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

March 4-5, 2004
Washington, DC

Final Meeting Summary

The tenth meeting of the NDWAC CCL Classification Process Work Group was held on March 4-5, 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; and
- Reach consensus on draft; or
- Decide on next steps for completing the report.

Welcome and Introductions

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

Ms. Arnold noted that this was the last planned meeting of the Work Group and that further work to finalize the report will be done via e-mail and telephone. She also proposed the use of a "SWAT Team" approach that would entail a 1 to 2 day, in-person meeting to give the document a rigorous and intensive edit. This Team would also work to reduce redundancy (e.g., between Chapters 4 and 6) and provide smoother transitions (e.g., between Chapters 5 through 7). The Team would not revise language and ideas to which the Work Group has specifically agreed. She noted that this approach could allow the Work Group to finalize the document for presentation to the NDWAC for consideration at its May 18-20, 2004 meeting, should the Work Group choose to work toward this deadline.

Review and Discussion of Draft Report

Ms. Arnold and Tom Carpenter, EPA/OGWDW, provided a review of the current state of the draft report (which was distributed to members prior to the meeting, in conjunction with the highlighted changes and remaining questions, 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 conference calls (to discuss Chapters 1, 4, 5, 6, and 7) convened since the January plenary meeting, as well as any remaining questions identified for Work Group attention. (The presentation materials used by Ms. Arnold and Mr. Carpenter are included as Attachment D.)

As they reviewed the status of each chapter, Ms. Arnold and Mr. Carpenter asked Work Group members to identify where additional substantive revisions were needed. (Members were also provided forms, on which to submit – either at or after the meeting – requests for editorial changes.) Members later discussed the issues they had identified as needing further revisions. These flagged issues and the Work Group's discussion of their resolution are summarized below. Unless otherwise specified, the described outcomes of these discussions constitute the consensus of the Work Group.

Chapter 1. Executive Summary

General

- Include only the higher level, overarching Work Group recommendations.
- Focus on and highlight the NRC recommendations that were discussed by the Work Group as well as the contributions of the Work Group that go beyond the NRC reports, especially in moving from the CCL Universe to the PCCL stage.
- Incorporate Figure 4.1 (see Attachment E) into this chapter.
- Highlight the importance of the prototype classification approach.
- Revise the chapter to reflect the balance of the current report.

Section 1.2.2 Charge to the NDWAC Work Group

- Expand this section to include the full charge to the Work Group.

Section 1.4 Guiding Principles and Overarching Issues

- Closely review the Work Group's guiding principles in this section and make certain they are consistent with those in Section 2.3 NDWAC CCL Classification Process Work Group Guiding Principles.
- Overall, Work Group members did not feel that they had sufficient time to address the following issues, but would note in the report that these might be considered next time the process is reviewed:
    - Automatically retaining the existing CCL onto the new CCL,
    - Sensitive subpopulations, and
    - Methods to improve the CCL process.

Chapter 2. Introduction

Section 2.1.1 The NRC Recommendations

- Include a brief summary of the NRC recommendations, to be drafted by the Work Group members who also participated on the NRC committee.
- Place the full list of NRC recommendations in an appendix.

Section 2.5 Role of the CCL in Protecting Public Health and Implications of Inclusion on the PCCL or CCL

- Review the text of this section to make certain that it accurately reflects the CCL process. Several members felt that this piece, i.e., the fifth paragraph through the end of the section, did not add to the section and that its removal from the report should be considered.
- Remove the third sentence of the second paragraph.

Chapter 3. Transparency and Public Participation

General

- Members decided to insert this chapter as a new Section 4.2, thereby eliminating Chapter 3.
- Avoid use of the phrase 'cost-effective'; throughout the section, replace this phrase to reflect a wise or efficient and effective use of resources.
- In this section and throughout the report, the terms *agent* and *contaminant* must be used consistently.
- A member observed that the section lacks discussion of several key concepts and asked for the addition of text to address these issues.

Chapter 4: Overview of Process and Overarching Issues

General

- Insert additional bullets in the chapter preamble to reflect additional overarching issues dealt with in Chapter 4, i.e., on information/data quality, expert judgment and review, transparency and public participation, and adaptive management.
- Members seemed to like the proposed revised Figure 4.1 (again, see Attachment E), but requested additional edits to more clearly distinguishing the three *steps* in the process, their component *tasks*, and the *products* resulting from each step.
- Incorporate into the overarching issues language related to acceptable misclassification rates. The Work Group supports a goal of minimizing false negatives in moving from the CCL Universe to the PCCL and of minimizing false positives in moving from the PCCL to the CCL.

Section 4.1.2.2 Integrating Expert Opinion into the Process

- Replace 'opinion' with 'judgment' in section title.
- Revise section based on small group's report of recommended revisions (Attachment F) and subsequent Work Group discussion. The intent of the Work Group is to avoid being overly prescriptive, allowing EPA the flexibility to decide what works best given the situation, while also ensuring transparency and public and stakeholder input.

Section 4.1.2.3 Dealing with Uncertainty in the CCL Process Revise

- Replace 'uncertainty' with 'information quality issues' in section title.

New, Section 4.1.2.4 Use of an Adaptive Management Approach

- Insert a Section 4.1.2.4 Use of an Adaptive Management Approach to reflect that the CCL classification approach goes beyond being iterative, but changes in response to the quality of its previous output. Several members volunteered to work with Ms. Arnold to revise the presented material (see Attachment G), providing a more detailed explanation of the figure.

Section 4.1.3.2 Screening from the Universe to the PCCL

- The Work Group came to the conclusion that it should not specify *potency* and *exposure* as the key characteristics when considering selection criteria for agents from the Universe to the PCCL. Rather, members opted to insert more general language into the last paragraph of this section referencing the 'data elements from the health effects and

occurrence attributes,' discussed in the succeeding section, 4.1.3.3 Characterizing the PCCL Contaminants.
- Language in Chapter 6 Approach to Chemicals in the CCL Classification Process must also be made consistent with this change.

Section 4.1.5 Incorporating VFARs: Long-term Growth in the CCL Process
- The Work Group replaced the term "VFARs" in the section title with "genomic information."
- Several members volunteered to assist in the drafting of additional language that highlights the need to continually monitor progress of genomics and related technologies as potential new tools for integration into the CCL process.
- The Work Group added a recommendation that the objectives of developing the CCL should guide data collection and analysis processes, rather than the other way around.

Section 4.2.2.2 Expedited Listing Process
- Use the term "accelerated" rather than "expedited" in both the section title and its text.

Section 4.3 Use of Quantitative Structure Activity Relationships (QSARs)
- Some Work Group members expressed concern that the use of proprietary QSAR models would limit the transparency of decisions based on those models and, consequently, recommended that the EPA should not use proprietary QSAR models. However, some Work Group members also noted that proprietary QSAR applications or computational algorithms were independently reviewed in their development even though the proprietary models are not available for subsequent reviews. Work Group members stated that if EPA elects to use proprietary QSAR models in the analysis, the Agency should include a rationale for the selection and use of QSAR models. The Work Group did not reach a consensus recommendation on the use of proprietary and non-proprietary QSAR models. They opted to summarize both options.

Section 4.4 Information Quality Considerations
- The Work Group agreed to use the phrase "quality of information" rather than "confidence."
- Members agreed to the addition of proposed text related to documenting the nature and type of data and information extracted form the data sources (i.e., "tagging,") to address concerns about the variability of the disparate types of data (see Attachment H).
- In item 1 under Section 4.4.3 Recommendations and Rationale, recognizing that good estimates may be better than good measurements, the Work Group agreed to eliminate the terms "demonstrated" and "potential" in favor of the terms "estimate" and "measurement."
- In addition, to provide greater clarity and consistency to Section 4.4.3 with the "tagging" approach, the Work Group revised items 2) and 3) under this section. (For the proposed revisions, accepted by the Work Group, see Attachment I.)

Chapter 5: Microbial Approach to the CCL Classification Process

Overall, members said that the new draft chapter was written in a simple and clear manner. As this was the first time a full draft of this chapter was considered in plenary, the microbial subgroup volunteered to work together to revised this draft following the meeting.

