

**Summary Minutes**  
**US Environmental Protection Agency Science Advisory Board**  
**Meeting**

**Public Teleconference Meeting**

**December 16, 2008**

**11:00 am – 5:00 pm (Eastern Time)**

**Meeting Location: Via Telephone Only**

**Purpose of the Meeting:** The Meeting was held to allow for the Chartered SAB to conduct a quality review of two draft SAB reports. The meeting agenda is in Attachment A. The list of SAB and other participants follows.

**Meeting Participants:**

**Members Participating in the Meeting:**

Dr. Deborah L. Swackhamer, Chair	Dr. David Allen
Dr. John Balbus	Dr. Greg Biddinger
Dr. Tim Buckley	Dr. Thomas Burke
Dr. James Bus	Dr. Deborah Cory-Slechta
Dr. Terry Daniel	Dr. Otto Doering
Dr. David Dzombak	Dr. Taylor Eighmy
Dr. John Giesy	Dr. James Hammitt
Dr. Rogene Henderson	Dr. James Johnson
Dr. Bernd Kahn	Dr. Cathy Kling
Dr. George Lambert	Dr. Jill Lipoti
Dr. Melanie Marty (Liaison CHPAC)	Dr. L.D. McMullen
Dr. Judith Meyer	Dr. Christine Moe
Dr. Granger Morgan	Dr. Duncan Patten
Mr. Steve Roberts	Dr. Joan Rose
Dr. Jon Samet	Dr. Kathy Segerson
Dr. Kristin Shrader-Frechette	Dr. V. Kerry Smith
Dr. Thomas Theis	Dr. Valerie Thomas
Dr. Robert Twiss	Dr. Thomas Wallsten
Dr. Daniel Watts (Liaison NACEPT)	Dr. Lauren Zeise

**MEETING SUMMARY**

**Tuesday, December 16, 2008**

This meeting was announced in the *Federal Register* (see 73 FR p 70344 of November 20, 2008 - Attachment B). The SAB Roster is in Attachment C.

**1. Convene the Meeting:** The DFO convened the meeting noting that it was a federal advisory committee meeting and that the Board's deliberations are held as "public meetings" pursuant to the Federal Advisory Committee Act (FACA), its regulations, and the policies of the US EPA for advisory

activities. Mr. Miller noted that no member of the public had requested time to speak but that one had provided written input for the Board's consideration in regards to Perchlorate, a contaminant linked to the Contaminant Candidate List 3 review conducted by the SAB DWC and the draft report which was a review item for this meeting.

Mr. Miller noted that SAB members must comply with Federal ethics and conflict-of-interest laws and that SAB ethics officials review relevant information to ensure that SAB panels reflect appropriate balance and that COI and bias issues are addressed and that the SAB members participating in this meeting had submitted information on whether they knew of any potential appearance of impartiality issues that could link them with the topics on the agenda. As a result of this process two Board Members (i.e., Dr. Jon Samet and Dr. Timothy Buckley) asked to be recused from participating in the PM Centers review because of past links to grants that are a part of the PM Centers Program. SAB Ethics Officials agreed that this was an appropriate recusal; they also determined that other Members on the call did not have any such issues within the meaning of the relevant ethics and conflict of interest requirements that apply to this advisory activity.

Mr. Miller then turned the meeting over to the SAB Chair, Dr. Deborah L. Swackhamer, to carry out the agenda. Dr. Swackhamer welcomed those participating in the review, noted the purpose of the meeting, and explained the nature of an SAB quality review.

**2. Quality Review of the Draft *Particulate Matter Research Centers Program Advisory Report*:** The Board conducted its quality review of the draft SAB advisory on *EPA's Particulate Matter Research Centers Program* (see Attachment D). Dr. Angela Nugent acted as the SAB Designated Federal Officer for the PM Centers Quality Review in lieu of Mr. Tom Miller who served as the DFO for the PM Centers Program Advisory Panel.

At the Chair's request, Dr. David Allen summarized the issue and the primary conclusions of the report.

SAB Member comments are embedded within the draft advisory report in Attachment D as are Dr. Allen's suggested edits as a result of those comments. Dr. Swackhamer asked Members if they wanted to highlight any of their written comments, or if they had other comments to raise in regard to the draft report.

Dr. Judith Meyer asked how the participants in the SAB review were constrained with respect to submitting future grant proposals that might be requested for the PM Centers program. Dr. Vu noted that this did not constitute a conflict nor appearance issue and that it was considered in her vetting of the panelists that conducted the SAB review. The panelists participating in this review are giving general advice on the program history and possible future structure and are not responding to specific items that might be a part of a future request for proposal that would ask for specific grant proposals.

Other members deferred to their written submissions that are covered in Attachment D. With that, a motion was made, and seconded, to approve the report conditioned upon the Panel Chair's editing the document to respond to those points made in member comments. The Chair called for a vote on the motion and the vote was to approve the report. There were no dissenting votes on the motion.

**ACTION:** Dr. Allen and the DFO Mr. Tom Miller will edit the advisory to reflect the comments provided by SAB Members. Once that is done the report will be transmitted to the EPA Administrator.

**3. Quality Review of the Draft 2 SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3).** This was a redrafting of the draft advisory that initially went through SAB quality review at the October 28, 2008 Board meeting. At that time, members provided written comments on the draft indicating the need for a significant edit to clarify certain report components. Since the October meeting, the DWC Chair and staff have responded to the Board members comments provided in the October 28, 2008 meeting (see Attachment E) and their revised report (see Attachment F) was sent to the Board for final consideration. Reflections on this redraft noted the improved clarity of the revised report (see Attachment G).

Dr. Swackhamer asked members if they had comments to make on the revised draft. Several noted their opinion of the improvements to the draft and their support for the revised document. One member offered to provide several references to support a number of un-cited statements in the text that she recommended have such support. There were no other comments made.

Dr. Swackhamer asked for a motion for dispensing with the report. A motion was made, and seconded, that the report be approved without the need for further consideration by the Board of final edits. A vote was taken and all members participating voted to approve the report.

**ACTION:** The report will undergo the several additional minor edits discussed and then be sent to the Administrator.

With the business concluded for the reviews, the Designated Federal Officer adjourned the meeting at 11:35 a.m.

Respectfully Submitted:

**/ Signed /**

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Mr. Thomas O. Miller  
Designated Federal Officer, Acting  
US EPA Science Advisory Board

Certified as True:

**/ Signed /**

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Dr. Deborah L. Swackhamer  
Chair, EPA Science Advisory Board

**ATTACHMENT A**

**U.S. Environmental Protection Agency  
Science Advisory Board  
Teleconference  
Agenda  
December 16, 2008**

(Telephone conference meeting: For call-in information, please call the  
SAB Staff Office at 202-343-9999)

*Purpose of the Meeting: The Board will meet to conduct two quality reviews of draft SAB reports.*

**Tuesday December 16, 2008**

11:00 a.m.	<b>Convene the Meeting</b>	<b>Mr. Thomas O. Miller</b> <i>Designated Federal Officer, EPA Science Advisory Board</i>
11:05 a.m.	<b>Purpose and Approach of the Meeting</b>	<b>Dr. Deborah L. Swackhamer</b> <i>Chair Science Advisory Board</i>
11:10 a.m.	<b>Quality Review of the Draft SAB <i>Particulate Matter Research Centers Program Advisory Report</i></b>	<b>Dr. Deborah L. Swackhamer</b> <b>Dr. David T. Allen</b> <i>Chair, SAB PM Research Centers Program Advisory Panel</i>
11:35 a.m.	<b>Quality Review of the Draft SAB <i>Advisory on EPA's Draft Third Drinking water Contaminant Candidate List (CCL3)</i></b>	<b>Dr. Deborah L. Swackhamer</b> <b>Dr. Joan Rose</b> <i>Chair SAB Drinking Water Committee</i>
12:00 p.m.	<b>Adjourn the Meeting</b>	<b>The DFO</b>

For assistance, contact FERC Online Support.

*For Further Information Contact:*  
Blake Condo at (202) 502-8914 or  
[blake.condo@ferc.gov](mailto:blake.condo@ferc.gov).

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. E8-27565 Filed 11-19-08; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2677-019]

#### City of Kaukauna, WI; Notice of Staff Participation in Meeting

November 14, 2008.

On December 1, 2008, Office of Energy Projects staff will participate by teleconference in a work group meeting to discuss information needs for an assessment of recreational boating flows in the bypassed reach of the Badger Development for the relicensing of the Badger-Rapide Croche Hydroelectric Project (FERC No. 2677-019). The meeting will begin at 1 p.m. CST.

For parties wishing to participate in the teleconference, the call-in number is 608-443-0390 (PIN# 7608). For further information please contact Arie DeWaal, Project Manager, Mead & Hunt, Inc., at (608) 273-6380, or e-mail at [arie.dewaal@meadhunt.com](mailto:arie.dewaal@meadhunt.com), or John Smith, FERC, at (202) 502-8972, or e-mail at [john.smith@ferc.gov](mailto:john.smith@ferc.gov).

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. E8-27567 Filed 11-19-08; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket Nos. OA08-62-000; ER08-1113-000]

#### California Independent System Operator Corporation; Notice of FERC Staff Attendance

November 14, 2008.

The Federal Energy Regulatory Commission (Commission) hereby gives notice that on the following dates members of its staff will attend stakeholder meetings of the California Independent System Operator (CAISO). Unless otherwise noted, these meetings will be held at the CAISO, 151 Blue Ravine Road, Folsom, CA or by teleconference. The agenda and other

documents for the meetings are available on the CAISO's Web site, <http://www.aiso.com>.

November 19, 2008: Integrated Balancing Authority Area compliance filing.

November 20, 2008: CAISO 2009 Transmission Plan.

Sponsored by the CAISO, these meetings are open to all market participants, and staff's attendance is part of the Commission's ongoing outreach efforts. The meetings may discuss matters at issue in the above captioned dockets.

For further information, contact Saeed Farrokhpay at

[saeed.farrokhpay@ferc.gov](mailto:saeed.farrokhpay@ferc.gov); (916) 294-0233 or Maury Kruth at [maury.kruth@ferc.gov](mailto:maury.kruth@ferc.gov); (916) 294-0275.

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. E8-27564 Filed 11-19-08; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. AD08-12-000]

#### State of the Natural Gas Infrastructure Conference; Supplemental Notice of Commission Conference

November 14, 2008.

On October 7, 2008, the Federal Energy Regulatory Commission (Commission) issued a notice announcing a conference in this proceeding, to be held on November 21, 2008. As mentioned in that notice, the focus of the conference is on natural gas demand and supply issues as they relate to the development of the domestic natural gas industry and the effect upon infrastructure. The Commission has invited industry representatives to provide perspectives and comments. The agenda for the conference is attached.

As noted in the October 7 Notice, the conference will be held at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 in the Commission Meeting Room (2-C) from 9:30 a.m. until 12:30 p.m. (Eastern Standard Time). All interested parties are invited, and there is no registration required.

This conference will be transcribed. Transcripts of the conference will be immediately available from Ace Reporting Company (202-347-3700 or 1-800-336-6646) for a fee. A free Webcast of this event is available through <http://www.ferc.gov>. Anyone

with Internet access who desires to view this event can do so by navigating to the Calendar of Events at <http://www.ferc.gov> and locating this event in the Calendar. The event will contain a link to its Webcast. The Capitol Connection provides technical support for the free Webcasts. It also offers access to this event via television in the Washington, DC area and via phone-bridge for a fee. If you have any questions, visit <http://www.CapitolConnection.org> and click on "FERC" or call (703) 993-3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to [accessibility@ferc.gov](mailto:accessibility@ferc.gov) or call toll free 866-208-3372 (voice) or 202-208-1659 (TTY), or send a FAX to 202-208-2106 with the required accommodations.

Questions about the conference should be directed to Raymond James by phone at 202-502-8588 or by e-mail at [raymond.james@ferc.gov](mailto:raymond.james@ferc.gov).

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. E8-27570 Filed 11-19-08; 8:45 am]

BILLING CODE 6717-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8742-4]

### EPA Science Advisory Board Staff Office; Notification of a Public Teleconference Meeting of the Chartered Science Advisory Board

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The EPA Science Advisory Board (SAB) Staff Office announces two public teleconference meetings of the chartered SAB to: (1) Conduct its quality review of several draft SAB reports, and (2) to receive a briefing from EPA on biofuels.

**DATES:** The meeting dates are Tuesday, December 9, 2008, from 1 p.m. to 3 p.m. (Eastern Time) and Tuesday, December 16, 2008, from 11 a.m. to 12 p.m. (Eastern Time).

*Location:* The meeting will be conducted by telephone only.

**FOR FURTHER INFORMATION CONTACT:** Any member of the public wishing to obtain general information concerning this public teleconference meeting should contact Mr. Thomas Miller, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), 1200

Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9982; fax (202) 233-0643; or e-mail at [miller.tom@epa.gov](mailto:miller.tom@epa.gov). General information concerning the EPA Science Advisory Board can be found on the SAB Web site at <http://www.epa.gov/sab>.

**SUPPLEMENTARY INFORMATION:** The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the EPA SAB will hold a public teleconference meeting to conduct several quality reviews and to receive a briefing on biofuels by EPA representatives.

*Background: SAB Telephone Conference, Tuesday, December 9, 2008:*

(a) SAB Quality Review of the Draft Report from the SAB Committee for the Valuation of Ecological Systems and Services (C-VPESS). The Chartered Science Advisory Board will conduct a quality review of the draft final SAB report from its Committee for Valuing the Protection of Ecological Systems and Services. The report is an original SAB study, initiated in 2003. The committee's charge was to assess EPA valuation needs; assess the state of the art and science of valuing protection of ecological systems and services; and identify key areas for improving knowledge, methodologies, practice, and research. The report takes a multi-disciplinary approach to ecological valuation issues. Additional information on this topic is available on the SAB Web site at [http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr\\_activities/Ecological%20Valuation?OpenDocument](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activities/Ecological%20Valuation?OpenDocument).

(b) *EPA Biofuels Briefing:* On October 27, 2008, the Science Advisory Board conducted a seminar entitled "Looking to the Future" as part of an ongoing effort to consider EPA's long-range strategic research vision. A part of that meeting focused on the environmental implications of biofuels. During the SAB's December 9, 2008 telephone conference, the Board will receive a briefing from representatives of the EPA OAR Office of Transportation and Air Quality on the status of the agency's renewable fuels program rule

development process. This information will provide additional background information to the SAB as it considers how it might further advise the EPA Administrator on the Agency's research program.

*Background: SAB Telephone Conference, Tuesday, December 16, 2008:*

(a) SAB Quality Review of the Draft SAB Panel Report on the EPA Particulate Matter (PM) Research Centers Program. The chartered Science Advisory Board will conduct a quality review of the draft SAB report from its Particulate Matter Research Centers Program Review Advisory Panel. In 1998, the Congress directed EPA to establish as many as five university-based PM research centers as part of the Agency's PM research program. The first PM Research Centers were funded from 1999 to 2005 with a total program budget of \$8 million annually. EPA's PM Research Centers program was initially shaped by recommendations from the National Research Council. In 2002, EPA requested that the Science Advisory Board conduct an interim review of EPA's PM Research Centers program. This review was instrumental in providing additional guidance for the second phase of the program (2005-2010). Five current centers are funded for 2005-2010 with the total program budget at \$40 million. EPA's National Center for Environmental Research (NCER), within the Office of Research and Development (ORD), requested that the SAB comment on the Agency's current PM Research Centers program and to advise EPA concerning the possible structures and strategic direction for the program from 2010 to 2015. The SAB formed the PM Research Centers Program Advisory Panel to conduct this review. The Panel met to review and discuss the program on October 1-2, 2008 and has now completed a draft report providing the results of its deliberations. Additional information on this review is available on the SAB Web site at [http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr\\_activities/2008%20PM%20Centers%20Program%20Review?OpenDocument](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activities/2008%20PM%20Centers%20Program%20Review?OpenDocument).

