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

November 13-14, 2003 Washington, DC

Meeting Summary

The eighth meeting of the NDWAC CCL Classification Process Work Group was held on November 13-14, 2003. The meeting objectives were

- For Universe to PCCL
 - Review and discuss screening alternatives
- For PCCL to CCL
 - Learn about insights gained at October 21 attribute scoring workshop and recommendations on how to address issues
 - o Review and discuss issues associated with developing a training data set
 - Review and discuss options for next steps –classification model (rule based, prototype) or other options (expert process)
- For all stages of moving from Universe to CCL
 - Implications of analysis and work group guidance on what work group needs to develop the report
- Discuss microbial and transparency issues, next steps
- Decide on next steps for completing the report to the NDWAC
 - Agree on work plan and questions to be addressed in order to develop a recommendation to the NDWAC
 - Agree on tasks to be conducted between November 2003 and January2004, and March 2004

Welcome and Introductions

Facilitator Abby Arnold, RESOLVE, welcomed everyone to the meeting (see attachment A for list of work group members in attendance). Following introductions, the work group reviewed the meeting agenda (see attachment B). Ms. Arnold explained that a key task for the meeting was to figure out where the group is and where members want the group to be at the end of the process in March.

Summary of Activities and Issues for Discussion

Amy Kyle, University of California, Berkeley, outlined the technical analyses and other activities completed since the September work group meeting (see attachment C). She explained that she was presenting only an overview, and more detailed information would be provided in other presentations throughout the day. She also presented questions framed by the technical/facilitation team for the work group to consider for discussion. Dr. Kyle shared a diagram listing the critical decisions regarding the process for moving from the CCL universe to the PCCL and the process for moving from the PCCL to the CCL, as well as considerations that overarch both processes (see figure 1).



Questions proposed by the technical/facilitation team for the work group's consideration included the following:

Universe to PCCL:

- Do you have recommendations for principles to consider when selecting an option for screening approaches?
- Do you agree that the options described are the correct set of options to consider? Are there others?
- What do you see as the advantages and disadvantages of these options?
- What do you recommend or what criteria should be used for how to choose a cutoff for entry to the PCCL in binning or ranking approaches? Do you agree with the five data elements proposed for the option that is based on use of a limited number of data elements? Should there be others or fewer?
- Which option(s) do you lean toward? Are any unacceptable?
- Is any additional technical analysis needed to prepare you to make a final recommendation in January?

PCCL to CCL: Attributes Scoring (for both chemical and microbial contaminants):

- What are your views about the general approaches proposed for the scoring protocols? .
- Do you have any comments are suggestions for further development of the scoring approaches?
- What is your reaction to the report from the scoring workshop?
- Do you have comments about principles for scoring?
- When should we take up the question about how many attributes need to be scored (3, 5, or another number)?

Figure 1. Critical path decisions.

PCCL to CCL: Training Data Set, Classification Algorithm, and Options

- What is your reaction to the presentation on the training data set?
- Should we continue with development of a training set and further testing of models at this time and/or focus on developing principles?
- Does it seem best to continue to develop a classification algorithm as the sole approach?
- What do you need to know to recommend an approach?
- Do you want to develop principles?

Following the presentation, work group members discussed the progress the group has made thus far and what is needed for the group to complete its work. One member noted that the task the work group undertook in its charge was an ambitious one, and the group may not be able to complete all of the components of the task to the level of detail originally envisioned. He commented that there were concerns about the way the first CCL was developed, which prompted this exploration of alternative methods. One option to address the concerns would be to expand or modify the facilitated discourse process used for the first CCL. Rather than pursue this option, the NRC (and consequently, the work group) proposed using an automated process and classification algorithm, largely due to a concern that the development of the first CCL did not look at enough compounds. The member commented that the challenge with using an automaton is determining when the automaton produces the right answer. He added that the only reason for using an automaton seems to be to allow the use of an amount of data that a person could not possibly handle. He asked whether the work group is at a point to say that the tools are not yet ready for a fully automated process. He suggested that the work group might recommend that EPA views a facilitated discourse process in the near term while continuing to develop a training data set and other requirements of an automated process. Another member added that data on vulnerable subpopulations are generally not available, so the automated process the work group has been considering would largely ignore these subpopulations unless the work group recommends a way to address such "data-less" groups. A member commented that the group needs to consider the unintended consequences of what seem to be positive steps. He said that moving too quickly to an automated process will not serve public health.

