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

FINAL ASSESSMENT

APPLICATION A588

VOLUNTARY ADDITION OF FLUORIDE TO PACKAGED WATER

SUPPORTING DOCUMENT 3

DIETARY INTAKE ASSESSMENT REPORT

Application A588 – Voluntary Addition of Fluoride to Packaged Waters
Draft Assessment
Dietary Intake Assessment Report

TABLE OF CONTENTS

1 Summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of fluoride to packaged water. The Applicant is seeking permission to voluntarily add sodium fluoride and sodium fluorosilicate (also called sodium silicofluoride) to packaged water to a total amount of between 0.6 to 1.0 mg fluoride/L. This amount is equal to the current level of fluoridation in reticulated water in Australia and New Zealand.

Dietary intake assessments were conducted for various scenarios in order to assess the potential impact the introduction of voluntary fortification of packaged waters with fluoride in Australia and New Zealand would have on fluoride intakes among the population groups.

Three scenarios were considered at Draft Assessment:

1. ***Water – 0.1 mg fluoride/L*** – to estimate fluoride intakes when all water (reticulated and packaged) is non-fluoridated
2. ***Water – 0.6 mg fluoride/L*** – to estimate fluoride intakes when all water is fluoridated at the lower concentration of the target range in *Australian Drinking Water Guidelines (2004)* and the *Drinking Water Standards for New Zealand (2005)* for fluoridated reticulated water This is also the minimum amount requested by the Applicant for packaged waters.
3. ***Water – 1.0 mg fluoride/L*** – to estimate fluoride intakes when all water is fluoridated at the maximum amount requested by the Applicant for packaged waters. This is also at the upper end of the range in the NHMRC public statement on the *Efficacy and Safety of Fluoridation* (2007) and the *Drinking-water standards for New Zealand* (2005).

The dietary intake assessments did not take into account fluoride from the use of supplements containing fluoride or from non-dietary sources (e.g. toothpaste, mouthwashes etc)

The dietary intake assessment indicates that:

- Less than 1% of Australians aged over 8 years and New Zealanders aged over 15 years (the age at which the New Zealand National Nutrition Survey commences) had intakes of fluoride that exceeded the upper level (UL).
- Children 8 years and under are the most likely population group to exceed the upper level (UL) of fluoride intakes when consuming fluoridated water.
- For Australians aged 4-8 years less than 5% exceeded the UL at the maximum fluoride level assuming all water consumed is fluoridated.
- For Australians aged 2-3 up to 22% exceeded the UL at the maximum fluoride level, assuming all water consumed is fluoridated.
- The major contributors to fluoride intakes for Australians 2 years and over and New Zealanders 15 year and over are beverages (non-alcoholic, alcoholic and waters).
- An individual of 9 years and over would need to consume approximately 8 L of water containing 1.0 mg/L of fluoride to exceed the UL, taking into account estimated mean fluoride intake from food and other beverages.
- Infants fed exclusively with infant formula made with non-fluoridated or fluoridated water exceed the UL.

- For infants aged 6-12 months consumption of fluoridated water on top of dietary fluoride sources, including infant formula, increase estimated fluoride intakes over the UL.

2 Background

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Ltd to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of fluoride to packaged water. The Applicant is seeking permission to voluntarily add sodium fluoride, sodium flurosilicate (also called sodium silicofluoride) and hydrofluorosilicic acid (or fluorosilicic acid) to packaged water up to a total of between 0.6 to 1.0 mg fluoride/L. This range is equal to the current level of fluoridation in tap water in Australia and New Zealand.

3 Dietary modelling approach

The methodology used to assess dietary fluoride intakes, the population groups assessed and the limitations and assumptions used in the assessments are discussed in detail in Appendix 1 and are summarised in Figure 1 below.

This is the first time FSANZ has estimated dietary intakes of fluoride, therefore providing baseline information on fluoride intakes from food and beverages other than water.

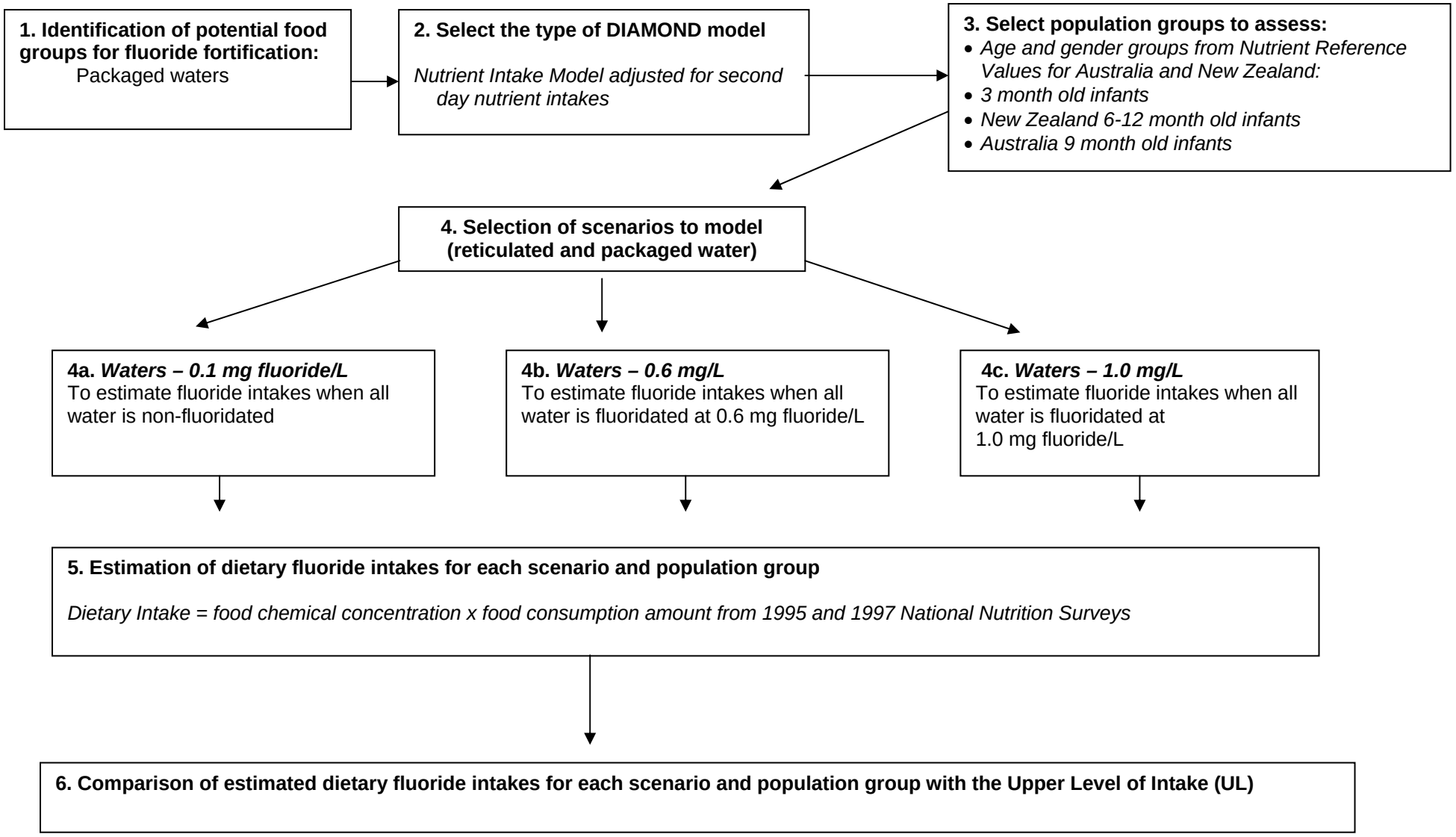


Figure 1: Dietary modelling approach used for assessing fluoride intakes for New Zealand and Australia at Draft Assessment

3.1 Population groups assessed

All ages within the Australian and New Zealand population were identified as potential consumers of packaged water. The NHMRC has established nutrient reference values (NRVs) for fluoride, including recommended Upper Level of Intake (ULs) for different age groups (NHMRC & NZMOH, 2006). Therefore where possible, dietary fluoride intakes were estimated for each of the NRV age groups in order for potential public health and safety risks to be assessed (see Table 1 for more details). The dietary intake assessments were conducted separately for both the Australian and New Zealand populations.

Table 1: Age groups used in the dietary intake assessments

Age groups DIA	Corresponding NRV age group	Australia	New Zealand
3 months	0-6 months	✓	✓
6-12 months	7-12 months		✓
9 months	7-12 months	✓	
2-3 years	1-3 years	✓	
4-8 years	4-8 years	✓	
9-13 years	9-13 years	✓	
14-18 years	14-18 years	✓	
15-18 years	14-18 years		✓
19-29 years	19-30 years	✓	✓
30-49 years	31-50 years	✓	✓
50-69 years	51-70 years	✓	✓
70 years & above	>70 years	✓	✓
2 years & above	-	✓	
15 years & above	-		✓

Note: Age groups do not match as this is restricted by the 1995 Australian NNS.

Infant formula has been identified as containing high fluoride levels in some cases. Therefore, dietary fluoride intakes of 3 month old infants was assessed since this population group is solely infant formula- or breast-fed. Six to twelve month old infants for New Zealand and nine month old infants for Australia were also assessed since these population groups consume both solid foods and infant formula or breast milk.

3.2 Fluoride concentration data

Two newly compiled fluoride datasets were specifically constructed by FSANZ for this assessment. These datasets were compiled for foods in the Australian and New Zealand National Nutrition Surveys (NNSs) with fluoride concentrations assigned to each of the approximately 4,500 and 5,900 foods in each survey respectively.

The majority of fluoride concentration values for foods were taken from analytical results for Australian foods published in NUTTAB 2006 (Food Standards Australia New Zealand, 2007), 1990/91 New Zealand Total Diet Study (Hannah *et al.*, 1995) and more recent data from the summer 2008 samples of the 23rd Australian Total Diet Study (unpublished FSANZ data). There is considerable uncertainty with the non-water fluoride values for a number of reasons including: limited analysed data for some food groups; considerable uncertainty in fluoride levels in some foods; poor sensitivity of the analysed methods used; and the high proportion of 'non-detected' results, for which assumptions on fluoride levels had to be made.

Where there were no Australian fluoride concentration data for specific foods, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand. In addition, a minority of values were imputed from German and US data (Souci *et al*., 1994; USDA, 2005). Fluoride values for multi-ingredient foods without analysed fluoride values were calculated using commonly used recipes. It was assumed that fluoride from water was not taken up by vegetables when boiled.

Where water is used for the preparation or cooking of certain foods in the home, the fluoride concentration in the water for the specific scenario was taken into account when determining the final fluoride content for these foods. Examples of these foods included tea, coffee, diluted cordial, juices made from concentrate, pasta, rice, noodles, cornmeal, couscous, oats, soup, stock, gravy and in other recipes where water was used.

Information provided by beverage manufacturers indicated that local water supplies (whether fluoridated or non-fluoridated) are used when making products in their processing plants. Therefore, beverages such as soft drinks and fruit juices were assigned the current mean fluoride content from analytical data for those types of beverages on the market. These values remained the same for all scenarios.

The fluoride concentration in water (reticulated and bottled) changed for each scenario according to the specified concentration for that scenario. The dietary intake assessments did not take into account fluoride from the use of supplements containing fluoride or from non-dietary sources (e.g. toothpaste, mouthwashes etc).

3.3 Scenarios Modelled

The concentration of fluoride in water for each scenario was applied to both reticulated and packaged water consumption as reported in the 1995 Australian and 1997 New Zealand NNS. Recent evidence suggests that sale of packaged waters in Australia has increased since the 1995 NNS was conducted (Levy & Tapsell, 2007). Therefore FSANZ considered that packaged water consumption patterns reported in 1995 and 1997 do not reflect current consumption patterns and are not suitable for the use in the assessment. Instead FSANZ had estimated intake from all sources of drinking and cooking water, assuming that total water consumption will be unchanged since 1995/97. By assigning the same fluoride concentration to all water in the NNS in each scenario it was assumed that the total volume of water consumed, regardless of whether it is reticulated or bottled water, has not changed since 1995. Three water fluoridation scenarios were assessed:

1. Water – 0.1 mg fluoride/L

This model represents estimated fluoride intakes when all water is non-fluoridated (including reticulated and packaged waters). This scenario might occur for those who live in areas where the municipal water supply is non-fluoridated, or tank water is consumed, and any packaged water is not voluntarily fluoridated. However, this model does not estimate fluoride intakes from water containing naturally high levels of fluoride and this is likely to have occurred in New Zealand.

2. Water – 0.6 mg fluoride/L

This model represents estimated fluoride intakes when all water is fluoridated at the lower concentration of the target range in *Australian Drinking Water Guidelines* (2004) and the *Drinking Water Standards for New Zealand* (2005) for fluoridated reticulated water. This is also the minimum amount requested by the Applicant for packaged waters.

3. Water – 1.0 mg fluoride/L

This model represents estimated fluoride intakes when all water is fluoridated at the maximum amount requested by the Applicant for packaged waters. This is also at the upper end of the range in the NHMRC public statement on the *Efficacy and Safety of Fluoridation* (2007) and the *Drinking-water standards for New Zealand* (2005). This scenario might occur for those who live in areas where higher levels of fluoride are added to reticulated water and who also choose to consume packaged water that is voluntarily fortified with fluoride.

Toothpaste, fluoride supplements and other topical products containing fluoride have not been taken into account when estimating fluoride dietary intakes. Separate estimated fluoride intakes from toothpaste for children and adults have been calculated and are outlined in Section 4.3.

4 Results

4.1 Estimated dietary fluoride intakes

4.1.1 Results for Australian and New Zealand children aged < 2 years, based on model diets

4.1.1.1 3 month old infants

The mean fluoride intake for exclusively breast fed 3 month old infants was estimated to be 0.002-0.008 mg fluoride/day, with 90th percentile intakes of 0.005-0.016 mg fluoride per day.

The estimated mean dietary fluoride intakes for exclusively formula fed infants were higher than those for exclusively breast fed infants, with an estimated dietary fluoride intake 0.2 mg fluoride per day for the *Water – 0.1 mg fluoride/L* scenario. When water was considered (*Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L*), the mean dietary fluoride intake ranged from 0.7 to 1.0 mg fluoride per day.

