

**Joint Government of Canada Response to
Environmental Petition No. 221 filed
under Section 22 of the *Auditor General Act*
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Petition to Discontinue Water Fluoridation

March 18, 2008

Minister of Health and the Minister for the Federal Economic
Development Initiative for Northern Ontario,
Minister of the Environment,
Minister of Indian Affairs and Northern Development
and Federal Interlocutor for Métis and Non-Status Indians, and
Transport Canada

Petition to Discontinue Water Fluoridation

The Response of the Federal Departments to the Petition

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.

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. The US EPA classifies hydrofluorosilicic acid as a Class 1 hazardous waste. Is hydrofluorosilicic acid a Class 1 hazardous waste or equivalent in Canada?

Health Canada Response:

The U.S. Resource Conservation and Recovery Act (RCRA) establishes a federal program to manage hazardous wastes from cradle to grave in the United States, to ensure that hazardous waste is handled in a manner that protects human health and the environment. It classifies waste in categories through a listing process. Hydrofluorosilicic acid is included in lists of commercial chemical products in a concentrated (unused) form. The RCRA focuses on ensuring the safe disposal of these waste products.

In Canada, the responsibility for managing hazardous waste rests primarily with the provinces and territories, who control the waste producers, the recycling, processing and elimination

facilities, and the transportation of waste within their territory. The federal government regulates international and interprovincial movements. The main definitions for hazardous wastes in Canada are under CEPA regulations for exports and imports of hazardous wastes and hazardous recyclable materials. Fluoridation additives certified for use in drinking water are not classified as hazardous waste in Canada.

Environment Canada Response:

It is difficult to make a direct comparison between the hazardous waste classification system applied by the US Environmental Protection Agency (EPA) and Canada's, due to the differences in legal statutory authorities. Although the Canadian system for hazardous waste and hazardous recyclable material classification for international movements has recently been harmonized as far as legally possible with the lists of hazardous waste set out in the US Code of Federal Regulations, Title 40 (40CFR), discrepancies continue to exist.

In Canada, the management of hazardous waste and hazardous recyclable material is a shared responsibility between the federal government and the provinces/territories. The federal statute controls the movements of hazardous wastes and hazardous recyclable materials crossing an international border, or for movements within Canada crossing between provinces or territories. The provinces and territories have jurisdiction over the transportation of hazardous waste and hazardous recyclable material within their respective boundaries, and the licensing and permitting of authorized facilities undertaking disposal or recycling operations, as well as licensing authorizing carriers.

Environment Canada implements and administers the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* (EIHWRMR) and the *Interprovincial Movement of Hazardous Waste Regulations* (IMHWR). The EIHWRMR apply to movements of hazardous waste and hazardous recyclable material crossing an international border when destined for a disposal or recovery operation respectively, whereas the IMHWR apply to interprovincial movements within Canada of hazardous waste and hazardous recyclable material. The EIHWRMR are also the means by which Canada implements its international obligations under a number of international agreements which are legally binding on the member countries. One of these international agreements is the United Nations, Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. Canada is a Party to the Convention, however the US is not which also gives rise to a variation in the controls placed the international transboundary movements of hazardous waste and hazardous recyclable material between the two countries.

Hydrofluorosilicic acid¹ (also known as fluorosilicic acid²) is identified as a dangerous good under the *Transportation of Dangerous Goods Regulations* and has been classified as a Class 8 corrosive substance. The Canadian federal transportation regulations are available for

¹ *Hydrofluorosilicic acid* is also known as dihydrogen hexafluorosilicate, hexafluorosilicic acid, fluorosilicic acid, hydrogen hexafluorosilicate or silicofluoric acid.

² Fluorosilicic acid is listed as UN1778 under the *Transportation of Dangerous Goods Regulations* (TDGR).

consultation at <http://www.tc.gc.ca/tdg/clear/tofc.htm>. It should be noted that this classification of the hydrofluorosilicic acid also agrees with the US Transportation rule set out in the US Code of Federal Regulations, Title 49 (49CFR).

The EIHWRMR references the hazard class criteria set out in the *Transportation of Dangerous Goods Regulations* as a means of classifying the hazard characteristics of waste and recyclable material. Therefore, fluorosilicic acid would meet the regulatory definition for a "hazardous waste" or "hazardous recyclable material" when it is intended for a disposal or recycling operation as set out in Schedules 1 or 2 of the EIHWRMR respectively. The actual text of the EIHWRMR is available to the public at the following website: http://www.ec.gc.ca/ceparegistry/documents/regs/g2-13911_r1.pdf

In the case of mixtures of waste or recyclable material, the Canadian EIHWRMR also controls hazardous constituents under a specified leachate test with regulated limits set in the parts per million level. Fluoride is one of the hazardous constituents listed and the waste or recyclable material would be considered hazardous when the concentration of the fluoride in the leachant exceeds the regulated limit of 150.00 mg/L. The leachate test referenced in the Canadian EIHWRMR is the US Toxicity Characteristic Leaching Procedure, SW846, Test Method 1311. In the case of fluoride, the regulated limit for leachate toxicity is based on Health Canada's drinking water quality guidelines.

2. *Can Health Canada or any other government department point to any toxicology study or studies demonstrating safety of the fluorosilicate products used to fluoridate drinking water for more than 60 years? If so, would that department please provide a reference to or copy of such documented research?*

Health Canada Response:

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. As a result, the research conducted to date has focussed on levels that would result from exposures in occupational settings. A review of the toxicological literature on Sodium Hexafluorosilicate and on Fluorosilicic Acid conducted for the National Institute of Environmental Health Sciences is available at the following URL:

http://ntp.niehs.nih.gov/ntp/htdocs/Chem_Background/ExSumPDF/Fluorosilicates.pdf

3. *Does Health Canada or any other federal government department believe that there is any legitimate government interest fulfilled by adding arsenic, lead, mercury, cadmium, barium, chromium and other contaminants which are bundled with hydrofluorosilicic acid, to our drinking water and hence our environment, in the process of water fluoridation? If so, how so?*

Health Canada Response:

Health Canada strongly recommends that all products added to drinking water during its treatment and distribution be certified as meeting the appropriate NSF standard(s). This is true for all additives used for fluoridation, and means that any impurity in the additive is below levels that could pose a risk to human health. Water properly treated with these certified additives would present no health risk to the consumer from either the fluoride or any impurity.

