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

January 22-23, 2004
Washington, DC

Final Meeting Summary

The ninth meeting of the NDWAC CCL Classification Process Work Group was held on January 22-23, 2004. The meeting objectives were:

- Review and discuss draft report overall and those sections that the work group identifies;
- Reach agreement on how to address issues and concerns raised by work group members;
- Reach agreement on how to accommodate all work group substantive comments and how we will incorporate editorial comment; and
- Decide on next steps for completing the report by March 4 meeting and submission to the NDWAC.

Welcome and Introductions

Facilitator Abby Arnold, RESOLVE, welcomed meeting participants (see Attachment A for list of work group members in attendance). Following introductions, the work group reviewed the meeting agenda (see Attachment B). The format of the meeting consisted of report back on the recent changes made to the report based on comment by the work group and review of outstanding issues. This was followed by discussion of these outstanding issues and planning of how the work group would like to move forward to complete its report.

Ms. Arnold introduced two newly added members of the Technical/Facilitation Team: Susan Savitt Schwartz will serve as editor of the work group report, and Jeff Citrin, RESOLVE, has assumed the responsibilities previously attended to by Sara Litke, who has recently left RESOLVE.

Review of Draft Report

Ms. Arnold provided a review of the current state of the draft report[1] (which was distributed to members prior to the meeting, see Attachment C), including an overview of the status of each section of the report, and where relevant, a summary of the direction suggested by work group members on the series of December and January briefing calls[2] (see Attachment D). In particular, Ms. Arnold drew participants' attention to issues associated with Chapters 3 through 7, which contained outstanding questions and/ or new text requiring members' discussion. An overview of her presentation follows:

[1] Revisions agreed to by the work group at this meeting have since been incorporated into a revised draft report dated February 6, 2004.

[2] Briefing calls were convened on Chapter 5: Building The CCL Universe Proposed Recommendations, Chapter 6: Selecting Contaminants in the Universe for the PCCL, Section 7.2: Recommended Approach to Select PCCL Contaminants for the CCL, Section 7.3: Attributes and Attribute Scoring, and Section 7.4: Training Data Set. In addition, a call was held on microbial considerations.

Chapter 1. Executive Summary

- Chapter remains to be written.

Chapter 2. Introduction

- No change has been made to the December 19 draft.

Chapter 3. Transparency, Risk Perception, and Risk communication CCL Work Group Process and Recommendations

- No change has been made to the December 19 draft.
- Comments have been received from two work group members, raising several issues for discussion:
    - The extent to which the general public needs to understand methodology as apposed to those who are "informed".
    - How to reach out to public and informed public; how to engage.
- Informal discussion shows agreement that if EPA uses this new methodology, transparency and communication are essential elements to its acceptance.

Chapter 4: Overview of Process and Overarching Elements

- Section 4.1.1: Chemical and Microbe Contaminant Approaches – new text on how microbials are integrated into methodology has been added *(this was address in Tom Carpenter's later presentation).*
- Section 4.2: Surveillance and Nomination – no change has been made to the December 19 draft.
- Section 4.3: Use of QSARS – no change has been made to the December 19 draft.
- Section 4.4: Characterizing and Qualifying Data and Information – no change has been made to the December 19 draft.
- Issues identified for work group discussion:
    - Is there agreement with the described approach to microbials?
    - Is there agreement with the described approach to surveillance? Does the approach adequately capture those contaminants for which there might not be available data or information for in real time?
    - Does the described approach to QSARSs address the previously identified caveats on use of QSARs?
    - Is characterizing and qualifying data and information adequately addressed? Is there more to say about this?
    - Reconcile Chapter 4 overview discussion with specific recommendations or discussion in other chapters.

Chapter 5: Building the CCL Universe

- The chapter has been modified based discussion on the January 6 conference call.
- General description of what is included in chapter:
    - The subgroup recommendation recognizes that multiple data sources will be needed.
    - The recommendations:
        - Is consistent with NAS report;

- Recognizes that data collection will need to be supplemented with a nomination and surveillance process to provide for stakeholder involvement; and
- Notes that the approach will be implemented in iterations that allow for a "measure of manageability."

- New text has been added that covers**:**
  - Changes in nomenclature;
  - Nomination and surveillance, as it applies to building the CCL Universe;
  - How to address data gaps;
  - Whether to address data quality issues in Chapter 4 or 5; and
  - How to address microbial contaminants.
- Issues identified for work group discussion:
  - How to address the proposed change to use "agents" instead of "contaminants" at the Universe level.
  - How to address the different approach for microbial vs. chemical agents.
  - Coordination and consideration of overlap between the Chapters 4 and 5 in their presentation of nomination and surveillance.

Chapter 6: Screening Universe to PCCL *(This chapter was addressed in greater detail in a later session.)*

- The chapter has been modified based discussion on the January 14 conference call.
- General description of what is included in chapter:
  - The subgroup members have agreed on the principles to screen the Universe and that the screening criteria should be based on a contaminants' potency and exposure.
  - The subgroup has narrowed the discussion to several options. Though there is not yet agreement on the specific data elements to characterize exposure. The evaluation of potency should be based on LOAEL and LD_{50}.
  - Defining the exposure and occurrence data elements has not been resolved at the subgroup level.
- New text has been added that**:**
  - Addresses what the NAS recommended, making the chapter format consistent with that of other chapters;
  - Discusses the need to address data elements for potency and exposure;
  - Offers suggestions for what should be flagged as data moves through Gate 1;
  - Considers values for solubility and persistence, requiring that each of these exceed a defined threshold for the contaminant to be considered to be a "yes" for exposure; and
  - Includes new language addressing microbials.
- Issues identified for work group discussion:
  - Recommendations regarding exposure data elements and exposure selection criteria.
  - The role of Gates in the screening process and flagging of contaminants with data or for which selection was based on estimates from QSARs or other models.
  - Specific recommendations for a microbial approach to screening.

Chapter 7: PCCL to CCL - Classification Prototype Approach, Attributes, and Training Data Set
(This chapter was addressed in greater detail in a later session.)
Changes based on January conference call.

- Section 7.2: Classification Approaches
  - The section has been modified based discussion on the January 12 conference call.
  - New text has been added that**:**
    - Craig Stow provided a new draft of the section and proposed the reorganization of the chapter.
  - Issues identified for work group discussion:
    - Current recommendations have not yet been discussed and agreed to by the full work group.
    - Whether and how to address rule-based approaches.
- Section 7.3: Attributes and Attribute Scoring
  - The section has been modified based discussion on the January 8 conference call.
  - Issues identified for work group discussion:
    - Current recommendations have not yet been discussed and agreed to by the full work group.
    - Attribute scoring protocols have been discussed to varying degrees during plenary, break out, and phone conference sessions. Issues and concerns have been raised on several details of the protocols, however they have not all yet been captured in the draft section and require additional work group input if they are to be included.
- Section 7.4: Training Data Set
  - The section has been modified based discussion on the December 29 conference call. However, this recommendation is contingent on the classification approach (Section 7.2); consequently it will need additional revision to make it consistent with the revised Section 7.2.
  - General description of what is included in chapter:
    - The subgroup agrees that a well thought out training data set is key to the success of the CCL process, no matter what method is used. They have considered that a training data set of as few as 50 contaminants may be sufficient.
    - While the training data set is crucial to classification approaches, it could also support rule-based approaches.
  - New text has been added that**:**
    - Discusses the appropriateness of use of construed data (i.e., interpolation of real data).
    - Considers the role of outside parties in reviewing data.
    - Deletes reference to values, focusing on the current state of information.
  - Issues identified for work group discussion:
    - Whether the work group is comfortable using only prototypes.