5.2.3 Screening Based Upon Biological Properties

- The subgroup should reconsider whether pathogenic respiratory viruses should be among the excluded pathogens from the PCCL (as is noted in Table 5.2).

5.2.5 Alternative Pathways for Adding Pathogens to the Microbial CCL Universe and the PCCL

- The subgroup should revise Figure 5.2 to provide greater explanation.

Chapter 6: Approach to Chemicals in the CCL Classification Process

6.1.3.3 Step-wise Integrated Process

- Insert text to Step 4) Accelerated Process indicating that the Work Group recommends that EPA develop a formal accelerated process, that this process be communicated to the public prior to or at the time EPA requests nominations, and that the process be open, transparent, and consistent with the overall CCL process.

6.1.3.4 Three-stage CCL Universe Identification Process

- Add "pharmaceuticals and personal care products (PPCP)" to the list of information sources that have a reasonable link (pathway) to drinking water concerns.

6.2.3 Key Characteristics

- As was discussed under Section 4.1.3.2 Screening from the Universe to the PCCL, the Work Group came to the conclusion that it should not specify *potency* and *exposure* as the key characteristics when considering selection criteria for agents from the CCL Universe to the PCCL. Rather, members opted to replace these terms with more general language referencing data elements that reflect certain aspects of health effects and occurrence.

6.2.6 Tagging Sources of Values for Data Elements and Implications

- Members noted that this section must be revised to be made consistent with Section 4.4 Information Quality Considerations.

6.2.7 Approaches to Classifying (Yes or No v. Scaling)

- Members noted the need for additional revision to the discussion of the two classification approaches, i.e., binning and scaling, and how they can be used "to draw the line" between contaminants included on or excluded from the CCL. The first of the two methods discussed for determining the criteria for inclusion on the CCL is an *a priori* approach, through which the limits are set at the beginning and an unspecified number of contaminants fall above or below the line. In another, *rule-based* approach, the data are plotted and then a line or surface is drawn to capture a certain number of contaminants or

is based upon how the data are arrayed. Several members volunteered to assist on this revision.

6.3 Attributes and Attribute Scoring for Chemicals

- In order to consolidate the related discussion common to both chemicals and microbes, the Work Group chose to move the majority of the text of this section into a new section 7.1 Attributes and Attribute Scoring. Text specific to chemicals and that necessary to introduce this discussion was retained in Section 6.3.
- The Work Group agreed to recommend that EPA go forward with some process of attribute scoring – several are discussed in the report – and be transparent as to how it is done.

Chapter 7: Moving from the PCCL onto the CCL

Several members cited the need for a conclusions section at the end of this chapter. They noted that this section might discuss what the outcome of the process should look like, e.g., specifying items that EPA will publish and whether a rationale is needed. The Work Group, however, did not come to consensus on whether prescribing such specificity was prudent.

7.2.2 NDWAC Work Group Recommendations

- Clarify the text to recommend that EPA move forward to test prototype approaches and identify the steps EPA should take to consider classification approaches.
- The Work Group recommendations should provide the Agency with principles that can be applied to the review of the process and determine the feasibility of the approach for CCL3 and steps to take for future CCLs.

7.3.2 NDWAC Work Group Recommendations

- Add text to indicate that the training data set should be chosen so that a discriminant surface can be defined.
- Revise Figures 7.1 and 7.2 to better communicate how good data are import to the ability to define a discriminant surface.

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 finalizing the draft Work Group report are:

- Work Group Draft Revisions to Report Due to Editor Susan Savitt Schwartz – – March 19
- SWAT Team Meeting – – April 1-2
- Draft Report to Work Group – – April 6
- Work Group Conference Calls on Revised Draft – – Week of April 12

For additional schedule details, see Attachment J. Volunteered contributions from Work Group members in revising the report are captured in Attachment K.

Future Meetings

As noted above, no further Work Group plenary meetings are anticipated.

Attachments

A. Work Group Members in Attendance
B. Agenda
C. February 27 Draft Report: Highlighted Changes and Remaining Questions
D. Presentation Slides for Abby Arnold and Tom Carpenter: Summary of CCL Work Group Report and Discussion Items
E. Proposed Revision of Figure 4.1
F. Small Group Report Regarding Use of Expert Judgment/ Expert Review: Draft
G. Proposed Language Regarding Use of an Adaptive Management Approach in the Development, Implementation, and Refinement of the CCL Methodology
H. Proposed Revised Section 4.4 Information Quality Considerations
I. Proposed Revised Section 4.4.3 3) Going form the PCCL to the CCL
J. Detailed Next Steps/Action Items
K. Volunteered Contributions from Work Group Members

Attachment A

CCL Process Work Group Members Participating in the March 4-5, 2004 Plenary Meeting

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
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

RESOLVE, Inc.
1255 Twenty-third St., NW, Suite 275
Washington DC 20037
202.944.2300

March 4-5, 2004

Draft Meeting Agenda

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 consensus on draft, OR*
- *Decide on next steps for completing the report.*

Thursday, March 4, 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
- Work Group members identify by page and line number
  - list issues can't live with or
  - issues needing refinement

10:45 - 11:00 **Break**

11:00 - 12:00 **Review and Comment on Chapters 1-3**

- **Executive Summary**
- **Introduction**
- **Transparency and Public Participation**

General work group comment on specific issues raised in chapters
Objective: Work Group discuss and address issues noted by Work Group members above.

12:00 - 12:30 **Grab Lunch and Return To Continue Work**

12:30 - 2:45	**Review and Comment on Chapters 4: Overview of Process and Overarching Elements** ***General work group comment on specific issues raised in chapters*** *Objective: Work Group discuss and address issues noted by Work Group members above.*
2:45 - 3:00	Break
3:00 - 4:00	**Review and Comment on Chapter 5: Microbial Approach to the CCL Classification Process** ***General work group comment on specific issues raised in chapter*** *Objective: Work Group discuss and address issues noted by Work Group members above.*
4:00 - 5:30	**Review and Comment on Chapter 6: Chemical Approach to the CCL Classification Process** ***General work group comment on specific issues raised in chapter*** *Objective: Work Group discuss and address issues noted by Work Group members above.*
5:30 - 5:45	**Public Comment** **Decide whether we need to have an evening session.**
5:45	**Adjourn for Dinner**
6:30	**Resume meeting?**

Friday, March 5, 2004

8:00 - 8:15	**Settling In – Review Agenda for Day 2**
8:15 - 9:30	**Review and Discuss Chapter 6,** *continued*
9:30 - 11:30	**Review and Discuss Chapter 7: Moving from the PCCL onto the CCL** ***General work group comment on specific issues raised in chapter*** *Objective: Work Group discuss and address issues noted by Work Group members above.*
11:30 - 12:15 *(including break)*	**Review and Discuss Executive Summary** ***General work group comment on specific issues raised in chapter*** *Objective: Work Group discuss and address issues noted by Work Group members above.*
12:15 - 1:00	**Grab Lunch and Return to Continue Work**
1:00 - 2:15	**Review and Reach Agreement on Outstanding Issues** ***General work group comment on specific issues raised in chapters*** *Objective: Work Group discuss and address issues noted by Work Group members above.*
2:15 - 3:00	**Review Work Plan, Draft Report Outline and Respective Sections 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 to complete Report*
3:00	**Adjourn**

NDWAC CCL Work Group

February 27 Draft Report: Highlighted Changes and Remaining Questions

This document highlights major changes to the document since the last draft was provided to you on February 6. The new draft is provided in *redline strikeout* so that you can view the changes made and it should be relatively easy to move between this document and the text of the report.

Chapter 1: Executive Summary

Editorial Issues

The executive summary will need extensive revision as a result of changes in other chapters. Editorial changes are not discussed due to the level of changes.

NDWAC Discussion/Update

Work group members held a conference call on February 23. Discussion focused on sections 1.1 to 1.4. Technical Team members noted that since the 2/6 draft was distributed conference calls on Section 4, 5, 6, and 7 resulted in changes to the language and specific recommendations discussed in the draft of Chapter 1.