A member noted that the work group's charge was to provide advice on the NRC recommendations, and the group has been doing valuable work to evaluate those recommendations. He suggested that based on what the work group has learned, the group might recommend that the automated process and classification algorithm are not the best approach with our current knowledge and data limitations. He noted, however, that the group has identified many valuable principles—such as those on nomination and surveillance—that should be incorporated into the CCL process.

A member commented that the essence of the task is to determine how to deal with uncertainty and data of uncertain quality and how to deal with large amounts of information of varying quality. He commented that if the group recommends just using data of a certain level of quality, it is avoiding the challenge.

A member suggested that the group should determine its goal and the best way to reach it. He observed that there are two sets of perspectives on the work group: a) the technical people who are intrigued by the methods presented and b) people with a broader picture of the CCL process and how it represents various interests. He noted that the perspectives have not always been in

synch and suggested that the group needs to consider how to meet the differing needs and expectations among members. He commented that evaluating the NRC recommendations requires testing the specifics of the proposed approach. He said that the group has not thoroughly explored many of the issues raised and the technical analyses have not always been in line with the work group's questions. The member commented that he believes there are better ways than facilitated discourse to develop the CCL. He observed that the key questions are how to improve the CCL process and how to use available tools to make better informed decisions and more transparent decisions. He suggested that in moving forward, the group needs to be clear when it is making a technical decision and when it is making a policy decision, and what rationale it is using for any decision. Another member noted that the group's reasoning does not have to be based solely on technical analysis. She also noted that the group is not expected to do all of the necessary technical analysis; it could recommend that EPA do further analysis and offer principles for the analysis.

Several members observed that the work group has never considered recommending a process that did not include expert judgment. The work group generally expressed support for the perspective that the approach the work group has been exploring shows promise, and none of the analysis thus far has indicated that EPA should not pursue the approach; however, it is not ready for implementation as a whole at this point, though some parts may be ready for implementation. Several members expressed confidence that the technical challenges of the approach, such as developing the attribute scoring protocols, could be resolved. Some members proposed that the work group should offer both recommendations to improve the CCL process in the near term by incorporating principles and some of the tools the work group has explored, and recommendations for pursuing the NRC proposed approach over the longer term.

A member again expressed concern about the limitations of the technical analyses as a basis for the work group's recommendations. Members of the technical/facilitation team suggested that to address this concern, the work group's report should be clear about what analysis was done, what the results were, what the group concluded based on the results, and what additional analysis needs to be done.

CCL Universe to PCCL: Evaluation of Options for Screening Approaches

Jo Anne Shatkin, Cadmus Group, presented an evaluation of options for screening from the CCL universe to the PCCL (see attachment D). She briefly described each option and listed some of its pros and cons. For the semi-quantitative option, she also listed some initial results of the analysis comparing ranking to binning and offered to discuss the results in more detail with any interested members. Dr. Shatkin noted that some members of the technical/facilitation team have suggested an additional option not previously presented to the work group: a "semi-qualitative" option. Under this option, a contaminant would pass from the CCL universe onto the PCCL if it 1) has occurrence data or information and 2) has some indication of a health concern. The pros and cons identified for each option included the following:

Qualitative Approach:

Pros:

- Transparent easy to describe data gathering process.
- Inclusive sends all contaminants with the health effects and occurrence data and/or information to the PCCL.

Cons:

• May be too inclusive nonselective enough for the downstream processes.

Semi-Qualitative Approach:

Pros:

- Simplifies data gathering.
- Includes consideration of some health concern; eliminates contaminants with no health concern.

Cons:

• Requires the effort of examining the data.

Semi-Quantitative (Binning or Ranking), Pragmatic Approach:

Pros:

- Simple requires only comparison to criteria.
- Automatable analysis can be structured to easily automate.
- Transparent can easily describe criteria.
- Somewhat selective identifies most important contaminants, but perhaps not all. Cons:
- Jons: Establishi
- Establishing criteria based on resources (e.g., want 1000 contaminants on the PCCL or the top 25% of contaminants on the PCCL) may be difficult to agree upon.
- Inclusivity may very depending on the available data.

