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 0.8-1.0 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) 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, along with recent food composition data. Models were developed for two scenarios at either the upper or lower fluoridation 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 sources contain fluorides 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 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 15% 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.
- 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)

The Ulcer 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:

- 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.

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 water supplies. 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 0.8-1.0 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.

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

<table>
<thead>
<tr>
<th>Population Age Group years</th>
<th>Age Group UL applied</th>
<th>Water Fluoridation (mg/L)</th>
<th>Mean Intake (mg/day)</th>
<th>Above UL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-5*</td>
<td>1.3</td>
<td>0.08</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>4-12</td>
<td>2.2</td>
<td>0.15</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>≥13</td>
<td>10</td>
<td>0.08</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

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

Footnotes
1. All data are based on the highest average daily nutrient intake likely to occur under normal conditions in the individual population group.
2. These age bands have been highlighted to identify specific age groups of concern, even in non-fluoridated areas.
3. Fluorosis occurrence data were obtained from the Australian dental comparison database NHMRC (2006), which included data from the summer 2008 samples of the 2006 Australian Nutrient Data Set Study.

References