

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

> OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

June 3, 2008

MEMORANDUM

- **SUBJECT:** U.S. EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Criteria – Determination of Committee Membership
- FROM: Thomas M. Armitage, Ph.D. /Signed/ Designated Federal Officers EPA Science Advisory Board Staff Office (1400F)
- THRU: Anthony F. Maciorowski, Ph.D. /Signed/ Deputy Director EPA Science Advisory Board Staff Office (1400F)
- 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 Committee. It provides background information on the subject SAB activity and addresses:

- 1. The general charge developed for the Committee;
- 2. The type of committee that will be used to conduct the review, the name of the Committee, and identification of the types of expertise needed to address the charge;
- 3. How individuals were placed on the "short list" of candidates for the Committee;
- 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 Committee; and
- 6. Selection of Committee membership.

A. Background

The Clean Water Act authorizes the EPA Administrator to develop and publish criteria for water quality that are protective of aquatic life. EPA's 1985 Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Life and Their Uses (Guidelines) have been used to derive ambient water quality criteria for the protection of aquatic life. However, some chemicals of emerging concern, such as pharmaceuticals and personal care products exhibiting endocrine disrupting activity or other toxic mechanisms, have features that require additional consideration when applying the Guidelines. EPA's Office of Water/Office of Research and Development Emerging Contaminants Workgroup has developed a white paper titled, *Aquatic Life Criteria for Chemicals of Emerging Concern: Challenges and Recommendation.*" The white paper describes technical issues in deriving aquatic life criteria for chemicals of emerging concern and recommendations for developing such criteria. In the white paper, EPA presents a model endocrine disrupter case study to illustrate issues relevant to the process of deriving water quality criteria. The Office of Water has asked the Science Advisory Board to comment on the scientific and technical merit of the recommendations and usefulness of the case study in the white paper.

B. Determinations

1) The general charge to the Committee:

The SAB has been asked to comment on: 1) the technical merit, practicality, and implementability of proposed recommendations to address six technical issues concerning derivation of water quality criteria for chemicals of emerging concern (these issues are: relevance of acute toxicity data, minimum taxonomic coverage required, use of non resident species, appropriate chronic toxicity data, selecting test endpoints, and involving expert panels in water quality criteria development); 2) whether EPA has identified the appropriate issues to be addressed in deriving water quality criteria for chemicals of emerging concern; 3) the usefulness of the case study in clarifying technical issues and illustrating how they should be addressed; and 4) suggestions to assist EPA in implementing proposed recommendations, particularly with respect to developing scientific data and information and providing expert scientific input.

2) <u>Type of committee that will be used to conduct the review, the types of expertise needed</u> to address the charge, and the name of the committee:

The advisory activity will be conducted by the EPA Science Advisory Board Ecological Processes and Effects Committee (EPEC) augmented with additional experts. The SAB Staff Office announced to the public through a *Federal Register* notice on May 2, 2008 that it was soliciting nominations of nationally recognized scientists in the field of aquatic toxicology with specific knowledge of the effects of endocrine disrupting chemicals to augment the expertise on the EPEC. The name of the committee is the "Ecological Processes and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Water Quality Criteria"

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

The SAB Staff Office identified 14 experts to be considered to augment the expertise on the EPEC. On May 20, 2008 the SAB Staff Office posted a notice on the SAB website inviting public comments on the "short list" of candidates to augment the EPEC for this advisory activity. In particular, the notice invited comments to provide relevant information or other documentation that the SAB Staff Office should consider in determining who should serve on the Committee, and asked that such comments be submitted no later than May 27, 2008. *The SAB Staff Office received no comments on the "short list" of candidates to augment the EPEC for the advisory on EPA's aquatic life water quality criteria.*

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

Potentially interested parties may 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*.

5) <u>Whether the charge involves a particular matter and how conflict of interest regulations</u> 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."

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 advisory activity, 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)(i)].

Particular Matter:

A "particular matter" refers to matters that "...will involve deliberations, 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 divers group of people." [5 C.F.R. 2640.103 (a)(1)].

