July 28, 1995

EPA-SAB-DWC-ADV-95-002

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

Subject: Advisory by the Science Advisory Board's Drinking Water Committee concerning EPA's Five-Year Research Plan on Disinfection/Disinfectant Byproducts (D/DBP)

Dear Ms. Browner:

On April 20-21, 1995, the Drinking Water Committee of the Science Advisory Board met to initiate its review of the Agency's Five-Year Research Plan on Disinfection and Disinfectant Byproducts (D/DBP). This review was conducted at an ongoing stage in the development of the Plan, therefore, the Committee has prepared this Advisory, which summarizes the Committee's views of the Agency's progress on this critical issue. An Advisory responds to the Agency's need for advice on whether an effort is on the right track and whether there are alternatives that need to be considered at an early stage, rather than at the end of a developmental effort. The scope of an Advisory is intended to be narrowly drawn. This minimizes the potential impact of providing early Committee advice on a program that will later be reviewed by the Committee as a final product.

1. Charge to the Committee

In this interim review, the Committee determined that an Advisory was appropriate because: a) the drinking water DBP research plan is in a relatively early stage; b) the Agency has indicated an intent to have the Committee review the plan, its implementation, results, and changes in an iterative fashion; and c) the interim charge is narrowly focused on a small part of the DBP research program.

The charge provided by the Agency is in two parts. Part one is a long-term (overall) charge which asks for Committee advice on: a) whether the Agency has identified the correct research issues to support development of the Enhanced Surface Water Treatment (ESWT) and the Stage 2 - Disinfectants/Disinfection Byproducts (D/DBP) rules; b) if the research underway or envisioned adequately addresses these issues, and if not, what other research topics should be pursued; and c) whether the Agency research priorities presented are appropriate.

Part two, is the near-term (interim) charge, in which the Agency requested Committee advice on: a) whether the priority it has assigned to six cancer bioassays requested from the National Toxicology Program (NTP) is appropriate; b) if five specific research projects, which would be funded if additional research funds become available in the near term, are both appropriate for, and the highest priority items for funding; and c) how the organization and content of the research plan can be improved to facilitate review by the Committee.

For now, the Agency has asked the Committee to provide advice in response to the interim charge and the Committee will limit its comments to that charge and a few general comments of broader applicability. Later, after the Agency has linked specific projects to various research issues needing resolution, further developed its rationale for the research projects and priorities, and revised the research plan, it will ask the Committee to address the overall charge. The Agency may also return periodically to brief the Committee on research results and to request advice on changes it might make to the research program because of those results or other factors.

2. Background

The issue of DBP research and regulation has been a recurrent item on the Drinking Water Committee agenda in recent years. In August of 1992, the Committee prepared a commentary (SAB, 1992) asking for the EPA Administrator's support in providing adequate resources to "[e]stablish a credible research program on combined disinfectant byproducts as a high priority endeavor." In December, 1992, after a briefing on the Agency's disinfectants and disinfection byproducts research program, the Committee registered concern (SAB, 1994a) regarding drinking water research budget reductions over successive years (i.e., FY 1992--$6.2 million; FY 1993--$4.2 million; FY 1994--$5.2 million). The Committee felt that reductions might cause "...serious delays in the acquisition of data that are critically needed in the microbial, disinfectant and disinfection by-product areas....The Committee's fundamental recommendation, therefore, [was] that the Agency commit sufficient resources to

develop a critical mass of research funding and personnel budgets for drinking water research, especially pollutant and disinfectant research."

In a Commentary, resulting from an August 17, 1993 briefing to the Committee (SAB, 1993), we noted our strong concern "...that a comprehensive, carefully targeted, and adequately funded research program is indispensable to fill critical knowledge gaps and to 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 estimated that another decade of intensive research [would] be necessary before a sound scientific basis [could] 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."

The Committee also reviewed the EPA proposed rule for monitoring requirements for public drinking water supplies (the information collection rule, or ICR) at a meeting on April 27, 1994. This rule was agreed to in the regulatory negotiation on drinking water disinfection, and the data to be provided under the rule is intended to be an additional source of information to support drinking water disinfection rule-making. In its report of July 28, 1994 (SAB, 1994b), the Committee noted that it generally supported the rule but the Committee was concerned "... that the Agency ha[d] not articulated an overall research plan to guide the collection and analysis of the data in a meaningful way. A clear research plan is critically needed to define the questions that the data are intended to answer, as well as the methods that will be used to analyze the collected data. Without such a plan, the rule may result in the collection of data that may not be necessary or usable, and thus may fail to adequately support the development of an ESWT rule or regulations for disinfectants and their byproducts." In addition, the same letter report noted that: "...the collection of occurrence data for microbial agents and disinfectants and their byproducts is not capable of resolving the health risk issues involved without parallel research quantifying the chemical and microbial risks that are associated with those occurrences...it is important to emphasize that there is a strong need for the Agency and others to continue to conduct and stimulate substantial research in these areas."

