SEPA CONTAMINANT CANDIDATE LIST RESEARCH PLAN: AN SAB REPORT

A REPORT BY THE DRINKING WATER COMMITTEE OF THE EPA SCIENCE ADVISORY BOARD



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

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

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Honorable Christine Todd Whitman Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Subject: Contaminant Candidate List Research Plan (CCLRP); An SAB Report

Dear Governor Whitman:

The Drinking Water Committee (DWC) of EPA's Science Advisory Board (SAB) met on June 12-13, 2001 to complete its review of the Environmental Protection Agency's draft *Research Plan for the Drinking Water Contaminant Candidate List* dated February 21, 2001. The Committee first reviewed an earlier draft plan at its August 8-9, 2000 meeting and that review resulted in an Advisory to EPA dated September 27, 2000 (EPA-SAB, 2000).

The Safe Drinking Water Act (SDWA, 1996) requires that EPA set priorities for addressing unregulated microbiological and chemical contaminants by establishing a list of candidate contaminants that might be regulated in the future (Contaminant Candidate List or CCL); selecting five or more contaminants from the list to determine if they should be regulated; and developing a regulation for those which meet the criteria for regulation. The regulatory criteria require that the Administrator determine whether the contaminant(s): a) may cause an adverse effect, b) are known to, or likely to, occur at levels of public health concern, and c) regulation provides a meaningful opportunity to protect public health. The *Research Plan for the Drinking Water Contaminant Candidate List* (US EPA, 2001) was developed as a plan for identifying research to support regulatory decisions for contaminants on the first list and the continuing identification of emerging pathogens and chemicals of potential public health concern.

The charge to the Drinking Water Committee asked if the two-phase decision process described in the research plan has a high probability of providing information appropriate for the Office of Water's regulatory determinations for CCL contaminants. Further, it asked if the Science Advisory Board had any suggestions for improving the integrated planning of research on unregulated contaminants.

The Committee believes that the current version of the Agency's research plan describes a research planning process that is a substantial improvement over that reviewed by the DWC during its August 2000 meeting. The two-phase process described in the plan is understandable and does have a high probability of producing appropriate information for the Office of Water's regulatory determinations on CCL contaminants. However, to be successfully implemented, more complete operational definitions will be required for many terms, concepts and criteria that are incorporated within the process. In particular, more explicit criteria need to be identified for ranking and evaluating contaminants. With regard to the critical need for criteria, EPA should begin their development by tying them to the general statutory criteria for regulatory decision making mentioned above. Finally, it will be necessary for the Implementation Team, envisioned in the plan, to have the authority, resources, time and administrative support needed to play its coordinating role.

The Committee believes that one of the research plan's strengths is in its integration of both the research decision making process with the Contaminant Candidate Listing regulatory process that it supports. This is an improvement in research planning even though it contributes to the complexity of the plan. Integration clearly shows that the two processes, regulatory and research, are inextricably linked and that the criteria to be met to move forward in the regulatory process will significantly influence the criteria for determining research needs and priorities. Because of the link between progress in the research program and movement in the regulatory program there is a need for a richer articulation of how the research and regulatory components of the overall process interact. Terms used to describe the critical decision points that are built into the processes need to be defined and criteria need to be developed for how those decisions are made in the regulatory and research components of the overall process. The Committee believes that developing operational definitions for these key terms, concepts and criteria will contribute to the achievement of the objectives of the research plan.

The Committee recommends that in carrying out its CCL responsibilities, the Agency:

- a) use current science research and established science policies to evaluate the basis for its regulatory concerns, employ a transparent decision-making approach, and make an effective use of public participation;
- b) articulate the manner in which the research planning process will balance short-term and long-term investments to maximize public health protection;
- c) include a short section in the plan which clearly distinguishes between Phase I and Phase II research, including criteria for distinguishing between the two and several examples of each;

- d) develop explicit criteria for evaluating and ranking research on contaminants that are being investigated under the CCL research plan; and
- e) make every effort to provide the Implementation Team with the necessary time, resources, administrative support and authority to allow them to function effectively in their important coordination role.

We appreciate the opportunity to review and provide advice on the Agency's research planning efforts for the Contaminant Candidate List. The EPA Science Advisory Board would be pleased to expand on any of the findings described in this report, and we look forward to your response.

