The following is an extract from:

Nutrient Reference Values for Australia and New Zealand
Including Recommended Dietary Intakes

VERSION 1.1

UPDATED MARCH 2017

ORIGINALLY ENDORSED BY THE NHMRC ON 9 SEPTEMBER 2005

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PUBLICATION APPROVAL

2006 Nutrient Reference Values

These guidelines were endorsed by the Chief Executive Officer (CEO) of the National Health and Medical Research Council (NHMRC) on 9 September 2005, under Section 7(1)(a) of the National Health and Medical Research Council Act 1992. In endorsing these guidelines the NHMRC considers that they meet the NHMRC standard for clinical practice guidelines.

2017 Update: Fluoride

Updates to the guideline recommendations for fluoride for 0-8 year olds were approved by the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) on 21 November 2016, under Section 14A of the National Health and Medical Research Council Act 1992. In approving these guidelines the NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. Approval of the guideline recommendations will be reviewed for currency after five years.

NHMRC is satisfied that the guideline recommendations are systematically derived, based on the identification and synthesis of the best available scientific evidence, and developed for health professionals practising in an Australian health care setting.

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FLUORIDE *(UPDATED 2017)*

TABLE OF UPDATES AND AMENDMENTS

Amendment Type	Amendment Detail	Date Updated	Version Number
Revision of fluoride NRVs as follows: • AI for children 0-8 years • UL for children 0-8 years Amendments to the resources across the NRV suite have been made to reflect the latest scientific evidence and recommendations.	NHMRC approved the revised NRV recommendations for fluoride on 21 November 2016 under Section 14A of the NHMRC Act 1992. The supporting material including the Methodological Framework, any literature reviews and evidence summaries are authored by the Australian Government Department of Health (formerly the Department of Health and Ageing) and the New Zealand Ministry of Health. https://www.nhmrc.gov.au/guidelines-publications/n35-n36-n37	March 2017	1.1

UPDATE 1.1: REVISION OF FLUORIDE (2017)

The fluoride AI and UL for 0-8 year olds were approved by the Chief Executive Officer of the National Health and Medical Research Council on 21 November 2016, under Section 14A of the National Health and Medical Research Council Act 1992.

Australia and New Zealand have pursued public health policy to adjust fluoride intake at the population level with the aim of preventing dental caries. It is considered desirable to have a fluoride intake that is sufficient to prevent dental caries (an AI) without exceeding intakes that are associated with severe dental fluorosis (a UL). The AI and UL refer to habitual intake of fluoride and are used to assess fluoride intakes at a population level.

Fluoride was identified as a priority for review, given recent estimates of fluoride intakes in Australia and New Zealand have suggested that the fluoride intake of a substantial proportion of infants and young children may exceed the UL set in 2006, without widespread occurrence of moderate or severe dental fluorosis, suggesting the UL needed revising. The scope of the review was narrowed to an AI and UL for fluoride for infants and young children up to eight years of age, as this is the period of time in which permanent teeth are formed and therefore the critical age group to consider for dental caries and fluorosis.

The supporting material including the 2017 technical report containing the literature review and evidence summaries can be found at www.nrv.gov.au/resources.

The recommendations for the revised AI and UL for fluoride for 0-8 year olds have no implications for the current Drinking Water Guidelines in Australia, the current Drinking Water Standards for New Zealand or for recommendations on fluoride ingestion from toothpaste.

The AIs and ULs for children and adolescents over 8 years of age, adults, pregnant and lactating women were not reviewed and remain as per the 2006 NRVs for Australia and New Zealand. This publication has been revised to incorporate the revised AIs and ULs for infants and children up to 8 years of age.

BACKGROUND

Fluoride is naturally present in the food and drink we consume and is considered a normal constituent of the human body. The fluoride concentration in bones and teeth is about 10,000 times that in body fluids and soft tissues (Bergmann and Bergmann 1991; 1995). Nearly 99% of the body's fluoride is bound strongly to calcified tissues. Fluoride in bone appears to exist in both rapidly and slowly exchangeable pools.

Fluoride is ingested from several sources including foods, fluoridated and unfluoridated water, fluoridated toothpastes and some dietary supplements. Fluoride intake from most foods is low. Both inadequate and excessive fluoride intakes can affect dental health. Inadequate intakes are associated with increased tooth decay (dental caries) and excessive intakes with damage to tooth enamel (dental fluorosis).