NSF Standards are voluntary standards, which can be referenced in legislation or regulation to make them enforceable. Products are certified as meeting a specific standard. An additive that does not meet the requirements of standard 60 cannot be certified.

The standard requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product, such as those mentioned. NSF International carried out tests of fluoridation additives using 10 times the maximum use level of the additive in water. The concentration of contaminants was compared to the single product acceptable concentration (SPAC), which is 10% of the Canadian guideline or the U.S. EPA Maximum Contaminant Level (based on a harmonized list of values). Limiting individual products to a contribution of 10% of the MCL for a given contaminant provides an extra margin of safety so that it is unlikely that the summation of the contributions from all potential sources will exceed the MCL at the tap. All contaminant levels, even when tested at 10 times the maximum use level, were well below the SPAC. Details on the results can be found on the NSF International website, at http://www.nsf.org/business/water_distribution/pdf/NSF_Fact_Sheet.pdf

4. *Are Health Canada, Environment Canada and other government departments aware that inorganic arsenic, lead, mercury and inorganic fluorides (e.g., hydrofluorosilicic acid) are on the CEPA 2006 toxic substances list and that hydrofluorosilicic acid is not naturally present in the environment?*

Health Canada Response:

Health Canada works with Environment Canada to assess substances under the *Canadian Environmental Protection Act, 1999* (CEPA), which includes prioritizing substances for assessment. Under the Act, 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). Substances determined to be "CEPA-toxic" may be added to the List of Toxic Substances (Schedule 1 of CEPA 1999). The process focuses on whether the substance is entering the environment at levels of concern.

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). These compounds were considered the most relevant of the inorganic fluorides on the basis of quantities released to the Canadian environment, environmental concentrations, and toxicological effects on biota.

Hydrofluorosilicic acid was not assessed for this classification.

Inorganic arsenic compounds, lead and mercury have been found to be entering the environment at levels that can pose risks to both human health and the environment. An assessment report is available for arsenic, which identifies the principal anthropogenic sources of releases into the environment as base-metal and gold-production facilities. In determining whether a substance should be declared "toxic" under CEPA 1999, the likelihood and magnitude of releases into the environment and the harm it may cause to human health or ecosystems at levels occurring in the Canadian environment are taken into account.

Environment Canada Response:

The above substances indeed appear on the CEPA 1999's List of Toxic Substances. Inorganic fluorides were added as a result of a Priority Substance List (PSL) Assessment on Inorganic Fluorides conducted under the Canadian Environmental Protection Act (CEPA) [http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/fluorides_inorg_fluorures/index_e.html]. This assessment concluded that these substances were entering the environment in quantities or under conditions that may be harmful to the environment. This conclusion was based on scenarios involving environmental concentrations of fluoride near anthropogenic sources such as phosphate fertilizer production, chemical production, and aluminum smelting. Note that the PSL assessment did not evaluate hydrofluorosilicic acid specifically.

5. *How many cases of osteosarcoma/bone cancer – the often fatal cancer associated with fluoride exposure – are reported in one year in Canada? Has Health Canada advised the Canadian Cancer Society of the increased risks for bone cancer associated with water fluoridation? If not, why not?*

Public Health Agency of Canada Response:

Canadian cancer data indicates there were 299 cases of bone cancer diagnosed in Canada in 2004, the last year for which data are available. Roughly one-third of bone cancers are osteosarcomas, suggesting that there are roughly 100 cases of osteosarcoma each year in Canada, an age-adjusted rate of about 0.3 cases per 100,000 population. The rates of bone cancer have been stable since 1969 when the national cancer reporting system began.

As the rates of bone cancer have remained stable, there is no science to support an increase in risk for bone cancer associated with water fluoridation. Consequently, there has been no need to contact the Canadian Cancer Society on this issue.

6. *Does Health Canada have current information regarding the incidence of dental fluorosis in Canada? If so, please provide data or source of data. If not, will Health Canada request this information from the Canadian Dental Association?*

Health Canada Response:

Dental fluorosis can be classified in a number of ways. One of the most universally accepted classifications, and the one used in this document, was developed by H.T. Dean in 1942. The individual's fluorosis score is based on the severest form of fluorosis recorded for two or more teeth. Dean's Index is described in the table below:

Classification	Criteria - Description of enamel
Normal	Smooth, glossy, pale creamy-white translucent surface
Questionable	A few white specks or white spots
Very mild	Small opaque, paper-white areas covering less than 25% of the tooth surface
Mild	Opaque white areas covering less than 50% of the tooth surface
Moderate	All tooth surfaces affected; marked wear on biting surfaces; brown stains may be present
Severe	All tooth surfaces affected; discrete or confluent pitting; brown stain present

Questionable, very mild and mild fluorosis have no effect on tooth function and may make the tooth enamel more resistant to decay. The end-point for cosmetic concern for fluoride is considered to be moderate dental fluorosis. 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 moderate dental fluorosis in Canada. In the United States, where the optimal level of fluoride in drinking water is between 0.7 and 1.2 mg/L, approximately 10% of dental fluorosis is attributable to water fluoridation and is in the very mild or mild fluorosis categories, neither of which would be of cosmetic concern.