The estimated 90th percentile dietary fluoride intake for exclusively formula fed infants for the *Water – 0.1 mg fluoride/L* scenario is 0.5 mg fluoride per day. When water was considered (*Water – 0.6 mg fluoride/L and Water – 1.0 mg fluoride/L*), the estimated 90th percentile dietary fluoride intakes ranged from 1.4 to 1.9 mg fluoride/day. Refer to Table A2.1 in Appendix 2 and Figure 2 for further details.

4.1.1.2 New Zealand infants aged 6-12 months

The estimated mean dietary fluoride intake for New Zealand infants aged 6-12 months for the *Water – 0.1 mg fluoride/L* scenario is 0.4 mg fluoride per day. When the fluoridated water was considered (*Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L*.), the mean dietary fluoride intake ranged from 0.6 to 0.9 mg fluoride per day.

The estimated 90th percentile dietary fluoride intakes for New Zealand infants aged 6-12 months for the *Water – 0.1 mg fluoride/L* scenario is 0.7 mg fluoride per day. When fluoridated water was considered (*Water – 0.6 mg fluoride/L and Water – 1.0 mg fluoride/L*), the estimated 90th percentile dietary fluoride intakes ranged from 1.3 to 1.7 mg fluoride/day. Refer to Table A2.2 in Appendix 2 and Figure 2 for further details.

4.1.1.3 Australian infants aged 9 months

The estimated mean dietary fluoride intakes for Australian infants aged 9 months for the *Water – 0.1 mg fluoride/L* scenario is 0.4 mg fluoride per day. When fluoridated water was considered (*Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L*.), the mean dietary fluoride intake ranged from 1.0 to 1.3 mg fluoride per day.

The estimated 90th percentile dietary fluoride intakes for Australian infants aged 9 months for the *Water – 0.1 mg fluoride/L* scenario is 0.7 mg fluoride per day. When fluoridated water was considered (*Water – 0.6 mg fluoride/L and Water – 1.0 mg fluoride/L*), the estimated 90th percentile dietary fluoride intakes ranged from 1.9 to 2.7 mg fluoride/day. Refer to Table A2.3 in Appendix 2 and Figure 2 for further details.

4.1.2 Results for Australians aged 2 years and above and New Zealanders aged 15 years and above

For all the population groups in the Australian and New Zealand NNSs, there would bean increase in estimated mean dietary fluoride intakes if non-fluoridated water (*Water – 0.1 mg fluoride/L* scenario) were substituted with fluoridated water *(Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L* scenarios). The results indicate that the Australian population aged 2 years and above have a lower mean iodine intake compared to New Zealand population aged 15 years and above across all three scenarios. This would be a result of the intakes of young children being incorporated into the summary statistics for this age group.

The results also indicate for both Australian and New Zealand populations groups that as age increases into adulthood, estimated fluoride intakes increase. For the New Zealand population groups assessed, respondents aged 30-49 years and 50-69 years generally had the highest mean dietary fluoride intakes for all water fluoride scenarios examined. Refer to, Figure 2 and Table A2.4 in Appendix 2 for further details. For the Australian population groups assessed, respondents aged 19-29 years and 30-49 years generally had the highest mean dietary fluoride intakes for all water fluoride scenarios examined. Refer to Figure 5 and Table A2.4 in Appendix 2 for further details. However, for New Zealanders 70 years and above and Australian 50 years and above, estimated fluoride intakes decrease as total food and liquid consumption decline.

4.2 Estimated increases in fluoride intakes

As expected, the highest increases in dietary fluoride intakes for all Australian and New Zealand population groups were between the non-fluoridated water scenario (*Water – 0.1 mg fluoride/L*) and the upper end of the range for fluoridated water (*Water – 1.0 mg fluoride/L* scenario). The highest proportional increases were seen in infants of 3 months. For those who live in non-fluoridated areas there will be a significant increase in fluoride intake if substituting non-fluoridated water for packaged water that is fluoridated. Refer to Table 2 for further details.

Table 2: Estimated increases in mean dietary fluoride intakes from the *Water – 0.1 mg fluoride/L* scenario

Country	**Population Group**	**Approximate increase in mean dietary fluoride intakes (mg/day) from the *Water – 0.1 mg fluoride/L* scenario (%)**	
		Water – 0.6 mg fluoride/L	***Water – 1.0 mg fluoride/L***
Australia	3 months#*	250	400
	9 months*	150	225
	2 yrs and above	65	135
New Zealand	3 months#*	250	400
	6-12 month*	50	125
	15 yrs and above	50	85

for exclusively formula-fed infants
* as determined using model diets

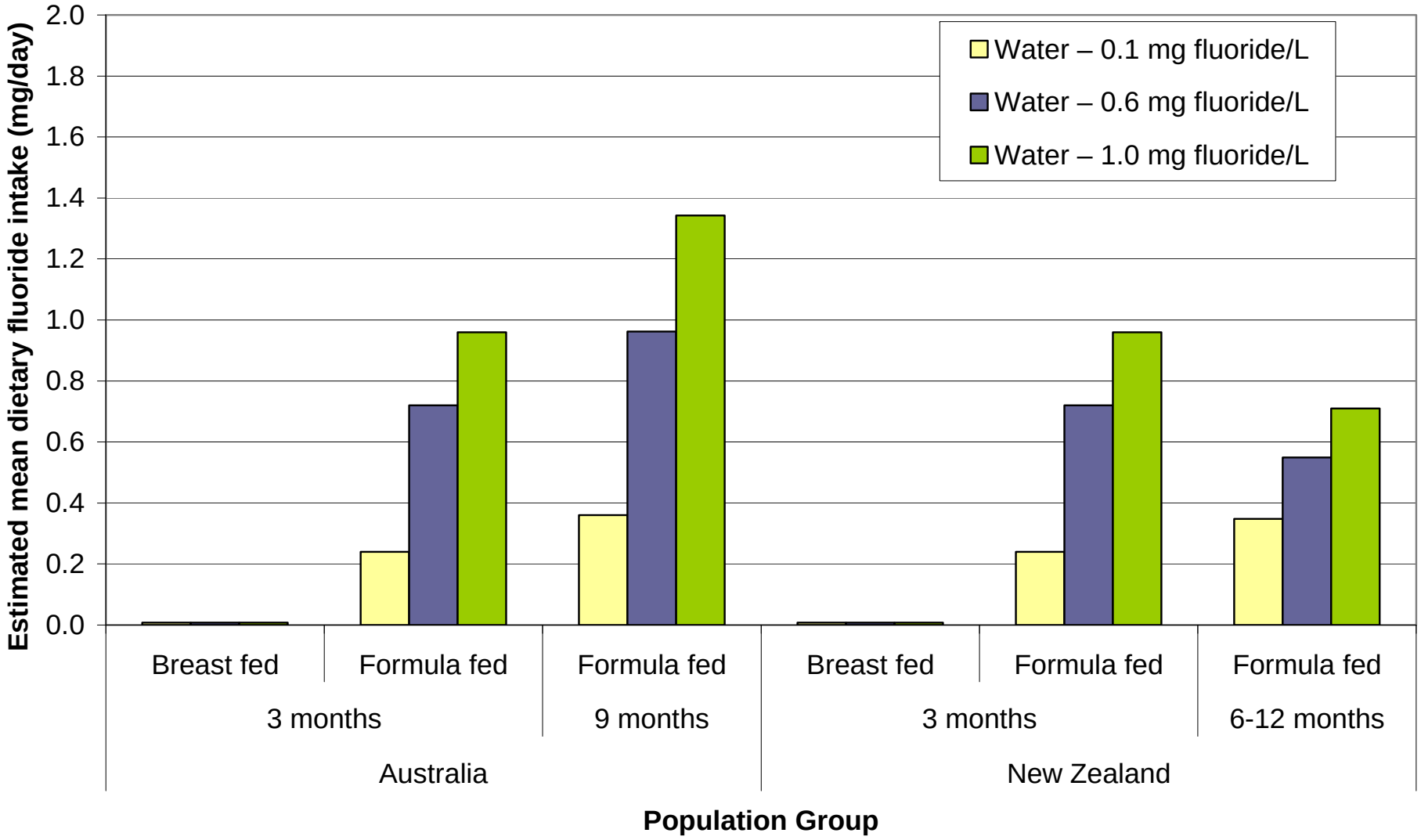


Figure 2: Estimated mean dietary intakes of fluoride (mg/day) for Australian and New Zealand infants for the three water scenarios 0.1 mg fluoride/L, 0.6 mg fluoride /L and 1.0 mg fluoride /L.

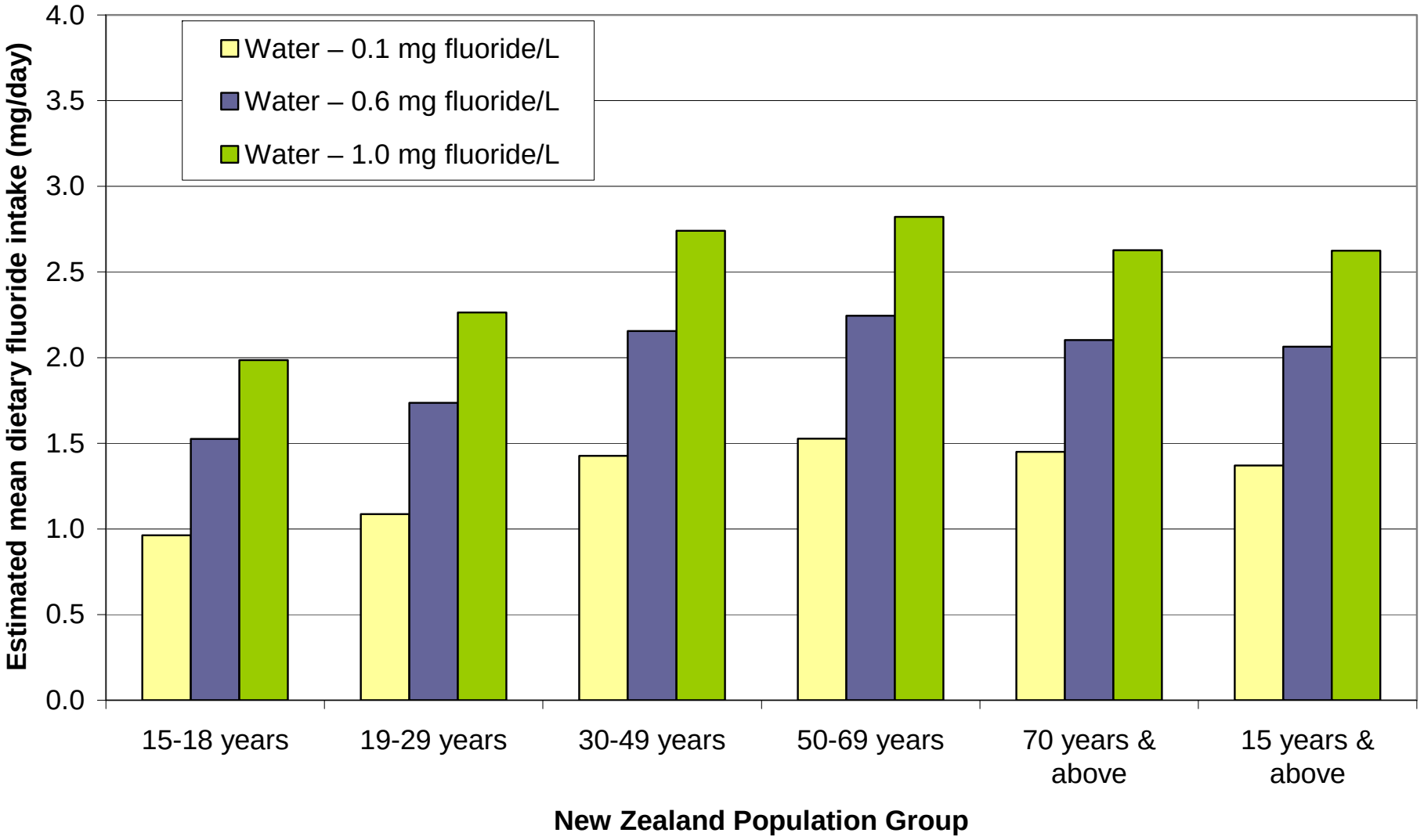


Figure 3: Estimated mean dietary intakes of fluoride (mg/day) for New Zealand population for the three water scenarios 0.1 mg fluoride/L, 0.6 mg fluoride /L and 1.0 mg fluoride /L.

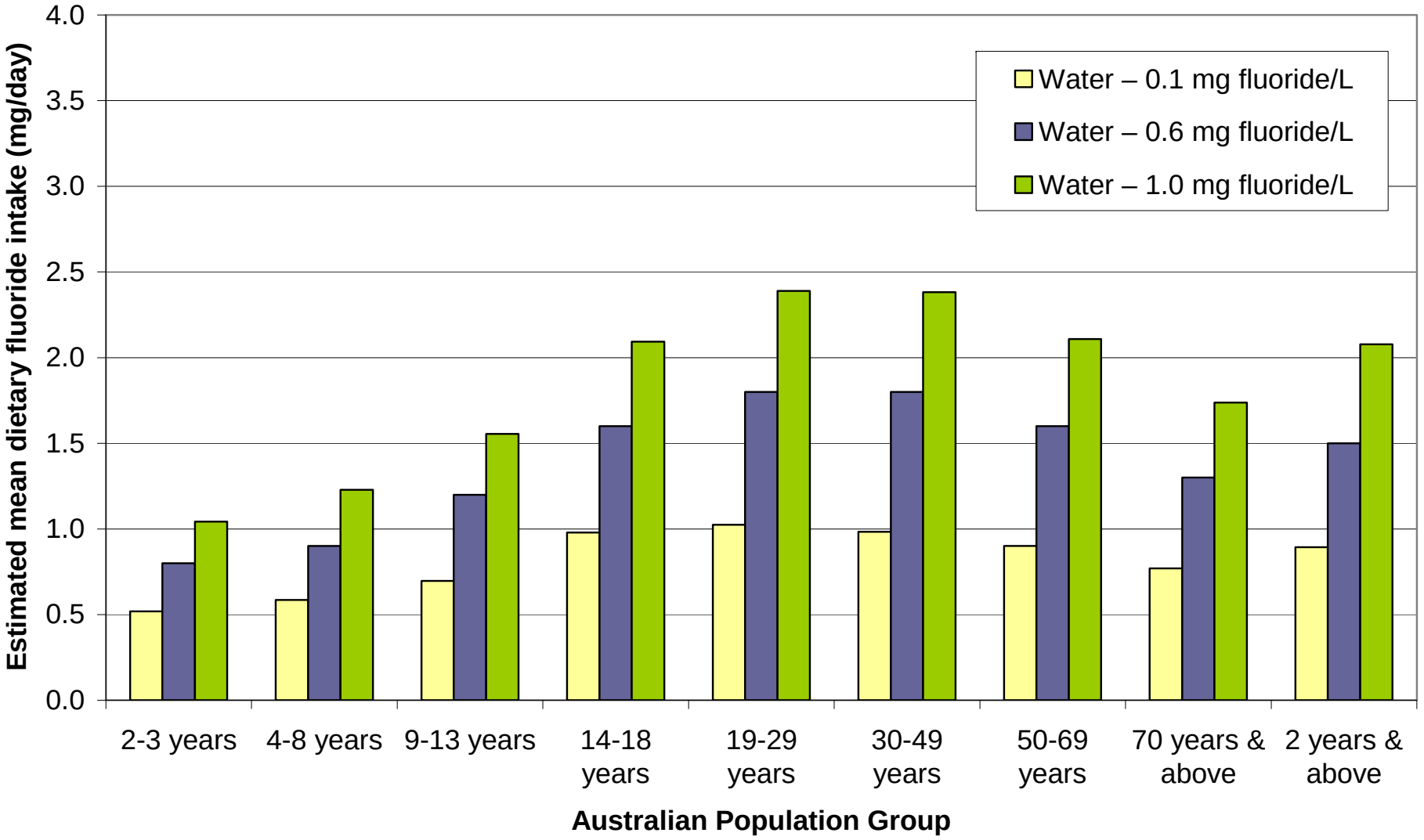


Figure 4: Estimated mean dietary intakes of fluoride (mg/day) for Australian population groups for the three water scenarios 0.1 mg fluoride/L, 0.6 mg fluoride /L and 1.0 mg fluoride /L.

