UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

[Date]

EPA-SAB-08-00_

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3)

Dear Administrator Johnson,

EPA's Office of Ground Water and Drinking Water requested that the Science Advisory Board (SAB) Drinking Water Committee (hereafter, the Committee) provide advice on its Draft Third Drinking Water Contaminant Candidate List (CCL 3) and the process used to derive it. EPA is required to publish this Contaminant Candidate List (CCL) every five years. This draft CCL 3 includes 93 chemicals or chemical groups and 11 microbiological contaminants which are known or anticipated to occur in public water systems. Contaminants on the CCL will be considered by the Agency for a regulatory determination.

The Committee believes that the process used to produce the draft CCL 3 represents an improvement over the former processes. While the draft CCL 3 uses a more data-driven and systematic approach, internal EPA expert panels were used to identify potential shortcomings of the data analysis, and ultimately, many decisions were still based on the expert judgment of EPA staff. The Committee views the current process as a first step toward a reformed CCL process, and acknowledges that, as recommended by the National Drinking Water Advisory Council (NDWAC), the process should be designed as an adaptive process that will improve with further experience and data. The Committee's comments on the limitations of the current process should be viewed in this context.

The Committee believes that the documentation of processes that produced the draft CCL 3 lacks transparency. EPA used professional judgments of its internal experts to revise the process in a way that was designed to change the contaminants on the list. The Committee was not concerned that the process underwent mid-course corrections, because such changes are part of the desired, adaptive assessment process. However, the Committee was concerned that these

modifications by Agency staff were not readily apparent in the current documentation. The Committee expressed some concern that the lack of clarity could impede the ability of others to understand the basis for decisions about the CCL, an enunciated criterion for transparency made during the reviews by the National Research Council and NDWAC. To improve transparency further, the Committee recommends that EPA document and justify why each of the contaminants from previous CCL lists were excluded from the draft CCL 3.

In addition to increasing the transparency of the process, the Committee has recommendations for improving the CCL selection process. The Committee believes that the draft CCL 3 includes contaminants that should not be considered for regulation and excludes contaminants that should be considered for regulation. For example for chemicals, the Committee suggested that the EPA should evaluate whether pesticides that were about to be cancelled completely should be on the list for additional SDWA regulation. This could be after some assessment to determine if the agent has been used previously used had any ongoing contamination issues using some occurrence as well as fate and transport data to determine whether the agent needed to be regulated or not. To not carry out at least some evaluation on cancelled chemicals could be shortsighted on the Agency's part. For pathogens, the Committee noted that two globally important waterborne pathogens, *Adenovirus* and *Mycobacteria*, were excluded from the draft CCL 3. The Committee also has suggestions both for the use of more of the publicly available data, as well as for more comprehensive use of the databases already used in the CCL process. The Committee acknowledges that any list will have some contaminants that a panel of experts would prefer to add or remove. Nonetheless, there was general agreement that the current process could be improved to generate a better list.

The current process also does not evaluate some of the less direct, potential hazards of contaminants. Exposure to antibiotics may lead to antibiotic resistant pathogens; the current CCL process would not identify this impact as a threat to human health. Similarly, secondary transmission of pathogens by vectors other than drinking water would also not be expected to be detected as a problem through the current process.

The Committee believes the draft CCL 3 list of contaminants is too large. Even if more than the requisite five contaminants are reviewed for potential regulation, one hundred contaminants can not be reviewed simultaneously. Some of the contaminants on the list are likely ready for a regulatory determination. Others, e.g., those that might be of concern primarily due to occurrence data, will lack the necessary toxicity information for a regulatory determination. Additional priority ranking based on such factors should be undertaken before contaminants are selected for regulatory review, else choice of contaminants from the list may appear arbitrary.

Thank you for the opportunity to provide advice on this important process. The SAB Drinking Water Committee looks forward to receiving your response to this advisory analysis.

