EXHIBIT J

AUGUST 12, 2009 EPA MEMORANDUM FROM THOMAS M. ARMITAGE, PH.D TO VANESSA VU, PH.D



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

August 12, 2009

MEMORANDUM

TO:

SUBJECT: Formation of Science Advisory Board (SAB) Ecological Processes and Effects

Committee Augmented for Review of Nutrient Criteria Guidance

FROM: Thomas M. Armitage, Ph.D. /Signed/

Designated Federal Officer (DFO)

EPA Science Advisory Board Staff Office (1400F)

THRU: Anthony F. Maciorowski, Ph.D. /Signed/

Deputy Director EPA Science Advisory Board Staff Office (1400F)

Vanessa Vu, Ph.D.

Director

EPA Science Advisory Board Staff Office (1400F)

EPA's Office of Water (OW) has developed a draft guidance document, *Empirical Approaches for Nutrient Criteria Derivation*, addressing the use of empirically-derived stressor-response relationships as the basis for developing numeric nutrient endpoints for water quality standards. OW has asked the Science Advisory Board to review the draft guidance document and comment on the technical soundness of proposed empirical approaches as the basis for future development of numeric nutrient criteria.

This memorandum addresses the set of determinations that were necessary for forming the SAB Ecological Processes and Effects Committee Augmented for Review of Nutrient Criteria Guidance including:

- (A) The type of review body that will be used to conduct the review, and the nature of the review;
- (B) The types of expertise needed to address the general charge;
- (C) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;

- (D) How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502 apply to members of the Committee; and
- (E) How individuals were selected for the Committee.

DETERMINATIONS:

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

The members of the Science Advisory Board Ecological Processes and Effects Committee (EPEC), supplemented by additional subject matter experts - known collectively as the Ecological Processes and Effects Committee Augmented for the Review of Nutrient Criteria Guidance - will provide advice and recommendations to EPA on the technical soundness of proposed empirical approaches as the basis for future development of numeric nutrient water quality criteria. Specifically, this will involve the Committee's review of EPA's draft guidance document, *Empirical Approaches for Nutrient Criteria Derivation*.

(B) The types of expertise needed to address the general charge.

The SAB Staff Office announced to the public through a *Federal Register* notice published on April 27, 2009 (74 FR 19084) that it was soliciting nominations of nationally and internationally recognized scientists in fields such as ecology, biology, environmental science, risk assessment, statistics, and zoology to serve on the Committee. The *Federal Register* notice further stated that, in particular, the SAB Staff Office sought nominees with specialized knowledge and expertise in the use of empirically-derived stressor-response relationships as the basis for developing nutrient assessment endpoints and criteria for the protection of aquatic life.

- (C) <u>Financial conflict of interest considerations, including identification of parties who</u> are potentially interested in or may be affected by the topic to be reviewed.
- (a) <u>Identification of parties who are potentially interested in or may be affected by the topic to be reviewed:</u> The principal interested and affected parties for this topic are: 1) federal, state, and local government agencies, elected officials, and non-government organizations involved in the development or implementation of water quality criteria for nutrients; and 2) those involved with the interests of private or public organizations that may be affected by policies or regulations developed on the basis of EPA's draft guidance document, *Empirical Approaches for Nutrient Criteria Derivation*.
- (b) Conflict of interest considerations: For Financial Conflict of Interest (COI) issues, the basic 18 U.S.C. § 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. If an element is missing the issue does not involve a formal conflict of interest;

however, the general provisions in the appearance of impartiality guidelines must still apply and need to be considered.

(i) Does the general charge to the EPEC Augmented for Review of Nutrient Criteria Guidance involve a particular matter? A "particular mater" 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)]. A particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties [5 C.F.R. § 2640.102(m)].

The activity of the EPEC Augmented for Review of Nutrient Criteria Guidance in addressing the charge for peer review of the draft document *Empirical Approaches for Nutrient Criteria Derivation* will qualify 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 involved with private or public organizations facing regulatory decisions related to water quality criteria for nutrients.