Section 1.1 General Recommendations

The majority of changes were to clarify the recommendations. This was accomplished with relatively minor editing and agreement on the conference call. Changes provided in redline strikeout.

Section 1.2 Background and Purpose

This section will need to use similar language to Chapter 2. Chapter 2 revision is discussed below (see notes)

Section 1.3 Transparency: Making the process Understandable

This section will need to use similar language to Chapter 3. Chapter 3 revisions is topics for discussion are discussed below

Section 1.4 Guiding principles and Overarching Issues

The language developed by work group members for guiding principles is included in bullet form. The bullet recommending equal rigor for all aspects of the CCL process may need to be evaluated by work group members in light of the parallel microbial and chemical CCL Processes.

> All aspects of the CCL process should apply the same methods, with equal rigor, to chemical and microbial agents, consistent with the data available for these two categories.

Data quality/ confidence will need to consistent with Chapters 4 and 6 where these issues are discussed. See notes below for the discussion issues.

Section 1.5 CCL Approach for Microbial Contaminants
Section 1.6 CCL Approach for Chemicals
Section 1.7 Classification Models and Training Sets
These sections have been modified to reflect the discussion conducted on conference calls. The text is either new or modified form the previous draft. Technical Team members have provided text for work group members discussion and modification.

ADDITIONAL QUESTIONS FOR DISCUSSION:

The purpose of the Executive Summary is to bring forward the most important aspects of the document. Does the Executive Summary achieve that goal?

As noted under Section 1.4, data quality/ confidence will need to consistent with Chapters 4 and 6 where these issues are discussed. See notes below for the discussion issues.

Chapter 2: Introduction

Editorial Issues
Provided in redline strikeout. The majority of changes are in Section 2.4 and 2.5.

NDWAC Discussion/Update
No conference call was held on this chapter and no comments were received from work group members. Technical Team members reviewed the draft of this chapter and changes have been made to reflect that review. Previous drafts discussed developing the CCL, making regulatory determinations, and risk considerations. Because the NDWAC Work Group was charged to only focus on the development of the CCL, the chapter has been modified to introduce the CCL statutory requirements, the NRC recommendations, to provide the role of the CCL listing process.

Additional Questions for Discussion

Should the introduction focus on the recommendation considered by the work group?

Is the list of NRC recommendation more appropriate for an appendix if the main text focuses on the major recommendations?

Do changes to sections 2.4 and 2.5 accurately reflect the work group's discussion and deliberations?

Chapter 3: Transparency and Public Participation

Editorial Issues
Provided in redline strike out.

NDWAC Discussion/Update
No conference call was held on this chapter. This draft includes comments provided by work group members focusing on the transparency section. There have been suggestions from Technical Team and work group members that this Chapter provides overarching recommendations and may be more appropriate in Chapter 4.

Chapter 4: Overview of Process and Overarching Issues

Editorial Issues
Overall – may yet reorder the sections of this chapter after the next review. Will transparency (currently Chapter 3) be added as another subsection?

Section 4.1. Overview of Recommended CCL Classification Process. This is a new section, just entering the review process, so more changes will be made later. Also, it is an overview based on the other chapters, so we will need to revisit it to make sure it is consistent with the new revisions to the other chapters.

Section 4.2. Proposed Surveillance and Nomination Processes. No editorial issues. A few comments on comments and formatting.

There are comments that the ongoing surveillance activities the CCL should interact is extensive and may be better suited to an appendix. This comment is included in the text.

Section 4.3. Use of Quantitative Structure Activity Relationships (QSARs). No further editorial additions at this time. The few items remaining should wait for resolution of the issues below.

Section 4.4. Information Quality Considerations. No further editorial additions at this time. There will be a discussion on this section and recommendation at the plenary session. See issues below.

Section 4.5. Use of Continuous Data/Functions ("Scaling") v. Categories ("Binning"). This is a placeholder with the material that Dan Wartenberg sent in. No changes at this time. See Issues below.

NDWAC Discussion/Update

Overall – Work group members thought that this chapter might need to be reorganized. The Technical Team focused on substantive changes during this round of revisions; any reorganization would take place after the March plenary meeting.

Will transparency (currently Chapter 3) be added as another subsection?

Section 4.1. Overview of Recommended CCL Classification Process. This is a new section, just entering the review process that provides an introduction to subsequent chapters. Changes discussed in the conference call have been included and will need review by all Workgroup members. As changes are made in other chapters, we will need to revisit it to make sure it is consistent with the new revisions to the other chapters.

In particular, Figure 4.1 needs to be revisited and made consistent with the agreed upon process discussions and the text. The figure provides a good schematic diagram of the process and builds on the NRC schematic. The discussion adds expert reviews of the PCCL, describes the position of surveillance and nomination, and adds a CCL contaminant validation in addition to the expert review discussed by Work Group members.

Section 4.2. Proposed Surveillance and Nomination Processes. Needs to be consistent with Figure 4.1.

Section 4.3. Use of Quantitative Structure Activity Relationships (QSARs). It has been suggested that:

1) This section is too detailed and too specific to the particular test and model work that was performed, and hence,
2) The recommendations are too specific to those conditions to be in the heart of the report.

Additional Question for Discussion

Include the one major conclusion (below) in the Overview - Section 4.1, and some minor supporting text; then move 4.3, and its specifics, with minor rewriting, to the Appendix as the summary of the QSAR testing, and it can reference the larger report. Here is the one recommendation to include:

4.3.2 Conclusions, Recommendations, and Rationale.

→ **Based upon the limited investigation of QSAR models performed, the work group offers a general recommendation that EPA pursue using QSAR models, or existing information that has been generated by them, in the CCL development process.** While it cannot be determined from the assessment done how successful the use of data generated by QSAR models will be in expanding the range of chemicals that can be included in the CCL process, it does appear that some of these models can provide sufficiently useful information and should, therefore, be included as a potential tool for EPA in developing the CCL.

This general conclusion seemed to be the point of agreement. Not all participated in the review of the QSAR work, and there was some anxiety over the specifics of the other conclusions.

Section 4.4. Information Quality Considerations. There are details of the language used, particularly for section 4.4.3, that need to be discussed by work group members and resolved. As noted in the conference call notes, some work group members were not clear, nor comfortable with the current presentation. The Technical Team will draft proposed substitute language for the meeting after consulting with work group members. Proposed language will be provided in redline strikeout format

Section 4.5. Use of Continuous Data/Functions ("Scaling") v. Categories ("Binning"). This is a placeholder with the material that Dan Wartenberg provided. Technical Team members suggested that the material be summarized to some key principles and if the specific examples are needed that they be put in an appendix.

Chapter 5: Microbial Approach to the CCL Classification Process

Editorial Issues

Minor editorial changes were made as a result of the February 13 conference call.

NDWAC Discussion/Update

A conference call was held on February 13 Conference call participants identified technical and editorial changes to the draft. These comments have been addressed in this draft.

The chapter provides recommendation to develop the microbial CCL in an approach that is similar to the approach used for chemical contaminants and described in the NRC.

The proposed screening criteria were rewritten to be more transparent to readers outside the microbiology discipline.

The section on pathogens associated with opportunistic infections was redrafted to be more inclusive of potential pathogens that could be included on the CCL. Work group members noted that the screening criteria for microbes on the CCL universe should not identify a separate large class of microorganisms that may be associated the opportunistic infections but they should be screened to a PCCL with criteria that would apply to all microorganism.

Work group members participated in developing draft microbial attribute scoring protocols. They are discussed in the draft and suggested as an appendix to the report.

Chapter 6: Chemical Approach to the CCL Classification Process

NDWAC Discussion/Update

Work group members held a conference call on February 11 to discuss Chapter 6. The majority of changes were to clarify the recommendations. This was accomplished with relatively minor editing and agreement on the conference call. An update and overview of the major changes requested are outlined for each section below.

Section 6.1. Building the Chemical CCL Universe

Comment – Under 6.1.3.4, 2) following the work group recommendation, the editor inserted the comment: "There was a request to clarify the distinction between data and information." In the last edits (now incorporated) we touched up the use of those terms in this section to try to ensure consistency. The bigger issue related to their use and distinction (and relationship to other terms, such as measured or estimated) was to be covered in Section 6.2.

