Stakeholder Meeting on the Contaminant Candidate List and the 6-Year Review of Existing National Primary Drinking Water Regulations November 16-17, 1999 Meeting Summary

The U.S. Environmental Protection Agency's (EPA) Office of Ground Water and Drinking Water (OGWDW) held the first in a series of stakeholder meetings regarding the contaminant identification and selection process and the process by which to perform a 6-year review of existing National Primary Drinking Water Regulations (NPDWRs) on November 16-17, 1999 in Washington, DC. The meeting was held at the offices of RESOLVE, Inc., and facilitated by Paul De Morgan, a Senior Mediator with RESOLVE, with assistance from Jeff Citrin, Associate. The 1996 Amendments to the Safe Drinking Water Act (SDWA) [Section 1412(b)(1)] require EPA to establish a list of contaminants (the Contaminant Candidate List or "CCL"), and revise it every five years, to aid in priority setting for the Agency's drinking water program. The SDWA requires EPA to make regulatory determinations for at least five contaminants every five years as to whether NPDWRs are necessary. The SDWA, as amended [Section 1412(b)(9)], also requires that, on a six-year cycle, EPA review and revise, as appropriate, each existing NPDWR ("6-Year Review"). All revisions must either maintain or provide for greater protection of the health of persons.

In regard to the CCL process, EPA provided a program update and sought comment from stakeholders on: 1) the regulatory determination process and, in particular, on specific factors to consider when making regulatory determinations from the first CCL, published in March 1998; 2) the draft research strategy EPA has formulated in order to fill data gaps for contaminants identified on the Agency's first drinking water CCL; and 3) the process for developing future CCLs. The portion of the meeting related to the 6-Year Review provided stakeholders with an opportunity to: 1) provide input on the process EPA should use for identifying and prioritizing NPDWRs for revision; and 2) engage in dialogue with EPA on the various components of the preliminary analyses planned or already initiated by the Agency, including its reviews of analytical methods, treatment technologies, health effects, occurrence, and exposure. The meeting agenda can be found as Attachment A.

Participants at the meeting included representatives of public water utilities, State drinking water programs, public health and environmental groups, local government, the private sector, EPA, and other federal agencies. A list of participants is included as Attachment B. EPA Issue Papers prepared for topics related to the CCL and those prepared for consideration of the 6-Year Review were provided to participants prior to the meeting. They are included as Attachment C.

Day 1 - Contaminant Identification and Selection Process

The first day of the two-day meeting was devoted to consideration of the current status and plans for the process of contaminant identification and selection. This includes the methods for making regulatory determinations for particular chemical compounds and microbes from the CCL. EPA managers and staff made eight presentations that included an overview of current EPA drinking water programs, the context of contaminant identification and regulation in SDWA, contaminant-specific information needs for making regulatory determinations (e.g., on contaminant occurrence, health effects, treatment technologies, and analytical methods), and the strategy and priorities for research activities to collect the necessary data. In addition, EPA presenters posed questions to encourage comment on issues they were particularly interested in hearing from stakeholders on. During the discussion that followed each presentation, participants and presenters made additional points, requested and provided clarification to the material presented, and posed and answered follow-up questions. Options for the process of making regulatory determinations from the CCL was the focus of considerable discussion on this day. A complete list of these questions posed by EPA presenters is included as Attachment D. Those on which participants

provided comments are included in the summary below. (Speakers' presentation materials are included as Attachment E.)

A.Overview of Drinking Water Program Goals and the Contaminant Identification and Selection and 6-Year Review Activities

Ephraim King (Acting Director, Standards and Risk Management Division, OGWDW) provided an overview of, and context for, SDWA and the methods by which EPA sets drinking water standards, in particular how the CCL and 6-Year Review are conducted and used. He also highlighted the stakeholder involvement process that will be used to inform development of these programs.

B. Contaminant Identification and Regulation Under SDWA

Mike Osinski (CCL Team Leader, OGWDW) supplied detailed background on the contaminant identification requirements of the SDWA Amendments of 1996, and the development of the first CCL and its importance in determining regulatory priorities. He also reported on the current status of Agency activities related to the contaminant identification and regulatory priorities determination process.

