UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA-SAB-EHC-89-006

October 6, 1988

OFFICE OF THE ADMINISTRATOR

Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Science Advisory Board's Review of the issues relating to the regulation of LEAD in drinking water.

Dear Mr. Thomas:

The Drinking Water Subcommittee of the Science Advisory Board's Environmental Health Committee has completed its review of the issues pertaining to lead. These issues relate to the proposed regulations from the Office of Drinking Water at its meeting in Cincinnati, Ohio, June 2-3, 1988. The Subcommittee was requested to review the procedure for determining what an adequate tap sample is for determining the drinking water concentration of lead. Although not part of the charge, the Subcommittee also commented on treatment technology.

The major recommendations of the Subcommittee include: basing compliance sampling upon random sampling at customer taps before requiring that the utility demonstrate optimal corrosion treatment; providing better justification for the definition of the worst case; providing better documentation of the relevance of the two-stage sampling plan; and allowing the utility to implement appropriate controls, when controls of some type are found to be needed.

We appreciate the opportunity to conduct this particular scientific review. We request that the Agency formally respond to the scientific advice provided herein.

Sincerely,

Norton Nelson
Chairman, Executive Committee

Richard A. Griesemer
Chairman
Environmental Health Committee

Gary P. Carlson
Chairman, Drinking Water Subcommittee

SUBJECT: SCIENCE ADVISORY BOARD'S REVIEW OF ISSUES RELATING TO THE REGULATION OF LEAD IN DRINKING WATER

SCIENCE ADVISORY BOARD COMMITTEE: DRINKING WATER SUBCOMMITTEE OF THE ENVIRONMENTAL HEALTH COMMITTEE

DATE OF REVIEW: JUNE 2-3, 1988

PLACE OF REVIEW: EPA LABORATORY, CINCINNATI, OHIO

The Subcommittee was requested to review the procedure for deteriming what an adequate tap sample is for determining drinking water concentrations of lead. Although not part of the charge, the Subcomittee also commented on treatment technology. In addition, the Subcommittee takes issue with the MCLG of zero as possibly being too conservative and with the low MCLs; e.g. 5 ug/L in some cases. These levels may or may not be realistic considering the existing information on health effects, especially that relating to the central nervous system. This review involved part of the proposed regulation; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper

General Comments

The MCLG for lead may be overly conservative. For example, the document does not present sufficient justification for concluding that there is no threshold for the inhibition of delta-aminolevulinic acid anhydrase especially since it gave four references, all with thresholds.

The document itself is persuasive in indicating what can be done in removing sources of lead contributing to that present in the water, such as the removal of lead pipe and lead connectors from distribution systems, the ban on lead solder, and the control of corrosivity. While these efforts are not simple, in many cases they are feasible and should result in a significant decrease in lead exposure via the drinking water.

Much of the documentation for indicating how systems might reach compliance and how stabilization of the water and other treatment technologies could be achieved are not targeted at the worst case. They are based on the old level of 50 ug/L and/or the possibility that the new level might be 20 ug/L, as opposed to 10 ug/L (i.e., the 10 ppb of the proposed standard). Indeed, the data presented would suggest that the action levels of 10 and 20 ug/dL will be very difficult for the water suppliers to meet. The Subcommittee recommends that EPA make a stronger and clearer justification for its selection.

The Subcommittee is concerned that the water quality requirement does not consider lead levels in the distribution system (at the tap) before requiring corrosion treatment. We

recommend that systems that are in compliance with the lead "no-action levels" not be required to meet arbitrary water quality requirements. Obviously, if the lead level requirements were not met, utilities would be required to demonstrate optimized control treatment.

Sampling Plan

The Subcommittee found that the basic purpose of the sampling for lead levels is not explicitly stated. There are no goals, criteria or focus given for this strategy. It is not clear what it represents. There is apparently more than one purpose to the sampling, in which case different methods appropriate for one purpose may be inappropriate for another. This Subcommittee recommends that the basic purpose of this sampling strategy be made quite clearly. It is difficult to evaluate the effectiveness of the sampling strategy if it does not represent the exposure of the general population or it may not truly represent the high risk population.

