

Response to Health Canada 2009 Review

Draft report, Fluoride in Drinking Water, by Health Canada; public comments due by Nov 27, 2009 <water_eau@hc-sc.gc.ca>

By Carole Clinch, BA, BPHE, Research Coordinator for People for Safe Drinking Water

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Addendum: Omissions

“Many of the factors determining oral health are found outside the mouth, including income, education, housing and sanitation, gender, ethnic origin, availability and access to health services.” FDI 2009, p 48.

“If the major determinants of health are social, so must be the remedies.”
quote by Michael Marmet, Epidemiology and Public Health Department, University College, London, 2005, in Beaglehole R, Benzian H, Crail J, Mackay J. FDI. The Oral Health Atlas. 2009. Mapping a Neglected Global Health Issue, p 48.

Introduction

The recent Health Canada review and update of the 1996 document for the Canadian Drinking Water Quality Guideline (CDWQG) called "[Fluoride in Drinking Water](#)", (in [French](#)) is now available for public comment. Comments may be sent by email to: water_eau@hc-sc.gc.ca

Due to the recent evidence from the recent and authoritative 2006 National Research Council Review on Fluorides in Drinking Water and subsequent new research, it is imperative that the Canadian policy on artificial water fluoridation be reviewed with scientific rigour and objectivity.

Canadians desire accurate, balanced and up-to-date presentations of the research literature when it comes to formulating government policy with taxpayers' money. This review does NOT present a review of "all currently available studies", as claimed. Because so much research is omitted without justification, this review cannot provide a "weight of evidence" assessment of the available scientific information.

Necessary Expertise Lacking for Proper Risk Assessment

The necessary expertise for a proper risk assessment of artificial water fluoridation is lacking from the external review panel because 4 out of 6 panel members are dentists. Dentists are not qualified to assess health impacts outside of the oral cavity nor are they trained in research methodologies.

"Dentists shall not represent their education, qualifications or competence in any way that would be false or misleading." [CDA Code of Ethics](#)

It is interesting to note that Health Canada did not consult with Canada's leading expert on fluoride toxicity and efficacy – Dr. Hardy Limeback, DDS, PhD, Head of Preventive Dentistry at the University of Toronto, committee member of the NRC 2006 Review and internationally respected author and researcher on fluorides. His international expertise in this area would have provided much-needed credibility to this panel.

The 2 non-dentists on this review panel have published no scientific articles regarding fluoride in any peer-reviewed journal, demonstrating a lack of expertise on this subject. The medical doctor on this panel should be aware of the [Medicine Act 1991](#) Advertising Regulations, Ontario Regulation 114/94, Part II, Section 6(2), which states:

"Information communicated under subsection (1) must not, be false, misleading or deceptive by the inclusion or omission of any information; contain a testimonial or any comparative or superlative statements; or contain any reference to a specific drug..."

As stated by [Dr. Philip Michael](#), Vice-President, Europe, of the International Society of

Doctors for the Environment:

“Proper risk assessment of the physiological effects would require the addition of extensive expertise in fluorosis (dental & skeletal) in developmental toxicity, in neuroscience including brain and IQ effects , in endocrinology including pineal gland effects , in thyroid function, in osteopathology including bone cancer , in nephrology, and in effects on the gastrointestinal tract, immune system, reproduction, respiratory function and include allergic/hypersensitive effects.”

If fluoridation has been extensively studied, these experts should exist in Canada and should be used for this review. If experts on fluoride do not exist, then it can be assumed that artificial water fluoridation is not a well evaluated and studied health policy in Canada, and any claims to the contrary are without merit:

“-we have much less information than we should, considering how long this has been going on. I think that’s why fluoridation is still being challenged so many years after it began. In the face of ignorance, controversy is rampant.” Chair of the NRC 2006 Review “Second Thoughts About Fluoride” January, 2008 Scientific American

“Until high quality studies are undertaken providing more definitive evidence, there will continue to be legitimate scientific controversy over the likely effects and costs of water fluoridation.” [Chair of the York Review 2000](#)

False Assumptions Used to Determine Risk Assessment

The risk assessments of this review are based on outdated information from Dean and McClure in the 1930s and 1940s. These risk assessments are also based on the false assumption that our exposure to fluorides in food is the same today as it was in 1940, even though the scientific evidence and statements in this review state that F sources have increased. Calculations based on such false assumptions are not scientifically valid.