Sincerely,

/Signed/ Dr. William H. Glaze, Chair EPA Science Advisory Board /Signed/
Dr. R. Rhodes Trussell, Chair Drinking Water Committee EPA Science Advisory Board

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1. BACKGROUND

1.1 Statutory Context

The 1996 amendments to the Safe Drinking Water Act (SDWA, 1996) require that EPA set priorities for addressing unregulated microbiological and chemical contaminants by first establishing a list of candidate contaminants that might be regulated in the future (Contaminant Candidate List or CCL); selecting five or more contaminants from the list to determine if they should be regulated; and then developing a regulation for those which meet the statutory criteria for regulation. The first CCL was promulgated in 1998 (USEPA, 1998) and the Agency's determination on whether or not to regulate five or more of the listed contaminants was to have been 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, or b) are known to, or likely to, occur at levels of public health concern. Further, the Administrator must determine that regulation provides a meaningful opportunity to protect public health. The *Research Plan for the Drinking Water Contaminant Candidate List* (USEPA, 2001) was developed to provide guidance on planning research to support regulatory decisions for contaminants on the first CCL and for the continuing identification of emerging pathogens and chemicals of potential public health concern.

1.2 The Draft Research Plan

The draft Research Plan (USEPA, 2001) addresses: 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 health effects, occurrence or treatment technology data or analytical methods development before a regulatory determination can be made). The goal of the CCL research effort "...is to provide scientific and engineering data needed to characterize and control the risks posed by exposure to unregulated contaminants of public health concern" (USEPA, 2001). 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 priorities category" or Phase II of the research process (i.e., the "research/occurrence priorities category"). Phase I considers available data to decide whether the contaminant might pose a public health hazard and if the contaminant can be treated with current practices. Some research may be needed during Phase I to support such decisions. The process culminates in a preliminary risk assessment/risk management analysis that decides whether the contaminant: a) presents an imminent threat to public health, b) poses a potential risk, or c) has an uncertain hazard potential. Imminent hazards would proceed immediately to the Regulatory Determination track while potential or uncertain risk/hazard contaminants would proceed to Phase II or Regulatory Determination depending on the adequacy of the existing data. It is important to note that for CCL Number 1, the Agency has already identified a subset of contaminants that have been determined to have sufficient data for a regulatory determination. These contaminants are identified in the Research Plan as "Regulatory Determination Priorities." The remaining contaminants are to go through the proposed research planning process to determine their research needs and whether they ultimately will need to be regulated.

In Phase II the Agency will identify and prioritize research needs based on their potential public health risk, conduct research to generate a comprehensive database, and then conclude 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. Phase II can then lead into the development of regulatory proposals and promulgation of drinking water standards (or possibly other types of guidance) for some of the contaminants.

The CCL Research Plan was developed by EPA in cooperation with a broad group of "stakeholders." It incorporates the results of an EPA-American Water Works Association Research Foundation (AWWARF) workshop in September 1999 (AWWARF, 1999; AWWARF, 2000). 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.

1.3 The Charge

The US EPA Science Advisory Board's Drinking Water Committee was given a charge that asked:

- a) if the two-phase decision process described in the research plan has a high probability of providing information appropriate for the Office of Water's regulatory determinations for CCL contaminants; and
- b) if the Science Advisory Board has any suggestions for improving the integrated planning of research on unregulated contaminants?

The final Charge to the Drinking Water Committee was shortened from the original charge that was the subject of the August 2000 meeting of the Committee. The charge now focuses on the decision logic that EPA has developed to identify research to be conducted on listed contaminants. The original charge asked for Committee advice on both the decision logic and the research developed on CCL Number 1. The Committee did not explicitly review the identified research, rather it focused on the decision logic itself. To the extent that the background information on specific CCL 1 research was a factor, it was in the sense that it provided a set of historical information to be used in evaluating that decision logic. That is, the information can be used to evaluate the logic to see, given the type of background information available for CCL 1, if the decision logic leads to a plan of research that will provide information needed by EPA's Office of Water to make its CCL regulatory determinations. The Committee response includes its conclusions, any concerns it has on a specific issue, and any suggestions for improvements that might be made by EPA in a combined discussion.