Mr. Osinski explained that the CCL contains 60 chemical contaminants and microbes. The Agency has the necessary data to support regulatory determinations for the 12 contaminants (11 chemical contaminants and one microbe, *Acanthamoeba*) now on the Regulatory Determination Priorities list. However, it is possible, although unlikely, that data gaps on other additional contaminants (e.g., MTBE, perchlorate) may be filled in time to move these contaminants into the Regulation Determination Priorities category and include them in the pool of contaminants for regulatory determination by 2001.

Based on a participants question Mr. Osinski clarified that, for a given contaminant, the regulatory determination process may result in a decision to regulate with a NPDWR, not regulate, or provide guidance on the contaminant (e.g., issue a Health Advisory). Once a regulatory decision is made for a contaminant, it will be removed from the CCL.

In response to a participant's comment on the need for transparency in the Agency's regulatory determination process, Mr. Osinski reported that EPA will produce a detailed Regulatory Determination Support Document in the process of making its regulatory decisions. This document will lay out the rationale for the Agency's decisions and provide a review of all the data used to support the decisions. Evelyn Washington (Associate Chief, Targeting and Analysis Branch (TAB), OGWDW), discussed the Expert Workshop on Drinking Water Research Needs. The American Water Works Association Research Foundation (AWWARF) and EPA jointly sponsored this meeting on September 27-29, 1999. Ms. Washington explained that a summary of this meeting is still in preparation, but will become available on the AWWARF EXIT Disclaimer web site. Mr. Osinski stated that the AWWARF workshop was also useful in confirming that EPA had classified the CCL contaminants in the appropriate categories.

Several participants noted that several of the compounds on the Regulatory Determination Priorities list, in particular Aldrin and Dieldrin, are pesticides that have been banned in the US for many years. They voiced their concern about the lag time in regulating such compounds and called for concentrating on compounds in current use. Mr. Osinski acknowledged these comments and noted that coordination between Agency programs (e.g., the Office of Pesticide Programs (OPP) and OGWDW) poses challenges.

Participants commented on the overall high quality and informative nature of the briefing documents.

C. Data Evaluation for Regulatory Priority Contaminants/Occurrence

Karen Wirth (OGWDW) provided a status report on EPA efforts to identify and gather adequate occurrence data on the 12 regulatory priority contaminants for use in the regulatory determination process.

EPA Question: What factors should be considered in the interpretation of the occurrence data?

- Several participants commented that decision makers should be the ones to set occurrence data gathering needs.
- One participant asked whether EPA, given its mandate to regulate contaminants on a national level, is able to identify regional contaminant problems. Mr. Osinski replied that, if the occurrence data indicate the number of people potentially exposed are small and limited geographically, the Agency could choose to issue related guidance (e.g., a Health or Consumer Advisory) for that contaminant. Another participant pointed out that States might choose to apply the guidance or to develop their own regulation under the States' primacy authorities.
- An EPA staff member from Region III noted that studies conducted by the United States Geological Survey (USGS) principally sample shallow wells and do not adequately represent the drinking water served to customers of public water systems (PWSs) in Pennsylvania, who are chiefly supplied by deep wells.

A. Data Evaluation for Regulatory Determinations / Health Effects

Joyce Donohue (Office of Water, Office of Science and Technology, Health and Ecological Criteria Division (OW/OST/HECD)) reported on the current status of EPA's health effects evaluations for CCL Regulatory Determination Priority Contaminants.

Rita Schoeny (Associate Director, OW/OST/HECD) noted that, for health effects data on pesticides and their metabolites, OW relies on the analyses and reports of the OPP. OPP houses the particular expertise for analyzing the toxicity of these substances.

In response to participant questions about contaminants on the Research Priorities list, Dr. Donohue reported that the OPP's reassessment of triazines would not be completed in time to allow for regulatory determination by 2001. Mr. Osinski reported that, as with all of the contaminants on the Research Priorities and Occurrence Priorities categories, once the data gaps for a given contaminant are filled, it will be moved to the Regulatory Determination Priorities category for consideration in the next five-year cycle. If there is evidence that the contaminant poses an urgent threat to public health, the Agency has authority under SDWA to issue an interim NPDWR more quickly than the normal regulatory process requires. EPA can also consider issuing a health or consumer advisory prior to the next CCL regulatory determination cycle.

Dr. Schoeny reported that the Agency currently uses a drinking water consumption rate of 2 liters per day, (90^{th} percentile) in risk assessments to support development of NPDWRs. A study assessing consumption patterns for many population groupings is currently being reviewed by EPA's Science Advisory Board.

EPA Question: Are there other types of health effects studies that should be considered in making regulatory determinations?

