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APR 04 2012

Regional Municipality of Peel
Office of the Regional Chair

APR 17 2012

RECEIVED

Mr. Emil Kolb
Regional Chair and Chief Executive Officer
Regional Municipality of Peel
10 Peel Centre Drive
Brampton, Ontario L6T 4B9

Dear Mr. Kolb:

Thank you for your correspondence of February 6, 2012, concerning Peel Regional Council's resolution to request that Health Canada regulate fluorosilicates (i.e., hexafluorosilicic acid and sodium silicofluoride) as drugs under the *Food and Drugs Act*. I regret the delay in responding.

In Canada, responsibility regarding the safety of drinking water generally lies with the provincial and territorial governments. Health Canada worked with the provinces and territories, through the Federal-Provincial-Territorial Committee on Drinking Water, to develop the *Guidelines for Canadian Drinking Water Quality*. The provinces and territories use the Guidelines to establish their own requirements for drinking water quality and have sole responsibility regarding implementation. For that reason, your request that Health Canada regulate municipal drinking water supply treatment chemicals as drugs is an issue that falls outside the jurisdiction of the *Food and Drugs Act*.

PROVINCE PASS
THE BUCKET IS
MURDER
WHY?

With respect to your request regarding a long-term toxicology study, Health Canada recommends that drinking water treatment additives such as fluoridation agents be certified to the appropriate standard, specifically NSF/ANSI Standard 60: *Drinking Water Treatment Chemicals - Health Effects*. This standard requires a toxicology review of the product to ensure its safety at the maximum use level and to evaluate potential contaminants in the product.

REVIEW
AVAILABLE

Regarding human clinical evidence of the efficacy of adding fluoride to water supplies, most published scientific studies on the effectiveness of water fluoridation are based on comparisons between communities with minimal fluoride levels in the water supply versus communities with fluoridation, rather than a clinical intervention. The first controlled clinical trial at a community level was conducted in the U.S. and published in 1956; a recent human double-blind placebo-controlled clinical trial on how effectively fluoride is taken up from drinking water was conducted in the U.K. in 2005.

BASED ON
PROCESS
HOW CAN WE
KNOW THAT
MURDEROUS
ACID IS NO
HARMFUL
PEOPLE.

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HE-63-1

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and Consumer Safety
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CanadaDirection générale,
Santé environnementale et
sécurité des consommateurs

Water, Air and Climate Change Bureau
Safe Environments Directorate
269 Laurier Avenue West
Address Locator 4905D
Ottawa, Ontario K1A 0K9

SEE PAGE 2+3

Your file Votre référence

Over file Note référence

December 22, 2011

Ms. Hazel McCallion, Mayor
City of Mississauga
300 City Centre Drive
Mississauga, Ontario L5B 3C1

REFERRAL TO _____
RECOMMENDED _____
DIRECTION REQUIRED _____
RECEIPT RECOMMENDED ☒

Dear Mayor McCallion,

This is in response to your letter of December 20, 2011, addressed to Michèle Giddings, in which you seek information regarding fluoride in drinking water. I would like to use this opportunity to also provide some clarification on the information included in your letter.

Fluoride occurs naturally in many source waters in Canada. Fluoridation is the process of adding an inorganic fluoride compound to municipal water supplies to adjust the level of fluoride to its optimal level for dental benefits. The fluoridation of drinking water supplies is a well-accepted measure to protect public health and is strongly supported by scientific evidence. Fluoride has been added to public drinking water supplies around the world for more than half a century, as a public health/dental health measure, and its use is 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 works in collaboration with the provinces and territories to develop the *Guidelines for Canadian Drinking Water Quality*. Guidelines are developed through a risk assessment process, and include a thorough review of the existing peer-reviewed scientific literature. The process also includes internal reviews, an external peer review, federal-provincial-territorial approval processes, as well as public consultation through the Health Canada website. The *Guidelines* are used by every province and territory as a basis to establish their own regulatory requirements for drinking water quality.