4.3 Estimated fluoride intakes from toothpaste

It is recommended that children should use low fluoride toothpaste (with a concentration of 400-500 mg/kg fluoride) and a 'pea sized' amount (assumed to be 0.5 g) (ADA, 2007). Fluoride intakes for young children from toothpaste are likely to be around 0.1-0.3 mg/day if current recommendations for tooth brushing are followed assuming that half or all of the toothpaste is swallowed respectively. This is possible given the poor swallow reflex of children. The potential fluoride intake from toothpaste is lower than intakes from food and water shown in Table A2.4 in Appendix 2 based on the assumptions outlined.

These estimated intakes from toothpaste may increase fluoride intakes for children by around 10% for those consuming fluoridated water and around 50% for those consuming non-fluoridated water. For people aged 6 years and over intakes from using a gram of adults toothpaste per day with minimal swallowing (up to around 10% of the toothpaste is swallowed in adults (Institute of Medicine, 1997)) would be 0.1 mg/day. This would increase intakes for this group between 4-10% in fluoridated areas.

4.4 Major contributors to fluoride intakes

The major foods contributing ≥5% to total fluoride dietary intakes are shown in Figure 5 – 10 for children aged up to 3 years, and for the New Zealand population aged 15 years and above and the Australian population aged 2 years and above, respectively. The calculations for major contributing foods for population groups 2 years or more were based on intakes derived from the first 24-hour recall data only. Refer to Appendix 1 for information on fluoride concentration data.

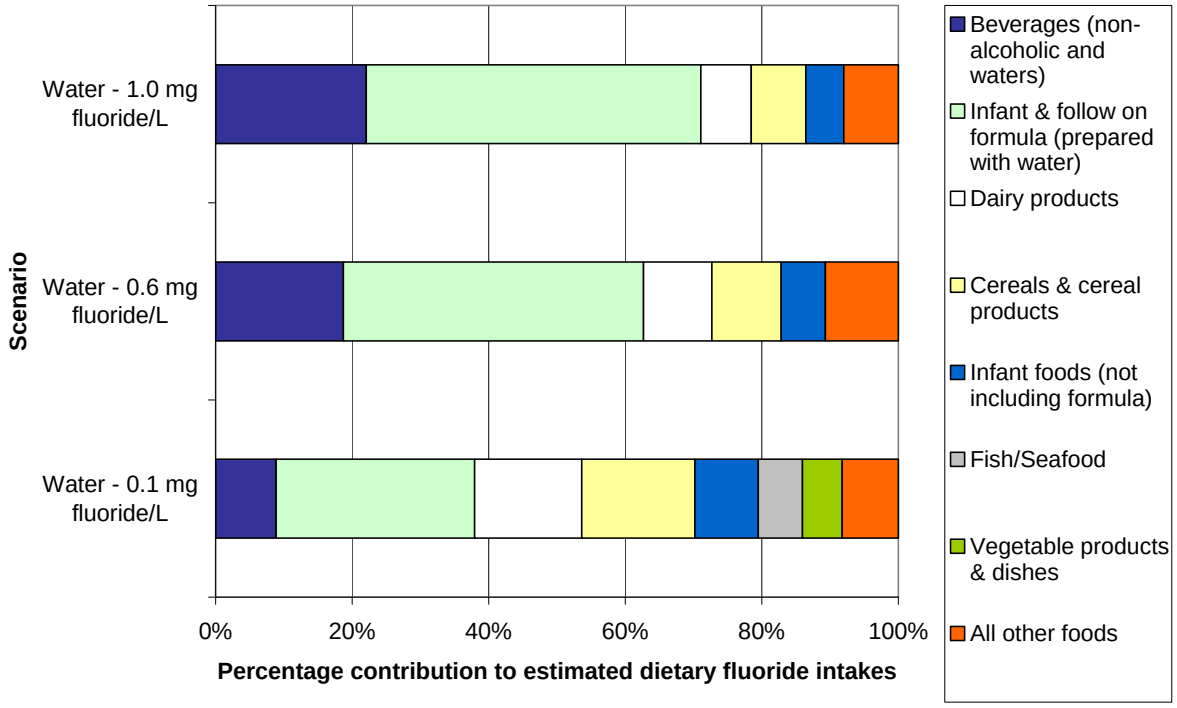
Further details on the percentage contribution of various foods to estimated dietary fluoride intakes, including definitions of the types of foods in the major contributor food groups, can be found in Table A2.5 to Table A2.10 in Appendix 2.

4.4.1 Australian and New Zealand children aged 3 months

The major and only contributor to fluoride intakes for infants 3 months old is either breast milk or infant formula (prepared with water).

4.4.2 New Zealand children aged 6-12 months

The major contributor to fluoride intakes for New Zealand children aged 6-12 months for all scenarios examined was infant and follow-on formula, contributing approximately 29-49% of total dietary fluoride intakes. When non-fluoridated water was considered (*Waters – 0.1 mg fluoride/L* scenario), infant and follow-on formula (prepared with water) (29%), cereal and cereal products (17%), dairy products (16%), infants foods (not including formula) (9%), beverages (non-alcoholic and waters) (9%), fish/seafood (6%) and vegetable products and dishes (6%) had the greatest contributions towards estimated dietary fluoride intakes. When fluoridated water was considered (*Waters –0.6 mg fluoride/L* and *Waters – 1.0 mg fluoride/L* scenarios), infant and follow-on formula (prepared with water) (44-49%), beverages (19-22%, where water on its own contributed 14-17%), cereal and cereal products (8-10%), dairy products (7-10%), and infants foods (not including formula) (6%) had the greatest contributions. Refer to Figure 5 and Table A2.5 in Appendix 2 for further details.

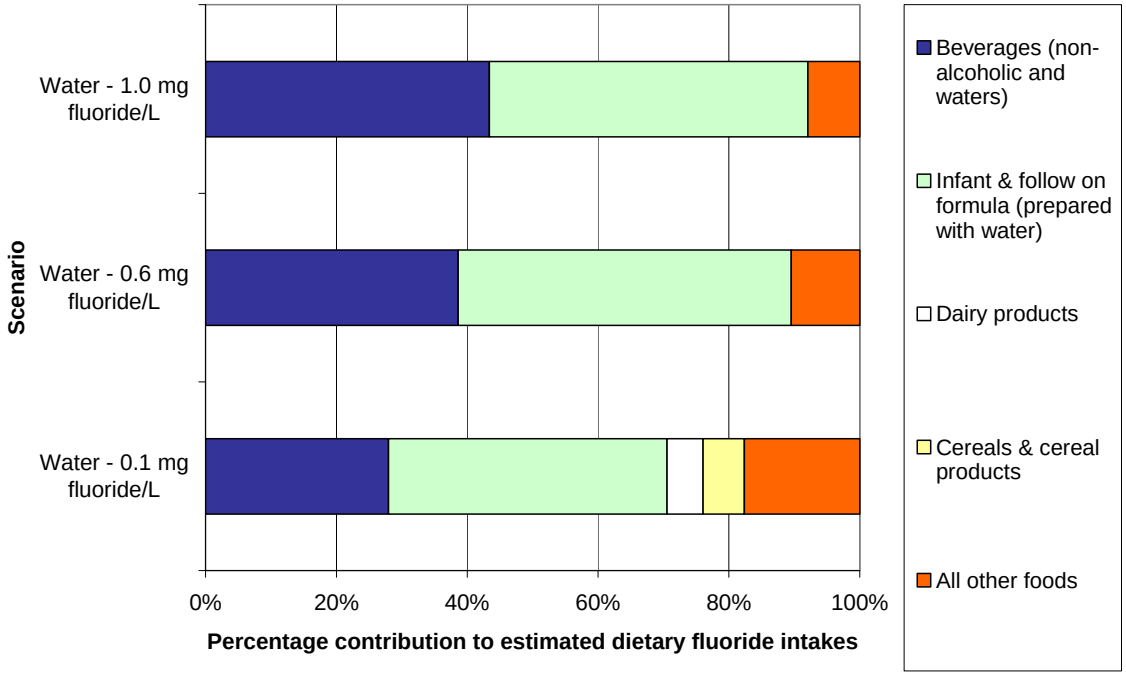


Note: The percent contribution of each food group is based on total fluoride intakes for all consumers in the population groups assessed. Therefore the total fluoride intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 5: Major contributors to total fluoride dietary intakes for New Zealand children aged 6-12 months

4.4.3 Australian children aged 9 months

The major contributor to fluoride intakes for Australian children aged 9 months for all scenarios examined was infant and follow-on formula, contributing approximately 45-51% of total dietary fluoride intakes. When non-fluoridated water was considered (*Waters – 0.1 mg fluoride/L* scenario), infant and follow-on formula (prepared with water) (45%), beverages (30%, where water on its own contributed 15%), cereal and cereal products (7%) and dairy products (6%) had the greatest contributions towards estimated dietary fluoride intakes. When the requested levels of fortification for packaged waters were considered (*Waters –0.6 mg fluoride/L* and *Waters – 1.0 mg fluoride/L* scenarios), infant and follow-on formula (prepared with water) (49-51%) and beverages (non-alcoholic) (39-43%, where water on it's own contributed 33-39%), had the greatest contributions. Refer to Figure 6 and Table A2.6 in Appendix 2 for further details.



Note: The percent contribution of each food group is based on total fluoride intakes for all consumers in the population groups assessed. Therefore the total fluoride intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

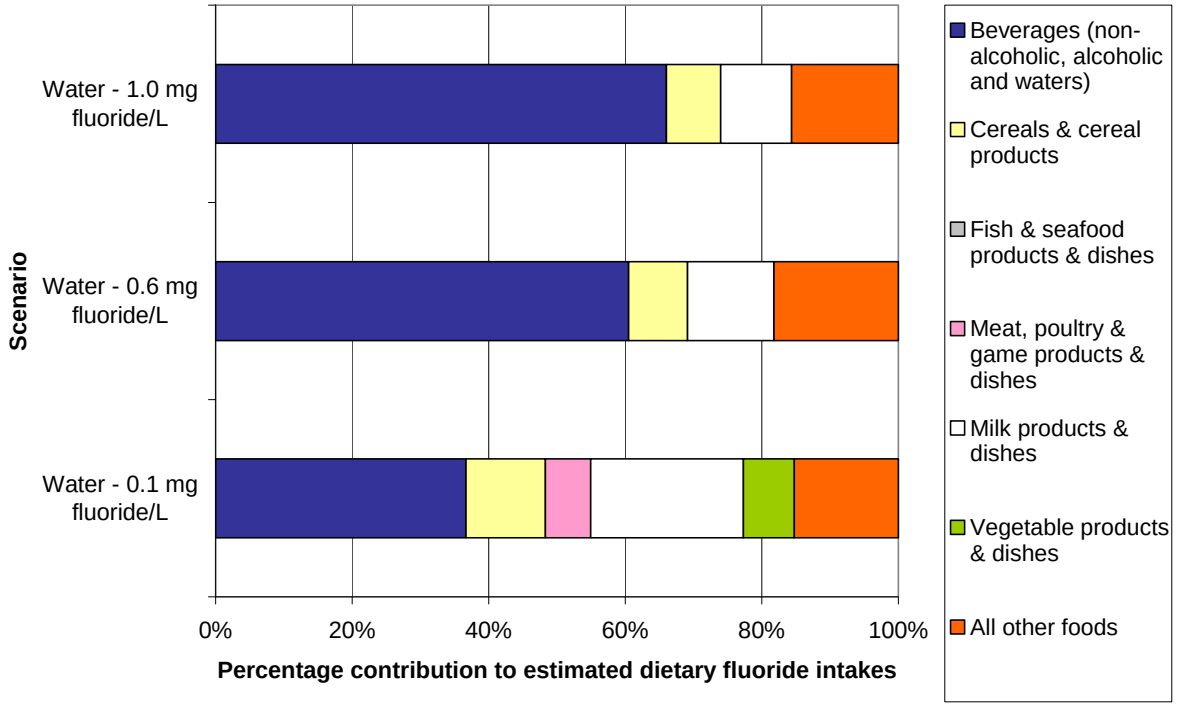
Figure 6: Major contributors to total fluoride dietary intakes for Australian children aged 9 months

4.4.4 Australian children aged 2-3 years and 4-8 years

The major contributor to fluoride intakes for Australians children aged 2-3 years for all scenarios examined was beverages (non-alcoholic, alcoholic and waters), contributing approximately 37-66% of total dietary fluoride intakes. When non-fluoridated water was considered (*Waters – 0.1 mg fluoride/L* scenario), fruit and vegetable juices and drinks (20%), including fruit drinks (7%), plain water (10%) and soft drinks, flavoured mineral waters and electrolyte drinks (6%) had the greatest contributions towards estimated dietary fluoride intakes. When fluoridated water was considered (*Waters – 0.6 mg fluoride/L* and *Waters – 1.0 mg fluoride/L* scenarios), plain water (36-46%) and fruit and vegetable juices and drinks (17-18%), including fruit-based or flavoured cordials and drinks (8-9%) had the greatest contributions of all beverages.

