National Drinking Water Advisory Council (NDWAC) Contaminant Candidate List (CCL) Classification Process Work Group

February 5-6, 2003
Washington, DC

Meeting Summary

- Final -

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Attachments

Welcome and Introductions

The third meeting of the NDWAC CCL Classification Process Work Group was held on February 5-6, 2003. The meeting objectives were to

- review and discuss revised draft ground rule language that pertains to activity group participation
- learn more about background and context for developing a methodology for CCL
    - EPA responsibilities for identifying contaminants to study and the process used to determine which contaminants to regulate
    - states' role, experience
    - industry's role, experience
- review work plan in light of activity group progress and evaluation of tasks
- report and provide feedback on activity group work to date:
    - identify questions and issues the work group needs to address
    - agree on tasks to be conducted to prepare for subsequent meetings
- identify additional technical expertise needed on the activity groups
- determine activity group tasks between February 5-6 and March 27-28, 2003

Facilitator Abby Arnold, RESOLVE, welcomed everyone to the meeting and asked the work group members and other meeting participants to introduce themselves (see attachment A). She reviewed the materials that were distributed for the meeting and then reviewed the agenda (see attachment B).

Cynthia Dougherty, U.S. EPA, welcomed the meeting participants and thanked the work group members for all of their work thus far. She announced that Jim Taft resigned his position at EPA to become the executive director of the Association of State Drinking Water Administrators (ASDWA). Ann Codrington will serve as interim chief of the Targeting and Analysis Branch.

Operational Protocols

Ms. Arnold presented some proposed revisions to the operational protocols. The revisions were intended 1) to reflect more accurately the structure and process the work group has created and 2) to clarify participation in the activity groups. Members discussed the revisions and proposed some additional modifications. The work group adopted the operational protocols as revised in attachment C. During the conversation a member noted that it is important to have a balance of interests and expertise on the activity groups. Ms. Arnold requested that if a member becomes concerned about balance on an activity group, he or she should raise the concern with her or the other facilitators.

Guiding Principles

The work group discussed and revised the draft guiding principles. The members present at the meeting reached consensus on the guiding principles as revised in attachment D, with the understanding that later in the process the work group will review them and decide what guiding principles to recommend for EPA. Work group members who were not present for the discussion on guiding principles will be given an opportunity to review the principles and raise concerns with the work group if they have any.

Background/Context for Developing a CCL Methodology

Tom Carpenter, U.S. EPA, presented an overview of the regulatory process for drinking water contaminants (see attachment E). He identified five stages in the process: 1) build the universe of potential contaminants, 2) develop the preliminary CCL, 3) develop the CCL, 4) make regulatory determinations, and 5) develop national priority drinking water regulation (NPDWR): proposal and final. The efforts of the CCL Work Group relate to the first three stages of the process. Each of the five stages requires an increased level of information and effort beyond the previous stage. The universe of contaminants and the preliminary CCL (PCCL) are developed using available data and information. Screening from the universe to the PCCL applies criteria to select from a large universe. Classifying contaminants from the PCCL onto the CCL identifies those contaminants for preliminary research. For agents on the CCL, information is sought in four areas: health effects, analytical methods, occurrence/exposure, and treatment. Research priorities are set based on data gaps and research needs. To move an agent to the regulatory determination stage sufficient information is needed in all four categories. Mr. Carpenter noted that prioritization is necessary because EPA does not have enough resources to research all agents on the CCL in the same timeframe.

Mr. Carpenter explained that initiating a regulatory determination process does not necessarily mean that the contaminant in question will be regulated. According to the Safe Drinking Water Act (SDWA), to issue a new rule for a contaminant EPA must determine that

- the contaminant adversely affects public health
- the contaminant is known or likely to occur in public water systems with the frequency and at levels posing a threat to public health
- regulation of the contaminant presents a meaningful opportunity for health risk reduction

If the contaminant satisfies these three criteria EPA begins the process for establishing a regulation, including stakeholder input, cost-benefit analysis, and other components.