(b) SAB Quality Review of the Draft SAB Contaminant Candidate List 3 Advisory. The Chartered Science Advisory Board will conduct a second quality review of the draft SAB Drinking Water Committee (DWC) report on EPA's Drinking Water Contaminant Candidate List 3. This report was the subject of a quality review at the SAB's October 28, 2008 meeting. At that meeting, the Chartered SAB asked for some revisions relative to the comments

made by SAB members during that meeting (see these comments on the SAB Web site at the following URL [http://yosemite.epa.gov/sab/sabproduct.nsf/A3B59D3624B2B1DA852574EB006DD0C9/\\$File/;SAB+Comments+on+CCL+3+Oct+28+08+Meeting.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/A3B59D3624B2B1DA852574EB006DD0C9/$File/;SAB+Comments+on+CCL+3+Oct+28+08+Meeting.pdf)) and that the report be returned to the SAB for completion of the quality review. The DWC review was conducted at the request of the EPA Office of Water. The 1996 Safe Drinking Water Act Amendments (SDWA) require EPA to (1) publish every five years a list of currently unregulated contaminants in drinking water that may pose risks and (2) make determinations on whether or not to regulate at least five contaminants from that list on a staggered five year cycle. The list must be published after consultation with the scientific community, including the SAB, after notice and opportunity for public comment, and after consideration of the occurrence database established under section 1445(g) of the SDWA. The unregulated contaminants considered for the list must include, but are not limited to, substances referred to in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), and substances registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Additional information on this review can be obtained on the EPA SAB Web site at [http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr\\_activities/CCL3](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activities/CCL3).

*Availability of Meeting Materials:* The agenda and other materials in support of this meeting will be placed on the SAB Web site at <http://www.epa.gov/sab> in advance of this meeting.

*Procedures for Providing Public Input:* Interested members of the public may submit relevant written or oral information for the SAB to consider during this teleconference.

*Oral Statements:* In general, individuals or groups requesting time to make an oral presentation at a public SAB teleconference will be limited to three minutes, with no more than one-half hour for all speakers. At face-to-face meetings, presentations will be limited to five minutes, with no more than a total of one hour for all speakers. To be placed on the public speaker list, parties interested in the December 9, 2008 meeting should contact Mr. Thomas Miller, DFO, in writing (preferably by e-mail), by December 2, 2008 at the contact information provided above. Parties interested in the December 16, 2008 meeting should contact Mr. Thomas Miller, DFO, in writing (preferably by e-mail), by December 9,

2008 at the contact information provided above.

**Written Statements:** Written statements relevant to the December 9, 2008 meeting should be received in the SAB Staff Office by December 2, 2008, and written statements relevant to the December 16 meeting should be received in the SAB Staff Office by December 9, 2008 so that the information may be made available to the SAB for their consideration prior to these teleconference meetings. Written statements should be supplied to the DFO via e-mail to [miller.tom@epa.gov](mailto:miller.tom@epa.gov) (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

**Accessibility:** For information on access or services for individuals with disabilities, please contact Mr. Thomas Miller at (202) 343-9982, or [miller.tom@epa.gov](mailto:miller.tom@epa.gov). To request accommodation of a disability, please contact Mr. Miller, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: November 14, 2008.

**Vanessa T. Vu,**

Director, EPA Science Advisory Board Staff Office.

[FR Doc. E8-27612 Filed 11-19-08; 8:45 am]

BILLING CODE 6560-50-P

## FEDERAL COMMUNICATIONS COMMISSION

### Notice of Public Information Collection(s) Being Submitted for Review to the Office of Management and Budget

November 13, 2008.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the

information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written Paperwork Reduction Act (PRA) comments should be submitted on or before January 20, 2009. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, (202) 395-5887, or via fax at 202-395-5167 or via Internet at

[Nicholas.A.Fraser@omb.eop.gov](mailto:Nicholas.A.Fraser@omb.eop.gov) and to [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov), Federal Communications Commission, or an e-mail to [PRA@fcc.gov](mailto:PRA@fcc.gov). To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the Web page called "Currently Under Review", (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

**FOR FURTHER INFORMATION CONTACT:** For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov).

**SUPPLEMENTARY INFORMATION:**

**OMB Control Number:** 3060-0645.

**Title:** Section 17.4, Antenna Structure Registration.

**Form No.:** N/A.

**Type of Review:** Extension of a currently approved collection.

**Respondents:** Business or other for-profit; not-for-profit institutions, and state, local or tribal government.

**Number of Respondents:** 25,600

respondents; 25,600 responses.

**Estimated Time Per Response:** .2-1.2 hours.

**Frequency of Response:** On occasion reporting requirement, recordkeeping

requirement and third party disclosure requirement.

**Obligation to Respond:** Required to obtain or retain benefits. Statutory authority for these information collections are contained in Sections 4 and 303; 47 U.S.C. 301 and 309.

**Total Annual Burden:** 40,329 hours.

**Total Annual Cost:** \$3,200,000.

**Privacy Act Impact Assessment:** N/A.

**Nature and Extent of Confidentiality:** This collection of information does not address information of a confidential nature. Respondents may request confidential treatment for information they believe should be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

**Needs and Uses:** The Commission will submit this information collection (IC) to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the full three year clearance from them. The Commission is requesting an extension (no change in the reporting, recordkeeping and/or third party disclosure requirements). The estimated hourly and/or annual cost burdens have not changed since this IC was last submitted to the OMB in 2006).

Section 17.4, Antenna Structure Registration, which became effective July 1, 1996, requires the owner of any proposed or existing that requires notice of proposed construction to the Federal Aviation Administration (FAA) must register the structure with the Commission. This includes those structures used as part of stations licensed by the Commission for the transmission of radio energy, or to be used as part of a cable television head end system. If a Federal Government antenna structure is to be used by a Commission licensee, the structure must be registered with the Commission. Section 17.4 also contains other reporting, recordkeeping and third party notification requirements subject to the Paperwork Reduction Act (PRA) and OMB approval. The information is used by the Commission during investigations related to air safety or radio frequency interference. A registration number is issued to identify antenna structure owners in order to enforce the Congressionally-mandated provisions related to the owners.

Federal Communications Commission.

**Marlene H. Dortch,**

Secretary.

[FR Doc. E8-27662 Filed 11-19-08; 8:45 am]

BILLING CODE 6712-01-P

**Attachment C**

**U.S. Environmental Protection Agency  
Science Advisory Board  
Teleconference Meeting  
December 16, 2008**

**CHAIR**

**Dr. Deborah L. Swackhamer**, University of Minnesota, St. Paul, MN

**SAB MEMBERS**

**Dr. David T. Allen**, University of Texas, Austin, TX

**Dr. John Balbus**, Environmental Defense Fund, Washington , DC

**Dr. Gregory Biddinger**, ExxonMobil Biomedical Sciences, Inc., Houston, TX

**Dr. Timothy Buckley**, The Ohio State University, Columbus, OH

**Dr. Thomas Burke**, Johns Hopkins University, Baltimore, MD

**Dr. James Bus**, The Dow Chemical Company, Midland, MI

**Dr. Deborah Cory-Slechta**, University of Rochester , Rochester, NY

**Dr. Terry Daniel**, University of Arizona, Tucson, AZ

**Dr. Otto C. Doering III**, Purdue University, W. Lafayette, IN

**Dr. David A. Dzombak**, Carnegie Mellon University, Pittsburgh, PA

**Dr. T. Taylor Eighmy**, University of New Hampshire, Durham, NH

**Dr. John P. Giesy**, University of Saskatchewan, Saskatoon, Saskatchewan

**Dr. James K. Hammitt**, Harvard University, Boston, MA  
Also Member: COUNCIL

**Dr. Rogene Henderson**, Lovelace Respiratory Research Institute, Albuquerque, NM

**Dr. James H. Johnson**, Howard University, Washington, DC

**Dr. Bernd Kahn**, Georgia Institute of Technology, Atlanta, GA

**Dr. Catherine Kling**, Iowa State University, Ames, IA

**Dr. George Lambert**, Robert Wood Johnson Medical School-UMDNJ, Belle Mead, NJ

**Dr. Jill Lipoti**, New Jersey Department of Environmental Protection, Trenton, NJ

**Dr. Lee D. McMullen**, Snyder & Associates, Inc., Ankeny, IA

**Dr. Judith L. Meyer**, University of Georgia, Lopez Island, WA

**Dr. Christine Moe**, Emory University, Atlanta, GA

**Dr. M. Granger Morgan**, Carnegie Mellon University, Pittsburgh, PA

**Dr. Duncan Patten**, Montana State University, Bozeman, MT

**Dr. Stephen M. Roberts**, University of Florida, Gainesville, FL

**Dr. Joan B. Rose**, Michigan State University, East Lansing, MI

**Dr. Jonathan M. Samet**, University of Southern California, Los Angeles, CA  
Also Member: CASAC

**Dr. Kathleen Segerson**, University of Connecticut, Storrs, CT

**Dr. Kristin Shrader-Frechette**, University of Notre Dame, Notre Dame, IN

**Dr. V. Kerry Smith**, Arizona State University, Tempe, AZ

**Dr. Thomas L. Theis**, University of Illinois at Chicago, Chicago, IL

**Dr. Valerie Thomas**, Georgia Institute of Technology, Atlanta, GA

**Dr. Robert Twiss**, University of California-Berkeley, Ross, CA

**Dr. Thomas S. Wallsten**, University of Maryland, College Park, MD

**Dr. Daniel Watts**, New Jersey Institute of Technology, Monmouth, NJ

**Dr. Lauren Zeise**, California Environmental Protection Agency, Oakland, CA

**SCIENCE ADVISORY BOARD STAFF**

**Mr. Thomas Miller**, Washington, DC

Attachment D

SAB Draft Report dated November 20, 2008 Quality Review Draft –

Do not Cite or Quote

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR  
SCIENCE ADVISORY BOARD

[Date]

**Comments Received from the following SAB Members:**

**B. Kahn:** I have reviewed the PM Research Centers Program Advisory Report. It is responsive to the EPA charge questions, clearly written, and has well-supported conclusions. Please consider the following suggestions – [DFO Note: The suggested edits and inclusions are embedded below in the document.]

**V. Thomas:** I have reviewed the PM Centers Draft Advisory. The charged questions are addressed well; it is clear and logical and the conclusions and recommendations are supported in the body of the report. The recommendations are very clear in continuing to support strong science at EPA and I commend the Panel on its good work.

**M. Karol:** The draft advisory report contains some excellent suggestions for future directions to strengthen the PM program. In response to questions: 1) The original charge questions to the SAB Panel are adequately addressed in the draft report; 2) The clarity of the report could be enhanced, specifically – [DFO Note: The suggested clarifications are embedded below in the document.]; 3) The conclusions drawn and/or recommendations made, are supported by information in the body of the report.

**T. Eighmy:** Here are answers to the three quality review questions on the Particulate Matter Research Centers Program Advisory Report. I liked the report, its direct and concise nature, and the recommendations made to the agency for managing its PM centers.

a) the original charge questions to the SAB Panel are adequately addressed in the draft report: The quality review addresses the three principal charge questions from the agency.

b) the draft report is clear and logical: I found the report to be concise and logical and clear in its response to the questions.

c) the conclusions drawn, and/or recommendations made, are supported by information in the body of the report. I think the recommendations made to the agency about the importance of PM research centers are sound and supported by information in the report.

Also, on page 3, see the spelling for national in the second paragraph from the bottom.

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**Agnes Kane:** The Particulate Matter Research Centers Program Advisory Report has satisfactorily addressed all of the charge questions asked.

**O. Doering:** I find that the report answers the charge and is extremely clear and logical. The charge asks for best judgment and that is what is provided – so detailed supporting information in the report is not necessary. There were a number of points I felt were right on target;

- Impact of centers not just from citations, but also from impact on policy decisions (p.3)
- Good recommendations for future performance measures (p. 3)
- Identification of what is being done and what needs to be done (p. 5 & 6)
- Good suggestions for addressing regional differences (p.6)

I also felt that the panel had well considered responses to the specific question posed by the agency – some of which would have narrowed scope of options for centers (p.7 & 8)

Overall, I find this a model for an advisory report of this kind.

**R. Henderson:** I found that the report adequately addressed the charge questions, was in general clear and logical and the recommendations were in general supported by the text.

See specific notes embedded below in the report.

Editorial comments:

On page 2 of the letter, responses numbered a to d are given in the first part of the bottom paragraph. All the replies are given in complete sentences except for d. So the "d"" sentence needs to be completed by adding "is encouraged" or some such phrase.

Page 3 of the report, next to last paragraph: "Nataional" Should be "National"

Page 7 of report, 4th line: "Change" should be "Charge"

**EPA-SAB-09-xxx**

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

Subject: Particulate Matter Research Centers Program Advisory Report: An SAB  
Advisory Report

Dear Administrator Johnson:

The EPA Science Advisory Board (SAB) Particulate Matter (PM) Research Centers Advisory Panel met on October 1-2, 2008 to consider questions posed by EPA on the future directions of its PM Research Centers program. The Panel concluded that this program has been very successful and that its continuation, especially in a form that would begin to move this area

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of research into integrated assessments [MK: What is meant by ‘integrated assessments?’ Perhaps a better statement is “research into assessment of mixtures of air pollutants.”] of multiple air pollutants, would be of great value. This report provides the SAB’s advice in response to EPA’s three charge questions, which addressed the contributions of the existing program, multiple pollutant strategies and Center structure.

Deleted: air quality from

In response to Charge Question 1, the SAB concluded that the existing PM Centers continue to advance research on key issues relevant to EPA’s mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure, and health impacts. The advances have been extensively cited in EPA documents supporting policy decisions and have been influential in the scientific community. The SAB recommends that the EPA continue to use a variety of performance indicators to assess Center performance and recommends additional measures be added to those already used in the Center evaluations. Additional measures should broaden the range of indicators of Center impacts on the scientific community and the range of indicators that document the extent to which Center work is used in support of Agency decisions. Additional measures should also characterize the extent to which Center resources are supplemented by research support from other EPA programs and from other governmental and non-governmental research programs.

The SAB also concluded that the Centers Program has produced benefits over those that would be expected in traditional STAR grant mechanisms involving individual investigators or small teams of investigators focusing on relatively narrow topical areas. These benefits included flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The SAB recommends that a substantial fraction of the EPA’s extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed, but also noted that both Centers and individual or small team research initiatives are essential.

In response to Charge Question 2, the SAB concluded that the Centers have already begun to address broad sets of air pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multipollutant approaches in the future Center activities. Specifically, the SAB recommends that multi-pollutant approaches should be strongly encouraged by EPA in applications for PM Research Centers, with clear encouragement of efforts to develop innovative methods that address multi-pollutant atmospheric transformation, exposure, toxicology, and epidemiology. Although the SAB generally agreed with the Agency’s suggestion that organizing its multi-pollutant efforts around sources could be useful, it cautioned that an over-emphasis ~~only~~ [MK] on near-roadway exposures in such efforts could under-represent the importance of other sources and the atmospheric transformation of their emissions that are significant contributors to exposure. The Panel also concluded that the future Center activities could usefully address another important and broad direction: the regional differences in pollutant mixtures, and potential differences in health effects.

[RH: See underlined section in this paragraph. There seemed to be some discrepancy between what was said on page 2 of the letter (bottom paragraph under a) and on page 7 of the

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report (under a) about whether the Centers should address the same research topics. In the letter, a strong "no" was given to this idea, but in the text a more flexible answer is given. Perhaps the letter can be modified to reflect the text.] Finally, in response to Charge Question 3, regarding recommendations for changes to the structure of the PM Centers, the SAB recognized the successes of the PM Centers program over its history. Because of the Program's success, some panel members questioned the need to make major changes in the structure of the program. The SAB offers some comments in this report on the strengths and weaknesses of several structural changes that were proposed by the EPA, as well as additional comments on important issues identified by the review Panel. Among these are that: a) the notion that all Centers should study identical research topics was not supported; b) requiring all Centers to have a Regional focus was not supported, though the need to consider regional differences in pollutant mixtures by some Centers was considered to be useful; c) requiring both large and small Centers within the total program was not supported, though some members noted that a limited number of small focused Centers could provide some benefits as well as some negative impacts to the results that have been historically noted to come from large Centers; and d) **there is a need to have** Center structures that support and encourage research partnerships. In addition, the SAB endorsed other activities that will enhance whatever structure that the EPA decides upon for the continued Centers program. Among these are that a) Centers must continue their use of outside, independent expert reviews of their programs to evaluate their progress, and b) Centers should be given the flexibility to change their program content to reflect advice obtained from these groups without jeopardizing their continued funding either as a result of changing research foci or from completion of specific components of the research. Additionally, Centers should continue to integrate programs across Centers and across the research programs conducted within the EPA intramural research programs.