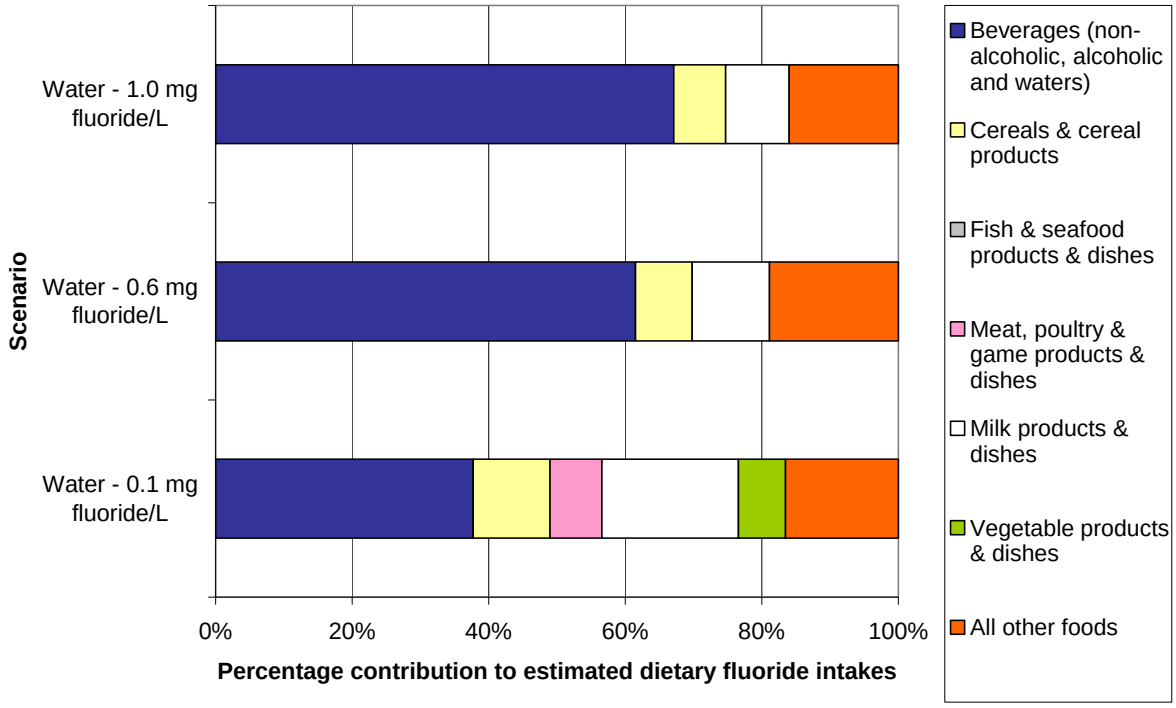
The major contributor to fluoride intakes for Australians children aged 4-8 years for all scenarios examined was beverages (non-alcoholic, alcoholic and waters), contributing approximately 38-67% of total dietary fluoride intakes. When non-fluoridated water was considered (*Waters – 0.1 mg fluoride/L* scenario), fruit and vegetable juices and drinks (17%), including fruit drinks (6%), soft drinks, flavoured mineral waters and electrolyte drinks (11%) and plain water (10%) had the greatest contributions towards estimated dietary fluoride intakes. When fluoridated water was considered (*Waters –0.6 mg fluoride/L* and *Waters – 1.0 mg fluoride/L* scenarios), plain water (36-45%), fruit and vegetable juices and drinks (15-16%), including fruit-based or flavoured cordials and drinks (8-10%) and soft drinks, flavoured mineral waters and electrolyte drinks (6-7%) had the greatest contributions of all beverages.

Cereals and cereal products (approximately 8-12% contribution) and milk products and dishes (approximately 10-22% contribution) were other important contributors to fluoride intakes for Australians aged 2-3 years and 4-8 years for all scenarios. For the *Waters – 0.1 mg fluoride/L* scenario, vegetables products and dishes (7%) and meat, poultry and game products and dishes (7%) were other important contributors to fluoride intake. Refer to 7 and 8 and Table A2.7 and Table A2.8 in Appendix 2 for further details.



Note: The percent contribution of each food group is based on total fluoride intakes for all consumers in the population groups assessed. Therefore the total fluoride intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 7: Major contributors to total fluoride dietary intakes for Australian children aged 2-3 years



Note: The percent contribution of each food group is based on total fluoride intakes for all consumers in the population groups assessed. Therefore the total fluoride intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 8: Major contributors to total fluoride dietary intakes for Australian children aged 4-8 years

4.4.5 New Zealand population aged 15 years and above and the Australian population aged 2 years and above

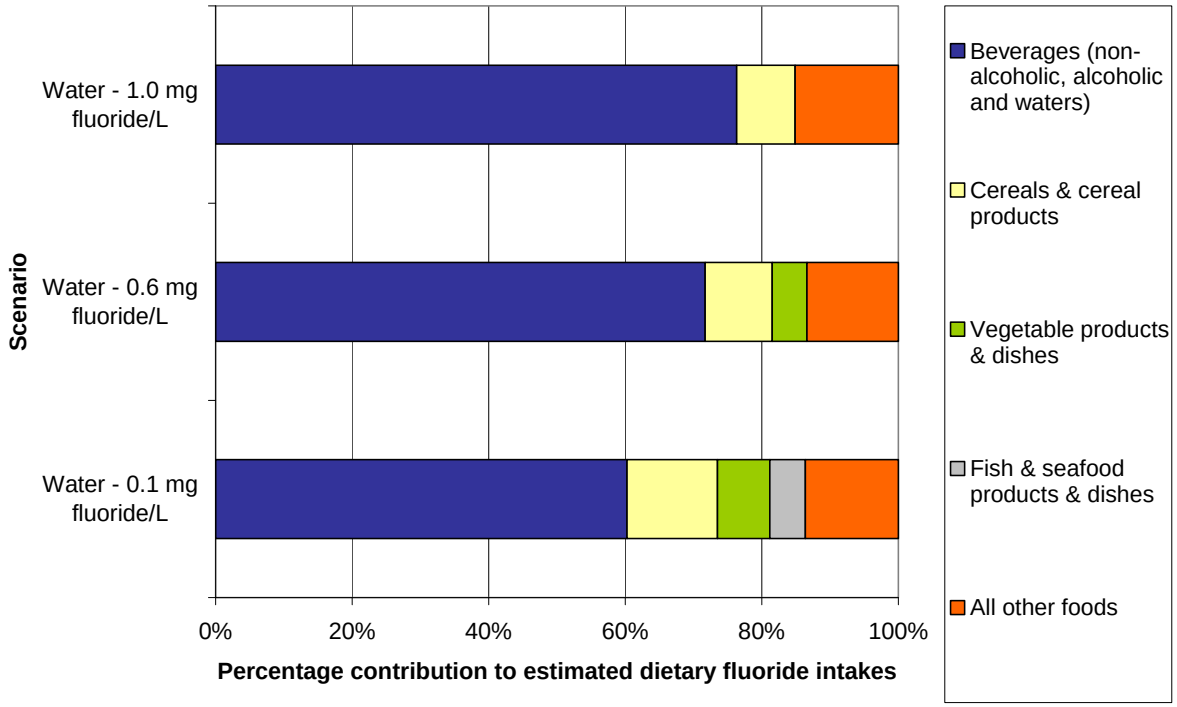
The major contributor to fluoride intakes for New Zealanders aged 15 years and above for all scenarios examined was beverages (non-alcoholic, alcoholic and waters), contributing approximately 64-78% of total dietary fluoride intakes. When non-fluoridated water was considered (*Waters – 0.1 mg fluoride/L* scenario), tea (50%) and plain water (6%) had the greatest contribution towards estimated dietary fluoride intakes. When fluoridated water was considered (*Waters –0.6 mg fluoride/L* and *Waters – 1.0 mg fluoride/L* scenarios), tea (41-44%) and plain water (23-30%) had the greatest contributions of all beverages.

Cereals and cereal products were other important contributors to fluoride intakes for all scenarios (approximately 9-13% contribution). For the *Waters – 0.1 mg fluoride/L* scenario, vegetables products and dishes (8%) and fish and seafood products and dishes (5%) were other important contributors to fluoride intake. For the *Waters – 0.6 mg fluoride/L* scenario, vegetables products and dishes contributed 5% of fluoride intakes. Refer to Figure 9 and Table A2.9 in Appendix 2 for further details.

The major contributor to fluoride intakes for Australians aged 2 years and above for all scenarios examined was beverages (non-alcoholic, alcoholic and waters), contributing approximately 44-72% of total dietary fluoride intakes.

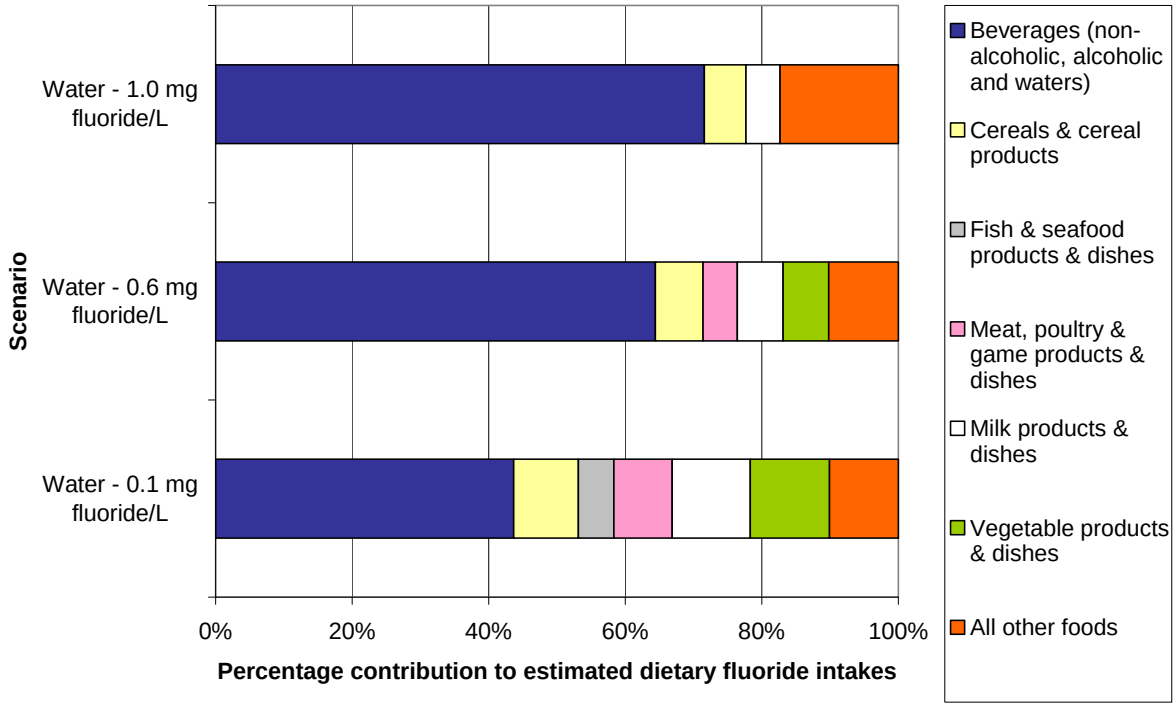
When non-fluoridated water was considered (*Waters – 0.1 mg fluoride/L* scenario), soft drinks, flavoured mineral waters and electrolyte drinks (10%), beers (10%), plain water (9%), and fruit and vegetable juices and drinks (5%) had the greatest contribution towards estimated dietary fluoride intakes. When fluoridated water was considered (*Waters – 0.6 mg fluoride/L* and *Waters – 1.0 mg fluoride/L* scenarios), plain water (31-39%), coffee (14-16%), soft drinks, flavoured mineral waters and electrolyte drinks (<5-6%) and beers (<5-6%) had the greatest contributions of all beverages.

Cereals and cereal products were other important contributors to fluoride intakes for all scenarios (approximately 6-9% contribution). For the *Waters – 0.1 mg fluoride/L* scenario, vegetables products and dishes (12%), milk products and dishes (11%), meat, poultry and game products and dishes (9%) and fish and seafood products and dishes (5%) were other important contributors to fluoride intake. For the *Waters – 0.6 mg fluoride/L* scenario, vegetables products and dishes (7%), milk products and dishes (7%) were important contributors to fluoride intake. Milk products and dishes contributed 5% of fluoride intakes for the *Waters – 1.0 mg fluoride/L* scenario. Refer to Figure 10 and Table A2.10 in Appendix 2 for further details.



Note: The percent contribution of each food group is based on total fluoride intakes for all consumers in the population groups assessed. Therefore the total fluoride intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 9: Major contributors to total fluoride dietary intakes for New Zealanders aged 15 years and above



Note: The percent contribution of each food group is based on total fluoride intakes for all consumers in the population groups assessed. Therefore the total fluoride intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 10: Major contributors to total fluoride dietary intakes for Australians aged 2 years and above

5 Comparison of the estimated dietary intakes with the Upper Level of Intake (UL)

In order to determine if dietary fluoride intakes will be of concern to public health and safety, the estimated fluoride intakes for all scenarios were compared with the Upper Level of Intake (UL) and are shown in Table A3 in Appendix 3. Full details of the proportions of each population group with estimated dietary fluoride intakes above the UL can also be found in this table.

5.1 Results for New Zealand children aged 3 months and 6-12 months and Australian children aged 3 months and 9 months, using model diets

Since dietary fluoride intakes for New Zealand children aged 3 months and 6-12 months and for Australian children aged 3 months and 9 months were estimated using 'model diets', the percentage of these population groups with dietary fluoride intakes above the UL could not be determined. As an alternative, the 90th percentile dietary fluoride intake (high consumers of fluoride) was estimated and then compared to the UL and expressed as a percentage of the UL.

Estimated dietary intakes for breast fed infants were under the UL, even at the 90th percentile. For formula fed infants mean and 90th percentile intakes were under the UL when non-fluoridated water was used to prepare the formula and at or above the UL when fluoridated water was used. Refer to table A3.1 in Appendix 3.

