

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

December 16-17, 2002  
Washington, DC

***Meeting Summary***

*- Final -*

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### **Attachments**

- A. Work Group Members
- B. Agenda
- C. Work Plan Overview Presentation
- D. Flow Chart Diagram of Draft Work Plan
- E. Regulatory Development Process Diagrams
- F. Revised Draft Work Plan
- G. Guiding Principles Presentation
- H. Comments on Draft Guiding Principles
- I. Universe Activity Group Presentation
- J. Classification Processes Activity Group Presentation
- K. VFAR Activity Group Presentation
- L. Operational Protocols

## **Welcome and Introductions**

The second meeting of the NDWAC CCL Classification Process Work Group was held on December 16-17, 2002. The meeting objectives were to

- review and approve draft work group ground rules discussed at September 2002 meeting
- review proposed CCL Classification Process Work Group Work Plan and schedule
- evaluate and possibly modify subgroups and subgroup member composition
- report and provide feedback on subgroup activities to date:
  - identify questions and issues the work group needs to address
  - agree on tasks to be conducted to prepare for subsequent meetings
- identify additional technical expertise needed on the technical subgroups
- determine subgroup tasks between December and February 5-6, 2003
- agree on meeting schedule for remainder of 2003

Facilitator Abby Arnold, RESOLVE, welcomed everyone to the meeting and thanked the National League of Cities for providing the meeting facility. Ms. Arnold then asked the work group members and other meeting participants to introduce themselves (see attachment A). She reviewed the materials that were distributed for the meeting and then reviewed the agenda (see attachment B). A work group member asked that time be allowed for public comment each day of the meeting.

Later in the meeting Ms. Arnold reported that two members of the work group had contacted her prior to this meeting about their intentions to resign from the work group. Ken Reckhow is resigning because of a change in commitments at his job that leaves him unable to serve on the group. Marguerite Young is resigning because she is leaving Clean Water Action. Dr. Reckhow and Ms. Young will submit their formal resignations to EPA. Ms. Arnold noted that neither member is resigning because of an issue with the work group.

## **Overview of CCL Work Group Work Plan**

Ms. Arnold, Doug Owen, Malcolm Pirnie, and Tom Carpenter, U.S. EPA, presented an overview of the proposed draft CCL Work Group Work Plan prepared by the facilitation team for review by the work group (see attachment C). Ms. Arnold began by reviewing the purpose of the work group and the conceptual approach recommended by the National Academy of Sciences National Research Council (NRC). She explained that the facilitation team prepared the draft work plan to attempt to define activities to develop the CCL process and to help give the technical support staff an idea of the materials they will need to develop to support the work group. She stressed that the draft work plan was intended to be a starting point for work group discussion and was not at all intended to be a directive from the facilitation team. The purpose of the work plan is to

- define discrete work tasks
- uncover relationships and sequencing among tasks
- estimate task duration
- identify roles and responsibilities

Mr. Owen then summarized the contents of the plan by outlining the tasks proposed for the universe activity, screening activity, classification activity, and virulence factor activity relationship (VFAR) activity. The draft work plan proposes that most of the work be conducted in “activity groups.” The role of the work group plenary would be to provide for information exchange, to review and approve the deliverables prepared by the activity groups, and ultimately to make recommendations to the NDWAC. The draft work plan also proposes some specific tasks for the plenary, including preparing training data sets and recommending the decision method and prototype approach (see attachment D). Mr. Owen stressed that although the work plan presents the work group process in distinct tasks, all of the work is very interconnected, with several tasks proposed to happen in parallel and information from many of the tasks feeding into other tasks. He also noted that activity groups are “fluid,” and the members participating on them may change as different expertise is needed. The proposed approach for reviewing deliverables from the activity groups is to allow at least two plenary meetings for review and approval by the full work group. Acknowledging that the draft work plan proposes an ambitious schedule, Mr. Owen noted that EPA is committing resources for support of the work group’s information and analysis needs.