Chapter 8: Applications of Genomics to the CCL Classification Process

- No change has been made to the July 2003 draft.

Tom Carpenter, US EPA/OGWDW, briefed members on the discussions on the CCL classification process for microbial contaminants, focusing on the differences and similarities

between the processes for chemicals and microbials in Chapters 3 through 8 (see Attachment E). He noted that while the CCL process for microbes would adhere to the same principles and focus on the same attributes as the CCL process for chemicals, different data elements and scoring would be used. Much of the report text focusing on the CCL process for microbes has yet to be written.

Ms. Arnold concluded her briefing by inviting members to submit editorial comments in writing to RESOLVE.

Following the presentations, work group members noted the following issues for consideration:

Chapter 1: Executive Summary

- Begin drafting this section now – framing key points succinctly, so that later we can make certain that the report conforms to our hopes.
- *Douglas Crawford-Brown, University of North Carolina at Chapel Hill, volunteered to write the initial draft.*

Chapter 3: Transparency, Risk Perception, and Risk Communication CCL Work Group Process and Recommendations

- Reproducibility may not be a feasible goal.
- Wise use of resources is a policy issues, not in the purview of this work group.
- Discussion citing the Clean Water Act is out of place in this chapter, as it is a separate and distinct EPA regulatory activity from CCL and SDWA.
- Rather than a chapter on transparency, we could include text in each chapter addressing transparency and a recommendation that EPA employ transparency throughout the process.
- The chapter contains no discussion of risk communication.

Chapter 4: Overview of Process and Overarching Elements

- EPA needs to take a more active role in surveillance and nomination, rather than leave the burden on the public.
- Microbes must be addressed in this chapter too.
- The work group should further discuss the use of QSARs.
- There is considerable overlap with Chapter 5; this redundancy must be addressed.
- Surveillance can be very resource intensive. We need to be realistic about what EPA can do in regard to surveillance given current resources. Consider recommending that EPA link efforts of its offices and branches that share surveillance duties.

Chapter 5: Building the CCL Universe Proposed Recommendations

- A discussion of "4) adoption of an expedited process for agents as needed," under 5.3.1 3), page 4 of 16, line 39, is missing and should be added.

Chapter 6: Selecting Contaminants in the Universe for the PCCL

- Clarify the rationale by which the work group selected LD_{50} and LOAEL as data elements to characterize potency. Look beyond these data elements to identify other options.
- Explore alternatives to the "binning" approach.

- To give the reader a clear understanding of the efforts undertaken by and recommendations of the work group, document the analyses of alternatives considered by the work group in its deliberations. Place these analyses in appendices to the report.

Chapter 7: Recommended Process for Classifying from the PCCL to the CCL

- Consider whether the recommendations in Section 7.2 are too prescriptive and specific. Either provide appropriate justification for these recommendations or reconsider the recommendations.
- For transparency sake, include rationale for each decision made by the work group.
- Avoid the use of "reproducibility" when discussing computer models in Section 7.2; computer models require expert judgment, which makes it very difficult to reproduce the results.
- Which can be validated first, the training data set or the model?
- The circularity to the process raises the concern that using a training data set may make it harder to identify new and emerging agents.
- Consider the organization of the chapter; which should come first, the discussion of the training data set or the models?
- Microbes must be addressed in this chapter too.

Universe to PCCL – Chapter 6: Selecting Contaminants in the Universe for the PCCL

Amy Kyle, University of California, Berkeley, led participants through Chapter 6 and gave an overview of the changes to the chapter since the November meeting. These modifications were made based on plenary discussion at the November 2003 work group meeting and small group discussion, both at the previous plenary meeting and on the January briefing call.

Following Dr. Kyle's briefing, participants contributed their thoughts on the revised chapter. The major themes of this discussion are summarized below:

- Solubility as a data element for exposure: some participants questioned the suitability of solubility as a good predictor of exposure. This issue was passed to a small group for further discussion. The screening exercise results and discussion presented at the September 2003 meeting will be incorporated into the text in some manner.

- Data elements for potency: LD_{50} and LOAEL were used as data elements to characterize potency because they are the most basic and widely available of the data elements considered. Furthermore, both have counterparts under QSAR that can be used to make estimates if data is not available. Some participants were uncomfortable with the use of LD_{50} and explored alternative data elements in its place.

- Binning vs. scaling: some members objected to the use of discrete binning, i.e., yes/no approach to classification. They offered a continuous ranking approach (also referred to as scaling and a distributional approach) as an alternative that could allow for the use of raw data (see Attachment F). It was noted that scaling could be used in both Chapter 6 and Chapter 7 as an alternative to binning. Members decided to include in the report for EPA's consideration a discussion of the advantages and disadvantages of each of these screening approaches, but to characterize that most members of the work group were

comfortable with attribute scoring and that a number of experts had difficulty with this approach. The September screening exercise can be included as an appendix as an example of the binning approach and can also be expanded to address the distributional approach.

- Normalizing data: a few participants suggested that instead of normalizing data according to bins or into compartments, normalizations could be done through an equation (or rule) that relates various data elements and uses that normalized score. The latter preserves the "absolute" magnitude of the original data.

- Decision thresholds: it was also noted that use of a fixed, "bright line" decision threshold – as is envisioned in the binning approach – may be inappropriate; recognizing EPA resource constraints, a more suitable threshold may be one that is more of a "moving target," that would allow EPA to address a specified number of the worst contaminants.

- Data quality, confidence, and certainty/ "tags" and Gates: Members discussed the use of "tags" for data to reflect that data that is estimated or modeled, e.g., through the use of QSARs, is potentially of different quality than actual or measured data. For example, a data confidence could be tagged as follows:

Data Confidence Tag	Potency		Exposure	
	Measured	Estimated	Measured	Estimates
I	X		X	
II	X			X
III		X	X	
IV		X		X
V				

In addition, such tags can be used to indicate the reliability of the data source and whether data reflects a single value or is represents a consolidation of values. These tags can be used in a modified Gates approach. Several work group members agreed to assist in exploring alternatives for more smoothly integrating the Gates discussion into Chapter 6. *Michael Dourson, Toxicology Excellence in Risk Assessment, will draft proposed text.*

- "On ramps" always available: The nomination and surveillance process is one "on ramp" that allows agents to be brought into the PCCL. Gate V also allows for experts to nominate agents. Chapter 6 must be made consistent with Chapter 5 in its discussion of nomination and surveillance and the redundancy should be eliminated.

- Addressing microbes: The screening process for microbes considers whether the organism is pathogenic or not. If it is a pathogen, then the agent goes into the PCCL. This will be addressed in a new chapter, to focus on the CCL process for microbes.

PCCL to CCL – Chapter 7: Recommended Process for Classifying from the PCCL to the CCL

The work group next heard overviews of substantive sections of Chapter 7, delivered by the principal authors of these sections.

Section 7.2: Recommended Approach to Select PCCL Contaminants from the CCL

Craig Stow, University of South Carolina, explained that on the briefing conference call concerning Section 7.2, participants indicated disappointment that the recommendations in this section did not go much beyond those in the NAS report. He had since revised the section, which was distributed to the work group for consideration the previous week, as part of the revised report. Dr. Stow noted that he had reorganized Chapter 7 such that the section on attributes and attribute scoring now precedes the section on classification approach. Dr. Stow also noted that the work group will not be able to decide on a recommended model until there is agreement on the training data set.

