

September 27, 2000

EPA-SAB-DWC-ADV-00-007

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: An SAB Advisory on EPA's Draft Contaminant Candidate List (CCL)
Research Plan

Dear Ms. Browner:

The Drinking Water Committee (DWC) of EPA's Science Advisory Board (SAB) met on August 8-9, 2000 to review the Agency's draft Contaminant Candidate List Research Plan. The Committee appreciates the opportunity to interact with EPA as it develops this important research program in support of EPA's implementation of this major new approach to evaluating and regulating drinking water contaminants.

1. BACKGROUND

1.1 Statutory Context

The Safe Drinking Water Act (SDWA, 1996) requires that EPA set priorities for addressing unregulated microbiological and chemical contaminants by first establishing a list of candidate contaminants (Contaminant Candidate List or CCL) and then selecting five or more contaminants from the list to determine if they should be regulated. The first such list was promulgated in 1998 (EPA, 1998) and the Agency's determination on whether or not to regulate five or more of the listed contaminants must be made by August, 2001. Specific actions for each of the contaminants selected for regulation must then follow within three and one-half years. The requirement to publish the list of candidate contaminants, and for making regulatory determinations, is cyclical with CCL Number 2 being required in 2003.

The criteria for regulating these contaminants are the same as that for any drinking water contaminant. The Administrator must determine whether these contaminant(s): a) may cause an adverse effect, b) is known or likely to occur at levels of public health concern, and c) that regulation provides a meaningful opportunity to protect public health. The Agency must evaluate data and information on each of these criteria in arriving at its decision on the need to develop a regulation. The *Research Plan for the Drinking Water Contaminant Candidate List* (EPA/ORD, 2000) was developed to provide guidance on research to support regulatory decisions for contaminants on the first CCL and the continuing identification of emerging pathogens and chemicals of potential public health concern.

1.2 The Draft Research Plan

The draft Research Plan (EPA 2000) addresses five issues: a) the Agency's plan for identifying and ranking CCL1 research needs, b) the analytical methods needed to address contaminant occurrence/exposure/health effects/treatability, c) occurrence and exposure associated with the contaminants in source water/finished water/distribution systems, d) the existence of significant health risks for the contaminants, and e) the effectiveness of treatment technologies for controlling these contaminants.

CCL1 itself lists contaminants in two categories: a) **Regulatory Determination Priorities** (those having sufficient data available to evaluate exposure and risk to public health and to support a regulatory decision), and b) **Research or Occurrence Priorities** (contaminants that require additional data before a regulatory determination can be made). The **research process** described in the plan, proceeds in two phases and the strength and completeness of existing data determines whether specific contaminants fall into Phase I or Phase II of the process.

Phase I involves screening contaminants to assign them to either the regulatory determination category or the research/occurrence category noted above. In Phase I a hazard identification process is used to evaluate existing data on exposure, dose response, and occurrence, and then the availability of analytical methods for the contaminant is considered. The intent is to determine if the contaminant poses, or potentially poses, a hazard. If it does, then the contaminant's treatability is evaluated. For contaminants determined in Phase I to be a hazard and which are not easily treated, **Phase II** then identifies and prioritizes research needs based on their potential public health risk, conducts research to generate a comprehensive database, and then concludes with a comprehensive human health risk/risk management options evaluation that informs managers of the risk posed by a contaminant and the likely consequences of implementing various risk management options.

The CCL Research Plan was developed in cooperation with a broad group of "stakeholders." It incorporates a number of other efforts including a) the results of an EPA-American Water Works Association Research Foundation (AWWARF) workshop in September 1999, b) the results of a special panel on risk assessment and risk characterization issues for the CCL Plan, and c) a series of

Health Effects Data Summary sheets. Appendices B and C to the Plan incorporate research priority recommendations resulting from the joint EPA-AWWARF workshop and Appendix D identifies elements of a Minimal Data Set for contaminants.

2. CHARGE

The Charge provided to the Drinking Water Committee by EPA asked the Committee:

- a) if the two-phase decision process described in the research has a high probability of providing information appropriate for the Office of Water's regulatory determinations for CCL contaminants;
- b) to evaluate the effectiveness of the plan in identifying data gaps and ranking research needs, and whether the plan systematically identifies:
 - i) the needs for analytical methods?
 - ii) needs for occurrence, exposure, health effects and treatability research?
 - iii) the occurrence and exposure associated with contamination in source water, in drinking water from natural sources and as a result of treatment processes, and from distribution systems?
 - iv) the significant health risks associated with exposure to CCL contaminants?
 - v) The most likely treatment technologies that will control CCL contaminants?
- c) if the information provided in Appendices B and C properly reflect EPA's understanding of the issues related to health, exposure, treatment and control and if the needs reflect the proper priority for the contaminant's potential hazard to public health, and whether there is there additional information that EPA should consider in this regard?
- d) if the relative priorities and timetable proposed in the CCL Research Plan are adequate for the planned research; and
- e) if the Science Advisory Board has any suggestions for improving the integrated planning of research on unregulated contaminants?

