



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 25, 2005

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

MEMORANDUM

SUBJECT: U.S. EPA Science Advisory Board (SAB) Aquatic Life Criteria Guidelines Consultative Panel

FROM: Thomas M. Armitage, Ph.D. */Signed/*
Designated Federal Officer
EPA Science Advisory Board Staff Office (1400F)

THRU: Daniel Fort */Signed/*
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TO: Vanessa Vu, Ph.D.
Director
EPA Science Advisory Board Staff Office (1400F)

This memorandum documents the process and addresses the set of determinations used in forming this Science Advisory Board Panel. It provides background information on the subject SAB activity and addresses:

1. The charge developed for the Panel;
2. The type of panel that will be used to conduct the review, the name of the Panel, identification of the Panel Chair, and the types of expertise needed to address the charge;
3. How individuals were placed on the "short list" candidates for the Panel;
4. Identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
5. Whether the charge involves a particular matter and how conflict of interest regulations apply to members of the panel;
6. How individuals were placed on the Panel.

A. Background

As required under the Clean Water Act (CWA), the Environmental Protection Agency (EPA) develops ambient water quality criteria for aquatic life to provide guidance to states and tribes for adopting water quality standards. Water quality standards are the basis for controlling

discharges or releases of pollutants. The current ambient water quality criteria for aquatic life are derived according to the *Guidelines for Derivation of Ambient Water Quality Criteria for the Protection of Aquatic Life and Their Uses* (the Guidelines), published in 1985. To ensure that ambient water quality criteria are derived from the best available science, EPA's Office of Water (OW) has assessed the need to update the Guidelines, identified issues that should be addressed in the revisions, and formed an interagency workgroup to review the state-of-the-science and recommend new or improved approaches for deriving ambient water quality criteria. OW has requested a consultation with the SAB on proposed approaches developed by the interagency workgroup for revision of the Guidelines. Following the initial consultation, OW plans to request further advice from the SAB regarding revision of the Guidelines.

B. Determinations

1) The charge to the Panel:

EPA is consulting the SAB to obtain advice on a framework for revising the *Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Aquatic-Dependent Wildlife*. EPA seeks comment on: 1) the scope of the proposed framework for revising the 1985 *Guidelines*, and 2) the scientific validity and appropriateness of proposed approaches for developing water-based, tissue based, and taxon-specific water quality criteria. EPA seeks comments on the following specific charge questions.

Charge Question 1.1 Please comment on the use of the *Guidelines for Ecological Risk Assessment* as an essential and relevant organizing framework for development of science-based criteria for the protection of aquatic life and aquatic-dependent wildlife? Does the SAB have any specific recommendations on how to improve or clarify the generic conceptual framework diagram?

Charge Question 1.2. Please comment on whether the proposed criteria types and the scientific focus for each criteria type are logical and scientifically valid for developing a holistic and integrated criteria framework.

Charge Question 2.1. Please comment on whether the kinetic toxicity models being considered by EPA are scientifically appropriate for use in deriving water-based criteria.

Charge Question 2.2. Please comment on whether the population models being considered by EPA are scientifically appropriate for use in deriving water-based criteria.

Charge Question 2.3. Please comment on whether the proposal for aggregating effects across species being considered by EPA is scientifically appropriate for use in deriving water-based criteria.

Charge Question 2.4 Please comment on whether the framework being considered by EPA for deriving water-based criteria is scientifically appropriate for use in deriving the criteria.

Charge Question 3.1. Please comment on the rationale and conceptual approach used for the development of tissue-based criteria for this group of chemicals. Is the SAB aware of other approaches for deriving criteria for these bioaccumulative chemicals that EPA should consider?

Charge Question 3.2. Considering the strengths and limitations of the more flexible approach used to derive tissue-based criteria, please comment on the rationale and preference for allowing flexibility in the procedures used?

Charge Question 3.3. Please comment on the rationale used by EPA for determining if/when to use population modeling in the development of Tissue-Based Criteria?

Charge Question 4.1. Please comment on the considerations for problem formulation outlined in the proposed framework for deriving Taxon-specific Criteria, specifically whether it will lead to scientifically defensible numeric criteria?

Charge Question 4.2. Of the approaches outlined for addressing surrogacy and gap analyses with regard to special status species, are there improvements to these tools that would provide more scientifically defensible numeric criteria where specific data are not available? Are these tools adequate for developing scientifically defensible numeric criteria? What other tools are available to provide more scientifically defensible criteria when there is an absence of toxicological data for a specific pollutant and taxon?

2) Type of panel that will be used to conduct the review, the name of the panel, and identification of the panel chair, and types of expertise needed to address the charge:

The consultation will be conducted by an SAB panel consisting of members of the Ecological Processes and Effects Committee and invited experts. Dr. Kenneth Dickson, a member of the Chartered SAB, will chair this SAB panel. The name of the panel is the, "Aquatic Life Criteria Guidelines Consultative Panel." An FR notice was published on February 15, 2005 requesting public nominations of experts in the following areas: aquatic toxicology, particularly kinetic toxicity modeling and tissue residue-based toxicity data and residue-response relationships; biology of aquatic and benthic species; bioaccumulation modeling, including both simple bioaccumulation factors (bioaccumulation factors and biota-sediment accumulation factors), and complex dynamic food web/chain models; and population modeling.

3) How individuals were placed on the "short list":

Forty-two (42) individuals were nominated (widecast) to serve as members of the SAB Panel. On the basis of candidates' qualifications and availability to participate in the review meeting, the SAB Staff Office identified 42 candidates to be on the "short list." On May 24, 2005, the SAB Staff Office posted a notice on the SAB website inviting public comments on the "short list" of prospective candidates for the Panel. The SAB Staff Office indicated that it intended to

select candidates from the “short list” to form an initial consultative panel as well as any future panels that may provide additional advice and peer review to EPA as the Guidelines are revised.