- A participant suggested the use of occupational data. Dr. Donohue replied that some has been used, but her office does not have much of this type of data.
- In reply to participants' comments, EPA staff noted that SDWA requires EPA to use the best available peer-reviewed science and that EPA's in-house analyses are subject to rigorous review.
- Dr. Donohue explained that when EPA is presented with conflicting studies, the Agency looks to the *mode of action* (i.e., information that helps explain critical events in an agent's influence on

the development of tumors) of the contaminant in causing the health effect(s). Studies not related to the mode of action are often de-emphasized. Dr. Schoeny added that, in addition, her office would consider the weight of evidence, whether the study was performed in accordance with risk assessment guidelines and other guidance documents, and whether any related information is available on EPA's Integrated Risk Information System (IRIS).

EPA Question: Are there additional sources of health effects information that EPA should consider in regulatory decision making?

- In response to a participant's suggestion, Dr. Donohue reported that health profiles from the Agency for Toxic Substances and Disease Registry are considered by her office.

A. Analytical Methods for CCL Regulatory Priority Contaminants

Jeanne Campbell (OGWDW) reviewed the status of existing analytical methods for the 12 contaminants that are ready for regulatory determinations. She also discussed the necessary next steps for contaminants if a decision is made to develop NPDWR for a contaminant.

B. Treatment Technologies

Yvette Selby (OGWDW) briefed participants on EPA's preliminary assessment of treatment technologies for the 12 regulatory determination priority contaminants.

A participant commented on the absence of an economical technique for treating large volumes of drinking water contaminated with boron. Ms. Selby noted that, for all contaminants selected for regulation, treatment costs will be considered during development of the proposed NPDWR. However, EPA's efforts to date have focused on identifying whether treatment technologies exist for the 12 regulatory determination priority contaminants. Ms. Selby noted that the Agency welcomes stakeholders' contributions of related data and supporting information.

In response to the issue of many small and tribal water systems' inability to afford expensive treatment, Jim Taft (chief, OGWDW/TAB) explained that under SDWA the affordability of listed treatment technologies to small systems and very small systems is analyzed. Where no affordable technologies are available, EPA identifies variance technologies and grants variances to small systems upon consideration of their applications.

C. Considerations in Making Regulatory Determinations From the CCL

Mr. Osinski explained the currently envisioned process by which regulatory determinations from the CCL will be made. Although the SDWA stipulates three general criteria to be met in order to make a decision to regulate a contaminant, there is a certain degree of flexibility in designing the process. He noted stakeholder input is welcome and can assist the Agency in designing a scientifically sound and transparent process that achieves the goals as stated by Congress in the SDWA.

Mr. Osinski explained that out of the three criteria specified in SDWA for making a regulatory determination, how to answer the first question will be straightforward (i.e., does the contaminant adversely affect public health?). To answer this question, the Agency will have developed a reference dose and/or a cancer assessment when a contaminant is placed in the regulatory determination priority category. He noted that EPA is very interested in stakeholder input on how to use the data and risk estimates to answer, both in quantitative and qualitative fashion, the other two SDWA criteria for making a regulatory determination.

EPA Question: What are the important quantitative and qualitative factors to assess in making regulatory determinations? Is it reasonable to rank or weight these factors? If so, how?

- Contaminants of greatest concern to the public and posing greatest potential risk to public health should receive priority for placement on the CCL and research to support regulatory determination. A participant advised the Agency to be cautious it does not simply focus on contaminants for which data is rich, to the exclusion of those that should be true priorities. Dr. Schoeny indicated EPA is sensitive to these concerns and consciously works to avoid penalizing those that gather and submit appropriate data of good quality.
- A participant commented that it is unclear what specific criteria EPA has used to decide when there is sufficient data to move a contaminant from the Research and Occurrence Priority category to the Regulatory Determination Priority category.
- A participant suggested that EPA should take into consideration the relative source contribution from drinking water in regulating the contaminant.

EPA Question: Is there occurrence data that can define the difference between a decision to regulate, develop guidance, or remove from the CCL? For example, under what situation(s)

would guidance (e.g., health advisory) be more appropriate than a regulation?

- A participant recommended that EPA use ambient water data in its analyses to support the decision whether to regulate or issue guidance for a contaminant.

