Nutritional risk assessment - addition of fluoride to packaged water

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Background

FSANZ routinely undertakes nutritional risk assessments of applications to amend food regulations. Sometimes these risk assessments raise issues that have broader ramifications beyond the immediate consideration for food regulation. In 2006, FSANZ received an application that would encounter such issues, which involved a request for the voluntary addition of fluoride to Australia and New Zealand packaged waters.

Objective of the Nutritional Risk Assessment

To identify any potential nutritional or public health risks associated with adding fluoride at the proposed range of 0.6-1.0 mg/L (total of naturally occurring and fluoride added to packaged water). This range reflects the fluoridation rates for municipal water supplies.

Design

FSANZ conducted two main activities to determine the potential nutritional and public health risks from water fluoridation (i.e. fluoride from all water sources):

Assessing dietary fluoride intakes

Estimated dietary fluoride intakes from all sources of water were compared with the Upper Level of Intake (UL)[1] for fluoride (NHMRC and NZMoH, 2006). These comparisons were undertaken using FSANZ's dietary modelling computer program (DIAMOND) and consumption data from the 1995 Australian and 1997 New Zealand National Nutrition Surveys[2], along with recent food composition data[3] for fluoride. Models were developed for two scenarios at either the upper or lower fluoride limits for Australian and New Zealand reticulated water supplies (0.6-1.0 mg/L), and assumed all drinking water was at either of these limits.

Review of adverse health effects

A literature review examined the adverse health effects that might be associated with excessive fluoride intakes in Australia and New Zealand. The majority of the studies obtained were cross sectional studies, with some case-control studies and systematic reviews also identified. From this literature, the only adverse effect from excessive fluoride intake was fluorosis. As a result, studies describing the prevalence of fluorosis in Australia and New Zealand were collected.

Results

Table 1 shows that up to 22% of children would exceed the UL for fluoride when water sources contain fluoride at 1 mg/L. The exceedances are primarily due to the low ULs up to the age of 8 years. From 9 years onwards, the ULs increase substantially, resulting in negligible proportions of the population with excessive intakes.

Table 1: Estimated proportion of the Australian and New Zealand populations that would exceed the UL for fluoride

Population Age Group (years)	Age Group UL (mg/day)	Water Fluoridation (mg/L)	Mean Intake (mg/day)	Above UL (%)
2-3*	1.3	0.6	0.9	5
		1.0	1.0	22
4-8*	2.2	0.6	1.0	<1
		1.0	1.2	5
9+	10	0.6	2.2	0
		1.0	2.6	<1

*** New Zealand dietary intake data were unavailable for these age groups.**

Table 2 summarises the prevalence of fluorosis in Australian and New Zealand children. In measuring fluorosis, Australian surveys typically use the Thylstrup-Fejerskov (TF) index, while New Zealand studies collect data on diffuse opacities.

Fluorosis is prevalent predominantly in the very mild and mild dental forms. Recent studies report a prevalence of between 19% and 25% for all levels of exposure to water fluoridation.

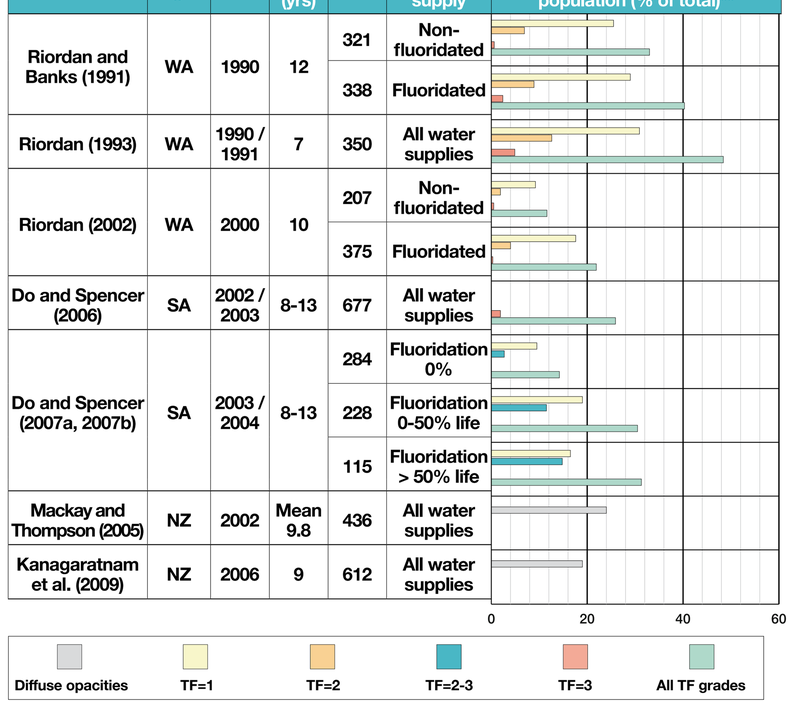
Grades of Dental Fluorosis (Dean's Fluorosis Index):

Very mild and mild dental fluorosis **– These forms are aesthetic in nature (making teeth stronger and whiter only) and are not considered to adversely affect the function of the tooth or to be a risk to population health. Examples include diffuse opacities and TF grades 1-3.**

Moderate and severe dental fluorosis **– Includes the staining, wearing and pitting of teeth. Examples include TF grades 4-9.**

Table 2: Prevalence of fluorosis in Australia and New Zealand (1990-2009)

