National Federation of Federal Employees

AUG 4 1989 Local 2050

Mr. William A. Whittington
Acting Deputy Assistant Administrator
Office of Water
U.S.E.P.A.
Washington, D.C. 20460

Dear Mr. Whittington,

As promised at our July meeting, NFFE Local 2050 is hereby submitting its "Recommendations for the Assessment of Risks from Fluoride Exposure." We have attempted to describe basic principles rather than to supply details on fluoride issues. We believe that, if the principles are followed, the reassessment of the scientific basis for the fluoride standards will be of high quality and a document of which we can all be proud.

We believe that the law is quite specific in giving direction to the risk assessment and we have noted these in recommendations #1 through #8. Please note the importance of our first recommendation which stresses the importance of utilizing health professionals and especially those with specialized training (genetics, epidemiology, toxicology, developmental toxicity, etc.) in determining health effects and the doses necessary to cause detrimental changes in the body.

Of equal importance are our recommendations on the use of outside experts (recommendation #9), on forming an independent panel of EPA professionals (recommendation #10), and on the ground rules for carrying out the assessment (recommendation #11). We have decided not to recommend a particular peer review system at this time.

We appreciate your interest in our views and look forward to continuing our dialogue.

Sincerely,

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

Recommendations for the Assessment of Risks from Fluoride Exposure.

I. REQUIREMENTS OF THE LAW AND THE IMPLICATIONS FOR RISK ASSESSMENT.

In developing the scientific bases for the Maximum Contaminant Level Goal (MCLG), the law gives guidance on assessing the risks posed by chemicals in drinking water. According to the Safe Drinking Water Act, MCLG's are to be set:

> "at a level at which...no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."(1)

As explained by NRDC, this means that the standard:

> "... must protect all members of the population, including especially sensitive subgroups, against all known and anticipated adverse health effects, allowing an adequate margin of safety. To accomplish this goal, Congress further directed EPA to err on the side of safety in evaluating health effects evidence."(2)

As further explained by NFFE,:

> "The language of the Act and its legislative history make clear that an RMCL" <now called MCLG> " must be a reflection of the opinion of health professionals ...".(3)

These requirements provide guidance in determining who is responsible for the risk assessment and how it should be designed.

RECOMMENDATION #1

> **Health professionals should make all determinations (with the benefit of peer review) of what are or may be adverse health effects from exposure to fluoride. They should have the necessary specialization to judge the health effects in question.**

It is clear that the Administrator relies upon the opinion of health professionals when promulgating a regulation. These professionals provide expert opinions from numerous specialties. This should be done under the scrutiny of a peer review system that validates these assessments.

RECOMMENDATION #2

> **Each health effect should be examined to determine if "there is some basis to believe it endangers public health. If there are uncertainties, they must be resolved on the side of protection of health."**

It is clear from the law and the legislative history that it is not necessary to prove conclusively that a health effect exists,

> "Rather, all that is required is that the Administrator make a reasoned and plausible judgement that a contaminant may have such an effect."(4)
>
> "We cannot afford to wait 20 years for health effects research to be completed to begin controlling contaminants which there is some basis to believe endanger public health. If there are uncertainties, they must be resolved on the side of protection of health."(5)

RECOMMENDATION #3

> **The assessment should only focus on proven or anticipated adverse health effects, not on benfits.**

Since the Safe Drinking Water Act (SDWA) is specifically designed to prevent harm to human health and EPA is specifically enjoined from recommending the addition of chemicals to water supplies, it would be inappropriate to assess any alleged benefits of fluoride exposure.(6) If beneficial effects were determined, the SDWA makes no allowances for weighing beneficial effects against adverse effects in determining a Maximum Contaminant Level Goal (MCLG). In addition, since fluoride is not removing a risk from water as chlorine does by eliminating pathogens, no relative risk determination need be made.

RECOMMENDATION #4

> **One of the purposes of the assessment should be to identify research that will attempt to answer the outstanding questions.**

Where evidence shows that more investigation is warranted before even a "may cause harm" decision can be reached, the assessment should identify the areas of research that are necessary to answer the outstanding questions. It should be a living document that acts as a basis for further study.