During this discussion and later in the meeting the work group explored the context and purpose of the CCL. Questions arose about where in the rule development process the CCL listing process fits, what has been used in the past as the foundation for building the current CCL, and where do hazard identification and risk assessment, as well as cost and benefit analyses, fit into the picture. EPA staff presented two diagrams illustrating the standard setting agenda and regulatory development process required by the Safe Drinking Water Act (SDWA) (see attachment E). The work of this work group to recommend a methodology for developing the contaminant candidate list (CCL) lies before the actual development of the list. The CCL is intended to capture contaminants in the environment with the potential to occur in drinking water and a potential to have an adverse health effect. The regulatory determination process looks for contaminants with demonstrated occurrence and effects, and the regulatory development process comes when the data indicate the need to regulate the contaminant in drinking water. This is the risk assessment phase, where there is a detailed assessment of the combination of hazard and occurrence.

The CCL, therefore, is upstream of making a decision to regulate. This clarification was important in thinking through what the ultimate product of the work group is and ought to cover.

#### *Discussion of CCL Work Group Work Plan*

A member asked whether EPA expects the work group to choose the training data set to be used. EPA staff responded that EPA would like as much input as possible, though the work group may not be able to reach consensus on an actual data set. EPA would like the work group to do a proof of concept demonstration and then based on the demonstration share lessons learned and provide recommendations.

A member observed that information about contaminants often develops in “bursts of knowledge.” He suggested that the CCL listing process should include a systematic way to identify and use such bursts of new information to fast-track the relevant chemical or pathogen

either onto the CCL or out of consideration as the new information indicates. Another member commented that a similar question came up in the discussions of the Universe Activity Group regarding how to handle emerging contaminants. The activity group did not come to any conclusions but plans to have further discussions on the issue. Another member observed that the CCL listing process that EPA puts in place likely will be more flexible than it now appears in regard to including newly identified contaminants, though any process will be dependent on the information available.

A member suggested that the work group's recommendations should include a recommendation that parts of the CCL process (e.g., the attributes used to classify potential contaminants from the PCCL to the CCL) be applied to determining maximum contaminant levels (MCLs) for the contaminants chosen for regulation. He expressed a concern that as much value as possible should come from the efforts to develop the CCL process and future CCLs. Another member noted that aspects of the CCL process are related to MCLs, but there also are many aspects between the CCL and determination of MCLs. EPA staff responded that the goal of the work group's efforts and related EPA efforts is to develop a list of potential contaminants for further consideration, and that goal in and of itself is extremely valuable. EPA staff also noted that existing laws are very specific about how MCLs are to be developed.

A member observed that the draft work plan did not include a task on public involvement and risk communication. He commented that these elements should be included so that they are addressed throughout the process and not just added at the end. The work group decided to add a task to the work plan and to designate a "transparency leader" in each activity group to help ensure that public involvement, transparency, and risk communication are considered along with other issues.

At several points during the meeting the work group discussed how best to structure the activity groups. Mr. Owen explained that in preparing the draft work plan, the facilitation team realized that the tasks related to developing a method to screen from the universe to the preliminary CCL (PCCL) were not explicitly covered by any of the activities designated at the September 18-19 work group meeting. Members commented that the screening tasks would require expertise from the people in both the Universe and Classification Process Activity Groups. A member suggested that most of the tasks in the work plan could be divided fairly well among data issues (quality and availability), methods (for screening from the universe to the PCCL and classifying from the PCCL to the CCL), and implementation (choosing and scoring attributes and developing a training dataset). After further discussion, the work group chose to divide the tasks among a Methods Activity Group, a Data Activity Group, a VFAR Activity Group, and the plenary work group. Members commented that the activity group structure could be revised if needed as the process progresses.

Other comments from individual work group members included the following:

- Exchange of written material among the activity groups is an important communication link.
- Unless the work group is task oriented it will not meet the schedule requested by EPA for the end product.
- The work group should begin thinking now about its final product and about the record of the group's process along the way.

Work group members further reviewed and revised the draft work plan in activity group breakout sessions (see attachment F). The work group will continue to review and revise the work plan as necessary based on the progress of the activity groups and plenary work group.

### **Reports from Activity Groups on Progress Made between Plenary Meetings**

#### ***Guiding Principles***

A member of the Guiding Principles Activity Group presented the draft principles developed by the group (see attachment G). She noted that the final three principles on the list were submitted by individual members after the activity group's conference call, so the group did not have a chance to review them prior to presenting them at this plenary meeting.