Following Dr. Stow's presentation, participants discussed the revised section. Members endorsed EPA moving forward with the development of one or more prototype models. While the work group seemed comfortable with the revised section overall, participants agreed that it should be revised to provide for the possibility that the preferred, *a posteriori* prototype classification model may not be ready in time for use in the next CCL. The work group recommended a phased approach to allow for the development of a good training data set for use in validating the model. In the meantime, the work group recommends that for CCL 3, EPA run a rough prototype, taking care to be transparent about what the rough model is and what it isn't. Stakeholders would provide input into the development of several training data sets and the rough prototype. EPA would seek expert judgment as well, and use a set of performance criteria to evaluate the pilot. In addition, the "on ramps" open to help catch anything that might otherwise be missed. Lessons learned from the CCL 3 rough prototype could be applied to the planning of the CCL 4 process. The work group also agreed that if, in EPA's judgment, it is unable to adequately develop the prototype model in time for use in CCL 3, it should leave adequate lead time so that it can complete an alternative process, which would probably be an approach relying on expert judgment and stakeholder input. (See also *Treatment of Alternatives for the Prototype Model*, under Report Out from Subgroup Meetings – Recommended Changes to the Draft Report, below.)

7.3: Attributes and Attribute Scoring

Work group members offered several comments regarding Section 7.3. Comments mainly focused on the decision to present the use of the raw data (or observed values) as an alternative scoring. A member pointed out that scoring might result in transformation of data into scaled scores. Text should be added, saying that one may use scores or raw data. It should also indicate that scores are used, this is the protocol; however here are the shortcomings of the approach. Alternatively, if observed values are used, here is the protocol, however here are the shortcomings of this approach. *Daniel Wartenberg, Environmental and Occupational Health Science Institute, is drafting text with Nancy Kim, New York State Department of Health, to mark it up.*

Members felt that Specific Recommendation #1 (under Section 7.3.4) should be rewritten to provide greater clarity. The scoring protocols will be included as an appendix under the header "Not Complete, Draft for Review" and will be framed as having been developed by a technical team as a product of a workshop, not a product of the full work group.

Report Out from Subgroup Meetings – Recommended Changes to the Draft Report

On the second meeting day, work group members – who had met informally, in small groups, on several remaining issues the night before – discussed and made the following revisions to various sections of the draft report:

Nomination and Surveillance – The small group on nomination and surveillance recommended:

- reviving some language previously removed from the report regarding related EPA activities and augment Section 4.2, which provides an overview, with language transferred from Chapter 5 (see Attachment G);
- in Chapters 5, 6, and 7, where there is mention of the nomination process, refer back to Chapter 4, which discusses the "on ramps," where by agents not in the Universe can advance to the PCCL and CCL through the nomination process following the application of evaluative criteria;
- use of "potency/exposure" rather than "evaluative criteria";
- acknowledging which LOAELs are based on new data and which on old data;
- EPA outreach to the state agency, researchers, water, and public health communities, possibly holding a biennial meeting for information exchange; frame this as a research activity for coordination with US EPA/ORD, from which funding may be available; and
- adding to the glossary the definitions of agent, known agent, new agent, emerging agent, and contaminant (Chapter 5, page 13).

Universe to PCCL Screen/ Solubility/ Indicators of Exposure and Potency – The small group addressing issues related to Chapter 6: the Universe to PCCL Screen reported the following related to the consideration of potency:

- because there are some compounds that may be highly toxic but relatively insoluble, solubility alone is not a good screen; such chemicals would be screened out and not reach the PCCL;
- LD_{LO} (the dose that causes observed mortality) should be added as a third data element for potency; the lowest value of either LD_{LO}, LD_{50}, or LOAEL should be used; LD_{LO} values can be found on the RTECs database;
- carcinogens should automatically be placed on the PCCL, using:
  - tumor total dose/day as the value of LOAEL for carcinogenic tumors;
  - tumor dose 05; or
  - value available from a list, e.g., IRIS, IARC.

This small group also addressed exposure, noting that persistence should be used as an "on" or "off" filter (and not as a scaled value) to screen out agents with short half-lives. In addition, when considering exposure, the source potential (i.e., the likelihood that this agent will show up in drinking water) should be taken into account.

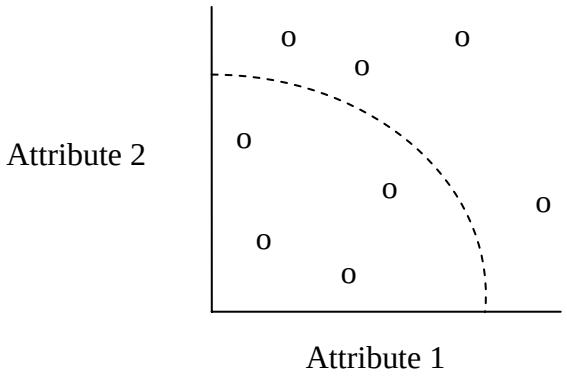
Members agreed to include in their recommendation that there should be a phased screening process including a toxicity screen followed by a persistence screen and to note that potency and exposure must also be addressed. Ms. Arnold invited members to submit in writing additional approach options for moving from the Universe to PCCL. Members discussed inserting a solubility/ potency screen, followed by a source screen, between the toxicity screen and persistence screen, but not all were comfortable with this suggestion. Although some participants noted that this might be a promising approach in that it automatically captures low solubility/ high toxicity chemicals, others pointed out that this set of screens might complicate the ability to screen many agents quickly, in an automated manner.

Transparency – The small group addressing issues related to Chapter 3: Transparency, Risk Perception, and Risk Communication CCL Work Group Process and Recommendations reported that the most contentious issue they addressed concerns the need for the CCL classification process to not only have integrity, but also be conducted in an efficient manner (i.e., that EPA use wisely its limited resources). The small group offered a revised and significantly shortened draft of Chapter 3 – narrowing the focus of Chapter 3 to transparency and public participation – for members' consideration (see Attachment H).

Microbial Approach – The small group addressing the microbial approach to the CCL classification process reported that they proposed the use of the same attributes as for the chemical approach. They noted that each attribute would have its own scoring system, distinct from the system(s) for chemicals. The microbial group was still in the process of testing several systems, with the severity attribute posing the most problems.

The small group suggested the insertion of a separate chapter (a new Chapter 5) addressing microbes and paralleling the discussion of the approach for chemicals in the current Chapter 5: Building the CCL Universe Proposed Recommendations, Chapter 6: Selecting Contaminants in the Universe for the PCCL, and Section 7.3: Attributes and Attribute Scoring, rather than integrating the microbial approach into each chapter. (The work group similarly chose to consolidate into a new chapter the discussion of the above-mentioned chapters and sections pertaining to the chemical approach (see Attachment I for the revised table of contents).)

Treatment of Alternatives for the Prototype Model – Douglas Crawford-Brown observed that the *a posteriori* prototype model process involves establishing a classification rule for determining whether to place a potential contaminant from the PCCL on the CCL. This classification rule can be represented as a discriminating surface on multi-dimensional axes of two attributes (see figure below). In order to construct this graph one would need to know the attributes in question and the rules for scoring them.



Dr. Crawford-Brown proposed that if the prototype model is not ready for use when it is need for the preparation of the next or succeeding CCL, EPA should convene facilitated discourse of experts to draw the discriminating surface, resulting in an *a priori* algorithm for use in the CCL process in question. This facilitated discourse would require the experts to:

- agree on the attributes;
- understand the scoring process;
- explain how they arrived at their approach; and
- decide on the classification rule that will determine the discriminating surface.

