Health Canada Santé Canada

April 2008

Findings and Recommendations of the Fluoride Expert Panel (January 2007)

Context:

As part of its review of the health effects of exposure to fluoride in drinking water, Health Canada convened a panel of experts in January 2007 to discuss this topic and to provide recommendations to ensure that exposure to fluoride remains below levels that could cause adverse effects (i.e., moderate and severe dental fluorosis) while achieving the public health benefit of preventing dental caries. Discussions were based on topic-specific literature reviews developed and presented by some of the invited experts.

The Expert Panel was asked to provide expert advice and to make recommendations to Health Canada and the Federal-Provincial-Territorial Committee on Drinking Water (CDW) regarding fluoride in drinking water. Advice was sought from the Expert Panel on five specific issues of concern:

- Total Daily Intake of Fluoride;
- Dental Fluorosis;
- Other Health Effects;
- Risk Assessment; and
- Drinking Water Fluoridation: Risks and Benefits

The Expert Panel reached a consensus on all key issues identified, and its main conclusions and recommendations to Health Canada and the Federal-Provincial-Territorial Committee on Drinking Water on each issue are provided below.

Expert Panel Members

- Steven M. Levy, Iowa College of Dentistry
- Christopher Clark, University of British Columbia
- Robert Tardif, Université de Montreal
- Michael Levy, Institut National de Santé Publique du Québec
- Jayanth Kumar, New York State Department of Health
- Albert Nantel, Institut National de Santé Publique du Québec

---

The opinions expressed in this report are those of the Expert Panel and do not necessarily reflect the views of Health Canada.

Canada

Total Daily Intake of Fluoride

Conclusions/Concerns:

- There appears to be a general decrease in the overall intake of fluoride in recent years. The use of supplements has decreased, as have the concentrations of fluoride in infant formulas.

- Experts were concerned about the assumptions used in the total daily intake calculation provided for the discussion. They all found that the ranges of age groups were too wide, especially for the 12 months to 4 years old category regarding differences in daily habits, body weight, food intake, and ingestion rates. *(Note from Health Canada: these are standard assumptions used by other groups within Health Canada. A working group at Statistic Canada is currently preparing the updated version of some of these exposure factors for the Canadian population.)*

- A concern was raised about the presence of Sulfuryl Fluoride residues as a pesticide that might be present in some food items. *(Note from Health Canada: This is not expected to be a concern in Canada, where there is a Maximum Residue Limit (MRL) of 0.1 ppm in unspecified food products, with actual levels observed usually much lower.)*

Recommendations:

- In the table summarizing the data for the total daily intake, ranges of intakes should be presented, rather than point estimates.

- In the table summarizing the data for the total daily intake, the range of the fluoride intake from toothpaste should be based on mean values of fluoride, and not on the 90th percentile.

- For infant formula, it is recommended that the "**All Formulae**" estimation, taking into account the average consumption of infant formula by Canadian infants, should be used. A footnote should be added at the bottom of the summary table of the Total Daily Intake from all sources to indicate that it does not represent the worst case scenario (powdered infant formula reconstituted with fluoridated water).

Dental Fluorosis

Conclusions/Concerns:

- There is no compelling evidence to challenge the statement that "22-26 months of age represents the period of greatest risk." However, the first three years of age should be considered as the period with the most significant concern, with 22-26 months old possibly being the period at highest risk.
- The end-point of concern for fluoride is still considered to be "moderate dental fluorosis," according to Dean's Index. It was agreed that this should not be considered a toxicological end-point, but that this endpoint is significant because it correlates with cosmetic problems.

Recommendations:

- A clear definition is needed for the end-point of concern "moderate dental fluorosis" as there are no generally accepted criteria, and existing rating systems are not generally compatible and/or comparable. Monitoring of the prevalence of dental fluorosis in the Canadian population should be done on an on-going basis, based on the resulting definition and using common criteria.
- The calculation of the tolerable daily intake (TDI) of fluoride to prevent the occurrence of moderate dental fluorosis (according to Dean's Index) should be mainly based on estimated total fluoride intake from fluid and food in Dean's time. These estimates, as described below, should still be relevant today and should be used in the calculation of the tolerable daily intake to prevent the occurrence of moderate dental fluorosis:

  1) 1600 µg/L of fluoride intake from drinking water, the level at which there was no moderate dental fluorosis in the 1940's, according to Dean's data (*Note from Health Canada: With an ingestion rate of 0.8 L/day and a body weight of 13 kg for a 1 to 4 year-old child, the fluoride intake from drinking water would be:*

  $$\frac{1600\ \mu g/L \times 0.8\ L/day}{13\ kg} = \textbf{\textit{98.5 µg/kg/day}}$$;

  2) Use the best food intake value to represent the situation in the 1940's. *(Note from Health Canada: New calculations, assuming a 1940's diet, indicate that the dietary intake of fluoride by a 1-4 year-old child living in a community with 1.5 ppm fluoride in the drinking water would have been about 27 µg/kg bw/day. Knowing that about 80% of the intake of fluoride from food comes from beverages (included in the 0.8 L/day), the breakdown amount comes to* ***5.4 µg/kg/day*** *for food intake only)*;

  3) The intake of fluoride from soil and air is assumed to be about the same as it was in the 1940's *(the values are* ***1.19 µg/kg/day*** *from soil and* ***0.01 µg/kg/day*** *from air).*

Fluoride – Other potential health effects

Conclusions/Concerns:

- *Skeletal fluorosis*: The primary functional adverse effect associated with excess fluoride intake (after dental fluorosis) is still skeletal fluorosis (milder forms), likely to occur at about 10 mg/day after 10 or more years of exposure. Definitions of the different stages of skeletal fluorosis should be developed.

