### Peeling Off the Layers of Deception

### **Executive Summary**

- NSF Certification & US Centers for Disease Control do not evaluate safety of fluoridation chemicals and have no regulatory responsibility to do so. To cite NSF certification or US CDC as authoritiies on safety of these chemicals is incorrect, therefore misleading.
- NSF International does not follow their own Standard 60 requirements. Therefore NSF certification according to these Standard 60 requirements is not a valid method for determining the safety of these products.
- 3. NSF Standard 60 does not follow Best/Good Manufacturing Practices, therefore their products do not safisfy the pharmaceutical requirements for a drug or natural health product.
- 4. NSF misrepresents artificial water fluoridation products as chemicals which treat water. Artificial water fluoridation products treat humans, not water.
- 5. Government guidelines for the natural contaminant called "fluoride" (MAC Canada , MCL USA) are incorrectly described as "safety" guidelines for all citizens.
- 6. Fluorides are acknowledged by all government agencies to be drinking water contaminants because they are toxic, persistent, bioaccumulative and man-made substances. The current exemption of fluoridation chemicals under existing Safe Drinking Water legislation is not justified. The premise that fluoride is beneficial is based on invalid science. The assumption that fluoride is not a "drinking water health hazard" is not valid, based on the available scientific research and the precautionary principle.

## 1. National Sanitation Foundation (NSF) & US Centers for Disease Control (US CDC) do not determine safety or efficacy of fluoridation products

The NSF is a private consortium funded by the product manufacturers to promote their products and is not a government agency accountable to the voters. The NSF agrees that the intent for adding fluoride to water is to prevent tooth decay in humans.

NSF claims that their standards are NOT designed to ensure safety or efficacy of the fluoride products used to manufacture fluoride water.

http://www.newmediaexplorer.org/chris/Clinch\_2009\_Who\_Regulates\_Water\_Fluoridation\_Ch emicals2.pdf

1. "The NSF International does not evaluate safety of the chemicals added to water for the purpose of the treatment or mitigation of disease in humans, and does not evaluate the product added to water but only the impurities within the product." Source: letter to

Dr. Bill Osmunson, DDS, MPH, dated 2/1/2007.

2. "NSF, in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this Standard by anyone. NSF shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this Standard." Source: National Sanitation Foundation International (NSF). 2000. Letter from Stan Hazan, General Manager, NSF Drinking Water Additives Certification Program, to Ken Calvert, Chairman, Subcommittee on Energy and the Environment, Committee on Science, US House of Representatives. July 7. Letter online at <a href="http://www.keepers-of-the-well.org/gov\_resp\_pdfs/NSF\_response.pdf">http://www.keepers-of-the-well.org/gov\_resp\_pdfs/NSF\_response.pdf</a>

However, the NSF does not refer to the regulatory body responsible for regulating drugs or natural health products (US Food and Drug Administration) but to the US Centers for Disease Control (US CDC) for drug guidance. Unfortunately, the US CDC also has no authority or regulatory responsibility regarding safety and efficacy of drugs as stated on their website: <u>http://www.cdc.gov/fluoridation/safety.htm</u>

"- it is not CDC's responsibility to determine what levels of fluoride in water are safe -"

Nor does the CDC determine the safe dosage of fluoride. Dosage is defined as the amount of fluoride consumed in a day based on body weight. Therefore, it is inappropriate to cite the US CDC for "safety" evidence.

The Fluoridation Act also does not refer to the fact that Health Canada now classifies fluorides as unregulated drugs and/or unregulated natural health products. This omission of material fact makes this legislation obsolete.

**Summary**: In Canada, Health Canada is responsible for the regulation of drugs and natural health products under the Natural Health Product regulations 2004 of the Food and Drug Act 1985. In the USA, the Food and Drug Agency is responsible for the regulation of drugs. Any reference to the NSF or the US CDC as a source for determining safety of these unregulated and unapproved drugs or natural health products is inappropriate, incorrect and misleading.