The SAB appreciates the opportunity to review and comment on EPA's plans to continue its Particulate Matter Centers program. We look forward to your response to our comments and we would be pleased to continue to work with EPA as it further develops and implements this important research program.

Sincerely,

Dr. Deborah L. Swackhamer  
Chair  
Science Advisory Board

Dr. David T. Allen  
Chair  
SAB Particulate Matter Research  
Centers Program Advisory Panel

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**NOTICE**

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA website at <http://www.epa.gov/sab>.

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**U.S. Environmental Protection Agency  
Science Advisory Board (SAB) Staff Office  
SAB Particulate Matter (PM) Research Centers Program Advisory Panel  
October 1-2, 2008**

**CHAIR**

**Dr. David T. Allen**, Gertz Regents Professor of Chemical Engineering, Department of Chemical Engineering, and Director, Center for Energy and Environmental Resources, University of Texas, Austin

**SAB MEMBERS**

**Dr. George Lambert [M.D.]**, Associate Professor of Pediatrics, Director, Center for Childhood Neurotoxicology, Robert Wood Johnson Medical School-UMDNJ, New Brunswick/Piscataway, NJ

**Dr. Bryan Shaw**, Commissioner, Texas Commission on Environmental Quality, Austin, TX

**OTHER PANEL MEMBERS**

**Mr. Bart Croes**, Chief, Research Division, California Air Resources Board, Sacramento, CA

**Dr. Terry Gordon**, Professor, Environmental Medicine, NYU School of Medicine, Tuxedo, NY

**Mr. Daniel Greenbaum**, President, Health Effects Institute, Charlestown Navy Yard, Boston, MA

**Dr. Frederick J. Miller**, Independent consultant, Cary, NC

**Dr. Peter Scheff**, Professor, Environmental and Occupational Health Sciences, School of Public Health, University of Illinois at Chicago, Chicago, IL

**Dr. Barbara Zielinska**, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

**FEDERAL EXPERTS**

**Dr. Bruce Fowler**, Assistant Director for Science, Division of Toxicology and Environmental Medicine, Office of the Director, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (ATSDR/CDC), Chamblee, GA

**Dr. Steven Kleeberger**, Professor and Lab Chief, Laboratory of Respiratory Biology, National Institute of Environmental Health Sciences, National Institutes of Health (NIH/NIEHS), Research Triangle Park, NC

**SCIENCE ADVISORY BOARD STAFF**

**Mr. Thomas Miller**, Designated Federal Officer, US EPA Science Advisory Board, 1200 Pennsylvania Ave., (Mail Code 1400F), Washington, DC 20460

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## **1. INTRODUCTION**

The EPA Science Advisory Board (SAB) was asked by the U. S. Environmental Protection Agency to conduct a review of its Particulate Matter Research Centers Program (US EPA, 2008). EPA was interested in the SAB's advice on: a) the worth of the PM Research Centers past contributions to advancing key particulate matter research in support of EPA's mission; b) the potential for broadening the Centers' programs to have more of a multi-pollutant focus; and c) the strengths and weaknesses of various alternative Center structures that might be used in the future. This advisory provides the SAB's advice to the Administrator as a result of an advisory meeting held on October 1 and 2, 2008 in Washington, DC.

### **1.1 Background Information:**

In 1998, the Congress directed the Environmental Protection Agency to establish as many as five university-based PM research centers as part of the expanded Office of Research and Development (ORD) PM research program. The first PM research centers were funded from 1999 to 2005 with a total program budget of \$8 million annually (see the following URL: <http://es.epa.gov/ncer/science/pm/centers.html>). In the original Request for Applications (RFA), prospective centers were asked to propose an integrated research program on the health effects of PM, including exposure, dosimetry, toxicology and epidemiology. ORD's PM Research Centers program was initially shaped by recommendations from the National Research Council.

In 2002, ORD requested that the Science Advisory Board conduct an interim review of EPA's PM research centers program, the report from which is found at the following URL: [http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/\\$File/ec02008.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/$File/ec02008.pdf). This review was instrumental in providing additional guidance to ORD for the second phase of the program (2005–2010).

In 2004, ORD held a second competition for the PM Research Centers program. This RFA asked respondents to address the central theme of "linking health effects to PM sources and components," and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages. From this RFA, five current centers are funded for 2005–2010 with the overall 5-year total program budget at \$40 million (see: [http://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19](http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19)).

At the request of EPA ORD's National Center for Environmental Research (NCER) the SAB Staff Office formed an expert panel to comment on the Agency's current PM research centers program and to advise EPA concerning the possible structures and strategic direction for the program as ORD contemplates funding a third round of air pollution research centers into the future, *i.e.*, from 2010 to 2015 (see *Federal Register*, 73 FR 5838, of January 31, 2008 which announced the formation of an SAB *ad hoc* panel for this advisory activity and requested public nominations of qualified experts to serve on this panel and the SAB Panel Formation record, US EPA SAB, 2008).

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## **1.2 EPA Charge to the SAB PM Research Centers Program Advisory Panel**

The Agency asked the SAB for advice on the effectiveness of the current Particulate Matter Research Centers Program and suggestions for an improved future Centers Program, and requested that the Panel focus on several charge questions during its review of the PM Research Centers Program:

### **1.2.1 Overall Charge Questions**

Within the context of the current state-of-the-science and the priorities for the EPA Air research program, ORD seeks advice on the possible structures and strategic direction of an Air Research Centers program for 2010 – 2015. Specifically,

**1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA’s mission?**

**2. What advice does the panel have on how to move to multi-pollutant approach in the PM Centers program?**

One prominent theme of EPA’s multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture. What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?

**3. What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?**

Given the strategic directions discussed above, please comment on various approaches EPA could consider for the *structure* of a future air pollution Centers program. For example, a future Centers program might continue with a common theme for all Centers, or might seek Centers that specialize in different research areas. In addition, some Centers might address a broad research portfolio while others have a more targeted focus. EPA may consider funding fewer Centers in order to maintain appropriate program balance with the individual STAR grants and intramural research programs. EPA is seeking the panel’s views on the strengths and weaknesses of different approaches for the structure of the program.

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## 2. RESPONSE TO CHARGE QUESTIONS

### **2.1 Charge Question 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?**

The PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure, and health impacts. The documentation reviewed by the panel demonstrated that PM Center investigators:

- a) are recognized as world leaders in PM health effects research,
- b) have improved understanding of the epidemiology and toxicology of particulate matter,
- c) have identified mechanisms for PM health effects,
- d) have improved our understanding of the populations most susceptible to PM health risks,
- e) have identified new micro-environments (e.g., roadways) that lead to ultra-fine particle exposures,
- f) have developed new technologies and instruments for PM research,
- g) have advanced the understanding of source specific health impacts, and
- h) have enhanced the range of expertise available to the EPA in assessing PM health impacts.

The first set of Centers, funded from 1999-2005, produced more than 500 publications, a rate of publications per dollar of funding that is 20% higher than the publication rate per dollar of funding for comparable STAR grants. These publications have been influential, as evidenced by citation rates that are higher than average citation rates in the fields covered by the publications. For example, a 2007 analysis of ORD Air Program publications indicated that about 37% of PM Center papers are in the top 10% in overall citation rate, 6% of PM Center papers are in the top 1%, and 3% are in the top 0.1%.

The assessments of a variety of expert panels have provided additional endorsements of the scientific impact and the relevance of the work of the PM Centers. These have included assessments by BOSC (BOSC, 2005) an SAB panel (US EPA SAB, 2002; the National Research Council of the National Academies (NAS/NRC, 2004) and professional organizations such as the American Heart Association (Brook, 2004), and the American Academy of Pediatrics (AAP, 2004).

The work of the Centers has also been extensively cited in EPA documents supporting policy decisions. The Centers' work contributed to the 2007 PM NAAQS review and the Integrated Science Assessment (ISA) for PM. PM Center work has also influenced policy decisions in regulatory organizations beyond EPA, such as the California law requiring that schools must be at least 500 feet from freeways.

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The panel recommends that the EPA continue to use a variety of performance indicators to assess Center performance, and recommends that additional measures be added to those already used in the Center evaluations.

One set of additional measures should characterize the extent to which Center resources are supplemented by other research support. Such supplemental funding from outside of the EPA should not become a requirement of the Centers program, but the extent of supplementation can serve as an indicator of the interest by organizations outside of EPA in the work of the Centers.

A second set of additional measures should broaden the range of indicators that assess Center impacts on the scientific community. Current measures are focused on numbers of journal publications, citations, and students trained. The Centers could also begin to track the impact that program graduates are having on the field after they leave the Centers.

A third set of additional measures should broaden the range of indicators that document the extent to which Center work is used in support of Agency decisions. Current measures focus on documents developed in support of setting National Ambient Air Quality Standards. The Center's work has also been used in Regulatory Impact Assessments, in assessing the costs and benefits of the Clean Air Act (Section 812 analysis), and in other documents developed by EPA in support of its regulatory mission. These uses of the Centers' work should be tracked.

Finally, the panel concluded that the Centers Program produced benefits over those that would be expected in traditional STAR grant mechanisms, involving individual investigators or small teams of investigators focusing on relatively narrow topical areas. These benefits include flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The advantages of Center programs, as compared to traditional STAR grant funding mechanisms, will be expanded on in response to charge question 3. The panel recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed, but also notes that both Centers and individual or small team research initiatives are essential.

**2.2 Charge Question 2. What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?**

EPA noted that, "*One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture.*" The Agency asked the SAB, "*What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?*"

In reviewing the contributions of the PM Centers program to date, and its potential for the future, the Panel found that the Centers have already begun to make contributions to efforts to address the broader set of pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multipollutant approaches in the next round

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of centers. The Panel also found that the next round of Centers could usefully address another important and broad direction: the regional differences in pollutant mixtures, and potential regional differences in health effects.

**Enhancing Multipollutant Approaches in the Centers Program:** In 2004, the NRC’s Committees on *Research Priorities for Airborne Particulate Matter* and *Air Quality Management in the United States* (NAS/NRC, 2004) recommended that the nation’s efforts to improve air quality should move from its historical single-pollutant-at-a-time regulatory approach to a multipollutant approach that provides both the science and the regulatory programs to allow for the most cost-effective interventions to reduce exposure and improve public health. Although the setting of multipollutant ambient air quality standards is likely well in the future, the agency is working with states to develop multipollutant air quality management plans, and seeking to move its air quality research program to a multi-pollutant perspective that can increasingly identify the effects of the simultaneous co-exposure to many different pollutants that humans and the ecosystem face.

[RH: I had a couple of comments on clarity. I did not understand the intent of the middle paragraph on page 5 (starts with "There are.." and ends with "...class of pollutants."), I read it several times and still did not understand what point was being made.] There are hundreds of compounds in the ambient mix of pollutants; the agency has focused on a subset of these which have been the main targets of the Clean Air Act: the so-called criteria pollutants (especially PM and ozone) as well as some air toxics. As the Centers begin to examine mixtures of air pollutants, the Panel agreed that a focus on mixtures of this subset is useful (e.g., considering the impacts of exposure to mixtures of PM and air toxics). The Panel also noted that there are significant “multipollutant” challenges within some pollutant classes, especially PM. For example PM can be viewed as a mixture of ultrafine particles and larger particles; PM can also be viewed as a mixture of inorganic acids and salts, organic compounds and soot-like material. Some of the same new methods that would be useful in broader multipollutant approaches across classes of pollutants (i.e. PM, ozone, and air toxics) would also be useful in addressing these significant mixture issues within one class of pollutants.

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The Panel agrees that the Agency should find ways to re-direct the PM Centers program so that it is better able to address the broader multi-pollutant context. The development of a more robust set of atmospheric chemistry, exposure, dosimetry, toxicology and epidemiology research methods will be essential to building the evidence necessary to support both nearer term decisions by states and localities about the best integrated intervention strategies, and to laying the foundation for the development of multipollutant ambient standards in the future.

Specifically, the Panel found:

- a) Multi-pollutant approaches should be strongly encouraged by EPA in applications for PM Research Centers, with clear encouragement of efforts to develop innovative methods that address multi-pollutant atmospheric transformation, exposure, dosimetry, toxicology, and epidemiology. These new methods could include a range

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of approaches, from computational toxicology and genomics to enhanced statistical methods for identifying principal components or factors, to novel analytic chemistry.

- b) The Panel felt that while the Agency should provide a strong incentive for multipollutant approaches, it should not mandate specific approaches, but rely on the skills and innovation of the research community to propose new approaches.
- c) The Panel generally agreed that the Agency’s suggestion that organizing its multipollutant efforts around sources could be useful, but cautioned that an over-emphasis only on near-roadway exposures in such efforts could substantially under-represent the importance of other sources and the atmospheric transformation of their emissions that are also significant contributors to exposure.
- d) [MK: The underlined lines are unclear and need editing.] Finally, it will be important to balance the interest in a multipollutant approach with the need to continue answering single pollutant questions that can inform nearer term decisions critical to the Agency’s mission to improve public health. This should include science to inform standard setting (e.g. better understanding PM exposure-response and the relative toxicity of PM components). It also should inform regulatory strategy, (e.g. better tools for source apportionment). But even in these instances, the Centers program should emphasize the need to produce such pollutant-specific evidence as much as possible in a multi-pollutant context to enhance its interpretation.

Deleted: an increasingly focused set of decision-relevant

Deleted: implementation

**Addressing Regional Differences:** The panel noted the well-known differences in pollutant sources and mixtures in different regions, and emerging evidence of differences in health effects, and found that exploring, characterizing, and understanding these regional differences in exposure and effect should also be a broader direction to be encouraged in a new round of Center awards.

- a) As with multi-pollutant approaches the Panel felt that systematic approaches to addressing regional differences should be strongly encouraged by EPA, with a clear indication that such efforts will enhance the applicant’s chances of being selected. Here too, the Panel felt that while the Agency should provide a strong incentive for addressing regional differences, it should not mandate specific approaches, but rely on the skills and innovation of the research community to propose new approaches.
- b) The Panel further found that addressing these regional differences could take two forms:
  - i First, individual centers that could demonstrate a systematic approach to exploring and understanding differences in exposure and health in two or more regions should be encouraged; and
  - ii Second, once centers are selected, and to the extent that they represent geographical differences in their location and focus, EPA should foster

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enhanced collaboration and coordination among the relevant centers on regional differences.

### **2.3 Charge Question 3. What strengths and weaknesses does the panel see in different options for a future Centers Research Program?**

The PM Centers panel recognizes the successes of the PM Centers program over the last 8 years as discussed in Charge question 1. In addition, the Panel noted that the program has been adaptive, adding and deleting elements in response to reviews and changing scientific understanding of key issues. Since the Program is successful, some members questioned the need to make major changes, suggesting “if it’s not broken, do not fix it.” However, as the Agency redirects the Centers toward more multi-pollutant approaches and examination of regional differences, some structural and operational changes should be considered. The panel considered both specific structural changes for the Centers program under consideration by the Agency, and broader structural and operational features of the Centers. These are described, by topic, in paragraphs a) through g). [Dr. Kahn notes that In discussing the effect of changes in requirements, a comment on the impact of changes requested (or of no changes) between the first and second rounds of awards would be instructive.]

