



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

June 23, 1999

OFFICE OF
WATER

The Honorable Ken Calvert
Chairman
Subcommittee on Energy and The Environment
Committee on Science
House of Representatives
Washington, DC 20515-6310

Dear Mr. Chairman:

Thank you for your May 10, 1999, letter to Carol M. Browner, Administrator of the United States Environmental Protection Agency (EPA) regarding fluoride and fluoridation. Fluoride in drinking water is a subject about which EPA continues to receive a steady series of questions from a number of concerned stakeholders. We have responded to each of your questions in the enclosure to this letter.

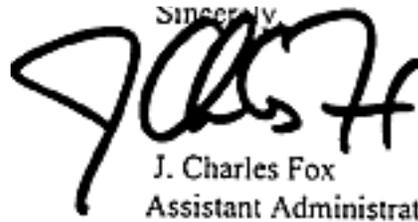
Fluoride in drinking water is regulated by EPA under Section 1412 of the Safe Drinking Water Act (SDWA). On April 2, 1986, EPA set a revised MCL at 4 mg/L to protect against crippling, skeletal fluorosis, an adverse health effect. In August 1993, the National Research Council (NRC) completed a review of fluoride toxicity and exposure for EPA. The findings of the NRC were published as, "Health Effects of Ingested Fluoride", National Research Council, National Academy Press, Washington, D.C. 1993. The NRC concluded that the current 4 mg/L standard is "appropriate as an interim standard" to protect the public health. In addition, EPA set a nonenforceable Secondary Maximum Contaminant Level of 2 mg/L to protect against objectionable dental fluorosis (tooth discoloration).

The SDWA prohibits EPA from requiring the addition of any substance (including fluoride) to drinking water for preventative health care purposes unrelated to contamination [Section 1412 (b)(1)]. As a consequence, State or local authorities determine whether or not to fluoridate their water supply. Depending on local conditions, fluoridation in this country is practiced at a level of about 1 mg/L, which is well below the current 4 mg/L SDWA Federal standard.

The Centers for Disease Control (CDC) is the principal Federal agency involved in research on fluoridation in this country. Some of the questions you have asked pertain to fluoridation rather than the EPA MCL/MCLG. For more detailed answers to those questions you may wish to contact:

Dr. Gene Sterritt
Oral Health Program
Program Services Branch
NCCDHP/CDC
Mail Stop F10
Davidson Building
2858 Woodcock Boulevard
Chamblee, Georgia 30341

Thank you for your thoughts and concerns. If you have any additional questions, please feel free to contact me or have your staff call Dr. Joyce Donohue, Toxicologist in the Office of Water, at (202) 260-1318.

Sincerely,

J. Charles Fox
Assistant Administrator

Enclosures

ENCLOSURE

Question 1

I understand that EPA does not endorse water fluoridation. Has the agency taken any steps to have EPA removed from the list of endorsers of water fluoridation published by the American Dental Association? If you have, have they complied?

Response

EPA lacks the authority to require the addition of any material to drinking water for preventive health care purposes unrelated to contamination [SDWA Section 1412 (b)(1)]. For this reason, in 1997 when we became aware that we were listed on their web page, EPA requested that the American Dental Association remove EPA from the list of organizations endorsing the fluoridation program. A copy of the letter to the American Dental Association is enclosed. The American Dental Association worked with EPA to insure that the reference to EPA on their web page accurately reflects our position relative to fluoridation.

Question 2

What chronic toxicity test data are there on sodium fluorosilicate?
On hydrofluorosilicic acid?

Response

Sodium fluorosilicate and hydrofluorosilicic acid are two of the chemicals used in the fluoridation of water supplies. In 1998, the Office of Water (OW) at EPA initiated the development of a fact sheet to provide information on both of these chemicals for interested citizens. A draft of that fact sheet has been completed and is presently under review before being finalized. In collecting the data for the fact sheet, EPA was not able to identify chronic studies for these chemicals. However, data from Crosby (1969) [copy included] indicate that both chemicals dissociate almost completely at the concentrations added to potable water forming hydrogen or sodium ions, fluoride ions, silicon dioxide and water. Thus, the data from chronic studies of sodium fluoride carcinogenicity by the National Toxicology Program (NTP, 1990) and Proctor and Gamble (Mauer et al., 1990) are applicable to sodium fluorosilicate and hydrofluorosilicic acid.

EPA does not regulate drinking water treatment chemicals. When a member of the public contacts EPA regarding fluoridation chemicals, EPA refers that person to the agencies that certify drinking water treatment chemicals, NSF International and Underwriter's Laboratories, for additional information. A copy of the enclosed Regulatory Fact Sheet is sent to the citizen with our response. When the enclosed draft fluorosilicate fact sheet is finalized it will also be sent to those making inquiries.

Question 3

What steps have you taken to address questions related to the EPA's Maximum Contaminant Level Goal (MCL[G]) for fluoride in drinking water? If you have not taken steps to address these questions, why not? If not, when will you take such steps? When do estimate that the work involved in addressing these questions will be complete?

Response

As required by the SDWA [Section 1412 (b) (B) (9)], EPA is in the process of reviewing all established MCL/MCLG values to determine which chemicals require reevaluation due to recent developments in our knowledge of their health effects. The chemicals that presently have MCL/MCLG values will be screened to select those needing reevaluation. Fluoride will be considered in the review process. EPA has started the review of new data on the regulated chemicals and intends to solicit stakeholder input regarding the review process at a meeting tentatively scheduled for sometime in the fall of 1999.

