Region of Peel
Working for you

Health Services

To:	Councillor John Sprovieri	**Date:**	June 24, 2014
From:	Janette Smith, Commissioner Dr. David Mowat, Medical Officer of Health	**Subject:**	**Response to Fluoride Related Questions**
cc:	Emil Kolb, Regional Chair Patrick O'Connor, Regional Solicitor & Director, Legal Services	**Our File:**	

John,

In follow up to the meeting we had with Patrick O'Connor and yourself regarding community water fluoridation, we are providing answers to the four outstanding questions.

1. Why hasn't Health Canada replied to your submission to them?

We have contacted Health Canada regarding your submission. They indicated that while your submission was very descriptive, they were unable to determine a specific question in the submission. If you wish to submit a question or reframe your submission, Health Canada is willing to address it.

We reviewed your submission to Health Canada. It expressed your concern that fluoridation was a violation of the Food and Drug Act. In December 2011, Health Canada provided Mayor McCallion a response to this topic. It can be found in the last paragraph on page 3 of the following link:

http://www.peelregion.ca/council/agendas/pdf/rc-20120112/communication-he-c3.pdf .

We have summarized the information here. Fluoride, either offered for sale in a final dosage form, used in large concentration and with a drug delivery system (e.g., dental rinse, toothpaste) or labeled for therapeutic use (or making therapeutic claims), would be considered a drug under the *Food and Drugs Act* and regulated under the Natural Health Product Regulations.

Where minerals are added to water or where food is fortified with a mineral (e.g., iron in cereals, or fluoride in water), the mineral is not classified as a drug. Fluoride used in drinking water fluoridation is not considered a drug under the *Food and Drugs Act* and cannot be regulated under the Natural Health Product Regulations.

2. How is Hydrofluorosilicic Acid (HFSA), which is used to fluoridate our drinking water, tested for toxins and their potential impact?

Government toxicology evaluations are based upon hundreds of published, referenced scientific research studies. Hydrofluorosilicic Acid (HFSA), which is used to fluoridate our drinking water, is not specifically listed as being evaluated because HFSA is not

present in drinking water. The studies are for the released substances in the treated water that people are actually exposed to.

The HFSA that we add to our water has the chemical formula H_2SiF_6, meaning that it is composed of two hydrogen ions (H), one silica ion (Si) and six fluoride ions (F). When the HFSA is added to water, the water molecules interact with the bonds that hold the HFSA together, causing the bonds to let go of the ions. The scientific term for this is hydrolysis. When the HFSA is added to the water, the ions are set free from each other and disperse into the water, meaning that no HFSA is left. Only the fluoride, silica and hydrogen ions remain. Though scientists have understood this process for quite some time, it was conclusively proven by a research team at the University of Michigan in 2006.

When government health agencies assess the safety of water fluoridation, they must look at what people are actually consuming (the treated water) and not the original chemicals that are added to treat the water. In the case of water fluoridation, people are exposed to the ions that are released from the HFSA, and also to impurities that exist in the HFSA (such as lead), but not to HFSA itself.

NSF International is a global organization offering services in more than 155 countries. With a professional staff of engineers, microbiologists, toxicologists, chemists, public health experts and certification specialists, NSF International develops public health standards and certifications that help protect food, water, consumer products and the environment.

Health Canada and the United States Environmental Protection Agency (USEPA) worked with NSF International and others to create the NSF/ANSI 60 purity standard for all chemicals used to treat drinking water, including those used for fluoridation. NSF 60 includes a process for the toxicological evaluation of all treatment chemicals and for the impurities that they contain. When toxicological limits for a substance have previously been determined by Health Canada or the USEPA, the NSF 60 standard uses these established limits in their assessment.

When HFSA is added to our water, the concentration of fluoride ions is increased, but trace amounts of other elements like lead and arsenic can also be present. The NSF looks to the toxicology studies that Health Canada and the USEPA have performed, and to the maximum limits that they have set for these impurities in water.

In 2011, Health Canada found that "The weight of evidence from all currently available studies does not support a link between exposure to fluoride in drinking water at 1.5 mg/L and any adverse health effects." It is important to note that the Region of Peel fluoridates to a level of 0.7 mg/L, which is less than half the level where Health Canada found no harmful effects.

Health Canada toxicology evaluations:
Fluoride:
www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2011-fluoride-fluorure/index-eng.php
Arsenic: www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/arsenic/index-eng.php
Lead: www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/lead-plomb/index-eng.php
Index of Health Canada evaluations:
www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/index-eng.php#guidance

3. Does the EPA HQ Union of Scientists oppose fluoridation?

Information provided to staff:

"...an employee came to the union with a complaint: he said he was being forced to write into the regulation a statement to the effect that EPA thought it was alright for children to have "funky" teeth... ...dental fluorosis, but since it had deemed the effect as only cosmetic, EPA didn't have to set its health-based standard at a lower level to prevent it....