Section 6.2. Process and Criteria for Selecting Agents from the Chemical CCL Universe for the PCCL

The potency and exposure sections were revised to include additional rationale and clarifications that were reflective of work group discussions.

A question was raised about whether demonstrated occurrence should be added as a data element for exposure. Language was incorporated to address this issue.

The use of the words *information, data, measured, estimated, and potential* were made clear in this version.

Additional Question for Discussion

Is additional discussion needed for contaminants that are insoluble or associated with solids or particulates?

The work group needs to discuss additional exposure screening criteria in addition to the persistence and solubility elements discussed on the conference call.

Section 6.3. Attributes and Attribute Scoring for Chemicals

Unfortunately, there was not quite enough time to discuss section 6.3 on the conference call. Some of the work group members sent comments and these have been incorporated into the document in italics.

The have also been suggestions by Work Group and Technical team members that the comments on the draft scoring protocols should be moved to the appendix containing the protocols.

Additional Question for Discussion

How to best to incorporate both options of scoring with categories (as essentially set out in the draft chemical protocols now) and scoring with continuous values using a system based on the "raw data" or some normalization of the raw data as suggested by Dan Wartenberg (see discussion of Section 4.5).

Is the attribute discussion in Section 6.3 and Chapter 5 consistent?

Chapter 7: Moving from the PCCL onto the CCL

Editorial Issues

Minor editorial changes were made as a result of the February 9 conference call.

NDWAC Discussion/Update

Section 7.2. Recommended Approach to Select the CCL

An appendix was developed by Craig Stow to elaborate on the "best" model discussion in Section 7.2.2.

Divided the 3rd specific recommendation under Section 7.2.2 into two separate recommendations:

- The first recommendation (3rd recommendation) focuses on developing alternatives in the near term (for CCL3).
- The second recommendation (new 4th recommendation) focuses on 1) determining the causes for why the algorithm approach is falling short of the desired criteria and 2) to proceed in the long term (CCL4 and beyond) using either an algorithm or an *a priori* approach depending upon the evaluation.

Section 7.3: Training Data Set

Revised 1st bullet recommendation in Section 7.3.2 to indicate that the contaminant attribute data should be distributed throughout the attribute space and the discriminant surface (the function that defines "include" and "don't include" decisions) should be based on data near both sides of that surface. Subsequent text is revised to indicate that the analysis should be structured to indicate the extent to which it is important to include "difficult" decisions or not in the training set rather than assuming that "difficult" decisions need to be included.

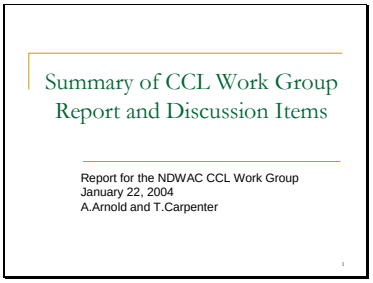
Additional Question for Discussion

It is not clear if last change noted above for Section 7.3.2 satisfies all work group members. Some work group members believe that the desired attribute space may be able to be filled with contaminants that are either clearly on or off the list whereas other work group members do not. The first bullet language of latest draft should be revisited to reach consensus.

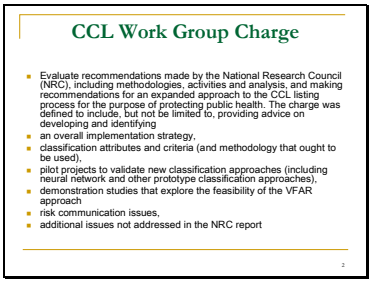
The work group needs to discuss the “performance criteria” for the training data set and the prototype algorithm to clarify details in this Work Group recommendation.

ATTACHMENT D

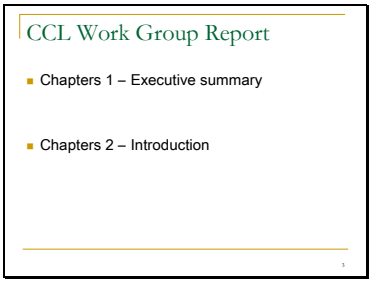
Slide 1



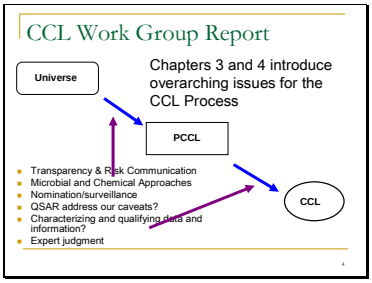
Slide 2



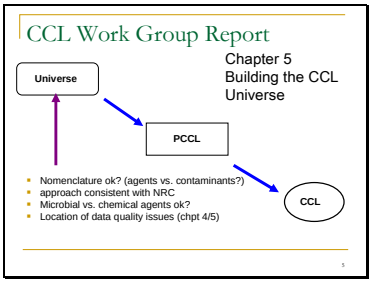
Slide 3



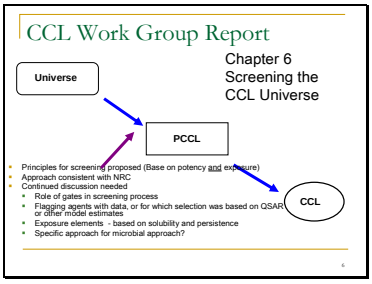
Slide 4



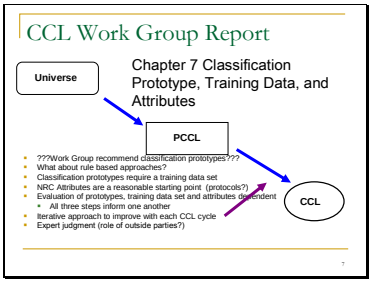
Slide 5



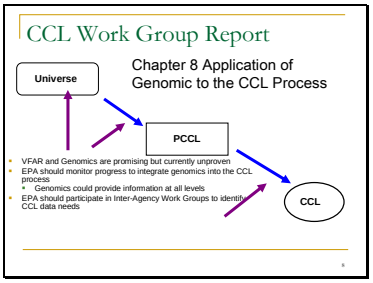
Slide 6



Slide 7

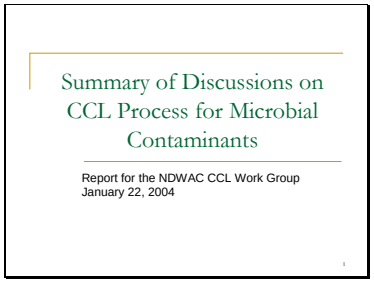


Slide 8

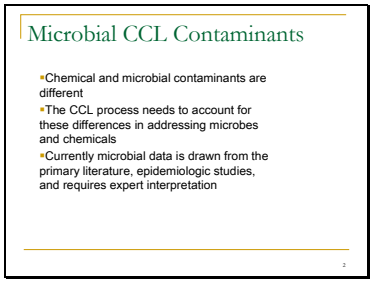


ATTACHMENT E

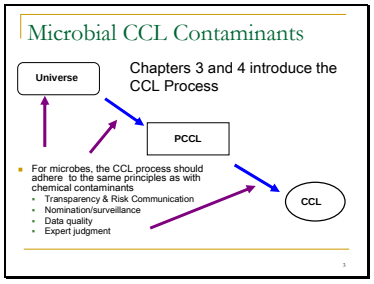
Slide 1



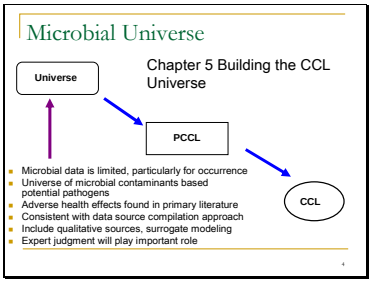
Slide 2



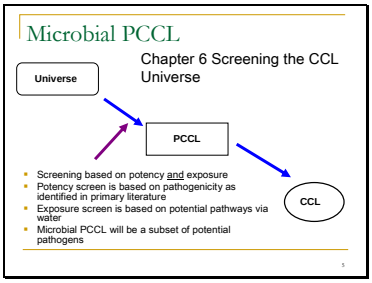
Slide 3



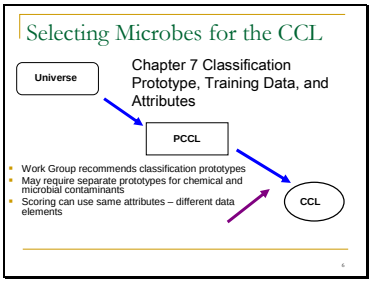
Slide 4



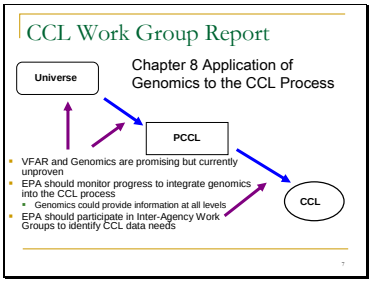
Slide 5



Slide 6



Slide 7


CCL Work Group Report
Chapter 8 Application of Genomics to the CCL Process
Universe
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