Semi-Quantitative (Binning or Ranking), Substantive Approach:

Pros:

- Simple requires only comparison to criteria.
- Automatable analysis can be structured to easily automate.
- Transparent can easily describe criteria.
- Inclusive substantive criteria can be set to be inclusive but also can be exclusive.
- Selective criteria can be based on selectivity.

Cons:

- Selected elements may not adequately capture key criteria.
- May not be inclusive if look only for a particular data element.

Quantitative Approach:

Pros:

- Inclusive criteria can be set to be inclusive (or not).
- Selective criteria can be based on selectivity.

Cons:

- Requires identifying many types of data and information.
- Requires significant documentation.

Dr. Shatkin listed some principles proposed by the technical/facilitation team for work group consideration:

- Simple Approach should not be overly complex are requires significant analysis.
- Automatable Approach should be designed to require a relatively low level of effort.
- Transparent Approach and criteria should be clear.
- Inclusive Approach should strive to include rather than exclude contaminants; criteria should be brought enough to be inclusive; elements should allow inclusivity.

 Substantive – Approach should strive to identify contaminants that may be important for future CCLs.

In closing, Dr. Shatkin referred members to the screening discussion questions from Dr. Kyle's presentation.

A member commented that the contaminants that end up on the CCL will be screened from the universe onto the PCCL no matter which of the options is used. He suggested that therefore, in choosing an option, the group should consider whether any is significantly faster or easier than the others. Dr. Shatkin commented that in the examples run for the analyses, ranking or binning required the least effort. A member commented that he was not sure all of the options would lead to the same end result. Another member noted that considerations of transparency and whether a method will stand up over time are also important. A member suggested that a research approach is necessary to test the options. He commented that how any of the options is employed (i.e., what data elements and criteria are used) is more important than which option is used.

Discussion of Principles

Members discussed the proposed principles. Two members suggested additional principles:

- Cost efficient Approach should maximize the use of resources.
- Approach should produce a PCCL with a manageable number of contaminants.

Another member commented that the key principle in her opinion is that *the approach should strive to assess as many contaminants as possible*. Another member agreed with her, noting that by some other definitions, being inclusive is contrary to seeking to produce a PCCL of a manageable size. A member commented that inclusivity provides incentive to gather pertinent data.

A member requested that the principle on *transparency* include "cost" as an element that needs to be clear, along with approach and criteria.

Decisions and Next Steps

The work group agreed that chapter 6 of the report to the NDWAC should include principles and a discussion of the screening options considered and their pros and cons. The group also agreed not to recommend pursuing the qualitative option, though this option and the rationale for its rejection should be discussed in the report.

The group did not request any further technical analysis. A small group (with support from the technical/facilitation team) was charged with further discussing the screening options, data elements, and criteria and preparing draft text for the work group's review.

PCCL to CCL: Attribute Scoring for Chemicals

Frank Letkiewicz, Cadmus Group, and Doug Owen, Malcolm Pirnie, shared an introduction to the scoring protocols, a summary of the technical/facilitation team's scoring workshop, and observations regarding attribute scoring (see attachment E). Mr. Letkiewicz noted that the purpose of the protocols is to develop a consistent method for scoring each attribute, across

diverse data sources and types of data. He observed that the general elements of all the scoring protocols include preferred data elements and data sources, a hierarchy in which to use the data elements, and a scaling system by which to assign scored values to the data. He then summarized the protocol for each attribute used by the members of the technical/facilitation team who participated in the October 21 scoring workshop. Mr. Letkiewicz presented some possible principles for attribute scoring, but noted that they were offered by the technical/facilitation team simply as ideas to prompt the work group's thinking.