The work group discussed the purpose of the principles. A member noted that some of the draft principles seemed to be directives to EPA though they were meant to guide the work group. Another member commented that some of the principles should be offered as recommendations to EPA (e.g., those on transparency). Other members disagreed, commenting that the activity group was tasked with developing principles to guide the work group. A member added that the activity groups will incorporate the principles into the recommendations they develop.

Members also commented on specific principles (see attachment H). In the course of the discussion several members commented on the importance of stressing the need for transparency. A member noted that the need for transparency may influence that group's decisions on which tools to recommend. As possible ways to increase the transparency and public involvement of this work group's deliberations, members suggested holding focus groups in communities or holding work group meetings outside of Washington, DC. Members also noted the need for a glossary to clarify and define terms used by the work group.

The Guiding Principles Activity Group will meet again by conference call to consider the comments provided and revise the draft principles. Work group members were asked to submit any further comments or language suggestions to RESOLVE by December 31, 2002.

#### ***Universe (renamed as the Data Activity Group later in the meeting)***

A member of the Universe Activity Group presented an update on the group's work (see attachment I). He outlined the issues the group is working to address, including consideration of whether the universe of potential drinking water contaminants should include all contaminants or those for which there are available data. The initial findings of the activity group were as follows:

- The work group should recommend guidelines/ principles that EPA could follow, tempered by practicalities.
- In developing the universe of potential contaminants, the work group should recommend a more pragmatic approach of establishing some minimum criteria for what is included in the universe based on certain data elements.
  - Step 1: Identify all possible data sources to populate the "conceptual universe"
  - Step 2: Determine which sources have the necessary data elements to be used in screening down to the preliminary CCL

- A pragmatic approach will give less weight to emerging potential drinking water contaminants; existing data sources will not identify the universe of emerging contaminants. The work group should recommend a process for addressing emerging concerns.
- Discussion with groups considering the rest of the process will be helpful.

A member pointed out the need for close communication between the activity groups, noting that the tasks of the Universe (Data) Activity Group are dependent upon the work of the Classification (Methods) Activity Group, and vice versa.

A member of the Universe Activity Group commented that much of the information reviewed by the group thus far focused on chemicals, but the group is aware of the need to consider microbes as well. Other members stressed the importance of including microbes and addressing them throughout the process.

### ***Classification Processes (renamed as the Methods Activity Group later in the meeting)***

A member of the Classification Processes Activity Group presented an update on the group's work (see attachment J). He noted that the group took a step back from the National Research Council's (NRC) recommendations to consider other options of decision-making approaches. The group has discussed considerations for choosing a decision process and considerations of how the available data affect the options. A matrix has been developed to help in the evaluation and selection of candidate decision systems. The matrix is being populated with specific candidate systems, sorted into three broad categories of options: prototype classification algorithms, expert judgment methods, and rule-based methods. An example application of the broad categories has been developed for the group to work through at this meeting. At this point the group is exploring the prototype approach and examining the benefits of the other methods and determining how a combination of methods could be used to augment the process.

Observing that one method may work better for one set of circumstances and another for other circumstances, a member expressed concern for choosing one method for all circumstances. He noted that if EPA commits to one approach it may later find that the data to support the approach are not available. Another member expressed concern with choosing a neural network approach without further consideration of the other options and the available data. A third member clarified that the NRC recommended a data rich approach and a prototype approach; the neural network method was only one suggestion of a prototype approach. EPA staff commented that EPA is open to hearing other recommendations from the work group if other decision approaches are found to be more useful.

A member explained that one concern with a prototype approach is the premise that the CCL can be determined based on past decisions. Another member pointed out that this concern assumes the training data set for the prototype approach is built on past regulatory decisions. Another possibility would be to use expert judgment to build the training data set.