3. Response to the Interim Charge

The Agency asked the Committee if it agreed with the priority it had assigned to a number of studies which are a part of the overall drinking water disinfection research plan. The Agency separated these into two categories: a) NTP bioasssays for cancer, and b) projects to be funded if additional research funds become available. In general,

the Committee favors Agency investments if the projects will answer outstanding critical research questions. However, the Committee notes that the existing plan has major information gaps which prevent it from responding to the Agency's questions on differential priorities within the various projects listed. Because of this, the Committee will limit its response on relative priorities until the revised research plan is available. However, in the following sections, the Committee will provide some initial thoughts on some of the studies that the Agency highlighted in the interim charge or otherwise in its briefings during the April 20-21, 1995 meeting.

3.1. Appropriateness of the priorities given by EPA to NTP cancer bioassay testing of DBPs (Mx, chlorate, cyanogen chloride, bromodichloro acetic acid (BDCAA), dibromo acetic acid (DBAA), glyoxal, and methyl glyoxal)

In its interim charge, the Agency asked if the Committee agreed with Agency priorities on a number of cancer bioasssays being negotiated through the National Toxicology Program (NTP). Since there is a question about the toxicity of certain disinfectants and disinfection byproducts in drinking water, the Committee agrees that priority should be given to bioassay testing by the NTP. The Committee has no reason to disagree with the priority list of D/DBPs to be recommended for bioassay testing by the NTP, but stresses the importance of close collaboration between the Agency and the NTP in designing these bioassays. The chronic carcinogenicity studies should include dose rates that will also generate information on chronic low-dose toxicity. However, the Committee is concerned about the timeliness of the results and recommends that the EPA make every effort to expedite timely consideration and execution by NTP.

3.2 Near term studies to be funded if additional research funds become available.

The Agency asked if additional research moneys become available shortly, whether a list of five specific projects warranted the highest priority, and were in priority order, for funding of new research? Also, it asked if these projects are appropriate for development of the interim ESWT rule and Stage 2 DBP rule?

The Committee has not had the opportunity to review the protocols that were used to establish the priorities presented and does not feel it appropriate to comment on them at this time. The Committee recommends that EPA more clearly articulate the priority categories, the basis for priority setting, and the role that these priorities will play in decision-making. Further, listing the next several research items beyond the first five would assist the Committee in evaluating the assigned priorities.

Even though the Committee does not feel that sufficient information has been given to permit it to provide advice on whether the five listed studies are the highest priority for near term funding, nor is it able to advise on the relative priority of the studies one to the other, it would like to offer the following comments on the studies mentioned under the interim charge for near term funding.

3.2.1 Treatment Optimization studies by EPA's Risk Reduction Engineering Laboratory

Treatment optimization studies are important to establish best available technology (BAT), to provide a basis for estimating the cost of regulatory impact, and to facilitate estimates of removal with alternate processes. The Committee received information near the end of the April 20-21, 1995 meeting that describes three projects [filtration damage viability studies, optimize conventional treatment for removal of oocysts, and evaluate biological (ozone) for inactivation and removal of oocysts] having a total cost of $405,000. Of these three, the latter two are a part of the interim charge. The information provided to the Committee also identified five additional projects to be considered in the future. None of these are a part of the Agency's interim charge.

a) Filtration Damage Viability Studies (spreadsheet item 177b) - The Committee agrees that Agency observations on filtration damage viability, discussed at the April meeting, constitute new information that is relevant to any filter design which uses straining as the principle mechanism of removal and where pressures can be high. However, the Committee does not believe that the ability of oocysts to change their shape under pressure is of significance in conventional granular media filtration as it is employed in most municipal drinking water treatment plants.

   The Committee recommends that when these studies are conducted they be directed toward determining the significance of the observations of the research so far on low pressure filter designs that depend on straining as their principle mechanism of removal, such as diatomaceous earth.

b) Optimize conventional treatment for removal of oocysts (spreadsheet item 177c) - The Committee agrees that the issues these studies will address are important and agrees that they should be conducted as part of this program.

c) Evaluate Biological (ozone) treatment for inactivation and removal of cysts (spreadsheet item 177d) - This project should be an important component of the overall research effort.

d) Additional Projects: The Committee offers suggestions, even though these projects are not part of the interim charge.