Matt Corson, Association of State Drinking Water Administrators, presented an overview of the state role in water supply and rule development and implementation (see attachment F). He noted that rule implementation is just one of the many responsibilities of state drinking water programs. He explained that under SDWA states are authorized to be granted primacy (i.e., primary enforcement responsibility) if they meet a set of requirements. Currently, all states but Wyoming have primacy. The states work with EPA and other stakeholders during the federal rule development process to help ensure that the rules are protective of public health and implementable. The state role in implementation of federal rules includes several responsibilities:

- review federal rule to understand requirements
- modify state program accordingly
- prepare state regulations
- prepare primacy revision application
- work with water systems to determine rule applicability and appropriate course of action

Under the SDWA, states have two years to submit a primacy revision application for a new rule, and states may also request a two-year extension. Mr. Corson commented that implementation challenges can arise if a state receives a two-year extension because the state would then have four years from rule promulgation to obtain primacy while utilities would be required to be in

compliance with the rule requirements three years after rule promulgation (unless the utility requested an extension due to the need for capital improvements). In these instances, the state and the EPA regional office need to work together to address implementation issues until the state receives primacy.

Brian Ramaley, Newport News Waterworks, presented an overview of drinking water regulation and supply from a utility perspective (see attachment G). He noted that drinking water systems today deal with about 90 regulated contaminants. He explained that the SDWA standards apply to all public water systems, and SDWA defines a public water system (PWS) as any system that serves at least 15 connections. There are more than 165,000 PWSs in the U.S. serving more than 283 million people. Mr. Ramaley noted that only a small fraction of the water treated and supplied by PWSs is consumed, but it is that fraction that is consumed that drives treatment requirements. He explained that surface water systems typically employ more complex treatment than groundwater systems, and many groundwater systems have no treatment. Mr. Ramaley outlined the general steps a PWS takes to respond to a new regulation, from data collection through compliance monitoring, and noted that the time required to come into compliance varies depending on the treatment challenge and ranges from a year to a decade. He pointed out that drinking water utilities are very capital intensive, so modifying a treatment and supply system to respond to a new regulation can be a major undertaking. He added that each regulation affects different systems differently; some regulations affect all PWSs while other regulations have a large effect on some systems and no effect on others.

Discussion

In response to questions, EPA staff clarified that the contaminants on the CCL for which a regulatory determination is not made are not required by statute to be included on the subsequent CCL. EPA has a protocol for these potential contaminants that tracks what research is being done and looks at which are likely to have enough information to move ahead in the process. The National Research Counsel (NRC) recommended keeping a potential contaminant on the CCL if there is insufficient information to make a regulatory determination. The work group will need to consider whether to recommend moving contaminants with little information to the next CCL or putting them back into the universe to go through the process again from the beginning.

A member raised the question of whether the CCL classification process should include consideration of whether exposure is large through drinking water compared to other media. EPA staff responded that the CCL process should focus on whether an agent is a hazard in drinking water, regardless of other media. They added that relative exposure is considered at later steps in the regulatory process.

A member commented that it is important to understand the timelines involved and the long lead time required to ultimately get to regulatory implementation. Another member observed that the work group is focused on the very first steps of the whole process. He suggested that the goal of the work group, therefore, should be a CCL process that is easy to understand and not resource intensive, recognizing that much more scrutiny will be applied at later steps in the process.

A member raised a concern about having false positives on the CCL and the effect this may have on the choice of where to apply limited resources. He acknowledged that false positives would be caught at the regulatory determination stage, but he noted that there are implications simply to being included on the CCL. Consumers may assume that anything on the CCL poses a health risk, and they may push a utility to take action.

At the end of the discussion Ephraim King, U.S. EPA, offered some closing comments. He referred participants again to the final slide of Mr. Carpenter's presentation. He observed that the three presentations together showed the range of activities and money involved in the whole regulatory process. He commented that the efforts of this work group, which affect the first few stages of the process, are important for several reasons. Developing the CCL through a transparent, balanced, scientifically sound process is essential for establishing legitimacy and credibility in the whole regulatory process. Developing the CCL is a crucial step in focusing research on the right agents and ensuring that limited resources are used in the best way possible.