“In the 1940s and 1950s, the major sources of fluoride were from drinking water and food. Since then, numerous sources of fluoride have become available, including dental products containing fluoride (e.g., toothpastes and mouth rinses) and fluoride dietary supplements.” Health Canada Sept 2009 Review

A recent 2009 publication in the [Journal of Public Health Dentistry](#) by a member of the Health Canada External Panel states:

“fluoride intake level is not based on any direct assessment of how such intake relates to the occurrence, or severity, of dental caries and/or dental fluorosis.”

“the basis for this estimate is largely from data originally obtained in the 1930s and 1940s by McClure (2) when there were no dental fluoride products available and

limited understanding of how fluoride worked to prevent dental caries.”

“In that era, most fluoride intake was from naturally fluoridated water (McClure estimated a range of 67-94 percent), with no fluoride dentifrice, supplements, or other fluoride products available (2). Moreover, in that era, it was believed that fluoride needed to be ingested early in life to provide caries prevention (1).”

Research by Ziegelbecker 1981,¹ 1993,² [2009](#) demonstrates that the early Dean data was scientifically fraudulent.

The book by Sutton³ discusses how the scientific data from the original 4 trials in North America were scientifically fraudulent. This book was peer-reviewed by: Professor Maurice Betz, Dept Head - Mathematical Statistics in the University of Melbourne & Sir Arthur Amies, Dean of the Faculty of Dental Science, University of Melbourne.

Eliminating fluoride sources from air, food, or consumer products is virtually impossible. Fortunately, eliminating fluoride from the single largest source of fluoride over-exposure is very easy – just stop putting it into drinking water.

Citations

1. Ziegelbecker R. Fluoridated water and teeth. *Fluoride* 1981;14:123-128.
2. Ziegelbecker R, Ziegelbecker RC. WHO Data on Dental Caries and Natural Water Fluoride Levels. *Fluoride* 1993;26(4):263-266.
3. Sutton PRN. *Fluoridation Errors and Omissions in Experimental Trials*. 1959 Melbourne University Press, Victoria, Australia

Basic Scientific Procedures Not Followed

Basic scientific procedure requires a scientific review to explain how they evaluate the merits of each study presented or rejected in the review document. An explanation must be provided as to why any study is retained as valid or why it is rejected. This Health Canada review does not explain their reasons for accepting or rejecting any of the research literature, demonstrating poor scientific technique.

Many claims made by the authors are not supported by any research evidence. This is scientifically unacceptable and make such claims invalid.

“since 1996 there has been an overall decreasing trend of dental fluorosis in Canada.”
No citation is given for this claim.

Health Canada then contradicts itself by stating the opposite, citing unpublished research:

“Over the last 55 years, in areas where fluoride is added to the drinking water to bring the total level of fluoride to approximately 1 mg/L (optimally fluoridated areas), there have been increases in the total prevalence of dental fluorosis. Also, in non-fluoridated areas, there is clear evidence that the total prevalence of dental fluorosis has increased over the last 40 years (Clark, 2006).”

Health Canada used unpublished papers (e.g., Clark 2006), yet ignored published, peer-reviewed papers ([Clark et al 2006](#)) by a member of the Health Canada review. The published, peer-reviewed paper demonstrates that artificial water fluoridation is not safe, leading to more than a doubling of the incidence of dental fluorosis and a significant increase in the severity, of dental fluorosis, a visible sign of fluoride toxicity.

Lack of Objectivity Demonstrated

Because a large volume of scientific research was omitted, without justification, the objectivity of this panel is put into question.

The known bias regarding artificial water fluoridation, of the 6 individuals selected to do the 2008 external review is also troubling. This puts into question the objectivity of Health Canada in their selection of the panel.