Reference*	Region	Date	Age (yrs)	n	Water supply	Dental Fluorosis amongst population (% of total)**
Riordan and Banks (1991)	WA	1990	12	321	Non-fluoridated	
				338	Fluoridated	
Riordan (1993)	WA	1990 / 1991	7	350	All water supplies	
Riordan (2002)	WA	2000	10	207	Non-fluoridated	
				375	Fluoridated	
Do and Spencer (2006)	SA	2002 / 2003	8-13	677	All water supplies	
Do and Spencer (2007a, 2007b)	SA	2003 / 2004	8-13	284	Fluoridation 0%	
				228	Fluoridation 0-50% life	
				115	Fluoridation > 50% life	
Mackay and Thompson (2005)	NZ	2002	Mean 9.8	436	All water supplies	
Kanagaratnam et al. (2009)	NZ	2006	9	612	All water supplies	



*** A study by Puzio et al. (1993) has been excluded, as its fluorosis grades were not comparable to the Thylstrup-Fejerskov (TF) index. The study was included in FSANZ's considerations for Application A588, and did not change the overall conclusions reached.**

**** It is difficult to compare dental fluorosis results due to the different rating scales employed. However Thylstrup-Fejerskov (TF) Index ratings of 1-3 and diffuse opacities can be considered approximately comparable to 'very mild' or 'mild' ratings using Dean's Fluorosis Index (cosmetic changes to the tooth surface only).**

Disagreement in data sets

The fluoride ULs for ages 1-8 years have been set as the intakes at which moderate dental fluorosis will develop in this age group, yet the data provided in Table 2 do not show any widespread occurrences of the more severe forms of dental fluorosis in Australia and New Zealand, even in fluoridated regions. This is despite the estimated dietary fluoride intakes for children (Table 1) showing that up to 22% would exceed the UL with the fluoridation of all water sources at 0.6-1 mg/L. FSANZ therefore considered that this apparent disagreement between the data on intake and dental fluorosis identified a problem with the current UL for fluoride.

The Upper Level for fluoride

The fluoride UL values for Australia and New Zealand were adopted without change from United States and Canadian values (Institute of Medicine, 1997). The United States and Canadian fluoride ULs were constructed as follows:

- **For children aged 8 years or less:**
  - **Moderate dental fluorosis was set as the endpoint for the UL.**
  - **Data from the 1940s in the United States showed that the incidence of caries and moderate dental fluorosis minimum had minimum rates that coincided at around 1 mg/L of fluoride in drinking water.**
  - **Using theoretical diet models and assuming a range of dietary fluoride intakes for children in regions with water fluoridation at 1 mg/L, an UL of 0.1 mg/kg bw/day (1.3-2.2 mg/day) was assigned to ages 1-8 years.**
- **For persons aged 9+ years:**
  - **Skeletal fluorosis was used as the endpoint for the UL.**
  - **This condition occurs with very high fluoride intakes, and so an UL of 10 mg/day was assigned.**

The application of a theoretical diet model to 1940s data during the development of the United States and Canadian ULs for children aged 1-8 years means that these values are unlikely to reflect current dietary practices. This is consistent with the discord observed between the dietary intake and fluorosis prevalence data obtained by FSANZ.

Conclusion

The UL values adopted for the 2006 Australian and New Zealand Nutrient Reference Values were based upon the best available information at the time. However, the low prevalence of moderate dental fluorosis in the Australian and New Zealand populations indicates that the apparent exceedances of the UL are not a safety concern. Using these findings, FSANZ permitted packaged water to contain a total amount of fluoride up to 1 mg/L.

The apparent disagreement between the dietary intake estimates and prevalence rates for fluorosis also indicates that the existing ULs for fluoride need to be reviewed.

References

1. Do, L.G. and Spencer, A.J. (2007a) Decline in the prevalence of dental fluorosis among South Australian children. *Community Dentistry and Oral Epidemiology* 35:282-291.
2. Do, L.G. and Spencer, A.J. (2007b) Risk-Benefit Balance in the Use of Fluoride among Young Children. *Australian Dental Journal* 86(8):723-728.
3. Kanagaratnam, S., Schluter P., Durward, C., Mahood, R., Mackay, T. (2009) Enamel defects and dental caries in 9-year-old children living in fluoridated and nonfluoridated areas of Auckland, New Zealand. *Community Dent Oral Epidemiol*. Jun;37(3):250-9
4. Institute of Medicine. (1997) *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. National Academy of Sciences, Washington.
5. Mackay, T.D. and Thomson, W.M. (2005) Enamel defects and dental caries among Southland children. *New Zealand Dental Journal* 101(2):35-43.
6. NHMRC and NZ MoH (2006) *Nutrient Reference Values for Australia and New Zealand*. Commonwealth of Australia, Canberra.
7. Puzio, A., Spencer, A.J. and Brennan, D.S. (1993) Fluorosis and fluoride exposure in South Australian children. *In: Concensus Conference: Appropriate fluoride exposure for infants and children, Perth*.
8. Riordan, P.J. (1993) Dental Fluorosis, Dental Caries and Fluoride Exposure among 7-Year-Olds. *Caries Research* 27:71-77.
9. Riordan, P.J. (2002) Dental fluorosis decline after changes to supplement and toothpaste regimens. *Community Dentistry and Oral Epidemiology* 30(3):233-240.
10. Riordan, P.J. and Banks, J.A. (1991) Dental Fluorosis and Fluoride Exposure in Western Australia. *Journal of Dental Research* 70(7):1022-1028.

Footnotes

1. The *Upper Level of Intake* is the highest average daily nutrient intake likely to pose no adverse health effects to almost all individuals in the general population.
2. These surveys show that non-alcoholic beverages are the main dietary sources of fluoride, even in non-fluoridated areas.
3. Fluoride concentration data were obtained from the Australian food composition database NUTTAB 2006, and the 1990/91 New Zealand Total Diet Study; as well as recent data from the summer 2008 samples of the 23rd Australian Total Diet Study.

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