### ***Virulence Factor Activity Relationship (VFAR)***

Members of the VFAR Activity Group presented an update on the group's work (see attachment K). One task of the work group is to evaluate the efficacy of using VFAR to estimate the potential of a microorganism to exhibit characteristics similar to other microorganisms with

known health impacts. To begin this task, the activity group needed to determine the availability of data for developing the VFAR concept. The group began a series of keyword searches on GenBank and the Comprehensive Microbial Resource (TIGR) databases to evaluate whether the data in these banks could be used for VFAR. The initial search of GenBank using seventeen keywords resulted in over 3 million “hits.” The group refined the search by limiting it to specific organisms to create a grid of hits by organism and keyword. Members of the activity group outlined some of the problems encountered in their efforts:

- Keyword searches are not always productive because there is no standard terminology
  - There is no systematic way of entering data.
- The grid reduces the number of hits, but is still limited by selected pathogen and keywords.
  - Unknown or unidentified waterborne pathogens are excluded.
- GenBank can produce redundant results.
- Sequence searches are confounded by fragments versus whole genes.
  - TIGR is limited to bacteria for which the entire genome is known.
  - Database searches with whole genomes may be more productive, if enough organisms are available.
- VFAR promises lots of potential uses, but these systemic problems, and possibly others, need to be addressed.

Next steps for the activity group:

- Conduct keyword searches to identify virulence, colonization, persistence genes from existing genomes.
- Conduct sequence searches for homology to identify all virulence, colonization, persistence genes from existing databases.
- Review Dr. Trudy Wassenaar’s proposal for a comparative genetics approach to identify the intersection of waterborne and pathogenic organisms using bioinformatics on a supercomputer.

Activity group members also noted the need for additional microbiology expertise for the work group. They offered to help identify the kind of expertise needed and possible people to provide the expertise.

Asked for ideas of how to incorporate microbes into the universe of potential contaminants, a member of the activity group pointed out that GenBank is included as a database for consideration in the universe. He suggested there may be a way to use information from keyword searches to develop the PCCL.

In response to a question, an activity group member explained that the person who enters information into GenBank is responsible for updating that information. GenBank contains errors, partially because species are in flux. For example, a species name may be changed, and if people who have entered information about it under its old name are not aware of the name change, their information will not be updated.

A member observed that the VFAR is on a longer timeframe than other issues being considered by the work group. He commented that an important question, therefore, is how the forthcoming CCL can incorporate microbes. He offered an example used in other efforts, which is to work



with veterinarians to identify pathogens with the potential to crossover to humans from other animals. Another member agreed that the VFAR approach would not be ready to use for the next CCL but commented that it is important to move forward with pilot efforts to test the methods and address various issues. A third member observed that although the full approach may need several years to develop, some aspects of VFAR may be useful in the meantime.

A member cautioned that the work group should be mindful to ensure that VFAR efforts do not have the unintended result of creating instructions for bioengineering the most virulent pathogen.

### **Reports from Activity Group Breakout Sessions**

As noted above, the activity groups met in breakout sessions to review the draft work plan. Revisions are included in attachment D. The groups also met to continue working on their tasks. Following the breakout sessions, each activity group reported back to the plenary work group.

#### ***VFAR***

Comments reported from the VFAR Activity Group included the following:

- Many pathogens that emerge are caught by existing treatment approaches. What needs to be addressed are unexpected organisms that can make it through treatment. VFAR alone will not detect all of these pathogens.
- VFAR is a promising technology, but further work is needed to determine how best to use it. Pilot projects are needed, and in the meantime, other tools are needed for incorporating microbial contaminants into the CCL process.
- The same methods may not be effective for identifying potential chemical contaminants and potential microbial contaminants for the CCL. The approach is much more developed for chemicals, and there is concern that microbes will be forced to fit that approach.
- Next steps:
  - Further review the materials provided and the results of the database searches run in November. Review the ongoing work on whole genomes (to be provided to the group in January).
  - Review Dr. Wassenaar's proposal and recommend a VFAR pilot project to the work group at the February plenary meeting.
  - Identify microbiology experts to serve as resources to the work group.
  - Identify alternative methods and data sources to create a list of microorganisms for the next CCL.
  - Schedule a conference call for January.

#### ***Data Activity Group***

A member of the activity group reported that the group's discussion focused on what needs to be done to prepare for the February 5-6 plenary meeting. The goal of the group is to develop two deliverables for February: 1) a summary of what data sources are available and what the activity group has done to evaluate them and 2) a straw proposal of what data elements are needed for the CCL process.

The activity group recognizes that the work on pathogens is a bit behind the work on chemicals. The group will work to include data elements for microbes as well as chemicals in its straw proposal for February.

A member of the activity group will draft a principle on looking beyond known information (i.e., not just “under the lamppost”) for consideration by the Guiding Principles Activity Group and the work group.