EPA has not demonstrated that the worst case houses give an appropriate indication that corrosion treatment is being optimized. A portion of high risk houses should be sampled to determine the need for public education, but corrosion control compliance should be based on random sampling. Random sampling gives a more reliable indication of the system-wide impact of corrosion control programs. Thus the Subcommittee recommends that random sampling be used as the basis of determining the action needed.

The Subcommittee recommends tap sampling for compliance with lead regulations (10 ug/L average and 20 ug/L 95% of time) be based upon random sampling at customer taps before requiring utility demonstration of corrosion treatment optimization. The sampling should be allowed where high lead levels are found. Thus the Subcommittee concludes that the form of the regulation is good in using an average and a 95% exceedance level.

As noted above, the design of a sampling plan depends on the purpose for which sampling is being done. If the purpose of the plan is to provide information about interventions such as corrosion control, then random sampling of high-risk targeted households is needed. If an intervention is required, then subsequent sampling at the same households is needed to assess the effectiveness of the intervention. If a system is regarded as non-compliant over a long time, then extension of the sampling to other households may or may not be done. No assessment of these possibilities was presented. The Subcommittee recommends that the statistical analysis and explanation of purpose be included in the regulations.

The two-stage plan presents a commendable effort to reduce the burden of sampling for situations in which there is clearly a problem or clearly not a problem. However, there was no

assessment of the performance of any of the sampling plans with respect to decision errors (requiring intervention when none is needed, or not requiring intervention when it might be helpful). Thus, no rational basis was presented for a choice of plans. Clearly, more detail on the applicability of the methods than was presented either in writing or orally would be needed to make a logical choice of methods. Another consideration is that no matter which plan is selected, there is a definite need for validation. The Subcommittee recommends that methods and validation be clearly developed.

The Subcommittee is concerned about the relevance of the justification of the two-stage sampling plan in the context of water lead sampling, which differs from a quality control model in several ways:

(i) There is a finite, potentially identifiable pool of high-risk households in each city, which can be sampled repeatedly over time.

(ii) The assessment of sampling plan performance by criteria such as average outgoing quality limit (AOQL) may not be appropriate. The AOQL calculations assume that all households in the targeted population will be brought to an acceptable levels of water lead. This is not so, as even BAT may not accomplish that. Some other assessment criteria for performance of the plans should be calculated under alternative scenarios about intervention effectiveness.

(iii) The proposed plans reduce the numeric information on lead levels to a dichotomous pass/fail variable with a somewhat arbitrary cutpoint (e.g. 15 ug/L). One-step and two-stage sampling plans for continuously distributed lead measurements should be evaluated.

The Subcommittee recommends that the relevance of the two-stage sampling plan be clearly explained and justified.

Lead Treatment Requirements

The no action levels for pH and alkalinity (i.e., the concentration of $CaCO_3$) are inappropriate for the following reasons:

A. If the lead levels (10 ug/L average; 20 ug/L maximum) can be met then it is not important how they are met. It is very likely that many suppliers will be able to meet the lead levels without meeting the proposed pH and alkalinity requirements. This is certainly going to be the case as the new lead free solders are used and aging reduces the contribution from the existing lead solders.

B. Utilities should be able to use inhibitors, e.g. zinc orthophosphate, without having to comply with a State approved treatment plan (which, in part, requires an evaluation of pH and

carbonate alkalinity). If the inhibitors are effective in controlling the lead then there should be no further concern. Lead is the health concern, not pH and alkalinity.

C. The EPA proposal presents no evidence that alkalinity itself is related to lead control.

The studies cited to support the alkalinity requirement do nothing to justify an alkalinity of 30 ug $CaCO_3$/L. The alkalinity in both studies (after treatment), was 15 ug/L or less. Additionally in these studies the pH was not controlled and in both cases was raised more than 2 pH units i.e. 5 to 7.2 and 6.2 to 8.2. A field study is needed which compares pH adjustment alone to both pH and alkalinity adjustments.