- a) The agency asked the panel to consider whether all Center applicants should address the same research topics.

[RH: There seemed to be some discrepancy between what was said on page 2 of the letter (bottom paragraph under a) and on page 7 of the report (under a) about whether the Centers should address the same research topics. In the letter, a strong "no" was given to this idea, but in the text a more flexible answer is given. Perhaps the letter can be modified to reflect the text.] The panel agreed that the PM Centers should be asked to choose from among a described set of priority research topics, as has been the case in the past, however, the notion that all Centers should study identical research topics was not supported. The RFA should describe the range of desired research and let the applicants decide on the exact research topics and approaches. It is then up to the Agency to select an appropriate research portfolio, based on quality, relevancy, and the extent to which the applicants propose research topics which complement other Intramural and Extramural research programs.

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- b) The agency asked the panel to consider whether all Center applicants should have a regional focus.

The consensus of the Panel was that the requirement of funding Centers based on their regional locations would not be a structurally beneficial alteration to the Program, despite some benefits in supporting regulatory decisions, such as providing closer links to regional, state, and local officials and facilitating identification of regional issues.

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There are important regional differences in atmospheric contaminants and health outcomes that need to be studied and understood. The development of regional centers may help delineate these differences; however, other scientific approaches may be scientifically better and more cost effective. For example, as noted above in response to Question 2, individual centers could explore and understand differences in exposure and health in two or more regions and EPA could foster enhanced collaboration and coordination among the centers on regional differences.

- c) The agency asked the panel to consider whether individual Centers should continue to be funded at their current level or whether a larger number of Centers, funded at a smaller level would be more effective.

There are advantages and disadvantages to having only Centers funded at or near the current level (large Centers) or a mixture of large and small Centers. The funding of both large and small Centers was favored by a minority of the panel. The main concern of most of the panel was that funding limited or small Centers would diminish the impact of the program and would diminish some of the advantages of large Centers cited in response to Charge question 1.

The funding of small Centers would allow Research Centers that are not as comprehensive or developed as the large Centers to be funded and develop their research program. The funding of small Centers also provides the agency the opportunity to select research programs that may fill a very specific research need. While the funding of small centers has advantages the loss of the large Center effect and the transfer of funding from large to small Centers was not supported by the majority of the Panel members.

- d) The panel encourages the Centers to develop core laboratories that can be shared and to pursue supplementary funding

Other potential structural elements that the Agency is encouraged to entertain is the potential use of Core laboratories shared among the Centers; and encouraging the Centers to identify complementary research programs that can supplement Center activities. The Panel also recommends that the EPA search to find research partners that may help fund this Program. NIEHS, NIHHL, NIGMS, ALA, AHA, ATS would be just some of the federal and non federal programs that may help fund this research. Other Centers programs of the EPA have been successful in developing outside EPA funding to share costs of the program. The focus of funding from other agencies should be to augment Center research, rather than as a replacement for EPA funding.

- e) The panel encourages the Centers to continue their tradition of ongoing evaluation and scientific flexibility

The Centers must continue to have a process for periodic evaluation of research programs. The Centers should have the flexibility to alter specific projects within the Center that have been completed, or that are unproductive or that need to move in new

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directions. This should be done in consultation with the Center oversight committees and the Agency.

- f) The panel encourages the Centers to continue their tradition of internal integration and integration with the agency.

The Centers have a strong tradition of integration of science, data, and methodology, allowing rapid progress of the state of the art in science and methods within individual Centers and within the PM Centers program. Integration with internal agency programs should be encouraged to the extent practicable.

- g) The panel encourages the Centers to continue their tradition of strong External Advisory Panels

The Centers and RFA should continue their use of external advisory Panels. Some panel members felt that it may be helpful if the Centers consider community involvement in the Panels, particularly if the Center has a regional focus, however there was not a panel consensus on this recommendation.

[Dr. Kahn suggests adding a list of abbreviations and acronyms]

## Attachment D

### SAB Draft Report dated November 20, 2008 Quality Review Draft –

#### Do not Cite or Quote

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**[MK: Are unnumbered EPA memoranda appropriate references/]**

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**Attachment E**  
**SAB Comments on Drinking Water Contaminant Candidate List 3**  
**Draft Panel Report**  
**With Responses**

**1. Dr. Meryl Karol**

a) *Are the original charge questions to the SAB Panel adequately addressed in the draft report?*

Yes

**Response:** No response necessary

b) *Is the draft report clear and logical?*

The draft report is logical and, in general, clear. However, the following lines would benefit from some careful editing:

**Response:** No response necessary

p. 2 lines 23-31

**Response:** This part of the letter has been rewritten and clarified.

p. 8 lines 40-43

**Response:** The text has been rewritten and clarified.

p.12 lines 17-18

**Response:** The text has been rewritten and clarified.

c) *Are the conclusions drawn, and/or the recommendations made supported by information in the body of the report?*

Yes

**Response:** No response necessary

d) *Errors/omissions*

p. 2 line 20 change as follows: .....in the determination ~~in~~ of whether....

**Response:** Done

p. 11 line 7 The flowchart was not included

**Response:** The text was changed to indicate that the DWC expects EPA to produce the flowcharts.

**2. Dr. James Sanders**

Are the charge questions adequately addressed?

Yes, the Committee addressed the charge questions adequately. While this draft report is brief, each of the questions is discussed, and the comments herein should help to improve the process for listing contaminants in the future.

**Response:** No response necessary

Is the report clear and logical?

For the most part, the report is clear. There are some typographical errors, and some wording that is not clear to me. For example:

p. 11, line 13. Does the committee mean “impart” instead of import?

p. 11, line 24. What are training chemicals?

p. 14, line 12. Broader, not boarder.

**Response:** All of the above have been changed

Are the conclusions supported?

The Committee has provided appropriate comments and recommendations. Their efforts should improve the process in the future.

**Response:** No response necessary

### **3. Dr. Thomas Wallsten**

I have read the three draft reviews. It appeared to me that all three adequately addressed the charge questions, were logically laid out, and provided supporting information for their conclusions and recommendations. I have three comments on the reports: ...

- b) The same white paper urges that attention be paid to the possible effects of mixtures of contaminants, not just contaminants acting alone. This point would seem to apply to the "SAB Advisory on EPA's Third Drinking Contaminant Candidate List," yet I did not see it mentioned there (although I may have missed it).

**Response:** The advisory addresses “grouping” of chemicals. The text now explicitly mentions mixtures.

### **4. Dr. Terry Daniel**

*The original charge questions to the SAB Panel are adequately addressed in the draft report, the report is clear and logical, and the conclusions and recommendations are supported by the information in the body of the report.*

**Response:** No response necessary

Some suggestions for extensions to some sections for the CCL3 review are presented below.

The Federal Register Notice implies that the lists of candidate contaminants are intended for both technical audiences (e.g., scientists and water utilities managers) as well as concerned citizens. An alphabetically arranged list with little or no information about the relevant characteristics (viz. criteria for drinking water safety) seems less than optimal for either audience. The SAB Committee noted in several places that it was difficult for readers to determine the reasons for inclusion of a chemical/pathogen on the list or to get any sense of the urgency, severity or priority

for regulation of one candidate over others. The Committee suggested that organizing the list even roughly on the basis of priority for consideration for regulation would be helpful. In particular it was suggested that the listing should first identify contaminants that are well researched and are known to have both significant occurrence and health risks. A second category for contaminants where adequate data is currently lacking could be divided to distinguish those for which occurrence data, health risk data or both is insufficient. This second group identifies contaminants for which there is a need for monitoring and for targeted research to close the indicated data gaps. Finally there are many nominated contaminants about which relatively little is known, so that this category calls for a broader and longer term program of research.

**Response:** The text has been rewritten to emphasize that the list is too long and requires additional prioritization based on the diverse uses of the CCL.

In addition to priority-based classifications, the Committee recommends that contaminants be grouped according to mode of action, occurrence, health effects and/or other relevant factors. Any meaningful grouping and prioritization would be an improvement over an alphabetically arranged list of 93 chemicals and 11 pathogens. However, the noted difficulty for readers seeking to determine why a given contaminant is on the list would need to be extended to include questions about why it has been assigned to a given priority class and why it is included in one or another grouping. One approach to addressing such questions is to include relevant information about each contaminant directly in the listing. That is, the list could be presented as a matrix, where priorities and groupings are explicitly designated, along with summary indicators of critical criteria, such as potency/concentration ratio, occurrence, mode of action, health effects, source, model scores, expert panel conclusions, etc. The committee also suggested that citations of government documents and other sources relevant to the evaluation of each candidate contaminant be more readily accessible for readers. Including all of the desired information in a printed listing would be unwieldy, so there would have to be constraints on the size of the suggested matrix. Of course, an electronic version of the matrix would be less restricted in this regard, as the reader could follow hyperlinks (in the matrix) to find additional information relevant to their questions about a particular contaminant.

**Response:** These concepts and recommendations have been incorporated into the text at the appropriate sites.

## **5. Dr. Rogene Henderson**

I found it difficult to follow the advisory without having seen the write-up of the process on which advice was being given. However, I thought the report addressed the charge questions in a logical and rational manner and I think the report would be clear to someone familiar with the process by which the CCL3 was developed. The tone seemed appropriate; it was helpful and not derogatory.

**Response:** No response necessary

## 6. Dr. David Allen:

- Page 5: There appears to be a header missing after "Other SAB Members"
- Page 11 Lines 7 and 8: The language led me to expect to see a flowchart, which was not included
- Page 17, line 2: grammatical error

**Response:** The text has been changed in response to all of the above comments.

## 7. Dr. Duncan Patten:

**General Comment.** In all three cases, the SAB review committees have offered excellent review and advice to EPA. The reviews are comprehensive and in sufficient detail to allow EPA staff to reconsider their positions on topics of concern and to rewrite or rework the materials presented in the white papers.

**Response:** No response necessary

In order to fully assess the responses of the SAB review committee, one would have to be more expert in the particular field of science than I am. Thus my comments are more general, but specific in some cases. ...

One question that comes to my mind as I read the reviews, and thus responses to EPA questions, especially those for "Aquatic Life Water Quality" and "Drinking Water Contaminant Candidate List" deals with the concepts of "cumulative effects" and "synergism" in effects of contaminants. Why aren't these concepts considered more critically in testing or selecting contaminants of concern? Only in the Aquatic Life Water Quality review is the concept of synergism (page 11) even considered, and apparently only in passing. Are not the synergistic interactions as well as cumulative effects among and within contaminants of importance in selection and testing of toxic effects?

**Response:** The advisory addresses "grouping" of chemicals. The text now explicitly mentions mixtures.

Comments specific to Contaminant Candidate List (CCL3):

The response of the SAB committee was quite thorough but some of its statements in response to EPA questions need more detail.

When the committee mentions that it acknowledges that the process should be "an adaptive process" (page 8, line 18) is the committee clear, or does it understand what this means? It should ask for goals and outputs to be identified in this process that will help the improvement of the report.

**Response:** While the goals and outputs are generally known, i.e., to produce a list of unregulated contaminants that should be considered for regulatory determinations, the advisory now clearly states the deficiencies of the current process and that it does not achieve the desired goal.

In the development of “models” for the SAB report, the committee should address how good the model development was (page 8, line 26).

**Response:** the text has been modified to make critiques of the models more explicit and specific.

Bottom of page 8 the committee emphasizes “transparency”. Is articulating the decisions by experts primarily the improvement needed to gain more transparency?

**Response:** Transparency is now a separate section.

Top of page 9. Committee members could not follow the decision making process for some contaminants. It is uncertain whether putting the information on the web site and developing hyperlinks will solve this. Better guidelines of how the process proceeds might be in order.

**Response:** The regulatory docket contained documents that had helpful information on the decision process. The text has been changed to reflect this, and additional text (suggested by another SAB member) has been added.

After page 9, line 37 there should be some statement that emphasizes longevity of pesticides in ecosystems which would be a criterion for cancelling or keeping a pesticide.

**Response:** Done

Part 2 on clarification regarding steps... that will make it more transparent is probably one of, if not the, most critical commentaries in the review. Clarity is one thing, but transparency of process and expert inputs for example, may be most important to acceptability of the CCL3 report.

**Response:** “Clarity” is now a subsection of the response to the first charge question

Decisions Regarding Data Sets...(paragraph lines 6-14, page 13) Emphasis on large populous states seems imbalanced. The committee should recommend some emphasis on geographic distribution (not necessarily within state boundaries but perhaps watersheds).

**Response:** The text has been revised to include this issue.

Page 13 (line 33)... should point out clearly how literature has appropriate data on outbreaks, etc.

**Response:** The text has been modified to expand on this issue.

Page 15, line 22. Good statement on consideration of “risk assessment”.

**Response:** No response necessary

Page 18, lines 13-14. Does the committee believe “these chemicals may be of lower priority..” because the assessment approach was wrong. Needs to be clear.

**Response:** The text has been clarified.

## 8. Dr. Bernd Kahn:

I have read the three draft Reviews and consider them to be well written.

**Response:** No response necessary

## 9. Dr. LD McMullen:

I had the opportunity to be part of the process in developing the first CCL as part of the National Drinking Water Advisory Council. We also helped in developing some of the ideas for the development of the second CCL.

I have read the document and have found it to be well organized and easy to follow. I believe it answers the charge questions that were presented to the committee.

**Response:** No response necessary

On page 9 first paragraph, I think an example might helpful such as an addition or removal. This could be helpful to the agency and make sure that the point is not missed. This is done very well in the second paragraph on page 9.

**Response:** The first paragraph is a general introduction. The rest of the section provides examples of specific chemicals.

The direction of the last paragraph on page 9 I agree with. However, I got a little lost in the process proposed. There are several different types of data needed for regulation. It seemed that the message was not to put anything on the list until all or most of the data was available. I don't think that was the intent of the CCL. We may want to talk about that.

**Response:** The CCL serves two purposes: to select contaminants for regulatory determinations and to highlight research needs for contaminants that may be of concern in drinking water. The revised text attempts to clarify the conflicts inherent in these potentially conflicting goals.

On page 10 second paragraph, I think I agree with the intent of the paragraph. However, it could be made a little more clear, by stating it was pathogens in the water that have been exposed to antibiotics in the water, or maybe I don't understand the point correctly.

**Response:** Text has been clarified.

On page 15 last paragraph and on to the top of page 16, I agree with the idea if we are sure that the science is there to support the idea. I did not follow the discussion of substitute a non-regulated compound for a regulated one. An example might be of help.

**Response:** The text has been changed to reflect why considering chemicals as a group would prevent substitutions.

On page 16 first fall paragraph, I agree with the statement that in some areas wastewater discharges can make up a significant portion of a water treatment plant

raw water source. However, there are many areas of the country where that is not the case such as the Midwest and Great Lakes area. We may want to qualify the paragraph a little more. Also, do we know that the NPDES monitoring results have emerging contaminants? I don't think it is common for municipal discharges.

**Response:** The text has been clarified to address this issue.

## **10. Dr. Timothy Buckley:**

This report seems more problematic in that it is not organized around the charge questions. It may very well be that the charge questions have been addressed, but it is very difficult to tell the way this report is currently organized. I also have a few editorial suggestions that can be taken or left.

**Response:** The advisory has been reorganized around the charge questions.

Letter, Page 2. Lines state that “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.” **I would break this up into two sentences and replace “enunciated” with “stated.”**

**Response:** Done

Letter Page 2, Line 31 **replace “better” in “to generate a better list” with “more scientifically credible”.**

**Response:** Done

Letter Page 2, Line 43, “make regulatory determination on” **Can you just say “regulate” here or “develop regulations.”**

**Response:** Since the CCL is used to determine which contaminants should be considered for a “regulatory determination” rather than “regulation”, these changes were not be made.

Report Body, Page 8, Line 14: **Consider replacing “data-driven” with “evidence-based.”**

**Response:** The Committee prefers the existing terminology.

Same Page, Line 44: **“stated” instead of “enunciated.”**

**Response:** Done

## **11. Dr. Judy L. Meyer**

I found this to be a readable report. The charge questions are addressed, although I found relatively little reference to additional data that could be used to either add or remove a chemical from the list (charge questions 3 and 4). The report is clear and logical.