Sincerely,

Dr. M. Granger Morgan, Chair
Science Advisory Board

Dr. Joan B. Rose, Chair
Drinking Water Committee

NOTICE

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Introduction

The 1996 Safe Drinking Water Act (SDWA) Amendments require EPA to publish a list of theretofore unregulated contaminants that are known or anticipated to occur in public water systems and may require regulation in drinking water in order to protect public health. EPA is required to publish this Contaminant Candidate List (or CCL) every five years. Following publication of the first list (CCL 1) in 1998, the Agency requested a review of the CCL process from the National Academy of Sciences' National Research Council (NRC) and their recommendations were published in 2001. NRC proposed a broader, more reproducible process to identify the CCL. In 2004, EPA's National Drinking Water Advisory Council (NDWAC) provided suggestions on how to implement the NRC's recommendations to be used for the CCL 3. As this approach was being developed, the second list, CCL 2, was published in 2005. Based on recommendations from NRC and NDWAC, EPA developed a more data-driven CCL selection process which was used for development of the CCL 3. The Agency also requested public nominations for chemical and microbial contaminants for the upcoming CCL 3. Information regarding the CCL processes and lists can be accessed through the CCL web page at: http://www.epa.gov/safewater/ccl/index.html.

The Drinking Water Committee (hereafter, the DWC or Committee) of EPA's Science Advisory Board (SAB) met in a public session on April 23 – 24, 2008 in Washington, DC, to review the draft CCL 3. Both the new process developed in response to the recommendations of the NRC and NDWAC, as well as the specific chemicals and microbial pathogens on the list, were subject to the DWC's review. The charge questions posed by EPA were as follows.

1. Please comment on whether the Federal Register Notice and support documents are clear, transparent, and adequate to provide an understanding of the overall processes and selection of contaminants for the draft CCL 3.

2. Please comment on whether the draft CCL 3 list represents those contaminants that have the highest potential to occur in public water systems and cause adverse human health effects.

3. Please provide any data that may suggest that contaminants which are currently on the draft CCL 3 list should not be listed.

4. Please provide any data that may suggest that contaminants which are currently not on the draft CCL 3 list should be listed.

The Committee discussed each of the above charge questions. This discussion is captured within the text of this report. The first section presents the general comments and overall conclusions of the Committee. The second section discusses recommendations for steps that will make the current process more transparent. The third section provides suggestions to improve the process when it is used for future CCLs. In the fourth section, recommendations with regard to specific contaminants are discussed. The fifth section highlights emerging issues and research needs that arose during discussion of the complex topic of identifying, selecting, and regulating contaminants in drinking water.

General Comments from the Committee

The Committee believes that process used to produce the CCL 3 (EPA, 2008) represents a major improvement from the processes used to generate CCL 1 and CCL 2. The process used to generate the first two lists relied heavily upon expert opinion and best professional judgment, as well as stakeholder nominations, with the potential health risk contributing to the first part of the assessment followed secondarily by whether the contaminant occurred in drinking water. The process for the CCL 3 outlined in the Federal Register Notice (FRN) uses a data-driven, systematic approach, focusing on assessing the information, including surrogate information to identify contaminants based on both the potential or known occurrence in drinking water and their potential or known ability to cause adverse effects in people. As recommended by the NRC and NDWAC, the CCL 3 process attempted to address the universe of contaminants and developed a Preliminary CCL (PCCL), using a more data-derived process. Expert panels were used along the way as part of the review of the approach. During the assessment, 6000 chemical contaminants and 1400 pathogens were identified. The Committee views the current process as a first step toward this data-derived CCL, and acknowledges that, as recommended by the NDWAC, the process should be designed as an adaptive process that will improve and develop with further experience and data. The Committee's comments on the limitations of the current process should be viewed in this context.

There are numerous challenges that must be overcome when whittling the initial "universe" of contaminants down to a CCL. EPA has documented its decision-making process and has described its attempts to identify biases in that process and to obtain expert feedback on the process. In general, the approach is scientifically justified and, particularly for the chemical list, is an intensified documented process and includes the development of models to create the chemical list.