Benson Kirkman will serve as transparency leader for the activity group.

### ***Methods Activity Group***

A member of the activity group reported that the group realizes that no classification method is free of expert judgment and it is rather a matter of where expert judgment comes in. The group has stepped back from the NRC recommendation to explore how more expert judgment could be incorporated up front in the process.

The group has begun to evaluate different decision making methods and will develop criteria to choose among the options. The group also has begun to discuss what constitutes a good training data set.

Daniel Wartenberg will serve as transparency leader for the activity group.

Some members expressed concern with moving ahead with selection of a method without knowing what data will be available to use in the method. A member of the Data Activity Group pointed out that this is an iterative process. A final data likely will not be available before the group chooses a method to recommend, but a description of the kinds of data available can be prepared and example data likely will be available to test the methods. A member observed that EPA will never have the perfect data set. He suggested a goal should be to find the point that is about 80% of the ideal to move forward, and then recommend what can be done about the remaining 20%. Data Activity Group members commented that they had begun to discuss the issue of making decisions with limited data. A member noted that explaining this issue to the public will be crucial though challenging. Another member suggested that the group should develop a recommendation on how EPA can improve data gathering efforts.

### **Context and Purpose of the CCL**

The work group began the second day of the meeting in plenary, with a discussion on the context and purpose of the CCL. A member requested that information be presented to the group to provide a context for the CCL, particularly in terms of what is currently regulated and what metrics are used (e.g., duration adjusted life years (DALYs)). He explained that it is important to know where regulation is and where it is going. He suggested, for example, that if there are no data on a contaminant to calculate a DALY, then perhaps it should not be on the PCCL. Another member commented that the approach developed probably will not rely on a metric. What will be required for the approach is some measure of exposure and health effect and an indication of how important they are. A member responded that knowing where the process is leading will help the group to determine what is important. Another member expressed a concern that such an

approach may be effective for chemicals but may not fit for microbes. He explained that the kind of information available about microbes is different from that on chemicals. Much of the information on microbes comes from control measures, such as which organisms are or are not controlled by chlorine. He commented that the work group does need to consider whether DALY information should be a factor in developing the CCL. Suggesting that if something is controlled by existing treatment measures it does not need to be a focus of additional effort, the member commented that the group should consider the objective of putting a microbe on the CCL.

A member observed that historically, chemicals and microbes have been addressed in the same way in that the same questions are asked for either a chemical or a microbe: 1) does it have a public health impact? 2) does it occur in water systems at levels or concentrations of public health concern? and 3) is there an opportunity for health risk reduction? The third question addresses risk and the treatment tools available. The member noted that the issue of how to treat a contaminant is not part of the CCL process and is addressed by a separate process. Development of the CCL is at the beginning of a multi-step process that, in the end, results in regulation of selected contaminants. The questions the CCL addresses are with what potential contaminants should the process begin and where should the limited resources for research be focused within the universe of potential contaminants. The member observed that there are some risks involved with making the wrong prioritization on the CCL, such as missing important contaminants or spending money on unimportant contaminants. He commented that although it is important to consider whether a hazard is something that is already being addressed, the question enters later in the process and should not be a consideration in developing the CCL. Noting that not all systems are required to disinfect their water, he cautioned against assuming that because a contaminant is controlled by technology it is not a concern.

A member commented that one approach in regard to chemicals and microbes would be to test two parallel methods and see whether they come together, without assuming or stipulating that they will. He noted that another question for the work group is how to address mixtures.

Reflecting on where the CCL process fits into EPA's rule making process, a member asked that the group agree on the endpoint and what is intended for the universe, PCCL, and CCL. He observed that the endpoint focuses on hazards involved and some understanding of occurrence but nothing about treatability and control. He summarized his understanding that the universe is anything that might occur and be a problem, including emerging contaminants; the PCCL is anything with a reasonable likelihood of a significant health effect and a list to which an algorithm can be applied; and the CCL is anything that merits significant thought, with some sort of prioritization. Another member stressed that risk assessment and cost-benefit analysis are later steps in the process, not considered in developing the CCL.