7. *What is the average cost to repair dental fluorosis for an individual? Will Health Canada see to it that those who are harmed by water fluoridation are appropriately reimbursed?*

Health Canada Response:

There is no cost associated with questionable, very mild or mild fluorosis as these affect neither tooth function nor cosmetic aspects. As mentioned earlier, the end-point for cosmetic concern is considered to be moderate dental fluorosis. Moderate dental fluorosis would not lead to any functional or disease issues that would require dental treatment. In some but not necessarily all cases of moderate dental fluorosis an individual may decide that cosmetic treatment is necessary. The actual prevalence of moderate dental fluorosis in Canada is very low, and all evidence suggests that there has been an overall decreasing trend of moderate dental fluorosis in Canada since 1996. Due to the low occurrence of fluorosis of cosmetic concern, there is no average cost available to report.

8. *Is any federal government department aware that these chemical additions are allegedly violating NSF Standard 60 and the Safe Drinking Water Act [SDWA] of Ontario and similar acts of other jurisdictions? What other provincial and territorial acts are being violated by fluoridation chemicals? Does Health Canada, environment Canada or any other federal government department have a mechanism for investigating such alleged violations?*

Health Canada Response:

NSF Standards are voluntary standards, which can be referenced in legislation or regulation to make them enforceable. Products are certified as meeting a specific standard. An additive that does not meet the requirements of standard 60 cannot be certified.

Health Canada recommends that products be certified to the appropriate standards. Certification bodies, as accredited by the Standards Council of Canada, can certify drinking water materials as meeting the standards. Certification bodies control the use of the certification mark and conduct regular audits, as well as unscheduled inspections, to ensure products continue to meet requirements. The Government of Canada does not regulate these standards. However, many provinces and territories have adopted such legislation and should be contacted directly for information regarding their regulatory programs.

9. *In the absence of safety studies, does any Canadian government department feel comfortable in claiming that hydrofluorosilicic acid is safe? In the absence of safety studies on the products used in water fluoridation, how do you justify your actions to promote the use of a hazardous waste product that has never been tested for safety?*

Health Canada Response:

As indicated in response to question 2, fluoridated drinking water is not a source of exposure to 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.

10. *According to the Ontario Ministry of Health & Long Term Care 1999 report, 20 to 75% of individuals in fluoridated communities have dental fluorosis. 12 to 45% of individuals in 35 non-fluoridated communities have dental fluorosis. The Chief Dental Officer for Canada is quoted as saying: "Fluorosis is not caused by Water Fluoridation". Would the CDO please explain how and why his opinion differs so much from the Ontario Ministry of Health, NRC 2006 Report, EWG 2006 and NAS Report? Will the government of Canada conduct a peer-review study to determine who is correct?*

Health Canada Response:

The context of the statement attributed to Dr. Cooney is that water fluoridated at an optimal level would not lead to dental fluorosis of a cosmetic concern (moderate or severe according to Dean's

Index). In Canada, it is the use of fluoridated toothpaste or fluoride supplements at the critical age which is of greater concern. The development of fluorosis is time and dose dependent, which means that sufficient fluoride during a specific age period is required to cause fluorosis of cosmetic concern (moderate according to Dean's Index). This is why Health Canada has the position that fluoride supplements should not be used and that children under age 3 should not use fluoridated toothpaste unless deemed appropriate by a health professional assessed on an individual basis.

11. *According to NRC reports, ATSDR reports and other sources those who drink more than average quantities of water (e.g. kidney disease patients, diabetic patients, lactating mothers) are at risk for fluoride toxicity. The Dental Officer of Health for Halton, Ontario states: "Even if you drink a whole lot of water it's impossible to overdose if water is fluoridated at the optimal level" Oakville Beaver, April 13, 2007. Would the government of Canada conduct a peer-review study to determine who is correct?*

Health Canada Response:

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.

However, as mentioned by the ATSDR 2003 report, this possible increased susceptibility to fluoride is not supported by science. Health Canada uses a population-based approach in the risk assessment process and 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. Based on these considerations, there is no need to conduct a peer-reviewed study.

12. *Is Health Canada genuinely capable of providing an estimated range of total daily water ingestion of fluoride by infants and children, by age, in all artificially fluoridated communities in Canada who use your recommended guideline of 0.8 mg/L – 1.0 mg/L? If Yes, please submit the data specific to this request and the source for the estimates. If No, please so state.*

Health Canada Response:

An estimated total daily intake of inorganic fluoride by the Canadian population was published

in 1993 for different age groups, comparing communities with and without fluoridated drinking water. The exposure data are presented as ranges of possible daily intake values of fluoride from all sources of exposure, to cover all communities. You can find the estimated exposure assessment for fluoride in the document at the following link:

http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/fluorides_inorg_fluorures/index_e.html

13. *Is Health Canada genuinely capable of providing an estimate for the full range of daily water ingestion of fluoride, by consumers of fluoridated water who use your recommended guideline of 0.8 mg/L – 1.0 mg/L, including specific ranges for labourers, athletes, the excessively thirsty such as those individuals with diabetes, and those encouraged by health professionals to use water for health or detoxifying purposes? If Yes, please submit the data specific to this request and the source for the estimates. If No, please so state.*

Health Canada Response:

Daily water ingestion rates would be specific to individuals within these groups. As mentioned previously, there is no science to suggest additional health concerns in these groups. Health Canada uses a population-based approach in the risk assessment process and 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.

14. *Can any Canadian or provincial government department or agency force an individual to be medicated with a substance that has not been specifically approved for the purpose it is intended, and especially approved in the manner it is administered? Does the approval of one substance, or manner of delivery, translate to an approval for another similar substance or different mode of delivery?*

Health Canada Response:

The purpose of fluoridating municipal drinking water is to provide a commonly available source of fluoride. Hydrofluorosilicic acid (HFA) or any other form of fluoride used in drinking water fluoridation is a source of the mineral nutrient fluoride. 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.