The work group agreed to recommend that EPA proceed with the development of an *a posteriori* modeling approach, seeking expert and stakeholder input in its development at critical stages. This would include seeking input into whether the model is ready for use in the next CCL process. The work group also recommends that EPA develop appropriate evaluation criteria for the prototype algorithm output, e.g., see the bulleted items on lines 3 through 10 on page 12 of Section 7.4. Additional evaluation criteria could include:

- how well the algorithm deals with missing data on attributes;
- the number of attributes requiring scoring needed to run the model;
- the usefulness of the output as a discriminator;
- the validity and reliability of the model and its output; and
- whether the model misses significant problems, glaring public health issues, or important contaminants.

Members noted that, in general, a model that provides comparable results, but requires less information (i.e., fewer attributes) is a better model. In addition, participants cited the need to incorporate the principles of:

- science and technical soundness;
- expert consultation throughout the process, with expert review at some defined point;
- public consultation and involvement;
- transparency; and
- timeliness.

Data Confidence and Certainty – Dr. Crawford-Brown proposed language to address concerns about the treatment of uncertainty and confidence in the CCL process (see Attachment J). Generally, participants seemed to agree that as one moves through the process from Universe to

PCCL to CCL, progressively more stringent criteria should be applied in terms of data confidence and certainty. Dr. Crawford-Brown's proposed text is consistent with this principle; he recommends against making uncertainty and confidence a screen, but suggests that databases be systematically assigned an overall assessment of quality or reliability and that each agent be tagged with this assessment as it enters the Universe.

At the level of moving from the Universe to the PCCL, the same assessment tag would be brought along. In addition, a tag would be assigned related to the general quality and reliability of any inference methods used (e.g., QSARs to establish solubility). At this stage, some screening of agents for uncertainty and confidence might be appropriate. Finally, at the PCCL to CCL stage these tags should be considered more fully.

The work group agreed to recommend such tagging for confidence and certainty, but chose not to specify how it should be done.

Public Comment

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

Next Steps

Overall, the next steps for in the revision of the draft work group report are:

- By January 30 – Authors will revise their sections and sent them to editor Susan Savitt Schwartz
- By February 4 – Editor will complete compilation of report and send to Work Group and Technical/Facilitation Team for review
- By February 18 – Work Group will convene conference calls to discuss and review revised draft chapters and sections
- By February 20 – Lead authors will revise sections and chapters and send to editor
- By February 27 – Editor will complete editing and formatting and send revised document Work Group and Technical/Facilitation Team for review
- At March 4-5 plenary meeting – Work Group will review report.

Future Meetings

The remaining work group meeting in 2004 is scheduled for March 4-5. It is expected that this meeting will be held at the RESOLVE offices.

The work group identified several additional meeting days should it become necessary to postpone the March meeting and/or schedule additional. These include:

- April 22-23, 2004
- May 11-12, 2004 (possible May 10)
- June 8-9, 2004

Attachments

A. Work Group Members in Attendance
B. Agenda
C. Report of the Contaminant Candidate List Classification Process Work Group to the NDWAC: Revised Draft, Sent to Work Group Members January 16, 2004
D. Abby Arnold's Presentation Slides on Overview of Draft Report
E. Tom Carpenter's Presentation Slides on Microbial Approach to CCLCP
F. Binning Versus Scaling in the CCL Process, January 22, 2004
G. Revisions/additions to Surveillance, based on evening conversation (1.22.04)
H. Chapter 3: Transparency and Public Participation, Revised based on Work Group comments 1/23/04
I. Discussion Draft Table of Contents, January 28, 2004 (based on January 22-23 CCL Work Group Meeting)
J. Proposed Language on the Treatment of Uncertainty and Confidence in the CCL Process

Attachment A

CCL Process Work Group Members Participating in the Meeting

Dr. Laura Anderko
Dr. Rick Becker
Dr. Douglas Crawford-Brown
Dr. Michael Dourson
Dr. Alan Elzerman
Dr. Wendy Heiger-Bernays
Mr. Buck Henderson
Dr. Nancy Kim
Mr. Ephraim King
Ms. Carol Kocheisen
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

ATTACHMENT B

NDWAC Contaminant Candidate List (CCL) Classification
Process Work Group

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1255 Twenty-third St., NW, Suite 275
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January 22-23, 2004

Draft Meeting Agenda
REVISED

Meeting Objectives:

- *Review and discuss draft report overall and those sections that the work group identifies*
- *Reach agreement on how to address issues and concerns raised by work group members*
- *Reach agreement on how to accommodate all work group substantive comments and how we will incorporate editorial comments*
- *Decide on next steps for completing the report by March 4 meeting and submission to the NDWAC*

Thursday, January 22, 2004

9:00-9:15 Welcome and Introductions

- Welcome - *OGWDW, EPA*
- Introductions - *Abby Arnold, Facilitator, RESOLVE*
- Review meeting objectives
- Review and adopt agenda

9:15-10:45 Review of Draft Report

- Overview of table of contents.
- Overview of status of each section of the report, and where relevant, overview and brief discussion of the direction suggested by work group members on December and January briefing calls.
- Overview of specific sections of the report not discussed by the work group.
- Overview of microbial activity group recommendations for treatment of microbials.
- General work group comments; assessment and adjustments of the agenda based on work group comments.

10:45-11:00 Break

11:00-12:00 Universe to PCCL

Chapter 6: Selecting Contaminants in the Universe for the PCCL Amy Kyle
Overview and discussion of chapter 6
Work group thoughts/conclusions about questions (see revised draft chapter 6) and comments on recommendations

12:00-12:45 Grab Lunch and Return To Continue Work

12:45-3:30 **PCCL to CCL**
(including break)

Chapter 7: Recommended Process for Classifying from the PCCL to CCL
Overview and discussion of chapter 7

- *7.2 Classification Approach* Craig Stow
- *7.3 Attributes and Data Elements (and Scoring Approach)* Frank Letkiewicz
- *7.4 Training Data Set* Stig Regli

Work group thoughts/conclusions about questions (see revised draft chapter 7 sections) and comments on recommendations

3:30-3:45 Break

3:45-4:45 **Issues From the Morning**
Discussion of parking lot issues raised during the day, and how we are going to address them. Or, begin breakout sessions – see 6:30 pm.

4:45-5:00 **Public Comment**

5:00 **Adjourn for Dinner?** *(group will decide if they want to work through dinner, or adjourn, get dinner and return to office to work)*

6:30-9:00 pm **Review and Comment on Specific Sections**
Break into small groups to review specific sections of the draft report

Transparency Group Meets
- Review draft/edit
- Edit/prepare report to plenary
- Develop plan for completion

Small Group Discussion on Chapter 6
- Further review one-text
  - Consider which option best reflects exposure
  - Comment on how to best represent persistence
  - Further consider whether to recommend additional data elements
- Edit/prepare report to plenary
- Develop plan for completion

Small Group Discussion on Chapter 7 *(may need to break into subsections)*
- Review one-text
- Edit/prepare report to plenary
- Develop plan for completion

Microbial Group May Meet
Other small group discussion needed (Chapter 4….?)