The Committee found that the data-supported process of the CCL 3 (as described in the FRN) generated a list of contaminants that was viewed as suboptimal, in the opinion of internal panels of EPA's internal experts. (The Committee also concurred with this.) EPA requested the opinions of internal experts for professional assessment of chemicals or pathogens to revise the process and therefore the contaminants on the draft CCL 3. The Committee was not concerned that, in developing the process, a review was needed and mid-course corrections were undertaken but was more concerned that these modifications (or suggestions) by Agency staff that were accepted or rejected were not readily apparent as the Committee reviewed the documentation in the FRN. In addition the justifications for the decisions in which expert opinion was accepted or rejected were not articulated. The Committee expressed some concern that the areas of the process without full transparency could impede the ability of others to go through the same exercise as the EPA with the same results when data drove the primary outcome and with a clear understanding of where experts were used to address key decisions in the process. Such reproducibility was an enunciated criterion for transparency made by the NRC and NDWAC.

Moreover, this apparent lack of clarity or transparency in the process led to frustration as Committee members attempted to determine why specific contaminants were retained or removed from the group of contaminants that would become the draft CCL 3. Committee

members who tried to follow the decision-making process for one or more contaminants could not do so. Some of the confusion arose from the previously mentioned role of EPA experts in the process that was not clear to the Committee. Additionally, some of the information about individual contaminants that had been organized by EPA was only available in the regulatory docket. Committee members either did not know that the docket might contain that information or had difficulty locating the docket and/or the information desired. The Committee recommends that both the FRN and the EPA web sites contain citations for all of these documents, and that the web site post the documents and/or hyperlinks directly to each document, as well as the location of the regulatory docket.

In addition to improving the transparency of the process in the written documentation, the Committee had recommendations for the existing and future CCL selection processes. These suggestions were often based on concerns about contaminants that were either retained or removed from the evolving CCL. In particular, an explanation should be included for those contaminants that were on the CCL 1 or CCL 2 that were not included in the new list via the new process with the appropriate justification. The DWC acknowledges that any list of contaminants would have some contaminants that each expert would prefer to add or remove. Nonetheless, there was general agreement that the current process could be improved to generate a list that would contain fewer surprises. For example, members believed that even a cursory sensitivity analysis could be used to improve the scoring systems and justify the cut-off points that were used to retain contaminants. Also, knowledge about a pesticide's regulatory status, particularly cancellation or impending cancellation of all or some its uses might obviate retention in a process designed to determine if more regulatory action is necessary. Pesticides that were no longer in use could be removed from the list after some preliminary assessment to determine if the agent previously used had any ongoing contamination issues and that occurrence as well as fate and transport data could be used to help determine whether the agent needed to be regulated or not. To not carry out at least some evaluation on cancelled chemicals could be shortsighted on the agency's part. The DWC further believes the list of chemicals on the CCL 3 is too large, and that additional priority ranking based on, for example, availability of data necessary for a regulatory determination, should be undertaken before chemicals are selected for regulatory review. This list serves to guide the future safety of drinking water via regulation, to focus research into methods of water treatment, and to interface with other rules such as the Unregulated Contaminant Monitoring Rule (UCMR). It is one of the most critical and important activities within the EPA and thus certainly deserves the efforts that the Agency has devoted to it. So the final list must be viewed within that context.

The Committee members also had suggestions for the use of more of the publicly available data and for the more comprehensive use of the databases already in the CCL 3. In particular, information in the peer-reviewed, published literature could be effectively used at certain junctures of the process, especially when the list of chemicals or pathogens considered for a particular decision is sufficiently small to reduce the burden of a literature search and retrieval. Similarly, the increasing use of wastewater affected sources of drinking water suggests that databases containing information on contaminants in wastewater effluents would inform the CCL process.

The Committee discussed specific ways in which the CCL process might need to be modified in the future. For example, general exposure to antibiotics may lead to antibiotic resistant pathogens, but the current CCL process for chemicals would not identify this adverse effect. Similarly, secondary transmission of pathogens by vectors other than drinking water would also not be expected to be identified as a problem through the current process.