### 2. National Sanitation Foundation does not follow their own Standard 60 requirements

NSF has no duty to permit the public to evaluate the evidence of their testing to ensure accuracy or even whether the testing was actually done. On July 7, 2007, a <u>letter was written</u> by Stan Hazan to Representative Ken Calvert indicating that no data are provided on individual tests that NSF has conducted. Hazan stated that: <u>http://www.keepers-of-the-well.org/gov\_resp\_pdfs/NSF\_response.pdf.</u>

"Individual test reports, as well as formulation information, are protected by

nondisclosure agreements with the certification clients." P. 6

According to the <u>NSF Fact Sheet</u> from the NSF web site: <u>http://www.nsf.org/business/water\_distribution/pdf/NSF\_Fact\_Sheet.pdf</u>

NSF Standard 60 "requires full disclosure of each chemical ingredient in a product. It also requires a toxicology review. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects."

In <u>deposition</u> before the House Subcommittee on Energy and the Environment, Hazan testified under oath that suppliers of fluorosilicic acid must supply toxicological information about contaminants, but then stated that NSF is not requiring so-called "certified" companies to comply with this Standard 60, section 3.2.1 requirement: <u>http://www.yes4cleanwater.org/Documents/HazanDeposition010304.pdf</u>

"I would say that the HFSA submissions have not come with the tox[icological] studies referenced." p. 50, lines14 and 15.

Furthermore, NSF tests only for regulated metals (p10) and not for biological agents, pesticides, etc. In an email from Lynn Kirby, Water Quality Engineer for Seattle, to Dr. Kailin August 13, 2008, Kirby provided data from a December 2006 Tolt Treatment Facility analysis. This analysis, besides being outdated, is deficient in that it included no analysis of organic contaminants added to or formed by the fluoride extraction process. Among others, these include dioxins, pesticides, oil defoamers, polymers, naphthalene, and Synspar. http://www.yes4cleanwater.org/secret/SeattleFSAanalysis/SeattleToltTreatmentAnal120506.p df

In the same deposition before the House Subcommittee cited above, Stan Hazan makes the following astonishing admission:

" NSF failed to follow its own Standard 60 procedures".

"Compositional analyses are not required by the NSF standard."

A letter from Mayor of Selmer, Tennessee, Mr. David Robinson to Mr. Ross White on March 26, 2010 states:

"We sent the attached RFB to 34 certified suppliers on the NSF website on Feb. 24, 2010. To date we have received three responses stating their inability to bid and no response from the remaining 31 (which included our previous supplier). I offer this information as further evidence of the acknowledgment by NSF that they do not adhere to the ANSI/NSF 60 standards required by Tennessee State law."

In a recent news article, "Chinese Fluoride In Mass. Water Raises Concern" a New York Company supplying fluoridation chemicals claims that their product is NSF certified, but NSF disagrees: <u>http://www.thebostonchannel.com/news/22814488/detail.html</u>

"The New York company that supplies the fluoride said it is certified by the National Sanitation Foundation which assures the quality of the product. But the NSF said the company has never been on its certification list."

Because of the above evidence, it would seem that NSF Standard 60 is NOT being applied by NSF to the companies that they "certify". Test reports are not accessible by the public to confirm accuracy because they are protected "by nondisclosure agreements". The validity of certificates of analysis with the NSF certification are questionable when the "compositional analyses are not required." When no records are kept "except for positive results" and when no individual reports are available, the certification process by NSF, a self-regulated private consortium, has questionable value to assure public safety.

NSF Standard 60 permits contaminants in products to provide no greater amount of a contaminant in water than 10% (Single Product Allowable Contaminant or SPAC) of the Health Canada Maximum Contaminant Level (MAC). The MAC for fluoride is 1.5 ppm and 10% of 1.5 is 0.15 ppm. Please note that the fluoride added to drinking water in Canada is 0.7 ppm, which is 5 times the SPAC of 0.15 ppm which is a 400% increase over the SPAC. This apparently violates the Standard 60 requirements for contaminants. Why is this ignored?