(1) A treatment series profiling oocysts, total organic carbon (TOC), precursors, biodegradable organic carbon (BDOC), assimilable organic carbon (AOC), spores, bromide, and bromate - These studies should have high priority if they can be designed to do an adequate job of characterizing and quantifying these entities in water sources in parallel through conventional treatment processes and likely options especially if the studies can be designed to examine impacts on the distribution system. Some additional constituents should also be considered, specifically, HPC, *E. coli, C. perfringens*, particle counts, oxidant residual, coliphage, and corrosion rate in the distribution system.

(2) Compare removal of oocysts, spores, particles and turbidity with enhanced and conventional coagulation - The Committee also encourages EPA to conduct these studies as they will help to more clearly establish what can be expected from these process requirements in the first phase of the D/DBP rule.

(3) Examine the effectiveness of diatomaceous earth for removing oocysts, spores, particles, and turbidity - Based on the Committee's earlier comments, EPA may want to combine this study with the Filtration Damage Viability Studies proposed earlier. If these studies are conducted, removal of bacteria and coliphage should also be examined so that the results are more broadly applicable.

(4) Conduct full scale studies using oocysts, spores, etc. - The Committee encourages the EPA to conduct several full-scale studies. A great deal can be learned from these projects that cannot be learned on a bench or pilot scale.

(5) Evaluate effectiveness of package plant and alternative technologies for same - The Committee also encourages EPA to evaluate removals being achieved in actual package plants and other small plants in the

field. The evaluation should not be restricted to oocysts and particles, but should be extended to include indicators for bacteria and viruses as well.

3.2.2 Inactivation of *Giardia* by sequential disinfectants (spreadsheet item 199e)

The Committee agrees that it is important to quantify the effects of sequential disinfectants on *Giardia* cysts. However, the Committee is very concerned that the Agency plans to use *Giardia* as the target organism for regulation because of the poor recovery of *Cryptosporidium* during the performance evaluation project. It has been established that *Cryptosporidium* is more resistant to disinfection than *Giardia*. How does the Agency plan to account for this difference when setting the treatment requirements? Before abandoning *Cryptosporidium* as the target organism, the Committee encourages the Agency to do another performance evaluation for *Cryptosporidium*, using filters dosed under conditions that more closely resemble field conditions with a wider range of oocyst concentrations.

3.2.3 Inactivation of Norwalk Virus by chlorine & ozone (spreadsheet item 183a)

The Committee is supportive of Agency efforts to learn more about the effectiveness of commonly used disinfectants against Norwalk virus, which is likely a major cause of waterborne illness. However, there are several points that the Committee must raise regarding this project. First, the effects of infection by Norwalk virus tend to be very mild and self limiting - much less severe than those associated with infection by other viruses. Second, there is no method by which this virus can be quantitated, so all results will have to be expressed in relative, rather than absolute, terms. Recognizing the points, the Committee suggests the following:

a) Establish a long-term research program to develop an infectivity assay for Norwalk virus so that quantitation is possible. This program could be a part of an in-house program using existing personnel and facilities.

b) Expand this program to include examining the effects of other disinfectants (such as ultraviolet radiation) on Norwalk virus and other viruses. This will be essential for ground-water systems as well as many surface water systems.

3.2.4 Developmental/Reproductive effects and cancer epidemiology feasibility studies

It is obvious that in order to adhere to the requirement of information gathering for the ICR, the ESWT, and the Stage 2 DBP rules, that epidemiological studies of microbial disease risk, developmental and reproductive toxicity, and cancer will need to be performed. Workshops on development and reproductive effects and cancer have been completed and recommendations given to the program for the five-year research plan. Feasibility studies for developmental and reproductive toxicity are partially funded but according to the research plan additional funds are needed in FY 1995 ($400K). Currently, California and New Jersey reproductive studies are underway as are studies on chlorinated DBP's in residential drinking water and an examination of the possible association between birth defects and levels of THM's, nitrates and certain volatile solvents in drinking water. Also, there is a series of methodological studies underway. Clearly this work needs additional funds to permit satisfactory completion.

The cancer feasibility studies have not been funded at this time. Approximately $600K has been requested for 1995. The components of these studies, as recommended by workshops, appear to be selected appropriately. However, it is hoped that the projected mutagenicity studies on water concentrates will be planned so as to overcome the problems with earlier studies of this type.

3.2.5 Microbiology epidemiology studies

The Committee also reminds the Agency that microbiological studies are also important in drinking water disinfection. The Committee believes that epidemiological studies addressing microbiological health effects are likely to produce useful information because such effects occur a short time after exposure and because the effects can often be supported by clinical diagnostic evidence and etiology. Although the interim charge to the Committee recommends that EPA study the feasibility of using epidemiology to study development, reproduction and cancer endpoints, it must be emphasized that the Committee also recommends that EPA continue to pursue the application of epidemiological techniques to obtain a better understanding of the risk of transmitting microbiological disease by drinking water.