A. Status of the CCL Research Strategy

Bob Clark (Senior Engineering Advisor, Office of Research and Development (ORD)) discussed the current strategy for research to fill CCL data gaps (i.e., for health effects, treatment technologies, and analytical methods).

Mr. Clark highlighted the opportunities for stakeholder input on the CCL Research Strategy, including the previously-mentioned EPA/AWWARF-sponsored Expert Workshop on Drinking Water Research Needs, meetings of the Science Advisory Board which are open to the public and allow for comment, and presentations at professional meetings and stakeholder meetings. Ms. Washington noted that EPA is contemplating initiating a stakeholder process with meetings focusing on the research strategy. She also explained that the Agency, based on a recommendation from the National Drinking Water Advisory Council, is planning on establishing a working group on the research strategy which will likely meet for the first time in early 2000. Ms. Washington told participants that a Federal Register notice would soon be published inviting interested individuals to identify themselves. She agreed to send this information to all meeting participants when it becomes available.

A participant recommended EPA consider degradation products when it examines pesticides. He noted that in New York, metabolites have been detected at higher levels than their parent compounds. Consequently it may be appropriate to consider regulating one or more metabolites of a pesticide in addition to, or in place of, the parent compound. Ms. Washington pointed out that OPP now assesses the parent component and all degradates when it analyzes pesticides.

B. Unregulated Contaminant Monitoring Under SDWA/Occurrence Priorities

Chuck Job (Unregulated Contaminant Monitoring Rule (UCMR) Team Leader, OGWDW) explained the role of the Unregulated Contaminant Occurrence Database in filling occurrence data gaps for contaminants on the CCL listed as occurrence priorities.

EPA Question: Should CCL 2003 include monitoring research as a category for contaminants if it is not obvious where and when they should be monitored to obtain the best results through the UCMR implementation?

- Mr. Job noted that *Aeromonas hydrophila* - which is now on the Occurrence Priorities list and the UCMR - poses monitoring problems. It exists both as biofilms and in distribution systems, where it may slough off. Although it is treatable, it can recur. He asked participants to suggest where, in PWSs, monitoring for this microbe should take place. A participant recommended that monitoring for any contaminant thought to be a threat to public health should be done where it is found to occur. For example, if it is found to occur in source water, the source water should be monitored. Otherwise, additional exposure may occur before the water reaches the monitoring point (e.g., if the contaminant occurs in surface water but is monitored somewhere in the distribution system, swimmers in the source water may be exposed to the contaminant).

A. Next Steps

Mark Gibson, of the Water Science and Technology Board at the National Research Council (NRC) provided citations for two recent documents National Research Council on emerging contaminants: "Setting Priorities for Drinking Water Contaminants" and "Identifying Future Drinking Water Contaminants." They are available on the National Academy Press EXIT Disclaimer web site, at http://www.nap.edu/. He also noted a current NRC project to develop quantitative and semi-quantitative methods for narrowing the broad universe of potential contaminants to those most likely to occur in drinking water resources.

Mr. Osinski thanked participants for their thoughtful input and encouraged stakeholders to continue to submit comments. Although there is no specified deadline, they should be submitted as soon as possible in order to receive more thorough consideration. He indicated overarching comments could be directed to himself or, if they are related to a specific presentation, to the appropriate EPA staff presenter (see Attachment F for contact information). EPA will move forward with its efforts in developing the regulatory determination process. Mr. Osinski stated that the Agency expects to present more concrete process options at future consultations with stakeholders. He noted there was not time in the agenda to address several additional topics at the meeting (e.g., future CCLs), and that the Agency would emphasize these activities in future stakeholder meetings.

- A participant requested EPA hold public meetings, on selected contaminants, during development of proposed NPDWR's. Mr. Osinski agreed and indicated frequent stakeholder outreach and dialogue is standard OGWDW practice during regulation development.

Day 1 - 6-Year Review of Existing NPDWRs

The 6-year review of existing NPDWRs was the focus of the meeting's second day. Topics for presentation and discussion included the current status of, and future plans for, EPA's activities to meet this mandate under the SDWA Amendments, as well as identification of gaps and solicitation of suggestions for improvements to these relatively early stage plans. EPA staff made five presentations including: 1) an overview of current EPA drinking water programs; 2) a review of EPA's program design for the 6-year review; and considerations related to 3) health effects, 4) occurrence, and 5) analytical methods. Each presentation, except for the first one, was followed by a public comment period. The final session of the day was an open discussion intended to give participants an opportunity to ask questions not already answered and raise related issues of interest.

