

**Response to
Environmental Petition 243 filed by Mr. Robert Button
under Section 22 of the *Auditor General Act*
Received May 2, 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. *Health Canada: Is the addition of hydrofluorosilicic acid to drinking water supplies intended to prevent tooth decay? If no, then why are we adding it to our drinking water?*

Water fluoridation is intended to reduce the prevalence of tooth decay. There are beneficial effects of fluoride from both topical and systemic exposures. The maximum reduction in dental decay is achieved when fluoride is available preeruptively (systemically) for incorporation during all stages of tooth formation and posteruptively (topically) at the tooth surface. Water fluoridation provides both types of exposure.

The purpose of fluoridating municipal drinking water is to provide a commonly available source of fluoride. Fluoride, when added at the recommended level, has been determined to contribute to the daily intake that is considered adequate for an optimal level to protect dental health by various health agencies.

Fluoridation is done through the addition of an additive that releases fluoride ions, such as hydrofluorosilicic acid or other fluorosilicate compounds, to water during treatment. Fluoridated drinking water is not a source of exposure to these compounds, because they hydrolyse completely when added to water to release fluoride ions.

2. *“A drug includes any substance or mixture of substances manufactured, sold or represented for use in: : a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings and animals.” In a previous petition (#221) Health Canada claims that “Under the Food and Drug Act, approval of a drug and its manner of delivery does not automatically translate to an approval for another similar substance or different mode of delivery. However, since fluoride used in drinking water fluoridation is not considered a drug the approval requirements are not considered applicable.” Does Health Canada deny that fluoride falls under the definition of a drug under part “a” above, if they claim it is used to prevent a disease - tooth decay? If so, how so?*

The *Food and Drugs Act* provides a definition for a 'drug' and the *Regulations* that accompany the *Act* describe Health Canada's regulatory authority related to the sale of drugs for human consumption. As an example, Health Canada has the regulatory authority to authorize the sale of a drug in its final dosage form (e.g. Anti-Caries Products for use in dentifrices (gel or paste)) for the Canadian market.

While Health Canada endorses the fluoridation of drinking water to prevent tooth decay, the decision to do so falls under the responsibility of provincial and territorial governments.

3. *Does Health Canada disagree with the US FDA that fluoride, when used to prevent cavities is a drug subject to the Food and Drugs Act or the US equivalent – the FDA? “Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal, is a drug that is subject to Food and Drug Administration (FDA) regulation”? If so, how so?*

The regulatory requirements for the sale of drugs for human consumption in the United States are different than the Canadian requirements.

4. *The legal definition of a medicinal product in the European Union (Codified Pharmaceutical Directive 2004/27/EC, Article 1.2) is any substance or combination of substances "presented as having properties for treating or preventing disease in human beings" or "which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action." Furthermore, in 1983 a judge ruled that fluoridated water fell within the Medicines Act 1968, "Section 130 defines 'medicinal product' and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within that definition." Source: Lord Jauncey. Opinion of Lord Jauncey in causa Mrs Catherine McColl (A.P) against Strathclyde Regional Council. The Court of Session, Edinburgh, 1983. Does Health Canada disagree with this assessment of fluoride as a drug? If so, how so?*

The regulatory requirements for the sale of drugs for human consumption in the European Union are different than the Canadian requirements.

5. *In a previous petition (#221) Health Canada states: "Health Canada does not regulate fluoridation additives". Why does Health Canada abdicate all responsibility regarding the regulation of this chemical additive, classified as a CEPA-designated toxic substance, hazardous waste which is not an "essential nutrient" but which is used as a drug?*

As stated in our response to a previous petition, Health Canada does not regulate fluoridation additives added to drinking water supplies because provincial and territorial governments are responsible for the safety and quality of public drinking water supplies. A substance is considered "CEPA-toxic" if it enters or may enter the environment in amounts that may pose a risk to human health, to the environment (such as fish or wildlife) and/or to the environment upon which life depends (such as water, soil, and air). Inorganic fluorides are "toxic" to the environment as defined under CEPA and this assessment focussed principally on four inorganic fluorides: hydrogen fluoride (HF), calcium fluoride (CaF₂), sodium fluoride (NaF), and sulphur hexafluoride (SF₆).

6. *The evidence for harm from fluoridation chemicals are doses currently used in Canada (0.5mg/L -1mg/L) is reviewed in the National Research Council 2006 Report. Why does the Chief Dental Office for Health Canada travel across the country spending taxpayers money promoting and supporting this unregulated water additive and CEPA-designated toxic substance to municipalities, stating that there is no evidence of harm? Is this his mandate under Health Canada?*

Among the roles of the Chief Dental Officer, one is to present Health Canada's position on water fluoridation, which is based on internal scientific reviews of original relevant scientific studies that are published in internationally recognized peer-reviewed journals, as well as to promote effective, preventive public health measures such as water fluoridation.