RECOMMENDATION #5

> **The assessment should identify the risks to sensitive individuals. These risks must be expressed in terms of the lowest level in mg/kg/day and/or mg/kg over a lifetime that may cause an effect in sensitive individuals.**

It is clear that susceptible individuals must be identified and protected by the standard, not just the "average" person. Thus, the assessment must determine such things as: the most sensitive age group, people with different dietary habits, and individuals with an existing health problem that puts them at particular risk. The latter would include such groups as people with impaired kidney function or those who are malnourished.

RECOMMENDATION #6

The assessment should determine the maximum (99th percentile) dose of fluoride in the population from sources other than water (food, beverages, air, toothpaste and drugs). This should be expressed as mg/kg/day and/or mg/kg over a lifetime of exposure.

It is clear from the legislative history that the exposure assessment must include all other sources of fluoride to which individuals may be exposed over a lifetime. Here again the "average" dose from drinking water and all other sources does not describe the full range of doses that are experienced by individuals in the population. The law requires that all people be protected. The assessment must determine the full distribution of doses from drinking water, beverages, food, air, tooth paste and drugs.

RECOMMENDATION #7

Each toxic effect should be assigned a level of certainty as should the doses from food, water, beverages, air, drugs, and toothpaste.

It is important that the assessment define the level of uncertainty with regards to each toxic effect and to the doses that are possible from water and other sources. The charge of the committee will be to determine the no effect level for each effect and the degree of certainty with which that determination is made.

RECOMMENDATION #8

The assessment should determine the possible role of other chemicals in raising or lowering the effect level.

It is clear that synergistic effects between fluoride and other chemicals in the environment must be considered in an assessment of the risks posed by fluoride. This could also include the effect of a deficiency of protective chemicals in the diet such as calcium and magnesium.

II. INVOLVE OUTSIDE EXPERTS IN IDENTIFYING ISSUES FOR LITERATURE SEARCH/ASSESSMENT

RECOMMENDATION #9

> Before the assessment is begun, efforts should be made to identify fluoride experts and have them assist in identifying issues and appropriate literature through written and oral presentations. Every attempt should be made to include working scientists and to have all scientific viewpoints represented.

EPA needs the advice of independent outside experts on the various facets of fluoride toxicity. There are numerous scientists in countries throughout the world who have conducted clinical and laboratory studies, and literature reviews on fluoride toxicity. These individuals should be brought in as consultants to provide both written and oral presentations to EPA. Oral presentations before the Fluoride Assessment Committee (described below) are essential to allow a full airing of opinions, facts and hypotheses and an opportunity for questioning by the committee.

III. CREATE INDEPENDENT SCIENTIFIC ASSESSMENT COMMITTEE

RECOMMENDATION #10

> An independent team of discipline experts and a technical manager should be formed to evaluate the testimony of outside experts, and conduct the risk assessment from literature review through peer review and public comment. Their final product should be forwarded to the Office of Drinking Water for use in updating regulations.

As noted in Recommendation #1, the assessment should be conducted by EPA scientists with expertise in the various specialties necessary to examine fluoride toxicity. These specialists should form a scientific committee - the Fluoride Assessment Committee (FAC) -charged with evaluating the submissions of outside experts and designing and carrying out the assessment. They should operate independently and have access to consultants to assist them in their evaluation. The actual assessment and judgments made on the data should be the sole responsibility of this committee. The chairman of the committee should be a professional with experience in conducting risk assessments on chemicals. The FAC should carry out the risk assessment, publish and forward the final product to the Office of Drinking Water.

IV. GROUND RULES FOR LITERATURE REVIEW/ASSESSMENT

RECOMMENDATION #11

> **The first order of business for the FAC should be to agree on ground rules for the literature review/assessment, including the mechanism for peer review.**

There needs to be an agreement on how the review/assessment should be conducted. Obviously all the literature since the last report should be gathered, as well as the literature identified by the outside experts that has relevance or could have relevance to the subject matter. This may include literature cited in the previous report if the outside experts believe that the citations erred in their interpretation or overlooked something of significance. If there is any question whether a report should be included, the decision should lean toward including rather than excluding data.

Valid peer reviewed scientific literature from foreign countries must be included especially literature from the Journal of the International Society of fluoride Research. Secondary reviews should be avoided. If a secondary review is desired, there must be no question as to the validity of that document. If the secondary literature is of questionable validity, it should be dropped and the primary literature examined instead. Abstracts should not be referenced.