.
- Slade, G.D. and Sanders, A. (2007) Trends in oral health 1987-2006. In: Slade, G.D., Spencer A.J., and Roberts-Thomson, K.F. eds. *Australia's dental generations. The National Survey of Adult Oral Health 2004-06*. Chapter 8. Australian Institute of Health and Welfare, Canberra.
- Spencer, A.J. and Do, L.G. (2008) Changing risk factors for fluorosis among South Australian children. *Community Dentistry and Oral Epidemiology* 36:210-218.

- Spencer, A.J., Sendziuk, P., Slade, G.D. and Harford, J. (2007) Interpretation of findings. In: Slade, G.D., Spencer A.J., and Roberts-Thomson, K.F. eds. *Australia's dental generations. The National Survey of Adult Oral Health 2004-06*. Chapter 9. Australian Institute of Health and Welfare, Canberra.
- Spencer, A.J., Slade, G.D. and Davies, M. (1996) Water fluoridation in Australia. *Community Dental Health* 13(Supplement 2):27-37.
- Suckling, G.W. and Pearce, E.I.F. (1984) Developmental defects of enamel in a group of New Zealand children: their prevalence and some associated etiological factors. *Community Dentistry and Oral Epidemiology* 12(3):177-184.
- Teo, C., Young, W.G., Daley, T.J. and Sauer, H. (1997) Prior fluoridation in childhood affects dental caries and tooth wear in a South East Queensland population. *Australian Dental Journal* 42(2):92-102.
- Thomson, W.M. (2004) Dental caries experience in older people over time: what can the large cohort studies tell us? *British Dental Journal* 196(2):89-92.
- Water Care Services Limited (2007) *Annual Water Quality Report 2007*. Water Care Services Limited.
- World Health Organization (2002) *Fluorides. Environmental Health Criteria 227*. World Health Organisation, Geneva.
- World Health Organization. (2003) *Diet, Nutrition and the Prevention of Chronic Diseases*. World Health Organization, Geneva. Technical Report Series, 916.
- Wright, J.C., Bates, M.N., Cutress, T.W. and Lee, M. (2001) The cost-effectiveness of fluoridating water supplies in New Zealand. *Australian and New Zealand Journal of Public Health* 25(2):170-178.
- Bassin, E. B., Wypij, D., Davis, R. B., & Mittleman, M. A. 2006, 'Age-specific fluoride exposure in drinking water and osteosarcoma (United States)', *Cancer Causes and Control*, vol. 17, no. 4, pp. 421-428.
- Centres for Disease Control and Prevention (1999) Ten Great Public Health Achievements - United States 1900-1999. In *Morbidity and Mortality Weekly Report*. April 2 1999, Vol 48, No. 12.
- Fawell, J., Bailey, K., Chilton, J. Dahi, E., Fewtrell, L. And Magara, Y. (2006) *Fluoride in Drinking-water*. World Health Organisation, Geneva.
- Public Health Association of Australia (2006) *Oral Health Policy*.
- Public Health Association of New Zealand (2003) *Water Fluoridation Policy*.
- Riordan, P.J. (1993b) Perceptions of dental fluorosis. *Journal of Dental Research* 72:1268-74.
- Schluter, P., Kanagaratnam, S., Durward, C., Mahood, R. And Mackay, T. (2008) Enamel Defects and Dental Caries in 9-Year-Old Children Living in Fluoridated and Non-Fluoridated Areas, Auckland. In *Proceedings of the 2008 Population Health Congress*, Brisbane 6-9 July 2008.
- W.B. Saunders Company (1995) *Dorland's Pocket Medical Dictionary*. 25<sup>th</sup> Edition. W.B. Saunders Company, Philadelphia

## APPENDIX 1

### NEW ZEALAND DATA ON DENTAL CARIES FOR CHILDREN

**Table 1: Dental Caries in New Zealand Children from School Dental Service data 1990-2006**

Year	5 year old children		12 year old children*	
	Mean dmft	% Caries free	Mean dmft	% Caries free
1990	2.03	51	1.98	36
1991	2.04	52	1.72	42
1992	1.98	51	1.49	47
1993	1.92	53	1.39	49
1994	1.83	55	1.33	51
1995	1.71	55	1.40	48
1996	1.61	55	1.43	42
1997	1.72	57	1.62	44
1998	1.75	55	1.59	44
1999	1.80	54	1.58	44
2000	1.82	52	1.61	42
2001	1.87	51	1.61	43
2002	1.83	52	1.59	44
2003	2.06	54	1.57	45
2004	2.11	52	1.57	46
2005	2.24	52	1.67	44
2006	2.15	53	1.57	46

\* Specified as Year 8 children 2002-2006 and Form 2 Children 2000-2001.