...Since then our opposition to drinking water fluoridation has grown, based on the scientific literature documenting the increasingly out-of-control exposures to fluoride, the lack of benefit to dental health from ingestion of fluoride and the hazards to human health from such ingestion. These hazards include acute toxic hazard, such as to people with impaired kidney function, as well as chronic toxic hazards of gene mutations, cancer, reproductive effects, neurotoxicity, bone pathology and dental fluorosis. First, a review of recent neurotoxicity research results...."

http://www.nteu280.org/Issues/Fluoride/NTEU280-Fluoride.htm

Response:
The National Treasury Employees Union (NTEU) represents 150,000 bargaining unit employees in 31 federal agencies and departments. Local Chapter 280 of the NTEU represents professional employees at the headquarters offices of the United States Environmental Protection Agency (USEPA). The USEPA regulates fluoride in drinking water to protect public health.

The link provided contains Local Chapter 280's view. We are unable to confirm the date of this information was issued or if this is the view of the entire National Treasury Employees Union. Also, we are unable to locate the entire complaint that is being referenced above to verify the accuracy of the description above.

4. According to Reuters, it's true that the US National Kidney Foundation dropped their support back in 2008: "Kidney Foundation Drops Fluoridation Support."

Information provided to staff:

http://www.reuters.com/article/2008/06/09/idUS123736+09-Jun-2008+PRN20080609

The Kidney Foundation now says:

"The benefits of water and dental products containing fluoride is the prevention of tooth decay and dental cavities in people of all ages. The potential health risks are a rare bone disease called skeletal fluorosis, bone fractures and severe enamel fluorosis. For more information on fluoride in CKD please refer to the documents below."

http://fluoridealert.org/studies/kidney07/

Response:

We contacted the National Kidney Foundation and they referred us to their website. They have not issued any specific recommendation regarding fluoride intake and kidney disease.

http://www.kidney.org/atoz/content/fluoride.cfm
https://www.kidney.org/atoz/pdf/Fluoride_Intake_in_CKD.pdf

The quotation that was provided to us was missing the first sentence. Please see the following for the entire quotation:

> "**The National Kidney Foundation has not issued specific recommendations regarding fluoride intake and kidney disease due to the limited available research on the topic**. The benefits of water and dental products containing fluoride is the prevention of tooth decay and dental cavities in people of all ages. The potential health risks are a rare bone disease called skeletal fluorosis, bone fractures and severe enamel fluorosis. For more information on fluoride in CKD please refer to the documents below."

The last review of the literature that they reference is 2006/2007.

Health Canada / Santé Canada

Access to Information and Privacy Division
7th Floor, Suite 700, Holland Cross, Tower B
1600 Scott Street
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Ottawa, Ontario K1A 0K9

Our file: A-2014-00168 / na

May 26, 2014

Joanne David
<address snipped>
EDMONTON AB T6R 0B4

Dear Ms. David:

This is in response to your request under the *Access to Information Act* (the *Act*) for: **Clarified Request Text:**
Reports, studies, toxicology and clinical tests relating to hydrofluosilicic acid in Canadian tap water

Original Request Text:
Documents pertaining specifically to hydrofluosilicic acid in Alberta and Canadian tap water:
- Studies from 1940 showing dental efficacy and human safety.
- Studies from 1950s showing dental efficacy and human safety.
- Any double blind study done by Canada or any province showing dental efficacy and human safety, of any date.
- Any double blind study done by anywhere in the world that was considered.
- Any toxicity study, of any date, done by Canada or the world that was considered.
- Evidence of any kind (not opinion) that shows statistical viability of water fluoridation in terms of efficacy, and margin of error calculations.
- Evidence of any kind (not opinion) that shows statistical viability of water fluoridation in terms of human safety over a life-time, and margin of error calculations.
- Evidence of any kind (not opinion) that shows statistical viability of water fluoridation in terms of human safety, and margin of error calculations, for infants, young children, elderly, or any adult with disability, diabetes, bone disease, autism, thyroid ailments, kidney disease, etc.
- Evidence of any kind of consideration of human rights and medical ethics, namely our human right to opt out of the forced water fluoridation program, and if that consideration exists, why the overriding of these well-established medical standards are breached.

After a thorough search for the requested information, no records were located which respond to your request.

If you have any questions or concerns about the processing of your request, please do not hesitate to contact Nancy Armstrong, the analyst responsible for this request, either by phone at (613) 960-4457, or by fax at (613) 941-4541, or by e-mail at nancy.armstrong@hc-sc.gc.ca with reference to the file number cited above.