Mr. Owen outlined the purpose and goals of the October 21 scoring workshop. He presented a summary of the scores calculated for the example chemicals by different groups of participants at the meeting. He commented that the meeting participants managed to observations based on the scores: a) if given the same data and the same protocols, different people generally calculate similar scores for a given contaminant and b) the protocols generally result in a range of scores among contaminants, thereby allowing discrimination among the contaminants. Mr. Owen outlined some of the issues and challenges that have been identified for each attribute. He then shared key observations and lessons learned from the workshop:

- Given the availability of data for these chemicals and defined protocols, consistent attribute scoring was feasible.
- It required considerable effort to get the data in a format that allowed the scoring to proceed in a consistent manner.
 - Data compilation could be more efficient based upon the experience.
- There are a number of outstanding technical issues critical to the scoring protocol:
 - Ensuring that data/information from various sources is applied consistently
 - Ensuring the equivalency of scores from different data elements
 - Reviewing the scales (e.g., 10 point vs. 3 point)
 - Understanding assumptions made during data extraction and compilation
 - Understanding the extent of the effort for data extraction
- It is not entirely clear whether or to what extent the scoring process can be "automated."
 Some interpretation was helpful.
- The participants discussed at some length the potential need for the attribute scoring process to evolve over time.

In closing, Mr. Owen referred members to the screening discussion questions from Dr. Kyle's presentation.

During the discussion, members identified several issues needing further consideration:

- Data element hierarchies, particularly for potency and prevalence elaborate and reconsider order for some.
- Should attributes be scored on the highest available data element in the hierarchy or on the data element that gives the most conservative score?
- Is median of detects the right measure to use when scoring magnitude?
- Should the link between severity and potency be dropped?

Additional comments and suggestions on specific protocols included the following:

• Consideration of sampling effort should be included for prevalence.

• Magnitude as a ratio of concentration to effect level is more useful than magnitude as just a concentration measure.

Following these suggestions members focused their discussion on the broader question of whether to recommend using an attribute scoring approach. A member reminded the group that scoring attributes essentially is a way to normalize data among contaminants. Another member commented that the workshop was a useful exercise: it illustrated that attribute scoring has the potential to be an excellent approach, though not completely ready for immediate application, and it identified challenges on which to focus a research strategy.

Other comments from work group members included the following:

- Further consideration may be needed regarding what to do when the required data are not available for scoring a given contaminant.
- Pursuing all five attributes will be complex; the group may want to reconsider whether to recommend using fewer attributes.

Decisions and Next Steps

The work group agreed to recommend using an attribute scoring approach. The group agreed that its recommendation to the NDWAC should identify a) those aspects of the scoring approach robust enough to incorporate into the development of CCL3, b) those aspects to develop for use for CCL4, and c) a strategy for working toward full use of the scoring approach. The group also agreed that

- the protocols used for the October 21 workshop are a good start but need some further modifications;
- considerations used for screening from the universe to the PCCL should be consistent with considerations used for classifying from the PCCL to the CCL;
- further discussion is needed to regarding how to address the issue of certainty/confidence;
- the five proposed attributes are sufficient, but the group may still want to consider recommending using fewer than five.

Members agreed to submit by email any additional comments on specific draft protocols.

PCCL to CCL: Training Data Set

Mike Messner, EPA, presented issues identified by members of the technical/facilitation team regarding a training set of chemical contaminants (see attachment F). He explained that as the technical team began to develop a training set of chemical contaminants, the team realized that training set development will be much more complex and important than originally expected. In light of this, he suggested three issues for work group consideration:

- 1. consider if prototype classification is the right way to go
- 2. provide some guiding principles for attribute scoring and decision-making
- 3. consider the added value of moving ahead with a limited "diagnostic" training exercise (to be completed by the January meeting) rather than focusing on items 1 and 2 above

Mr. Messner explained some of the transparency issues with a training set-based classification approach. Developing a training set involves difficult judgments about which training

contaminants are listed and which are not and it assumes that "correct" decisions can be identified. The ultimate rule derived by the algorithm may be transparent, but the decisions associated with the training contaminants, which led to the rule, may not be transparent.

Mr. Messner outlined some of what the technical team has learned about these considerations and then discussed several training set issues. He explained that a training set is developed so that the model can determine where the discriminant function – the border dividing "list" contaminants from "don't list" contaminants – lies. A good training set would cover the full range of PCCL contaminants in terms of attributes and scores and be sufficiently large for training and validation, and its decisions would be "correct." Mr. Messner explained that the NRC thought that a training set could include contaminants for which the decision of "list" or "don't list" was obvious, but based on initial analysis, the technical team believes that a good training set must include contaminants in the gray area of less obvious decisions. He outlined a process for developing a good training set:

- 1. Establish principles for scoring, training, and decision making.
- 2. Determine draft attribute scoring protocols (should be close to final protocols).
- 3. Build training set by iterative process (diagnostic exercise).
- 4. Develop formal data quality objectives.
- 5. Reduce number of algorithms if appropriate.
- 6. Finalize the attribute scoring protocols.
- 7. Develop the "real" training set.
- 8. Train the algorithm.