Fluoride available systemically during tooth development is incorporated into teeth as fluorapatite in tooth enamel. Fluorapatite in tooth enamel alters its crystalline structure, reducing the solubility of enamel to acid dissolution, or demineralisation. At higher fluoride intakes the crystalline structure may be disrupted during tooth development periods, forming porosities which are the basis of dental fluorosis, a change in the cosmetic appearance of teeth (Aoba 1997, Fejerskov et al. 1994, Aoba and Fejerskov 2002). Moderate dental fluorosis is uncommon and severe dental fluorosis is rare in Australia and New Zealand. Prolonged exposure to very high fluoride intakes can result in outcomes such as skeletal fluorosis and bone fractures, however there have been no reported cases in Australia (Jack et al. 2016).

Fluoride at the surface of enamel can also form calcium fluoride, a more rapidly exchangeable pool of fluoride to alter the demineralisation-remineralisation balance, which is the dynamic process underlying dental decay (Aoba 1997, Fejerskov et al. 1994, Aoba and Fejerskov 2002). Tooth decay (dental caries) is a largely preventable but highly prevalent chronic disease in Australian and New Zealand children and adults. It remains the most common form of childhood infection and creates a significant health burden (Do and Spencer 2016). The fluoridation of drinking water aims to bring fluoride levels up to a range that can help to prevent or minimise tooth decay by 26-44% in children, teenagers and adults (Jack et al. 2016).

2017 REFERENCE BODY WEIGHT DATA 0-8 YEARS

The fluoride AI and UL for 0-8 year olds were updated in 2017. The following updated reference bodyweights were used when the NRVs were expressed in mg fluoride/day; 0-6 months 6 kg, 7-12 months 9 kg, 1-3 years 12 kg, 4-8 years 22 kg.

The most recent United States reference bodyweight data (IOM 2005) was used for infants and young children aged 1-3 years (mean bodyweight of 12 kg), as no suitable Australian and New Zealand data were available.

New reference bodyweight data was derived from the 2011-2012 Australian Health Survey (AHS) and the 2011-12 New Zealand Health Survey for Australian and New Zealand children aged 4-8 years (ABS 2014) and rounded up to the nearest whole number, resulting in a mean bodyweight of 22 kg for children aged 4-8 years.

1 mmol fluoride = 19 mg fluoride

RECOMMENDATIONS BY LIFE STAGE AND GENDER

Infants and young children	**AI**	**Fluoride**
0–6 months*	**–**	
7–12 months*	**0.5 mg/day#**	
1–3 yr*	**0.6 mg/day**	
4–8 yr*	**1.1 mg/day**	

* The fluoride AI and UL for 0-8 year olds were updated in 2017. The following reference body weights were used when the 2017 NRVs for infants and young children aged 0-8 years were expressed in mg fluoride/day; 0-6 months 6 kg, 7-12 months 9 kg, 1-3 years 12 kg, 4-8 years 22 kg.
# Rounded to the first decimal place

Rationale: The purpose of the AI for infants and young children is to provide information on the level of intake that provides protection from inadequate intake, which in the case of fluoride results in increased risk of dental caries.

An AI has not been established for infants less than six months of age: The review of evidence did not find a preventive effect (reduction in dental caries) with fluoride intake in the first six months of life. This is in line with the view expressed by the Institute of Medicine (IOM) in 1997 and supported by the American Dental Association's Council on Scientific Affairs statement in 2011 that the preventive effect of fluoride in the first six months of life has not been established.

This does not impact on infant formula composition.

AI for 6 months to 8 years of age: A reduction in the prevalence and severity of dental caries associated with communities having fluoridated water (approx. 1 mg F/L) has been confirmed by numerous epidemiological studies conducted in several countries throughout the world (Murray et al. 1991, McDonagh et al. 2000, Rugg-Gunn and Do 2012). The average daily dietary intake of fluoride under conditions that results in near maximal caries prevention is approximately 0.05 mg /kg/ day and as such the AI of 0.05 mg F/kg bw/day was reaffirmed to be an intake likely to be associated with appreciably reduced rates of dental caries in a population for infants aged 6 months and over and young children up to 8 years.

Children & adolescents	**AI**	**Fluoride**
Boys		
9–13 yr	**2.0 mg/day**	
14–18 yr	**3.0 mg/day**	
Girls		
9–13 yr	**2.0 mg/day**	
14–18 yr	**3.0 mg/day**	

***Rationale*:** The AI for 9-18 year olds were not reviewed in the 2017 update. The AI for for 9-18 year olds is based on the requirement of 0.05 mg/kg body weight/day and adjusted for the standard body weights of 40 kg for 9–13 year olds, 64 kg for boys aged 14–18 years and 57 kg for 14–18 year-old girls. Supplements may be necessary for children in non-fluoridated areas (Burt 1992).