The recommendations are supported by the text of the report.

**Response:** No response necessary

I have a couple additional comments:

Is there not an Executive Summary? I recognize that section 1 provides a broad overview, but an Executive Summary would also include the highlights of conclusions from the other sections. I don't recall seeing any other SAB report without an Executive Summary.

**Response:** An Executive Summary has been added.

pp. 15-16: I was pleased to see the recommendation on grouping compounds by mode of action. A similar recommendation was part of the report EPEC produced on Aquatic Life Criteria for Contaminants of Emerging Concern.

**Response:** No response necessary

p. 17, line 13: I have some misgivings about including the DWC "throughout" the process. That recommendation strikes me as being pretty vague. Furthermore, if the DWC is involved throughout the process, then its ability to be an objective reviewer of the final list is compromised. I suggest the committee identify a couple specific points in the process where input from the DWC would be sought.

**Response:** The text now reads, "the DWC at critical junctures throughout the process."

I also found some typos:

p. 15, line 11: should be "of concern so that resources"

**Response:** Done

p. 15, line 29: "concentration" would seem to be a more appropriate term here than "level"

**Response:** Done

p. 17. line 1: should read "that the same exceptions"

**Response:** Done

p. 17. line 12: should read "We recommend that EPA include the DWC"

**Response:** Done

p. 17. Line 49: should read "in the previous sections"

**Response:** Done

p. 18, line 7: should read "Also, there is a consensus"

**Response:** Done

p. 18, line 23: should read "to improve the process that should be explored" – note in addition to adding "that" I changed "must" to "should" which seems more appropriate for a report like this.

**Response:** Done

## 12. Dr. Valerie Thomas

The Committee has worked carefully through the CCL3 and appear to have developed a useful set of recommendations for the Agency. These recommendations would be more readily adopted by the Agency if the draft advisory were revised to increase its clarity. In particular, the draft advisory does not clearly or directly address all of the EPA's charge questions. Charge question 1 is clearly answered ("no"). Charge question 2 is also implicitly answered "no", although the response to this question could be made more clear in the letter to the Administrator and in the body of the report. Charge question 3 and 4 are not answered: no data are provided, although the document does say that some contaminants on the list should not be listed and some not listed should be. The Committee could come closer to providing these "data" by providing references and a clearer and more organized statement, backed up with data or references to the extent feasible, of which contaminants or types of contaminants should or should not be listed. Alternatively, it would be legitimate for the Committee to not answer some of the charge questions; in this case the Committee should clarify that it is providing advice that diverges from the charge, and explain why.

The Advisory diverges from the Charge Questions in a way that suggests that discussion with the EPA during the Advisory process may have suggested to the Committee a different charge. The letter begins by saying that the EPA asked for advice on the Process, and the Advisory contains a substantial section on how the EPA could improve the process in the future. However, the charge questions do not ask for comments on the process, and they do not ask for comments on future CCLs; they ask for comments on the list itself that is being used for this CCL3.

I think that the Committee could usefully revise the Advisory to more directly and unambiguously address the written charge questions.

**Response:** The advisory has been reorganized around the charge questions. Additional text has been added, where necessary.

Detailed Comments:

Letter to the Administrator, p. 2, lines 15-23. This statement is not clear.

Line 15: remove the words "example for": this is not an example; it is a main point of the advisory.

**Response:** Done

Line 16: Change "suggested" to "suggests" – present tense.

**Response:** Done

Line 16: Change "were" to "are".

**Response:** Done

Line 23: cut "so as not to be shortsighted on the Agency's part."

**Response:** Done

Lines 33-37. Does the Committee recommend that these contaminants be included in the CCL?

Line 35: Change “would” to “does”, and similarly revise the next sentence.

**Response:** Done

Lines 40-41: The meaning is not clear. Does the Committee means to say that EPA should identify those contaminants ready for regulatory determination and those for which more data are required? The phrase “prioritize between” is confusing.

**Response:** Text modified, and broken into two sentences.

p. 8 line26. What does “intensified” mean here? Should this word be deleted?

**Response:** Text modified

p. 9, line 16: change “were” to “are”

**Response:** Done

p. 9, lines 28-37. This is confusing.

**Response:** Text modified

p. 9, lines 28-30. Does the Committee mean to say “For example, all uses of nitrofen were cancelled in 1983, yet nitrofen appears in the CCL3.”?

**Response:** Text modified

p. 9, lines 30-32. This sentence does not seem to be related to anything else in the paragraph. Is there a chemical listed in the CCL3 for which EPA proposed a national drinking water standard based on a TRI release from one site?

**Response:** Text modified, and broken into two sentences.

p. 9, lines 32-37: Here again the discussion of canceled pesticides is unclear.

**Response:** The last three sentences of this paragraph have been rearranged and modified.

p. 9, line 40: It seems that “for example” should be cut. The prioritization based on data availability is a key finding of the Committee, not an example.

**Response:** Done

p. 10, line 3. Change “in” to “used to develop”

**Response:** Done

p. 10, lines 11-15. This paragraph is written as a report of what the Committee discussed. Does the committee want to recommend that the CCL process might indeed need to be modified in the future in these ways, or does the Committee simply want to say, as written, that the topic was discussed?

**Response:** Recommendation taken

p. 10, lines 17-20. Again, does the Committee, as written, simply want to record that these issues were discussed? Or does the Committee in fact identify any emerging issues or research needs?

**Response:** Text appropriately modified

p. 10, line 23. Clarify the heading. Perhaps “Improving the Transparency of the CCL Process.”?

**Response:** Reorganization around charge questions changed all headings.

p. 10, lines 41-43. This is a clear recommendation. Should it be included in the letter to the Administrator?

**Response:** While important, the issue of chemicals that were on the CCL 2 but are not on the CCL 3 is only one of the examples of the lack of clarity and transparency. Improving the transparency would allow all such questions to be answered, and we are attempting to keep the letter to the Administrator short and not dwell on the shortcomings of the draft CCL 3.

p. 11, lines 5-6. This statement is not clear. Is the Committee saying that expert opinions would (why is the word “might” used here?) have been more acceptable than internal expert opinions? Did only some members conclude this, or the entire Committee? Is the Committee saying that external expert opinions need less transparency than internal expert opinions?

**Response:** Text of sentences at the end of the paragraph has been clarified.

p. 11, line 24. This is not clear

**Response:** Text revised as two shorter sentences.

p. 11, line 43: Is the word “listing” correct? Or is “regulatory determination” meant here? At this stage in the process, the contaminant is already listed; the context implies that the algorithm would refer to the readiness for regulatory determination.

**Response:** Change made

p. 12, line 1. The word “additional” might be inserted before the word deficiencies.

**Response:** Done

p. 13, lines 6-13. This paragraph suggests that the Committee might be saying that people living in small states should be less protected than people living in highly populated states. There is a good point embedded here; however the paragraph should be carefully revised to avoid misinterpretation.

**Response:** This text has been revised to address the above comment and other comments on this issue.

p. 13, lines 36-37: “did not appear to be able to provide a resolution regarding details to the scoring algorithm.” This statement is unclear.

**Response:** Sentences have been modified.

p. 14, line 4. Change “effects” to “potential effects.” Unused data couldn’t have had effects.

**Response:** Done

p. 14, line 5. Change “represents” to “is.”

**Response:** Done

p. 14, line 12. Change “boarder” to “broader.”

**Response:** Done

p. 14, line 14. Change “or” to “and.”

**Response:** Done

p. 15, lines 24-p. 17 line 14. Overall, the purpose and implication of section 3, “Suggestions to improve the process for future CCLs” is not clear. The charge to the committee relates to this CCL, not to future CCLs, and the items included in the suggestions for future CCLs are also included in the previous discussion of this CCL. Why does the Committee recommend these changes for future CCLs rather than this one?

**Response:** Reorganization around charge questions changed all headings.

p. 15, lines 26-29. It would be helpful if the Committee would list the lessons learned. Two examples are given in this paragraph. Is this the complete list? If not, what are the other lessons learned?

**Response:** The text has been modified to indicate that this is not a complete list, as well as to describe why a complete list of lessons learned could not be provided.

p. 18, line 7. The subject of the sentence (“there” or “it”) needs to be added.

**Response:** Done

p. 18, lines 35-38. There is only one Committee-provided reference. The EPA’s charge specifically requested data; if the committee cannot specifically identify useful data, that should at least be stated clearly in the report.

**Response:** The report now explains why the Committee could not provide the requested data, for example, because the CCL process was not clear or transparent as to what types of data were used and how they influenced the selection of the draft CCL 3.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR  
SCIENCE ADVISORY BOARD

[Date]

EPA-SAB-09-00

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 DWC or Committee) provide advice on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3). Contaminants on the CCL 3 can be chosen by the Agency to undergo a regulatory determination (which will determine whether or not to regulate the contaminant). The CCL 3 also influences the research agenda and other rules such as the Unregulated Contaminant Monitoring Rule.

The Agency asked whether the Federal Register Notice (FRN) 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. The Committee concludes that the documentation of the processes lacks transparency. The CCL 3 uses a more data-driven process than previous CCLs, as well as some models and algorithms, to whittle the universe of contaminants (Universe) to a Preliminary CCL (PCCL) and the CCL. However, EPA also used experts' professional judgments to revise the process and to modify the contaminants on the list. These modifications were not readily apparent in the current documentation. An understanding of the decision-making process is an important criterion for transparency, according to the reviews by the National Research Council and National Drinking Water Advisory Council. The Committee recommends that EPA develop a CCL 3 process flow chart for chemicals and for pathogens that includes links to other documents (data and models) used, as well as delineates where expert judgment was used. Developing one or more flowcharts will: (1) increase transparency; (2) allow a stakeholder to track the progress of a contaminant through the system; (3) highlight decisions that might suggest improvements for future CCL processes; and (4) clarify why contaminants that were included on previous CCL lists were excluded from the draft CCL 3.

**Do Not Cite or Quote**

1  
2 The Committee was asked whether the draft CCL 3 list includes contaminants that have  
3 the highest potential to occur in public water systems and cause adverse human health effects.  
4 This question goes to the heart of prioritization and decision-making in the selection process  
5 from the Universe to the PCCL to the CCL 3. The Committee's major conclusions are:  
6

- 7
- 8 • For chemicals, the list is too large to achieve the stated objectives of the CCL process or  
9 to review by the DWC in the time allocated. To fulfill the Agency's objectives of  
10 choosing chemicals that have the greatest opportunity for improving the safety of  
11 drinking water and protecting public health, the Committee recommends additional  
12 prioritization of the current list. A shorter list will clarify which chemicals have a  
13 reasonable probability of being selected for regulatory determination.
  - 14 • For pathogens, the waterborne disease outbreak data base was used to address both  
15 occurrence and health effects. This data base does not adequately address whether there  
16 is a substantial likelihood that the pathogen will occur in public water systems with a  
17 frequency and at levels of public health concern. The Committee recommends that  
18 occurrence be based on endemic disease data and published literature on occurrence.  
19

20 The Committee was asked to provide any data that suggest: (1) contaminants that are  
21 currently on the draft CCL 3 list **should not** be listed; and (2) contaminants that are **not** currently  
22 on the draft CCL 3 list **should** be listed. The Committee concludes that the draft CCL 3 includes  
23 contaminants that should not be listed and excludes contaminants that should be included.  
24 Rather than attempting to examine each of the 104 contaminants on the draft CCL 3, the  
25 Committee offers suggestions that could be used to identify chemicals and pathogens that should  
26 have a lower priority for regulatory determinations. Similarly, the Committee provides sources  
27 of additional, publicly available data that are expected to raise the priority of contaminants of  
28 greater public health concern.  
29

30 Thank you for the opportunity to provide advice on this important process. The SAB  
31 Drinking Water Committee looks forward to receiving your response regarding this advisory.  
32  
33

34 Sincerely,  
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38

39 Dr. Deborah L. Swackhamer, Chair  
40 Science Advisory Board

Dr. Joan B. Rose, Chair  
Drinking Water Committee

**NOTICE**

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3 This report has been written as part of the activities of the EPA Science Advisory Board (SAB),  
4 a public advisory group providing extramural scientific information and advice to the  
5 Administrator and other officials of the Environmental Protection Agency. The SAB is  
6 structured to provide balanced, expert assessment of scientific matters related to problems facing  
7 the Agency. This report has not been reviewed for approval by the Agency and, hence, the  
8 contents of this report do not necessarily represent the views and policies of the Environmental  
9 Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor  
10 does mention of trade names of commercial products constitute a recommendation for use.  
11 Reports of the SAB are posted on the EPA website at <http://www.epa.gov/sab>.

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**U.S. Environmental Protection Agency  
Science Advisory Board  
Drinking Water Committee**

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**Draft Report Prepared by the Drinking Water Committee for Quality Review and Approval by the Chartered Science Advisory Board (SAB). This document does not represent EPA policy.**

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## **Executive Summary**

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3  
4 EPA's Office of Ground Water and Drinking Water requested that the Science Advisory  
5 Board (SAB) Drinking Water Committee (hereafter, the Committee or DWC) provide advice on  
6 EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3) and the process used to  
7 derive it. This list is the source of contaminants that are considered for a regulatory  
8 determination. In addition, the CCL 3 interfaces with the Agency's research agenda.  
9

10 In regard to whether the Federal Register Notice (FRN, EPA 2008) and support  
11 documents are clear, transparent, and adequate to provide an understanding of the overall  
12 processes and selection of contaminants for the draft CCL 3, **the Committee concludes that the**  
13 **documentation, i.e., the FRN, is not transparent. Committee members with decades of**  
14 **experience reviewing and analyzing EPA regulatory documents could not follow specific**  
15 **contaminants through the process as presented in the FRN. The document is not clear.**  
16 **Interpretation by several Committee members of the published CCL 3 processes differed**  
17 **and were only clarified after discussion with EPA staff.** The lack of clarity in the process led  
18 to frustration, and Committee members who tried to follow the decision-making process for one  
19 or more contaminants could not do so. The Committee recommends that both the FRN and the  
20 EPA web sites contain citations for all documents used in the process, and that the web site post  
21 the documents and/or hyperlinks directly to each document, as well as the location of the  
22 regulatory docket.  
23

24 The Committee recommends that EPA develop CCL 3 process flow charts for chemicals  
25 and pathogens. These flow charts should include links to other documents (data and models)  
26 used, as well as delineate where expert judgment was used to go from the universe of  
27 contaminants (Universe) to the Preliminary CCL (PCCL) to the CCL 3. Developing flowcharts  
28 that a stakeholder can use to track the progress of a contaminant through the system (with the  
29 appropriate references and URLs for each step) would not only make the process more  
30 transparent, but they might also highlight decisions that might suggest improvements for future  
31 CCL processes. The Committee also recommends that EPA document and justify why certain  
32 contaminants that were included on previous CCL lists were excluded from the draft CCL 3.  
33 This will improve readers' understanding of the evolution of the process as well as its  
34 transparency.  
35

36 In regard to whether the draft CCL 3 list represents those contaminants that have the  
37 highest potential to occur in public water systems and cause adverse human health effects, **the**  
38 **CCL 3 does not clearly achieve the stated objectives of the CCL process for prioritization.**  
39 If the goal is to consider at least five contaminants per five-year review cycle for regulatory  
40 determinations, a process that yields 104 contaminants has not whittled the Universe sufficiently  
41 to be efficient or effective. Such a large list can not clearly communicate which contaminants  
42 might – or might not – be considered for regulatory determination. The Committee has several  
43 specific recommendations. For chemicals, explanations should be attached to each bullet  
44 (Section III.A.4; page 9644 of the FRN), as it moves from the PCCL to the CCL, so that the  
45 decision rules are more clearly explicated for the high, medium, and low uncertainty bins. It is  
46 further recommended by the Committee that EPA should “re-train” the model, this time using

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1 only chemicals that would fall into the medium certainty bin. Certainty and data should drive the  
2 prioritization of the contaminants, where there is sufficient information to make a regulatory  
3 determination. For pathogens, the cutoff for moving from the PCCL to the CCL 3 was arbitrary  
4 and not determined based on priority. The Committee recommends that occurrence based on  
5 endemic disease data and published literature on occurrence be used to modify the  
6 priorities/rankings of the pathogen PCCL.

