.

Building the CCL Universe

This discussion paper describes an approach for building the CCL universe on the basis of a set of fundamental inclusionary principles, as discussed by the NDWAC's CCL-CP Workgroup/Data Activity Group (AG) in their February 5-6, 2003 meeting. Included in this paper are proposed definitions to distinguish known, new and emerging contaminants, and processes for including them in the CCL universe consistent with the inclusionary principles.

After review of NRC's recommendations, available data sources, and consideration of the potential scope of the universe of known contaminants, the Data AG concluded that a principles-based approach, as described by the NRC, would be an inclusive method to develop a universe of contaminants for consideration early in the CCL Classification process. The approach captures the NRC's principles of including contaminants with demonstrated or potential occurrence in drinking water and contaminants with demonstrated or potential health effects.

The approach is <u>inclusionary</u> with respect to contaminants that are not robustly characterized, and considers them at an early stage in the CCL selection or classification process. The approach does not limit the number and types of contaminants or data sources that can be considered for inclusion in the universe, yet it acknowledges that data may not be available for the new and emerging contaminants. Therefore, this approach will also identify contaminants that may need preliminary research and data collection to provide a more thorough characterization of potential harmful exposure in drinking water.

Inclusionary Principles

A principles-based approach would provide a process for defining the CCL universe on the basis of a set of fundamental premises regarding the nature of the contaminants that should be considered. In their February 5-6, 2003 meeting, the Data AG recognized the NRC's (2001) fundamental recommendations for the contaminants that should be included in building the CCL Universe. Two basic principles form the foundation of the CCL Universe (also see Exhibit 1 at end of issue paper):

> 1. The CCL Universe should include those contaminants that have demonstrated or potential occurrence in drinking water.
>
> 2. The CCL Universe should include those contaminants that have demonstrated or potential adverse health effects.

The Group recognized the general nature of these principles, and identified the need to more specifically define the data sources and data elements consistent with them. To accomplish this, the Group recommended reviewing over 200 data sources for their representation of NRC's Tables 3-1 and 3-5.

Proposed Definitions

- <u>contaminants</u>: any physical, chemical, or biological agent that does, or may, occur in water.

- known contaminants: physical, chemical, or biological agents that have been identified in the technical literature and adequately characterized to enable a judgment regarding their inclusion in the CCL universe

- emerging contaminants: a subset of known physical, chemical, or biological agents previously evaluated as not requiring inclusion in the CCL, for which new information becomes available which heightens concern and triggers re-evaluation.

- new contaminants: physical, chemical, or biological agents that are or may be newly-discovered or synthesized, for which little is known about their potential occurrence or adverse health effects.

A discussion of the considerations for distinguishing and evaluating known, emerging and new contaminants is presented in a later section.

Background

In previous deliberations, the Data AG began review of the number and types of known contaminants and available data sources, and identified alternative, data-based approaches for building the CCL universe. In the "Dimensioning the Chemical Universe" discussion paper the numbers and types of known, new and emerging chemicals were characterized within a hierarchy of available data sources. In a later discussion paper the advantages and disadvantages of two alternative data-based approaches were discussed. One approach was the process of reducing a large array of contaminant data sources to a relevant subsets of records ("reducing data sources approach"). The second approach was the process of merging or recombining discrete data sources to compile novel sets of records with multiple criteria (the "data source compilation approach").

The Data AG agreed that the data source compilation approach was logistically favorable for identifying the universe of known agents that are potential drinking water contaminants. The group also agreed that although the reducing data sources approach could include emerging and new contaminants it may present challenges in developing a manageable universe of potential contaminants. Because both approaches are presented significant challenges the group agreed to further evaluate principles to adequately identify new and emerging contaminants.

In their February 5-6, 2003 meeting, following plenary discussions with the Methods AG, the Data AG identified an inclusionary, principles-based approach for defining the CCL universe. This approach would be similar to the data source compilation approach; but the data sources would be identified on the basis of agreed principles rather than the specific data available in the sources. It was suggested that a principles-based approach would also have sufficient breadth to include known as well as new and emerging contaminants, consistent with the NRC's recommendations. The process for implementing this approach is discussed below.

NRC's Recommendations

The NRC (2001) recommended that the CCL universe include contaminants with "demonstrated

or potential health effects" and "demonstrated or potential occurrence in drinking water."   In their February 5-6, 2003 meeting, the Data Activity Group recognized these recommendations as the two key principles representing the foundation of the CCL universe.

The NRC further defined "demonstrated" and "potential" characteristics of CCL candidate contaminants in Tables 3-1 through 3-5 of their 2001 report. Tables 3-1 and 3-5 contain examples and/or characteristics of the classes of contaminants recommended for consideration. Tables 3-2 through 3-4 recommend various data sources for review in identifying CCL candidates. (The NDWAC-CCL Technical Team has since expanded the potential data source list to more than 200.)