A. Overview of Drinking Water Program Goals and the Contaminant Identification and Selection and 6-Year Review Activities

Jim Taft (Chief, Targeting and Analysis Branch, OGWDW) reiterated the points made by Mr. King at the start of the previous day's deliberations. In doing so, he provided an overview of and context for SDWA and the methods by which EPA sets drinking water standards, in particular how the CCL and 6-Year Review are conducted and used. He again highlighted the stakeholder involvement process that will be used to inform development of these programs.

B. Overview of 6-Year Review

Marc Parrotta and Judy Lebowich (6-Year Review Co-Team Leaders, OGWDW) reviewed the mandate for the 6-year review under SDWA, and assumptions being made by the Agency as well as the timeline and the process protocol for meeting the first review by 2002.

While one participant voiced concern that relaxing standards should not be an option resulting from review and revision of an NPDWR, another pointed out that if health effects information shows that a contaminant poses lower health risk than was believed at the time of its original regulation, EPA should consider revising the maximum contaminant level goal (MCLG) upward. Mr. Taft stated that changes to the MCLG have to at least maintain health protection. Consequently, he indicated, upward adjustments could be interpreted by the EPA Office General Counsel as acceptable under SDWA.

In response to a question as to whether States must continue to test for contaminants that have been shown to be absent from its water, Ms. Lebowich informed participants that States with low vulnerability may have less frequent monitoring needs and may be allowed to scale back testing for such contaminants, resulting in monitoring cost savings. To do so, States must apply to EPA for waivers. Mr. Taft explained that in the upcoming 6-Year Review, the Agency has greater flexibility than in the past to make risk-based regulatory decisions.

EPA Question: Any suggestions on scheduling of 6-year review to meet statutory requirements?

- A participant encouraged OGWDW to collaborate with other EPA offices, which make use of MCLs, on the NPDWR revision process. Although, Ms. Lebowich noted there has been some discussion with the Office of Solid Waste, Mr. Taft explained that MCLs are established for the use of PWSs and their use for other purposes is not a primary consideration.

EPA Question: How should priorities for regulatory revision be set?

- A participant urged EPA to focus its limited resources in the 6-Year Review on opportunities to improve public health, rather than reviewing all 66 existing standards eligible for review.
- A participant suggested EPA consider incremental costs and benefits in making decisions.

EPA Question: Is the draft protocol reasonable?

- A participant commented that the draft protocol seems reasonable. He expressed concern that, if sufficient data for a NPDWR revision analysis is not ready in time for the 6-Year Review, a contaminant might miss the review and be placed on hold for another 6 years. Mr. Taft explained that if data becomes available in the period between two 6-Year Reviews, EPA would probably be inclined to act on that contaminant sooner than the next 6-Year Review. Another participant suggested the Agency also consider revisions to health advisories as an interim tool.
- As an additional proposed screen, a participant suggested EPA could identify geographic areas in which the contaminant does not occur. PWSs located in these areas would then be allowed to scale back on the monitoring frequency - thereby saving on monitoring costs - once they show the contaminant not to be a problem.

EPA Question: Is stakeholder strategy sufficient? When/where should stakeholder meetings be held?

- A participant suggested that in order to encourage broader State and wider geographic input, a future stakeholder meeting should be held in Denver.

A. Chemical Health Effects

Joyce Donohue (OW/OST/HECD) addressed the factors that will go into the evaluation of health effects of the contaminants to be screened under the 6-year review.

In response to a participant's question on whether and how EPA seeks health effects data from manufacturers of compounds that are drinking water contaminants, Dr. Donohue explained that after EPA identifies data gaps, it attempts to make them known so that entities (e.g., industry) with applicable data can identify where they can help. Further, when data is accepted from manufacturers, it undergoes review both internally, at the Agency, and is also sent for independent, outside review.

EPA Question: Do EPA IRIS and OPP assessments represent a reasonable way to screen contaminants for review? Would there be other assessments upon which to base a screening decision?

- A participant, who agreed the proposal seems reasonable, also suggested EPA consider making use of the World Health Organization documentation.
- Another participant recommended that the most vulnerable populations should be the focus of such assessments. Dr. Schoeny explained that when EPA re-evaluates NPDWR contaminants, it will perform complete evaluations, which will include analysis of sensitive subpopulations (including those that consume drinking water at the high end of the frequency distribution and people of low body weight) and characterization of health end points. She noted, however, that the Food Quality Protection Act 10-fold safety factor will not be applied universally.