For New Zealand children aged 6-12 months, when non-fluoridated water was considered (*Water – 0.1 mg fluoride/L* scenario), all were under the UL, even at the 90th percentile. When fluoridated water was considered (*Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L* scenarios), all were either at or above the UL for both the mean and 90th percentile, except for the mean at the *Water – 0.6 mg fluoride/L* scenario. Refer to table A3.2 in Appendix 3.

For Australian children aged 9 months, when non-fluoridated water was considered (*Water – 0.1 mg fluoride/L* scenario), all were under the UL, even at the 90th percentile. When fluoridated water was considered (*Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L* scenarios), all were above the UL for both the mean and 90th percentile. Refer to table A3.2 in Appendix 3.

When comparing the intakes between 3 month old fluoride intakes with 9 month old Australians and 6-12 month old New Zealanders, it is noticeable that Australian intakes increase with age, while New Zealand intakes decrease. This may be due to methodological differences in the model diets. Refer to Appendix 1.4.2 for information on the model diets.

5.2 Population groups 2 years or older using NNS data

5.2.1 Results for non-fluoridated water (Water – 0.1 mg fluoride/L scenario)

When non-fluoridated water was considered (*Water – 0.1 mg fluoride/L* scenario), the only population group in which any respondents had dietary fluoride intakes above the UL were Australians aged 30-49 years (<1% of the population group). This was due to only one respondent with an unusually high intake. Refer to table A3.1 in appendix 3.

5.2.2 Results for fluoridated water

When fluoridated water was considered (*Water – 0.6 mg fluoride/L* and *Water – 1.0 mg fluoride/L* scenarios), the population groups with dietary fluoride intakes above the UL were Australians aged 2-3 years (5-22% of the population group), 4-8 years (<1-5% of the population group) and 30-49 years (<1% of the population group) and New Zealanders aged 30-49 years (<1% of the population group) and 50-69 years (<1% of the population group). Refer to table A3.1 in appendix 3.

Figure 11 – 14 shows the dietary fluoride intake distributions for the three scenarios for Australian children aged 2-3 years, 4-8 years and 2 years and above and New Zealand 15 years and above, including a comparison with the UL, respectively.

5.3 The indicative amount of water that can be consumed before exceeding the UL

As beverages, including water, are the major contributors to fluoride intakes it is important to understand whether high water consumers could be at a higher risk of exceeding the UL.

Therefore FSANZ undertook some calculations to determine the indicative amount of additional water that could be consumed before the UL is exceeded, taking into account estimated fluoride intakes from existing food and beverage consumption patterns, including water.

For the 0-6 month infants no calculation was performed for the breast fed infants assuming 3 month olds would not consume significant amounts of water in addition to breast milk, and zero intake was considered from other sources for formula fed infants given they would have the majority of water consumption from the prepared formula. For 7-12 months population group the estimated mean fluoride intake already exceeds the UL. Refer to Table 4 for further details.

Table 4: Indicative amount of water (L) that could be consumed before exceeding the UL for the *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L* scenarios taking into account estimated mean fluoride intakes

NRV Age Group	UL (mg/day)	Indicative amount of water (L)			Estimated Mean Fluoride Intake (mg/d) #
		Water – 0.1 mg/L	***Water – 0.6 mg/L***	***Water – 1.0 mg/L***	
0 - 6 months (formula fed)	0.7	7	1.2	0.7	0.0**
7 - 12 months	0.9	0*	0*	0*	1.3
1 - 3 years	1.3	3.0	0.5	0.3	1.0
4 - 8 years	2.2	10	1.7	1.0	1.2
9 - 13 years	10.0	84	14	8	1.6
14 - 18 years	10.0	79	13	8	2.1
19+ years men	10.0	76	13	8	2.4
19+ years women	10.0	80	13	8	2.0
Pregnancy	10.0	80	13	8	2.0
Lactation	10.0	80	13	8	2.0

***** the UL has already been exceeded
Equation: Maximum consumption < (upper level – mean intake)/fluoride concentration
estimated mean fluoride intake for Australians when water contains 1 mg/L fluoride
** for exclusively breast fed infants

5.4 Water consumption figures based on the 1995 National Nutrition Survey

Based on the 1995 NNS, FSANZ derived the total amount of water consumed (including reticulated or packaged). This is useful for comparison to the indicative amount of water that could be consumed before exceeding the UL as set at in the previous section (Section 5.3).

For 2-3 year old Australians the consumption for a high consumer (95^{th} percentile) is 1,250 ml/day. For 4-8 year olds Australians the consumption for a high consumer is 1,530 ml/day. 95^{th} percentile consumption for age groups above this were 2,100 ml for 9-13 years, 2,500 ml for 14-18 years Australians and 2,400 ml for 15-18 years New Zealanders, 2,100 ml for 19 years and above Australians and 2,500 ml for 19 years and above New Zealanders.

When comparing the 95th percentile consumption data to the indicative amount of water that can be consumed before exceeding the UL (Table 4) all population groups above 2 years of age reported above are under the indicative amount, even for the *Water – 1.0 mg fluoride/L* scenario. In addition, the older age groups are well under the indicative amount.

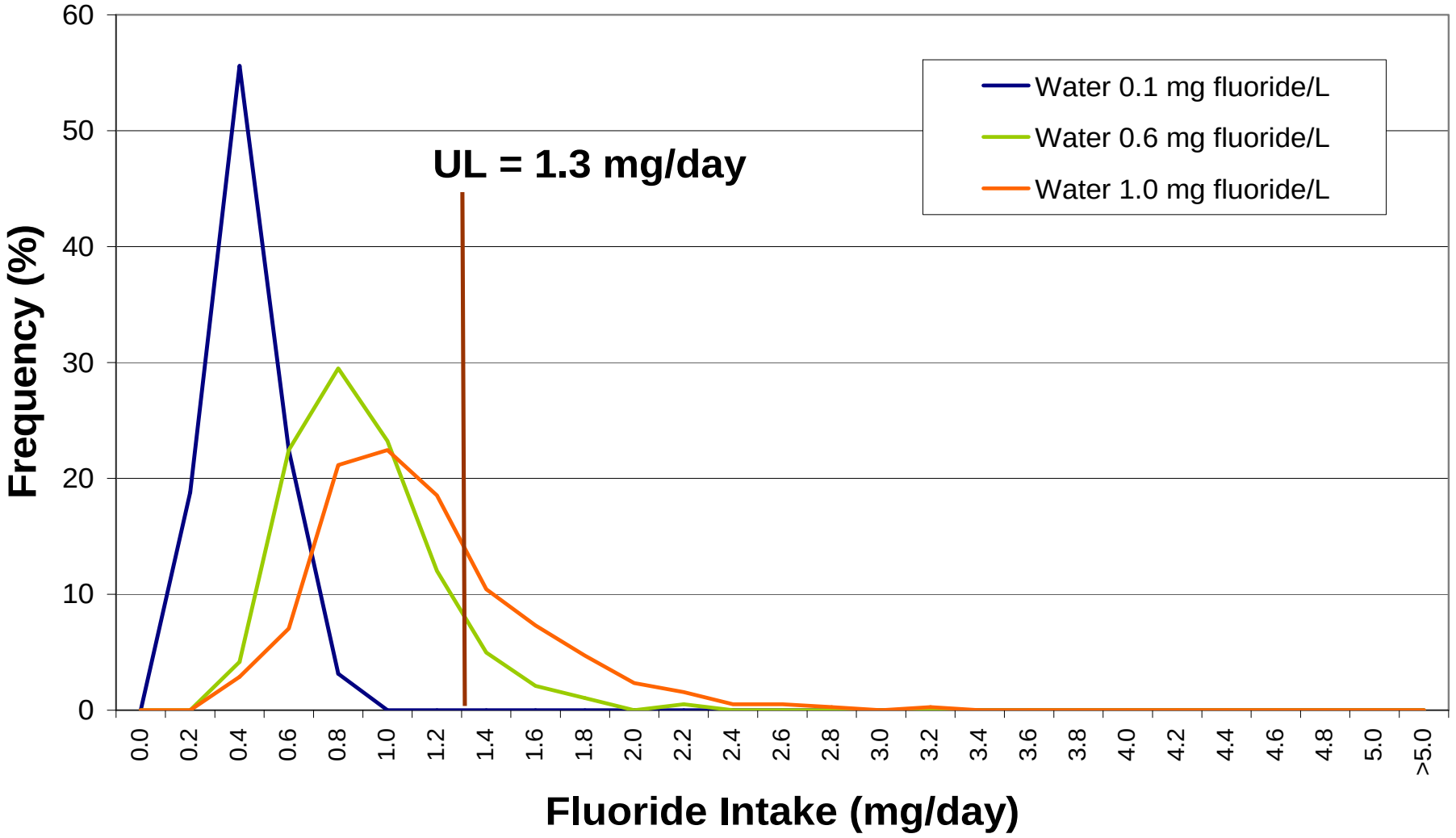


Figure 11: Distribution of dietary intakes of fluoride (mg/day) for Australian children aged 2-3 years for the three scenarios: Water – 0.1 mg/L, Water – 0.6 mg/L and Water – 1.0 mg/L.

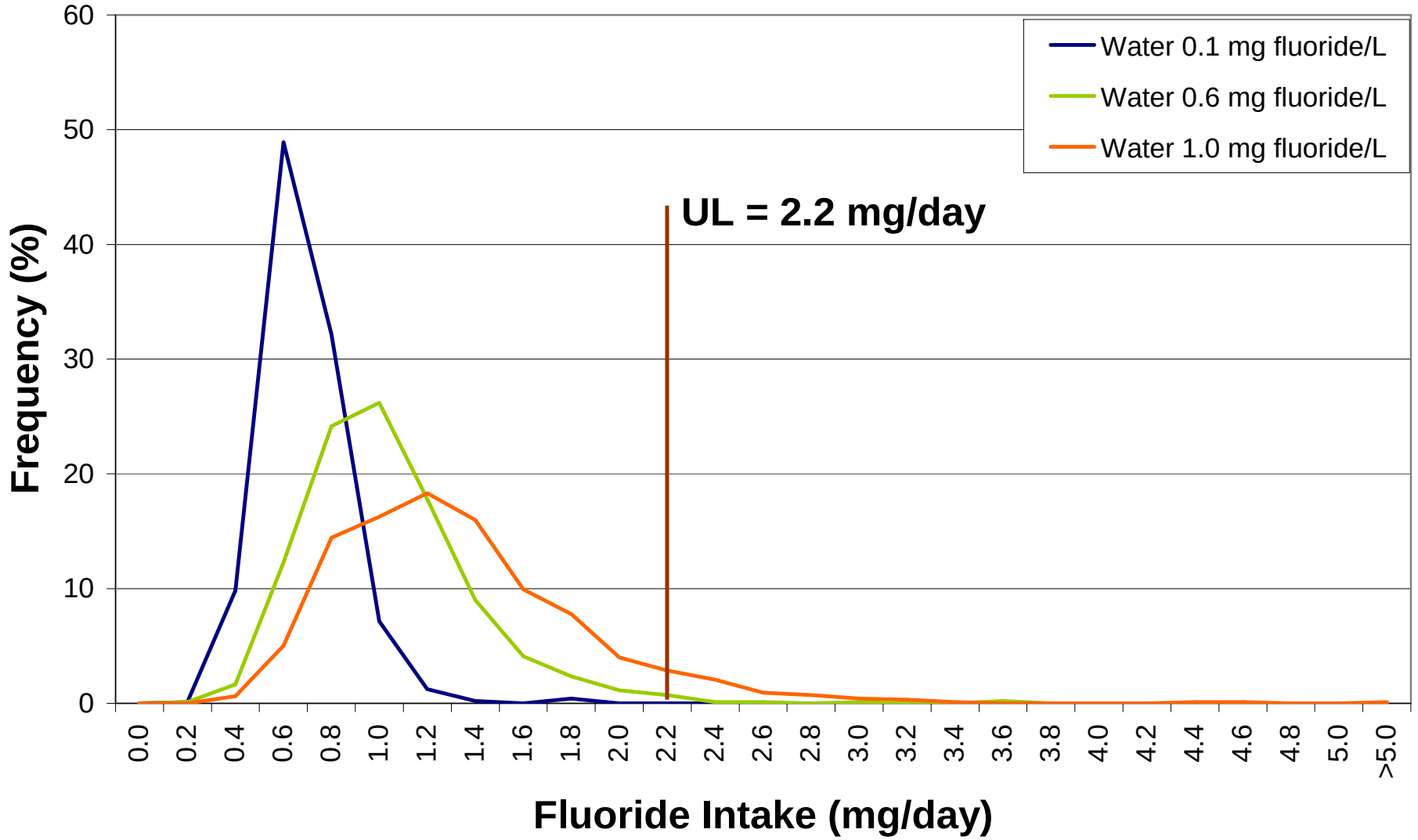


Figure 12: Distribution of dietary intakes of fluoride (mg/day) for Australian children aged 4-8 years for the three scenarios: Water – 0.1 mg/L, Water – 0.6 mg/L and Water – 1.0 mg/L.