<u>It is clear that epidemiological study of microbial disease risk from drinking water must be given high priority and dealt with more adequately than has been the case for the past 8 or more years.</u> The validation of the Payment et al (1991) study represents only a beginning. This program needs greater knowledge of the incidence of

waterborne diseases. Further comments on this issue will be made as the research plan takes on greater structure and scientific detail.

3.3 How can the organization and content of the research plan be improved to facilitate review by the Committee

The Agency asked the Committee for advice on improvements to the research plan which would facilitate later reviews by the Committee. To focus the current review, the Agency provided the Committee with an initial document entitled, "Five-Year Research Plan to Support Regulation Development for Controlling Disinfectants/ Disinfection Byproducts and Pathogens in Drinking Water" (dated April 12, 1995). This document consists of a narrative and various figures which discuss the regulatory background of the disinfection issue; the broad relationship of the "Plan" to the disinfection rule-making in progress; a statement on research funding sources; an extensive spreadsheet which lists various critical research projects (and resource levels) by category; and a series of brief summaries for each of the projects listed on the "spreadsheet." Additional detail was provided in the Agency briefings during the April 20-21, 1995 Committee meeting.

The Committee has a number of concerns with the initial documentation provided for review. Little information is included on the rationale for elements in the plan. Neither Agency goals, nor how pieces of the research projects relate to the goals, are discussed. Insufficient information is provided on what is to be done, by when, and with what funds. Further, the spreadsheet listing research projects does not show the EPA funding shortfall for each of the research items; partial funding by others; the range of resource needs; total shortfall over five years; or upper and lower end resource estimates.

In its letter of July 28, 1994, the Committee recommended, "...that the Agency develop an overall research plan to underpin the ICR effort, with more clearly defined scientific objectives and methodology." The Committee extends this recommendation to the current effort. First, the Agency should identify the principle scientific issues to be resolved in developing the regulations and the questions to be answered by research that will address these issues. The Agency should also assign component research elements, within the overall plan, to specific priority categories that are based upon clear criteria, and determine the role that priority setting will play in decision-making. Finally, the Agency should clearly articulate its thinking on each of these items. It would be helpful to separate the text and spreadsheet into the four categories mentioned at the review meeting: Treatment, Analytical, Risk, and Health Effects.

4. Research Program Coordination

The research effort required for succeeding in the second phase of these regulations is vast in scope and involves many independent parties. The program is also unusual in that, although EPA may assign one individual as responsible, it cannot give the assigned individual full authority to direct the program because important elements of the program are being conducted by other parties.

The Committee is concerned that there is no clear indication of who controls the planning and implementation of the disinfectant/disinfection byproduct research program. There seem to be many managers responsible for pieces, but no one is identified as in control of the plan and the budgets. Such a diffuse control network provides unique management challenges. Further, the Committee is concerned that the situation could deteriorate if individual laboratory participants in the planning process described at the meeting become lobbyists for their own labs and not custodians of the overall program.

The Committee recognizes efforts already being made. However, as the program is currently structured, each of the participants maintains such a high degree of independence that the prospects for success are seriously compromised. This independence exists at three levels: a) within the EPA; b) between the EPA and other government units; and c) between all the units inside and outside government.

The Committee suggests two actions to the Administrator in the interest of successful planning and execution of this critical research program:

a) <u>Need for a structure for coordinating the effort</u> - Success will, in large part, depend on the degree to which the Administrator can find ways to structure the coordination of the effort so that all involved parties work effectively together. The Committee recommends that the Administrator take steps to ensure that coordination and strategic execution are achieved, both within government, and between government and the private sector.

   One way in which better coordination and execution could be accomplished would be for the Administrator to establish a small executive Committee for the program. An individual from the Office of Research and Development (ORD) could be appointed to coordinate the effort inside ORD and across offices. Representatives from each EPA

unit (program offices and ORD laboratories) would be designated to assist in this coordination.

This executive Committee would meet at regularly scheduled intervals to review current progress on the strategic plan and make appropriate revisions. Members of the executive Committee would be given the power to reallocate or redeploy project resources within their respective organizations. Responsible organizations would be designated for implementation of pieces of the overall plan.

b) Use of more formal scheduling and resource management techniques - For such a multi-faceted research program to be successful, formal methods for project scheduling and resource management should be applied in addition to the regularly scheduled meetings discussed above. The Committee recommends that EPA seriously examine the implementation of more formal project management, including the addition of a computer-based scheduling component to the project management team.