DRAFT

Expert Judgment / Expert Review

Context

From the Work Group conference call discussions of Chapter 1, the Executive Summary, and related discussions of draft Figure 4.1 (and related text) that invoked the use of Expert Reviews in the CCL process (in Chapter 4), it was noted that we need to clarify the use and meaning of expert judgment and expert review.

The charge from the conference call was to: develop a definition and discussion for these terms that would guide their use in the report, and to rewrite a section of the Executive Summary to capture a component of the expert process and other thoughts. The proposed definitions are presented below. The revised paragraphs follow. We will need to go through the report, based on this week's meeting's discussions, to apply the terms consistently.

Observations by Small Group *(italics indicate that edits were made to attempt to address issue)*

1. Be very clear to distinguish independent expert review distinguished from experts within process.
2. *Provide text to demonstrate value-added nature of expert review.*
3. *Elaborate on expert involvement to identify "expert collaboration" explicitly.*
4. *Find alternative word for "Validation" step in revised CCL Process graphic and text. Alternative might be "Confirmation".*
5. *Provide option to re-use the same external expert panel for two external panels recommended.*
6. *Clearly indicated that expert processes can occur concurrent with other activities*
7. Provide reference or definition of "expert reasoning"
8. With future CCL processes there may not be substantial modifications and hence (1) the need for expert review may be less and (2) expert review can be focused on more smaller set of topics.
9. *Expert review of the draft PCCL is meant to be a checkpoint for EPA process, where opinion from experts from outside the process provides a check on screening process, focusing first on the characteristics of the PCCL. This check is not envisioned as a full, external peer-review panel (i.e., are we on track?).*
10. *It would be helpful to reference EPA peer review policy noting that the proposed approach is consistent with that process, particularly in that it incorporates expert review into the CCL process.*

<u>Proposed Definitions for Glossary.</u>

Delete current definitions for **Expert judgment** and **Expert review** or **peer review**.

Add:
Expert: one who has special skill or knowledge derived from training or experience relevant to the particular subject matter or technical analysis at hand. In the context of expert review or expert processes, panels of "experts" from a range of pertinent fields are organized to provide a range of relevant expertise. The selection of a balanced range of appropriate experts is as critical to obtaining expert judgment as finding individuals with the relevant expertise.

Expert Judgment: opinion of an authoritative person(s) on a particular subject based upon relevant technical analysis (e.g., determination that one model is "better" than another to support the classification algorithm) or garnered as a technical consensus based on available information and representative of state of knowledge in the relevant field of expertise (e.g., the presence of a given genetic sequence is likely to increase potential for waterborne disease from a microbe with that sequence). At various times in the CCL process EPA will have to explicitly use specific expertise to make or assess a decision, assess a component of the process, or evaluate the use or outcome of a model to ensure that the decision or process is technically sound and credible. Decisions made through expert judgment should be well documented; in particular the underlying rationale should be clearly articulated.

Add:
Expert Review: critical or deliberate examination of a decision or process by authoritative person(s). In the context of the CCL the purpose of such a review is as an assurance of technical validity and scientific rigor in the analysis underlying individual steps in the CCL Process or the specific products of produced by the process; expert review in intended both as a scientific safeguard and as a mechanism that enhances stakeholder trust in the CCL process. Expert review is typically a formal process that engages experts not immediately engaged in matter subjected to review; review by experts from outside the agency can further enhance such reviews. Example expert review processes providing external expertise frequently employed by EPA include: the Science Advisory Board, a standing expert panel, and expert reviews on specific documents prior to release in lieu of publication in a peer review journal. Expert review processes are well documented, and the resulting recommendations warrant consideration and response by the agency.

Add:
Expert Processes: are structured processes that organize advice from authoritative persons in such a manner as to provide the following: (1) consistently organize and prioritize available information, (2) organize the decision process so that consensus opinions can be reached (and minority opinions documented) and patterns in expert decision-making process can be discerned, (3) maintain consistency in the decisions underlying the advice generated by the group of experts, and (4) capture information used and specific output provided by the experts to justify the advice offered.

Role of Expert Review is Relevant to Specific Portions of Draft Report

Section 4.1.2.2, Page 27, Line 1

Change Title:
Change “Expert Opinion” to “Expert Judgment” in the title.

Add New Paragraph:

We observed like the NRC panel that “expert judgment” is inherent to developing both the CCL process and executing that process once it is developed. Expert judgment is essential to the follow activities and a host of others in the CCL process:

1. Determining which QSAR algorithms should be considered and under what circumstances they should or should not be used.
2. Selecting which contaminants should be included in the CCL training data set(s).
3. Selecting which statistical algorithm to pursue in crafting the classification algorithm
4. Developing technically sound, fair, and consistent attribute scoring systems, and applying that system.

In these and other instances where expert judgments are to be made the agency should use the accepted practice in the relevant field and bring relevant expertise from both within and outside the agency to bear, to the extent possible given resource constraints. In these instances expert judgement may be taken using expertise within the agency or engage external experts through expert collaboration. With the ubiquity of expert judgment in the process it is important to also distinguish that there are key points in the CCL process where expert judgment should take the form of expert review, as described below.

Section 4.1.2.2, Page 27, Line 33

Add New Paragraph:

In addition to validating the CCL list there are several additional critical junctures in the CCL process were expert review is especially relevant:

1. Reviewing the draft PCCL that emerges from the application of screening criteria to the CCL universe.
2. Reviewing the training data set(s), which are used to test the draft CCL classification algorithm, and reviewing the draft CCL classification algorithm’s performance classifying the contaminants in the training data set(s).
3. Reviewing the classification algorithm’s performance processing the PCCL to a draft CCL.

Each of these reviews would benefit from a range of relevant expertise from both inside and outside the agency. There are however, significant time and resource constraints to consider in constructing the CCL process. To best utilize the agency’s limited resources formal expert

review is most critical when evaluating the draft CCL; in the workgroup's opinion this review should involve external experts. This review would consider the performance of the CCL classification algorithm, considering not only what was listed and if the contaminants listed are appropriate, but also, looking selectively at the PCCL to identify inconsistencies or biases in the algorithm's performance. This review would be separate but related to confirmation of the CCL as the latter process will extend beyond expert review and analysis to the items previously stated above.

In emphasizing this review in Step 3 of the CCL process we do not intend to diminish the importance of first three identified expert review needs, rather to emphasize the criticality of a structured expert review of the draft CCL. Expert review earlier in the process will indeed be critical. In some instances (i.e., item 1 above), the expert review could have a less formal character and focus on very specific questions, such as are there apparent systematic gaps or biases in the PCCL that are inconsistent with basic precepts of the CCL process? This particular application of expert review is an important quality assurance check on development of the CCL process, but is not envisioned as an extensive external peer-review type activity. It is also important to note that this review and others recommended should be integrated into the overall CCL process so that concurrent activities can occur and overall progress toward proposal of the CCL can occur in a timely fashion.

