



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

March 27, 2015

MEMORANDIUM

SUBJECT: Determinations Associated with Science Advisory Board Review of the *Draft Fourth Contaminant Candidate List (CCL4)* for Drinking Water

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The EPA Office of Water has asked the Science Advisory Board (SAB) to review the *Draft Fourth Contaminant Candidate List (CCL4)* that was published for public review and comment on February 4, 2015. The Safe Drinking Water Act (SDWA) requires EPA, after consultation with the scientific community including the Science Advisory Board and opportunity for public comment, to publish a list every five years of currently unregulated contaminants that are known or anticipated to occur in public water systems and may require regulation under the SDWA. This list is subsequently used to identify priority contaminants for further research needs and to make determinations on whether or not to regulate at least five contaminants from the CCL with national primary drinking water regulations. The draft CCL4 includes 100 chemicals or chemical groups and 12 microbial contaminants.

The EPA has requested that the SAB provide advice on: the clarity and transparency of the process used to select contaminants for the CCL4; other sources of data on drinking water contaminants that should be considered; and whether there are contaminants on the draft CCL4 that do not merit inclusion or contaminants not on the draft CCL4 that should be added.

This memorandum addresses the set of determinations that were used in selecting the SAB Drinking Water Committee to conduct this review, including:

1. The type of review body that will be used to conduct the review, and the nature of the review;

2. The types of expertise needed to address the general charge;
3. Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
4. How regulations concerning “appearance of a loss of impartiality” pursuant to 5 C.F.R. § 2635.502 apply to members of the committee;
5. Other considerations that might affect the objectivity of members of the committee; and
6. How individuals were selected for the committee.

DETERMINATIONS:

1. The type of review body that will be used to conduct the review, and the nature of this review.

The SAB Drinking Water Committee is a standing committee of the Board that provides advice through the chartered SAB on the technical aspects of EPA’s national drinking water standards program. The chair of the DWC is a member of the chartered SAB and the committee’s report will be reviewed by the chartered SAB before it is transmitted to the EPA Administrator.

2. The types of expertise needed to address the general charge.

The DWC includes experts with experience in drinking water issues, including expertise in one or more of the following disciplines: environmental chemistry; environmental engineering; epidemiology; microbiology; public health; risk assessment; and toxicology. The committee includes the relevant expertise needed to address the charge for the CCL4 review.

3. Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic reviewed.

(a) Identification of parties (or class of parties) whose financial interests may be affected by the matter to be reviewed: The SAB review of the methods and data used to develop the draft CCL4 will involve consideration of a wide range of chemicals manufactured and used in commerce, including agrochemicals, industrial solvents and pharmaceuticals. The CCL4 does not impose any requirements on public water systems and any future decision by the EPA to regulate a listed contaminant would be subject to a separate rulemaking process. *Thus, the DWC’s deliberations will not be focused on the interests of specific parties or a discrete and identifiable class of parties.*

(b) Conflict of interest considerations: For Financial Conflict of Interest (COI) issues, the basic 18 U.S. Code § 208 provision states that: “An employee is prohibited from *participating personally or substantially* in an official capacity in any *particular matter* in which he, to his knowledge, or any person whose interests are imputed to him under this statute has a financial interest, if the particular matter will have a *direct and predictable effect* on that interest [emphasis added].” For a conflict of interest to be present, all elements in the above provision must be present.

- (i) Does the general charge to the committee involve a particular matter? A “particular

matter” refers to matters that “...will involve deliberation, decision, or action that is focused upon the interest of specific people, or a discrete and identifiable class of people.” It does not refer to “...consideration or adoption of broad policy options directed to the interests of a large and diverse group of people.” [5 C.F.R. § 2640.103(a)(1)]. *Review of the draft CCL4, as reflected in the EPA charge to the SAB, does not focus on the interests of specific parties or a discrete and identifiable class of parties. As such, the charge to the SAB DWC constitutes simply a matter, rather than a particular matter.*

(ii) Will there be personal and substantial participation on the part of the committee members?

Participating personally means direct participation in this review. Participating substantially refers to involvement that is of significance to the matter under consideration. [5 C.F.R. § 2640.103(a)(2)] *The charge to the SAB DWC for review of the draft CCL4 constitutes a matter, rather than a particular matter. When a charge is not a particular matter, then 18 U.S.C. 208 does not apply and a COI cannot arise.*

(iii) Will there be a direct and predictable effect on committee members’ financial interests? A

direct effect on a participant’s financial interest exists if “... a close causal link exists between any decision or action to be taken in the matter on the financial interest.... A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect.” [5 C.F.R. § 2640.103(a)(ii)]. *The charge to the SAB DWC for review of the draft CCL4 constitutes a matter, rather than a particular matter. When a charge is not a particular matter, then 18 U.S.C. 208 does not apply and a COI cannot arise.*

4. How regulations concerning “appearance of a loss of impartiality” pursuant to 5 C.F.R. § 2635.502 apply to members of the committee.