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.

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.

15. *Is fluoride considered to be a drug that is subject to Health Canada or any other regulation(s)?*

Health Canada Response:

When fluoride is offered for sale in a final dosage form, used in large concentration and with a drug delivery system (e.g., dental rinse, toothpaste) and is labeled for therapeutic use (or makes therapeutic claims), the products are considered drugs under the *Food and Drugs Act* and are regulated under the *Natural Health Product Regulations*. Since the *Natural Health Product Regulations* came into force on January 1, 2004 with a transition period till December 31, 2009, some of the products may still be regulated under the *Food and Drug Regulations*.

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 a considered a drug under the *Food and Drugs Act*.

16. *Have fluorosilicates ever been approved as a drug in Canada?*

Health Canada Response:

There are a number of drugs that contain various forms of fluoride that have received market authorization. Three of these drugs with valid Drug Identification Numbers (DIN) contain fluorosilicates. Of these three, two are homeopathics and one is an over-the-counter anti-fungal product. Information for the two homeopathics products and for the anti-fungal product can be obtained from the following links:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index_e.html

<http://cpe0013211b4c6d-cm0014e88ee7a4.cpe.net.cable.rogers.com/dpdonline/displayInfo.do?drugCode=6L6aHfFUgEY%3D>

To date, no Natural Health Products (NHP) containing fluorosilicates have been licensed for sale in Canada. Should Health Canada one day licence for sale a fluorosilicate-containing NHP, this product would bear an NPN or DIN-HM on the label.

17. *Do fluorosilicates have a Drug Identification Number [DIN]?*

Health Canada Response:

Yes, in the case of those fluorosilicate-containing drugs and/or NHPs that have been licensed for

sale by Health Canada. Fluorosilicate-containing drugs that have received market authorization will have a DIN on the label whereas licensed fluorosilicate-containing natural health products would have an NPN or DIN-HM on the label.

18. *As fluoride is not removed by simple carbon filtration, what is the estimated cost for installation and yearly maintenance for a drinking water system that adequately filters fluoride [e.g. reverse osmosis, distillation]? Please identify your source.*

Health Canada Response:

Drinking water treatment systems vary in cost and complexity depending on the exact needs of the homeowner and the quality of the source water. Systems certified to reduce fluoride would also reduce the concentration of other inorganic substances and minerals, which would affect the maintenance cost for the system. Costing information would also depend on: the capacity and expected lifespan of the device and its components; any additional certified claim; type of installation; plumbing configuration for the installation; local water and electricity costs and the inclusion of service agreements.

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.

19. *Who should pay the cost for installation and maintenance of any fluoride removal system for a consumer identified in government scientific literature as unusually susceptible to fluoride's adverse health effects, i.e., the consumer, an entity promoting or endorsing fluoridation, the local dental society, the Canadian Dental Association, an insurance company, the water system operator, the department of health, etc?*

Health Canada Response:

The use of residential-scale treatment devices on municipally treated water is generally not necessary but primarily based on individual choice. As such, any consumer wishing to remove fluoride from their drinking water would be responsible for bearing the costs of installation and maintenance of a device for this purpose.

For Canadians who rely on private wells as their source of drinking water, the quality of the water, including the installation and maintenance of any treatment system, is the responsibility of the individual.

20. *Does Health Canada provide documentation of known sources of fluoride exposure in foods and beverages? If not, why not?*

Health Canada Response:

From a dietary perspective, the Food Directorate has recently included fluoride as part of the

chemicals to monitor within the Canadian Total Diet Study. Data on concentration of fluoride in selected foods is being generated and will be used in support of intake calculation from food of fluoride from food sources.

21. *Do government departments such as Fisheries and Wildlife, Natural Resources, Environment Canada have any duty to inform those involved in fisheries and wildlife of the inherent risks of water fluoridation to our ecosystem?*

Environment Canada Response:

There is no such duty incumbent on the Minister of the Environment.

It is to be noted that the ecological component of the Priority Substance List (PSL) Assessment on Inorganic Fluorides was based on three scenarios (air, water, vegetation) where environmental concentrations near anthropogenic sources were found to be comparable to levels capable of causing effects in organisms. The scenario for the aquatic environment involved concentration ranges of fluoride ion found in water bodies near anthropogenic sources such as phosphate fertilizer production, chemical production, and aluminum smelting. The extent of inorganic fluoride releases into aquatic environments from the fluoridation of municipal drinking water and the effects on aquatic life were not specifically evaluated.

22. *There is ample evidence that fluoride interferes with the body's ability to utilize essential nutrients such as calcium, magnesium, iodine, etc. via various metabolic pathways, [see NRC Canada 1977, US NRC 2006]. Is fluoride an essential nutrient? If so, please provide evidence. If not, does Health Canada or any other federal government agency have adequate grounds to justify that purported benefits of fluoridation of drinking water should outweigh and compromise the good nutrition of our citizens?*

Health Canada Response:

Evidence shows that fluoride competes with some ions (e.g., calcium) in the metabolism of teeth and bone formation. This is the same process that provides beneficial effects to prevent tooth decay. Health Canada does not consider fluoride as an essential nutrient. However, fluoride is considered to have a beneficial effect in humans to reduce dental caries. The Institute of Medicine (IOM) in United States established an adequate intake (AI) for fluoride based on maximal dental caries reduction without unwanted side effects. By definition, an AI is an average nutrient intake that appears to be sufficient to sustain a defined nutritional state in a specified population.

23. *Does Health Canada believe that statements of endorsement for the public policy of fluoridation also are endorsements for use of the products actually used for water fluoridation?*

Health Canada Response:

Health Canada and its Chief Dental Officer have endorsed drinking water fluoridation as a public

health measure to protect and maintain dental health, and reduce tooth decay. Health Canada does not endorse specific products or chemicals, but recommends that any product used in the treatment or distribution of drinking water be certified to the appropriate standard by an accredited certification body. See responses to questions 3 and 8 for additional information regarding the certification process.