Canada

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/...2

HE - C3 -2-

The safety and efficacy of water fluoridation has been frequently studied and continues to be supported by current science. Health Canada's recent review of the existing scientific literature on fluoride has found no adverse health effects from water containing fluoride at, or below, the maximum acceptable concentration of 1.5 mg/L. Canadian and international studies agree that water that was fluoridated at an optimum level (0.7 mg/L) does not cause adverse health effects.

There are several fluoridation additives that can be used in municipal drinking water supplies, including sodium fluoride as well as fluorosilicates. Health Canada recommends that drinking water treatment additives be certified as meeting the appropriate standard developed by NSF International, in this case NSF/ANSI Standard 60: Drinking Water Treatment Chemicals - Health Effects. NSF International is an independent not-for-profit international standards writing body, which uses outside expertise (including Health Canada) to establish health-based performance standards. NSF standards have been designed to safeguard drinking water by helping to ensure the material safety and performance of products that come into contact with drinking water. NSF/ANSI Standard 60 requires a toxicology review of the product to ensure its safety at the maximum use level, including from any potential contaminant in the product. Certification to this standard ensures that the fluoridation additive, as produced in a specific plant, meets the requirements of the standard. Certification organizations, which provide assurance that a product conforms to applicable standards, must be accredited by the Standards Council of Canada (SCC). An up-to-date list of accredited certification organizations can be obtained from the SCC website at www.scc.ca. Many Canadian provinces, including Ontario, require certification to the NSF Standard for drinking water additives.

To clarify some of the information provided in your letter, I would note that, despite our thorough review of the existing scientific literature, Health Canada is not aware of any data supporting the statement that "lead levels in blood and tissues are higher when fluorosilicates are used in drinking water". There have been claims that the use of hydrofluorosilicic acid would reduce the pH and hence increase leaching of lead present in the distribution system, however the pH of drinking water is adjusted at the treatment plant before distribution thereby eliminating this concern.

Your letter states that the Walkerton Inquiry and the Ontario Safe Drinking Water Act of 2002 have determined that municipalities have legislative responsibility and authority with respect to drinking water safety. I would note that the Walkerton Inquiry's recommendations were mostly targeted to the provincial government, rather than municipalities. The Ontario Safe Drinking Water Act, which was adopted following recommendations from the Walkerton Inquiry, establishes the responsibilities of municipal governments in Ontario with respect to drinking water quality. This includes sampling requirements in both fluoridated and non-fluoridated systems.

1.3

HE-C3 -3-

Finally, in response to your question regarding the regulation of fluoridation products by Health Canada, I would provide the following information: 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 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 not considered a drug under the Food and Drugs Act and cannot be regulated under the Natural Health Product Regulations.

IRON NOT
TOXIC.

Conclusion. - Sodium Fluoride - CLINICAL GASE IS A MEDICATION.

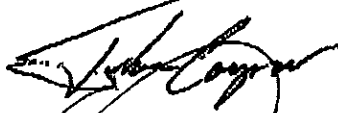
For specific questions regarding the fluoridation of drinking water in Ontario, I would suggest you contact your provincial representative on the Federal-Provincial-Territorial Committee on Drinking Water, Dr. Satish Deshpande, at the following coordinates:

HYDROFLUOROSIS
ACID. A. TOX
CHEMICAL CANIT
REGARDED AS
DRUG.

Mr. Satish Deshpande, Team Leader, Water Standards Section
Standards Development Branch, Ministry of the Environment
40 St. Clair Ave W, 9th Floor
Toronto, ON M4V 1M2
416-327-4689
Satish.Deshpande@ontario.ca

I hope that this information will be helpful for your Regional Council discussion. Please do not hesitate to contact me if you need clarification regarding the information I have provided in this letter.

Sincerely yours,



John Cooper
Director