NRC (1999b and 2001) also noted that an "ideal CCL development process" would identify the entire universe of potential candidates and result in CCLs listing only what would need to be regulated. "However, EPA's resources are still constrained; no comprehensive list of potential drinking water contaminants yet exists; and health effects, occurrence, and other related data for the vast majority of potential contaminants are poor or nonexistent (NRC 2001, p. 43)."

The NRC's examples and characteristics, as listed in Tables 3-1 and 3-5 of NRC, 2001, provide further definition of the two key principles of "demonstrated or potential occurrence and human health effects". The examples and characteristics are related to five subject areas: 1) chemical classes and types of microbes (e.g., "pesticides", "naturally-occurring agents in water"); 2) transformation products (e.g., "reaction and combustion byproducts"); 3) chemical uses and functions (e.g., "gas additives", "military munitions"); 4) types of biological effects (e.g., "enzyme inhibitor", "hormonally active compounds"); and 5) sources of chemicals and microbes with potential to enter drinking water (e.g., "compound widely applied to land", "constituent found in a landfill leachate"). These five areas may provide a useful framework for extending the NRC's examples and characteristics into a broader context for CCL universe identification, consistent with a principles-based approach.

Distinguishing Known, New and Emerging Candidates

The Data AG recognized that, conceptually, the principles-based approach defined above has adequate breadth to encompass the full range of known, new and emerging contaminants. For implementation purposes, however, the approach must be tailored to each of the three types of candidate contaminants.   This section evaluates each type of contaminant in relation to the principles-based approach.

1. <u>Known contaminants.</u>   These are CCL candidates which, by definition, can be identified through analysis of existing data sources. Potential data sources of known contaminants have been identified and characterized to date, and the list continues to expand. EPA's Technical Team is performing an analysis of how the data sources identified to date, numbering over 200, relate to the examples cited in the NRC's Tables 3-1 and 3-5.

2. <u>New contaminants</u>. Identification of new contaminants is challenging in several respects. The rate of synthesis and discovery of new contaminants was determined in an earlier issue paper ("Dimensioning the Chemical Universe") to be prodigious. For example, an average of approximately 4,000 candidates are assigned CAS registry numbers daily. The majority of these candidates have little data beyond name and structure. The rate of synthesis and discovery of new candidates suggests that a more frequent or continuous process for updating the CCL universe candidate list may be required than

for known contaminants. The data source compilation approach, using sources of known contaminants would not likely capture many of this class of contaminants.

3. <u>Emerging contaminants</u>.   This group contains candidate contaminants that were either: a) not included in previous CCL lists; or b) contaminants for which new information becomes available that may heighten concerns and trigger additional review.

The Data AG suggested a combination of surveillance and nomination processes would be desirable to provide frequent, if not continuous identification of new and emerging contaminants. This approach addresses the inclusionary principles by identifying research needs for contaminants that may be identified as potential drinking water contaminants, but have data gaps.

Proposed Process for Building the Universe

The Data AG concluded that a principles-based approach would be most consistent with NRC's recommendations, as it could: a) incorporate the NRC's recommendations for including contaminants with demonstrated or potential occurrence in drinking water and those with demonstrated or potential health effects; b) provide a framework to include (versus exclude) contaminants at the earliest stage of the CCL universe identification process; and c) not limit the number and types of contaminants or data sources (i.e., known, new or emerging) that could be considered for inclusion in the universe, now or in the future; and d) be implemented using a data source compilation process.

A step-wise process for building the universe may include the following: 1) construct a database of known contaminants; 2) a surveillance process for new and emerging contaminants, 3) a nomination process for new and emerging contaminants, and 4) an expedited process, as described below:

1. Constructing the CCL Universe.

Data sources would be identified that provide relevant information about known contaminants that may be potential drinking water contaminants. Data from these sources would be merged or recombined, using the data source compilation approach, from discrete databases to compile novel sets of records with multiple criteria. An example would be merging databases for High Production Volume Chemicals and the Registry of Toxic Effects of Chemical Substances (RTECS) to identify and combine relevant information for a specific contaminant of interest. The physical process of the known contaminants approach would involve exporting output from various databases into a new database.

2. Surveillance Process for New and Emerging Contaminants.

The Data Activity Group suggested a combination of surveillance and nomination processes would be desirable to provide mid-cycle identification of new and emerging contaminants. While the approach has not been characterized in depth, the following aspects have been suggested:

- institutionalization of a proactive process to survey or obtain information from institutions and organizations that might be expected to observe or generate new information about occurrence or health effects of contaminants. These could include state or local health departments, environmental agencies, drinking water utilities, and research institutions. This would include an ongoing process for communication with these institutions.

- identification of key published data sources (or criteria for their selection) based upon consistency with the inclusionary principles, and updated with adequate frequency to provide the most current information available on contaminants (e.g., this might include a mid-cycle report);
- a means for identifying new information from recent updates of data sources to minimize redundant searching;
- a review process that is technically sound and logistically practical, and;
- a means for documenting the process and any decisions reached (transparency).