24. *Derivation of the Maximum Allowable Contaminant levels [MACs] is based largely on the level of carcinogenicity assigned to a toxic substance; 1) carcinogenic; 2) probably carcinogenic; 3) possibly carcinogenic; 4) probably not carcinogenic. What classification was given to fluoride? Why?*

Health Canada Response:

The approach used in the establishment of a Maximum Acceptable Concentration is dependent upon the carcinogenicity classification of the substance under evaluation. A cancer approach would be used for any chemical contaminant which is classified as a human carcinogen or as a probable human carcinogen, based on the results of both epidemiological and toxicological studies.

In the case of fluoride, there are major limitations in human studies conducted to date, which prevents the interpretation of carcinogenicity of fluoride. Data from animal studies are also inadequate to allow an evaluation of carcinogenicity. There is an important body of scientific studies, which fails to show a causal link between exposure to fluoride in drinking water and cancer.

The criteria used for classification of carcinogenicity can be found at:

http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/existsub/approach/index_e.html

Based on these criteria, and using the available scientific information, fluoride is classified in Group VI - *Unclassifiable with respect to carcinogenicity in humans*. This corresponds to the International Agency for Research on Cancer (IARC) classification which classifies fluorides (inorganic, used in drinking-water) in Group 3: Not classifiable as to its carcinogenicity to humans.

25. *Is Health Canada aware of the following quote by a report by the Ontario Ministry of Health & Long Term Care 1999: "Efforts are required to reduce (fluoride) intake among the most vulnerable age groups, children aged 7 months to 4 years..."? Does Health Canada have evidence that their initiative to reduce the recommended guideline from 1.0-1.2 mg/L to 0.8-1.0 mg/L in 1999 has significantly reduced fluoride exposures in vulnerable populations and significantly reduced associated health risks, such as bone cancer [especially in young men between the ages of 6-20], dental fluorosis ["mottled teeth"], thyroid suppression, etc? Please provide references.*

Health Canada Response:

Health Canada is aware of this report, which was prepared by a consultant for the Ontario

Ministry of Health and represents the opinion of the author. Health Canada had established an optimal range of 1.0 – 1.2 mg/L in 1978, which was reduced to 0.8 – 1.0 mg/L in 1996. According to the Findings and Recommendations of the 2007 Expert Panel Meeting, 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. Furthermore, the weight of scientific credible evidence does not support a link between exposure to fluoride in drinking water and cancer or thyroid suppression.

26. *Does Health Canada acknowledge that timing of the fluoride exposure, and vulnerability of the child to fluoride exposure are important in fluoride toxicity?*

Health Canada Response:

The timing, level and length of exposure to fluoride are important factors to take into account when assessing the health effects of fluoride. As mentioned previously, 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.

27. *In regard to the statement made by Health Canada; “There are no studies indicating an association between fluoridated water in reconstituted infant formula and moderate or severe dental fluorosis”, is anyone at Health Canada aware of the 56 studies demonstrating an association between the use of fluoridated water use in reconstituted infant formula and the risk of dental fluorosis of varying severity? If not, why not?*

Health Canada Response:

Only a few of the 33 individual studies cited above found an association between greater use of infant formula reconstituted with fluoridated water and a greater prevalence of dental fluorosis (please note that 28 of the provided studies were duplicates). However, none of these studies examined a link between exposure to infant formula reconstituted with fluoridated water and moderate and severe forms of dental fluorosis. Consequently, the references provided do not alter Health Canada’s statement cited above.

28. *Is Health Canada aware that the American Dental Association, The Academy of Dentistry, the Center for Disease Control have all issued advisories on their websites in letters, recommending that parents should not give children under the age of 1 year fluoridated water mixed with infant formula? Not all parents have computers or visit these particular websites. The concerns of fluoridated water and fluoridated toothpaste mentioned in the September 20, 2000 letter from the Ontario Ministry of Health has not been conveyed to the general public. Is it the intent of Health Canada to inform parents in Canada of these concerns? If not, why not?*

Health Canada Response:

Health Canada is aware of the current advisories made in the U.S. regarding infant formulas reconstituted with fluoridated drinking water and recognizes the importance of protecting infants from possible adverse effects from fluoride. Health Canada is also aware that these advisories reflect potential exposure levels in the U.S. that are much higher than Canadian levels.

Health Canada communicates with the public and public health professionals through web publications and by working directly with the provinces and territories in this area. However, there is no evidence to support a link between the exposure to infant formula reconstituted with drinking water at the Maximum Acceptable Concentration (MAC) for fluoride in Canada and moderate and severe forms of dental fluorosis in the population. The incidence of dental fluorosis is best correlated with the total cumulative fluoride exposure to the developing dentition. According to the Findings and Recommendations of the Expert Panel Meeting recently held in Canada (to be published on Health Canada's website), an increased risk of dental fluorosis would be associated with extended periods (e.g., multiple years) of exposure to excessive amounts of fluoride, 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.

29. *With the publication of the NRC 2006 Report, and evidence contained therein that endocrine systems and thyroid functions are impaired at exposure levels to fluoride below the consumption levels expected from drinking "optimally fluoridated water", what does Health Canada or any other federal department, plan to do to inform the consumer of such risks to their health?*

Health Canada Response:

Scientific reviews conducted by a number of international agencies are in agreement that the science is inadequate to support a link between the exposure of fluoride in drinking water and an adverse effect on thyroid function. The regulation of thyroid function is dependent upon a wide range of factors, which means that results from epidemiological studies need to be considered cautiously in order to assess the link between any environmental chemical and adaptive response or even potential adverse health effects on the thyroid function. Current science does not indicate a causal relationship at or below the currently established Maximum Acceptable Concentration for fluoride in drinking water of 1.5 mg/L.