Canada

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL RISK MANAGEMENT RESEARCH LABORATORY
CINCINNATI, OH 45268

November 16, 2000

OFFICE OF
RESEARCH AND DEVELOPMENT

Roger D. Masters
Research Professor of Government
Dartmouth College
Department of Government
6108 Silsby Hall
Hanover, New Hampshire 03755-3547

Dear Professor Masters:

We have received your letter dated September 27, 2000, requesting empirical scientific data we may have on the health effects of fluosilicic acid or sodium silicofluoride and manganese neurotoxicity.

To answer your first question on whether we have in our possession empirical scientific data on the effects of fluosilicic acid or sodium silicofluoride on health and behavior, our answer is no. Health effects research is primarily conducted by our National Health and Environmental Effects Research Laboratory (NHEERL). We have contacted our colleagues at NHEERL and they report that with the exception of some acute toxicity data, they were unable to find any information on the effects of silicofluorides on health and behavior.

In answer to your question on empirical information we may have on manganese neurotoxicity, NHEERL scientists forwarded to us several manuscripts with reference sections that contain information on the neurotoxicity of manganese. These are enclosed for your information.

I apologize for the delay in responding to your request and hope you find the enclosed information useful.

Sincerely,

Robert C. Thurnau

Robert C. Thurnau, Chief
Treatment Technology Evaluation Branch
Water Supply and Water Resources Division

Enclosures

NSF International
Ann Arbor, MI • Sacramento, CA • Washington, D.C. • Brussels, Belgium

July 7, 2000

The Honorable Ken Calvert
Chairman Subcommittee on Energy and the Environment
Committee on Science
U. S. House of Representatives
Suite 2320, Rayburn House Office Building
Washington, DC 20515-6301

Dear Mr. Chairman:

Thank you for your letter of May 8, 2000 to Dr. Joseph Cotruvo wherein you request information from NSF International (NSF) on fluoride containing compounds. We appreciate having received an extension in order to allow NSF staff sufficient time to provide a comprehensive response to your request.

This response is comprised of a general information section entitled *Background on NSF and the Drinking Water Additives Program* and a section that answers the 8 questions in your letter. I have attached additional documents that will also assist in answering your questions.

It is important to note that your questions relate to two separate issues, and departments, within NSF – standards and product certification. First, ANSI/NSF Standard 60 – the American National Standard developed by NSF and a consortium of major stakeholders consisting of the American Water Works Association (AWWA), the AWWA Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the now inactive Conference of State Health and Environmental Managers (COSHEM) was developed from 1985 to 1987. Second, NSF operates a separate product testing, certification and listing program based on the requirements of the standard.

The health based principles of Standard 60 were originally developed by the NSF Health Advisory Board (HAB) which is a panel of non-NSF health science experts. This group continues its role in an advisory and oversight function to NSF and its Toxicology staff to assure that ANSI/NSF Standards are consistent with current public health principles.

The standard and the certification program are recognized and utilized by AWWA and its member utilities, and adopted in most state regulations. More than 43 states have regulations in place requiring product compliance with ANSI/NSF Standard 60. (See Attachment 14). The program provides a product quality and safety assurance that aims to prevent addition of harmful levels of contaminants from treatment chemicals.

P.O. Box 130140 Ann Arbor, Michigan 48113-0140 USA
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Fluorosilicate products are comprised of a fluoride entity as well as a silicate entity. Based on previously published studies, there is virtually complete dissociation of the fluoride and silicate entities in dilute solutions. As such, the toxicological evaluation of fluorosilicate products is conducted through the evaluation of each entity separately.

ANSI/NSF Standard 60 requires, when available, that the U.S. EPA regulated Maximum Contaminant Level (MCL) be used to determine the acceptable level for a contaminant. The MCL for fluoride is 4 mg/L of drinking water. As such, NSF has not independently developed toxicology data to support this level of human exposure. The Maximum Allowable Level (MAL) for fluoride ion in drinking water from NSF Certified treatment chemicals is 1.2 mg/L, or less than one-third the EPA's MCL. The product Maximum Use Level (MUL) certified by NSF ranges from 4 - 6.6 mg/L.

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, ANS/NSF Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a Maximum Drinking Water Level (MDWL). NSF has established a Maximum Drinking Water Level of silicate at 16 mg/L. A fluorosilicate product MUL of 4-6.6 mg/L results in silicate drinking water levels substantially below the 16 mg/L MAL established by NSF for silicates. Attachment 15 outlines the derivation of the NSF MAL for silicates.

In general, NSF Certified fluoridation products have been tested and found to comply with the requirements of ANSI/NSF Standard 60 for 12 additional inorganic chemicals. Additional testing of these products for radionuclides has resulted in no measurements above the detection limits. The specific answers below provide additional detail.

If there is any more information that you need, please do not hesitate to contact me.

Sincerely,

Stan Hazan
General Manager
Drinking Water Additives Certification Program
734-769-5105
hazan@nsf.org

cc: Dr. Joe Cotruvo, NSF
Dr. Lori Bestervelt, NSF