Finally, the Committee's discussions highlighted emerging issues and research needs for consideration by EPA for future. Identifying and obtaining data appropriate for the decision to be made are necessary for the optimal operation of the CCL process.

Clarifications Regarding Steps In The Process That Will Make It More Transparent

Obtaining the list of contaminants for the draft CCL 3 involved development of a new contaminant-selection process. The goal of this process was to use data, not just expert opinion, to derive the list of contaminants. The developing process and the available data affect each other. Determination of the questions to be answered and the issues to be resolved identify the essential data. Selection of the databases with specific attributes can determine whether parameters are estimated directly or when surrogates must be used. Lack of readily available data can constrain the decision options within the process. The DWC considered these aspects of the CCL process, as well as their implications on the selection of chemicals and pathogens for potential regulation.

Models and Selection Processes

The process of selecting the CCL 3 involved three major steps: identifying the "Universe" of contaminants that might be of concern; using data on occurrence and potential to cause adverse effects to obtain a "Preliminary Contaminant Candidate List" (PCCL); and using data, processes, and opinions from EPA's internal experts to refine the selection into a draft CCL. To improve transparency between CCL 2 and CCL 3, the Committee recommends that EPA list all contaminants from CCL 2 that are not included in CCL 3, and provide the reason the contaminant is not on CCL 3.

The improvements in the selection process that were recommended by EPA's internal experts are consistent with the theme of adaptive management recommended by NWDAC and endorsed in the FRN. Thus, the methodology for the listings can be adapted as more experience with the CCL-listing process is gained. The use of internal EPA panels of experts to modify the process, however, was not clear and transparent to the Committee members. These revised procedures that were the basis for the recommended CCL 3 need to be more fully explained. Furthermore, Committee members thought that the CCL 3 list, as modified by the internal experts, might have been more acceptable if external experts' opinions had also been sought. A schematic flowchart could be developed which shows where in the process experts (internal or external) were used (see below).

The discussion in the FRN regarding the methodology for moving chemicals from the PCCL to the CCL is organized in a chronological manner. This presentation imports

significance to a complex and somewhat cumbersome initial methodology that was ultimately subsumed within a new methodological framework proposed by EPA's internal expert panels. This complex, initial approach was not used to determine which chemicals moved from the PCCL to the CCL. The actual approach began by dividing the chemical PCCL into three groups (high, medium, and low uncertainty) depending on the type of data available to characterize the contaminant. For each of these groups, a new decision rule was developed to determine whether or not the contaminant should move forward to the CCL. While these decision rules are indicated in the bullets in Section III A4 (page 9644 of the FRN), the explanations attached to each bullet need to be expanded so that the decision rules are more clearly explicated. Moreover, since the initial classification model was only used for chemicals in the medium certainty bin, EPA should "re-train" the model using only training chemicals that would fall into this bin.

The DWC suggests developing one or more flowcharts that a stakeholder can use to track the progress of a contaminant through the system, with the appropriate references and URLs for each step. Such flowcharts would not only make the process more transparent, but they might also highlight decisions that might suggest improvements for future CCL processes. Also, parameters chosen for the models, as well as the stopping rules or specification decisions, should be provided (in more detail than is provided in Appendix E). To further improve the clarity of the process, approaches that were discarded should be moved to the end of the document, perhaps in an appendix. The training set used for calibration should be readily available in the documentation via links to the web site.

The Committee noted that the draft CCL 3 gives equal weight to all chemicals, although some chemicals are likely to be ready for regulatory determination while others will require a significant amount of additional research before a regulatory determination can be made. Therefore, prioritization within the current CCL is considered important. Additional data and processes should be used to priority rank those chemicals, for example, by a method that will select chemicals that have sufficient existing information for a data-based regulatory decision. Priority ranking contaminants may also require reformulating or retraining the algorithms, since the dependent variable of the algorithm must now indicate whether a contaminant should be studied for listing, and with what urgency the contaminant should be studied.