3. GENERAL CONCLUSIONS AND RECOMMENDATIONS

The Drinking Water Committee commends the Agency for its progress in developing a research plan to addresses the regulatory program office's (Office of Water - OW) needs and the resources available to the EPA's Office of Research and Development (ORD) in this important area. The Committee notes the substantial progress made since it was first briefed on the information needs to support the CCL program during Fiscal Year 1999. When complete, this plan will fill an important need both within EPA and as a communication instrument to interested parties outside the agency.

The nature of the charge questions demonstrates that the Agency has a good grasp of the tasks that the CCL Research Plan must address. However, it became clear to the Committee at its August,

2000 meeting, both from the Agency's briefing and the discussions on the charge questions that ensued, that the DWC did not have sufficient information on the individual contaminants and the process and procedures used by EPA to arrive at their current version of the plan, to completely respond to the charge questions. It also became clear that additional information is available and could be supplied to the Committee. As a consequence, the Committee decided to conduct the review in two successive interactions. The first was the August 2000 meeting, the results of which are being provided to the Agency in this Advisory report. The second will be a meeting scheduled for January 2001 after the Committee receives additional information and a revised version of the draft research plan. Any revisions and supplemental details must be provided to the Committee not later than December 11, 2000 to give the members sufficient time to prepare for the January meeting.

The Agency has agreed to provide additional information to the Committee including at least: a) the notebook of "Health Effects Data Summaries (CD format would be helpful); b) the AWWARF workshop report – actually delivered to the DWC during the August meeting, and c) occurrence data used in developing CCL1. The Committee suggests that the Agency consider responding to comments made in the August meeting about the clarity and content of the current draft research plan by developing a revised research plan. The Agency is also asked to determine whether there are other documents that could be provided to help the Committee understand the Agency's development of the CCL research process.

In the interim, the Committee will review the material that was provided at, and subsequent to, the meeting. In preparing for the second meeting, the DWC will hold a telephone conference meeting about two weeks before the meeting to evaluate where it is in terms of readiness for the January 2001 meeting.

4. SPECIFIC COMMENTS

There are seven specific points that the Committee wishes to make. These should help EPA move to the next step in developing its CCL research plan. These are:

- a) The plan is not in the form of a plan. Rather it appears to be structured as a research strategy. It lacks the product and time commitments that are cardinal attributes of a research plan. Designing a Research Plan to address the Candidate Contaminant List requires the integration of a broad spectrum of technical information to develop perspectives on what research might be done to gain the knowledge necessary to make an informed decision on the regulation of each of the contaminants on the list. A research plan is typically a series of proposed projects with a design rationale, a set of priorities, and a time line and responsibility for each project. Further, in the current draft, the role of the Implementation Team and other advisory groups is not clear. Who is the Implementation Team accountable to? What steps are envisioned for continued internal and external peer review of the plan? The Plan needs to be self-contained and

include a description of the origins, the purpose, and the end results (e.g. a regulatory determination) of the CCL in the introduction to the Plan.

- b) The decision processes used in phases I and II are not transparent. It appears that the process was primarily driven by one or more expert workshops. That is understandable in the early development of the plan; however, there is a need for this process to evolve, both to affirm the usefulness of the workshop approach in the near term, and to guide the development of more formal decision processes in the future. This document needs to clarify the processes through which CCL agents are chosen, the mechanisms for making the decision to regulate or not, and the manner in which regulatory determinations are made. While the process might be clarified through the use of some explicit decision rules, because the data sets are necessarily situational, these should be flexible. The need is for a contaminant by contaminant determination of the key questions that must be answered to move forward on regulatory decision-making. This will define the minimal data sets required for regulatory determination.
- c) The Committee's most important advice to EPA is to place more emphasis on the process of prioritization. The current document clearly demonstrates that the research needs will be substantially greater than the resources available to the Agency (even when cooperative programs elsewhere in the government and in the private sector are considered). Consequently the CCL Research Plan must address the translation of this knowledge into practical priorities that determine the allocation of scarce resources that will maximize the protection of public health. This information is critical to the document and must detail the expected public health benefits in relation to their costs. The public health benefit must be articulated to understand how to prioritize the development of the database necessary for regulation. The priorities should not simply be set by a priority list of the contaminants, but must also include a clear statement of the problem that was perceived when the contaminant was placed on the list. For each contaminant there should be an effort to identify the critical question(s) that must be answered to move the contaminant to the next step in the process (regulatory determination, further research, or regulatory action). The Committee encourages the Agency to identify those high priority research questions which may require considerable time to resolve and recognize that in some cases smaller, but important, gains can be made expeditiously with a lower investment of resources on a lesser problem. The more these issues can be explicit in the planning process the better. It is not clear how these many research needs will be prioritized and who will do this.
- d) As new approaches develop, it is important to understand the process that is currently being used. Expert workshop decisions involve both formal decision rules that can be articulated and a considerable amount of judgment. Generally, if such a process is necessary, it is because that judgment is a better predictor than the formal decision