3. Nomination And Evaluation Process for New and Emerging Contaminants.

The Data AG also suggests that EPA develop a nomination and evaluation process for new and emerging contaminants, to enable agencies and interested stakeholders from public and private sectors to "nominate" contaminants for consideration in the CCL process. The nomination and evaluation process requires further definition. The nomination process may include these elements:
- criteria for identifying prospective stakeholders;
- recommendations for systematic communications with prospective stakeholders.

The evaluation process may include developing:
- information and documentation requirements;
- a means for confirming that the information offered has not previously been considered;
- a process and criteria for taking appropriate action for those found to have merit, and;
- a means for documenting the process and any decisions reached.

4. Expedited Process.

As new contaminants are identified, or as new information becomes available, there may be justification to accelerate their passage to the CCL universe, from the universe to the PCCL, or from the PCCL to the CCL. A re-evaluation process based on key criteria may be considered to allow contaminants of immediate concern to be expedited or "fast-tracked". EPA could, if the data warrant, move a contaminant to a higher level of assessment within the CCL process, or could exercise other statutory authority to deal with these contaminants through other regulatory processes.

Exhibit 1. Graphical Representation of the Universe
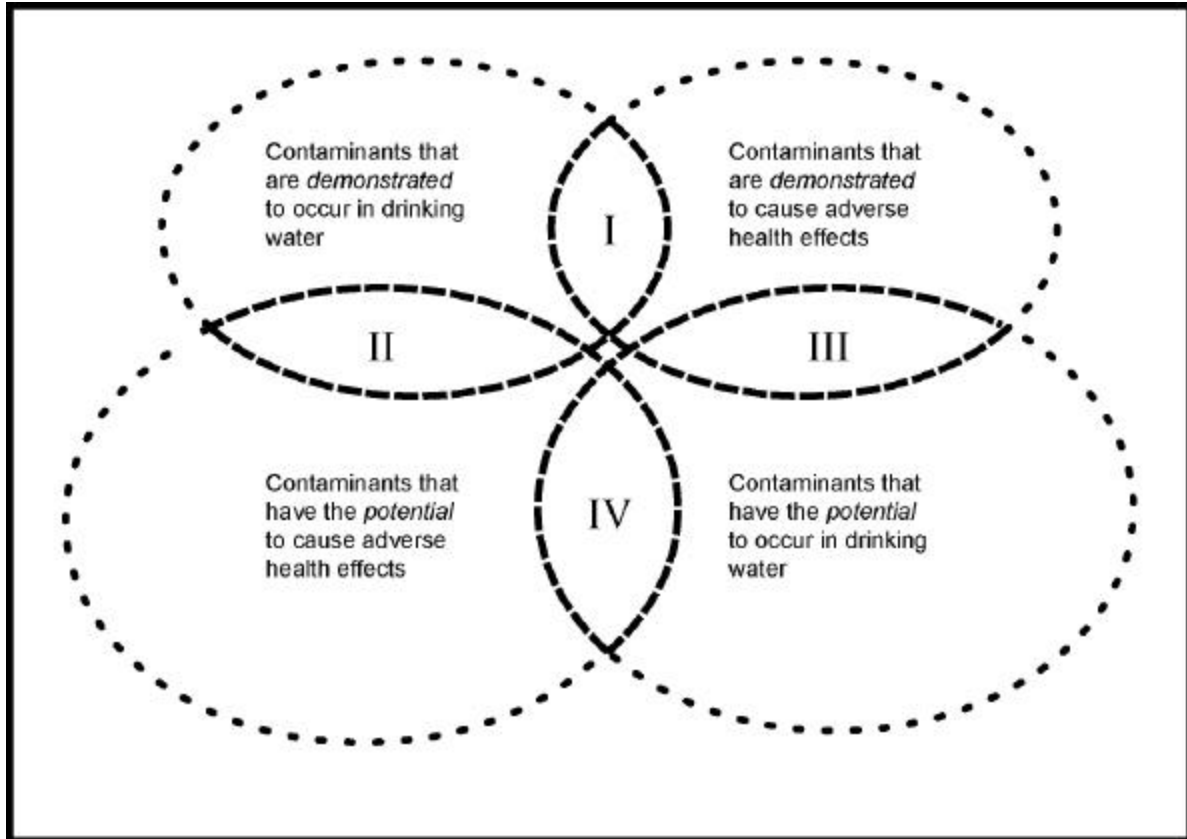
Graphical Representation of the CCL Universe. In Exhibit 1, adapted from NRC (2001) Figure 3-1, the box represents all possible agents in the universe of contaminants. Each oval within the box comprises part of the CCL Universe of potential drinking water contaminants (a subset captured by the inclusionary principles).