EPA Question: Is the proposed overall approach sufficient to support EPA's decision making on revisions to a NPDWR?

- A participant suggested that additional screens to trigger a contaminant as a Health Effects Priority may include "Is the MCLG for a non-carcinogen much higher than if it was a carcinogen?" and one that considers a contaminant's structural/family history. These would help address concerns relating to compounds such as 1,1,1,-trichloroethene, which is a class D non-carcinogen to which populations are exposed at high levels, yet no significant health effects studies have been performed on this contaminant for decades.
- Another participant suggested surveying regulatory practices in other developed countries and those used by States.

A. Regulated Contaminant Occurrence

Peter Lassovszky (OGWDW) highlighted the background and approach to be used in regard to occurrence to satisfy the data needs of the 6-year review. Ed Thomas (OGWDW) then briefed participants on the Agency's current status in gathering this data and pointed to specific data gaps. Andrew Schulman (OGWDW) explained the need for, and constraints in, applying statistical methods to the available occurrence data in order to arrive at contaminant-specific estimates of national occurrence.

In response to a participant's questions, Mr. Parrotta and Ms. Lebowich explained that EPA plans to produce an occurrence document and will have supporting documents available at the time the draft list of NPDWRs is published for review in the Federal Register in August 2001. These documents will include the results of the screening phase as well as an explanation of the analyses performed to reach them. Ms. Washington noted that this information will probably be out for comment sometime between Fall 2000 and Fall 2001. She further pointed out that there will be additional opportunities for stakeholder involvement prior to August 2001. The inquiring participant suggested that stakeholders could use this

information as a tool to identify where additional data is needed and guide their efforts in voluntarily pulling together available data for submission to EPA to fill those gaps.

EPA Question: Is the approach and sampling of States used to generate a national cross-section of contaminant occurrence reasonable?

- A participant indicated using data from 12 States seemed reasonable, given the lack of other data. Mr. Thomas and Mr. Lassovszky noted several barriers to EPA's requesting data from many States; these include requirements of the Office of Management and Budget (information collection process), the time lag from request to receipt, and the need for high quality data (i.e., data that has undergone quality control and assurance analyses). They stated that voluntary submissions of applicable State databases are welcome. A participant stated his belief that EPA will receive a considerable amount of State occurrence data once a determination reaches Stage 2.
- Another participant articulated his support for the outlined approach.
- A participant suggested that EPA consider making use of MCL violation data. Mr. Thomas explained that the only tool for accessing this data is the State Drinking Water Information System (SDWIS). Recognizing the difficulties posed by the use of SDWIS for this purpose, the participant withdrew the suggestion.

EPA Question: Is the proposed statistical screen reasonable? Are the criteria for high occurrence and low occurrence reasonable?

- A participant indicated the proposed statistical screen is reasonable.

EPA Question: What additional information is required for a reliable, scientifically sound analysis of occurrence?

- A participant suggested that relative source exposure (e.g., through food consumption, inhalation, etc.) be considered in assessing population exposure.
- A participant requested EPA incorporate consideration of populations potentially exposed into its occurrence analysis. In response, Mr. Thomas replied that the data can be linked to SDWIS. Mr. Schulman indicated EPA will make this link.

A. Analytical Methods and Reassessment of Practical Quantitation Limits

Wynne Miller (OGWDW) focused on the potential need for and methods for reassessing contaminant practical quantitation limits (PQLs).

EPA Question: What other issues or factors should be considered for the initial PQL screening process?

- In looking at State data, a participant suggested EPA might want to examine the laboratories reporting and the methods used in the last few years. This would require combining the PQL consideration with the occurrence data. If, upon inspection, the PQLs are near the acceptable cancer levels, it may be necessary to reduce these PQLs.

A. Open Discussion

At the end of the second day, EPA staff asked participants to pose outstanding questions and voice additional suggestions on any issues related to the 6-year review process. In addition, based on the

earlier discussions, EPA staff identified four questions, building on the comments throughout the meeting, they felt might be useful to focus the discussions. These questions, and associated comments, are below.

A participant suggested EPA consider developing administrative changes that can simultaneously improve public health protection and also allow for better use of resources (i.e., savings of funds and time).

EPA Question: Is there a fundamental flaw in the basic approach?