Elaborating on step 3, Mr. Messner explained that a diagnostic exercise could be performed as a pilot run of the training data, and would require development of a draft training set, complete with attribute scores, supporting data and information, and list/don't list decisions. The diagnostic exercise would provide lessons and information both from the discourse involved in developing the training set, characterizing error rates, and interpreting the algorithm output and from observing the development and output of the model by the computer. Mr. Messner also expressed some concerns with running a diagnostic exercise for the January work group meeting:

- Scoring for chemicals and microbials should be based on common principles. To date, no such principles have been developed.
- Attribute scoring protocols have not been finalized.
 - What we learn may be sensitive to changes in the protocols (results could be misleading) who.
 - Resources spent in conducting the exercise could be better spent finalizing the protocols.
- The means of expressing and estimating decision errors (algorithm performance) need to be developed.
- The tolerances for decision errors need to be systematically developed.
- The time and energy devoted to building the exercise's training set could perhaps be better spent on other efforts such as developing principles for scoring and decision-making.

Mr. Messner posed a question to the work group of whether to move ahead with a diagnostic training exercise now, or pause to complete some other work first. He suggested that rather than conducting a diagnostic exercise between now and the next meeting, the work group could focus

on developing principles, refining the scoring and decision-making protocols, discussing what information and analyses are needed to inform the work group's recommendation on the approach, and beginning to develop data quality objectives.

Following the presentation, a member pointed out that decision makers can communicate their rationale, so expert judgment can be transparent. Another member agreed and observed that judgment will be a component of any approach that is chosen.

A member commented that the group must determine how it is going to evaluate the methods and decide which is best for the CCL, for transparency, and for public health. He said that it is difficult to agree to recommend using a training set without knowing how the training set will be used. Another member responded that the group does not necessarily need to determine how the group will evaluate the methods, but rather could focus on what approach to recommend EPA use to evaluate the adequacy of its actions.

A member commented that he thought the group was beyond the question of whether to use a prototype classification approach. He said that none of the considerations raised thus far indicate to him that a prototype classification model is not the method to pursue. He noted that the group has been aware all along that data availability may be a challenge. He reminded the group that the model will be a tool, and experts will make the final decisions. He commented that there are challenges to developing a training data set that need to be addressed, but the challenges should not cause the group to abandon a prototype classification approach. Another member pointed out that data limitations will present the same challenges for a rule-based method as for a prototype classification method.

A member of the technical team responded that a major concern is the difficulty of explaining the thinking that went into creating the training set. He suggested that EPA needs to consider what will be the easiest method about which to have a dialogue with the public, and the logic behind a decision rule is more explicit and easier to explain, given that each decision has a stream of rationale behind it. He also reiterated a point from the presentation: the NRC assumed that the training set would be built of obvious-decision contaminants; inclusion of "gray area" contaminants makes building the training set more difficult and resource intensive. Several work group members disagreed that a prototype classification method is necessarily less transparent than a rule-based method. Some members suggested that the work group could provide guidance to EPA regarding how to communicate with the public about the recommended methods. They commented that information can be provided in a positive way, and that message delivery should be tailored for each audience. One member of observed, however, that the training set will be difficult to explain, for example, during a twenty-minute time slot in front of a congressional committee or city council.

A member observed that developing a training set is beneficial because calibration will be necessary no matter what method is chosen. He commented, however, that a model algorithm cannot completely mimic an expert group, in which various experts gather, bringing with them lots of literature, with data in multiple forms, which they review and use to make instant decisions. He observed that it would require a huge effort to build a database to approximate this process, which may not be the best use of resources. The member suggested that if EPA builds a training set, that training set essentially would be CCL3; or if a rigorous expert discourse process is used to build CCL3 and there is agreement that it is a good list, that list could be used as a training set for developing future CCLs. Another member commented that although humans are better at integrating information, the reason the NRC recommended a new approach for developing the CCL was to decrease subjectivity and increase objectivity. He observed that the decisions about listing various contaminants are not just yes-no decisions, but rather yes-no decisions with varying degrees of certainty. He explained that the model is a tool; experts will use the model output along with additional information and considerations to make the final decisions. He agreed that if EPA builds a training set, it essentially would be the next CCL. He suggested, therefore, that a prototype classification tool could be used in the relatively near term.