5. Research Program Funding Commitments

Although the spreadsheet included in the Agency documentation for the research plan is not clear about funding issues, it is clear that the resource level applied to this important program is small. The small amount of resources being invested is striking, especially since the regulations which might be required by analyses supported by the existing inadequate data could cost in the billions of dollars. In light of this, the Agency's partnering with other organizations to bring together and leverage resources is a positive step.

The overall spreadsheet that lists the ongoing and necessary, but not currently active research projects, has been discussed as an inventory of current research and future needs assuming existence of adequate resources. The Committee notes that far from being a list of all possible research on this issue, the spreadsheet should be viewed as a bare-bones listing of the essential research in the D/DBP area. Further, the spreadsheet inventory is based upon today's understanding. As more research is conducted, we will learn of additional issues and these issues will tend to expand our list of research needs and the dollars required to fund the research.

Finally, the Committee is concerned that the Agency investment in this research program might affect the perception of its commitment to the spirit of the agreements

made in the regulatory negotiation for this issue. The Agency should take steps to ensure that its commitment to this research program is clearly understood by all stakeholders.

6. Summary

a) There is a need for a clearer rationale and definition for components of the research plan, as well as prioritization of these components to permit greater emphasis on those that contribute most to the enhancement of public health. This prioritization is essential in view of the severe limitations of current resources and data. Near-term research efforts that are targeted at critical knowledge gaps are needed to guide a sturdy plan of action.

b) Due to the multifacted nature of the research plan and the number of interactions both within and outside of EPA, the coordination of the overall project needs to be closely monitored and have adequate representation from the several major sectors (e.g., OW, ORD, AWWARF (American Water Works Association - Research Foundation)) that should meet on a regular schedule. This coordination of effort could include an executive Committee established by the Administrator that has well-defined project scheduling, review of research productivity and resource management functions.

c) The Committee has made a number of recommendations previously in its response to the Agency on the information collection rule. However, we feel the need to repeat and reemphasize that the collection of occurrence data for microbial agents and disinfectant byproducts is not capable of resolving health risk issues without parallel research quantifying the chemical and microbial risks associated with those occurrences.

d) The Committee was presented a series of proposed projects for comment including: (1) NTP cancer bioassay of DBP's; (2) a group of near term studies to be funded if additional research funds become available; (3) inactivation of *Guardia* by sequential disinfectants; (4) inactivation of Norwalk Virus by chlorine and ozone; and (5) development/reproduction effects, cancer epidemiology feasibility studies and microbiology epidemiology studies. In addition, a series of additional projects were discussed that are not part of the interim charge. The Committee commentary on all these studies was restricted due to the staff having

inadequate information on what is to be done by when and with what funds.

Issues in drinking water disinfection are complex and much uncertainty exists about risks presented by both microbial and chemical contaminants in drinking water. The Committee understands the need for the Agency's D/DBP research plan to be dynamic and require alteration over the next several years as ongoing research provides results which lead to an improved understanding of risks that may be associated with drinking water. The Committee looks forward to a continuing interaction with the Agency as this research proceeds and the plan evolves.

The Drinking Water Committee commends the Agency for its initial efforts to articulate its drinking water disinfection research plan, and for its efforts to build a coalition of interested organizations, both governmental and nongovernmental, to pursue these complex and costly research issues. We are pleased to have had the opportunity to review this plan during its development and provide this Advisory. We look forward to a full review of the D/DBP Research Plan at a future meeting of the Committee. In the interim, we hope that these comments are useful and look forward to your response.

Sincerely,

Genevieve M. Matanoski

Dr. Genevieve M. Matanoski, Chair
Executive Committee
Science Advisory Board

Verne A. Ray

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

GLOSSARY OF ACRONYMS

AOC	Assimilable Organic Carbon
AWWARF	American Water Works Association Research Foundation
BAT	Best Available Technology
BDCAA	Bromodichloro Acetic Acid
BDOC	Biodegradeable Organic Carbon
DBAA	Dibromo Acetic Acid
DBP	Disinfection Byproducts
D/DBP	Disinfectant and Disinfection Byproducts
EPA	Environmental Protection Agency
ESWT	Enhanced Surface Water Treatment
HPC	Heterotrophic Plate Count (Bacteria)
ICR	Information Collection Rule
IESWTR	Interim Enhanced Surface Water Treatment Rule
NTP	National Toxicology Program
ORD	Office of Research and Development
OW	Office of Water
THM	Trihalomethanes
TOC	Total Organic Carbon

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