

Dr. Terry Yosie
Director
Science Advisory Board (A-101)
U.S. Environmental Protection
Agency
Washington, D.C. 20460

APR 20 1987

Dear Dr. Yosie,

EPA is now circulating for review a proposed response to the first citizen's petition under Title III of the new Superfund Act. The scientific basis for this response is a document that was used to support the drinking water standard for fluoride published in November of 1985. In our opinion, the proposed response contains errors that invalidate the conclusions and raise serious generic questions about the methodology for determining safe levels of contaminants in drinking water. To demonstrate the basis for our concerns, we have attached an analysis of one aspect of the response to the citizens petition - the exposure assessment. In summary:

- The assessment assumes that 2 liters/day defines the maximum tap water intake by people in the U.S. This grossly underestimates possible consumption by a factor of three.
- The assessment assumes that no more than 0.8 mg/day of fluoride can be obtained from sources other than drinking water. This is shown to underestimate other possible sources by at least a factor of five.

We are also claiming that use of the drinking water document is inappropriate for use as a regulatory support document because the disclaimer inside the front cover states:


"This document is a preliminary draft. It has not been released formally by the Office of Drinking Water, U.S. Environmental Protection Agency, and should not at this stage be construed to represent Agency policy. It is being circulated for comments on its technical content." (emphasis added).

To our knowledge, it is not being circulated for comments, nor has it been reviewed by experts in the appropriate scientific disciplines.

As civil servants who believe we are charged with protecting public health and the environment, we are concerned that EPA may publish unvalidated and inaccurate information about a major public health issue. We are also concerned that publication by EPA of a preliminary scientific document of poor quality will harm the reputations of the entire community of EPA professionals here at Headquarters, whom we represent.

Since the SAB is now responsible for reviewing scientific documents produced by the Office of Drinking Water, we ask that the Science Advisory Board (SAB) review the scientific support documents for this proposed action and the implications for drinking water standards in general. We would appreciate the opportunity to present our concerns in person to the appropriate committee of the Science Advisory Board.

Sincerely,


Robert J. Carlton, Ph.D.
President
NFFE Local 2050

cc. Hon. Lee Thomas

ATTACHMENT

Analysis of the Maximum Exposure to Fluoride Expected to Occur from Tap Water and Diet. (USEPA 1987).

° The assessment assumes that 2 liters/day defines the maximum tap water intake by people in the U.S. This grossly underestimates possible consumption by a factor of three.¹

The basis for our concern that EPA used the wrong water consumption figures in determining the maximum amount of fluoride that can occur at the MCL of 4 mg/l is an analysis done by a researcher at the National Cancer Institute for EPA in October of last year. (Cantor 1986). This analysis used raw data from a study by the U.S. Dept. of Agriculture, which was the result of a survey of over 30,000 people over a period of 1 year. It provides the most reliable figures to date for water consumption in the U.S. This report raises questions about all the currently existing primary drinking water standards - not just fluoride.

The response to the citizen's petition states categorically that the Lowest Observable Adverse Effect Level (LOAEL) for crippling skeletal fluorosis is 20 mg/day for a 20-year exposure period.² It states that the maximum drinking water exposure is 8 mg/day based on a 2 liter per day consumption at the Maximum Contaminant Level (MCL) of 4 mg/l (which is also the Recommended Maximum Contaminant Level or RMCL). The primary reference used to support the response to the petition also uses the 2 liter per day figure in calculating the maximum intake of fluoride from drinking water. (USEPA 1985).

The use of an average figure of drinking water consumption in calculating the maximum possible exposure to fluoride is obviously wrong. The new study of water consumption mentioned above shows that about 50% of the U.S. population ingests more than 2 liters of tap water daily. In fact, this study shows that 1% of the males in the U.S. between the ages of 40 and 59 take in more than 6 liters per day for the average weight male of that age group. Using 6 liters/day as a reasonable figure for some portion of the U.S. population, we find that a toxic amount of fluoride - 24 mg/day - can be obtained from drinking water alone at the current MCL and RMCL for fluoride of 4 mg/l.

1. Our analysis is based on the assumption that over 90% of the water consumed by individuals in the U.S. comes from tap water.

2. Crippling skeletal fluorosis is the only chronic adverse health effect of fluoride acknowledged by EPA and is the effect upon which the drinking water standard is based.

° The assessment assumes that less than 1 mg/day of fluoride can be obtained from sources other than drinking water. This is shown to underestimate other possible sources by at least a factor of five.

EPA also uses "typical" figures for dietary exposure of 0.2-0.8 mg/day and assumes there are no other significant sources of fluoride in the environment. Studies have shown that up to 5 mg/day of fluoride exposure can occur from ingestion of tooth paste. (National Research Council of Canada 1977). Tea drinking can add 2.7 mg/day as a result of the extraction of fluoride from the tea leaves themselves. (WHO 1984) Sardines, apparently because of the fluoride present in the bones, can add 0.8 mg/day. (Smith 1985). Thus, there is a potential from just these sources for some people to ingest 8.5 mg.

While this is not an exhaustive analysis of the exposure assessment, it shows that there are major errors, all underestimating exposure to fluoride to some portions of the U.S. population. The faulty exposure assessment methodology is used to determine safe levels of contaminants in drinking water.

References

1. USEPA, Draft Federal Register Notice, Emergency Planning and Community Right-To-Know Programs, Table 1. Adverse Health Effect Level vs. Exposure Levels from Various Sources of Fluorides. Office of Toxic Substances. 1987.
2. Cantor, K., Ph.D. National Cancer Institute, "AS22 - USDA Statistics Study", dated October 14, 1986. unpublished.
3. USEPA, Final Draft for the Drinking Water Criteria Document on Fluoride. Criteria and Standards Division, Office of Drinking Water. 1985.
4. National Research Council of Canada, Associate Committee on Scientific Criteria for Environmental Quality, Environmental Fluoride, 1977.
5. World Health Organization, Environmental Health Criteria 36, Fluorine and Fluorides. p 31, 1984.
6. Smith, G.E. "A surfeit of fluoride?" Sci. Prog. Oxf. 69, 429-442. 1985.