In August 1993, the National Research Council (NRC) completed a review of fluoride toxicity and exposure for EPA. The findings of the NRC were published as, "Health Effects of Ingested Fluoride", National Research Council, National Academy Press, Washington, D.C. 1993. The NRC concluded that the current 4 mg/L standard is "appropriate as an interim standard" to protect the public health.

Question 4

Do you interpret Section 101 (b) (4) of the Safe Drinking Water Act of 1996 as requiring EPA to set its MCL(G) at a level that protects all person's including sensitive populations, such as infants, children, people who drink 4 or more liters of water per day, people with allergies or hypersensitivity to fluoride and people with renal disease?

Response

The published Safe Drinking Water Act of 1996 does not have a Section 101 (b) (4). Section 1412 (b) (4) (a) states that "Each maximum contaminant goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the heath effects of person's occur and which allows an adequate margin of safety."

As required by the SDWA [Section 1458 (a) (1)], EPA is working on collecting information to identify groups within the general population with increased sensitivity to contaminants such as infants, children, the elderly, persons with allergies or hypersensitivity to chemicals. When the MCL/MCLG for fluoride is selected for review, data on sensitive populations will be collected and EPA will publish and seek public comment on its findings as required by the SDWA Section 1412 (b) (3) (C) (i) (V).

Question 5

Is the Agency satisfied with fluoride doses delivered to the public via drinking water under an MCL(G) of 4 milligrams /liter (mg/L) when added to the fluoride intake from dental products, pesticide residues, food and beverages will not cause an adverse health effect?

Response

EPA realizes that the use of fluoride in dental products has increased since fluoride was regulated in 1986. In 1998, we commissioned an evaluation of the exposure data for fluoride including data on amounts in foods and dental products. We found that the data published in the peer reviewed literature were limited but did not differ substantially from the data available when fluoride was regulated. A copy of the draft exposure report is included for your records. When fluoride is selected for reevaluation of its MCL/MCLG, the agency will again examine at relative sources of exposure.

Question 6

What is the margin of safety for infants who consume drinking water containing 4 mg/L fluoride?

Response

The agency does not recommend that infants consume water containing 4 mg/L fluoride. The Agency requires that all families who receive water from a system with greater than 2 mg/L fluoride receive a public notification recommending that alternate sources of water be used for infants and children in that family [40CFR 143.5]. A copy of the public notification statement is enclosed for your records. The Agency believes that the 2 mg/L SMCL protects children against dental fluorosis as well as adverse health effects. The Agency acknowledges that the MCL of 4 mg/L does not protect infants and children against dental fluorosis, a cosmetic effect rather than an adverse health effect.

Question 7

What is the margin of safety for person's receiving kidney dialysis treatment, diabetes, or those who have a hypersensitivity or allergy to fluoride who consume drinking water containing 4 mg/L fluoride?

Response

Agency regulations for potable water do not apply to water used in dialysis. We suggest that you contact the American Association for Medical Instruments (AAMI) for the standards that apply to dialysis waters. The address for a contact at AAMI is as follows.

Dr. Ronald H Abrahams
American Association of Medical Instruments
Renal Disease and Detoxification Committee
Suite 3330 Washington Boulevard
Arlington, VA 22201-4598
703 (525-4890)

The 1993 NRC report on the health effects of ingested fluoride addressed the concern for fluoride retention in persons with impaired renal function, a group which includes individuals with diabetes. They concluded that additional research was needed to adequately assess the risk. EPA is not aware of new data on the health effects of fluoride in persons with impaired renal clearance. Neither the NRC (1993) report nor the ATSDR (1993) Toxicological Profile on fluoride provide data that identify any individuals with a fluoride-specific hypersensitivity or allergy.

Question 8

Does the incidence of dental fluorosis among at least 22% of American children indicate that, at least among these children, an overdosing is occurring?

Response

The National Survey of Dental Caries in US school children (1986-1987) reported a prevalence of dental fluorosis of 22.3%. Nearly all of the cases were mild to very mild. These data reflect exposures that occurred before the EPA MCL/MCLG was implemented. Data from a comparable study would have to be available for a time period before and after this survey in order to determine if the prevalence of dental fluorosis in the population is actually changing.

The National Survey of Dental Caries data were considered by the NAS in their 1993 review of fluoride. They concluded that the most "effective approach to stabilizing the prevalence and severity of dental fluorosis without jeopardizing the benefits to human health, is likely to come from the more judicious control of fluoride in foods, processed beverages, and dental products, rather than a reduction in the recommendation for fluoride in drinking water." NAS encouraged the EPA to reevaluate the MCL/MCLG as more data on the factors contributing the severity of fluorosis became available.

Question 9

What steps has the agency taken to address the hazards identified with fluoride in the following publications that appeared since EPA reaffirmed its drinking water standard for fluoride? (Seven references are cited.)

Response

OW has reviewed each of the seven references listed and participated in discussions with the EPA Office of Research and Development (ORD) regarding the strengths and weaknesses of each study. (See the enclosed memorandum from William Marcus dated 5/22/98 and the 6/3/98 response from Hugh Tilson of ORD.) The data presented in these publications will be utilized in the review of the MCL values for presently regulated compounds discussed in the response to Question 3 above.