With respect to item 2 above (Reviewing the training data sets(s) and draft CCL classification algorithm's performance classifying the contaminants in the training data set(s).), the critical question is "Does the draft classification algorithm performance warrant actual application to the PCCL?". Discerning the answer to this question deserves a structured expert process adequate to:

1. Support the agency making a "go / no go" on the use of the draft classification algorithm as it exists at the time,
2. Provide a basis for an alternative descriminant surface function in the classification algorithm based on structured expert reasoning.

To realize these objectives the use of expert processes that are clearly structured and involve external experts, indeed involvement of the same experts in this review and in the later CCL confirmation review may afford both logistic and technical advantages. In this instance key components of structured expert processes identified in the glossary to this report are critical. Beyond these defining components it is important that these processes follow clearly articulated rules that establish:

1. Who will be the final arbiter and how will be final decisions be made regarding, the process to be followed, the participants in the process, roles and responsibilities of the participants, and the recommendations offered.
2. The setting of, adherence to, and demonstration of compliance with *a priori* expectations for the process.

Add new topic

The integration of expert judgement and expert review into the CCL process offers several advantages that are worth noting. First, inclusion of expert review in the CCL process as it develops offers assurance that the final product, the proposed CCL, will be technical sound and scientifically defensible. The inclusion of expert review early in the CCL process also affords the agency opportunities to spot problems early and avoid wasting limited time and resources. A third advantage is increased transparency with the stakeholder community, as expert review provides technical checks on the process as it evolves rather than placing an inordinate burden of proof on stakeholders at the end of the process when they believe the process has gone awry. A final consideration that stems from the above, is that embracing expert review as a component of the CCL process is consistent with and expected by agency managers responsible for general oversight of the quality of agency products (i.e., Data Quality Guidelines, etc.).

Proposed revision of the paragraphs in Chap 1, Sec 1.1, Page 2, Lines 27 - 35

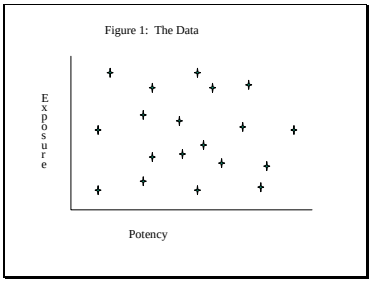
The Agency should move forward with these steps immediately, in concert with development of a pilot prototype classification approach. The prototype classification approach should be assessed periodically to evaluate the feasibility of this approach for the next and future CCLs. The Agency should evaluate the prototype approaches against suggestions and criteria, discussed later in this report, and other criteria that the Agency will develop applicable to the approaches or models that are selected.

The Work Group recognizes that there is no prototype approach ready to implement at the time of this report. If the prototype classification approach is not feasible in the short run, the Agency may need to utilize an expert process, or other approaches for creating a next PCCL and CCL. The results of the eight steps mentioned above (i through viii) will be needed and useful to the Agency for creating the PCCL and CCL in any process that is used. A structured expert process should be conducted of the (prototype and/or other) process utilized for developing the CCL. The outcome of the process and the expert review will be useful to further train and guide the process and ensure its continued improvement.

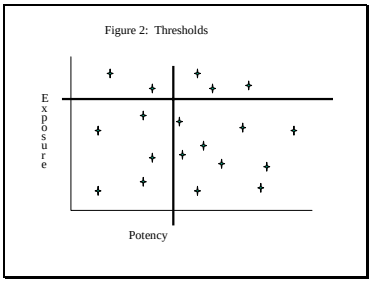
Proposed revision of the paragraphs in Chap 5, Sec 5.3.3, Line 31, Page x

"….Meanwhile, expert processes will be required to conduct attribute scoring, to evaluate the validity of scoring results, and to determine the threshold for placing agents on the CCL." <u>The conduct of attribute scoring, and validating the scoring will be another example of where appropriately structured expert processes will be critical to adequately discerning appropriate scores with clearly articulated rationales that are adequate documented for subsequent scrutiny during placement of contaminants on the CCL.</u>

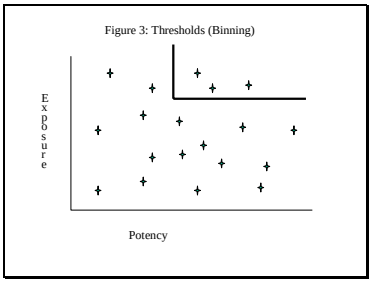
Slide 1



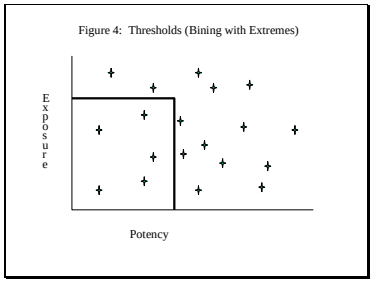
Slide 2



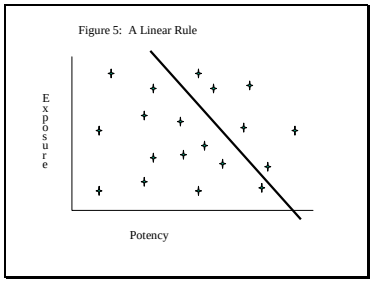
Slide 3



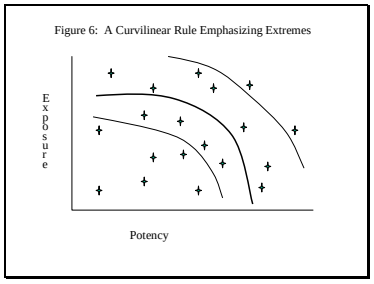
Slide 4



Slide 5



Slide 6



Slide 7

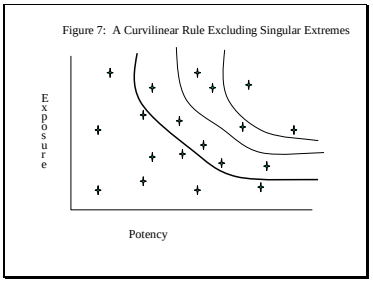


Figure 7: A Curvilinear Rule Excluding Singular Extremes
Exposure
Potency

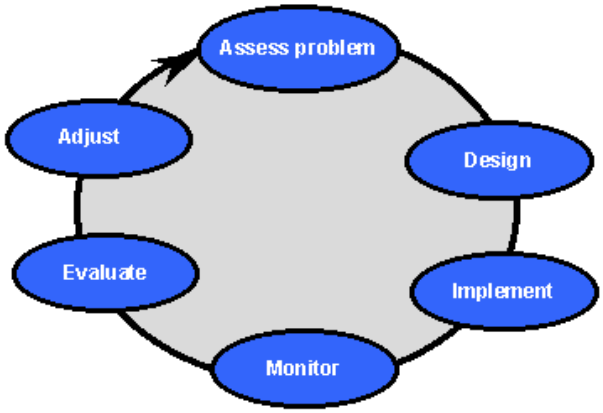
Proposed Language Regarding Use of an Adaptive Management Approach in the Development, Implementation, and Refinement of the CCL Methodology

4.1.2.4 Use of an Adaptive Management Approach (page 29, bottom)

During implementation of this method to generations of future CCL lists, the Work Group proposes applying an adaptive management approach. Adaptive management techniques could be applied in the development, implementation, and refinement of the three-step CCL method, particularly in the initial phases of implementation (i.e., CCL 3 and CCL 4; see Figure 4.x, below).

Under an adaptive management approach, reducing uncertainty is an important principle in implementation of each generation of the method. This evolutionary process allows for systematic and continual integration of design, management, and monitoring, which would enable EPA to make informed adjustments and adaptations, resulting in an improved methodology based on experience from the outcomes of iterative generations of implementing the Universe to CCL approach.

Figure 4.X. Diagram schematic of an adaptive management process.



Source: British Columbia Ministry of Forests, Forest Practices Branch, http://www.for.gov.bc.ca/hfp/amhome/Amdefs.htm, August 9, 2000.

Elements each step in the process should consider:

- Evaluative criteria for each phase;
- Iterative learning process;
- Characterizing data quality;
- Transparency;
- Use of expert judgment /review.

