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

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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-DWC-COM-94-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Subject: Drinking Water Committee commentary on negotiated regulation for disinfectants and by-products.

Dear Ms. Browner:

On August 17, 1993 the Drinking Water Committee of EPA's Science Advisory Board (SAB) was briefed by Stig Regli and Jim Elder of the Office of Ground Water and Drinking Water on the outcome of the negotiations regarding the rules for Disinfectants and Disinfection By-products (D/DBPs), Enhanced Surface Water Treatment (ESWTR) and Information Collection (ICR). The Committee requested this briefing and is keenly aware of the public health importance of the disinfection debate. We recognize that these issues are national in scope and involve primarily the public sector, and also that there is a clear mandate for addressing them under the provisions of the Safe Drinking Water Act.

Given the sensitive nature of the negotiations, the Committee does not wish to comment directly on the draft rules that were the products of the process. The Committee is very concerned, however, that the negotiations did not result in a viable mechanism to resolve the key scientific and technical gaps that initially prompted the negotiations. The negotiators themselves estimated that $30 million

will be needed in the next four years to adequately assess the carcinogenic risks posed by chlorination and ozonation by-products, and to establish whether these risks should require major changes in water treatment processes, which could potentially increase the incidence of waterborne infectious disease. No comprehensive research program exists, however, within the Agency or elsewhere, to address these scientific gaps.

Toxic by-products of water disinfectants were discovered in 1974 and a research effort was begun within EPA, but over the past decade support for this program has eroded substantially. The resources currently available to the Agency in this area cannot effectively address the many knowledge gaps regarding specific chemical and microbial hazards, or the very complex challenges of comparative risk posed by them. If research efforts had been maintained at the level seen in the early 1980's, the problem of drinking water disinfectants and their by-products might well have been resolved.

The Committee feels strongly, therefore, that a ***comprehensive, carefully targeted, and adequately funded research program*** is indispensable to fill critical knowledge gaps and effectively integrate our knowledge of occurrence, exposure, toxic potential, treatment and prevention approaches for the competing chemical and microbial risks associated with drinking water disinfection. The Committee estimates that another decade of intensive research will be necessary before a sound scientific basis can be established for the production of drinking waters that minimize both chemical and microbial risks. At present funding rates, the issue may well not be resolved in less than 20-30 years.

Without a comprehensive research program, the Agency will not be able to resolve the critical scientific questions before the regulations are revisited in 1998. As a result, you may be forced to promulgate rules that do not address the complex and competing chemical and microbiologic hazards posed by water disinfection in the most cost-effective manner. In the worst scenario, the failure to address key scientific questions may result in rules that address the *wrong* hazards.

The major purposes of this letter are to briefly highlight the key research needs that such a program must adequately address now if the final round of the

negotiations in 1998 are to be succesful, and to recommend a substantive effort on the part of the Agency to tackle the thorny issue of comparing chemical and microbial risks. These needs can be summarized as follows:

a. CORRECT IDENTIFICATION OF TOXIC BY-PRODUCTS OF CHLORINATION. The carcinogenic risks estimated from human epidemiology indicate very high risks of bladder and rectal cancer following exposure to chlorinated water (greater than 1/10,000 lifetime). There are large qualitative and quantitative inconsistencies, however, between these findings and those obtained with experimental animals exposed to individual by-products, raising fears that the critically important by-products in chlorinated water are yet to be identified. Indeed, the substances responsible for the observed excess cancer risks may well prove to be *brominated by-products*, due to oxidation of bromide by chlorine, rather than the more intensively-studied chlorinated ones.

b. IDENTIFICATION AND ADEQUATE CHARACTERIZATION OF TOXIC BY-PRODUCTS OF ALTERNATIVE TREATMENT PROCESSES. Treatment processes that may replace chlorination have been poorly researched. A key concern is the possibility that chlorination, a treatment whose potential hazards are not yet well understood or quantified, but whose disinfection benefits are well established, may be replaced by processes with poorly understood health impacts, both chemically and microbiologically. For example, many by-products of chlorination, particularly brominated by-products, can also result from alternative forms of disinfection. It is essential that new treatment technologies be evaluated for their efficacy in reducing toxicologic and microbiologic hazards to avoid the adoption of methods that increase rather than decrease hazards to health.

c. COLLECTION OF ADEQUATE RISK AND OCCURRENCE DATA FOR MICROBIOLOGIC HAZARDS. Major gaps exist and must be filled in our understanding of the relationships between exposure to microbial agents and the development of disease. In addition, the resources that are currently allocated to monitoring microbial

contaminants under the draft ICR, relative to the chemical contaminants, are inadequate.

d. ADEQUATE CHOICE, COLLECTION AND ANALYSIS OF DATA UNDER THE INFORMATION COLLECTION RULE TO ADDRESS CLEARLY IDENTIFIED RESEARCH NEEDS. The mere collection of vast amounts of occurrence data (both chemical and microbiological) under the ICR will not automatically answer the critical scientific questions surrounding the disinfection rule. The data required under the rule need to be specifically designed to address these questions, and adequate resources must be provided for their proper collection and analysis.

e. APPROPRIATELY WEIGHING CHEMICAL VS. MICROBIAL RISKS. There are potential health risks (both microbial and chemical) that can arise in improperly treated and disinfected drinking water (e.g., the South American experience with cholera, Milwaukee's problems with *Cryptosporidium*, and the estimated risks of cancer from disinfection by-products). However, the available data do not point to any specific modifications in treatment that would reduce one set of risks without increasing the other.