Double Standard Used

There is no discussion in this review regarding the absence of epidemiological studies indicating effectiveness of ingested fluoride that conform to scientific standards for broad-based or random selection, blinded examinations, and appropriate controls for “confounding variables” as discussed in the [York Review 2000](#):

“Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitations of previous research.”

This committee's concern for adequate control of confounding variables is selectively applied only to research evidence which demonstrates health harm. Very high scientific standards are demanded for evidence demonstrating health harm. Very low scientific standards are demanded for evidence demonstrating the effectiveness of artificial water fluoridation in the prevention of cavities. This is scientifically unacceptable because it demonstrates a double standard, therefore research bias.

Petition responses from Health Canada incorrect

[7 petitions](#) were filed via the Auditor General Act, Section 22, regarding artificial water fluoridation to Health Canada and other government agencies. Health Canada recently

admitted to providing incorrect information to the petitions office and petitioner. This brings into question;

1. How many people in the Health Canada ministry reviewed this false information?
2. How many people in the Health Canada department are not providing comprehensive and correct information to the Minister of Health?

Health Canada misrepresents NRC 2006 Review

1. “These studies performed in China were also reviewed by other organizations and/or committees, which also mentioned that the significance of these studies is uncertain (IPCS, 2002; ATSDR, 2003; NRC, 2006).” Health Canada 2009 review

- Health Canada implies that the NRC 2006 committee reviewed the [23 studies](#) from China and other countries. The majority of these studies were only translated into English and made available to the North American audience in 2008, 2 years after the NRC review was published.

2. “The [NRC] Committee restricted its attention to studies that examined long-term exposure to fluoride in the range of 2–4 mg/L or above in drinking water.” Health Canada 2009 review

- This Health Canada statement is false. The committee examined a large number of studies examining artificially fluoridated communities using F concentrations of 1 mg/L. All Tables in Chapter 2, Chapter 5: Musculoskeletal Effects, Table 5-1, Table 5-2, Table 5-5, Chapter 7: Neurotoxic Effects, Chapter 8: Endocrine Effects, Figure 8-2, Appendix B, Tables B-11, B-12, B-13, B-14, Appendix E, Tables E-1, E-4, E-12, E-16, E-17.
- This comment is misleading because it perpetuates the misinformation regarding concentration and dose. The amount of fluoride ingested in a day (i.e., the dose) is the relevant information required to do a proper risk assessment, not the amount of fluoride in a litre of water (i.e. The concentration).

3. “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, including those related to ... genotoxicity and neurotoxicity.” Health Canada 2009 review

Health Canada presents conclusions which contradict the conclusions of the most authoritative review to date on genotoxicity and neurotoxicity, the NRC 2006 Review. To ignore the conclusions of the NRC 2006 Review and suggests that their conclusions are based on the “weight of evidence” is not credible.

“Genotoxicity tests indicate the potential for fluoride to cause mutations, affect the structure of chromosomes and other genomic material; affect DNA replication, repair, and the cell cycle; and/or transform cultured cell lines to enable them to cause tumours when implanted into host animals.” p304, NRC 2006 Review

“On the basis of information largely derived from histological, chemical, and molecular studies, it is apparent that fluorides have the ability to interfere with the functions of the brain and the body by direct and indirect means.” p187 NRC

“Fluorides also increase the production of free radicals in the brain through several different biological pathways. These changes have a bearing on the possibility that fluorides act to increase the risk of developing Alzheimer’s disease.” p186 NRC 2006 Review

4. “Skeletal fluorosis is the most serious adverse health effect clearly associated with prolonged exposure to high levels of fluoride in drinking water. Skeletal fluorosis can occur at very high exposure levels, and has rarely been documented in Canada.” Health Canada 2009 review