Friday, January 23, 2004

8:30-8:45 **Settling In – Review Agenda for Day 2**

8:45-9:45 **Review and Discuss Chapter 4**

9:45-11:30 **Review and Comment on Specific Sections,** *continued*
Break into small groups to review specific sections of the draft report – (see evening session)

11:30-12:15 **Grab Lunch and Return To Continue Work**

12:15-2:15 **Report Out from Subgroup Meetings, Recommended Changes To Draft Report**

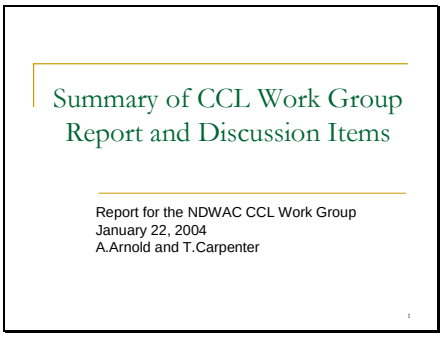
2:15-3:00 **Review Work Plan, Draft Report Outline and Sections (Chapters 5, 6, 7), and Next Steps/Overall Schedule**

- *In light of discussion above, progress made, and tasks to be done, what are our next steps?*
  - *What questions and issues remain to be addressed for each chapter? How should we address them?*
- *Who will do what by when, assignments?*
- *Weekly plan from January 23 to March 4-5, 2004*

3:00 **Adjourn**

Attachment C:

Slide 1



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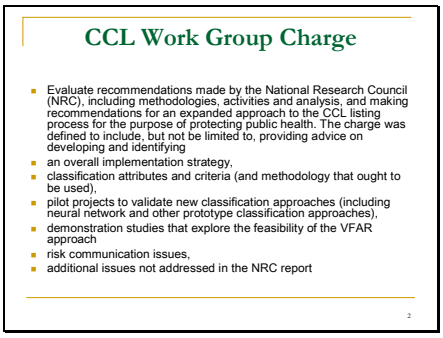

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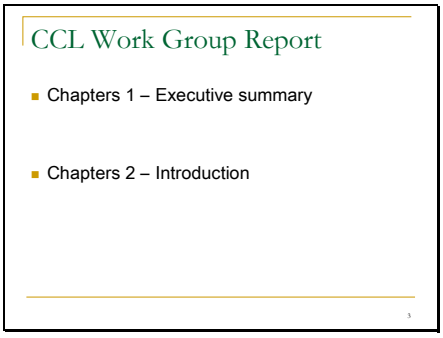

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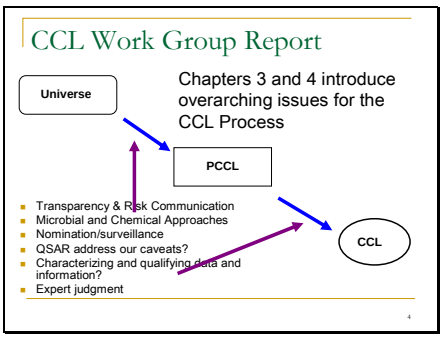

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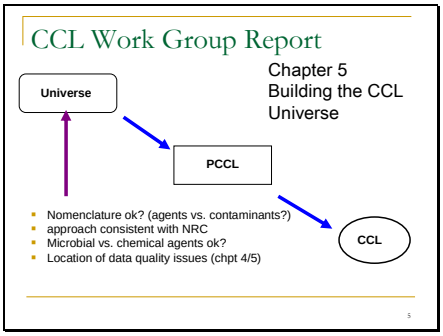

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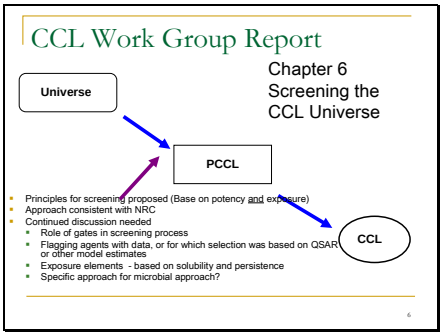

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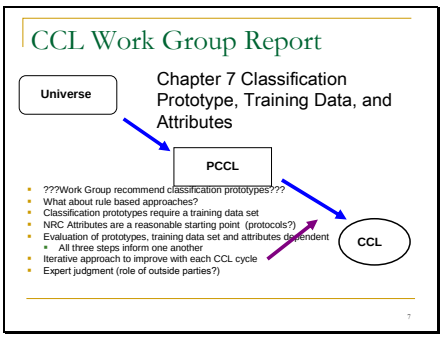

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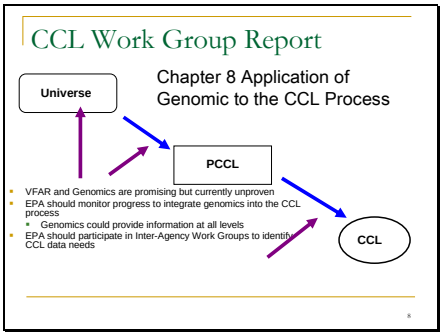

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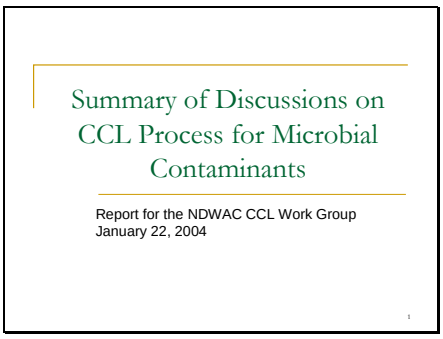

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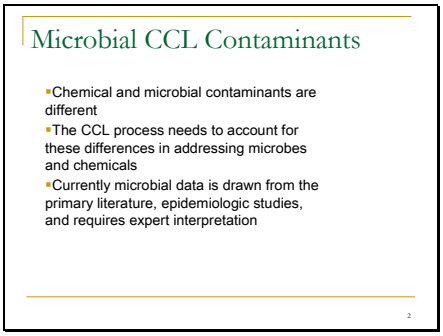

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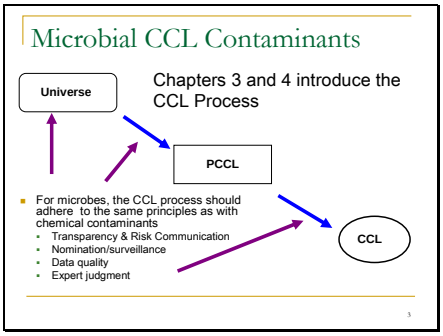

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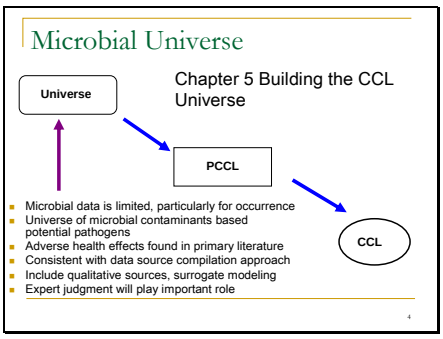

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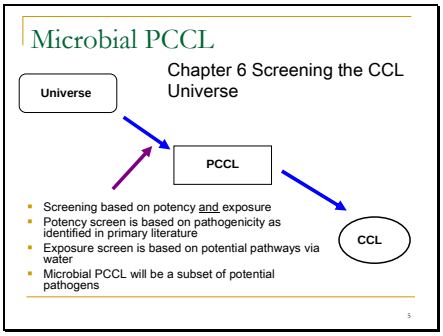

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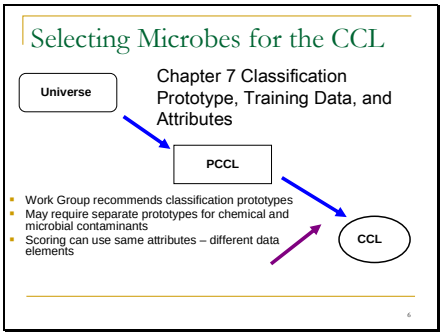