The Committee also noted some deficiencies in presentation of the process. Details are lacking, for example, as to how fate parameters like the octanol/water partition coefficients were used in the evaluation. Also, all parameters should include the appropriate units, e.g., on LD_{50} and related parameters in Exhibit 9.

The process for selection of pathogen contaminants, as outlined in the FRN documentation, was overall judged a relatively transparent one, however issues emerged with the approach used that were not resolved. There was an analytical protocol employed; however, it did not discretely quantify potency, for example, in terms of dose-response relationship as it had for the chemicals proposed for CCL 3 inclusion. Nonetheless, there was much more of a quantitative underpinning which was superior to previous CCL formulations which appeared much more subjective. The sources of information and data that were used in candidate selection are clear, and the effort to be inclusive in receiving information from non-government organizations (NGOs), the public, professional organizations, and municipalities is apparent.

The development of the universe and the PCCL were data driven; however, the resolution of the details of the information that was used to assign a numerical rating to the pathogen was limited.

The process for moving pathogens from the PCCL to CCL is not sufficiently clear. In particular, it is somewhat ambiguous as to how the ultimate pathogen scores for this process were developed. For pathogens, it appears that the internal EPA experts adjusted the scoring system. This adjustment should be presented more prominently. The Committee believes decisions regarding the selection of data sets and resolution of the information within those data sets (as discussed further in the next section) were partially responsible for the suboptimal results. The Committee believes that the relative weighting of Center for Disease Control and Prevention (CDC) Waterborne Disease Outbreaks (WBDO), "Occurrence," and "Health Effect Scoring," as well as data normalization, is described, but not necessarily transparent. It is recommended that the limitation of WBDO data sets be articulated clearly, for example, in regard to underestimation of waterborne disease via a passive surveillance and the percentages of outbreaks where no etiological agent is identified. Exhibit 15 shows evidence of WBDO using the CDC surveillance database. Over the more than three decade period in question, the scoring system does not differentiate between pathogens that have caused many outbreaks and those that caused only two outbreaks. Furthermore, scoring of the WBDO data does not appear to take into account the geographic dispersion of the outbreaks. Also lacking are data on specific, identified pathogens for the majority of studied outbreaks. Furthermore, a rudimentary sensitivity analysis of the pathogen-weighting criteria would have demonstrated that the results are not robust to small changes in the scoring. For example, a change of only "1" unit in WBDO score would move some organisms on or off the list. Also, the use of "Occurrence" data does not appear to be a quantitatively robust term, i.e., the 1-to-3 ranking scale may have less utility than initially expected. An occurrence term of 3 appears only to mean that it has been found in U.S. drinking water, but not that it is found with any type of frequency or geographic distribution in U.S. drinking waters. In fact, a score of 3 may mean that it was only found once in drinking water. Outbreak data were not independent of occurrence, as an outbreak would in and of itself suggest that the organism had been found in drinking water and influenced that score. This gave the WBDO a greater weight in the ranking. If it were only detected once, the exposure potential, and therefore the risk, may be quite low.

Decisions Regarding Data Sets

In several places EPA appears to use data that may not be optimal for its stated intent of offering equal protection to water consumers. For example, on page 9640 of the FRN, prevalence is defined as "…the percent of public water systems or monitoring sites across the nation with detections, number of states with releases…" Neither of these measures takes into account the number of people who are potentially exposed to contaminants through these drinking water systems. A contaminant that is found in two or three small states could receive greater weighting than one found in a large, populous state. The reasons for and implications of such decisions should be discussed.

EPA also used a hierarchical approach for data sources to indicate health effects. For full transparency, the order in this hierarchy of references should be clearly presented. Furthermore, for food-use pesticides, it would seem more appropriate to use the population adjusted dose

(PAD), i.e., the dose that incorporates the additional uncertainty factor for children under the Food Quality Protection Act, rather than the reference dose (RfD) in the calculation of a health reference level (HRL). Therefore, the Committee recommends that the Agency recalculate the health-concentration ratios for those pesticides on the PCCL that have PADs smaller than their respective RfDs. It is possible that additional substances may qualify for inclusion on the draft CCL 3 because their revised ratio could now be 10 or less.