A member noted that the Data Activity Group is still working to determine what the universe should include. Another member suggested using the NRC recommendations and the concept of the universe presented in the Venn diagram as a starting point. A member commented that potential and demonstrated health effects and occurrence need to be at some dose level. A member responded that the NRC did not consider dose at the universe level but did factor dose considerations into scoring the attributes to classify potential contaminants from the PCCL to the CCL. Another member cautioned against relying on dose-response data as they are not available

for all contaminants. She expressed concern that contaminants without dose-response data might then be left out of the process.

A member commented that developing the CCL is a prognostic exercise, not a formal assessment of data. Another member responded that it is all right to use surrogates for some data, but the prognostication must be based upon data and reasonable judgment; there must be documentation for the belief that an effect may occur.

A member observed that much of what the group has discussed is already examined in the NRC reports, including five criteria for defining the universe of potential drinking water contaminants. EPA staff commented that EPA does not want the group simply to “rubber stamp” the NRC recommendations but rather wants the group to examine them and decide whether to support them.

### **Operational Protocols**

The work group reviewed the operational protocols as revised on September 19, 2002. Additional minor revisions were made to section 6 to reflect the schedule currently planned for the group. Contingent upon agreement by the absent member, the work group adopted the operational protocols as revised (see attachment L).

### **Public Comment**

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

### **Next Steps**

- **Additional expertise to support the work group** - Members will contact RESOLVE with their ideas for additional microbiology experts and exposure data experts to support the work group.
- **Revised draft work plan** - RESOLVE will incorporate the revisions discussed at this meeting and circulate the revised draft to members for review.
- **Activity group summaries** - In the interest of keeping everyone aware of each activity group’s work, the summary of each activity group conference call will be made available to all members and interested parties through email or a website. Members also will be provided an inventory of the materials distributed to the various groups so all members can be aware of all the information being exchanged.
- **Guiding principles** - By December 31, work group members will send any comments or draft language for the guiding principles to RESOLVE. RESOLVE will distribute the information to the Principles Activity Group to discuss on the January 21 conference call.
- **Draft glossary** - The facilitation team (EPA, RESOLVE, and consultants) will begin a draft glossary to be built as the process continues.
- **Final product** - The facilitation team will begin assembling a list of issues/items raised by work group members for the work group’s final product.

## ***Activity Groups***

### *Guiding Principles*

Conference call: Tuesday, January 21 at 11:00 a.m. Eastern

### *Data*

Conference calls: Thursday, January 9, 12:00 – 2:00 p.m. Eastern  
Wednesday, January 15, 12:00 – 1:00 p.m. Eastern  
Thursday, January 23, 12:00 – 2:00 p.m. Eastern  
Wednesday, January 29, 12:00 – 1:00 p.m. Eastern  
(Tentative: Wednesdays at noon following the February 5-6 meeting, to be decided based on experience with January calls)

### *Methods*

Conference calls: Monday, January 6, 12:00 – 1:30 p.m. Eastern  
Tuesday, January 28, 1:30 – 3:30 p.m. Eastern

### *VFAR*

- Members other than Dr. Griffiths, Dr. Stine, and Dr. Ramirez-Toro who would like to participate in the VFAR Activity Group should contact RESOLVE.
- RESOLVE will contact members to schedule conference calls to review requested analyses, determine next steps in regard to the Wassenaar recommendations, and discuss strategies for incorporating microbials into the CCL process in the near term.

## **Future Meetings**

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

- |                      |                         |
|----------------------|-------------------------|
| ▪ February 5-6, 2003 | ▪ July 16-17, 2003      |
| ▪ March 27-28, 2003  | ▪ September 17-18, 2003 |
| ▪ May 12-13, 2003    | ▪ November 13-14, 2003  |

Suggested items for February meeting agenda:

- Activity group discussions (topics to be decided based on outcomes of conference calls)
- Report from VFAR Activity Group on a plan for how to deal with microbes
- Presentations by EPA and water system representatives to provide context for the CCL process
  - What is currently regulated?
  - What is already being done by water systems? How does this vary throughout the country?
  - How are changes in the regulations tracked? How do water systems plan for and react to regulations and factor changes into their planning? Look at large, medium and small system approaches as well as the state-level approach.
  - What are the big issues the states are facing?
  - For what contaminants do systems currently monitor? How many of these contaminants are found and not found?