30. *Is Health Canada aware that the US NRC 2006 Review states that 0.7 mg/day with a 75 kg individual, of ingested fluoride, when iodine insufficient, may cause thyroid suppression? If so, why is Health Canada permitting the additions of an inorganic fluoride such as hydrofluorosilicic acid in our drinking water, which account for most of our total fluoride consumption? What does Health Canada intend to do to protect the population from iodine deficiency and fluoride over-exposure, which in combination, apparently leads to increasing numbers of people with thyroid insufficiency?*

Health Canada Response:

Scientific reviews conducted by a number of international agencies are in agreement that the science is inadequate to support a link between the exposure of fluoride in drinking water and an adverse effect on thyroid function. As stated in the U.S. NRC 2006 review, it is difficult to predict the effects fluoride may have on thyroid function, at which concentrations, and under what circumstances. Health Canada's population-based approach to establish drinking water guidelines based on the sub-population likely to be most affected (young children aged 22-26 months old) remains most protective of all Canadians.

31. *Is Health Canada aware that doctors in Europe from 1930-1970 used fluoride to suppress thyroid function?*

Health Canada Response:

Historical medical strategies are only relevant today if they have been supported by credible peer-reviewed studies. Health Canada has reviewed the available information regarding the potential effects of fluoride on thyroid function and found that current science does not show a causal relationship between exposure to fluoride and thyroid function.

32. *Is Health Canada aware that ethnicity also seems to be important in regards to toxicity of fluoride exposure? E.g. Moderate to severe dental fluorosis is found in many black and aboriginal children whose cumulative dose from fluoridated water and foods processed in fluoridated water is identical to poor white children with milder cases of fluorosis.*

Health Canada Response:

At optimal levels, water fluoridation is not correlated to moderate or severe fluorosis (according to Dean's Index) for any segment of the population. Severe fluorosis rarely occurs in Canada, but may be found in certain immigrant populations that have been exposed to very high levels of fluoride before they arrived in Canada. However, there are no scientific peer-reviewed studies available to determine whether ethnicity could play a role in the effects of fluoride.

33. *The protection of minorities is enshrined in the Canadian Charter of Rights and Freedoms, section 15, Equality Rights. Do Health Canada and relevant government agencies have an obligation to protect these minorities with regard to fluoridation of drinking water and the dispersal?*

Health Canada Response:

As mentioned earlier, there are no scientific peer-reviewed studies available to determine whether ethnicity could play a role in the effects of fluoride. Health Canada's population-based approach to establish drinking water guidelines based on the sub-population likely to be most affected (young children aged 22-26 months old) remains most protective of all Canadians.

34. *In regard to the statement made by Health Canada: “Possible higher exposure in the first year would be mitigated by lower exposures in the subsequent two years of life.” According to the NRC 2006 Report, p21, dental fluorosis cannot be reversed by lowering the intake of fluoride after the exposure; “The condition is permanent after it develops in children during tooth formation, a period ranging from birth until about the age of 8.” Would Health Canada please explain how and why they differ from the evidence of the NRC 2006 report? Please provide peer-reviewed scientific evidence of this claim.*

Health Canada Response:

Health Canada agrees that dental fluorosis is a permanent condition that develops in children during tooth formation, which does not contradict our statement. The incidence of dental fluorosis is best correlated with the total cumulative fluoride exposure to the developing dentition, particularly with a fluoride intake that is elevated for all of the first 3 years of life. Fluoride intake (in mg/kg-body weight) declines substantially after 6 months of age and remains steady thereafter. The risk of dental fluorosis in permanent teeth is therefore smaller, because permanent teeth start forming after this higher exposure level. In addition, extended periods (e.g., multiple years) of exposure to fluoride would be associated with an increased risk of dental fluorosis, and a higher exposure in the first year of life is less of a concern if it is followed by low exposure.

35. *In regard to the statement made by Health Canada: “Fluoride must still meet standards of purity and quality before it is used in drinking water treatment,” This product is bundled with many toxic substances such as arsenic, lead, cadmium, mercury, etc. Does this product meet Health Canada’s standard for purity and quality? If so, how so? If not, why does Health Canada make this claim?*

Health Canada Response:

As stated in our response to question 3, Health Canada strongly recommends that all products added to drinking water during its treatment and distribution be certified as meeting the appropriate standard(s). This is true for all additives used for fluoridation, and means that any impurity in the additive is below levels that could pose a risk to human health. Water properly treated with these certified additives would present no health risk to the consumer from either the fluoride or any impurity. Most the provinces and territories require that additives such as fluoride meet NSF Standard 60. The standard requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product, such as those you have mentioned.

NSF International carried out tests of fluoridation additives using 10 times the maximum use level. The concentration of contaminants was compared to the single product acceptable concentration (SPAC), which is 10% of the Canadian guideline or the U.S. EPA Maximum Contaminant Level (based on a harmonized list of values). Limiting individual products to a contribution of 10% of the MCL for a given contaminant provides an extra margin of safety so that it is unlikely that the summation of the contributions from all potential sources will exceed

the MCL at the tap. All contaminant levels, even when tested at 10 times the maximum use level, were well below the SPAC. Details on the results can be found on the NSF International website, at http://www.nsf.org/business/water_distribution/pdf/NSF_Fact_Sheet.pdf

36. *In regard to the statement made by Health Canada on their website: “Public water fluoridation has been ranked one of the top ten public health measures of the twentieth century by the World Health Organization”; Will Health Canada provide the WHO documentation to support the above statement? If not, why does Health Canada use this quote on their website?*

Health Canada Response:

This statement is not found on Health Canada’s website. Nevertheless, the WHO and many other public health organizations support fluoridation as a public health measure to protect dental health.