The data used (or more specifically, the data not used) and the resulting pathogens selected, were not necessarily the optimal set to consider for regulation. For example, a choice was made by EPA to primarily rely on national data sources and use only data sources with entries (in this case, for recorded outbreaks) for all of the organisms. This led to heavy reliance on CDC databases and lack of use of the peer-reviewed, published scientific literature. This process does not necessarily represent the "best available science." While there was general agreement that the existence of a WBDO should bring special attention to a microbial pathogen, the WBDO grading system did not appear to be able to provide a resolution regarding details to the scoring algorithm, thus the full breadth or range of data available was not used (for example, there is no resolution between organisms which have caused outbreaks in the Marshall Islands (*Cholera*) and an organism that has caused several outbreaks in the continental U.S. (norovirus and *Campylobacter*)). The potential problems caused by highly endemic diseases that are never detected as outbreaks are not fully explained. A supplementary table containing the published, waterborne-attributed, case reports for each of the organisms would be useful. There is also a lack of data and discussion about the prevalence of organisms in sewage and wastewater. As a result, organisms such as *Naegleria* or *Vibrio* may receive a pathogen PCCL score higher than expected because of this weighting for “Occurrence.”, which is tied to whether there has been an outbreak. An environmental frequency or distribution score for pathogens, rather than or in addition to its “Occurrence” score, is needed. The ranking and the line that separated the PCCL from the CCL seemed arbitrary and should be better described (Exhibit 18).

Perhaps what is less clear are the effects of the information that was not used in developing candidates for CCL inclusion. The exclusion of outbreak and occurrence data from other parts of the world (especially Europe and Canada with similar cultures and infrastructures) should be discussed, and its inclusion in future analyses should be considered. It would be very helpful to provide the current, best estimates of the total annual number of known cases for each organism in the US, Europe, and Canada. Similarly, information on the regulatory decisions about other pathogens in other countries might improve the process.

Peer reviewed research articles in journals and periodicals received less attention as data sources than disease monitoring or surveillance data from other agencies, state, or municipal sources. Given the relatively limited number of microbial pathogens proposed for inclusion on the CCL, reviews of the scientific literature might be possible in addition to the sources that were used to develop this draft CCL 3. Exceptions to the process where by journal articles were used for bacteria included publications on *Arcobacter* and *Mycobacterium avium* complex (MAC). It is likely that other organisms would change position if outside data and internal and outside professional judgment were used. The literature may also be more current with respect to sensitivity, selectivity, and specificity than those derived from some more standard methods.

There was discussion in the document about not using susceptibility to water treatment to guide the selection list. This may be appropriate for the PCCL as well as the CCL; however, it seems that, as with the chemicals, prioritization and discussion should be addressed for the list created in regard to investment in generating more data (on methods, occurrence and health effects) or rule development. Thus, if it is believed that the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) or the Ground Water Rule (GWR), for example, already addresses risk management for specific pathogens, this could begin to be articulated. It does not benefit public health or water science to have a number of pathogens on a CCL that can just be taken off once they are "controlled" without formally establishing an MCL or treatment technique. Thus, for example, the large numbers of *Legionella* cases and the fact that no current regulatory approach can be documented to reduce this risk may place this type of pathogen in a higher priority category on the CCL.

Use Of The CCL For Regulatory Decisions

The CCL 3, as currently defined, serves two distinct purposes. The first is to identify unregulated chemicals that might have potentially sufficiently high occurrence and produce adverse effects of concern that resources might be directed to obtaining more information. Toward this end, either data on occurrence or data on adverse effects should lead to development of a regulatory control. In contrast, the second goal is to select those contaminants that should be considered for imminent regulatory action. In general, such action would require the existence of, rather than the generation of, information on both occurrence and adversity. Priority setting should use this criterion, as absent this information, future CCLs will not achieve their stated goal.