processes. The Committee recognizes the need for using groups of experts and believes the Agency management teams properly used this approach. Nevertheless this approach is inherently not open or transparent and the only people who really understand the decisions that are made are those persons that participated in the exercise. To the extent possible, it is important to attempt to formally describe before hand the decision process to be used, and subsequently report this process, and the specific judgments that were obtained in applying the method.

- e) The DWC struggled with the question of what minimal data sets are necessary to make decisions in the CCL process. The principal problem is that each contaminant is unique and, as indicated above, the decision process is complex. As a consequence, reviewers of the plan have to almost repeat the process in detail to determine if it worked appropriately. As the plan was discussed in our August 2000 meeting, it became clear that the minimum data set for a regulatory determination is considerably different than that needed to develop a formal regulation. It is important to develop a clear definition of the minimum data set required for regulatory determination and the minimum data set required for the development of full regulations. Although the Committee recommends that the Agency invest time in developing a clear definition of these minimum data sets, it recognizes that this task will be difficult to accomplish as each contaminant brings with it certain unique considerations. An important example is the requirement to identify potential relationships that occur between the effects of chronic toxicity and carcinogenicity. It is important that the minimum data-set definitions recognize this reality. However, it would be very useful if some effort could be made to provide an indication of what a minimum data set would be set for microbial or chemical contaminants to support CCL decisions. Given the limitations of the SDWA to require the development of data by the regulated community, these minimum data sets will likely be different from those used in registration laws such as FIFRA that have extensive data generation requirements.
- f) Caution must be used when determining whether an organism is a waterborne pathogen. As discussed on page 16 of the plan, information from epidemiologic investigations, biology and life cycle of the organism, occurrence and survival in the aquatic environment should all be considered, as a body of evidence, when determining the likelihood of waterborne transmission. If an organism is associated with a waterborne disease outbreak, then a clear concern for health effects and occurrence exists. However, absence of information documenting waterborne disease outbreaks with a specific pathogen does not mean that waterborne transmission of the organism is not a concern. Substantial under-recognition and under-reporting of waterborne disease outbreaks is likely. Also, even when outbreaks are recognized, the specific etiologic agent is not identified in a significant portion of the outbreaks.

- g) The Committee agrees that discussions of the need for analytical methods for various microbial contaminants should specify why the method is needed. Different analytical methods could be used for compliance monitoring, study of microbial occurrence, or for use in outbreak investigations. For example, highly sophisticated and time consuming experimental methods may be adequate to give some indication of occurrence; however, they would not be appropriate for compliance monitoring purposes. For some uses, determination of viability is not always essential - especially in source water samples; however, for outbreak investigations, illness in the population indicates viability and infectivity. The discussion of analytical methods in the document showed limited vision in terms of development and application of new molecular methods. Based on information about the biology of the target organisms and similar organisms, EPA scientists should be able to judge which methods are more likely to be developed in the near future and which methods are more difficult to develop and will require a longer time to develop.

The Drinking Water Committee was pleased to conduct this review of the draft research plan and looks forward to the response of the Assistant Administrator of the Office of Research and Development (ORD). The Committee looks forward to continuing to interact with EPA's Office of Research and Development and Office of Water on this plan in its January 2001 meeting.

Sincerely,

/S/

Dr. Mort Lippmann, Interim Chair
Science Advisory Board

/S/

Dr. Richard J. Bull, Chair
Drinking Water Committee
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ROSTER

**U.S. Environmental Protection Agency
Science Advisory Board, Drinking Water Committee (DWC)
August 8-9, 2000 Meeting**

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REFERENCES

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EPA. 2000. *Research Plan for the Drinking Water Contaminant Candidate List*. US EPA, Office of Research and Development, Draft dated August 8, 72000.

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