In particular, the notice on the SAB website stated that the Staff Office would welcome any information, analysis or documentation that the SAB Staff Office should consider in evaluating the candidates on the “short list,” and asked that any advice, observations or comments which would be helpful in selecting the final candidates be provided to the SAB Staff Office no later than June 15, 2005. *The SAB Staff Office received comments on the “short list” of candidates for the Aquatic Life Criteria Guidelines Consultative Panel from three individuals and/or organizations (see attachment 1 for the list of commenters).*

4) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed:

Potentially interested and affected parties include: 1) federal, state, and local government agencies, elected officials, and non-government organizations that focus on environmental policy or face regulatory decisions related to water quality criteria; 2) those involved with the interests of industries and governments that may be affected by policies or regulations developed on the basis of the “Guidelines for Derivation of Ambient Water Quality Criteria for the Protection of Aquatic Life and Their Uses,” and 3) academic/industry/government researchers addressing aquatic life water quality criteria.

5) Whether the charge involves a particular matter and how conflict of interest regulations apply to members of the panel:

18 U.S.C. 208 provision states that:

"An employee is prohibited from participating personally and 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. If an element is missing, the issue does not involve a formal conflict of interest. However, the general provisions in the "appearance of a lack of impartiality guidelines" may still apply and need to be considered.

Personal and Substantial Participation:

Participating personally means participating directly. Participating substantially refers to involvement that is of significance to the matter [5C.F.R. 2640.103(a)(2)]. For this review, panel members will be participating personally in the matter through attendance at meetings, teleconferences and other means.

Direct and Predictable Effect:

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 and any expected effect of the matter on the financial interest...A particular matter does not have a direct effect...if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. 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)(i)]. A predictable effect exists if, "...there is an actual, as opposed to a speculative, possibility that the matter will affect the financial interest." [5 C.F.R. 2640.103(a) (ii)].

Particular Matter:

A "particular matter" refers to matters that "...will involve deliberation, decision, or action that is focused upon the interests 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)].

The Aquatic Life Criteria Guidelines Consultative Panel's activity qualifies as a particular matter of general applicability because the resulting advice will be part of a deliberation, and under certain circumstances the advice could involve the interests of a discrete and identifiable class of people but does not involve specific parties. That group of people constitutes those who are associated or involved with the potentially interested or affected parties, as identified above.

Appearance of a Lack of Impartiality Considerations:

The Code of Federal Regulations [5 C.F.R. 2635.502(a)] states that:

"Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee."

Further, 5 C.F.R. 2635.502(a)(2) states that:

"An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter."

Each potential advisory panel member was evaluated against the 5 C.F.R. 2635(a)(2) general requirements for considering an appearance of a lack of impartiality. Information used in this evaluation has come from information provided by potential advisory panel members (including, but not limited to, EPA 3110-48 confidential financial disclosure forms) and public comment.

To further evaluate any potential appearance of a lack of impartiality, the following five (5) questions were posed to all prospective advisory panel members:

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

As a result of a review of these forms, the responses to the five questions above, public comments, and information gathered by SAB staff as well as each prospective panel member, the Deputy Ethics Official of the Science Advisory Board, in consultation with the SAB Ethics and FACA Policy Officer, has determined that there are no conflict of interest or appearance of a lack of impartiality for the members of this panel.

6) How individuals were selected for the final Panel:

The SAB Staff Office Director - in consultation with the Aquatic Life Criteria Guidelines Consultative Panel Chair - makes the final decision about who serves on the Panel. Selection criteria included: scientific and technical credentials and expertise; the need to maintain a balance with respect to members' qualifying expertise background and perspectives; willingness to serve on the Panel, and availability to meet during the proposed time period; the absence of conflict of interest; and absence of any appearance of lack of impartiality. The final panel was selected from candidates on the "short list."

Accordingly, based on the above-specified criteria, an Aquatic Life Criteria Consultative Panel of the following fourteen (14) experts was selected:

1. Dr. Kenneth Dickson, University of North Texas (TX) (Chair)
2. Dr. John Connolly, Quantitative Environmental Analysis (NJ)
3. Dr. Frank Gobas, Simon Fraser University (Canada)

4. Dr. Christian Grue, University of Washington (WA)
5. Dr. Charles Hawkins, Utah State University (UT)
6. Dr. Michael Hooper, Texas Tech University (TX)
7. Dr. Lynn McCarty, McCarty Scientific Research and Consulting (Canada)
8. Dr. Joseph Meyer, University of Wyoming (WY)
9. Dr. Judith Meyer, University of Georgia (GA)
10. Dr. Michael Newman, College of William and Mary (VA)
11. Mr. Robin Reash, American Electric Power (OH)
12. Dr. William Stubblefield, Parametrix, Inc. (OR)
13. Dr. Daniel Schlenk, University of California, Riverside (CA)
14. Dr. Judith Weis, Rutgers University (NJ)

Concurred,

/signed/

8-25-05

Vanessa Vu, Ph.D.
Director
EPA Science Advisory Board Staff Office (1400F)

Date

Attachment 1

List of Commenters on “Short list” Candidates for the
Aquatic Life Criteria Guidelines Consultative Panel

1. Robert A. Goldstein, Electric Power Research Institute
2. Keith Hansen, Utility Water Act Group
3. Fredric Andes, Federal Water Quality Coalition