- A participant observed that while the ways in which the approach deals with known and new information is well thought out, how to deal with "unknowns" is not.
- He also noted that addressing these needs must be made a priority in the research budget.
- In regard to the previous point, Ms. Washington explained that while 6-year review is a drinking water program priority, it is not yet a research priority. Review-related topics must be incorporated into OGWDW's Comprehensive Research Plan, which the office will complete in cooperation with ORD by the end of 2000. However, she reminded participants that, as OGWDW is engaged in many significant activities (e.g., CCL, M/DBP, Arsenic Rule, 6-Year Review), there are many competing demands on its limited research budget.
- A participant called for the end to the exclusion of private well water users from NPDWR requirements and occurrence sampling. Ms. Washington pointed out that this topic was beyond the scope of this meeting, but noted that EPA is discussing internally how and whether it can participate in such activities.

EPA Question: Are there additional screens we should be considering?

- In response to a participant's question, Mr. Parrotta explained there is no treatment technology screen because treatment is not a driver for setting MCLs. However, EPA will update available treatment technologies for smaller systems.

EPA Question: Are there concerns about particular contaminants?

- A participant on the phone commented on the application of the lead rule and the experience of its implementation in Madison, Wisconsin. Mr. Parrotta advised that in order to change this legislative mandate the participant might consider seeking to influence Congress.
- A participant suggested that EPA consider revisiting the Total Coliform Rule as an opportunity to rework the rule to be more protective of human health. The problem seems to be in the implementation rather than with the standard itself.
- In regard to the previous comment, a Association of State Drinking Water Administrators representative indicated they will prepare written comments for submission.

EPA Question: Thoughts on how we pull it all together and begin to prioritize?

- A participant proposed that at some time, early on, a higher level staff member should look at the process from the "top down" in order to give an overarching assessment.

A. Wrap-Up And Next Steps

Mr. Thomas noted EPA is relying on the assumption that, in general, the existing drinking water standards are pretty good and will not require much revision. Dr. Donohue announced that the Safe Drinking Water Hotline (1-800-426-4791) could provide referrals to individual chemical managers.

Mr. Parrotta thanked stakeholders for their input and asked that they continue to provide written comments, especially on how to put the screens together. He indicated overarching comments could be directed to Ms. Lebowich and himself or, if they are related to a specific presentation, to the appropriate EPA staff presenter (see Attachment F for contact information). Ms. Lebowich explained that a draft list of the NPDWRs expected to need revision, as well as supporting documentation laying out the rationale for these decisions, will be available by August 2001. EPA will then take comment on this list. In the shorter term, however, she indicated more information related to this effort will be placed on the EPA web site and EPA staff will start planning for the next stakeholder meeting.

Attachments

A. Discussion Questions Posed by EPA Presenters
B. EPA Staff Presenters Contact Information

Discussion Questions posed by EPA staff

Contaminant Identification and Selection Process

Occurrence

- What additional data sources should EPA be reviewing (States, industry, or the scientific community)?
- What factors should be considered in the interpretation of the occurrence data?

Health Effects

- Are there other types of health effects studies that should be considered in preparation for regulatory decision making?
- Are there additional sources of health effects information that EPA should consider in regulatory decision making?
- What factors should be considered in prioritizing the toxicological review work?

Analytical Methods

- Has EPA appropriately considered the role of analytical methods in the regulatory determination process?

Treatment Technologies

- Has EPA appropriately considered the role of Analytical Methods and Treatment Technologies in making regulatory determinations?

Regulatory Determinations

- What are the important quantitative and qualitative factors to assess in making regulatory determinations? Is it reasonable to rank or weight these factors? If so, how?
- Is there occurrence information that can define the difference between a decision to regulate, develop guidance, or remove from the CCL? For example, under what situation(s) would guidance (e.g., health advisory) be more appropriate than a regulation?
- How should ambient water quality data be used with PWS occurrence data to support regulatory decisions? Under what circumstances is it reasonable to make a regulatory determination in the absence of PWS occurrence data?
- In what ways should the regulatory determination process be different for microbes and chemicals?
- Should occurrence data be weighted with release or production data? If so, how?