When the NSF was asked by Dr. Bill Osmunson, DDS, MPH, as to why the contaminant called fluoride met the Standard 60 requirements when it was significantly higher than the contaminant levels permitted by NSF Standard 60 under their own 10% rule, the response was that NSF tests the contaminants they wish to define as contaminants, but omit the actual product, which is also a contaminant, for inclusion under their own requirements.

Although fluoride is defined by Health Canada as both a "contaminant" (see definitions of Health Canada Maximum Contaminant Level guidelines below (MAC and MCGL)) and as a natural health product or drug, fluoridation products do not seem to be in compliance with the NSF Standard 60 SPAC (10% of MAC) requirements for "contaminants".

**Summary:** This evidence demonstrates that; a) NSF is not following their own standard; b) "NSF certified" companies are not in compliance with NSF Standard 60. This suggests that the voluntary use of NSF certification by provincial and state government agencies does not provide the protections for safety that the public assumes and deserves.

### 3. NSF Standard 60 does not follow Good/Best Manufacturing Practices required for regulated pharmaceutical products

No site license is available from any importer/manufacturer, processer, distributor, and seller of fluoridation products to demonstrate that they are in compliance with <u>Good Manufacturing</u> <u>Practices.</u> In <u>deposition</u>, Mr. Hazan, General Manager, Drinking Water Additives Certification

Program, NSF, before the House Subcommittee on Energy and the Environment stated that **batch testing is not a requirement of NSF Standard 60.** Manufacturers are only required to have testing once a year on their manufactured product:

http://www.yes4cleanwater.org/Documents/HazanDeposition010304.pdf

"Contaminant testing is performed initially upon application, and at least annually thereafter."

This is confirmed by Cargill (now MOSAIC), the largest producer in North America, and Lucier, the largest distributor of Cargill's products in North America, who state that only one annual sample of artificial water fluoridation products is required for analysis from their mining operations to satisfy NSF standard 60.

http://www.keepers-of-the-well.org/product\_pdfs/Committee\_Personnel.pdf

Because there is no batch testing, the Certificate of Analyses for hydrofluorosilicic acid does not necessarily reflect the ACTUAL content of the fluoride product delivered to any municipality.

"NSF test results are not routinely compared to Certificate of Analyses results."

**Summary:** The "once yearly" Standard 60 testing clearly does not provide batch testing as required by Good/Best Manufacturing Practices, to ensure consistency of batches. This is a requirement for REGULATED, APPROVED drugs/natural health products (Canadian legislation). The actual content of so-called "certified" products may not be accurately represented in the Certificate of Analysis.

### 4. NSF misrepresentation of fluoride as a mere "water additive"

The NSF claims on their web page:

"This fact sheet provides information on the fluoride containing **water treatment additives** (emphasis added) that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects."

This statement mislabels fluoridation products as "water treatment additives". Chlorine products are "water treatment additives" because they are added to drinking water to "treat" the water to kill microorganisms in the water that are harmful to human health. On the other hand, fluoridation products are drugs or natural health products used to "treat" human dental disease.

**Summary:** Standard 60 is not relevant to any discussion regarding the safety of a drug or a natural health product (e.g., fluoridation products or fluoride water).

### 5. Government Regulatory Guidelines and the Safe Drinking Water Act do not support the addition of these drinking water contaminants

Confusion also exists regarding the regulatory guidelines of this drinking water contaminant used by various government agencies. Please refer to: <u>http://www.agswater.com/mclg.html</u>

"Fluoride is one of the natural contaminants found in public drinking water supplies" National Research Council Review 2006 "fluoride in Drinking Water", p 13

### The Safe Level (MCLG or Maximum Contaminant Level Goal)

The Safe Level (MCLG) maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, over a lifetime, and which allows an adequate margin of safety for all susceptible populations (infants, children, the elderly, those with other health problems). In the USA the MCLG for arsenic and lead is ZERO because there is NO KNOWN SAFE LEVEL.