A member reminded the group that its objective is to report to the NDWAC whether or not the NRC approach has merit and should be pursued further. Another member reminded the group that the CCL process is not a regulatory decision making process; the CCL is a list for developing a research agenda. He added that the process the group recommends does not need to be perfect or final; it can undergo iterative refinements and improvements.

Decisions and Next Steps

The work group charged a small group (with support from the technical/facilitation team) with the task of considering the points raised during the discussion and identifying common ground and issues, addressing issues if possible, and proposing a plan for beginning a draft section on the training set and classification approach for the report to the NDWAC.

Small Group Reports

Work group members met and small groups to continue discussions and move forward on various issues. Following the discussions the groups reported back to the plenary work group.

<u>Big Issues</u>

A small group met briefly to identify some of the overarching issues the work group needs to consider in preparing its recommendation to the NDWAC (see attachment G). This list of issues was shared with each of the other small groups for consideration during the discussions.

Microbial Contaminants

Common Ground Agreement in the Small Group

- The conceptual process for microbial contaminants is parallel to NRC recommendations: universe → PCCL→ CCL.
- Data sources: Few data bases exist for microbial contaminants, and quality varies among sources. Peer-reviewed literature is the primary source of data. Occurrence data are limited.
- Data collection is the primary goal; automation of collection is a longer term target. Identify
 the data and data-format needs so that other collection efforts can provide data to the CCL
 process. Coordinate with the national Department of Defense database efforts.
- Attribute scoring and screening criteria need to be developed specific to microbe data.
- Virulence factor activity relationship (VFAR) is a concept for the future (recommendations are in chapter 8).

- Develop a plan for a toolbox approach so an iterative approach can be used to develop future CCLs based on NRC, NDWAC and future discussions.
- Surveillance and nomination language needs to include microbes and should be a continuous process.

Issues Addressed

- CCL Universe
 - Parallel microbe approach to the approach for chemical contaminants.
 - Use primary literature.
 - Use NRC recommendations for inclusion of a microbe to the CCL universe.
 - The literature survey of pathogens conducted by Taylor, et al, is a good example and starting point for microbe universe.
- Universe to PCCL
 - Use screening criteria to reduce the contaminants identified in the primary literature from health effects (pathogens) based on occurrence or potential occurrence in water.
 - Screening criteria examples will use qualitative information (e.g., with history and biological requirements) and quantitative data (presence/absence or concentration of occurrence).
- PCCL to CCL
 - Attribute scoring protocols have been developed but need further refinement.
 - Qualitative and quantitative information and data will be used.
 - Data elements for attribute scoring are different from those used for chemical contaminants. Proposed scoring for microbes is based more on epidemiological data and reports.
 - Develop refined attribute scoring protocols and data extraction to facilitate the process in a defensible and transparent manner.

Issues to Be Resolved

- Reconciliation between chemical and microbial contaminants
 - Recommending parallel efforts seems reasonable at this point, and as progress is made, the integration between chemical and microbial contaminants should evolve.

One-Text Plan

Recommendations related to microbial contaminants will be integrated into the appropriate chapter for each step of the process. The Microbe Small Group will continue to work on resolving remaining issues. Recommendations on VFAR will remain a separate chapter (chapter 8).

CCL Universe to PCCL Screening

Common Ground Agreement in the Small Group

• Universe to PCCL screening will be based on considerations of potency and exposure. Data elements for potency will be lowest observable adverse effect level (LOAEL) and lethal dose (LD₅₀), with use of quantity structure activity relationship models (QSARs) to fill data gaps. Data elements for exposure will be some combination of persistence and solubility, with use of QSARs to fill data gaps.

• The qualitative option will not be recommended. The small group preference is to recommend a two-bin semi-quantitative approach.

Issues to Be Resolved

• Use of confidence tags

One-Text Plan

Amy Kyle will prepare a draft text summarizing the small group discussions of the options, preferences, and rationale. The small group will review the draft text and incorporate it into chapter 6 for review by the full work group.