An expert panel was formed to provide Health Canada with advice and recommendations on the current state of relevant science with respect to the fluoridation of water. The report from the panel reinforces Health Canada's position that water fluoridation is important from a public health perspective and that our position on water fluoridation is sound. The report's recommendations are based on the latest science. In undertaking the study, Health Canada consulted with a number of experts including scientists from the Universities of British Columbia, Toronto, Iowa; scientists from many areas of Health Canada; and also received input from the Canadian Dental Association, the U.S. Environmental Protection Agency and public health experts from Canada and the U.S.

Health Canada endorses the fluoridation of drinking water to prevent tooth decay, but does not make the decision on whether or not to fluoridate drinking water. Provincial and territorial governments are primarily responsible for the safety of drinking water. In collaboration with their municipalities, they decide whether or not to fluoridate and the amount of fluoride to be added.

7. *In a previous petition (#221) Health Canada states: "Where minerals are added or where food is fortified with a mineral (e.g., iron in cereals), the food does not become a drug. Fluoride used in drinking water fluoridation is therefore, not considered a drug under the Food and Drugs Act." Are water fluoridation chemicals regulated under the Food and Drugs Act classified as minerals? If not, when does Health Canada plan to assert their power to stop the sale and use of these unregulated drugs?*

Fluoridation chemicals are considered to be treatment additives in the drinking water treatment processes and as such are regulated by the provinces and territories.

8. *In a previous petition (#221) Health Canada states: "Health Canada does not regulate fluoridation additives added to drinking water supplies because provincial and territorial governments are responsible for the safety and quality of public drinking water supplies in municipalities." Is this an admission by Health Canada that they have no right to recommend the use of this unregulated drug if they accept no responsibility for the use of this unregulated drug?*

For municipalities that choose to fluoridate, Health Canada recommends that they use fluoridation additives that have been certified as meeting the appropriate health-based standards, in this case ANSI/NSF Standard 60 for direct water additives. The decision on whether or not to fluoridate is made by the municipality, in consultation with its citizens and the provincial or territorial government.

9. *In a previous petition (#221) Health Canada states that: "Health Canada recognizes the importance of protecting all Canadians from possible adverse health effect related to drinking water, including sub-groups at highest risk. Some sub-groups in the population could potentially be more susceptible to fluoride, for example people with kidney problems, osteoporosis, or poor nutrition. Similarly, some sub-populations may be exposed to a greater amount of fluoride on a daily basis, such as those working outdoors, living in hot climates, or living in proximity to fluoride-emitting facilities. This is more of*

a concern in the U.S., where the MCL for fluoride is established at 4 mg/L (compared to a MAC of 1.5 mg/L in Canada) and where individuals are normally expected to consume more water in response to higher temperatures.” Is Health Canada aware of the large number of communities in southwestern Ontario (e.g. as Stratford (2.1 mg/L), Sebringville (2.76 mg/L), Chepstow (1.89 mg/L), Mitchell (1.93 mg/L)) to name just a few, that have fluoride levels in excess of the 1.5 mg/L? Is this of any concern Health Canada?

As stated above, the provinces and territories are responsible for regulating drinking water quality and programs. The appropriate provincial department should be contacted to answer specific questions related to municipalities within their area of jurisdiction.

10. *The US PHS recommends fluoride concentration levels of 0.7-1.2 mg/L. Health Canada recommends fluoride concentration levels of 0.8-1.0 mg/L. The concern raised in this petition regards the use of artificial fluoride chemicals which have never undergone chronic toxicological testing and which are considerably more toxic than “natural” fluorides such as calcium fluoride. Would Health Canada explain why 4 ppm of “natural” fluoride is relevant to this petition regarding the addition of artificial water fluoridation chemicals?*

We are assuming your question relates to a previous answer. Questions received by Health Canada often refer to specific reports out of the U.S., where acceptable levels of fluoride are up to 4 ppm (4 mg/L). This is particularly relevant when discussing the 2006 report from the U.S. National Academies of Science (NAS) because its scope was limited to natural fluoride in the U.S. It reviewed current research on various health effects from exposure to fluoride, including studies conducted in the last 10 years, and concluded that the U.S. EPA's Maximum Contaminant Level of 4.0 mg/L for naturally occurring fluoride was not protective against adverse health effects. The report does not suggest any health concerns at a concentration of 1.5 mg/L, which is Canada's current drinking water guideline.

11. *In a previous petition (#221) Health Canada states: “Fluoride, when added at the recommended level,” Health Canada seems to confuse concentration and dose. Fluoride added to water at the recommended concentration levels does not determine the dose of fluoride that anyone receives in a day. Please refer to fluoride dose calculator above. Can Health Canada or any agency which recommends the addition of H₂SiF₆ to drinking water adequately control the dose of this water additive for each individual if you cannot control the quantity of water consumed in a day or the quantity of food consumed in a day by any individual? If yes, does Health Canada believe that “Fluoride, when added at the recommended (concentration) level” determines the dose?*

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>).