1.4 The Review

The Drinking Water Committee (DWC) of EPA's Science Advisory Board (SAB), convened on June 12-13, 2001 to complete the review of the Environmental Protection Agency's draft *Research Plan for the Drinking Water Contaminant Candidate List* dated February 21, 2001. The Committee first reviewed an earlier draft of the plan at its August 8-9, 2000 meeting and that review resulted in an Advisory to EPA noting their belief that it did not then have sufficient information on the individual contaminants, and the decision process and procedures used by EPA to decide on the research needs, to completely respond to the detailed charge questions. The Committee provided interim advice and asked for additional information in an Advisory dated September 27, 2000 (EPA-SAB, 2000).

The Advisory noted that:

- a) the document reviewed was more a research strategy than a plan. It lacked product and time commitments that the Committee considered to be cardinal attributes of a research plan. Further, the plan's treatment of the roles of the Implementation Team and others was not clear;
- b) the decision processes used in phases I and II were not transparent;
- c) EPA should place more emphasis on the process of research prioritization. The Committee believed it to be clear that the research needs substantially exceeded the resources available to the Agency for the program;
- d) the need for using expert groups in developing the first plan was recognized by the Committee and they believed that the Agency teams appeared to properly use 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 participate 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 specifics that are obtained in applying the method;
- e) their struggle with the question of what minimal data sets are needed to make decisions in the CCL process. They believed that the minimum data set for a regulatory determination was likely to be considerably different from that needed to develop a formal regulation. They recommended the development of a clear definition of minimum data sets required for regulatory determination and for development of full regulations;
- f) caution should be used when determining whether an organism is a waterborne pathogen. 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. Also, even when outbreaks are recognized, the specific etiologic agent is not identified in a significant portion of the outbreaks; and
- g) 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.

2. CONCLUSIONS AND RECOMMENDATIONS

The Committee considers the most recent version of the Research Plan for the Drinking Water Contaminant Candidate List (USEPA, 2001) to be a substantial improvement over the version reviewed during the Committee's August 2000 meeting. The Committee views the document provided by the Agency to be more a strategy describing a decision making process for developing a research plan than a plan itself. The two-phase process described in the research plan is understandable and does have a high probability of producing appropriate information for the Office of Water's regulatory determinations on CCL contaminants. However, for this process to be successfully implemented, more complete operational definitions will be required for many terms, concepts and criteria used throughout the plan. In particular, more explicit criteria need to be identified for ranking contaminants. With regard to the critical need for criteria, EPA should begin their development by tying them to the general statutory criteria for regulatory decision making (the determination that a contaminant may have an adverse effect on the health of persons, that it occurs with a frequency and at levels of public health concern, and that regulation presents a meaningful opportunity for health risk reduction). Finally it will be necessary for the Implementation Team to have the resources, time, and administrative support needed to play its coordinating role.

2.1 Science, Transparency and Public Involvement

<u>Recommendation Number 1</u>: The Committee recommends that in carrying out its CCL responsibilities, the Agency:

- a) use science effectively to evaluate the basis for its regulatory concerns,
- b) use a transparent decision-making approach, and
- c) make effective use of public participation.

The Committee believes that the general process outlined in the CCL Research Plan is basically sound and that one of its strengths is in its integration of the research decision making framework with the regulatory decision making framework. However, because of this integration, the task of evaluating and implementing the plan is much more complex. The regulatory process for the CCL and the research process reflected in the CCL Research Plan are clearly linked and each will have profound effects on the other. The integration reflected in the Plan also makes it more obvious that firm decision making criteria are absent from the plan for most of the critical decision points relevant to research directions as well as regulatory directions. The need for clear criteria are discussed further in this report.

Concerns about the decision-making framework were discussed by the Committee during its review meeting and the Committee is, therefore, making a number of recommendations that address some general concerns. Though not necessarily focused on the research elements of the

CCL process alone, the Committee felt that it was important to mention these issues because they are critical to the success of the research (science) and regulatory (policy) processes mentioned in the plan. These include the need for: a) transparency, b) adequate public participation, and c) science throughout the research and regulatory process.