7  
8 With regard to providing any data that may suggest that contaminants which are currently  
9 on (or not on) the draft CCL 3 list, and should not be listed (or should be listed), the list is too  
10 large for the committee to complete a full review of these issues in the time allotted. There are  
11 **104 contaminants on the draft CCL 3, and members of the Committee could not effectively**  
12 **review each contaminant on the draft CCL 3, or the numerous potential contaminants that**  
13 **are not on the draft CCL 3.** Rather, the Committee chose to present some critical examples of  
14 contaminants that their expertise and experience suggested should not have a sufficiently high  
15 priority to be on the draft CCL 3 and suggest reasons why the current process might have  
16 excluded others.

- 17
- 18 • For chemical contaminants, the Committee recommends that EPA should evaluate  
19 whether pesticides that have been or are about to be cancelled completely should be on  
20 the list for additional SDWA regulation. This determination could be made after some  
21 assessment of use, occurrence (transport and fate), and particularly persistence, which  
22 will help to determine if the agent as used previously would have any ongoing  
23 contamination issues. This will assist in the determination of whether the contaminant  
24 should be considered for a regulatory determination or not. In some cases, these types of  
25 pesticides may not require additional regulation and should be excluded from the CCL  
26 process. The Committee recognizes that at least some evaluation of cancelled pesticides  
27 would be necessary.
  - 28
  - 29 • The Committee also recommends that N-nitrosodimethylamine (NDMA), methyl tertiary  
30 butyl ether (MTBE), perchlorate, and perfluorooctanoic acid (PFOA) should be a high  
31 priority for consideration by the Agency, because there is a higher degree of certainty  
32 about their toxicity, occurrence, and treatability.
  - 33
  - 34 • For pathogenic contaminants, the Committee noted that two globally important  
35 waterborne pathogens, *Adenovirus* and *Mycobacteria*, were excluded from the draft CCL  
36 3. These pathogens should be on the list. Other pathogens, *Vibrio cholera* and  
37 *Entamoeba*, were included and should be excluded from the list. Rare outbreaks, and the  
38 outbreak data base in general, were used in determining the ranking and placement on the  
39 CCL 3. The Committee recommends that endemic disease data sets, numbers of  
40 outbreaks, geographical distribution of outbreaks and outbreak venues, as well as the  
41 peer-reviewed literature (which would better inform occurrence in U.S. waters), be used  
42 for the pathogens. Both the use of more of the publicly available data, as well as more  
43 comprehensive use of the databases already used to develop the CCL process, would  
44 improve the ranking.
- 45

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- 1       • The CCL 3 process also does not evaluate some of the less direct, potential hazards of  
2       contaminants. For example, exposure to antibiotics may lead to antibiotic resistant  
3       pathogens. The CCL 3 process does not identify this impact as a threat to human health.  
4

5       The CCL is used for several diverse purposes, and the CCL process may need to be  
6       modified to reflect these uses. At a minimum, a further prioritization of the CCL should be  
7       undertaken for each of these purposes. For example, the CCL 3 list should be used to distinguish  
8       between those contaminants with nearly a sufficiency of information for regulatory  
9       determination and those with greater uncertainty, i.e., with the need for collection of additional  
10      data before a contaminant would move off the CCL 3 toward a regulatory determination.  
11

12      The Committee’s report begins with background information on the CCL 3 process with  
13      web addresses where additional information can be found. The Agency’s charge questions are  
14      then presented, first *in toto* and then separated with the Committee’s response to each question.  
15      The final section contains references cited by the Committee.

## 1 **Background and Introduction**

2  
3 EPA's Office of Ground Water and Drinking Water requested that the Science Advisory  
4 Board (SAB) Drinking Water Committee provide advice on EPA's Draft Third Drinking Water  
5 Contaminant Candidate List (CCL 3) and the process used to derive it. The CCL 3 is a list which  
6 contains potentially harmful drinking water contaminants that may require regulations in the  
7 future that are currently not regulated. The process for the CCL 3 is outlined in the Federal  
8 Register Notice (FRN; EPA, 2008 available at: [http://www.epa.gov/fedrgstr/EPA-](http://www.epa.gov/fedrgstr/EPA-WATER/2008/February/Day-21/w3114.pdf)  
9 [WATER/2008/February/Day-21/w3114.pdf](http://www.epa.gov/fedrgstr/EPA-WATER/2008/February/Day-21/w3114.pdf)). This document states:

10  
11 "Section 1412(b) (1) of SDWA, as amended in 1996, requires EPA to publish the  
12 Contaminant Candidate List every five years. SDWA specifies that the list must include  
13 contaminants that are not subject to any proposed or promulgated NPDWRs, are known  
14 or anticipated to occur in public water systems (PWSs), and may require regulation under  
15 SDWA.

16  
17 "The 1996 SDWA Amendments also specify three criteria to determine whether a  
18 contaminant may require regulation:

- 19
- 20 • The contaminant may have an adverse effect on the health of persons;
  - 21
  - 22 • The contaminant is known to occur or there is a substantial likelihood that the  
23 contaminant will occur in public water systems with a frequency and at levels of  
24 public health concern; and
  - 25
  - 26 • In the sole judgment of the Administrator, regulation of such contaminant  
27 presents a meaningful opportunity for health risk reduction for persons served by  
28 public water systems."
  - 29

30 EPA's web page titled, "Drinking Water Contaminant Candidate List and Regulatory  
31 Determinations," (available at: <http://www.epa.gov/safewater/ccl/ccl3.html#overview>) states:

32  
33 "In developing the draft CCL 3, we implemented a different process from that used for  
34 CCL 1 and CCL 2. This new process builds on evaluations used for previous CCLs and  
35 was based on substantial expert input and recommendations from the National Academy  
36 of Science's National Research Council (NRC) and the National Drinking Water  
37 Advisory Council (NDWAC).

38  
39 "We used a multi-step CCL process to identify contaminants for inclusion on the draft  
40 CCL 3. The key steps include:

- 41
- 42 • Identifying a broad universe of potential drinking water contaminants (called the  
43 CCL 3 Universe). We initially considered approximately 7,500 potential chemical  
44 and microbial contaminants.
  - 45

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- 1           •       Applying screening criteria to the universe we identified 560 of those  
2                   contaminants that should be further evaluated (the preliminary CCL or PCCL)  
3                   based on a contaminant’s potential to occur in public water systems and the  
4                   potential for public health concern.  
5
- 6           •       We then selected 104 contaminants from the PCCL to include on the CCL based  
7                   on more detailed evaluation of occurrence and health effects and expert judgment  
8                   applied in a transparent reproducible manner.  
9
- 10          •       We incorporated information from the public, expert input, and expert review in  
11               the CCL process.”

12  
13 Information regarding the CCL processes and lists can be accessed through the CCL web page  
14 at: <http://www.epa.gov/safewater/ccl/index.html>.  
15

1 **Review of the Draft CCL 3: EPA’s Charge Questions to and the Meetings of the Drinking**  
2 **Water Committee of the Science Advisory Board**

3  
4 The new process developed in response to the recommendations of the NRC and  
5 NDWAC, as well as the specific chemicals and microbial pathogens on the draft CCL 3 list,  
6 were subject to review. The charge questions posed to the DWC by EPA follow.

- 7  
8 1. Please comment on whether the Federal Register Notice and support documents are clear,  
9 transparent, and adequate to provide an understanding of the overall processes and  
10 selection of contaminants for the draft CCL 3.  
11  
12 2. Please comment on whether the draft CCL 3 list represents those contaminants that have  
13 the highest potential to occur in public water systems and cause adverse human health  
14 effects.  
15  
16 3. Please provide any data that may suggest that contaminants which are currently on the  
17 draft CCL 3 list should not be listed.  
18  
19 4. Please provide any data that may suggest that contaminants which are currently not on  
20 the draft CCL 3 list should be listed.

21  
22 The DWC of EPA’s SAB met in a public session on April 23 – 24, 2008 in Washington,  
23 DC, to review the draft CCL 3. The Committee held a subsequent teleconference call on August  
24 13, 2008 to discuss its draft advisory report.

1 **Charge Question 1**  
2

3 **Please comment on whether the Federal Register Notice and support documents are**  
4 **clear, transparent, and adequate to provide an understanding of the overall processes and**  
5 **selection of contaminants for the draft CCL 3.**  
6

7 **Committee Response**  
8

9 **The FRN (EPA, 2008) that describes the process is not transparent and is not**  
10 **adequate to provide an overall understanding of the selection of contaminants for the draft**  
11 **CCL 3. At the April meeting, Committee members, each with decades of experience**  
12 **reviewing and analyzing EPA regulatory documents, stated that they could not follow**  
13 **specific contaminants through the process as presented in the FRN.**  
14

15 The Committee affirms that the process used to produce the CCL 3 represents a major  
16 improvement from the processes used to generate CCL 1 and CCL 2. The processes used to  
17 generate the first two lists relied heavily upon expert opinion, best professional judgment, and  
18 stakeholder nominations. Potential health risks contributed to the first part of the assessment,  
19 followed secondarily by whether the contaminant occurred in drinking water. The CCL 3  
20 process outlined in the FRN uses a more data-driven, systematic approach, focusing on assessing  
21 information (including surrogate information) to identify contaminants based on: the potential or  
22 known occurrence in drinking water; and their potential or known ability to cause adverse effects  
23 in people. As recommended by the NRC and NDWAC, the CCL 3 process attempted to address  
24 the Universe and developed a PCCL. Expert panels were used along the way as part of the  
25 review and to modify the process. During the assessment, 6000 chemical contaminants and 1400  
26 pathogens were identified. **The Committee views the current process as a first iteration of a**  
27 **data-derived CCL**, and acknowledges that, as recommended by the NDWAC, the process  
28 should be adaptive to improve and further develop with additional experience and data. The  
29 Committee's comments on the limitations of the current process should be viewed in this  
30 context.  
31

32 Numerous challenges must be overcome when whittling the initial Universe down to a  
33 CCL. EPA has documented its decision-making process, described its attempts to identify biases  
34 in that process, and obtained expert feedback on the process. In general, the approach is  
35 scientifically justified and, particularly for the chemical list, is a labor-intensive process that  
36 includes the development of mathematical models to create the chemical list. The current  
37 models are useful in sorting through the chemical and pathogen contaminants, but as discussed  
38 further in this report, are expected to improve during additional iterations of the process.  
39

40 The Committee found that use of an only data-supported process, i.e., without  
41 professional judgment, for the CCL 3 (as described in the FRN) generated a list of contaminants  
42 that is suboptimal. Based on the changes made by EPA's panel of internal experts, the  
43 Committee infers that EPA's scientists also agreed that expert judgment was necessary at several  
44 points in the process for developing the CCL 3. Therefore, EPA requested the opinions of  
45 internal experts for professional assessment of chemicals or pathogens to revise the process, and  
46 thus the contaminants, on the draft CCL 3. The Committee was not concerned that, in

1 developing the process, a review was needed and mid-course corrections were undertaken.  
2 Rather, **the Committee found that these modifications (or suggestions) by Agency staff that**  
3 **were accepted or rejected were not readily apparent as the Committee reviewed the**  
4 **documentation in the FRN. In addition, the justifications for the decisions in which expert**  
5 **opinion was accepted or rejected were not articulated.** The Committee found that this lack of  
6 full transparency would impede the ability of other people to repeat the CCL 3 process and  
7 obtain the same results as EPA – either with the current contaminants or with additional  
8 contaminants that might be of interest. **In particular, the Committee could not discern at**  
9 **which steps the data drove the primary outcome and at which steps the experts were used**  
10 **to address key decisions in the process.** Such reproducibility of process was a stated criterion  
11 for transparency made by the NRC and NDWAC. Additionally, some of the information about  
12 individual contaminants and decisions made about them were only available in the regulatory  
13 docket. Committee members either did not know that the docket might contain such information  
14 or had difficulty locating the docket and/or the information desired.

15  
16 The Committee recommends that both the FRN and the EPA web sites contain citations  
17 for all of the documents used in this process, and that the web site post the documents and/or  
18 hyperlinks directly to each document, as well as the location of the regulatory docket.  
19 Additionally, use of hypertext in an online matrix of the contaminants might allow interested  
20 parties to readily access the appropriate section of the documents where the information  
21 influenced the related decisions in the process. Such a hypertext matrix could also be used to  
22 provide readers with a summary of indicators or critical criteria, such as potency-to-  
23 concentration ratios, occurrence data, mode-of-action decisions, health effects of concern, model  
24 scores, expert panel conclusions, etc.

25  
26 **The document is not clear. At the April meeting, Committee members asked for**  
27 **clarification of the process for selecting the draft CCL. After additional information was**  
28 **presented by representatives of EPA's Office of Water, several Committee members stated**  
29 **that they had interpreted the text or tables differently, based on their independent reading**  
30 **of the FRN. These statements apply both to the process used to select the chemicals and to**  
31 **the process used to select the pathogens.**

32  
33 The lack of clarity in the process led to frustration, as Committee members attempted to  
34 determine why specific contaminants on the PCCL were retained or removed from the group of  
35 contaminants that would become the draft CCL 3. **Committee members who tried to follow**  
36 **the decision-making process for one or more contaminants could not do so.** The process for  
37 selecting the chemicals was quite clear and logically presented until after the three models were  
38 run and the resulting lists were created. At that point, the presentation became very murky.  
39 Committee members expressed the difficulty in determining what supporting data were used for  
40 each of the chemicals that did get onto the list. For example, it is not shown what level of  
41 certainty “bin” each came from, what the data were in the exposure and health effects category,  
42 and what the modeled list-not list determinations were. A table presenting these results is  
43 recommended. In addition, it would be helpful to show similar results for at least a subset of the  
44 chemicals that remained on the PCCL, to help inform the reader as to why these were not  
45 selected. The Committee specifically raised numerous questions about the bullet points in  
46 section 4 on p. 9644 of the FRN. It was not clear from the text that the 36 chemicals in the high

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1 certainty bin, for example, were included irrespective of the model results, whereas the 24  
2 pesticides chosen from the medium certainty bin included only those with an “L” or an “L-L?”  
3 ranking. This information needs to be clarified. In addition, there needs to be a clearly written  
4 justification for diverging from the results of the model at the end of the process.  
5

6 The Committee recommends that explanations be attached to each bullet (Section  
7 III.A.4., page 9644 of the FRN) for the chemical list as it moves from the PCCL to the CCL so  
8 that the decision rules are more clearly explicated for the high, medium, and low uncertainty  
9 bins. Since the “training” of the model used chemicals from all certainty bins, the Committee  
10 also recommends that EPA “re-train” the model, using only chemicals that would fall into the  
11 medium certainty bin, i.e., the bin of chemicals for which the model was ultimately used. Clear  
12 identification of certainty of the data should then drive the prioritization of the contaminants in  
13 those cases where there is sufficient information to make a regulatory determination.  
14

15 **The Committee recommends that EPA develop one or more flow charts that a**  
16 **stakeholder can use to track the progress of a contaminant through the system, with the**  
17 **appropriate references and URLs for each step.** Such flow charts would not only make the  
18 process more transparent, but they might also highlight decisions that suggest improvements for  
19 future CCL processes. Also, parameters chosen for the models or specification decisions, should  
20 be provided (in more detail than is provided in Appendix E of the FRN). The CCL 3 process  
21 flow charts should include links to other documents (data and models) used, as well as delineate  
22 where expert judgment was used to go from the Universe to the PCCL to the CCL 3. The  
23 Committee also recommends that EPA document and justify why certain contaminants that were  
24 included on previous CCL lists were excluded from the draft CCL 3. This will improve readers’  
25 understanding of the evolution of the CCL process, as well as its transparency.  
26