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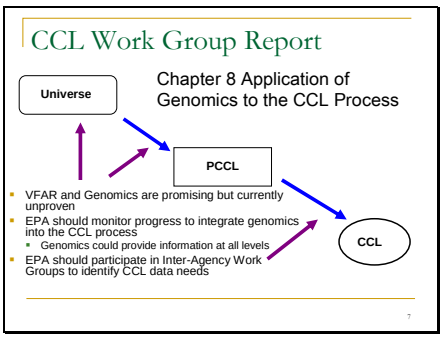
CCL Work Group Report
Universe
Chapter 8 Application of Genomics to the CCL Process
PCCL
CCL
VFAR and Genomics are promising but currently unproven
EPA should monitor progress to integrate genomics into the CCL process
Genomics could provide information at all levels
EPA should participate in Inter-Agency Work Groups to identify CCL data needs
7

ATTACHMENT F

January 22, 2004

Binning Versus Scaling in the CCL Process

The overall process of selecting agents to be placed on the CCL is an attempt to classify a large number of agents into a set of three ordered categories: the universe (i.e., compounds and biologicals with sufficient data for evaluation); the PCCL (i.e., a large list of approximately several to tens of thousands of compounds and biologicals with data and/or information that suggests that they may occur in drinking water and, if people use that water, may cause adverse human health effects); and the CCL (i.e., a small list of approximately 50-100 compounds and biologicals that are highly likely to occur in drinking water and cause adverse human health effects). The classification rules are based both on the properties of the compounds and biologicals and size of the lists that are deemed manageable by regulators.

Two alternative strategies have been proposed for classifying compounds and biologicals. One approach, called binning, is based on the *a priori* determination of specific cutpoints of the properties and list size. The other approach, called scaling, is based on first ordering all of compounds and biologicals based only on their properties, and then applying a rule based combination of criteria that could include both the relative magnitude of the properties and the number of compounds that can be placed in a specific class.

There are advantages and limitations to both strategies. The binning approach, because the cutpoints are determined *a priori*, is transparent, can be applied easily by those with limited technical training and is consistent with current knowledge of how predictive the specified properties are of occurrence and adverse human health effects. However, to be implemented, one must reach agreement on the *a priori* cutpoints, it does not include possible interactions between the occurrence and health effects data (i.e., effect modification), and does not differentiate with respect to properties among the compounds and biologicals within each category, particularly for those extremely close to the cutpoint and those that are not.

The scaling approach has the advantage of using the properties of the compounds and biologicals independently of any decision process but based only on the scientific interpretation of these properties. In addition, the scaling approach allows for consideration and specification of a variety of different types of interaction among the properties from the extreme of no interaction (i.e., the case of binning), to additive, synergistic (i.e., greater than additive) and antagonistic (i.e., less than additive) situations. Further, the interactions can be linear, curvilinear, etc. One also could use a variety of statistical methods to identify groups of similar compounds and biologicals (e.g., clusters), and then define classification boundaries between these groups defined by the data. Third, because the compounds and biologicals are ordered, the relative positions of each compound and each biological can be assessed at any point in the process. Therefore, for example, once classified, experts can review those compounds and biologicals nearest the cutpoints to review whether they belong in the class assigned or

the neighboring class. Similarly, one can consider the range of compounds and biologicals within a class, noting that those at the top of the CCL might warrant more rapid and broad-reaching consideration than those near the lower cutpoint. The method also is transparent in that one can draw a simple graph of the classification process to communicate both its application and the result (see below). It is relatively easy to conduct a sensitivity analysis of the specific classification rule applied, to see whether the final classification of compounds and biologicals changes markedly if there is a slight shift of the line or curve. Finally, from a more technical perspective, transforming interval data (i.e., the measured or estimated values for the properties) into ordered categories (i.e., the universe, PCCL and CCL) results in a substantial loss of information and markedly decreases the sensitivity of subsequent analyses of the data.

The process of selecting agents as currently proposed uses information for two properties of compounds and biologicals: potency and exposure. (The methods for measuring or estimating quantitative values for these properties are discussed elsewhere.) The figures below show how a few different classification rules can be applied to a small, hypothetical data set. Figure 1 shows the hypothetical data set, with several compounds plotted on two axes, potency and exposure, based on the scaling approach. Figure 2 shows the application of a binary, binning classification rule to these data plotted for the scaling approach. That is, the binning approach can be considered a subset of the scaling approach, albeit a rather restrictive one. Based on the four different regions defined by the cutpoints for potency and exposure, one could determine which compounds get classified into the more severe category and which do not. For example, one could say that only those that have both high potency and high exposure are classified in the severe category (e.g., moving from the PCCL to the CCL). Those compounds are in the upper right area of the graph defined by the thick lines. Or, one could say that compounds that have either high exposure (without consideration of potency) or high potency (without consideration of exposure), or those that are moderate to high in both exposure and potency, are classified in the severe category (e.g., moving from the universe to the PCCL). For this rule, those compounds are in the lower left area of the graph, defined by the thick lines, are the only ones that would not be classified in the severe category.

Figure 3 shows the application of a linear classification rule. This incorporates a statistical interaction between potency and exposure. That is, those compounds with high potency and low to moderate exposure would be classified in the severe bin, as would those with high exposure and low to moderate potency, and those with both moderate to high potency and moderate to high exposure. The slope of the line determines the relative importance of potency versus exposure. The place of the line with respect to the origin would determine the number of compounds that are classified in the severe category.

Figures 4 and 5 show the application of two different curvilinear classification rules. These are applied in a similar manner to the linear rule, but are more flexible.

ATTACHMENT F

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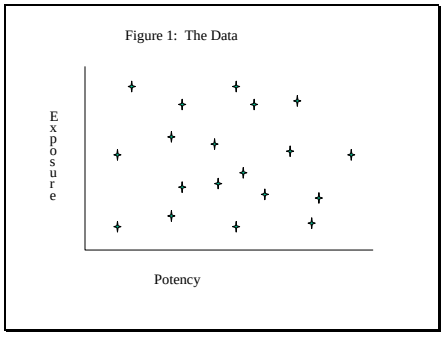

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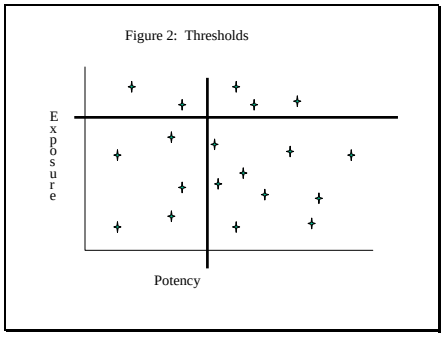

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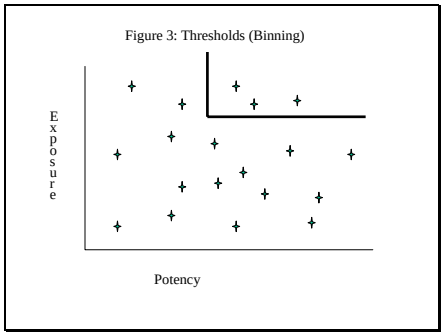

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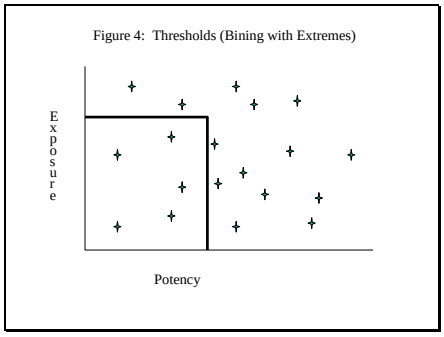