Source: Ministry of Health

**COMMON RATING SCALES FOR DENTAL FLUOROSIS****Criteria for Dean's Fluorosis Index**

<b>Score</b>	<b>Criteria</b>
Normal	The enamel presents the usual translucent semi-vitriform type of structure. The surface is smooth, glossy, and usually of a pale creamy white colour.
Questionable	The enamel discloses slight aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is utilized in those instances where a definite diagnosis of the mildest form of fluorosis is not warranted and a classification of 'normal' is not justified.
Very Mild	Small opaque, paper white areas scattered irregularly over the tooth but not involving as much as approximately 25 per cent of the tooth surface. Frequently included in this classification are teeth showing no more than about 1-2 mm of white opacity at the tip of the summit of the cusps of the bicuspid or second molars.
Mild	The white opaque areas in the enamel of the teeth are more extensive but do not involve as much as 50 per cent of the tooth.
Moderate	All enamel surfaces of the teeth are affected, and surfaces subject to attrition show wear. Brown stain is frequently a disfiguring feature.
Severe	Includes teeth formerly classified as 'moderately severe' and 'severe'. All enamel surfaces are affected and hypoplasia is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is the discrete or confluent pitting. Brown stains are widespread and teeth often present a corroded-like appearance.

Source: (Dean, 1942)

### Clinical Criteria and Scoring for the TF (Thylstrup-Fejerskov) Index

Score	Criteria
0	Normal translucency of enamel remains after prolonged air-drying.
1	Narrow white lines corresponding to the perikymata.
2	<i>Smooth surfaces:</i> More pronounced lines of opacity that follow the perikymata. Occasionally confluence of adjacent lines. <i>Occlusal surfaces:</i> Scattered areas of opacity <2 mm in diameter and pronounced opacity of cuspal ridges.
3	<i>Smooth surfaces:</i> Merging and irregular cloudy areas of opacity. Accentuated drawing of perikymata often visible between opacities. <i>Occlusal surfaces:</i> Confluent areas of marked opacity. Worn areas appear almost normal but usually circumscribed by a rim of opaque enamel.
4	<i>Smooth surfaces:</i> The entire surface exhibits marked opacity or appears chalky white. Parts of surface exposed to attrition appear less affected. <i>Occlusal surfaces:</i> Entire surface exhibits marked opacity. Attrition is often pronounced shortly after eruption.
5	<i>Smooth surfaces and occlusal surfaces:</i> Entire surface displays marked opacity with focal loss of outermost enamel (pits) <2 mm in diameter.
6	<i>Smooth surfaces:</i> Pits are regularly arranged in horizontal bands <2 mm in vertical extension. <i>Occlusal surfaces:</i> Confluent areas <3 mm in diameter exhibit loss of enamel. Marked attrition.
7	<i>Smooth surfaces:</i> Loss of outermost enamel in irregular areas involving <1/2 of entire surface. <i>Occlusal surfaces:</i> Changes in the morphology caused by merging pits and marked attrition.
8	<i>Smooth and occlusal surfaces:</i> Loss of outermost enamel involving >1/2 of surface.
9	<i>Smooth and occlusal surfaces:</i> Loss of main part of enamel with change in anatomic appearance of surface. Cervical rim of almost unaffected enamel is often noted.

Source: Thylstrup and Fejerskov, 1978. As reproduced in (NHMRC, 2007b)

### Clinical Criteria and Scoring for the TSIF (Tooth surface index of fluorosis)

Score	Criteria
0	No evidence of fluorosis
1	Definite evidence of fluorosis
2	Parchment-white fluorosis on at least 1/3 visible surface
3	Parchment-white fluorosis on at least 2/3 visible surface
4	Enamel staining with any preceding levels fluorosis
5	Discrete enamel pitting
6	Discrete pitting and staining of intact enamel
7	Confluent pitting of enamel surface

Source: (NHMRC, 2007b)