### The "Regulated" Level (MAC or Maximium Acceptable Contaminant)

The maximum level which may be DETECTED with the crude technology and treatment techniques currently available to most municipalities but DOES NOT PROTECT all citizens.

### The "Detection" Level of Contaminants

The level of a contaminant which a municipality is able to detect is limited. Health Canada explains these limits in available treatment technology

http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/committee-31-comite/chemical-chimiqueseng.php

However, the levels of these contaminants added to drinking water from the fluoride products CAN BE MEASURED BEFORE DILUTION into our drinking water to find out how much we are adding. Any organization which claims that these contaminants cannot be measured are not providing the whole truth.

Almost all of the arsenic added to drinking water (90 percent) from the production of fluoride water is from fluoridation chemicals (hydrofluorosilicic acid).

Wang C, Smith DB, Huntly GM. Treatment Chemicals contribute to Arsenic Levels. Opflow (AWWA), October 2000.

http://www.newmediaexplorer.org/chris/Clinch\_2008\_Arsenic\_in\_Fluoridation\_Chemicals1.pdf

The Ontario Safe Drinking Water Act 2002 does not permit the addition of "drinking water health hazards", and "dilution no defence". (SDWA 2002, section 2, 20(1,3))

1997 Binational Toxics Strategy <u>http://www.ijc.org/php/publications/html/bts/btse.html#lot</u> "...will work in cooperation with their public and private partners toward the goal of virtual elimination of persistent toxic substances resulting from human activity, particularly those which bioaccumulate, from the Great Lakes Basin." (emphasis added)

http://www.newmediaexplorer.org/chris/Clinch\_2009\_Time\_Line.pdf

The US Safe Drinking Water Act 1974 requires that contaminants be controlled to prevent no adverse health effects.

"In 1974, Congress passed the Safe Drinking Water Act. This law requires EPA to determine the level of contaminants in drinking water at which **no adverse health effects are likely to occur**." (emphasis added) <u>http://www.epa.gov/ogwdw000/contaminants/basicinformation/fluoride.html#one</u>

**Ecological Fallacy:** To state that a single factor such as water fluoridation is the "cause" of any differences in cavity rates (effects) between individuals or groups, without assessing the many factors determining oral health is an ecological fallacy which makes such claims invalid.

# CAUSE EFFECT

"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 Oral Health Atlas p 48.

### Great Marketing – Invalid Science

"Fluoridation is one of the 10 most important public health achievements of the 20th century" US Centers for Disease Control (US CDC)

This Ecological Fallacy from the US CDC was based on the percentage of population residing in areas with fluoridated community water systems and mean number of decayed, missing, or filled permanent teeth (DMFT) among children aged 12 years – United States, 1967-1992.

The "many factors deterimining oral health" were NOT included in this US CDC analysis.

**Summary:** The Ontario Safe Drinking Water Act 2002 prohibits the voluntary addition of "drinking water health hazards" and the dilution of such chemicals is not permitted. The US Safe Drinking Water Act requires that contaminants be controlled to prevent no adverse health effects. Fluorides are acknowledged by all government agencies to be drinking water contaminants because they are toxic substances. The curious exemption of fluoridation chemicals under existing Safe Drinking Water legislation is not justified. The premise that fluoride is beneficial, therefore not a contaminant, is based on invalid science. The assumption that fluoride is not a "drinking water health hazard" is not valid, based on the available scientific research and the precautionary principle.

The presentation of the US Maximum Contaminant Level (MCL) of 4 ppm as a level of

"safety" for concerned citizens is incorrect, therefore misleading. The Canadian Maximum Acceptable Contaminant level (MAC) has also been described as a guideline for health safety by many individuals and organizations. This is both false and misleading.

Intentionally adding contaminants to drinking water seems to be in violation of Safe Drinking Water Legislation in both the USA and Canada.