The Ecological Processes and Effects Committee activity in addressing EPA's charge concerning aquatic life water quality criteria for chemicals of emerging concern does not constitute a particular matter because it does not include matters that involve deliberation, decision or action that is focused upon the interest of specific people, or a discrete and identifiable class of people. The SAB Committee's activity does not include matters which involve formal parties or extend to legislation or policy-making that is narrowly focused upon the interests of a discrete and identifiable class of persons. EPA's white paper, *Aquatic Life Criteria for Chemicals of emerging Concern: Challenges and Recommendations*, identifies technical issues and provides recommendations for developing aquatic life water quality criteria for a variety of chemicals, such as endocrine disrupting compounds, that may require additional consideration when applying the Guidelines. As such, this is something that is directed to the interests of a large and diverse group of people and is a matter of general applicability. Thus, the criterion for particular matter concerning specific parties is not met and no financial conflict of interest as defined in 18 USC 208 exists.

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 who 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."

Candidates were 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 as well as their responses to the following questions:

- 1. Have you had any previous involvement with EPA's white paper on technical challenges and recommendations for deriving aquatic life water quality criteria for emerging contaminants including authorship, collaboration with authors, or previous review functions? If so, identify that involvement.
- 2. Have you made any public statements (written or oral) or taken a position on the subject of developing aquatic life water quality criteria for emerging contaminants such as pharmaceuticals and personal care products exhibiting endocrine disrupting activity? If so, please identify those statements.
- 3. Have you served on previous advisory panels or committees that addressed EPA's white paper on technical challenges and recommendations for deriving aquatic life water quality criteria for emerging contaminants? If so identify those activities.
- 4. Do you know of any reason why you might be unable to provide impartial advice on EPA's white paper on technical challenges and recommendations for deriving aquatic life water quality criteria for emerging contaminants or any reason why your impartiality in the matter might be questioned?

As a result of a review of all relevant information including financial disclosure, the responses to the four questions above, and public comments, 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 conflicts of interest or appearances of a lack of impartiality for the members of this Committee.

6) Selection of Committee membership:

The SAB Staff Director makes the decision about who serves on the Ecological Processes and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Criteria. For the SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. Specific criteria to be used in evaluating an individual committee member include: (a) scientific and/or technical expertise, knowledge, and

experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, for the committee as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, etc. The final Committee was selected from candidates on the "Short List" and appointed members of the SAB Ecological Processes and Effects Committee. The membership of the Committee includes the following individuals:

Dr. Judith Meyer, University of Georgia (GA) (Chair) Dr. Richelle Allen-King, University at Buffalo (NY) Dr. Fred Benfield, Virginia Tech (VA) Dr. Ingrid Burke, Colorado State University (CO) Dr. G. Allen Burton, Wright State University (OH) Dr. Peter Chapman, Goulder Associates (BC, Canada) Dr. Loveday Conquest, University of Washington (WA) Dr. Kenneth Dickson, University of North Texas (TX) Dr. Karen Kidd, University of New Brunswick (NB, Canada) Dr. Wayne Landis, Western Washington University (WA) Dr. Ellen Mihaich, Environmental and Regulatory Resources (NC) Dr. Charles Rabeni, U.S. Geological Survey (MO) Dr. Amanda Rodewald, Ohio State University (OH) Dr. James Sanders, Skidaway Institute of Oceanography (GA) Dr. Daniel Schlenk, University of California, Riverside (CA) Dr. Heiko Schoenfuss, St. Cloud State University (MN) Dr. Geoffrey Scott, National Oceanic and Atmospheric Administration (SC) Mr. Timothy Thompson, Science, Engineering, and the Environment (WA) Dr. Glen Van Der Kraak, University of Guelph (ON, Canada) Dr. Ivor van Heerden, Louisiana State University (LA) Dr. R. Thomas Zoeller, University of Massachusetts (MA)

Concurred,

/Signed/

6/3/08

Date

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