- Health Canada ignores the authoritative evidence in the NRC 2006 review, [Table 2-4](#), which demonstrates that susceptible populations in North America are exposed to “very high exposure levels” from drinking water alone, which can lead to known health effects. Ignoring the NRC 2006 conclusions and evidence suggests that Health Canada's conclusions are not based on the “weight of evidence.”
- Health Canada ignores the authoritative evidence from the NRC 2006 review, [Chapter 8](#) which demonstrates that thyroid derangement is the adverse health effect associated with the lowest fluoride concentrations in drinking water and the lowest fluoride dose. Adverse effects have been demonstrated with the consumption of as little as 1 litre of fluoridated water per day, assuming 0.7 mg/L fluoride concentrations, when individuals are iodine deficient. (70kg person)

“In humans, effects on thyroid function were associated with fluoride exposures of 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine intake was inadequate.” p 218 NRC 2006 Review

Iodine Deficiency is Highly Prevalent in the World Today

[36% of women in USA](#)

[70% of women in Australia](#)

[~ 50% of children in Europe](#)

[Australia, Germany, New Zealand, Switzerland](#)

Health Canada's conclusions (that thyroid derangements, neurotoxicity or carcinogenicity are “less serious” than skeletal fluorosis), are highly debatable, and very likely wrong. Since Health Canada did not review the research on thyroid and pineal gland, and dismissed the evidence on neurotoxicity and carcinogenicity, a meaningful discussion regarding these relative concerns is omitted.

Health Canada misrepresents the World Health Organization

The WHO has never officially endorsed artificial water fluoridation. There is no WHO criteria document endorsing artificial water fluoridation.

Health Canada implies that the WHO has an official policy position on artificial water fluoridation by citing a document produced by their oral health consultants:

“According to the World Oral Health Report 2003, water fluoridation where technically feasible and culturally acceptable has substantial advantages in public health.”

Chief Medical Officer for Health Canada claims in the press (Carstairs Courier, Aug 8, 2008):

“Many governments and health organizations, including ... the World Health Organization endorse the fluoridation of drinking water to prevent tooth decay.”

It should be noted that the WHO has stated clearly that they are not responsible for the statements made by their many consultants. [WHO ENVIRONMENTAL HEALTH CRITERIA 36, 1984](#), states:

“This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the United Nations Environment Programme, the International Labour Organisation, or the World Health Organization”

Health Canada Misrepresents Concentration & Dose

This review panel continues to perpetuate the elementary confusion between concentration and dose of fluoride. While engineers can usually control the concentration of the fluoride added to the water supply (fluoride per litre of water), no one can control the amount of fluoride you ingest from all sources, (drinking water/beverages, food, air, 300 drugs) or the dose people get each day. Dosage has different effects as a function of age, weight, and underlying medical conditions. Dosage is known to vary considerably (see NRC Review 2006 Review, [Table 2-4](#)), with some individuals consuming 10 times the average fluoride dose from drinking water alone.

It would seem evident that the inability to control the dose of this unregulated drug, let alone provide individual medical monitoring of any effects, is of concern and very relevant to Canadians.

This review panel demonstrates this confusion when they claim that IQ studies done in China dealt with fluoride levels which are substantially higher than the levels used in Canada, implying that they are not relevant. This is not correct.

For example, in one of [23 studies](#) published on this matter the authors found a 5-10 point IQ difference in children between a village with fluoride levels in well-water below 0.7 ppm and another village with well-water between 2.5 and 4.5 ppm. The authors estimated that IQ would begin to be lowered at 1.9 ppm.

A member of the Health Canada external review panel, who also did an internal review for Health Canada, (Tardiff 2006) notes the evidence and concerns regarding “-the impact of endemic fluoride on intelligence (cognitive effects) that seems to occur at lower levels (less than 1 ppm).” This evidence from Health Canada’s own internal review process is ignored in the Health Canada review.

A child drinking two litres of water, as currently recommended by Health Canada, at 1 ppm fluoride concentrations, would get a higher dose of fluoride than a child drinking one litre at 1.9 ppm, thus it is incorrect to claim that this study is irrelevant to Canada.

Omissions

Omission of Published Research by Health Canada Panel

The omission of recent and relevant published papers by 3 members of the external panel ([Kumar Clark Levy](#)) which demonstrate that artificial fluoride is not safe and not effective also gives the perception that this review process was not objective.