37. *Will the Government of Canada commit to establishing long-term health based objectives for drinking water contaminants, similar to the Maximum Contaminant Level Goals (MCLGs) established by the U.S. Environmental Protection Agency? If not, why not?*

Health Canada Response:

The guideline development process already addresses this issue. Guideline Technical Documents include the calculation of the “health-based value”, which is based solely on health considerations. The Maximum Acceptable Concentration is normally established at this value, unless the Federal-Provincial-Territorial Committee on Drinking Water has identified a need to risk manage the guideline to take into account limitations, usually analytical methods or treatment technology. This health-based value is similar to the U.S. EPA Maximum Contaminant Level Goals (MCLG).

38. *Will Health Canada immediately prohibit any dental association, medical association or public health organization from promoting water fluoridation until a parliamentary committee has had a chance to review the accumulated peer-reviewed evidence which documents the public health concerns, environmental concerns, ethical concerns and legal concerns associated with water fluoridation? If not, why not?*

Health Canada Response:

Current science would not support such action. The effects of fluoride to prevent and reduce tooth decay are well documented around the world. The decision on whether or not to fluoridate a drinking water supply is made by the province and the municipality affected. Health Canada does not participate in this decision.

39. *Will the Department of Justice and the Public Accounts Office please investigate these potential legal violations and their implications to taxpayers, of NSF Standard 60, the Safe Drinking Water Act, the Fisheries Act and other relevant government legislation? If not, why not?*

Health Canada Response:

On basis of the information provided, there does not appear to be grounds on which to conduct the requested investigation. To Health Canada's knowledge, there has been no violation of federal statutes in regard to the fluoridation of drinking water. The Government of Canada is not responsible for the enforcement and compliance of provincial legislation.

40. *Information on drinking water fluoridation*

Health Canada Response:

Drinking water fluoridation is still considered to be a safe and effective public health method to reduce the prevalence of dental caries in the population, as supported by many International Organizations (e.g., World Health Organization, Australian Government, U.S. Centers for Disease Control and Prevention, American Dental Association, Canadian Dental Association, British Dental Association, Institute of Medicine, etc.). As Health Canada uses a population-based approach in the risk assessment process, drinking water guidelines are based upon the sub-population of greatest risk and are therefore protective of all Canadians.

41. *Will Health Canada organize immediately a public education campaign to offset the misconceptions the public has about the safety and efficacy of fluoride, when ingested, at recommended doses in drinking water?*

Health Canada Response:

In Canada, the provinces and territories have primary responsibility regarding the provision of drinking water. Health Canada's role is mostly in the area of scientific leadership and coordination and as such already provides information regarding fluorides and human health to the public through its website.

Health Canada endorses the fluoridation of drinking water to prevent tooth decay, but does not participate in the decision to fluoridate a water supply. Provincial and territorial governments are generally 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. Hence Health Canada will not organize a public education campaign on water fluoridation.

42. *Will Health Canada inform the public, dental and public health officials of the correct mode of action of fluoride; purported benefits are topical [applied directly to the surfaces of the teeth], not systemic [swallowed]? If not, why not?*

Health Canada Response:

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. Health Canada is informing the public and public health professionals through web publications and by working directly with the provinces and territories in this area.

43. *Has Health Canada advised parents of young children [especially under the age of one] explicitly not to use fluoridated drinking water? If not, why not?*

Health Canada Response:

The incidence of dental fluorosis is best correlated with the total cumulative fluoride exposure to the developing dentition. According to the Findings and Recommendations of the Expert Panel Meeting recently held in Canada (to be published on Health Canada's website), an increased risk of dental fluorosis would be associated with extended periods (e.g., multiple years) of exposure to excessive amounts of fluoride, 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.

Water that is optimally fluoridated does not pose a problem with respect to moderate fluorosis for any age group and does not create a need to advise parents of a health concern. 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 is recommending 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.

44. *Has Health Canada advised those who are unable to adequately filter fluoride of their higher risks associated with water fluoridation [e.g., young children, elderly, kidney patients, diabetic patients, Walkerton, Ontario residents with impaired kidney function]? If not, why not?*

Health Canada Response:

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. There are 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 typical levels found in drinking water (e.g., at the maximum acceptable concentration of 1.5 mg/L) would result in adverse effects in these potentially susceptible sub-populations.

The issue of filtering water for individuals requiring dialysis applies to many minerals and not specifically to fluoride. Dialysis teams who support such individuals are already aware of the need for mineral removal from water used for dialysis.

45. *Has Health Canada advised those who drink larger than normal quantities of water [e.g. athletes, lactating mothers, soldiers, diabetic patients] of the higher risks associated with water fluoridation? If not, why not?*

Health Canada Response:

As mentioned previously, 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 typical levels found in drinking water (e.g., at the maximum acceptable concentration of 1.5 mg/L) would result in adverse effects for those consuming larger quantities of drinking water.

46. *Has Health Canada advised those with poor nutrition [e.g., calcium, magnesium, iodine, selenium] of their higher risks associated with water fluoridation [see ATSDR, NRC Canada 2007, NRC 2007]? If not, why not?*

Health Canada Response:

As mentioned previously, 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. Any potential health risk from fluoridation in Canada would be much lower than the risks associated with poor nutrition.

47. *Have those working with Fisheries and Oceans, Natural Resources, Environmental Agency advised those involved with fisheries of the inherent risks of water fluoridation to many species of fish and the insects upon which they feed? If not, why not?*

Environment Canada Response

By memorandum of understanding between the Minister of Fisheries and Oceans and the

Minister of the Environment, the Minister of the Environment implements the pollution prevention provisions of the Fisheries Act (sections 36, 38, 40). The Minister of the Environment does not have a statutory duty to inform the fisheries industry or the public of the use of fluoridation chemicals (or other substances) under these sections of the Fisheries Act. There are also no provisions that require the Minister of the Environment to inform fish farms and fisheries regarding known harmful substances in water under the Canadian Environmental Protection Act, 1999, and other wildlife legislation that deals with fish, such as the Canada Wildlife Act and the Species at Risk Act.