Attribute Scoring

Common Ground Agreement in the Small Group

- Recommend using an attribute scoring approach to normalize the data.
- Start with five attributes and use fewer depending on the requirements of the chosen approaches.
- Data element hierarchies should be used, but the draft hierarchies need to be reviewed.
 Principles should be developed. The principles and hierarchies may be different at different stages of the process (universe to PCCL versus PCCL to CCL).
- Careful consideration is needed of how to microbial protocols and the chemical protocols compare.
- Data quality should be considered at all levels of attribute scoring. The small group recommends developing data quality flags, but using the information from the flags only for expert review and consideration.
- A recommended principle: keep the model simple.

Issues to Be Resolved

Should the attributes be scored only on the top data element available for a given contaminant or should scores be calculated on multiple data elements for a contaminant and compared?

One-Text Plan

No further analysis is requested from the technical team. Frank Letkiewicz and George Hallberg will review the comments from the October 21 scoring workshop, notes from discussions at this work group meeting, and any additional comments from work group members on specific protocols. Based on these, they will prepare a draft text of issues, considerations, options, principles, and recommendations. The small group will review the text before distributing it to the full work group for review.

Training Set/Classification Method

Common Ground Agreement in the Small Group

- Transparency issues and concerns will be important, whatever approach and tools are used.
- Prototype classification is a useful tool for informing PCCL-to-CCL decisions.
- Expert judgment enters the process at different points and its role is not diminished by using different tools (expert intervention is essential).

- Approaches and tools evolve over time, as do contaminant lists (universe and PCCL) and their data/information (training set as a tool to test PCCL to CCL process, whatever the process).
- A diagnostic exercise is not needed now for chemicals; other issues (scoring, data hierarchies, etc.) should be worked through first. There is concern about linking microbe and chemical lists.
- Training set requires gray-area (difficult) decisions and coverage of attribute space.
- Algorithms will not make decisions. They simply allow for comparisons between outputs of multiple approaches and narrow the field to the point where human decision makers can make thoughtful, well-considered decisions.
- In making the final "list/don't list" decision for training contaminants (and ultimately for CCL contaminants), the key question to consider is "which of these are causing the greatest harm to consumers of drinking water in the U.S.?"

One-Text Plan

Based on the discussions and previous work group documents, technical team members will prepare a draft text of principles and a discussion/recommendation of how a training set could be used, and a draft text of classification method options, pros/cons, and principles. The small group will review the text before distributing it to the full work group for review.

Transparency

Common Ground Agreement in the Small Group The chosen method should be transparent.

One-Text Plan

Abby Arnold will revise the transparency chapter outline and prepare a draft text for review by the small group and outside experts. The chapter will include recommendations of ways for EPA to communicate with the public about the CCL process. Transparency considerations will be incorporated into other chapters as appropriate.

Public Comment

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

<u>Next Steps</u>

Work group members requested that draft one-texts be distributed prior to the holidays. Attachment H provides a list of next steps and a schedule to meet this request.

Future Meetings

The remaining work group meetings in 2004 are listed below. It is expected that both meetings will be held at the RESOLVE offices.

- January 22-23, 2004
- March 4-5, 2004

Attachments

- A. Work Group Members in Attendance
- B. Agenda
- C. Summary of Activities and Issues for Discussion
- D. Screening the CCL Universe to the PCCL
- E. Attribute Scoring
- F. Training Set of Chemical Contaminants
- G. Big Issues
- H. Next Steps

Attachment A

CCL Process Work Group Members Participating in the Meeting by Phone or in Person

Dr. Laura Anderko Dr. Rick Becker Dr. Douglas Crawford-Brown Dr. Michael Dourson Dr. Alan Elzerman Dr. Jeff Griffiths Dr. Wendy Heiger-Bernays Mr. Buck Henderson Dr. Nancy Kim Mr. Ephraim King Dr. Benson Kirkman Mr. Gary Lynch Mr. Ken Merry Mr. Brian Ramaley Dr. Graciela Ramirez-Toro Dr. O. Colin Stine Dr. Craig Stow Mr. Ed Thomas Ms. Lynn Thorp Dr. Daniel Wartenberg