A recent published paper in the [Journal of Public Health Dentistry](#) by one member of the Health Canada panel (Levy) states that, “*These findings suggest that achieving a caries-free status may have relatively little to do with fluoride intake, while fluorosis is clearly more dependent on fluoride intake.*” The authors go on to say, “*Current evidence strongly suggests that fluorides work primarily by topical means through direct action on the teeth and dental plaque. Thus ingestion of fluoride is not essential for caries prevention.*”

Two papers by a member of the Health Canada review panel ([Kingston-Newburg trial – 50 years later](#)) (Kumar) demonstrate that there are no benefits from artificial water fluoridation. The [2009 study](#) by Kumar shows that 7- to 17-year-olds have similar cavity rates in their permanent teeth whether their water supply is fluoridated or not.

A recent paper by another member of the [Health Canada Review panel](#) (Clark) analysed 3 communities in British Columbia (Courtenay, Comox and Campbell River) which discontinued CWF. It found a “*marked decrease*” in the rates (from 58% to 24%) and severity of dental fluorosis with CWF cessation - “*as expected*”. The social costs of dental fluorosis and monetary costs to repair dental fluorosis are considerable.

The unpublished paper by Tardiff 2006/7 which was part of the internal review process raises many concerns which seem to be ignored in the Health Canada review. For example, Tardiff

raises concern about “-the impact of endemic fluoride on intelligence (cognitive effects) that seems to occur at lower levels (less than 1 ppm).”

The Chief Dental Officer for Health Canada claims a “20 to 40 % decay reduction” which is not consistent with research results from a member of the Health Canada panel (Levy) who demonstrates only a 0.9% reduction in cavities. See American Association for Dental Research (AADR) 35th Annual Meeting in Orlando, FL, March 8-11, 2006: Abstract # 0153 - Dental caries and fluorosis in relation to water fluoride levels, I Hong, SM Levy, J Warren, B Broffitt.

“Conclusions: Fluorosis prevalence increased significantly with higher water fluoride levels; however, caries prevalence did not decline significantly.”

Dr. Peter Cooney, in Thunder Bay on July 20, 2009, claims a 10-12% prevalence of dental fluorosis, which is not consistent with the research findings of a member of the Health Canada panel (Levy, J Public Health Dent 2006;66(2):92-6) who demonstrates a 70.9% prevalence of dental fluorosis in artificially fluoridated cities in the USA, at 0.7-1.2 Fmg/L, the Ontario Ministry of Health & Longer Term Care 1999 Review which demonstrates 25-70% incidence of dental fluorosis in artificially fluoridated cities, or the York Review 2000, which demonstrates a 48% incidence of dental fluorosis.

Omissions of Material Fact

The fundamental reasons why health effects other than dental fluorosis are not found frequently in North American research are as follows:

- No medical school in North America teaches doctors how to diagnose or treat fluorosis disease of the skeletal and soft tissues. For this reason an [Internship in fluorosis for teaching faculty of medical and dental schools of developed countries, January 18–22, 2010, Delhi, India](#) is now offered.
- No commercial laboratory in Canada does the essential tests to assess fluoride concentrations in blood, saliva or other body tissues.
- Researchers who have published results indicating health concerns have lost their funding and their jobs for doing so ([Dr. Mullenix](#)).
- Scientists working with government agencies have been fired for raising concerns on this issue ([Dr. Marcus, US EPA toxicologist](#)).
- Too many reviews that favour fluoridation -- including the Health Canada review -- ignore evidence that is contrary to their position and conclusions, without justification.

Children in Need of Treatment (C.I.N.O.T.) cost per capita in nonfluoridated Thunder Bay was \$1.60 in 1991. CINOT cost per capita in fluoridated Toronto was \$7.06. (Hettenhausen Extraordinary Dental Health in Thunder Bay. Dental Bites)

[Recent research](#) demonstrates that in the nonfluoridated city of Portland, Oregon, citizens spend less (\$176 per person per year) on dental care than in fluoridated Vancouver, Washington (\$180 per person per year).

