

**Response to
Environmental Petition 244 filed by Mr. James S. Beck
under Section 22 of the *Auditor General Act*
Received April 18, 2008**

**Petition for the discontinuation of the addition of toxic substances to our
drinking water (inorganic fluorides, inorganic arsenic, lead)**

August 30, 2008

**Minister of Health and the Minister for the Federal Economic
Development Initiative for Northern Ontario**

Background:

Health Canada works with the provinces and territories to develop the Guidelines for Canadian Drinking Water Quality. The Guidelines are then used by each province and territory as a basis to establish their own requirements for drinking water quality. Fluoride is one of the many substances for which a guideline has been established. The Maximum Acceptable Concentration (MAC) for fluoride has been established taking into consideration all sources of exposure to fluoride, including foods and dental products. In Canada, the fluoridation of drinking water supplies is a decision that is made by each municipality, in collaboration with the appropriate provincial or territorial authority. This decision may also include consultation with residents, often through a referendum.

Fluoride occurs naturally in many source waters in Canada. It can also be added to drinking water as a public health measure to protect dental health and prevent or reduce tooth decay. The fluoridation of drinking water supplies is a well-accepted measure to protect public health and is strongly supported by scientific evidence. Fluoride is used internationally to protect dental health. It has been added to public drinking water supplies around the world for more than half a century, as a public health/dental health measure. The use of fluoride in the prevention of dental caries continues to be endorsed by over 90 national and international professional health organizations including Health Canada, the Canadian Dental Association, the Canadian Medical Association, the World Health Organization and the Food and Drug Administration of the United States.

As part of its ongoing review of the health effects of exposure to fluoride in drinking water, Health Canada convened a panel of experts in January 2007 to provide advice and recommendations based on the current state of relevant science with respect to the fluoridation of water. Advice was sought from the Expert Panel on five specific issues of concern including Total Daily Intake of Fluoride; Dental Fluorosis; Other Health Effects; Risk Assessment; and Drinking Water Fluoridation: Risks and Benefits. Discussions were based on topic-specific literature reviews developed and presented by some of the invited experts.

The report produced by the Expert Panel will be used to help inform the development of an updated fluoride guideline for Canadian drinking water, by ensuring our analysis is based on the latest scientific evidence. The Expert Panel report was posted online and can be found at <http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2008-fluoride-fluorure/index-eng.php>.

Health Canada will continue to monitor the science and review new scientific reports and articles which explore possible links between fluoride and various health effects to ensure the health of Canadians is protected.

- 1. What is clearly emerging in the research literature is that fluoride is a toxic substance which should not be ingested. What does Health Canada consider to be a safe daily dosage of fluoride, with an adequate safety margin? Please consider all potential recipients including persons with thyroid disease, persons with kidney disease, infants*

and children and fetuses. Please show calculations, justifications and references for your determination.

Health Canada uses a population-based approach in the risk assessment process; drinking water guidelines are developed to be protective of the sub-population at greatest risk and are therefore protective of all Canadians. Fluoride is a mineral nutrient used by the human body to maintain dental health. The sub-population most affected by exposure to fluoride is young children aged 22-26 months old, which is also the sub-population used for establishing a drinking water guideline which is protective of all Canadians. There is very limited data to support or refute an increased susceptibility to fluoride in any sub-population other than small children. There are no data to suggest that exposure to fluoride at the Canadian maximum acceptable concentration of 1.5 mg/L would result in adverse effects in these potentially susceptible sub-populations.

2. *How can a Canadian citizen determine the daily dose of fluoride from all sources? Please show calculations and references to justify your response.*

Determining the daily dose of any specific nutrient from all sources on an individual basis is complicated, as it is dependant on a number of factors such as: the level of fluoride in the water you drink and use for food preparation, and the amount consumed; the amount of fluoride in your foods and the amount consumed; the amount of fluoride in any food supplements or vitamins consumed; etc. If a Canadian citizen is interested in determining their daily dose of fluoride from all sources, they would need to keep a detailed food journal, have access to a laboratory that can analyze their samples and would likely need the support of a qualified professional to help identify all the variables that would affect their daily dose.

3. *Health Canada warns against all intake sources of fluorides from toothpaste, mouthwash, and supplements for young children under 6. Health Canada also warns the public not to give fluoridated dental products to children: "Children under six years of age should be supervised while brushing, and children under the age of three should have their teeth brushed by an adult without using any toothpaste." "Never give fluoridated mouthwash or mouth rinses to children under six years of age, as they may swallow it." Health Canada's "Fluoride-Containing Anti-Caries Products Monograph" states that the labels of fluoride containing mouthwashes and toothpastes must carry the following cautionary statement by 2009: "If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Centre right away". Why is the pharmaceutical grade fluoride from toothpaste considered to be unsafe and yet the industrial grade fluoride from water is considered to be safe? Please provide references.*

The cautionary statements regarding paediatric exposure/ingestion of fluoride that appear in Health Canada's "Fluoride-Containing Anti-Caries Products Monograph" take into account that the pharmaceutical grade may present certain risks depending on the age of the sub-population and how the product is used. In addition, cautionary statements that speak to the potential for an accidental exposure are considered useful for consumer information purposes since they are better informed and know what to do should such a situation arise.