Reports from Activity Groups on Progress Made between Plenary Meetings

Methods Activity Group

A member of the Methods Activity Group presented an update on the group's work since the December 16-17 plenary meeting (see attachment H). He reported that the group continued to review decision methods for classifying contaminants from the PCCL to the CCL and also began to identify methods to consider for screening contaminants from the universe to the PCCL. For classifying from the PCCL to the CCL the group has considered three approaches—expert discourse, rule-based algorithms, and prototype algorithms—and is exploring a combination of these approaches. The combined approach being explored would use expert judgment to select and score the training set for a prototype model or models. The model(s) would be run to generate a "draft CCL, " and expert judgment would be used again to challenge and verify the results of the model(s). The group is considering how to address microbial contaminants and whether a different model will be needed for them. The group also has begun to discuss options for addressing contaminants with little or no data.

Data Activity Group

A member of the Data Activity Group presented an update on the group's work since the December 16-17 plenary meeting (see attachment I). He reported that the group continued its discussions on defining the universe of potential drinking water contaminants and selecting chemical data sources to build the universe. The group intends to give equal consideration to microbial data elements and data sources, but has not yet discussed them extensively.

The group discussed two options for constructing the universe:

1. Begin with all known and envisioned chemicals and microbes and reduce the list to a "manageable" universe through some form of screening. For this approach for chemicals, the activity group considered beginning with the Chemical Abstract Services (CAS) database of over 44 million chemicals and apply filtering criteria.
2. Merge or recombine discrete data sources to compile a set of records with multiple criteria. For this approach, the group considered starting with a combination of existing data sources (other than CAS) from among the more than 200 sources identified by EPA, work group

members, and other stakeholders (e.g., High Production Volume Chemicals Lists, Toxic Effects of Chemical Substances database).

The group acknowledged that some challenges exist with either approach:

- New information is developed rapidly, making reproducibility a "moving target."
- Cross-referencing can be difficult because unique identifiers for agents may not be compatible among databases.
- Inconsistency in identifiers can lead to unintentional omissions of or redundancies in data.

The Data Activity Group proposed not building the universe from the CAS database but rather from a combination of other data sources (option 2 above). The recommendation was based broadly on reasons of logistics, selectivity, and searchability. The group also identified limitations and issues of the proposed approach.

The group discussed data elements and prepared a draft list of chemical data elements. The list can be considered a work in progress and will continue to be developed as data sources are reviewed. The group also discussed a process for addressing emerging contaminants.

Discussion

Some work group members expressed concern that building the universe from a set of existing data sources effectively applies a screen that should be applied instead in going from the universe to the PCCL. Some expressed concern that newly identified or unexpectedly created harmful substances, such as chemical mixtures or byproducts from industrial sites, would be missed with this proposed approach. Data Group members responded that building the universe from CAS also would not ensure that such substances were captured, and that the group is discussing a separate process to address emerging contaminants. A member commented that the level of effort required to build the universe from CAS would be more effectively spent on other parts of the process. Another member commented that many of the entries in CAS are chemicals created one time in a laboratory that have essentially no chance of contaminating a water supply. She explained that substances of concern could be captured more efficiently through other data sources.

A member commented that one way to help address emerging contaminants would be to establish a petitioning process to add potential contaminants for which there are few data to the universe. She also suggested that it may be possible to use models to predict environmental degradates from chemicals and include those potential degradates in the universe. Another member observed that microbes may present additional challenges to be considered, such as metabolic products and small protein molecules.

A member observed the need for a process that assures the public that potentially injurious agents are included in the universe. Another member commented that much of that assurance will come from the process that is developed to address emerging contaminants. A member suggested that the whole CCL process should begin with a universe as large as possible—44 million to 100 million agents—and then use simple criteria to rapidly eliminate large blocks, perhaps through quantitative structure activity relationships (QSARs). Another member

responded that beginning with so many agents presents the challenge of explaining to the public how the process began with 44 million and screened down ultimately in a meaningful way to the ten or so contaminants that merit concern.

Virulence Factor Activity Relationship (VFAR)

A member of the VFAR Activity Group presented an update on the group's work (see attachment J). He outlined some of the findings and challenges of the three phases of database searches conducted between September and December. He summarized some of the overall initial findings:

- GenBank may not be well suited for VFAR purposes.
- The Comprehensive Microbial Resource (TIGR-CMR) is better organized and indexed than GenBank but contains fewer entries, so initial efforts may need to focus on selected databases.
- New databases are being developed (e.g., Department of Defense).
- The VFAR concept appears feasible for bacteria, and additional work is warranted for assessing VFAR potential for viruses.
- No whole protozoan parasite sequences were found in GenBank, so the VFAR approach was not explored with these microorganisms; however, Cryptosporidium and malaria genomes are now done and "in the wings."