Occurrence Priorities and the Unregulated Contaminant Monitoring Rule

- Is the timing of data receipt adequate for informing the decisions for occurrence priorities and /or regulatory determination for CCL 2003?
- How should the data be made available to best inform the decisions for occurrence priorities of CCL 2003: in raw form, summary form, statistical presentation, geographically portrayed, or other formats?
- What should happen with contaminants for which there will still be limited or no data at the time of finalizing CCL 2003?
- There is a 1½-year lag between UCMR and CCL updates. Although this lag provides an opportunity to develop analytical methods for newly listed contaminants, should these two processes be brought closer into synch?
- Should and how could the UCMR monitoring process be adjusted to provide more data sooner to the CCL 2008 development process?
- Should CCL 2003 include monitoring research as a category for contaminants if it is not obvious where and when they should be monitored to obtain the best results through the UCMR implementation?

6-Year Review of Existing NPDWRs

Program Design

- Any suggestions on scheduling of 6-year review to meet statutory requirements?
- Should EPA consider another way to group NPDWRs for review? How?
- Is there any scenario under which a contaminant may be "deregulated"?
- How should priorities for regulatory revision be set?
- Is the draft protocol reasonable?
- Is stakeholder strategy sufficient? When/where should stakeholder meetings be held?

Health Effects

- Do EPA IRIS and OPP assessments represent a reasonable way to screen contaminants for review? Would there be other assessments upon which to base a screening decision?
- Is the end of Fiscal Year 2000 a reasonable cut-off date for considering new health effects information for the first 6-Year round of review?
- Should EPA update health effects information for only those contaminants that are on the final list of priority chemicals requiring review?

- Should EPA consider concerns other than developmental and reproductive effects in its evaluation of health criteria?

Occurrence

- Is the proposed overall approach sufficient to support EPA's decision making on revisions to a NPDWR?
- Is the approach and sampling of States used to generate a national cross-section of contaminant occurrence reasonable?
- Is the proposed statistical screen reasonable? Are the criteria for high occurrence and low occurrence reasonable?
- What additional information is required for a reliable, scientifically sound analysis of occurrence?

Analytical Methods

- What other issues or factors should be considered for the initial PQL screening process?
- Other questions or comments?

Open Discussion

- Is there a fundamental flaw in the basic approach?
- Are there additional screens we should be considering?
- Are there concerns about particular contaminants?
- Thoughts on how we pull it all together and begin to prioritize?
- Are there any additional compounds missing that seem should be on the list for NPDWR revision but will not be caught by the screens?

EPA STAFF PRESENTERS' CONTACT INFORMATION

Contaminant Candidate List Process (CCL)

Name	Address/Mail Code *	Phone	Fax	E-Mail
Mike Osinski Team Leader	4607	202/260-6252	202/260-3762	osinski.michael@epamail.epa.gov
Karen Wirth Occurrence	4607	202/260-0720	202/260-3762	wirth.karen@epamail.epa.gov
Joyce Donohoe Health Effects	4304	202/260-1318	202/260-1036	donohoe.joyce@epa.gov
Yvette Selby Treatment Technologies	4607	202/260-4050	202/260-3762	selby.yvette@epamail.epa.gov
Jeanne Campbell Analytical Methods	4607	202/260-7770	202/260-3762	campbell.jeanne@epamail.epa.gov
Bob Clark Research Priorities/ Strategy	26 W. Martin Luther King Drive (MS 689) Cincinnati, OH 45268	513/569-7201	513/569-7658	clark.robertm@epamail.epa.gov
Chuck Job	4607	202/260-	202/3762	job.charles@epamail.epa.gov

Occurrence Priorities/ Unregulated Contaminants Monitoring		7084		

6-Year Review of NPDWRs Process

Name	Address/Mail Code *	Phone	Fax	E-Mail
Judy Lebowich Team Co-Leader	4607	202/260-7595	202/260-3762	lebowich.judy@epa.gov
Marc Parrotta Team Co-leader	4607	202/260-3035	202/260-3762	parrotta.marc@epa.gov
Joyce Donohoe Health Effects	4304	202/260-1318	202/260-1036	donohoe.joyce@epa.gov
Peter Lassovszky Occurrence	4607	202/260-8499	202/260-3762	lassovszky.peter@epa.gov
Andrew Schulman Occurrence	4607	202/260-4197	202/260-3762	schulman.andrew@epa.gov
Ed Thomas Occurrence	4606	202/260-0910	202/260-3762	thomas.edwin@epa.gov
Wynne Miller Analytical Methods	4607	202/260-0259	202/260-3762	miller.wynne@epa.gov

*EPA Headquarters, 401 M Street, SW, Washington, DC 20460