A recent report from [Oshawa](#) demonstrates that cavity rates are very high, especially in the lower socio-economic neighbourhoods of this fluoridated city. If artificial water fluoridation helps in the prevention of cavities, especially for the socially disadvantaged, as claimed, high rates of oral health problems would not be expected to be selectively high in these neighbourhoods.

Any claims that artificial water fluoridation helps to prevent cavities, especially for those in lower socio-economic brackets, is not convincing in the face of such evidence. Any claims that artificial water fluoridation is cost effective is also not convincing. A review which ignores evidence which does not agree with the conclusions without justification, is not convincing.

Omissions of Available Published Research (see addendum)

As such, this draft document on Fluoride does NOT accurately present the “*weight of evidence from all currently available studies*,” as claimed. Conclusions based on such selective use of the available research literature are highly suspect. Justification for the exclusion of this broad range of research literature is not provided. Conclusions based on the safety of fluoridation chemicals, when virtually no research exists on the actual chemicals used, can only be described as speculative.

- 1. Actual chemicals (fluorosilicates) put into drinking water** are not reviewed.
- 2. Substitution of sodium fluoride for man-made fluorosilicates, without public knowledge or consent** is not reviewed. This is known in legal circles as “bait and switch”.
- 3. Extensive human research discussed in the NRC 2006 Review ([Chapter 8](#)), on endocrine function** (e.g., thyroid, pineal) is not reviewed.
- 4. Environmental impacts** are not reviewed. Hydrofluorosilicic acid (silicofluorides) are a Hazardous Waste and all inorganic fluorides are toxic substances.
- 5. Health Canada, after 60 years of endorsing this policy, has not regulated the [fluoride drugs](#) used in artificial water fluoridation**, nor have they undertaken any monitoring of the use of these unregulated drugs to determine its side effects.
- 6. The medical principle of obtaining and maintaining informed consent in the administration of drugs** is not reviewed (e.g. [Health Care Consent Act 1996, Ontario](#)).
- 7. The appropriateness of using drinking water as a vehicle for delivery of an unregulated drug** in uncontrolled and unmonitored dosages without due regard for age, race, social-economic status. or health-dependant differences in peoples' abilities to cope with

or avoid toxic effects of excess exposure."

8. Health Canada warnings to not swallow fluoride because it is not a nutrient are not reviewed. "[Health Canada](#) does not consider fluoride as an essential nutrient." Answer #22; & "[Health Canada](#) does not recommend the use of fluoride supplements (drops or tablets)."

9. The [research papers](#) which were decisive for the cessation of fluoridation in many European countries were not reviewed.

10. Reviews which disagree with their conclusions are not reviewed.

11. Discontinuation of artificial water fluoridation research is not reviewed.

12. No Margin of Safety for Fluoridation Chemicals. "-the RfD for fluoride contains no uncertainty factor or modifying factor, although RfDs for other substances contain uncertainty factors to account for things such as variability within the human population." p 84, NRC 2006

Concluding Remarks

Health Canada has chosen a panel which does not have the necessary expertise to evaluate the efficacy and safety of artificial water fluoridation. Four (4) dentists were chosen to evaluate the health effects of ingesting an unregulated drug which is clearly beyond their expertise and in violation of the CDA code of ethics. The remaining 2 panel members have no published papers on fluoride, demonstrating a lack of expertise in this field of research. How was the "expert" panel chosen? By what criteria?

Health Canada has permitted the use of information that is "false, misleading or deceptive by the inclusion or omission of any information" in this latest review document. If the Ministry of Health chooses to allow this false and misleading information to exist and persist, it could be viewed as a deliberate effort on the part of Health Canada to misinform the taxpayers of Canada.

If the federal and provincial governments wishes to play a constructive role in dental health care rather than continue to support a controversial policy which has not proven to be effective, they should establish a national dental hygiene & health insurance program to fill in the gap of current coverage from private sector plans. This would especially be ethical and efficient for ~20% of Canadians who do not have access to adequate dental health care.

Delaying the development or diagnosis of cavities is not the goal.

Preventing cavities should be the goal.

Preventing fluorosis diseases of teeth, bones and soft tissues should be the goal.