It is clear that a letter cannot possibly do full justice to all the complexities of the issues surrounding disinfection. The abbreviated list above attempts to convey only the ***key*** concerns regarding the unmet research needs in this important area of Agency activity. Attached to this letter is an addendum that provides additional details regarding the needs for an Agency research agenda in the areas of health risk, monitoring needs, water treatment, and prevention. Your attention is also called to the Committee's most recent communication to the previous Administrator on these same issues [letter to W. Reilly, August 18, 1992 (EPA-SAB-DWC-COM-92-008)], and to the SAB's review of strategic research issue planning (EPA-SAB-RSAC-92-022).

The Committee also recommends that the Agency initiate a special effort to develop a *comparative* quantitative risk assessment of the multiple chemical and microbial risks associated with disinfection of drinking water. A comprehensive

effort in this regard by the Agency is urgently needed, in its own right, to help address this crucial public health dilemma. In addition, such an effort could serve as a model for future Agency efforts in comparative risk assessment and risk ranking.

The SAB appreciates the opportunity to assist and provide suggestions towards the resolution of this complex problem in public health. We also wish to applaud the dedication and effort of the EPA staff to this difficult negotiation process, especially the efforts of Mr. Stig Regli, who contributed greatly to the conduct of the negotiations and who also maintained the Drinking Water Committee well informed of their progress. We look forward to your response to this letter and offer to assist you and the Office of Drinking Water in the implementation of the above recommendations.

Sincerely,

Raymond C. Loehr

Dr.Raymond C. Loehr, Chair
Executive Committee
Science Advisory Board

Verne A. Ray

Dr. Verne A. Ray, Chair
Drinking Water Committee
Science Advisory Board

Attachment

ADDENDUM

Health Research Agenda

A central gap in our knowledge of the risks of water disinfection is that there is substantive but not conclusive evidence that chlorination poses a significant carcinogenic hazard to humans. The human data indicate that chlorination accounts for 9% of annual U.S. bladder cancer cases (4200 cases/year attributable to chlorination) and 15% of the rectal cancers (6500 cases/year attributable to chlorination) (Morris et al., 1992). If true, the epidemiological data indict chlorination of drinking water as a major cause of human cancer.

There are substantive qualitative and quantitative discrepancies, however, between the human and animal data. First, human epidemiology suggests that the major target organs are bladder and rectum (Cantor et al., 1987; Alvanja et al., 1978; Gottleib et al, 1982), while by-products studied in the usual animal models suggest that the major targets should be liver and kidney (NCI, 1976; Jorgensen et al., 1985; NTP, 1987; NTP, 1989; Herren-Freund et al., 1987; Bull et al., 1990; DeAngelo et al., 1991; Daniel et al., 1992). This lack of correspondence in tumor sites has been disregarded in Agency regulatory activites in the past, for policy reasons. However, it is dangerous to ignore it in the present circumstance, because most of the uncertainty stems from the simple fact that most by-products *have yet to be tested in experimental animals*.

Secondly, the risks calculated from human epidemiology data are about two orders of magnitude greater than those calculated from summing the risks of those few by-products that have been characterized in animal tests, although the latter are still quite substantial (in the range of 1/10,000 lifetime). Alternate forms of disinfection, such as ozone, may pose risks of similar magnitude, although the supporting evidence is much weaker (Bull and Kopfler, 1991).

These discrepancies between the animal and human cancer findings may reflect: 1) that the epidemiology studies are in error (i.e., unidentified confounders); 2) that humans are more sensitive than animals to bladder and intestinal tumors; or 3) that there are as yet unidentified but highly carcinogenic

by-products of chlorination. Whatever the reasons, the discrepancies must be resolved if the Agency is to develop a scientific basis for a disinfection rule. Yet the negotiations did not result in a specific charge or commitment for research to resolve these issues of cancer risk. Rather, the attention was surprisingly directed towards research of reproductive and developmental effects, although the available evidence does not suggest that these are serious concerns with major by-products of chlorination.

With regard to microbial risks, the quantitative relationships between exposure to microbial agents and the development of disease are poorly defined. Unless research is done to better define these relationships, the uncertainties of microbial risk assessment for drinking water will not be reduced, regardless of how much data are collected on microbial occurrence or reduction by treatment. The critical research needs in microbial health effects have been articulated previously (Sobsey et al., 1993) and include the following key points:

1. Reliable quantitative dose-response data from human studies for key waterborne pathogens such as *Giardia*, *Cryptosporidium*, hepatitis A virus and Norwalk virus.