Finally, the number of contaminants on the CCL keeps increasing in every iteration, and yet regulatory determinations are only made for 5 to 10 contaminants every five years. The continued increase in contaminants on the list may give the public a sense that water quality is declining with time. EPA should consider how to address this issue of risk perception in its documents on the CCL process.

Suggestions To Improve The Process For Future CCLs

If EPA uses this process again, the Committee believes that it will be important to incorporate the lessons learned in generating the next CCL. For example for chemicals, the models will need to take into consideration the level of certainty, and also some measure of the ratio between the level of concern and the potential drinking water level.

The databases used by the EPA in the CCL 3 analyses do not include much of the journal literature that could be a rich source of information. While these sources might be difficult to search for the "Universe" of chemicals, these data could more easily be included in the PCCL to CCL process, especially for the limited number of pathogens. The use of advanced text-processing software should be investigated for this application. E-government initiatives throughout the federal government, as well as a lively and innovative academic community, are

potential sources of help for EPA in pursuing this approach. Similarly, use of available computational toxicology data might improve the selection of chemical contaminants.

EPA should consider regulating chemicals with similar mechanisms of action and microbial pathogens with similar potency and disease endpoints (for example, diarrhea, pneumonia, meningitis) as groups. As an example, the Committee posed the question of what would have happened if the trihalomethanes (THMs) were evaluated individually rather than as a mixture.

The Committee agreed that it will be important to consider information regarding wastewater concentrations on the exposure side of the assessment. This will be important both because wastewater discharges are increasingly a greater percentage of water supplies and are being processed into potable water. Also, wastewater contains a wide variety of contaminants including pharmaceuticals, personal care products, enteric pathogens, and other emerging contaminants. In the case of pharmaceuticals, perflourinated surfactants, and other contaminants that are prevalent in wastewater effluent, EPA may want to consider using data obtained in wastewater effluent monitoring programs for the CCL screening process. Large water systems may be subjected to significant discharges of wastewater effluent, and it is likely that the concentrations of contaminants measured in wastewater effluent could be used as a surrogate for concentrations in raw water. An approach for predicting the role of unplanned wastewater reuse that may be appropriate for predicting concentrations in raw water sources is presented in Anderson et al. (2004).

The listing criteria for chemicals should also consider including an element that evaluates analytical methods used to quantify the chemical contaminant concentrations in occurrence data. Without a “standard” method and an established detection limit, the quality of the occurrence data will reflect the self documented capabilities of the laboratories doing the analytical work. There can be significant differences in the analytical capabilities of the laboratories that must be accounted for when reviewing the occurrence data. As a result, some members of the Committee cautioned against using the 90th percentile of the measured water concentrations in combination with a 10-fold ratio. It is clear that, for the very skewed distributions of concentrations in water, some water utilities could be in a zone of concern and the chemical would still be screened off the list, using the existing criteria and algorithm.

Significant limitations in understanding which microbial pathogens were considered for the CCL 3 list include the lack of occurrence data, very limited surveillance for most of the microbial pathogens, and the broad range of potential health effects. The CDC WBDO database, for example, is widely acknowledged to be an incomplete reflection of the true number of outbreaks, and it does not capture the burden of disease relating to endemic, lower level transmission. Thus, the Committee considers its concerns regarding the pathogens selected for the CCL 3 to be a signal for the acquisition of better data on occurrence and surveillance regarding human disease. In general, given the small numbers of pathogens, greater details from the data sets could be used as well as endemic disease rates. Data on occurrence is particularly poor, and thus the literature on surveys will require more scrutiny. The Committee recommends that same exceptions made for *Arocbacter* and MAC in how a WBSO is defined should be applied to the other pathogens for which there is are high-quality, peer-reviewed reports.