Concepts of adaptive management are a consistent theme in both the NRC and NDWAC recommendations (See the bulleted list in text box). Moreover, this report emphasizes features that are well described in the context of adaptive management: (1) identify an approach, (2) define evaluative criteria (factors to evaluate), (3) iteratively implement the approach, (4) transparently assess evaluative criteria and (5) make changes to improve performance of the approach. Adaptive management also recognizes the utility of comparing alternative approaches. Perhaps most importantly, adaptive management, integrates interim evaluations into the overall approach so that change can take place as information becomes available.

4.4 Information Quality Considerations

4.4.1 NRC Discussion and Recommendations

In its 2001 report on classifying drinking water contaminants for regulatory consideration, the NRC addresses[1] some of the difficulties and challenges that EPA will face in applying data and information to any classification designed to sort a very large number of chemical and microbiological contaminants into exclusive categories: On or Off the PCCL; On or Off the CCL.

The NRC recognized that EPA would likely encounter many challenges in implementing a classification scheme where imperfect or incomplete data must be used to determine whether a specific chemical or microbiological organism may or may not pose an existing or potential threat to consumers of public drinking water.

The NRC did not, however, make specific recommendations in its 2001 report as to how EPA should address or resolve issues related to the quality of the information used in the CCL development process. NRC refers to section 1412(b)(3)(A) of the SDWA Amendments which addresses the use of science in decision-making under this statute, specifying that EPA shall "use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data)."

In their discussion of this issue, NRC also emphasized the substantial role that expert judgment must play in this process, and reiterated a statement from their earlier (1999) report that:

> "…identifying and agreeing on what is sound science is itself a difficult and error-prone enterprise. [The report] makes no recommendations on what "soundness" entails, letting the accepted mechanisms of peer regard, peer review, and scientists' habits of critical thinking continue to serve as the ultimate arbiters."

4.4.2 NDWAC CCL Work Group Considerations

The CCL Work Group also considered the issues related to ensuring the use of the best available information and methods with respect to the data sources to be accessed, the data elements to be extracted from those sources, and the processes to be applied using those data elements to screen or classify a very large number of contaminants in the universe to reduce it to the relatively smaller numbers on the PCCL and then the CCL. The Work Group recognized that EPA's process should explicitly address compliance with Agency data quality guidelines and the Information Quality Act. The Work Group also recognizes, however, that the Agency must have some flexibility in the data quality guidelines to fully embrace the inclusionary principles. Work Group members noted that contaminants considered in the CCL process will not be robustly characterized and the data available for those contaminants will consist of different types of data. Members also recognize that the data used to identify the

[1] In the section titled "The Nature of the Task."

universe will differ from data used to select the CCL. To address the variability of the disparate types of data, all steps in the CCL process should document the data and information about the data sources (e.g., what quality assurance procedures were in place during data gathering, processing, or analysis). Additionally, the CCL process will apply more scrutiny to contaminants when selecting the CCL than screening contaminants from the Universe to the PCCL. The nature of the data used to support these steps should be documented for review in the later steps of the CCL process. Different data quality approaches can be established commensurate with the purpose for which the data will be used (e.g., screening from the CCL Universe to the PCCL versus classifying from the PCCL to the CCL). This is a priority setting process that does not require the same detailed analysis of a rulemaking process, and therefore data quality considerations should recognize this difference. It is important for EPA to establish their data quality approaches prior to identifying the CCL Universe.

Deleted: ,

Deleted: not a

→ **The Work Group, therefore, recommends that some consideration of confidence in the information used and the judgments made be introduced into the CCL process.** This raises two questions.

Formatted: Bullets and Numbering

- How is confidence to be summarized at any stage in the process from building the CCL Universe to selecting the CCL itself? and
- What are experts, or algorithms, to *do* with this summary at each stage?

The answers to these questions must reflect the fact that an assessment of confidence in or uncertainty about some "best estimate" of a numerical value (such as the exposure or potency for an agent) can be resource intensive, often requiring more resources than does determining the "best estimate" value itself.

4.4.3 Recommendations and Rationale

→ **As an overall recommendation, the Work Group recommends that EPA collect and consider the "best available" data sources and data elements without restrictions or screening-out of information based on any minimum quality criteria developed in advance.** The Work Group also offers the following specific recommendations regarding the consideration of information quality at the major stages of the CCL development process.

- ***Establishing the CCL Universe:*** It will be possible to "tag" the contaminant with a reference to the quality of the data source or other information used to assign that agent to the Universe. This indicator would refer to quality considerations of the information source, and not be specific to information on the agent itself obtained from that source. Since the quality of information on different agents in the same information source can vary, it is recommended that this "tag" not be used for screening agents out of the Universe, but only to provide an indication of the general reliability of the source of information that should be considered at later stages.

Formatted: Bullets and Numbering

Deleted: only

Deleted: agent

Going from the Universe to the PCCL: Even at this stage of the process, it will not be feasible to perform an uncertainty analysis specific to a contaminant. It will be possible, however, to provide a richer "tag" for each contaminant. Specifically, the "tag" should now include an indication of whether information for data elements used for potency or exposure were "measured" or "estimated." (These are analogous to the terms "demonstrated" and "potential" in the NRC report.) In addition, if a procedure such as QSAR was used to produce any estimate, the "tag" should include a statement of the general reliability of this procedure for the class of contaminants into which a specific contaminant falls. Since the "tag" still does not reflect a full uncertainty analysis at this stage, it is not necessary to use the "tag" to screen contaminants off the PCCL.

Deleted: However, if the PCCL becomes too large in the judgment of the EPA or the experts guiding the process, it may be possible to use the "tag" to screen off those contaminants that are "estimated" for both potency and exposure, and where the procedures underlying these estimates generally are unreliable.

Going from the PCCL to the CCL: The Work Group recommends that the EPA (and Expert Reviewers) consider the uncertainty or confidence "tag" more fully at this stage than at the earlier stages of the process. There are three steps that need to consider the data used to either develop the classification prototype or select contaminants for the CCL, 1) developing the training data set and algorithm, 2) scoring PCCL contaminants and running the algorithm, and 3) the expert review of the proposed CCL.

To develop the training data set and calibrate the classification prototype, individuals making the judgments regarding which training set contaminants belong on the CCL and which do not may consider uncertainty (explicitly or tacitly) in those judgments. To the extent that this is the case, the role of uncertainty or confidence in these determinations should also be consistently considered in the development of the algorithm of the prototype.

- Work Group members discussed alternatives to address uncertainty within the attribute scoring protocols. Alternatives included 1) documenting the nature and type of information used to score contaminants e.g. assigning a "tag" for further consideration (and in a manner that is consistent with the development of the prototype classification algorithm), 2) developing an overall uncertainty score, and 3) considering the uncertainty in scoring each attribute. The draft protocols reviewed by the Work Group (see section 6.3 and Appendix C) do not address alternatives 2 and 3. Work Group members noted that the nature of the data and information does not indicate whether an attribute score should be raised or lowered to reflect uncertainty in the data. Members did agree that the nature and type of information used at this step in the process needs to be documented so that it may be considered at subsequent steps in the CCL process.

Formatted: Bullets and Numbering

- Work Group members agreed that the list of contaminants selected for the CCL should undergo an expert review. Members noted that documenting the nature and type of information by assigning a "tag" used throughout the CCL process for consideration at this step allows this information to be used in the final analysis for the listing decision. By fully documenting the information used in the process, the review

of the information used, and the decisions made to develop the CCL can be conducted in an open and transparent manner.

More specifically, the Work Group recommends using the "tag" as part of the expert review process. For example, the review process could allow contaminants to move from the PCCL to the CCL only if the "tag" indicated sufficiently high reliability of the evidence supporting inclusion of a contaminant on the CCL. This would prevent the CCL from being populated with a number of contaminants that will, upon further review, be rejected both for regulation and for further research. The disadvantage of this approach is that it could require resources be devoted to performing a contaminant-specific uncertainty analysis for each contaminant that is a candidate for movement from the PCCL to CCL. Alternatively, considering the nature and type of information used to select contaminants afteryte draft CCL listing may be useful in determing whether a contaminant remains on the CCL and establishing priorities for regulatory determination.