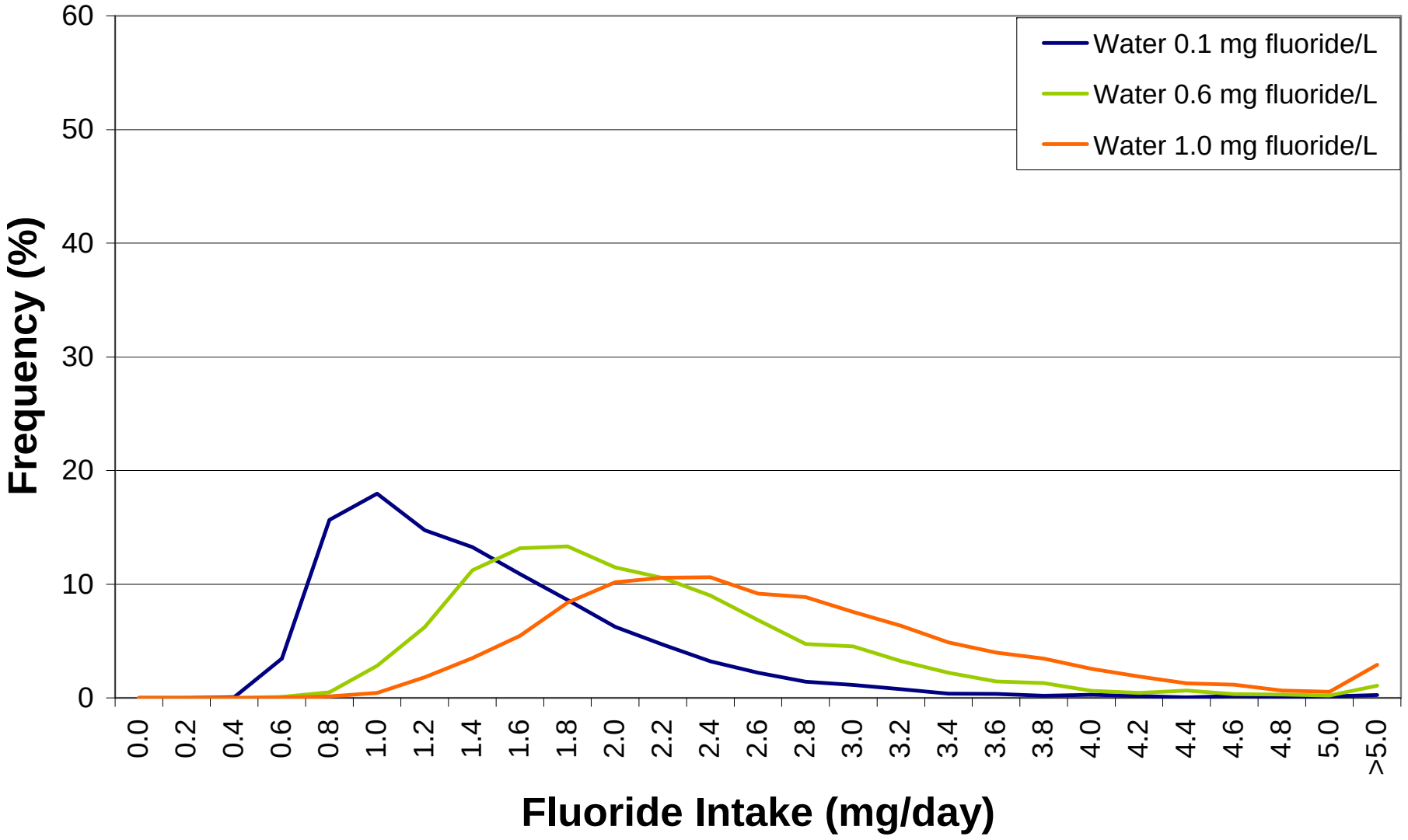


Figure 13: Distribution of dietary intakes of fluoride (mg/day) for New Zealanders aged 15 years and above for the three scenarios: Water – 0.1 mg/L, Water – 0.6 mg/L and Water – 1.0 mg/L.

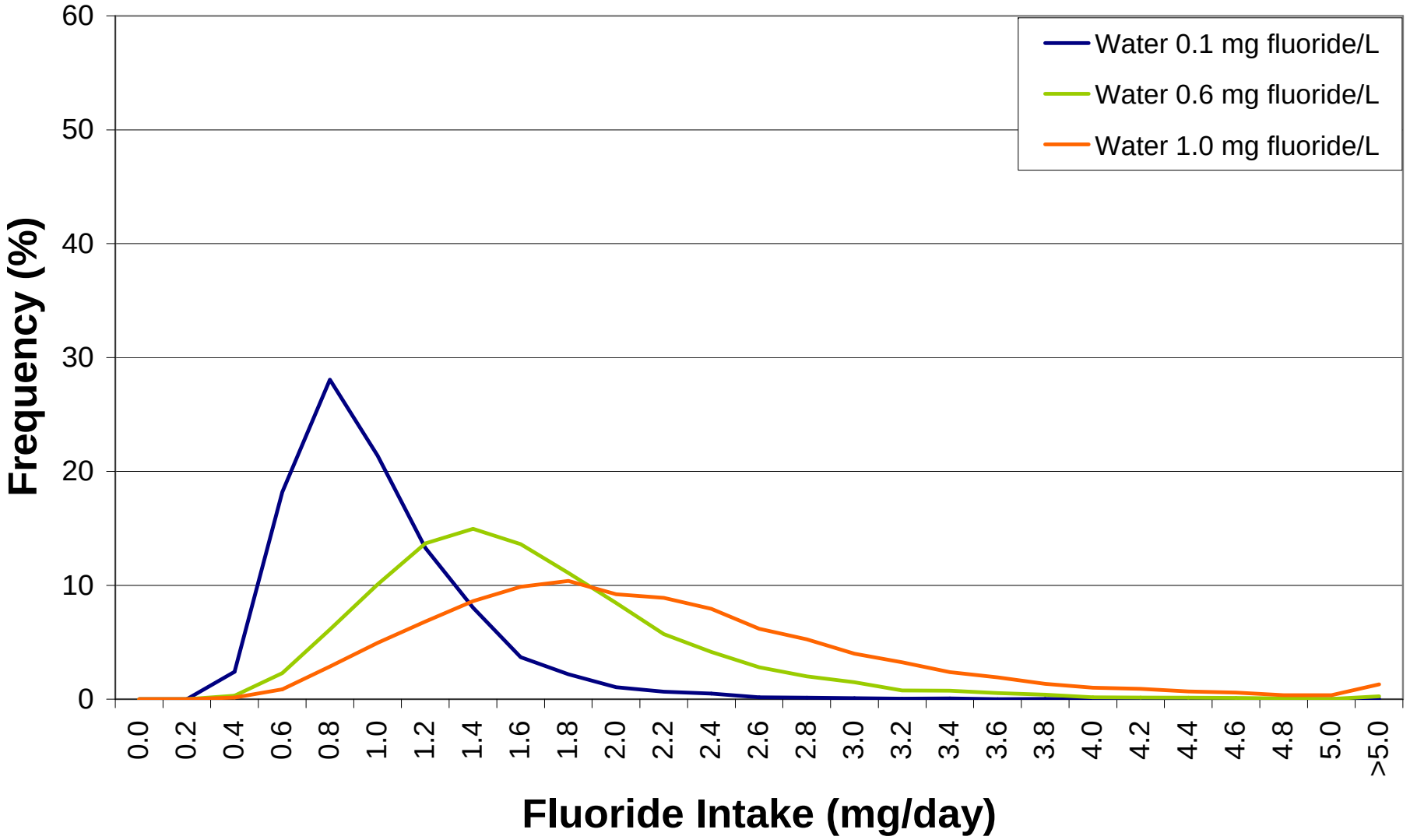


Figure 14: Distribution of dietary intakes of fluoride (mg/day) for Australians aged 2 years and above for the three scenarios: Water – 0.1 mg/L, Water – 0.6 mg/L and Water – 1.0 mg/L.

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Appendix 1

A1 Dietary Intake Assessment Methodology

An international expert in dietary exposure assessments from the US Food and Drug Administration (Dr Mike DiNovi), reviewed all FSANZ dietary exposure assessment principles and modelling procedures and the supporting systems in 2006. The conclusions from the peer reviewer were very positive overall in terms of the FSANZ dietary modelling capability, expertise of staff and consistency of methodologies with international best practice. The peer reviewer prepared a report on his findings which included some recommendations to enhance FSANZ capabilities further. A strategy has been put in place to deal with the recommendations.

A1.1 What is dietary modelling?

Dietary modelling is a tool used to estimate dietary exposure to food chemicals, including nutrient intakes, from the diet as part of the FSANZ risk assessment process. To estimate dietary exposure to food chemicals, records of what foods people have eaten are needed along with reports of how much of the food chemical of interest is in each food. The accuracy of these dietary exposure estimates depends on the quality of the data used in the dietary models. Sometimes, all of the data needed are not available or their accuracy is uncertain so assumptions have to be made, either about the foods eaten or about chemical levels, based on previous knowledge and experience. The models are generally set up according to international conventions for food chemical dietary exposure estimates. However, each modelling process requires decisions to be made about how to set the model parameters and what assumptions to make. Different decisions may result in different answers. Therefore, FSANZ documents clearly all such decisions, model assumptions and data limitations to enable the results to be understood in the context of the data available and so that FSANZ risk managers can make informed decisions.

A1.2 Dietary modelling approach

The dietary intake assessments discussed in this attachment were conducted using FSANZ's dietary modelling computer program, DIAMOND for the population groups aged 2 years and above. Model diets were constructed for children less than 2 years.

Dietary Intake = nutrient concentration x food consumption amount

Fluoride intakes were estimated by combining usual patterns of food consumption, as derived from National Nutrition Survey (NNS) data and model diets, with current concentrations of fluoride in food and beverages and the proposed level of voluntary fluoride fortification in packaged waters.

A1.3 Dietary survey data

A1.3.1 Australians aged 2 years and above and New Zealanders aged 15 years and above

DIAMOND contains dietary survey data for both Australia and New Zealand which were used for the dietary intake assessments.

The 1995 NNS from Australia surveyed 13,858 people aged 2 years and above, and the 1997 New Zealand NNS surveyed 4,636 people aged 15 years and above.

Both of these surveys used a 24-hour food recall methodology. A second 24-hour recall was also conducted on a subset of respondents in both surveys for a non-consecutive day. Standard methodologies were used to estimate nutrient intake based on consumption data from the first 24 hour recall (day one), which were then adjusted to estimate 'usual intake' by using consumption information from the second 24 hour recall (day two). The second day adjustment nutrient intake methodology is discussed in detail in Section A1.4.1.

FSANZ does not currently hold food consumption data from the 2002 National Children's Nutrition Survey (CNS) in the correct format to enable dietary fluoride intake assessments to be conducted for New Zealand children aged 5-14 years. The results of the 2007 Australian National Children's and Physical Activity Survey were not available to FSANZ at the time of writing the report.

It is recognised that the survey data used have several limitations. These are discussed in Section A3.

A1.3.2 Australians aged 3 months and 9 months

As there were no data available from the 1995 Australian NNS for children aged < 2 years, model diets were constructed to estimate dietary fluoride intakes for children aged 3 months and 9 months. For Australia, dietary fluoride intakes were assessed for 9 month old children using a model diet that was based on consumption data for a 2 year old Australian child from the NNS and modified for consumption patterns for infants. See Section 1.4.2.2 for more details on the infant diets.

A1.3.3 New Zealanders aged 3 months and 6-12 months

As there were no data available from the 1997 New Zealand NNS or 2002 New Zealand Children's NNS for children aged < 5 years, a model diet was used for New Zealand children aged 3 months. Estimated fluoride intakes for New Zealand children aged 6-12 months were based on food consumption data from a constructed model diet that was used in the analysis of the New Zealand Total Diet Survey (NZ TDS) (Vannoort and Thomson, 2005). See Section 1.4.2.3 for more details on the infant diets.

A1.4 How were the estimated dietary fluoride intakes calculated?

A1.4.1 For all population groups except Australian and New Zealand children aged <2 years

Fluoride intakes were calculated for each individual in the NNSs using their individual food consumption records from the dietary survey. The DIAMOND program multiplied the specified concentration of fluoride for an individual food by the amount of the food that an individual consumed in order to estimate the intake of fluoride from each food. Once this had been completed for all of the foods specified to contain fluoride, the total amount of fluoride consumed from all foods was summed for each individual. Adjusted nutrient intakes were first calculated (see below) and population statistics (such as mean intakes) were then derived from the individuals' ranked intakes.

Adjusted nutrient intakes, which better reflect 'usual' daily nutrient intakes, were calculated because NRVs, such as the UL, are based on usual or long term intakes and it is therefore more appropriate to compare adjusted or 'usual' nutrient intakes with NRVs.

A1.4.1.1 Calculating adjusted intakes

To calculate usual daily nutrient intakes, more than one day of food consumption data is required. Information for a second (non-consecutive) day of food consumption was collected from approximately 10% of Australian NNS respondents and 15% of New Zealand NNS respondents. In order to calculate an estimate of more usual nutrient intakes using both days of food consumption data, an adjustment was made to each respondent's fluoride intake based on the first day of food consumption data from the NNS. The adjustment took into account several pieces of data, including each person's day one nutrient intake, the mean nutrient intake from the group on day one, the standard deviation from the day one sample and the between person standard deviation from the day two sample. This calculation is described in Figure A1.1. For more information on the methodology of adjusting for second day intakes, see the Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File (Australian Bureau of Statistics, 1998).

Adjusted value = $x + (x_1 - x) * (S_b/S_{obs})$

Where: x is the group mean for the Day 1 sample
x_1 is the individual's day 1 intake
S_b is the between person standard deviation; and
S_{obs} is the group standard deviation for the Day 1 sample

Source: (Australian Bureau of Statistics, 1998)

Figure A1.1: Calculating adjusted nutrient intakes

The age-gender groups used to calculate the second day adjusted fluoride intakes were as outlined in Table A1.1. The age groups used for adjusting nutrient intakes are different to those used for reporting nutrient intakes. This is because there needs to be a certain number of people with a second day of food consumption data to enable a correct adjustment to be made. Reporting however, can be broken down into the age/gender groups as required.

Table A1.1: Age-gender groups used to calculate second day adjusted fluoride intakes

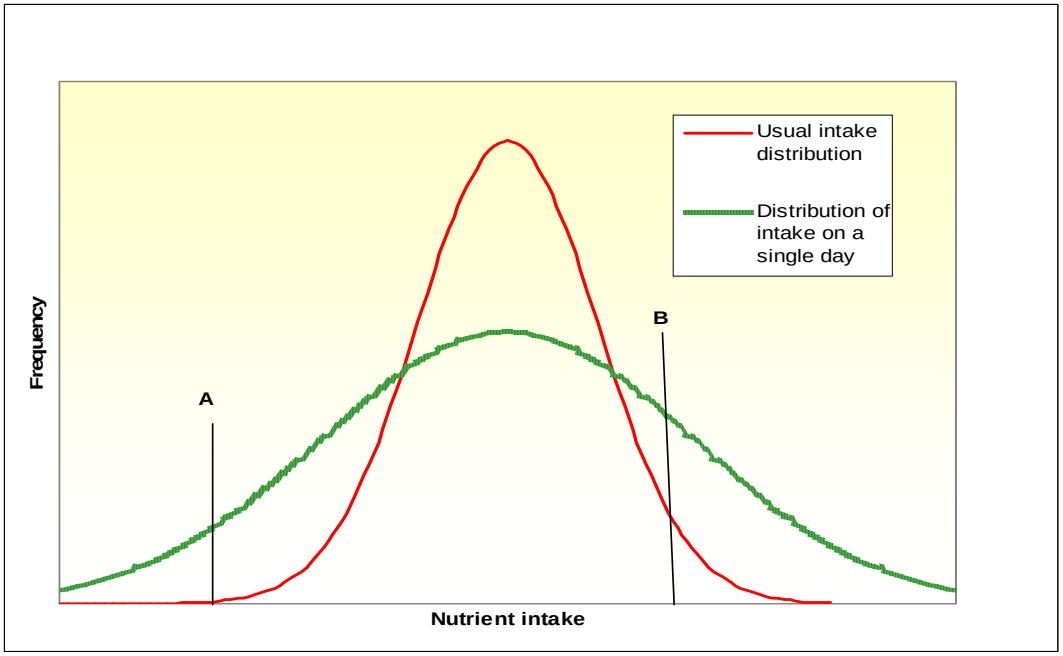
Country	Age Group	Gender	
		Male	Female
Australia	2-13 years	✓	✓
	14-34 years	✓	✓
	35 years and above	✓	✓
New Zealand	15-34 years	✓	✓
	35 years and above	✓	✓

A1.4.1.2 Comparison of one day and usual intake distributions

The range of intakes from respondents is broader based on a single day of food consumption data than the range of usual intakes (Note: A and *B* represent a reference health standard. For example *A* may represent the EAR and *B* may represent the UL.