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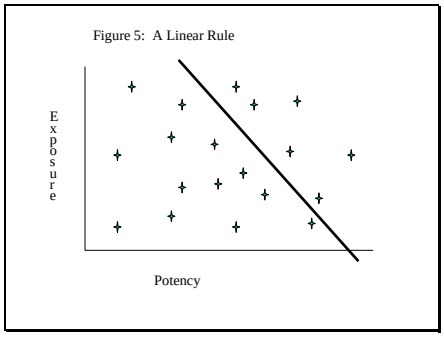

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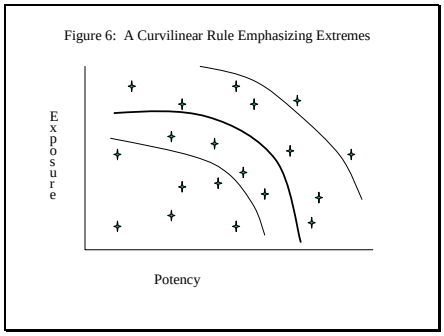

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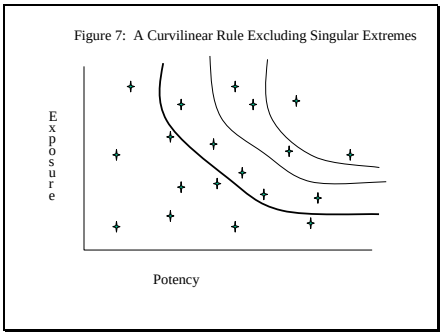
Figure 7: A Curvilinear Rule Excluding Singular Extremes
Exposure
Potency

ATTACHMENT G

3. TRANSPARENCY AND PUBLIC PARTICIPATION

Chapter 2 of the NRC report discusses that to achieve acceptance of the adopted CCL methodology, the methodology *"needs to be based on sound science, risk perception, social equity, legal mandates to consider the risks of vulnerable populations, and the proper role of transparency and public perception."*

Like the NRC, the CCL Work Group believes that the credibility of the CCL methodology EPA adopts depends on sound science, -- The method will need to withstand peer review or scientific critique – where scientists take the same information and test conditions and achieve the same results. Acceptance will also depend on how the method is developed and how transparent – clear it is to the public. The explanation of the CCL process will need to be expressed so that the public can generally understand the method used. This does not necessarily mean the process will be simple or easy to understand.

Decision makers, treatment operators, and drinking water consumers need to be able to understand why EPA has selected the CCL contaminants and why further research on these contaminants is a good use of resources. The public will want explanations regarding why investment in the methods used to select contaminants and investment in research on certain contaminants is cost effective and will lead to improved protection of public health. If EPA is transparent in decision making, the public will have the rationale it needs for how the method works and what is on the list.

As recommended by the NRC, the CCL Work Group discussed the importance of noting uncertainties in data or information used in the methodology, as well as uncertainties in the concluding CCL. If EPA is clear about these uncertainties, it will provide the decision maker and the public with the tools needed to determine whether they believe EPA has made the appropriate determinations consistent with protection of public health, good science, occurrence in drinking water**.** The public will also want to know EPA has used resources wisely in developing the CCL.*– some members of the subgroup want this sentence, others want it to remain.—need full Work Group comment.*.

The CCL Work Group endorses the following steps proposed by the NRC to encourage transparency of the recommended methodology (pp. 64-66 of NRC report):

- One of EPA's major goals in developing future CCLs should be to explain the process sufficiently so that the reader can understand the rationale behind including particular contaminants on the CCL. To achieve this goal would require that transparency be incorporated into the method used in the decision making process in addition to being an integral component in communicating the details of the decision making process to the public (p. 61).
- The use of a classification tool needs explanation or rational..
- The methodology for designing and calibrating the decision-making process must be explained.-

If decision making for including or excluding certain contaminant on future CCLs will ultimately depend on a combination of the results of a classification tool and EPA judgement, then this relationship must be fully articulated along with the background assumptions and underlying agency judgments. Key criteria, data, or assumptions that affect inclusion or exclusion in potential controversial cases ought to be noted, where possible so the reader can follow the logic regarding why decisions are made.

Public Participation

As quoted by the NRC, "'*public participation encompasses a group of procedures designed to consult, involve, and inform the public to allow those affected by a decision to have an input into that decision' (Rowe and Frewer, 2000)"* (p. 66). The NRC also points out that *"a central tenet of public participation is that the public is, in principle capable of making wise and prudent decisions"* (p 66).

The CCL Work Group agrees with the NRC that sufficiently broad public participation will be needed to implement the CCL methodology. Without this, it will be difficult to obtain buy-in from various stakeholder groups. The CCL Work Group principles on public participation follow:

- The CCL decision making process must be open, accessible, and available to all stakeholders who are interested.

- The CCL Work Group encourages EPA to provide the opportunity for public involvement at key steps along the way. Broad participation that is representation of the range of affected and interested parities should be a priority, thereby considering public health values, viewpoints, and principles.

The NRC recommended integration of technical expertise with values and concerns of stakeholders. This NDWAC CCL Work Group process is a beginning toward achieving this integration. The work group recommends that EPA consider additional, ongoing consultation with key stakeholders and outreach to the public as implementation proceeds. The work group agrees with the NRC that the public involvement program needs to be tailored to the public's needs and should start early in the process.

*** Want to refer to discussion about public acceptance, steps discussed in PCCL-CCL prototype classification approach section???

***Note, reference to SDWA needs to be incorporated into Introduction.

Report of the Contaminant Candidate List Classification Process Work Group To the National Drinking Water Advisory Council

Discussion Draft Table of Contents (based on January 22-23 CCL Work Group Meeting)

1. Executive Summary ***(not yet written)***
    1.1. Background and Purpose
        1.1.1. EPA's Requirement to Develop a CCL
        1.1.2. Original EPA Process
        1.1.3. NRC Review of EPA Process
        1.1.4. Charge/mission of the NDWAC Work Group
    1.2. Making the Contaminant Listing Process Understandable
        1.2.1. The Need for Transparency
        1.2.2. The Extent to Which the Process Can Be Reproducible
        1.2.3. Risk Communication
    1.3. Overall Principles that Apply to the Contaminant Listing Process At All Stages
        1.3.1. Nomination and Surveillance
        1.3.2. Characterizing the Data (Confidence and Certainty)
        1.3.3. Use of QSARs
        1.3.4. Unified Principles Between Microbes and Chemicals
    1.4. Differences Between Microbes and Chemicals and How They Affect Identifying and Prioritizing Contaminants Through the CCL Process
    1.5. CCL Approach for Microbial Contaminants
        1.5.1. Identifying the CCL Universe
        1.5.2. Screening from the Universe to the PCCL
        1.5.3. Scoring Attributes for Microbes
        1.5.4. Application of Genomics to the CCL Process
    1.6. CCL Approach for Chemicals
        1.6.1. Identifying the CCL Universe for Chemicals
            1.6.1.1. Principles for Identifying the CCL Universe
            1.6.1.2. Alternatives for Identifying the Universe
            1.6.1.3. Recommended Approach to Identifying the Universe
        1.6.2. Screening from the CCL Universe to the PCCL for Chemicals
            1.6.2.1. Principles for the Screening Process
            1.6.2.2. Characterizing Exposure and Health Effects
            1.6.2.3. Alternatives for Screening (Binning, Gates and Combinations)
            1.6.2.4. Threshold Criteria Versus Ranking
            1.6.2.5. Recommended Approach
        1.6.3. Scoring Attributes for Chemicals
            1.6.3.1. Principles for the Classification Process
            1.6.3.2. Alternatives for the Classification Process
            1.6.3.3. Recommended Approach
    1.7. Classification Models for Identifying Contaminants for the CCL from the PCCL
    1.8. Items for Future Consideration