Each of the three elements is related to the other. It might seem that science, alone, is the best solution. Unfortunately consensus in science requires many iterations of discussion, research, and peer review. Its pace is deliberate and does not always respond to the time requirements of the Agency. Regulations, on the other hand, are made in a legal climate and by their very nature they must respond to the schedules prescribed in the law.

Within the confines of scientific consensus, most scientists will give the same answer to questions on technical issues that are well understood (e.g., most will give the same answer when asked to determine the speed at which a steel ball will hit the ground when it is dropped from a height of 100 ft.). Where that consensus does not yet exist, many honest, competent scientists will give different answers (e.g. many will give a different answer when asked if a specific drinking water contaminant acts as a threshold carcinogen). As a result, scientific consensus cannot be expected to answer all our regulatory questions on schedule. The CCL Research Plan responds to the need for effective use of science in decision making by providing a framework for identifying specific research needs to support regulatory determinations and decisions. However, time and budget constraints may still impede the development of consensus for each contaminant of interest according to the schedule the regulatory process must meet.

Thus, the role of decision makers becomes critical because they are charged, on behalf of the public, with making the subjective judgements required when scientific consensus does not exist. While the decision maker must finally make those judgements he/she must also explain/defend the process used to make those decisions. These comments apply to decisions as to the quality of information and its suitability for use in regulatory determinations as well as in the regulatory determinations themselves.

This likely lack of consensus on many technical points, combined with the responsibility for decision makers to take decisive action, leads to the need to have transparency and public involvement. When procedures and outcomes are transparent, it is evident that a decision process is not subject to manipulation to achieve a desired outcome.

The call for public involvement is about stakeholders having the opportunity to participate in the decision-making dialogue and to attempt to protect their interests when they believe that the outcome of the decision process could threaten them. Transparency makes effective public participation possible. EPA should consider which decisions will be made in the CCL planning process that should be open to public involvement. The Committee believes that the decision that a contaminant is ready for regulatory determination, or that more information is needed, is one that should be made with full public involvement.

2.2 Near-Term Versus Long-Term Balance

<u>Recommendation Number 2</u>: The Committee recommends that the Agency articulate the manner in which the decision process will balance short-term and long-term investments to maximize public health protection.

An important planning issue that any organization must face is the natural tendency of circumstances to favor expediency over long-term investment. It is likely that EPA research managers will feel pressure to favor near-term investments designed to make progress in the current regulatory cycle (before the next CCL is published) and, as a result, will be pressed to defer some investments in long-term research. In such an environment, there is risk that long-term research that is of great importance to public health will not be funded. There is also another side to this same issue. First, some long-term research efforts sometimes develop fatal flaws that only become evident once the effort has been underway for some time. Second, even experienced research managers often need outside help in deciding when to wrap up an effort, because their focus is necessarily on what can be done to learn more.

In finalizing the CCL Research Plan, the Committee recommends that a substantial effort should be made to articulate how the decision process will balance short-term and long-term investments to maximize public health protection and how projects will be reviewed to measure the benefit of their continuation. Wherever possible objective guideposts should be provided.

2.3 Criteria for regulatory determinations, regulation development, and research prioritization

Recommendation Number 3. Regulatory and Research Integration. The Committee recommends that the Plan include a short section which clearly distinguishes between Phase 1 and Phase 2 research, including criteria for distinguishing between the two and several examples of each.

The general process outlined in the Research Plan is basically sound, however, EPA should provide operational definitions of many terms, concepts and criteria, mentioned in the plan or its goals may not be fully achieved (e.g., terms such as "adequate evidence," "quality study," "uncertain risk, etc.).

The Committee believes that the general process outlined in the CCL Research Plan is basically sound. As noted earlier, the Committee believes that a strength of the research plan is in its integration of both the research decision making and implementation process with the regulatory process that is envisioned for handling contaminants listed on the CCL. This is an improvement to research planning even though it contributes to the complexity of the plan. Integration clearly shows that the two processes, regulation and research, are inextricably linked and that the criteria to be met to move forward in the regulatory process will significantly influence the criteria for determining research priorities during Phase I and Phase II of the research process.