D. The references cited by EPA in other EPA documents also present no data to support statements made concerning the need to adjust alkalinity.

The Murrell report (p.19) concludes that "lead leaching is reduced by increasing pH and alkalinity to result in a less corrosive water". This conclusion is not supported by the data presented in the report. The data presented on pp. 76-78 are not controlled for pH, and none of the data relate to locations where adjustments were made to increase the alkalinity. The low alkalinity (8 ug/L) water used in the data base had a low pH (<6.4). Additionally, the waters with highest alkalinity (30 ug/L, South Huntington Water District) had a high pH (>8.0). Clearly the conclusions reached regarding alkalinity are misleading.

E. A preliminary evaluation of the data from the American Water Works Service Co. lead survey indicates that pH, but not alkalinity has a relationship to the lead contamination. A comparison of average lead levels and the percent of sample exceeding 20 ug/L for groupings of pH and alkalinity was made. In the pH range 7 to <8 the average lead levels were actually lower (8 ug/L vs. 13 ug/L) when the alkalinity was below 30 ug $CaCO_3$/L. In the samples with pH $\geq$8 there was no difference in the lead levels when alkalinities above and below 30 ug $CaCO_3$/L were compared. Average lead levels were 5 ug/L in both cases.

Based on the preceding comments the Subcommittee recommends that EPA simply require "corrosion control" and allow the utility to implement the appropriate controls for their system.

Additional Concern

The Subcommittee expressed the concern that the charge was too narrow. Specifically, they also discussed certain health issues, which had been treated in an earlier Agency document (viz; Air Quality Criteria for Lead, EPA-600/8-83/028) and examined by the Clean Air Scientific Advisory Committee of the Science Advisory Board in 1986.

U.S. Environmental Protection Agency
Science Advisory Board
Drinking Water Subcommittee

CHAIRMAN AND VICE CHAIRMAN

Dr. Gary Carlson [CHAIR], Department of Pharmacology and Toxicology, School of Pharmacy, Purdue University, West Lafayette, Indiana 47907 (317) 494-1412

Dr. Robert Tardiff, [VICE-CHAIR], Principal, Environ Corporation, 1000 Potomac St., N.W., Terrace Level, Washington, DC 20007 (202) 337-7444

MEMBERS AND CONSULTANTS

Dr. Julian B. Andelman, Graduate School of Public Health, 130 Desoto Street, Parran Hall - Room A-711, University of Pittsburgh, Pittsburgh, PA 15261

Dr. Rose Dagirmanjian, Professor, Department of Pharmacology and Toxicology, University of Louisville, Louisville, Kentucky 40292 (502) 588-5160

Dr. William Glaze, Director, School of Public Health, University of California, Los Angeles, 650 Circle Drive South, Los Angeles, CA 90024 (213) 206-1278

Dr. J. Donald Johnson, Professor, School of Public Health, University of North Carolina, Chapel Hill, NC 27514 (919) 966-3856

Dr. David Kaufman, Department of Pathology, University of North Carolina, Rm. 515 Brinkhous-Bullitt, Chapel Hill, North Carolina 27514 (919) 966-1396

Dr. Nancy Kim, Director, New York Department of Health, Bureau of Toxic Substance Assessment, Room 359, Tower Building, Empire State Plaza, Albany, New York 12037 (518) 474-2084

Dr. Verne Ray, Medical Research Laboratory, Pfizer, Inc. Groton, Connecticut, 06340 (203) 441-3564

Dr. Harold Schechter, Professor, Chemistry Department, Ohio State University, 140 West 18th Avenue, Columbus, Ohio 43201 (614) 292-6300

Dr. Thomas Tephly, Professor, Department of Pharmacology, The Bowen Science Bldg., University of Iowa, Iowa City, Iowa 52242 (319) 335-7979

EXECUTIVE SECRETARY

Dr. C. Richard Cothern, Executive Secretary, Science Advisory Board (A-101F) U.S. Environmental Protection Agency, Washington, D.C. 20460 (202) 382-2552