- *Cancer*: Weight of evidence does not support a link between exposure to fluoride and increased risks of cancer. It is important to avoid any generalization and over-interpretation of the results of the Bassin *et al*. (2006) paper and to await the publication of the full study before drawing conclusions and particularly before influencing any related policy. In addition, there is supplemental negative evidence from the 2005 NTP study, even with higher levels of fluoride than the original 1992 NTP study.

- *Intelligence Quotient*: - Weight of evidence does not support a link between fluoride and intelligence quotient deficit. There are significant concerns regarding the available studies, including quality, credibility, and methodological weaknesses such as the lack of control for confounding factors, the small number of subjects, and the dose of exposure.

- *Bone fracture*: Studies that do not control for confounding factors, such as intake of calcium, fluoride, or vitamin D supplements, intake of other medication, or consideration of traumatic fractures, should be interpreted cautiously.

- *Immunotoxicity, reproductive and developmental toxicity, genotoxicity and neurotoxicity*: Weight of evidence does not support a link between exposure to fluoride in drinking water at 1.5 mg/L and any adverse health effects regarding immunotoxicity, reproductive/developmental toxicity, genotoxicity and/or neurotoxicity.

Recommendations:

- Weight of evidence does not support modifying the current Health Canada position/opinion on the carcinogenicity of fluoride. Policy decisions should not be based on the Bassin *et al.* (2006) paper.

- The current Maximum Acceptable Concentration (MAC) of 1.5 mg/L of fluoride in drinking water is unlikely to cause adverse health effects, including cancer, bone fracture, immunotoxicity, reproductive/developmental toxicity, genotoxicity, and/or neurotoxicity.

Risk Assessment

Conclusions/Concerns:

- The consumption of powdered infant formula reconstituted with fluoridated water could lead to excessive intake of fluoride in infants, although the following points should be considered:
    1. A few studies have found a positive association between greater use of infant formula reconstituted with fluoridated water and a greater prevalence of dental fluorosis; however, there are no studies that have been conducted to assess possible associations between fluoridated water and risk of moderate/severe dental fluorosis;
    2. The bioavailability of fluoride in reconstituted infant formula is likely to be less than in drinking water;
    3. Extended periods (e.g., multiple years) of exposure to fluoride are associated with increased fluorosis risk, and a higher exposure in the first year of life may not be as much of a concern if it is followed by low exposure;
    4. The risk of excessive intake of fluoride is higher for infants consuming larger quantities of infant formulas.

- Probabilistic exposures and outcomes are important to consider, rather than just point estimates.

Recommendations:

- Based on earlier and updated data, the current drinking water guideline of 1.5 mg/L for fluoride is still unlikely to be a cause of moderate dental fluorosis in the Canadian population.

- The MAC of 1.5 mg/L for fluoride in drinking water should be reaffirmed.

- Monitoring of fluoride levels in food items for the Canadian population known to contain high levels of fluoride should be done on an on-going basis.

- Further study is required to identify any possible links between dietary factors, fluoride intake and health impacts.

Water fluoridation - risks and benefits

Conclusions/Concerns:

- Under modern conditions of exposure, Heller *et al*. (1997) concluded that 0.7 mg/L of fluoride in drinking water provides a suitable trade off between the risk of dental fluorosis and the protective effect against dental caries. A previous analysis by Eklund and Striffler (1980) indicated that the effectiveness of water fluoridation seems to plateau at a concentration higher than 0.6 ppm of fluoride in drinking water.

- From a health perspective, there is no reason to be concerned about the actual prevalence of very mild and mild dental fluorosis in Canada. In addition, the actual prevalence of moderate dental fluorosis in Canada is low, and all evidence suggests that since 1996 there has been an overall decreasing trend of dental fluorosis in Canada.

- Community drinking water fluoridation is still an effective public health method to reduce the prevalence of dental caries in the Canadian population.

- It is now unlikely necessary to determine a range for the optimal target concentration of fluoride, partly because seasonal variability in drinking water consumption appears to be less significant now than before, with more indoor temperature control and fewer people working outdoors.

Recommendations:

- To adopt a level of 0.7 mg/L as the optimal target concentration for fluoride in drinking water, which would prevent excessive intake of fluoride through multiple sources of exposure.

- To promote and encourage the availability of lower-concentration fluoride dentifrices for children, which are already available in other countries.

- Because the greatest variability in fluoride ingestion from food comes from infant formula, the affected industry should be requested to continue to lower and standardize the fluoride concentration in infant formula.