An option being considered by the group is to look at whole "pathogenicity islands" rather than just aligning sequences. Pathogenicity islands are clusters of genes that control the production, elaboration, and function of virulence factors and are frequently exchanged among bacteria, conferring virulence on previously avirulent strains.

The group also will gain information from a parallel project proposal by Trudy Wassenaar, Molecular Microbiology and Genomics Consultants, that is being considered for funding.

Activity Group Breakout Sessions

The Methods and Data Activity Groups met in breakout sessions the afternoon of February 5th and the morning of February 6th and reported back to the plenary work group the afternoon of February 6th. The VFAR Activity Group met following the plenary meeting on the afternoon of February 6th and will report on the group's activities at the March 27-28 plenary meeting.

Methods Activity Group

Methods Group members reported on their breakout session discussions. The group is considering a rule-based method to screen from the universe to the PCCL and is exploring the possibility of using two attributes rather than five for this step. For classifying from the PCCL to the CCL the group is testing three methods: a logic tree, a regression model, and a risk-based model. The results of the methods will be compared for overlap. Members noted that the approach being considered is generally compatible with the NRC recommendations. The group is still exploring three key questions:

- Should scored attributes or raw data be used?
- Should a value be assigned for each of the five attributes for each contaminant or should the method move forward with data gaps for some contaminants?

- Should risks be calculated or should the importance of pieces of information be decided?

A member asked how a risk calculation could be used to classify from the PCCL to the CCL when many of the contaminants will not have enough information for a risk calculation. Another member clarified that method being explored would not actually involve a risk calculation but would combine information in a way similar to a risk calculation.

Data Activity Group

Members of the Data Group reported that they took the work group members' comments from the previous day into consideration and refined their proposed approach. The group will develop "inclusion principles" for data sources to build the universe. A member stressed that the group is looking at data sources, not data, and will build on the NRC recommendations. The group will look at all the data sources that can be found and use the inclusion principles to include as many data sources as possible.

The group realizes the concern about contaminants missed by this approach, either because they are new contaminants or because new information develops on a known contaminant. The group will propose a definition for these two kinds of emerging contaminants and a process for addressing them. Possible elements of the process identified so far include

- surveying published literature
- working with health departments, state environmental agencies, academics, water departments, and other entities
- a nomination process to change the inclusion principles

A member of the Methods Group commented that it would be useful if the Data Group could indicate a confidence level for using a given data set for a given attribute. He commented that the methods may require a measure of uncertainty of the data. A member noted that there are several kinds of uncertainty that may be involved. The Data Group is considering identifying the best data elements for each attribute and will discuss the issues of confidence, quality, and uncertainty.

Public Comment

No members of the public expressed an interest in making comments to the work group at this meeting.

Next Steps

Draft Glossary

By the February 21, members will send any comments or draft language for the draft glossary to Sara Litke (slitke@resolv.org). Suggestions will be incorporated and made available for review by work group members. The draft glossary will be maintained as a work in progress as the process continues and reviewed as necessary on activity group calls and at plenary meetings.

Operational Protocols

RESOLVE will contact members who were not present to verify that they can live with the language, and distribute the revised protocols to work group members.

Guiding Principles

RESOLVE will revise the guiding principles as discussed, contact members who were not present to verify that they can live with the language, and distribute the revised principles to work group members.

Activity Groups

Data
Conference calls: Thursday, February 27, 3:00 - 5:00 p.m. Eastern
Thursday, March 13, 12:00 – 2:00 p.m. Eastern
Thursday, March 20, 12:00 – 1:00 p.m. Easter

Methods
Conference calls: Wednesday, February 26, 1:30 –3:00 p.m. Eastern
Wednesday, March 12, 1:00 – 2:30 p.m. Eastern

VFAR
Conference calls: Tuesday, February 25, 1:30 - 3:00 p.m. Eastern

Future Meetings

The work group chose dates for meetings through 2003 as listed below. It is expected that all meetings will be held at the RESOLVE offices.

- March 27-28, 2003
- May 12-13, 2003
- July 16-17, 2003
- September 17-18, 2003
- November 13-14, 2003