27 Other recommendations for the chemical selection process include:  
28

- 29 • To further improve the clarity of the process, approaches that were discarded should be  
30 moved to the end of the document, perhaps in an appendix.
- 31
- 32 • The training set used for the initial calibration of the model for chemicals should be  
33 readily available in the documentation via links to the web site.
- 34
- 35 • Additional deficiencies should be corrected in the details of the presentation of the  
36 process. Details are lacking, for example, as to how fate parameters like the  
37 octanol/water partition coefficients were used in the evaluation.
- 38
- 39 • All parameters should include the appropriate units, e.g., on LD<sub>50</sub> and related parameters  
40 in Exhibit 9.
- 41

42 The process for selection of pathogen contaminants, as outlined in the FRN, was overall  
43 judged a relatively transparent one. However, derivation of the relative numerical rankings was  
44 not clear. An analytical protocol was employed; however, it did not discretely quantify potency,  
45 for example, in terms of dose-response relationship as it had for the chemicals proposed for CCL

1 3 inclusion. The sources of information and data that were used in candidate selection are clear,  
2 and the effort to be inclusive in receiving information from non-government organizations  
3 (NGOs), the public, professional organizations, and municipalities is apparent. The development  
4 of the Universe and the PCCL were data driven.  
5

6 As with the process used to select chemicals, FRN lacked transparency with regard to the  
7 selection of pathogens. Details about how information was used to assign a numerical rating to  
8 the pathogens, for example, were not clear. Although outbreak data were critical to the selection  
9 process, the role of these data, used to rank both the exposure and the health risks, was not  
10 readily apparent. The cut-off for the PCCL to the CCL 3 for pathogens was arbitrary and not  
11 determined based on a specific understanding of the data or uncertainty of the data. Thus,  
12 support for this cut-off was not adequate. **The Committee recommends that occurrence based**  
13 **on endemic disease data, and published literature on occurrence be used to modify the**  
14 **priorities and rankings of the pathogens on the PCCL as they move to the CCL.**

1 **Charge Question 2**  
2

3 **Please comment on whether the draft CCL 3 list represents those contaminants that**  
4 **have the highest potential to occur in public water systems and cause adverse human**  
5 **health effects.**  
6

7 **Committee Response**  
8

9 **The CCL 3 does not clearly achieve the stated objectives of the CCL process. If the**  
10 **goal is to consider at least five contaminants per five-year review cycle for regulatory**  
11 **determinations, a process that yields 104 contaminants has not whittled the Universe**  
12 **sufficiently to be efficient or effective. Such a large list can not clearly communicate to the**  
13 **DWC, other specific interested parties, and/or the general public which contaminants**  
14 **might – or might not – be considered for a meaningful regulatory determination.**  
15

16 Obtaining the list of contaminants for the draft CCL 3 involved development of a new  
17 contaminant-selection process. The process of selecting the CCL 3 involved three major steps:  
18 (1) identifying the Universe of contaminants that might be of concern; (2) using data on  
19 occurrence and potential to cause adverse effects to obtain a PCCL; and (3) using data,  
20 processes, and opinions from EPA’s internal experts to refine the selection into a draft CCL.  
21 This goes to the heart of the question on prioritization and decision making in the selection  
22 process from the Universe to the PCCL to the CCL. The uncertainty analysis for health effects –  
23 and particularly for occurrence – should be articulated to address this issue. Selection of the  
24 databases with specific attributes can determine whether parameters are estimated directly or  
25 when surrogates must be used. Lack of readily available data can constrain the decision options  
26 within the process. In particular, data selection should include identifying and obtaining data  
27 that are necessary for the optimal operation of the CCL process. This applies both to data that  
28 are appropriate for understanding the occurrence of contaminants and to data on the potential  
29 health effects of those contaminants. Key areas to improve the process that should be explored  
30 and addressed in the future include: sensitivity analysis of models and data; data uncertainty;  
31 and data quality.  
32

33 The Committee recommends consideration of emerging issues and on-going research  
34 when selecting chemicals. There are also some clear categories of contaminants that need  
35 special attention in selecting the CCL including pharmaceuticals, personal care products,  
36 endocrine disruptors, antibiotics, and algal toxins. Such contaminants may warrant changes in  
37 the CCL selection processes. General exposure to even low levels of antibiotics in drinking  
38 water, for example, may lead to antibiotic-resistant pathogens either in a person drinking the  
39 water or the general environment. The current CCL process for chemicals would not identify  
40 this as an adverse effect. In addition, opportunistic pathogens (e.g., *Serratia* and *Pseudomonas*)  
41 should be addressed, as waterborne disease from these pathogens in hospital settings has been  
42 documented. The Committee recommends that EPA explore approaches that would bring in  
43 these atypical health-related data and occurrence data into the CCL process.  
44

1 Models and Selection Processes

2  
3 Chemical Contaminants

4  
5 The discussion in the FRN regarding the methodology for moving chemicals from the  
6 PCCL to the CCL is organized in a chronological manner. This presentation imparts  
7 significance to a complex and somewhat cumbersome initial methodology that was ultimately  
8 subsumed within a new methodological framework proposed by EPA's internal expert panels.  
9 This complex, initial approach was not used to determine which chemicals moved from the  
10 PCCL to the CCL. The actual approach began by dividing the chemical PCCL into three groups  
11 (high, medium, and low uncertainty) depending on the type of data available to characterize the  
12 contaminant. For each of these groups, a new decision rule was developed to determine whether  
13 or not the contaminant should move forward to the CCL. While these decision rules are  
14 indicated in the bullets in Section III.A.4. (page 9644 of the FRN), the explanations attached to  
15 each bullet need to be expanded so that the decision rules are more clearly explicated. The initial  
16 classification model was "trained" using chemicals of all types. Since this model was only used  
17 for chemicals in the "medium certainty" bin, EPA should "re-train" the model, using only  
18 chemicals that would fall into this bin.

19  
20 The Committee noted that the draft CCL 3 gives equal weight to all chemicals, although  
21 some chemicals are likely to be ready for regulatory determination, while others will require a  
22 significant amount of additional research before a regulatory determination can be made. Thus,  
23 the Committee recommends further prioritization within the CCL 3. Additional data and  
24 processes should be used to priority rank the CCL 3 chemicals, by a method that will  
25 differentiate between chemicals that have sufficient, existing information for a data-based  
26 regulatory decision and those that do not. Priority-ranking chemicals may also require  
27 reformulating or retraining the algorithms, since the dependent variable of the algorithm must  
28 now indicate whether a contaminant should be studied for regulatory determination, and with  
29 what urgency the contaminant should be studied.

30  
31 Pathogen Contaminants

32  
33 The process for moving pathogens from the PCCL to CCL does not sufficiently address  
34 priority of occurrence or of health impacts. In particular, it is somewhat ambiguous as to how  
35 the ultimate pathogen scores for this process were developed. For pathogens, it appears that the  
36 internal EPA experts adjusted the scoring system. **This adjustment by expert judgment  
37 should be presented more prominently, and the decision rules explained in more detail.**  
38 The Committee concludes decisions regarding the selection of data sets, and the level of  
39 resolution of the information within those data sets, was partially responsible for the suboptimal  
40 results. The relative weighting of Center for Disease Control and Prevention (CDC) Waterborne  
41 Disease Outbreaks (WBDO) "Occurrence" and "Health Effect Scoring", as well as data  
42 normalization, is described, but not necessarily adequate, for addressing the most important  
43 pathogens. The Committee recommends that the limitations of WBDO data sets be articulated  
44 clearly. Such limitations, for example, include underestimation of waterborne disease via a  
45 passive surveillance and the percentages of outbreaks where no etiological agent is identified.  
46 Exhibit 15 of the FRN shows evidence of WBDO using the CDC surveillance database. Over

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1 the more than three-decade period in question, the scoring system does not differentiate between  
2 pathogens that have caused many outbreaks and those that caused only two outbreaks.  
3 Furthermore, scoring of the WBDO data does not appear to take into account the geographic  
4 dispersion of the outbreaks. Also lacking are data on specific, identified pathogens for the  
5 majority of studied outbreaks. Furthermore, a rudimentary sensitivity analysis of the pathogen-  
6 weighting criteria would have demonstrated that the results are not robust to small changes in the  
7 scoring. For example, a change of only "1" unit in WBDO score would move some organisms  
8 on or off the list. Also, the use of "Occurrence" data does not appear to be a quantitatively  
9 robust term, i.e., the 1-to-3 ranking scale may have less utility than initially expected. An  
10 occurrence term of 3 appears only to mean that it has been found in U.S. drinking water, but not  
11 that it is found with any type of frequency or geographic distribution in U.S. drinking waters. In  
12 fact, a score of 3 may mean that it was only found once in drinking water. Outbreak data were  
13 not independent of occurrence, as an outbreak would by itself imply that the organism had been  
14 found in drinking water and influence that score. This interrelationship gave the WBDO a  
15 greater weight in the ranking. If the pathogen were only detected once, the exposure potential,  
16 and therefore the risk, may be quite low.

17  
18 Decisions Regarding Data Sets

19  
20 In several places EPA appears to use data that may not be optimal for its stated intent of  
21 offering equal protection to water consumers. For example, on page 9640 of the FRN,  
22 prevalence is defined as "...the percent of public water systems or monitoring sites across the  
23 nation with detections, number of states with releases..." Neither of these measures takes into  
24 account the number of people who are potentially exposed to contaminants through these  
25 drinking water systems. A contaminant that is found in two or three small states could receive  
26 greater weighting than one found in a large, populous state. Similarly, geographic distribution  
27 (not necessarily within state boundaries but perhaps watersheds) might be an additional  
28 consideration for exposure. The reasons for and implications of such decisions should be  
29 discussed.

30  
31 The Committee recommends the use of more of the publicly available data and the more  
32 comprehensive use of the databases already used to develop the CCL 3. In particular,  
33 information in the peer-reviewed, published literature could be effectively used at certain  
34 junctures of the process, especially when the list of chemicals or pathogens considered for a  
35 particular decision is sufficiently small to reduce the burden of a literature search and analysis.  
36 Similarly, the increasing use of wastewater affected sources of drinking water suggests that  
37 databases containing information on contaminants in wastewater effluents would inform the  
38 CCL process.

39  
40 Chemical Contaminants

41  
42 EPA used a hierarchical approach for data sources to indicate health effects. For full  
43 transparency, the order in this hierarchy of references should be clearly presented. Furthermore,  
44 for food-use pesticides, it would seem more appropriate to use the population-adjusted dose  
45 (PAD), i.e., the dose that incorporates the additional uncertainty factor for children under the  
46 Food Quality Protection Act (FQPA), rather than the reference dose (RfD) in the calculation of a

1 health reference level (HRL). Therefore, the Committee recommends that the Agency  
2 recalculate the health-concentration ratios for those pesticides on the PCCL that have PADs  
3 smaller than their respective RfDs. It is possible that additional substances may qualify for  
4 inclusion on the draft CCL 3 because their revised ratio could now be 10 or less.

5  
6 Pathogen Contaminants  
7

8 The data used (or more specifically, the data not used) and the resulting pathogens  
9 selected, were not necessarily the optimal set to consider for a regulatory determination. For  
10 example, a choice was made by EPA to rely primarily on national data sources and use only data  
11 sources with entries (in this case, for recorded outbreaks) for all of the organisms. This led to  
12 heavy reliance on CDC databases and lack of use of the peer-reviewed, published scientific  
13 literature. This process does not necessarily represent the "best available science." While there  
14 was general agreement that a pathogen's presence in the WBDO should bring special attention to  
15 that microbial pathogen, the WBDO grading system does not appear to provide sufficient  
16 resolution regarding details to be useful as a scoring algorithm without modifiers. **Thus, the full  
17 breadth or ranges of available data were not used.**  
18

19 The WBDO has several limitations that are not addressed in the FRN. This data base  
20 does not distinguish between an organism that has caused outbreaks in the Marshall Islands  
21 (*Cholera*) and an organism that has caused several outbreaks in the continental U.S. (norovirus  
22 and *Campylobacter*). The potential problems caused by highly endemic diseases that are never  
23 detected as outbreaks (and therefore not in the WBDO) are not fully explained by the Agency in  
24 the FRN.  
25

26 A supplementary table containing the published, waterborne-attributed, case reports for  
27 each of the organisms would be useful. There is also a lack of data and discussion about the  
28 prevalence of organisms in sewage and wastewater. As a result, organisms such as *Naegleria* or  
29 *Vibrio* may receive a pathogen PCCL score higher than expected because of this weighting for  
30 "Occurrence," which is tied to whether there has been an outbreak. An environmental  
31 frequency or distribution score for pathogens, rather than or in addition to its "Occurrence"  
32 score, is needed. The ranking and the cut-off level that separated the PCCL from the CCL  
33 seemed arbitrary and should be better described (Exhibit 18).  
34

35 The potential effect of the information that was not used is less clear. As EPA is aware,  
36 the CDC is the premier organization in reporting disease statistics and occurrence for organisms  
37 typically associated with waterborne disease. EPA has partnered well with CDC, including  
38 evaluating the likelihood of disease outbreaks, as the consequences of global environmental  
39 change become manifest. CDC also partners with many other organizations and associations in  
40 disease surveillance. Perhaps most notable are state public health offices, responsible for first  
41 response in reporting disease associated with water and food-borne exposure. EPA should  
42 explore methods for accessing such data. CDC accesses a broader base of data, which may or  
43 may not be immediately available to the EPA, as data indicators for PCCL consideration. Some  
44 of these sources include United States Geological Service (USGS) well-monitoring programs,  
45 and the National Environmental Health Association (NEHA). NEHA also has many partner  
46 organizations such as the Council for State and Territorial Epidemiologists (CSTE). Other

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1 organizations such as the Bureau of Environmental Epidemiology (Florida) or the New York  
2 City Department of Environmental Protection, Waterborne Disease Risk Assessment Program,  
3 may prove useful, as other data or sentinel sources of information on outbreaks.  
4

5 At the international level the United Nations Food and Agricultural Organization (UN-  
6 FAO) and World Health Organization (WHO) monitor and report relevant outbreak and disease  
7 incidence. Significantly, the European counterpart to the CDC, the European Center for Disease  
8 Prevention and Control (ECDC), continues to develop its waterborne disease and monitoring  
9 program and makes data relatively available through its Enter-net databases for waterborne  
10 disease organisms. It is likely the EPA is aware of all these sources, but it may wish to  
11 investigate whether these and other information channels could facilitate more robust and  
12 quantitative tools in assessment of PCCL consideration and CCL listing.  
13

14 Peer-reviewed research articles in journals and periodicals received less attention as data  
15 sources than disease monitoring or surveillance data from other agencies, state, or municipal  
16 sources. Given the relatively limited number of microbial pathogens proposed for inclusion on  
17 the CCL, reviews of the scientific literature are desirable in addition to the sources that were  
18 used to develop this draft CCL 3. Exceptions to the process whereby journal articles were used  
19 for bacteria included publications on *Arcobacter* and *Mycobacterium avium* complex (MAC). It  
20 is likely that other organisms would change position with regard to CCL listing, if outside data  
21 and professional judgment were used. The literature may also be more current with respect to  
22 sensitivity, selectivity, and specificity than the information derived from some more standard  
23 methods.  
24

25 There was discussion in the FRN about not using susceptibility to water treatment to  
26 guide the selection list. This may be appropriate for the PCCL as well as the CCL. However, as  
27 with the chemicals, further prioritization is recommended for the CCL 3 with regard to  
28 sufficiency of the data for regulatory determination as compared with investment in generating  
29 more data (on methods, occurrence, and health effects). For example, if the Agency  
30 demonstrates that the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) or  
31 the Ground Water Rule (GWR) already address risk management for specific pathogens, this fact  
32 could be articulated and influence selection for the CCL. Neither public health nor water  
33 science benefits from having a number of pathogens on a CCL that can readily be removed once  
34 they are “controlled”, without formally establishing an MCL or treatment technique. The large  
35 numbers of *Legionella* cases, and the fact that no current regulatory approach can be documented  
36 to reduce this risk, for example, suggest that this type of pathogen be given a higher priority on  
37 the CCL.  
38

### 39 Use Of The CCL For Regulatory Decisions

40  
41 The CCL 3, as currently defined, serves two distinct purposes. The first is to identify  
42 unregulated contaminants that might have sufficiently high occurrence and produce adverse  
43 effects of concern, so that resources might be directed to obtaining more information. Toward  
44 this end, either data on occurrence or data on adverse effects could lead to development of  
45 sufficiency to move to a regulatory determination. In contrast, the second goal is to select those  
46 contaminants that should be considered for imminent regulatory determination. In general, such

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1 action would require the existence of, rather than the generation of, information on both  
2 occurrence and adversity. Priority setting within the draft CCL 3 should use such criteria.  
3 Absent this prioritization, the CCL 3 will not achieve its stated goal.  
4

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

1 **Charge Question 3**

2  
3 **Please provide any data that may suggest that contaminants which are currently on**  
4 **the draft CCL 3 list should not be listed.**

5  
6 **Committee Response**

7  
8 **With 104 contaminants on the draft CCL 3, members of the DWC could not**  
9 **effectively review each contaminant. For example, one member provided short summaries**  
10 **of a subset of the chemical contaminants (appended to the minutes of the meeting), and the**  
11 **list was 15 pages long (available on web site). Instead, the DWC chose to present some**  
12 **critical examples of contaminants that their expertise and experience suggested should not**  
13 **have a sufficiently high priority to be on the draft CCL 3, and suggest reasons why the**  
14 **current process excluded them.**

15  
16 The DWC concluded that the list of chemicals on the CCL 3 is too large and that it may  
17 be appropriate for some to remain on the PCCL. Additional priority ranking based on, for  
18 example, availability of data necessary for a regulatory determination, should be undertaken.  
19 The CCL serves both to guide the future safety of drinking water via regulatory determinations,  
20 to focus research (into methods for detection, methods of water treatment, and assessing health  
21 effects), and to interface with other rules such as the Unregulated Contaminant Monitoring Rule  
22 (UCMR). It is one of the most critical and important activities within the EPA and thus certainly  
23 deserves the efforts that the Agency has devoted to it. The final list must be viewed within that  
24 context.