NOTE: By the term "uncertainty analysis", the Working Group does not mean to imply the full, quantitative, often Monte Carlo-based analyses performed in regulatory risk assessment. ***We mean, instead, a qualitative, expert-based judgment of the quality of evidence for a contaminant.*** This analysis should reflect the general reliability of the source of any data (analytic methods, sampling protocol, etc); the spatial and temporal variability and extent of the data; whether the data are used as "measurements" or to develop "estimates"; the range of human health effects considered (such as the database completeness issue raised in assigning uncertainty factors when developing RfDs); etc. ***It should be conducted by experts at some point before the CCL is finalized***, and the results of this assessment should be used to determine whether a contaminant should remain on the CCL or be removed (with perhaps replacement by another contaminant for which this same assessment of uncertainty would be performed).

Deleted: The Work Group recommends that the EPA consider the uncertainty or confidence "tag" more fully at this stage. As one option, it is possible that any training set used for prototype methods will reflect uncertainty in the information used to construct that training set. Individuals making the judgments as to which training set contaminants belong in the CCL and which do not may be considering uncertainty (explicitly or tacitly) in those judgments. If this is the case, uncertainty or confidence must be one of the attributes placed into the algorithm of the prototype. An alternative (if a prototype method is not used, or if it is found that uncertainty or confidence is not one of the attributes used in forming judgments), is to use the "tag" to screen a contaminant out before it enters the CCL, or to remove it from the CCL at some point. In the former case, the process would only allow contaminants to move from the PCCL to the CCL if the "tag" indicated sufficiently high reliability of the evidence supporting inclusion of a contaminant on the CCL. This would prevent the CCL from being populated with a number of contaminants that will, upon further reflection, be rejected both for regulation and for further research. The disadvantage of this approach is that it will require resources be devoted to performing a contaminant-specific uncertainty analysis for each contaminant that is a candidate for movement from the PCCL to CCL. Another alternative is to consider the "tag" soon after a contaminant has moved onto the CCL, with the understanding that a contaminant might be moved back off the CCL if the "tag", supplemented by a more contaminant-specific uncertainty analysis, indicates the need to do so. ¶

ATTACHMENT I

Proposed language for Section 4.4.3, item 3:

1. ***Going from the PCCL to the CCL:*** The Work Group recommends that EPA (and Expert Reviewers) consider the information quality "tag" more fully at this stage than at earlier stages of the process. The step at which it should be considered, and the nature of this consideration, will depend on the result of the activities involved in development of the training set and the algorithm. If those activities indicated that information quality is an essential factor that must be considered by individuals in making the "on" or "off" determinations to develop training sets, EPA should seriously consider developing information quality tags for the PCCL entries and using those tags explicitly both in developing the algorithm and in using it to create the CCL. If, however, the development of the training set indicates information quality is *not* an important attribute considered by individuals in making the "on" or "off" determinations, explicit consideration of the "tags" can occur after the algorithm has been applied to the PCCL, but before the CCL is published.

ATTACHMENT L

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

March 4-5, 2004
Washington, DC

Volunteered Contributions from Work Group Members

⇨ Chapter 2: Introduction

- 2.1.1 The NRC Recommendations – **Jeff Griffiths** and **Nancy Kim** will review new language on the NRC recommendations, to be provided by EPA.

⇨ Chapter 4: Overview of Process and Overarching Issues

- New Section 4.1.2.4 Adaptive Management – **Laura Anderko, Douglas Crawford-Brown, Mike Dourson, Brian Ramaley,** and **Craig Stow** will work with **Abby Arnold** to revise proposed text on adaptive resource management.
- 4.1.2.2 Integrating Expert Opinion into the Process – **Rick Becker, Gary Lynch,** and **Dan Wartenberg** will work with **Abby Arnold** on revised language.
- 4.1.3.2 Screening from the Universe to the PCCL – **Mike Dourson** will propose language, in consultation with **Dan Wartenberg**, on the proposed attributed to be used in this screening step.
- 4.1.5 Incorporating Genomic Information: Incorporating VFARs… – Long-term Growth in the CCL Process
    - **Jeff Griffiths** will provide a revised title for this section.
    - **Rick Becker** and **Wendy Heiger-Bernays** will draft language on genomic tools for chemical contaminants that may be available and useful for future CCL efforts.
- 4.4.2 NDWAC CCL Work Group Considerations – **Rick Becker** will provide language beyond avoiding false negatives in the U to PCCL stage and avoiding false positives in the PCCL to CCL stage. This language will also be worked into 6.1.3.1 Data Source Compilation Approach.
- 4.5 Use of Continuous Data/Functions ("Scaling") v. Categories ("Binning") – **Mike Dourson** will revise the section to remove the "artificial distinction" between binning and scaling, place a greater focus on the figures, and set up the discussion, which will be moved to Chapter 6. **Nancy Kim** and **Dan Wartenberg** will provide review.

⇨ Chapter 6: Approach to Chemicals in the CCL Classification Process

- 6.1.3.3 Step-wise Integrated Process, Step (4) Accelerated Process – **Rick Becker** will provide additional language.
- 6.2.3 Key Characteristics
    - **Mike Dourson** will provide additional language regarding *health effects, exposure, demonstrated,* and *potential.*
    - **Nancy Kim, Alan Elzerman,** and **Joyce Donahue** will draft language to be added to the second bulleted recommendation to address compounds that may be missed but shouldn't be, e.g., DBP, in the screening from the Chemical Universe to the PCCL; they will

include references to scaling vs. binning. They will also revise the subsequent bulleted recommendations so that they are consistent this change.

- 6.2.4 Screening for Potency
  - **Nancy Kim** will revise fourth paragraph after the first bulleted recommendation to address acute effects.
  - **Nancy Kim** will edit paragraph after second bulleted recommendation re: LOAEL and LD_{50}.
- 6.2.5 Screening for Exposure – **Alan Elzerman** will work with **Amy Kyle** to clean up terms in this section.
- 6.2.6 Tagging Sources of Values for Data Elements and Implications – **Alan Elzerman** will work with **Amy Kyle** to rewrite section to reflect tagging only for source of information in the U to PCCL stage, not information quality and make Section 4.4 consistent with thes revisions.
- 6.2.7 Approaches to Classifying (Yes or No v. Scaling) – **Mike Dourson, Dan Wartenberg, Douglas Crawford-Brown** and **Amy Kyle** will edit the discussion of scaling relocated from Chapter 4, specifying how scaling and binning (three options use raw numbers, bins, lo/med/high, i.e., different methods that EPA should consider in deciding how to develop criteria) applies to the U to PCCL and PCCL to CCL stages, and noting that EPA can then choose for itself how to do it.
- 6.3 Attributes and Attribute Scoring for Chemicals – **Mike Dourson, Dan Wartenberg, Douglas Crawford-Brown, Amy Kyle, and Frank Letkiewicz** will develop text to address on using the attributes, recognizing that there are a range of alternatives for scoring protocols, and recommend that EPA move forward to develop attribute scoring protocols for chemical contaminants.
- 6.3.3 NDWAC Workgroup Evaluation of Attributes – **Nancy Kim** and **Wendy Heiger-Bernays** will draft language related to the consideration of the philosophy of scoring.

⇨ <u>Chapter 7: Moving from the PCCL onto the CCL</u>

- 7.1 Overview and Consideration of Classification Approaches – **Craig Stow** and **Douglas Crawford-Brown** will edit to improve the accuracy of the language and make consistent with language on experts in Chapter 4, the glossary, and elsewhere.
- 7.3 Training Data Set – **Craig Stow** will provide language for the third paragraph to address a validation data set, or splitting the training data set into two sets, one for training and one for validation.
- Figure 7.2 – **Mike Dourson** will work with authors to show the range of possible discriminant surfaces a prototype could develop based on a range of training set data. the figure will be made 2 dimensional to better illustrate this concept and the importance of training data set decisions.
- Overall Chapter – **Craig Stow** and **Mike Dourson** will revise chapter to reflect revision to Figure 7.2.