Figure A1.2) as the latter reduces the variation in day to day intakes within each person. The only process for estimating day to day variation in intakes within individuals is to collect multiple (minimum 2) days of information from the same individual (Rutishauser, 2000).

Using adjusted intakes provides better information for risk characterisation purposes. Use of adjusted (or usual) nutrient intakes will have little or no impact on estimated mean nutrient intakes, but is likely to result in an estimated 95th percentile intake, for example, that is lower than the 95th percentile intake from a single day only, or a 5th percentile intake that is higher than the 5th percentile intake based on day one intakes only.



Note: *A* and *B* represent a reference health standard. For example *A* may represent the EAR and *B* may represent the UL.

Figure A1.2: Comparison of one day and usual intake distributions

A1.4.1.3 Comparison of intakes with ULs

Where the proportion of each population group is expressed as exceeding the UL, each individual's total adjusted intake (mg/day) was compared to the UL for their corresponding age and gender and a percentage exceeding the UL was calculated based on the total number of respondents in the population group being assessed.

A1.4.2 For Australian and New Zealand children aged <2 years

Since the model diets were based on mean food consumption amounts only, individual records were not available to derive a distribution of food consumption amounts and hence a distribution of nutrient intakes.

The proportion of these population groups with dietary fluoride intakes above the UL could therefore not be calculated. As an alternative, the 90th percentile dietary fluoride intake was estimated and then compared to the UL, using the equation:

90th percentile intake = mean intake x 2

(Ratio derived from Office of Premarket Approval, C.F.S.A.N., U.S. FDA, 1995)

90th percentile intakes were used to represent intakes of high consumers.

A1.4.2.1 Australian and New Zealand infants aged 3 months

The recommended energy intake for a three-month-old boy (FAO, 2004) at the 50th percentile weight (WHO, 2007) was used as the basis for the model diet. Boys' weights were used because boys tend to be heavier than girls at the same age and therefore have higher energy and food requirements. Dietary intakes of fluoride were calculated as follows for exclusively formula fed infants:

1. Calculate the energy requirements for 3 month old infant:

   = Estimated energy requirement (kJ/kg bw/day) x body weight (kg)
   = 343 kJ/kg bw/day x 6.4 kg
   = 2195 kJ/day

2. Calculate the amount of infant formula required to meet energy requirements:

   = Estimated energy requirement (KJ/day) ÷ energy content of infant formula (KJ/100g)
   = $\frac{\text{2195 kJ/day}}{\text{274 kJ/100 g formula}}$
   = 800 g infant formula per day

3. Calculate the estimated mean dietary intake of fluoride

   = Daily amount of infant formula x concentration of fluoride in formula

In calculating the estimated dietary intakes of fluoride for exclusively breast-fed infants, it was assumed that exclusively breast fed infants consume 800 g of breast milk per day, equivalent to the amount consumed by formula fed infants. Concentration levels of fluoride in breast milk are 0.003-0.01 mg/L (Chowdhury *et al*, 1990; Fawell *et al*, 2006; Institute of Medicine, 1997). The concentration level of fluoride in unprepared infant formula is 0.2 mg/L and was averaged from data published by Silva and Reynolds (1996). Prepared infant formula was calculated with the addition of water at the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L.*

A1.4.2.2 Australian infants aged 9 months

As there were no data available from the 1995 Australian NNS for children aged < 2 years, a model diet was constructed to estimate dietary fluoride intake for infants aged 9 months.

The model diet for Australian children aged 9 months was based on information on recommended energy intakes, mean body weight and the proportion of milk and solid foods in the diet for a 9 month old child, and data from the 1995 NNS on foods consumed by a 2 year old child.

The recommended energy intake for a nine-month-old boy (FAO 2004) at the 50th percentile weight (WHO 2007) was used as the basis for the model diet. Boys' weights were used because boys tend to be heavier than girls at the same age and therefore have higher energy and food requirements. The body weight of a 50th percentile nine month old boy that was used in the calculation of the model diet was 8.9 kg.

It was assumed that 50 per cent of energy intake was derived from milk (as infant formula) and 50 per cent from solids (Hitchcock *et al*., 1986). The patterns of consumption of a two-year-old child were taken from the 1995 NNS and the amounts of foods scaled down to determine the solid portion of the 9 month old's diet. Certain foods such as nuts, tea, coffee and alcohol were removed from the diet since nuts can be a choking risk (National Health and Medical Research Council, 2001) and coffee and alcohol are unsuitable foods for infants (ACT Community Care, 2000) (see Table A1.2 for further details). Consumption of breakfast cereals was assumed to be in the form of either infant cereal or single grain breakfast cereals. All milk consumption was assumed to be in the form of infant formula.

The amount of water that was consumed in the infant diet was determined using the estimated fluid requirements for infants as follows:

Amount of water = Total fluid requirements – (amount of formula + amount of soft drink + amount of juice)
= (135 ml/kg bw x 8.9 kg) – (674 ml)
= 1,202 ml – 674 ml
= 528 ml

Table A1.2*:*
Rationale for foods excluded from the 9 month old infant diet

ATDS Food	Rationale
Tree nuts	Nuts pose a choking hazard to infants and are not recommended for consumption (Hillis & Stone, 1993; The Children's Hospital at Westmead & Sydney Children's Hospital at Randwick, 2003; NHMRC, 2003) thus they were excluded from the infant diet.
Beer	Alcoholic beverages are unsuitable for infants therefore have been excluded from the infant diet (NHMRC, 2003; ACTCC, 2007).
Breakfast cereal, mixed grain	As standard mixed grain breakfast cereals are not intended for infant consumption they were excluded from the infant diet. It was assumed that the consumption of mixed grain cereals was in the form of infant cereal in the infant diet. The energy value from standard mixed grain cereal was therefore mapped to mixed grain infant cereal. Single grain breakfast cereals were also included to account for the consumption of single grain cereals by infants.
Milk	Milk is listed as an unsuitable fluid for babies. Cow's milk contains higher levels of protein, sodium, potassium, phosphorous and calcium than infant formula. It also contains lower levels of iron, vitamin C and linoleic acid, therefore the composition is not suitable for infants because of the protein and solute load (NHMRC, 2003). It was assumed that all milk is consumed in the form of infant formula.

ATDS Food	Rationale
Peanuts & peanut butter	The NHMRC (2003) lists nuts as "foods not suitable for infants or which require care in their use", citing both the choking hazard and the risk of allergy as reasons. A food intake model run on DIAMOND to determine the consumption of forms of foods in 2 year olds diets indicates that all consumption of food in this category was as peanut butter. However, due to the range of ages suggested in the literature for the introduction of peanuts, peanut butter was excluded from the infant diet.
Soy beverage	Soy beverages (excluding soy infant formulas) are inappropriate for the first two years of life as the levels of protein and fat are not suitable for infants (NHMRC, 2003; ACTCC, 2007).
Tea and coffee	Tea and coffee contain caffeine and are unsuitable fluids for infants (NHMRC, 2003; ACTCC, 2007).
White wine	Alcoholic beverages are unsuitable for infants therefore have been excluded from the infant diet (NHMRC, 2003; ACTCC, 2007).

A1.4.2.3 New Zealand infants aged 6-12 months

As there are no data available from the 1997 New Zealand NNS or 2002 New Zealand children's NNS for children aged < 5 years, a model diet was used to estimate dietary fluoride intakes for New Zealand children aged 6-12 months.

The Simulated Diet for 6-12 month old infants that was used in the analysis of the 2003/04 New Zealand Total Diet Survey (NZ TDS) was used to estimate the mean dietary fluoride intakes in this assessment. The Simulated Diet was a 14-day diet constructed to represent average consumers and was derived from regional studies, rather than national studies of food and nutrient consumption (Vannoort and Thomson, 2005).

A1.4.3 How were the percent contributors calculated?

Percentage contributions of each food group to total estimated fluoride intakes were calculated by summing the intakes for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the intakes of all individuals from all food groups containing fluoride, and multiplying this by 100. These calculations were done using the day one 24-hour recall data.

For the model diets the estimated intake for each food was simply calculated as a percentage of total fluoride intake from all foods.

A2 Assumptions used in the dietary modelling

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

The assumptions made in the dietary modelling are listed below, broken down into several categories.

A2.1 Consumer behaviour

- Consumption of foods as recorded in the NNSs represent current food consumption amounts;
- The total volume of water consumed in the NNSs reflects current total water consumption;
- consumers select products that, on average, contain fluoride at the concentrations specified;
- for Australian children aged 9 months, 50 per cent of energy intake was derived from milk (as infant formula) and 50 per cent from solids;
- for Australian children aged 9 months, all milk is consumed in the form of infant formula; and
- consumers do not alter their food consumption habits and /or amounts upon fluoride fortified products becoming more available on the market.

A2.2 Concentration Data

- Where there were no Australian fluoride concentration data for specific foods, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand;
- all foods in the Australian and New Zealand datasets were assigned a fluoride concentration.
- where a food was not included in the intake assessment, it was assumed to contain a zero concentration of fluoride;
- fluoride from water was not taken up by vegetables when boiled;
- all water consumed (whether reticulated or packaged) has a fluoride concentration at the specified level for that scenario;
- there is no contribution to fluoride intakes through the use of complementary medicines (Australia) or dietary supplements (New Zealand); and
- where a concentration of fluoride was reported by laboratories as being below the limit of reporting (LOR), the food was assigned a concentration equivalent to half LOR or a zero value, depending on quantifiable levels in similar foods.

A2.3 General

- The additional fluoride from voluntary fortification is absorbed into the body at a similar rate to the fluoride from the general food supply; and
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. orange juice).

A3 Limitations of the dietary intake assessment

FSANZ always ensures the data and methodologies used for dietary intake assessments are the most up to date and the best available. FSANZ evaluates all data sets prior to modelling for any project and has been proactive in obtaining and using other data and methodologies where applicable and undertaking validation processes where required. FSANZ notes any limitations associated with the dietary intake assessment so that the results can be interpreted correctly.

Dietary intake assessments based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food for individuals and the resulting estimated dietary intake of a nutrient for the population. FSANZ has undertaken an assessment of changing food consumption patterns across the diet over time and concluded that consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997 (Cook *et al*., 2001a; Cook *et al*., 2001b). The NNS food consumption data were not 'updated' for dietary modelling as it is not possible to modify the actual NNS data for use in DIAMOND.

A3.1 Other limitations

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, a limitation of the dietary intake assessment is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997.

There are a number of limitations associated with the fluoride concentration data. Analytical values used may not fully reflect actual levels because of variation in fluoride concentrations in foods due to season and geographic location. The analytical method used to analyse foods and beverages has a high limit of reporting, therefore a high number of non-detected values were found.

The increase in packaged water consumption since the collection of the 1995 NNS data has not been taken into account in the intake estimates. All water is fluoridated at the same level in each scenario regardless of whether it is reticulated or packaged and based on the assumption that total water consumption has not changed since 1995. The model is reasonable for baseline estimates of intake and estimates of intake where direct substitution of one type of water for another occurs. A recent article by Levy and Tapsell (2007) on the purchasing patterns of non-alcoholic beverages in Australia from 1997-2006 is considered within the DAR. Current Single Source data from Roy Morgan Research only dates back to 2006 for information on water consumption. This is considered unsuitable to determine the trends of packaged waters versus reticulated water as well as whether total water consumption has varied or stayed the same since the NNS data were collected.

A limitation of estimating dietary intake over a period of time using information from a recall method is that people may over- or under-report food consumption, particularly for certain types of foods. Over- and under-reporting of food consumption has not been accounted for in this dietary intake assessment. However, adjusting intakes based on two days of food consumption data accounts for some of the within individual variation.

Since the 1995 Australian NNS does not report on respondents aged below 2 years, the 1997 New Zealand NNS does not report on respondent aged below 15 years and the 2002 New Zealand National Children's Nutrition Survey (CNS) does not report on respondents aged below 5 years, model diets were used to estimate dietary fluoride intakes for New Zealand children aged 6-12 months and Australian children aged 9 months.

Mean food consumption amounts in the model diets are used to represent food consumption patterns for an age group as a whole and may not be as accurate as the data derived for other population groups from the NNSs that use food consumption data of individuals. However, they are the best data available for these age groups.

Although some data on the use of complementary medicines (Australia) or dietary supplements (New Zealand) were collected in the NNSs, data were either not in a robust enough format to include in DIAMOND or have simply not been included in the DIAMOND program to date. Consequently, intakes of substances consumed via complementary medicines or dietary supplements could not be included directly in the dietary intake assessment conducted using DIAMOND.

Fluoride intake is likely to be slightly underestimated due to the difficulty of capturing all sources of water in the composition dataset.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In addition, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs which make the data representative of the actual population as a whole. Maori and Pacific peoples were over-sampled in the 1997 New Zealand NNS so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary intake assessment because population weights were not used.