The Code of Federal Regulations at 5 C.F.R. 2635(a)(2) describes general requirements for considering an appearance of a loss of impartiality for employees of the Executive Branch (including Special Government Employees) participating in a *particular matter involving specific parties*. *The SAB Staff Office has determined that the charge to the SAB DWC for review of the draft CCL4 is not a particular matter involving specific parties; i.e., this matter does not involve “any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest” [5 C.F.R. 2637.102(a)(7)].*

5. Other considerations that might affect the objectivity of members of the committee.

Members of SAB committees and panels must be scientific and technical experts who are objective and open-minded, able to engage in deliberative discussions with scientists who may have disparate perspectives. To evaluate candidates, the SAB Staff Office considers information provided by the public in response to the invitation for public comment on the candidates, information provided by candidates (including on the EPA Form 3110-48), and information independently gathered by SAB staff.

As part of a determination that committee or panel members are objective and open-minded on the topic of the review, and consistent with the agency's Peer Review Policy, the SAB Staff Office considers previous involvement in the matter before the committee. This evaluation includes responses provided by candidates to the following supplemental questions contained in EPA Form 3110-48:

- (a) Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the panel/committee/subcommittee or any reason that your impartiality in the matter might be questioned?
- (b) Have you had any current or previous involvement with the review document(s) under consideration including authorship, collaboration with the authors, or previous peer review functions? If so, please identify and describe that involvement.
- (c) Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- (d) Have you made any public statements (written or oral) on the issue that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

The SAB Staff Office has determined that there is no reason to believe that the members of the SAB Drinking Water Committee would not be objective and open-minded and able to engage in deliberative discussions with scientists who may have disparate points of view on the matter before the Committee.

6. How individuals were selected for the DWC CCL4 Review.

Members of SAB standing committees, including the DWC, are appointed by the Administrator for staggered 3-year terms. As part of the annual membership process, candidates are sought for positions on the SAB and its standing committees for members whose terms are ending and an opportunity is provided for public comments on the candidates. Prior to each review activity, members' confidential financial disclosure forms are evaluated to ensure that no financial COI or other ethics issues will arise due to the nature of the matter to come before the committee.

For the SAB and its standing committees, a balanced committee or panel is characterized by candidates who possess the necessary domains of scientific knowledge, relevant perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge. Specific criteria to be used in evaluating an individual panel member include: (a) scientific and/or technical expertise, knowledge, and experience; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality pursuant to 5 C.F.R. § 2635.502; (e) skills working on advisory committees and panels (including objectivity and open-mindedness); and (f) for the committee as a whole, diversity of scientific expertise and viewpoints.

The SAB Staff Office Director makes the final decision about who participates in the SAB DWC review of the draft CCL4 based on all of the relevant information, including a review of each member's confidential financial disclosure form (EPA Form 3110-48), the responses to the questions above, public comments, and information independently gathered by SAB Staff.

On the basis of the above-specified criteria, all current members of the Drinking Water Committee are eligible to participate in the review of the Draft CCL4:

SAB Drinking Water Committee (2015):

- Dr. Kimberly L. Jones, Howard University (CHAIR)
- Dr. George Alexeeff, California Environmental Protection Agency
- Dr. Mark Benjamin, University of Washington
- Dr. Joel Ducoste, North Carolina State University
- Dr. Russell Ford, CH2M HILL
- Dr. Susan Korrick, Harvard Medical School
- Dr. Frank Loge, University of California-Davis
- Dr. Kristina D. Mena, University of Texas Health Science Center
- Dr. William Mitch, Stanford University
- Dr. Eileen Murphy, Rutgers University
- Dr. Stephen Randtke, University of Kansas
- Dr. A. Lynn Roberts, Johns Hopkins University
- Dr. Kellogg J. Schwab, Johns Hopkins University
- Ms. Janice Skadsen, CDM Smith
- Dr. Shane Snyder, University of Arizona
- Dr. Craig Steinmaus, California Environmental Protection Agency
- Dr. Mark Wiesner, Duke University
- Dr. Lloyd Wilson, New York State Department of Health
- Dr. Marylynn Yates, University of California-Riverside

Concurred,

/signed/

March 27, 2015

Christopher S. Zarba
Director and Deputy Ethics Official
EPA Science Advisory Board Staff Office (1400R)

Date