12. *In a previous petition (#221) Health Canada states: "Fluoride, when added at the recommended level, has been determined to provide the daily intake that is considered adequate for optimal nutrition by various health agencies." Would Health Canada please define what is an "adequate" amount of fluoride for every individual which Health Canada considers to be "not essential"? Please provide evidence.*
13. *In a previous petition (#221) Health Canada states: "Health Canada does not consider fluoride as an essential nutrient." Health Canada continues with the following statement: "Hydrofluorosilicic acid (HFA) or any other form of fluoride used in drinking water fluoridation is a source of the mineral nutrient fluoride." Health Canada at first states that fluoride is NOT an essential nutrient, then describes it as a nutrient. Is it an essential nutrient or not? If fluoride is not an "essential" nutrient, why does Health Canada recommend that we ingest it?*

Answer to Questions 12 and 13:

Fluoride is considered to be a mineral nutrient, but is not considered an essential nutrient. For further information on fluoride as a nutrient, please consult the Dietary Reference Intakes established by the Food and Nutrition Board of the U.S. Institute of Medicine (<http://www.iom.edu/CMS/3788/4008/4253.aspx>).

14. *Is Health Canada aware that the US Centers for Disease Control have stated several times that fluoride mechanisms are now known to be topical; "Fluoride's predominant effect is posteruptive and topical." MMWR Weekly Report. Vol 50, No. RR-14, August 17, 2001, p. 4. & its actions primarily are topical for both adults and children." MMWR Weekly Report. 1999;48:933-940 and that the American Dental Association, in the cover story of the JADA, July 2000, also described why ingesting fluoride is ineffective and how the topical mechanisms are now purported to be effective? If so, why do you still recommend that Canadians ingest this CEPA-designated toxic substance?*

There are beneficial effects of fluoride from both topical and systemic exposures. The maximum reduction in dental decay is achieved when fluoride is available preeruptively (systemically) for incorporation during all stages of tooth formation and posteruptively (topically) at the tooth surface. Water fluoridation provides both types of exposure.

15. *Does Health Canada believe that there is a disease called "fluoride deficiency"? If so, please provide references providing evidence of this disease.*

As stated above, fluoride is considered to be a mineral nutrient, but is not considered an essential nutrient.

16. *In toxicology, a margin of safety is required to protect susceptible populations. Ideally, we would want a margin of safety between the toxic dose and the purported "therapeutic" dose of 10-100 to ensure that it is protective of consumption over an entire lifetime. (Objectives for Chemicals in Drinking Water," Part I of the 1989 Guidelines for Canadian Drinking Water Quality — Supporting Documentation.) In other words, if we fluoridate water at 0.8 mg/L, we would not want to see a toxic effect in humans at less*

than 8-80 mg/L. We are seeing toxic effects at far less than 8mg/L. Does Health Canada believe that there is an adequate margin of error between the doses currently used and doses where no harm occurs? Please provide evidence.

Margin of safety is not a concept that is routinely used in the development of the Guidelines for Canadian Drinking Water Quality. However, it is important to note that mild to moderate dental fluorosis is a cosmetic endpoint, not a toxicological one. Skeletal fluorosis is the adverse health effect associated with fluoride, and it would occur at exposure levels that are greater than 10 times the Canadian optimal concentration for fluoridation.

17. *In a previous petition (#221) Health Canada states: “Certified point-of-use reverse osmosis unit prices start at \$200 for a portable or under-sink unit, with replacement pre-filters ranging in price from approximately \$100 - \$200 each. Certified point-of-use distillation units start at about \$300.” The petitioner requested an “average” price and Health Canada provided the lowest price available on the market without any source provided for the price estimate, as requested. Will you please provide sources for the price estimates given and a range of prices available on the market today?*

Health Canada does not compile statistics on the cost of treatment technologies. Please contact the appropriate distributor to enquire on specific prices in your area.

18. *According to 2 advisors for the York Review 2000 published in the prestigious British Medical Journal 2007; “If fluoride is a medicine, evidence on its effects should be subject to the standards of proof expected of drugs, including evidence from randomised trials.” “There have been no randomised trials of water fluoridation.” Why does Health Canada permit the use of this unregulated drug before any randomized trials have been done on hydrofluorosilicic acid?*

As stated in a response to an earlier petition, fluorosilicate compounds such as hydrofluorosilicic acid readily hydrolyse in water to release fluoride ions, which means that drinking water is not a source of exposure to these compounds. Fluorosilicate compounds are added as a source of the mineral nutrient fluoride. In addition, it is important to note that it is not appropriate for Health Canada to comment on the opinion of these individuals.

19. *Has H₂SiF₆ recommended by use in drinking water and widely used in food processing ever been approved by the proper authorities either as food additive, a drug or as medication? If so, by whom? Please provide references.*

Fluorosilicates, including hydrofluorosilicic acid, are not food additives and they have never been approved as food additives in Canada.

20. *Would Health Canada provide a time line for when they will regulate fluorosilicates in drinking water?*

Health Canada has well established processes to regulate products according to their risk and/or use. Any changes to regulations or new regulatory initiatives would be announced through the Canada Gazette. However, provinces and territories have the mandate to regulate drinking water.