Because of the link between progress in the research program and movement in the regulatory program there is a need for a richer articulation of how the research and regulatory components of the overall process interact. There is also a need to define various terms used to describe the critical decision points that are built into the processes and to develop criteria for how those decisions are made. The Committee is concerned that because no operational definitions are provided for many key terms, concepts and criteria, the plan may not fully achieve its objectives. For example, terms such as "adequate evidence," "quality study," "uncertain risk," "regulatory determination", "regulatory decision" and so forth are used throughout the document without further definition.

The current CCL research plan does not clearly describe the information necessary to make a decision that a contaminant should be regulated and the information necessary to construct the regulation itself. The plan appears to indicate that the information needs for both decisions are the same. However, it seems that the time interval between regulatory determination and actual development of the regulation can be two or more years. Therefore, there is an implication that the information needs could be different at each of the two points in time.

When EPA evaluates the adequacy of information for making a regulatory determination, the outcome could be: a) to not regulate the contaminant, b) to regulate the contaminant, c) to develop guidance (health advisories), or d) to continue to conduct research on the contaminant. With this range of possible outcomes of regulatory determination, the goal of the CCL Research Plan should be to provide sufficient information on occurrence, health effects and treatability to support whatever outcome the Agency selects. Early recognition of the likely direction of the Agency decision will be important in prioritizing the research to be conducted. Over time, EPA should strive to have a research plan that reflects an appreciation for the different requirements of these four outcomes and that leads the research effort through a logical progression of information development.

Figure 2 of the Plan depicts an overview of the research and regulatory decision making process in a simplified manner. Figures 3 and 4 depict, separately, the process included in each of the two research program phases. Figure 4, a simplified flow diagram of Phase II of the research program, though helpful in understanding the process in general will not be a useful operational tool for the implementation team unless it more effectively captures some of the complexity of the process. As a minimum, this figure would benefit from more explanatory text on each of the process components, including details of the activities, decisions, decision criteria, and outcomes for each element in the process depicted.

The overall decision tree should more clearly identify "on ramps" and "off ramps" that reflect how contaminants might enter the process (other than via the CCL listing effort itself) or might be removed from further consideration.

2.4 Health Effects Criteria

<u>Recommendation 4:</u> The Committee recommends that EPA develop explicit criteria for ranking chemical contaminants that are being investigated under the CCL research Plan.

The objective of the CCL is to provide a "meaningful opportunity to reduce public health risk." The Committee is not clear about how the Agency ensures that contaminants with the greatest public health risks are placed on the list and, therefore, accorded a high priority for research and regulatory action. Listing should involve a systematic consideration of contaminant toxicity and occurrence/likelihood of occurrence to determine the potential for a health concern. The Committee's suggested goal would be to have research and regulatory priorities driven by health risk, and secondarily by costs, treatability and so on. The process should focus on real public health threats not just those that are easiest to remove from the list or those that have received the most attention in the news media.

The prioritization scheme discussed in the plan relies on expert judgement. The plan is not explicit in discussing the criteria used to make judgements in planning research, therefore, the Committee could not reconcile the results of the "test run" (from the EPA/AWWARF workshop) with the information presented for the specific chemicals. The Committee commented in its September, 2000, Advisory on issues and concerns with prioritization.

The Committee recognizes that in the design of any research or regulatory process there is an inherent tension between the desire to make the process as objective and transparent as possible and the realization that many subjective decisions are ultimately involved in the interpretation of scientific evidence. Further, it is likely that in any sequential process the early stages will necessarily be less formal and elaborate than the later stages.

Without objective criteria to judge the results of the research program for any contaminant, it will be difficult to identify a stopping point for the activity. Researchers can always uncover elements about which more useful information can be developed. In addition, the advice of experts is an excellent way to facilitate rapid decisions of a complex nature, but, studies have shown that the quality of the decision-making by expert groups is substantially improved when objective criteria for decision-making are identified.

The Plan should include a table specifying the criteria for prioritization of chemical research analogous to that included in Table 3 for Microbial Contaminants in the Plan (page 12 Feb 21, 2001 document). Flexibility should be allowed in application of the criteria. Inclusion of these criteria will provide transparency and lessen the perception that a chemical's priority is determined more by degree of public concern or private influence than by degree of public health threat.

Some specific attributes of chemical agents that can result in a public health threat are listed below. These can be used to guide the development of criteria for the prioritization or

ranking of chemicals for listing in the CCL, for further research and characterization, and for regulatory action.