2. Introduction
2.1. Background on the Contaminant Candidate List and the National Academy of Sciences (NAS) National Research Council (NRC) Recommendations
2.2. Convening and Membership of the NDWAC CCL Classification Work Group
2.3. NDWAC CCL Classification Process Work Group Charge and Guiding Principles
2.4. Summary of the CCL Classification Process Work Group Deliberation Process
2.5. Explanation of the Role of the CCL in Protecting Public Health and the Implications of Inclusion on the PCCL or CCL
2.6. Organization of the Report and How It Addresses Microbes and Chemicals ***(new section)***

3. Transparency, Risk Perception, and Risk Communication CCL Work Group Process and Recommendations
3.1. Why Transparency Is Important for the CCL
3.2. Public Participation

4. Overview of Process and Overarching Elements
4.1. Overview of Recommended CCL Process ***(not yet written)***
4.2. Surveillance and Nomination Processes Proposed Recommendations *[incorporates language from former chapter 5??]*
4.2.1. Surveillance Process for New and Emerging Agents
4.2.1.1. Primary Source Literature Review
4.2.1.2. Additional Surveillance Activities and Recommendations
4.2.1.3. Surveillance and Expert Judgment
4.2.2. Nomination and Evaluation Process for New and Emerging Agents
4.2.2.1. Additional Nomination Activities and Recommendations
4.2.2.2. Expedited Listing Process
4.3. Use of QSARs
4.3.1. Background
4.3.2. Conclusions and Proposed Recommendations, and Rationale
4.4. Characterizing and Qualifying the Data and Information *[incorporates confidence and certainty language from other chapters??]*
4.4.1. NRC Discussion and Recommendations
4.4.2. Work Group Considerations
4.4.3. Recommendations and Rationale
4.5. Unified Principles and Their Application in the Microbial CCLCL ***(new section)***
4.5.1. Commonality of Chemical and Microbial Approach
4.5.1.1. Surveillance and Nomination Processes
4.5.1.2. QSAR/VFAR Approach
4.5.1.3. Characterization and Quality of Data
4.5.2. Population Susceptibility
4.5.2.1. Normal populations
4.5.2.2. Susceptible Sub-populations

5. Microbial Approach to the CCL Classification Process ***(new chapter)***
[incorporating text from former 4.1.1 Chemical and Microbe Contaminant Approaches, former 5.3.2 Microbial Contaminant Discussion and Recommendations, former 6.9 Microbial Considerations]
5.1. Building the CCL Microbial Universe
5.1.1. NRC Recommendations for the Microbial Universe
5.1.2. Dimensioning the CCL Universe
5.1.2.1. Pathogens as the Basis for the Microbial Universe
5.1.2.2. Occurrence Principles for Insuring Inclusivity
5.2. Selecting Microbial Agents in the Universe for the PCCL
5.2.1. NRC Recommendations for the PCCL
5.2.2. Rationale for PCCL Screening
5.2.3. Health Effects and Occurrence Criteria
5.2.4. Screening Based Upon Biological Properties of Microbes
5.2.5. Opportunistic Pathogens and Their Position on the PCCL
5.3. Recommended Process for Classifying Microbes from the PCCL to the CCL
5.3.1. NRC Recommendations for the CCL
5.3.2. Rationale for PCCL Screening
5.3.3. Attributes for Scoring PCCL Microbes
5.3.3.1. Potency
5.3.3.2. Severity
5.3.3.3. Prevalence
5.3.3.4. Persistence
5.3.3.5. Magnitude
5.3.4. Calibration Data Set and Automating the Selection Process
5.3.4.1. Scoring options
5.3.4.2. Reconciliation of chemical and microbial data
5.3.4.3. Recommendations for further evaluation
5.4. Applications of Genomics to the CCL Classification Process ***(former Chapter 8)***
5.4.1. Introduction
5.4.2. National Research Council Recommendations on Genomics
5.4.3. Potential Applications of Genomics
5.4.4. Challenges to Use of Genomics for the CCL Classification Process
5.4.5. Pilot Projects Currently Underway
5.4.6. Recommendations for Genomic Applications
5.4.7. References

6. Chemicals Approach to the CCL Classification Process
6.1. Building the CCL Chemical Universe ***(former Chapter 5)***
6.1.1. Background
6.1.2. Overall Recommendations
6.1.3. Specific Recommendations
6.1.3.1. Chemical Contaminant Recommendations
6.2. Selecting Chemical Agents in the Universe for the PCCL ***(former Chapter 6)***
6.2.1. Principles for Screening Criteria

6.2.2. Characteristics of Interest
6.2.3. Data Elements for Potency and Exposure
6.2.4. Obtaining Values for Data Elements and Implications of Different Types of Values
6.2.5. Combining Values for Data Elements for Potency and for Exposure
6.2.6. Combining the Characteristics
6.2.7. Use a "Yes or No" Approach Defining the "Yes or No" (or "On or Off") Values
6.2.8. Supplemental Procedures
6.3. Attributes and Attribute Scoring ***(former Section 7.3)***
6.3.1. Summary of the NRC Recommendations
6.3.2. Background
6.3.3. Overall NDWAC Recommendations
6.3.4. Specific NDWAC Recommendations
6.3.5. Comments and Observations on Attribute Scoring Protocols

7. Recommended Process for Classifying Microbes and Chemicals from the PCCL to the CCL
7.1. Developing the CCL from the PCCL ***(not included)***
7.1.1. Expert Judgment ***(former Section 7.4.4.1)***
7.1.2. Facilitated Discourse ***(former Section 7.4.4.2)***
7.1.2.1. *A Priori* Rule-Based Approaches ***(new section)***
7.1.3. Prototype Classification Algorithm ***(former Section 7.4.4.3)***
7.2. Recommended Approach to Select PCCL Contaminants from the CCL
7.2.1. NRC Recommendations
7.2.2. NDWAC Recommendations
7.2.2.1. Linear Discriminant Analysis
7.2.2.2. Logistic Regression
7.2.2.3. Artificial Neural Networks
7.2.2.4. Classification and Regression Trees (CART)
7.2.2.5. Multivariate Adaptive Regression Splines (MARS)
7.3. Training Data Set ***(former Section 7.4)***
7.3.1. NRC Recommendations on Training Set
7.3.2. NDWAC Recommendations
7.3.3. Considerations and Rationale Supporting the Above NDWAC Recommendations
7.3.4. Recommendations for How Training Sets Could Be Used for Different Approaches

8. Glossary

Appendices
Comments and Observations on Attribute Scoring Protocols *(former subsections under 7.3.5.)*
Potency Scoring Protocols
Severity Scoring Protocols
Prevalence Scoring Protocols
Magnitude Scoring Protocols

Persistence/Mobility Scoring Protocols

NDWAC Recommendations *(former subsections under 7.2.2.)*
Linear Discriminant Analysis
Logistic Regression
Artificial Neural Networks
Classification and Regression Trees (CART)
Multivariate Adaptive Regression Splines (MARS)