48. *Will the Government of Canada commit to starting national bio-monitoring studies to regularly identify and track the exposure of Canadians to fluoride by testing blood, urine, saliva, etc.? If not, why not?*

Health Canada Response:

The Government of Canada's Chemical Management Plan has committed to conducting national biomonitoring studies to monitor Canadians' exposures to environmental chemicals. Statistics Canada, in partnership with Health Canada and the Public Health Agency of Canada, is conducting the Canadian Health Measures Survey (CHMS) between March 2007 and Winter 2009. Through personal interviews and the collection of physical and chemical measurements from 5,000 Canadians aged 6 to 79 years, the CHMS will provide nationally representative data on indicators of environmental exposure (i.e. biomonitoring), chronic diseases, infectious diseases, fitness and nutritional status, as well as risk factors and protective characteristics related to these areas. Blood and urine specimens will be collected in a mobile clinic and analysed for a number of different classes of substances including; metals, phthalates, polychlorinated biphenyls (PCBs), brominated flame retardants, perfluorinated compounds, organochlorine pesticides and pyrethroid pesticides, organophosphate insecticide and phenoxy herbicide metabolites.

Fluoride measurements are not included in the current CHMS as it was not identified as a priority measurement in the consultations undertaken as part of the development of the survey.

49. *Would Health Canada enhance their website to include pictures of dental fluorosis so that the population and dentists can better identify this health concern?*

Health Canada Response:

Dentists and other health professionals have access to scientific and medical documents to identify issues such as moderate to severe dental fluorosis. As with any medical condition, moderate to severe dental fluorosis should be identified by trained professionals and not by the general public.

50. *Will Health Canada instruct the manufacturers of fluoridated toothpaste and mouthwash to put warning labels similar to the FDA warnings in the USA?*

Health Canada Response:

When fluoride is used in large concentration and with a drug delivery system (e.g. dental rinse, toothpaste), the products are considered drugs under the *Food and Drugs Act* and are regulated under the *Natural Health Product Regulations*. Since the *Natural Health Product Regulations* came into force on January 1, 2004 with a transition period till December 31, 2009, some of the products may still be regulated under the *Food and Drug Regulations*. Under these regulations, a warning is required on the labels of fluoridated toothpastes and mouthwashes sold in Canada. The warning is established in Health Canada's "Fluoride-Containing Anti-Caries Products Monograph", which states that the labels of fluoride containing mouthwashes and toothpastes must carry the following cautionary statement: "If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Centre right away".

51. *Testimony under oath to the US Congress by National Sanitation Foundation indicates that NSF is violating its own Standard 60 requirements for chemical additives. [see Stan Hazan testimony] NSF is certifying companies which are not in full compliance with Standard 60. [section 3.2.1 requires full and accurate documentation of all impurities in these products and maximum percent or parts by weight, CAS number, chemical name, toxicology studies, selected spectra, etc.]*

Health Canada Response:

This statement was later corrected by Stan Hazan during the same deposition to the Superior Court of California for the District of San Diego (March 9, 2004). NSF assesses the toxicity of chemicals using available toxicity information and the protocol under Annex A which outlines the toxicology data requirements. These requirements are generally met when there is a MAC or MCL established by the relevant agency. The requirement under section 3.2.1 of Standard 60 is to provide published and unpublished toxicology studies when available. The toxicity assessment is done on the chemical form that it is found in drinking water. Because fluorosilicate compounds readily hydrolyses completely to release fluoride ions, NSF's assessment is based on the toxicology of inorganic fluoride.

52. *How can Environment Canada, Natural Resources, Transport Canada, Fisheries and Oceans, Public Health Agency, Indian and Northern Affairs, Public Health Agency, Environmental Assessment Agency or other relevant government agencies ensure that the public and the environment will be adequately protected from an accidental spill of this product [hydrofluorosilicic acid] if Standard 60 information is not available for the NSF-certified products?*

And

53. *How can emergency response workers be protected from potential accidents if the content of these products is not fully disclosed?*

Health Canada Response:

NSF Standards are designed to ensure the safety of products within acceptable concentrations in drinking water. They do not address concerns related to accidental spills or occupational exposures. Other mechanisms exist for such situations, including the Hazardous Products Act, Part 2, which requires a Materials Safety Data Sheet to be made available by the manufacturer, and requirements under the Transportation of Dangerous Goods Act and regulations.

Public Health Agency of Canada Response:

The issues are the responsibility of provincial and territorial governments.

Environment Canada Response:

Currently, Environment Canada does not regulate hydrofluorosilicic acid under the Environmental Emergency Regulations nor does it have any plans to do so in the near future. These regulations under CEPA 1999 require emergency plans to be prepared and implemented for listed substances at or above specified threshold quantities.

Transport Canada Response:

In Canada, transportation of dangerous goods is strictly regulated under the Transportation of Dangerous Goods Act, 1992. The Act promotes public safety during the transportation of dangerous goods. Transport Canada's TDG program is based on the premise that dangerous goods must be properly classified and transported in a proper means of containment. Proper containment, along with proper safety markings and shipping documents, amongst other requirements, are crucial elements in the safe transportation of dangerous goods. A person in Canada who is handling, offering for transport, transporting or importing a dangerous good must follow the TDG Act and its regulations. Transport Canada conducts inspections to verify compliance with the Act and its regulations. Should a person fail to comply, then enforcement action can be taken. As the TDG Act is criminal law, the enforcement action could lead to an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars for a first offence, and not exceeding one hundred thousand dollars for each subsequent offence. Or the enforcement action could lead to an indictable offence and liable to imprisonment for a term not exceeding two years.