Appendix 2

Complete information on dietary intake assessment results

Table A2.1: Estimated mean and 90th percentile dietary fluoride intakes for exclusively formula fed and exclusively breast fed Australian and New Zealand children aged 3 months for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

	Scenario	Estimated dietary fluoride intake (mg/day)		Adequate Intake# (mg/day)
		Mean	***90th percentile***	
Formula fed infants	*Water – 0.1 mg/L*	0.2	0.5	0.01
	Water – 0.6 mg/L	0.7	1.4	0.01
	Water – 1.0 mg/L	1.0	1.9	0.01
Breast fed infants*	-	0.002 – 0.008	0.005 – 0.016	0.01

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

* a range of estimated dietary fluoride intakes has been calculated for breast-fed infants due to the range in concentrations of fluoride in breast milk

Table A2.2: Estimated mean and 90th percentile dietary fluoride intakes for New Zealand children aged 6-12 months for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Scenario	Estimated dietary fluoride intake (mg/day)		Adequate Intake#
	Mean	***90th percentile***	(mg/day)
Water – 0.1 mg/L	0.4	0.7	0.5
Water – 0.6 mg/L	0.6	1.3	0.5
Water – 1.0 mg/L	0.9	1.7	0.5

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

Table A2.3: Estimated mean and 90th percentile dietary fluoride intakes for Australian children aged 9 months for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Scenario	Estimated dietary fluoride intake (mg/day)		Adequate Intake (mg/day)
	Mean	***90th percentile***	
Water – 0.1 mg/L	0.4	0.7	0.5
Water – 0.6 mg/L	1.0	1.9	0.5
Water – 1.0 mg/L	1.3	2.7	0.5

[#] The Adequate Intake (AI) is defined as the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a groups (or groups) of apparently healthy people that are assumed to be adequate

Table A2.4: Estimated mean dietary fluoride intakes for New Zealand and Australian population groups for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Country	Population Group	Estimated mean dietary fluoride intake (mg/day)			Adequate Intake[#] (mg/day)	
		Water – 0.1 mg/L	***Water – 0.6 mg/L***	***Water – 1.0 mg/L***	***Males***	***Females***
New Zealand	15-18 years	1.0	1.5	2.0	3.0	3.0
	19-29 years	1.1	1.7	2.3	4.0	3.0
	30-49 years	1.4	2.2	2.7	4.0	3.0
	50-69 years	1.5	2.2	2.8	4.0	3.0
	70 years & above	1.4	2.1	2.6	4.0	3.0
	15 years & above	1.4	2.1	2.6	4.0	3.0
Australia	2-3 years	0.5	0.8	1.0	0.7	0.7
	4-8 years	0.6	0.9	1.2	1.0	1.0
	9-13 years	0.7	1.2	1.6	2.0	2.0
	14-18 years	1.0	1.6	2.1	3.0	3.0
	19-29 years	1.0	1.8	2.4	4.0	3.0
	30-49 years	1.0	1.8	2.4	4.0	3.0
	50-69 years	0.9	1.6	2.1	4.0	3.0
	70 years & above	0.8	1.3	1.7	4.0	3.0
	2 years & above	0.9	1.5	2.1		

[#] The Adequate Intake (AI) is defined as the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a groups (or groups) of apparently healthy people that are assumed to be adequate

Table A2.5: Major contributors (≥5%) to estimated fluoride intakes for New Zealand children aged 6-12 months for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Food Group Name	**Major contributors to Fluoride Intakes (% fluoride intake)**		
	Water – 0.1 mg/L	***Water – 0.6 mg/L***	***Water – 1.0 mg/L***
Beverages (non-alcoholic and waters)	9	19	22
Water		14	17
Infant & follow on formula	29	44	49
Dairy products	16	10	7
Cereals & cereal products	17	10	8
Infant foods (not including formula)	9	6	6
Fish/Seafood	6		
Vegetable products & dishes	6		
All other foods	8	11	8

Notes:
[1] The numbers in **bold** indicate the major contributor to fluoride intake for the population group for that scenario.
[2] The percent contribution is listed only if it is ≥ 5% - the shaded cells indicate that the food contributes to fluoride intakes but that the contribution is < 5%.

Table A2.6: Major contributors (≥5%) to estimated fluoride intakes for Australian children aged 9 months for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Food Group Name	**Major contributors to Fluoride Intakes (% fluoride intake)**		
	Water – 0.1 mg/L	***Water – 0.6 mg/L***	***Water – 1.0 mg/L***
Beverages (non-alcoholic and waters)	30	39	43
Water	15	33	39
Infant formula	45	51	49
Dairy products	6		
Cereals & cereal products	7		
All other foods	19	10	8

Notes:
[1] The numbers in **bold** indicate the major contributor to fluoride intake for the population group for that scenario.
[2] The percent contribution is listed only if it is ≥ 5% - the shaded cells indicate that the food contributes to fluoride intakes but that the contribution is < 5%.

Table A2.7: Contributors to estimated fluoride intakes for the Australian population aged 2-3 years for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Food Group Name	Major contributors to fluoride intakes (% fluoride intake)		
	Water – 0.1 mg fluoride/L	***Water – 0.6 mg fluoride/L***	***Water – 1.0 mg fluoride/L***
Beverages (non-alcoholic, alcoholic and waters)	37	58	66
- Coffee			
- Fruit and vegetables juices and drinks	20	18	17
- Fruit drinks	7		
- Fruit-based or flavoured cordials & drinks		8	9
- Soft drinks, flavoured mineral waters & electrolyte drinks	6		
- Beers			
- Plain water	10	36	46
Cereals & cereal products	12	9	8
Fish & seafood products & dishes			
Meat, poultry & game products & dishes	7		
Milk products & dishes	22	14	10
- Dairy milk	7		
- Ice cream			
Vegetable products & dishes	7		

1. **Beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water, tap water, beers, wines, spirits, liqueurs, ciders and mixed alcoholic beverages.
2. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls (including flat breads, fruit breads and topped breads), breakfast cereals (including porridges cooked with water/milk), English-style muffins, crumpets, tortillas, pastas, noodles and rice.

3. **Fish and seafood products and dishes** includes fresh, frozen, smoked, canned, crumbed and battered raw and cooked fish, molluscs and crustacea, fish fingers, fish cakes and mixed dishes containing fish or other seafood.
4. **Meat, poultry & game products & dishes** includes all cuts of raw and cooked beef, veal, lamb, pork, ham, bacon, game meat, poultry, offal, sausages, processed meats (e.g. salami) and mixed dishes containing these foods.
5. **Milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
6. **Vegetable products and dishes** includes raw, frozen, cooked, canned, dried, battered and crumbed vegetables (including, hot potato chips and wedges, mashed potatoes) and herbs and mixed dishes made from these foods (e.g. salads, dips). It does not include dried legume and pulses (e.g. kidney beans).

Table A2.8: Contributors to estimated fluoride intakes for the Australian population aged 4-8 years for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Food Group Name	Major contributors to fluoride intakes (% fluoride intake)		
	Water – 0.1 mg fluoride/L	***Water – 0.6 mg fluoride/L***	***Water – 1.0 mg fluoride/L***
Beverages (non-alcoholic, alcoholic and waters)	38	59	67
- Coffee			
- Fruit and vegetables juices and drinks	17	16	15
- Fruit drinks	6		
- Fruit-based or flavoured cordials & drinks		8	10
- Soft drinks, flavoured mineral waters & electrolyte drinks	11	7	6
- Beers			
- Plain water	10	36	45
Cereals & cereal products	11	9	8
Fish & seafood products & dishes			
Meat, poultry & game products & dishes	8		
Milk products & dishes	20	12	9
- Dairy milk			
- Ice cream	8		
Vegetable products & dishes	7		

1. **Beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water, tap water, beers, wines, spirits, liqueurs, ciders and mixed alcoholic beverages.
2. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls (including flat breads, fruit breads and topped breads), breakfast cereals (including porridges cooked with water/milk), English-style muffins, crumpets, tortillas, pastas, noodles and rice.

3. **Fish and seafood products and dishes** includes fresh, frozen, smoked, canned, crumbed and battered raw and cooked fish, molluscs and crustacea, fish fingers, fish cakes and mixed dishes containing fish or other seafood.
4. **Meat, poultry & game products & dishes** includes all cuts of raw and cooked beef, veal, lamb, pork, ham, bacon, game meat, poultry, offal, sausages, processed meats (e.g. salami) and mixed dishes containing these foods.
5. **Milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
6. **Vegetable products and dishes** includes raw, frozen, cooked, canned, dried, battered and crumbed vegetables (including, hot potato chips and wedges, mashed potatoes) and herbs and mixed dishes made from these foods (e.g. salads, dips). It does not include dried legume and pulses (e.g. kidney beans).

Table A2.9: Contributors to estimated fluoride intakes for the New Zealand population aged 15 years and above for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Food Group Name	Major contributors to fluoride intakes (% fluoride intake)		
	Water – 0.1 mg fluoride/L	***Water – 0.6 mg fluoride/L***	***Water – 1.0 mg fluoride/L***
Beverages (non-alcoholic, alcoholic and waters)	64	74	78
- Tea	50	44	41
- Fruit Juices			
- Soft Drinks			
- Plain Water	6	23	30
Cereals & cereal products	13	10	9
- Regular bread and rolls	6		
Fish & seafood products & dishes	5		
Meat, poultry & game products & dishes			
Milk products & dishes			
Vegetable products & dishes	8	5	

1. **Beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water, tap water, beers, wines, spirits, liqueurs, ciders and mixed alcoholic beverages.
2. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls (including flat breads, fruit breads and topped breads), breakfast cereals (including porridges cooked with water/milk), English-style muffins, crumpets, tortillas, pastas, noodles and rice.
3. **Fish and seafood products and dishes** includes fresh, frozen, smoked, canned, crumbed and battered raw and cooked fish, molluscs and crustacea, fish fingers, fish cakes and mixed dishes containing fish or other seafood.
4. **Meat, poultry & game products & dishes** includes all cuts of raw and cooked beef, veal, lamb, pork, ham, bacon, game meat, poultry, offal, sausages, processed meats (e.g. salami) and mixed dishes containing these foods.
5. **Milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
6. **Vegetable products and dishes** includes raw, frozen, cooked, canned, dried, battered and crumbed vegetables (including, hot potato chips and wedges, mashed potatoes) and herbs and mixed dishes made from these foods (e.g. salads, dips). It does not include dried legume and pulses (e.g. kidney beans).

Table A2.10: Contributors to estimated fluoride intakes for the Australian population aged 2 years and above for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Food Group Name	Major contributors to fluoride intakes (% fluoride intake)		
	Water – 0.1 mg fluoride/L	***Water – 0.6 mg fluoride/L***	***Water – 1.0 mg fluoride/L***
Beverages (non-alcoholic, alcoholic and waters)	44	64	72
- Coffee		14	16
- Fruit and vegetables juices and drinks	5		
- Fruit drinks			
- Fruit-based or flavoured cordials & drinks			
- Soft drinks, flavoured mineral waters & electrolyte drinks	10	6	
- Beers	10	6	
- Plain water	9	31	39
Cereals & cereal products	9	7	6
Fish & seafood products & dishes	5		
Meat, poultry & game products & dishes	9		
Milk products & dishes	11	7	5
- Dairy milk			
- Ice cream			
Vegetable products & dishes	12	7	

1. **Beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water, tap water, beers, wines, spirits, liqueurs, ciders and mixed alcoholic beverages.
2. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls (including flat breads, fruit breads and topped breads), breakfast cereals (including porridges cooked with water/milk), English-style muffins, crumpets, tortillas, pastas, noodles and rice.

3. **Fish and seafood products and dishes** includes fresh, frozen, smoked, canned, crumbed and battered raw and cooked fish, molluscs and crustacea, fish fingers, fish cakes and mixed dishes containing fish or other seafood.
4. **Meat, poultry & game products & dishes** includes all cuts of raw and cooked beef, veal, lamb, pork, ham, bacon, game meat, poultry, offal, sausages, processed meats (e.g. salami) and mixed dishes containing these foods.
5. **Milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
6. **Vegetable products and dishes** includes raw, frozen, cooked, canned, dried, battered and crumbed vegetables (including, hot potato chips and wedges, mashed potatoes) and herbs and mixed dishes made from these foods (e.g. salads, dips). It does not include dried legume and pulses (e.g. kidney beans).

Appendix 3

Complete information on risk characterisation

Table A3.1: Estimated mean and 90th percentile dietary fluoride intakes as a percentage of the UL, for Australian and New Zealand children aged 3 months exclusively breast fed or formula fed

	Scenario	UL	Estimated dietary fluoride intake (%UL)	
		(mg/day)	Mean	90th percentile
Formula fed infants	*Water – 0.1 mg/L*	0.7	30	70
	Water – 0.6 mg/L	0.7	100	200
	Water – 1.0 mg/L	0.7	140	270
Breast fed infants	-	0.7	<1-1	<1-2

Table A3.1: Estimated mean and 90th percentile dietary fluoride intakes, as a percentage of the UL, for New Zealand children aged 6-12 months, based on model diets

Scenario	UL	Estimated dietary fluoride intake (%UL)	
	(mg/day)	Mean	90th percentile
Water – 0.1 mg/L	0.9	45	80
Water – 0.6 mg/L	0.9	65	140
Water – 1.0 mg/L	0.9	100	190

Table A3.3: Estimated mean and 90th percentile dietary fluoride intakes, as a percentage of the UL, for Australian children aged 9 months, based on model diets

Scenario	UL	Estimated dietary fluoride intake (%UL)	
	(mg/day)	Mean	90th percentile
Water – 0.1 mg/L	0.9	45	80
Water – 0.6 mg/L	0.9	110	210
Water – 1.0 mg/L	0.9	140	300

Table A3.4: Estimated proportion of New Zealand and Australian population groups with dietary fluoride intakes above the Upper Level (UL) for the three scenarios: *Water – 0.1 mg/L*, *Water – 0.6 mg/L* and *Water – 1.0 mg/L*

Country	Population Group	UL (mg/day)	Estimated proportion of the population with dietary fluoride intakes > UL (%)		
			Water – 0.1 mg/L	***Water – 0.6 mg/L***	***Water – 1.0 mg/L***
New Zealand	6-12 months	1.3			
	15-18 years	10.0	-	-	-
	19-29 years	10.0	-	-	-
	30-49 years	10.0	-	<1	<1
	50-69 years	10.0	-	<1	<1
	70 years & above	10.0	-	-	-
	15 years & above	10.0	-	<1	<1
Australia	9 months	0.9			
	2-3 years	1.3	-	5	22
	4-8 years	2.2	-	<1	5
	9-13 years	10.0	-	-	-
	14-18 years	10.0	-	-	-
	19-29 years	10.0	-	-	-
	30-49 years	10.0	<1	<1	<1
	50-69 years	10.0	-	-	-
	70 years & above	10.0	-	-	-
	2 years & above	*	<1	<1	<1

* The appropriate UL for each age group was used for each individual respondent.

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