25  
26 The DWC acknowledges that any list of contaminants would have some contaminants  
27 that each expert would prefer to add or to remove. Nonetheless, there was general agreement  
28 that the current process could be improved to generate a list that would contain fewer surprises.  
29 For example, members conclude that even a cursory sensitivity analysis could be used to  
30 improve the scoring systems and justify the cut-off points that were used to retain contaminants.

31  
32 Knowledge about a pesticide's regulatory status under the Federal Insecticide, Fungicide  
33 and Rodenticide Act (FIFRA) and FQPA, might obviate retention in a process designed to  
34 determine whether a regulatory determination is necessary under SDWA. Cancelled pesticides,  
35 or those for which cancellation is underway, should be considered differently than those  
36 expected to be used for a longer time. For example, all uses of nitrofen (which is on the draft  
37 CCL 3) were cancelled in 1983, and existing stocks were depleted within a few years. It appears  
38 that nitrofen is on the draft CCL 3 because it was listed as a Toxics Release Inventory (TRI)  
39 release from just one site in just one year. The Committee does not agree that such limited data  
40 constitutes an appropriate surrogate for exposure for decisions regarding decision on the  
41 development of a national drinking water standard. Similarly, the Committee questions the value  
42 of considering, for additional SDWA regulation, those pesticides for which cancellation of all or  
43 many uses is in progress (e.g., molinate and some organophosphates). The Committee  
44 recognizes that at least some evaluation of cancelled pesticides would be necessary, so as not to  
45 be shortsighted on the Agency's part. The Committee recommends that pesticides no longer in  
46 use should be removed from the CCL unless an assessment determines that they present ongoing

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1 contamination issues such as: (1) the potential longevity of pesticides in ecosystems; or (2) fate  
2 and transport data. In addition, proposed CCL chemicals such as germanium, hexane, and  
3 quinoline appear to be on the list mainly because they scored highly in one category (e.g.,  
4 production volume for hexane and toxicity for germanium). The Committee recommends that  
5 such chemicals not be considered for regulatory determinations at this time.

6  
7 For the chemical contaminants, the Committee recommends that the models take into  
8 consideration the level of certainty, and also some measure of the ratio between the  
9 concentration of concern and the potential drinking water concentration. Thus, some chemicals  
10 on the draft CCL 3 might remain on the PCCL, as the current data suggest their occurrence in  
11 public water systems is not at a frequency and concentration that would be of public health  
12 concern. Furthermore, the databases used by the EPA in the CCL 3 analyses do not include  
13 much of the journal literature that could be a rich source of information. While these sources  
14 might be difficult to search for the Universe, these data could more easily be included in the  
15 PCCL to CCL process, especially for the limited number of pathogens. The use of advanced  
16 text-processing software should be investigated for this application. E-government initiatives  
17 throughout the Federal government, as well as a lively and innovative academic community, are  
18 potential sources of help for EPA in pursuing this approach. Similarly, use of available  
19 computational toxicology data might improve the selection of chemical contaminants.

20  
21 The Committee experts in pathogens had not expected to see *Entamoeba histolytica* and  
22 *Vibrio cholerae* on the draft CCL. Other countries' environmental agencies look to the EPA's  
23 CCL. Thus, when the system that is used reveals pathogens that are no longer considered  
24 waterborne disease risks in the U.S., the reasons for this should be addressed, and the data-based  
25 numerical approach should be investigated and corrected. The Committee recommends that  
26 EPA examine data on endemic disease, numbers of outbreaks (dates), and geographic locations  
27 (Marshall Islands), and venues (the *Entamoeba* outbreak was listed with other pathogens in a  
28 prison where sexual transmission is known to occur), as well as provide a better assessment on  
29 the frequency of occurrence in drinking water supplies in the U.S. These microbial contaminants  
30 are not likely to occur in public water systems with a frequency and concentration of public  
31 health concern. Clearly, these are globally important, waterborne pathogens; however, for U.S.  
32 waters their inclusion on the CCL 3 is not warranted.

1 **Charge Question 4**  
2

3 **Please provide any data that may suggest that contaminants which are currently not**  
4 **on the draft CCL 3 list should be listed.**  
5

6 **Committee Response**  
7

8 **Given, as stated in the response to the previous question, the draft CCL 3 was too**  
9 **long to review the contaminants efficiently, it was not feasible for the DWC to consider all**  
10 **possible additional contaminants that might warrant a higher priority for consideration for**  
11 **regulatory determination through the CCL process. Moreover, as the FRN was neither**  
12 **transparent nor clear, it would not have been possible for the Committee members to have**  
13 **provided appropriate data to justify their selection of additional contaminants prior to**  
14 **discussion with EPA at the primary review of the document in April. Thus, the DWC**  
15 **chose to provide critical examples of contaminants that, given their experience and**  
16 **expertise, they expected to be on the draft CCL 3 and suggest – to the best of their current**  
17 **understanding of the process – why they might not have made it through the current**  
18 **process.**  
19

20 The Committee recommends that an explanation be included for those contaminants that  
21 are on the CCL 1 or CCL 2, but were not included in the new list via the new process, with the  
22 appropriate justification. As already stated, this will improve transparency and understanding of  
23 the evolution of the process.  
24

25 EPA should consider addressing the cumulative effects of chemicals with similar sources  
26 and mechanisms (or modes) of action, and microbial pathogens with similar potency and disease  
27 endpoints (for example, diarrhea, pneumonia, or meningitis). The draft CCL 3 was constructed  
28 with consideration only about individual chemicals and pathogens. Grouping has been used for  
29 other drinking water contaminants (e.g., trihalomethanes and haloacetic acids) because  
30 occurrence, health effects, and/or treatment options are related. In the draft CCL 3, (1)  
31 perflourochemicals and (2) acetochlor, metolachlor, and their degradates are examples where it  
32 may be helpful to list the compounds as a group. Not all of the compounds in the group may be  
33 released from the same source, nor would they likely always occur together. A group could  
34 consist of “exposure groups” similar in sources, transport, or solubility. Similarly, “health  
35 groups” would be composed of contaminants with similar toxicity or adverse health effects.  
36 Thus, some agents not on the CCL 3 would join their appropriate groups. Additionally, the  
37 Committee recommends that EPA consider groups of chemicals where only some have been  
38 considered for regulation because others are not yet in common use. The Committee is  
39 concerned that, if the group is not considered as a whole, users could substitute a non-regulated  
40 chemical for a regulated one and, thus, escape regulatory concern. Some groups of chemicals  
41 may need to be considered in different ways depending on the goal of the analysis. For example,  
42 many nitrosamines have similar toxicities and carcinogenicities. Therefore, they should be  
43 considered together when they co-occur in the same drinking water samples when evaluating  
44 risk. If they do not occur together, if they can not be used as substitutes, or if they require  
45 different treatment methods for removal, grouping for these purposes is not recommended.  
46

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1           The Committee concludes that it will be important to consider information regarding  
2 wastewater concentrations when evaluating potential exposure in the CCL process. In some  
3 areas of the country, wastewater discharges are increasingly a greater percentage of water  
4 supplies, and they are being processed into potable water. Wastewater contains a wide variety of  
5 contaminants including pharmaceuticals, personal care products, enteric pathogens, and other  
6 emerging contaminants. In the case of pharmaceuticals, perfluorinated surfactants, and other  
7 contaminants that are prevalent in wastewater effluent, EPA may want to consider using data  
8 obtained in specialized wastewater effluent monitoring programs for the CCL screening process.  
9 Large water systems may be subjected to significant discharges of wastewater effluent, and  
10 concentrations of contaminants measured in wastewater effluent could be used as a surrogate for  
11 concentrations in raw water. An approach for predicting the role of unplanned wastewater reuse  
12 that may be appropriate for predicting concentrations in raw water sources is presented in  
13 Anderson et al. (2004).

14  
15           The Committee recommends that EPA include the DWC earlier in the process.  
16 Requesting advice from the DWC at critical junctures throughout the process, and not just at the  
17 end, would allow EPA to take better advantage of the expertise of the DWC.

18  
19           *Chemical Contaminants*

20  
21           The Committee experts in health effects of chemicals conclude that the isomers of  
22 hexachlorocyclohexane that were on or off the list did not appear appropriate. Pesticides that did  
23 not appear on the CCL 3 that were mentioned as potentially worthy of listing included some for  
24 which information was provided to EPA by public commenters, e.g., degradation products of  
25 dacthal and DDT; Fonofos; Terbacil; s-ethyl dipropylthiocarbamate (EPTC); and 1,3-  
26 dichloropropene (Telone). The absence of data on the occurrence of pharmaceuticals in surface  
27 waters was also noted. The Committee recommends use of the data from the USGS, or any of  
28 the numerous studies in the peer-reviewed literature, to include these chemicals. Also, the  
29 Committee recommends that N-nitrosodimethylamine (NDMA), methyl tertiary butyl ether  
30 (MTBE), perchlorate, and perfluorooctanoic acid (PFOA) should be a high priority for  
31 consideration by the Agency, because there is a higher degree of certainty about their toxicity,  
32 occurrence, and treatability.

33  
34           The listing criteria for chemicals should consider including a parameter that evaluates  
35 analytical methods used to quantify the chemical concentrations in occurrence data. Without a  
36 “standard” method including an established limit of detection, the quality of the occurrence data  
37 will reflect the capabilities of the analytical laboratories. The potentially significant differences  
38 in the analytical capabilities should be a component of evaluating the occurrence data. As a  
39 result, the Committee cautions against using the 90th percentile of the measured water  
40 concentrations as the denominator in a potency-to-concentration ratio where the cut-off value for  
41 listing is less than or equal to 10. It is clear that, for the very skewed distributions of  
42 contaminant concentrations in water, some water utilities could be in a zone of concern, and the  
43 chemical would still be screened off the list, using the existing, above-stated algorithm and  
44 criterion for listing.

1           Pathogen Contaminants

2  
3           Significant limitations in understanding which microbial pathogens were considered for  
4 the CCL 3 list include: the lack of occurrence data; very limited surveillance for most of the  
5 microbial pathogens; and the broad range of potential health effects. The CDC WBDO database,  
6 for example, is widely acknowledged to be an incomplete reflection of the true number of  
7 outbreaks. The WBDO does not capture the burden of disease relating to endemic pathogens  
8 with lower level transmissions. Thus, the Committee recommends the acquisition of better data  
9 on occurrence and surveillance regarding human disease. In general, given the small numbers of  
10 pathogens, greater details from the data sets could be used, as well as endemic disease rates.  
11 Data on occurrence is particularly poor, and thus the literature on surveys will require more  
12 scrutiny. The Committee recommends that the same exceptions made for *Arcobacter* and MAC  
13 in how a WBSO is defined should be applied to the other pathogens for which there is are high-  
14 quality, peer-reviewed reports.

15  
16           *Adenovirus* and *Mycobacteria* should be considered for inclusion in the CCL 3. As  
17 discussed earlier, the weighting of documented outbreaks on health effects, and the approach  
18 used regarding occurrence ranking, moved *Entamoeba* and *Vibrio* higher on the list. The  
19 Committee recommends that information on endemic disease and occurrence in water, based on  
20 the literature, be examined for *Adenovirus* and *Mycobacteria*. Health effect scoring should also  
21 distinguish acute from chronic effects. The potential for pathogen occurrence in ambient waters  
22 could be considered based on contaminants occurrence in wastewater (as described in the  
23 previous sections). Thus, the Committee concludes that the data sets selected, the scoring  
24 process used, and the poor occurrence information may have significantly influenced these  
25 results. It is clear that the process can be improved.

1 **References**

- 2
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## **Attachment G**

### **CCL 3 Comments QR 2 December 15, 2008**

#### **1. Dr. Taylor Eighmy**

I have looked at the revised report and feel that the concerns articulated by the recent QR, especially about the FRN process, are adequately included in this revision.

#### **2. Dr. Judy Meyer**

Overall, the revision is a distinct improvement over the previous document. I found the Letter and Executive Summary exceptionally clear and hard-hitting.

I have one remaining concern, which relates to the recommendation for involvement of the DWC “at critical junctures throughout the process.” (p. 25, line 16). The authors added “at critical junctures” which is an improvement over the vagueness of the recommendation in the previous version. However, this recommendation could be made clearer and hence potentially be more effective (i.e., acted upon) if the authors would specify where in the process DWC review would be most effective. Are there a couple “critical junctures” where DWC review would be able to make a difference? Could those be specified or even just included as examples in a parenthetical phrase? This comment is intended to provide improvement, not prevent approval of the report.

#### **Dr. David Dzombak**

I have reviewed the revised SAB Drinking Water Committee report on EPA's Third Drinking Water Contaminant Candidate List (CCL3). The revised report, now organized by charge question, is much improved in organization. It is now clear that all four charge questions are addressed, whereas the previous version appeared to focus on Charge Question 1 with little attention to Charge Questions 2, 3, and 4.

My only suggestion for additional revision to improve clarity and logic flow is to list the charge questions in summary manner at the beginning of the Executive Summary on page 6. Specifically, I recommend inserting a new second paragraph of the Executive Summary on page 6 that presents the four charge questions. This will provide the reader of the Executive Summary with an outline of what is addressed in the report right at the front of the Executive Summary.

### **3. Dr. Kristin Shrader Frechette**

I have gone through the CCL 3 report and think it is excellent. It does a good job of noting lack of transparency in EPA report, and it makes a good suggestion to add prioritization to the list. I do not believe that 104 contaminants is too long a list (although some will be added later and some removed later), provided that folks rank different contaminants as to their priority for abatement or for presenting a threat. A shorter list (which parts of the report seem to recommend) does not seem reasonable, given massive problems with water contamination, so prioritization of items on the list seems to way to go.