Adults	**AI**	**Fluoride**
Men		
19–30 yr	**4 mg/day**	
31–50 yr	**4 mg/day**	
51–70 yr	**4 mg/day**	
>70 yr	**4 mg/day**	
Women		
19–30 yr	**3 mg/day**	
31–50 yr	**3 mg/day**	
51–70 yr	**3 mg/day**	
>70 yr	**3 mg/day**	

***Rationale*:** The AI for adults were not reviewed in the 2017 update. The AI for adults is based on the requirement of 0.05 mg/kg body weight/day outlined above and adjusted for the standard body weights of 76 kg for men and 61 kg for women.

Pregnancy	AI	Fluoride
14–18 yr	**3 mg/day**	
19–30 yr	**3 mg/day**	
31–50 yr	**3 mg/day**	

***Rationale*:** The AI for pregnancy were not reviewed in the 2017 update. There is no evidence that requirements in pregnancy are greater than those of the non-pregnant woman.

Lactation	AI	Fluoride
14–18 yr	**3 mg/day**	
19–30 yr	**3 mg/day**	
31–50 yr	**3 mg/day**	

***Rationale*:** The AI for lactation were not reviewed in the 2017 update. There are no studies of the metabolism of fluoride in pregnancy. Fluoride concentrations in milk are very low and fairly insensitive to differences in the fluoride concentration of maternal drinking water. The AI is not greater than that of women in the non-pregnant, non-lactating state.

UPPER LEVEL OF INTAKE - FLUORIDE

Infants and young children

0–6 months*	**1.2 mg/day**
7–12 months*	**1.8 mg/day**
1–3 yr*	**2.4 mg/day**
4–8 yr*	**4.4 mg/day**

* The fluoride AI and UL for 0-8 year olds were updated in 2017.The following reference body weights were used when the 2017 NRVs for infants and young children aged 0-8 years were expressed in mg fluoride/day; 0-6 months 6 kg, 7-12 months 9 kg, 1-3 years 12 kg, 4-8 years 22 kg.

Rationale: The purpose of the UL is to provide information on the upper level of intake above which the risk of an adverse effect increases, in the case of fluoride, severe dental fluorosis. The estimated UL for fluoride, based on the endpoint of enamel pitting or loss and visible as severe dental fluorosis is 0.20 mg/kg bw/day for children aged 0 to 8 years. The estimated UL is based on the 95th percentile of fluoride intake (representative of high consumers) and a theoretical water fluoridation level of drinking water of 1.9 mg fluoride/litre (beyond which several enamel fluorosis is likely to appear). Beyond 8 years of age, when the enamel forms on permanent teeth, the ingestion of fluoride does not cause further developmental changes to teeth.

Upper Level 0-6 month olds: The UL for the 0-6 month age range is primarily focused on fluoride intake among infant formula fed and complementary fed infants, as the review of evidence found that breast milk is low in fluoride and fluoride intakes for breastfed infants of this age are unlikely to exceed the UL. The mean bodyweight of 6 kg was applied for 0-6 month olds when expressed in mg fluoride/day.

Infant formula sold in Australia and New Zealand contains very low amounts of fluoride (reported 0.07 mg fluoride/kg) (Clifford et al. 2009). Guidance is given in the Australia New Zealand Food Standards Code for labelling infant formula products in relation to fluoride content. A labelling statement on the package is required if the fluoride concentration is more than 17 µg/100 kJ in powdered or concentrated product prior to reconstitution, or more than 0.15 mg/100 mL (1.5 mg fluoride/L) in ready to drink formula products. This statement should indicate that consumption of the formula has the potential to cause dental fluorosis plus a statement recommending that the risk of dental fluorosis should be discussed with a medical practitioner or other health professional (FSANZ 2016).

Children and Adolescents	
9–13 yr	**10.0 mg/day**
14–18 yr	**10.0 mg/day**
Adults 19+ yr	
Men	**10.0 mg/day**
Women	**10.0 mg/day**
Pregnancy	
All ages	**10.0 mg/day**
Lactation	
All ages	**10.0 mg/day**

***Rationale*:** The UL for 9 year olds and over were not reviewed in the 2017 update. The UL was set on the basis of moderate enamel fluorosis. A LOAEL of 0.10 mg/kg body weight for infants and children up to 8 years was set on the basis of community studies (Dean 1942, FNB:IOM 1997). A UF of 1 was applied, as the adverse effect is cosmetic rather than functional. For older children and adults, a NOAEL of 10 mg/day was derived based on data on the relationship between fluoride intake and skeletal fluorosis (FNB:IOM 1997, Leone et al. 1954, 1955, McCauley & McClure 1954, Schlesinger et al. 1956, Sowers et al. 1986, Stevenson & Watson 1957). A UF of 1 was selected, as there are no signs of symptomatic skeletal fluorosis at this level of intake. No data exist to show increased susceptibility in pregnancy or lactation, so the same UL was adopted.

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A complete reference list for the 2017 Technical Report can be found at www.nrv.gov.au/resources.