- a) occurrence of chemical in source and finished water.
- b) concentration of chemical in source and finished water.
- c) exceedence of the target concentration level and frequency of detection at various degrees of exceedence.
- d) potency metrics for health effects (RfD, risk level, slope factor).
- e) observed concentrations or actual exposures relative to potency metrics for various adverse health effects.
- f) availability of dose response data for health endpoints: genotoxicity, cancer, reproductive and developmental effects, neurotoxicity, endocrine, immunotoxicity, or other target organ toxicities.
- g) subpopulations likely or known to be sensitive to the chemical (by reason of age, genetic predisposition, socioeconomic status, nutritional status, underlying diseases, etc).
- h) populations likely to be exposed (numbers of people exposed, and their characteristics).
- i) are other source contributions relevant (common exposures and relative source contribution should be considered).

The ranking criteria could be weighted to maximize public health benefit, such that research priorities focus on filling the data gaps for those chemicals with adverse health effects at plausible exposures. The rationale for why specific agents were included on the current CCL was not provided.

The implementation team is entrusted with the responsibility for determining a minimal data set for prioritization yet the criteria to be used have not been well laid out. Since the range of health effects is both wide and complex, this cannot be prescriptive. Still a minimal data set could be used for provisional RfD generation on the most sensitive/important toxicity endpoint(s). Although Appendix C contains some information on the health effects of the chemicals, there is no established criterion for placing agents in the high, medium, or low groupings. Furthermore, for the high priority compounds, what is known is not given.

Within the context of the research plan itself, the following criteria might be considered for distinguishing between Phase I and Phase II research:

- a) An over-arching criterion could be time. Phase I research would be research that could be designed, conducted and utilized in the current regulatory cycle (before the next CCL is published). Phase II research would be research that will not be completed and available in time to be utilized until subsequent regulatory cycles.
- b) A second criterion might be that research based on study, compilation and analysis of the literature would be classified as Phase I and research that will require significant field or laboratory work would be classified as Phase II.

2.5 The Implementation Team

<u>Recommendation Number 5</u>: The Committee recommends that the EPA make every effort to provide this team with the necessary time, resources, administrative support and authority to allow them to function effectively in this important coordination role.

The Implementation Team described in the revised CCL Research Plan of February 2001 plays a critical role in coordinating CCL-related research activities (both internal and extramural research). This group is also responsible for assessing the availability of data on CCL compounds and deciding whether the compound should be moved to regulatory determination, Phase II research or stay in Phase I. The Implementation Team is composed of senior scientists and managers from the Office of Water, the Office of Research and Development, the Office of Groundwater and Drinking Water, and the Office of Science and Technology. Currently, these individuals meet by telephone approximately every month to discuss ongoing CCL activities in their respective Offices and consider research needs and priorities. It is apparent that the successful implementation of the CCL Research Plan depends on effective interactions between these representatives from different parts of EPA. The Committee recommends that the EPA make every effort to provide this team with the necessary time, resources, administrative support and authority to allow them to function effectively in this important coordination role. Recommendations from the Implementation Team on funding for CCL research priorities need to be followed by appropriate budget commitments from the fiscal administrators otherwise this CCL Research Plan will not be viable.

REFERENCES

- AWWARF (1999). *Drinking Water Research Needs Expert Workshop*. Background information for the workshop held jointly between US EPA and the American Waterworks Association Research Foundation, September 27-29, 1999. American Water Works Association Research Foundation, 1999.
- AWWARF (2000). Research Needs Report: Report From Expert Workshop on Drinking Water Research, Leesburg, Virginia, September 27-29, 1999. American Water Works Association Research Foundation, 2000.
- EPA Science Advisory Board (2000). An SAB Advisory on EPA's Draft Contaminant Candidate List Research Plan. EPA-SAB-DWC-ADV-00-007, September 27, 2000.
- Safe Drinking Water Act Amendments of 1996 (1996). Public Law 104-182; August 6, 1996.
- USEPA (1998) Announcement of the Drinking Water contaminant Candidate List. Federal Register Vol. 63, No. 40, pp. 10274-10287m March 2, 1998.
- USEPA (2001). Research Plan for the Drinking Water Contaminant Candidate List. US EPA Office of Research and Development. February 21, 2001.