2. Data on the relative risks of the different health endpoints (infection, illness and death) for humans of differing susceptibilities due to age, immunocompetency and other host factors.

3. Data on the risks of endemic waterborne microbial disease from conventionally treated drinking water supplies. The only available study reported about one-third of community wide gastroenteritis was attributable to drinking water.

Immunocompromized individuals are also a source of concern to the Committee, not only as a sensitive population, but as an increasing source of microorganisms that are resistant to medical treatment.

The Committee is also very concerned that changes in water treatment practice, which might be forced by over-interpretation of the cancer data that are currently available, might impact the incidence of waterborne infectious disease.

The Committe does not think that there are sufficient data to understand how, or whether, infectious disease risks will be effectively controlled as water systems are compelled to change treatment practices to avoid disinfection by-product formation. The recent epidemic of waterborne *Cryptosporidium* in Milwaukee illustrates the potential dangers that inadequate disinfection may pose.

Finally, in both the chemical and microbial areas, there is a critical need for well designed and focused epidemiological research. It is essential to determine whether the putative cancer risks arising from chlorination are real or not. It is also crucial to determine the extent to which brominated vs. chlorinated by-products contribute to the problem of cancer risks, since other forms of disinfection also produce brominated by-products. In the area of microbial disease, epidemiologic studies are needed to understand how the interaction of different water sources with varying types of treatment affect potential risks.

Monitoring Agenda

The monitoring required under the proposed Information Collection Rule would require the collection of both microbial and chemical occurrence data that will allow much better assessment of exposure to be made on a national level. The Committee is very concerned, however, that no funding has been provided for analyzing these data in a systematic way, either within the Agency or extramurally. This gap needs to be addressed or it will considerably reduce the value of the data collected at a very large expense to water utilities.

It is also extremely important to make sure that data on individual by-products are preserved and analyzed. There has been a tendency to regulate disinfection by-products by group. It is clear from available data on trihalomethanes that their potency as carcinogens may differ by as much as two orders of magnitude, and evidence is also emerging that the carcinogenic mechanisms involved are quite distinct. Consequently, it is likely that some members of a by-product group will not require regulation while others will. Therefore, the Agency must anticipate that individual criteria will be needed at the time of renegotiation of the rule. In addition, EPA must take steps to assure that the appropriate exposure and treatment information is available for appropriate cost-benefit analyses.

The major reason for monitoring the occurrence of disinfection by-products is to provide the exposure information that is needed to evaluate the health hazards that are associated with alternative forms of treatment, as well as to document the benefits that will result from altering treatment practices. Therefore, any monitoring scheme must allow for the fact that most by-products of disinfectants, particularly those produced by alternatives to chlorine, have not been characterized toxicologically. It is impossible to predict which of those by-products will be important in the future. Hundreds of compounds are probably produced in trace quantities, and a monitoring program cannot anticipate all the possibilities. However, a well-designed effort can provide the basis for predicting the occurrence of by-products by including many basic characteristics of water supplies in the proposed collection of data. This part of the negotiated rule appears to have been well thought out. As mentioned above, however, the utility of these data is very much compromised by the fact that no provision or commitment to analyze them seems to have been made by the Agency.

The information collection program for microbes has focused on two key protozoans, *Giardia* and *Cryptosporidium*, and on culturable human enteric viruses. Except for coliform bacteria (including fecal coliforms or *E. coli*), little attention is devoted to surrogates or indicators for microbial pathogens. Because new waterborne pathogens continue to be discovered, the Committee recommends that more attention be devoted in the research effort to find reliable indicators of microbial pathogens in drinking water. It is inappropriate to assume that the worst case pathogens have already been identified and characterized, with respect to occurrence, reduction by treatment or health effects.

Treatment Research Agenda

It is necessary that research be conducted to 1) provide a better understanding of the by-products that are produced with physical and chemical methods of treatment to control waterborne infectious disease and 2) evaluate non-chemical means of treatment (especially membrane technologies) that have the potential of lowering or eliminating the need for using reactive chemicals in drinking water treatment. Non-treatment mitigation or prevention approaches also should be considered, e.g., minimizing the input of precursors to disinfection by-products and of pathogens to the water supply source. It is essential that

appropriate toxicological and microbiological evaluations of these technologies keep abreast of their development to avoid the institution of methods that increase rather than decrease net hazards to health.

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Mr. Manuel R. Gomez, Designated Federal Official, Science Advisory Board (A-101F), U.S. EPA, 401 M Street, SW, Washington, DC 20460

Mrs. Marcy Jolly, Staff Secretary, Drinking Water Committee, Science Advisory Board (A-101F), U.S. EPA, 401 M Street, SW, Washington, DC 20460

Members not present at the meeting: Dr. Vernon L. Snoeyink, Mr. Charles C. Johnson, Jr.