The references that appear to have been cited further to statements in a Labelling Standard or Monograph (Labelling Standard: Fluoride-containing Treatment Gels and Rinses for Consumer Use. 2003-01-15; Monograph- Fluoride-containing anti-caries products, August 16, 2007), are noted below:

FDA 1995: USA Department of Health and Human Services, Food and Drug Administration. 21 CFR Part 355. Anticaries Drug Products for Over-the-Counter Human Use, Final Monograph. 1995. [Accessed 2007-05-17]. Available at: [www.fda.gov/cder/otcmonographs/Anticaries/anticaries\(355\).pdf](http://www.fda.gov/cder/otcmonographs/Anticaries/anticaries(355).pdf)

Smith RG. Prevention of hygiene-related oral disorders. In: Berardi RR, DeSimone II EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002

CDA 2005b: Canadian Dental Association. CDA Position on Use of Fluorides in Caries Prevention. 2005. [Accessed 2007-05-17]. Available at: www.cda-adc.ca/files/position_statements/fluorides.pdf

4. *"The major dietary source of fluoride for most people in the United States is fluoridated water..." (NRC 2006 p.24) Why does Health Canada not advise against this fluoride source intake for young children?*

6. *According to Health Canada, prescribing controlled doses of pharmaceutical grade of fluoride, under the care of a doctor is no longer recommended. "Health Canada does not recommend the use of fluoride supplements (drops or tablets). This guideline is consistent with recommendations made by Health Canada's First Nations and Inuit Health Branch (FNIHB) and the Canadian Association of Public Health Dentistry (CAPHD)." (http://www.hc-sc.gc.ca/iyh-vsv/environ/fluor_e.html) Why is the use of uncontrolled doses of hydrofluorosilicic acid, an industrial grade of fluoride which is not regulated by our federal government (it has no DIN) promoted for use in our drinking water in Canada by the Public Health Service and Health Canada when controlled doses of pharmaceutical grade fluorides are not recommended? Does Health Canada believe that administering uncontrolled doses is preferable to controlled doses?*

Answer to Questions 4 and 6:

Fluoridated drinking water is not a source of exposure to fluorosilicate compounds such as hydrofluorosilicic acid. When added to water, fluorosilicate compounds readily hydrolyse completely to release fluoride ions, which means that drinking water is not a source of exposure to these compounds. It is also important to note the significant concentrations of fluoride in toothpastes, which are in the range of 1000 to 1500 ppm.

Health Canada has taken into account exposure to fluoride from all sources to determine the maximum acceptable and optimal concentrations in drinking water. For further information, please consult the Guideline Technical Document on Fluoride available on the Health Canada website (<http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/fluoride-fluorure/index-eng.php>).

Water that is optimally fluoridated does not pose a problem with respect to moderate fluorosis for any age group. Rather, it is the use of fluoride supplements and the ingestion of fluoridated toothpaste during the critical ages that is of concern. As a result, Health Canada recommends the following steps to minimize exposure in small children:

- Never give fluoridated mouthwash or mouth rinses to children under six years of age, as they may swallow it.
- Talk to your dentist before using fluoridated mouthwash.
- Health Canada does not recommend the use of fluoride supplements (drops or tablets). This guideline is consistent with recommendations made by Health Canada's First Nations and Inuit Health Branch (FNIHB) and the Canadian Association of Public Health Dentistry (CAPHD).
- Make sure that your children use no more than a pea-sized amount of toothpaste on their toothbrush, and teach them not to swallow toothpaste. Children under six years of age should be supervised while brushing, and children under the age of three should have their teeth brushed by an adult without using any toothpaste.

For further information, please consult the It's your Health publication available on the Health Canada website (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/environ/fluor-eng.php>).

5. *Does Health Canada believe that one can control the daily dose of fluoride ingested from fluoride in food and beverages? If so, how? If not, how do you justify ignoring such sources? Please show calculations and references to justify your response.*

Health Canada has taken into account exposure to fluoride from all sources to determine the maximum acceptable and optimal concentrations in drinking water. For further information, please consult the Guideline Technical Document on Fluoride available on the Health Canada website (<http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/fluoride-fluorure/index-eng.php>).

7. *Examples of high water consumers from NRC 2006 illustrate that many individuals consume more than 5mg/day, while the WHO states that bone effects are expected to occur with such exposure. Does Health Canada consider these individuals to be consuming a safe dose?*

It is not appropriate for Health Canada to comment on possible exposures in other countries, particularly as their acceptable levels are much higher than those in place in Canada. Our conclusions are based on internal comprehensive scientific reviews of original relevant scientific studies that are published in internationally recognized peer-reviewed journals.

8. *The 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards does a risk assessment which illustrates that many individuals consume more than 0.7mg/day where many (especially women) may be vulnerable to thyroid effects. Does Health Canada disagree with the risk assessment done by the NRC 2006 Committee? If so, on what points and why? If you agree, why does Health Canada insist that recommended concentration levels are safe for everyone? Please provide references you use to come to your conclusions.*

As stated earlier, Health Canada uses a population-based approach in risk assessment and therefore establishes drinking water guidelines based on the sub-population likely to be most affected. The sub-population most affected by exposure to fluoride is young children aged 22-26 months old, which is also the sub-population used for establishing a drinking water guideline which is protective of all Canadians. There are no data to suggest that exposure to fluoride at the Canadian maximum acceptable concentration of 1.5 mg/L would result in adverse effects for those consuming larger quantities of drinking water.

It is not appropriate for Health Canada to comment on the opinion or position of individuals or agencies. Health Canada's conclusions are based on internal comprehensive scientific reviews of original relevant scientific studies that are published in internationally recognized peer-reviewed journals.