Some contaminants that may be considered in the future may need a different algorithm for the selection process. For example, concern about general exposure to antibiotics includes the development of antibiotic-resistant pathogens that would not be measured in the current score for adverse effects. Similarly, secondary transmission of pathogens and that affect on burden of disease might require additional considerations. Furthermore, while the index case might be due to exposure from drinking water, subsequent transmission might be by a variety of vectors. This issue is neither discussed in the document nor addressed in the current process.

It would seem wise to include the DWC earlier in the process. Requesting advice from the DWC throughout the process, and not just at the end, would seem to take better advantage of the expertise of the Committee.

Contaminant-specific Recommendations

The Committee members were surprised by some of the chemicals and pathogens that made the list and by some that did not. The members acknowledge that any procedure would likely include contaminants that individual experts believe should or should not be included in the CCL. Furthermore, the members did not attempt to create the CCL process. Nonetheless, the Committee recommended reconsideration of certain aspects of the process that might enhance the utility of the CCL.

The Committee experts in pathogens had not expected to see *Entamoeba histolytica* and *Vibrio cholerae* on the CCL list, and they were surprised not to see *Adenovirus* or *Mycobacteria*. As discussed earlier, the weighting of documented outbreaks on health effects, and the approach used regarding occurrence ranking, moved *Entamoeba* and *Vibrio* higher on the list, whereas, if endemic disease, numbers of outbreaks, and geographic locations and venues, as well as better assessment on occurrence had been used, these two globally important waterborne pathogens would have moved off the list for the US, while information on endemic disease and occurrence in water based on the literature would have moved the *Adenovirus* and *Mycobacteria* on to the list. Expert opinion both internal and external would likely have questioned *Vibrio* and *Entamoeba* on the CCL. Other countries' environmental agencies look to the EPA's CCL. Thus, when the system that is used reveals pathogens which are no longer considered waterborne disease risks in the US, the reasons for this should be addressed and the data based numerical approach should be investigated and corrected. Health effect scoring should distinguish acute from chronic effects. The potential for pathogen occurrence in ambient waters could be considered based on contaminants occurrence in wastewater (as described in the previous selections). Thus, the Committee believes that the data sets selected, the scoring process used, the poor occurrence information may have significantly influenced these results and it is clear that the process can be improved.

The Committee experts in chemicals had not expected to see pesticides that had been cancelled on the CCL (see earlier comment). Similarly, they questioned the value of considering pesticides that were about to be cancelled completely for additional SDWA regulation. The isomers of hexachlorocyclohexane that were on or off the list did not appear appropriate, and other pesticides that did not appear on the CCL 3 that were mentioned as potentially worthy of

listing included some for which information was provided to EPA by public commenters. The absence of data on the occurrence of pharmaceuticals in surface waters was also noted, and it was thought that use of the data from the U.S. Geological Survey (USGS) or any of the numerous studies in the peer-reviewed literature would have included these chemicals. Also, there appears to be a consensus among experts that N-nitrosodimethylamine (NDMA), methyl tertiary butyl ether (MTBE), perchlorate, and perfluorooctanoic acid (PFOA) should be a high priority for consideration by the Agency, because there is a higher degree of certainty about their toxicity, occurrence, and treatability. In contrast, proposed CCL chemicals such as germanium, hexane, and quinoline appear to be on the list mainly because they scored highly in one category (e.g., production volume for hexane and toxicity for germanium). The Committee believes that these chemicals may be of a lower priority for regulatory action at this time.

The Future: Emerging Issues and Data Needs

As discussed in the previous sections, the Committee concluded that the CCL 3 is a major improvement on the previous CCL process. While some of the limitations may be overcome by using existing data more effectively, the Committee recognizes that additional data would serve to increase the effectiveness of selection of contaminants both for priority research and/or possible regulation. Key areas to improve the process must be explored and addressed in the future include: sensitivity analysis, data uncertainty, and data quality.

There are also some clear categories of contaminants that need special attention. These may be on the PCCL or in the universe. These include pharmaceuticals, personal care products, endocrine disruptors, antibiotics, and algal toxins. Opportunistic pathogens (e.g., *Serratia* and *Pseudomonas*) may need to be addressed in the future.

References

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