- (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)]. For this review, the SAB Staff Office has determined that the SAB Committee members will be participating personally in the matter. Committee members will be providing the Agency with advice and recommendations on development of the EPA document Empirical Approaches for Nutrient Criteria Derivation, and such advice is expected to directly influence the Agency's guidance on future development of numeric nutrient water quality criteria. Therefore, participation in this review will also be substantial.
- (iii) Will there be a direct and predictable effect on SAB EPEC Augmented for Review of Nutrient Criteria Guidance members' financial interest? 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 speculative, possibility that the matter will affect the financial interest." [[5 C.F.R. § 2640.103(a)(ii)]

The SAB staff office has determined that the work this SAB committee will perform will not have a direct and predictable financial effect on any Committee member's financial interests.

(D) <u>How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R.</u> § 2635.502, apply to members of the Committee

The Code of Federal Regulations at 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 has received authorization from the agency designee." Further, § 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 for the Committee 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 committee members (including, but not limited to, EPA 3110-48 confidential financial disclosure forms) and public comment as well as their responses to the following supplemental questions (included on the EPA 3110-48 confidential financial disclosure form):

- 1. 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?
- 2. Have you had any 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.
- 3. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- 4. 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.

As a result of a review of all relevant information including financial disclosure, the responses to the four questions above, and public comments, the SAB Staff Office has determined that there are no conflicts of interest or appearances of a lack of impartiality for the members of this Committee.

(E) How individuals were selected for the Panel

The SAB Staff Office identified 27 experts to be considered for the Committee in addition to the members of the SAB EPEC. On June 23, 2009 the SAB Staff Office posted a notice on the SAB Web site inviting public comments on the EPEC members and the "short list"

of candidates for the Committee by July 14, 2009. The SAB Staff Office received comments on this "Short List" from the following members of the public:

- Dianne R. Brake, PlanSmart NJ
- Michael Delaney, Des Moines, Iowa
- Dionysios D. Dionysiou, University of Cincinnati
- Karen Hamilton, U.S. EPA Region 8
- Brian Dorn, Illinois Association of Wastewater Agencies
- John C. Hall, Hall and Associates
- Tina Laidlaw, U.S. EPA Montana Office
- Frank W. Harksen, Jr., Virginia Association of Municipal Wastewater Agencies
- Peter R. Jaffe, Princeton University
- Alan J. Rabideau, University at Buffalo
- Charles S. Spooner and Pixie A. Hamilton, National Water Quality Monitoring Council
- Rao Y. Surampalli, USPHS

The SAB Staff Office Director makes the final decision about who serves on the EPEC Augmented for Review of Nutrient Criteria Guidance, based on all relevant information. This includes a review of the member's confidential financial disclosure form (EPA Form 3110-48) and an evaluation of an appearance of a lack of impartiality. 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 general 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.

On the basis of the above-specified criteria, the members of the EPEC Augmented for Review of Nutrient Criteria Guidance are as follows:

EPEC Members

- Dr. Judith Meyer, University of Georgia (GA), Chair
- Dr. Richelle Allen-King, University at Buffalo (NY)
- Dr. Fred Benfield, Virginia Polytechnic Institute and State University (VA)
- Dr. Ingrid Burke, University of Wyoming (WY)
- Dr. G. Allen Burton, University of Michigan (MI)
- Dr. Peter Chapman, Golder Associates, (BC, Canada)
- Dr. Loveday Conquest, University of Washington (WA)
- Dr. Wayne Landis, Western Washington University (WA)
- Dr. James Oris, Miami University, (OH)
- Dr. Charles Rabeni, University of Missouri (MO)

- Dr. Amanda Rodewald, Ohio State University (OH)
- Dr. James Sanders, Skidaway Institute of Oceanography (GA)
- Mr. Timothy Thompson, Science and Engineering for the Environment (WA)
- Dr. Ivor van Heerden, Louisiana State University (LA)

Consultants

- Dr. Victor Bierman, LimnoTech (GA)
- Dr. Elizabeth Boyer, Pennsylvania State University (PA)
- Dr. Mark David, University of Illinois (IL)
- Dr. Douglas McLaughlin, National Council for Air and Stream Improvement (MI)
- Dr. Patrick Mulholland, Oak Ridge National Laboratory (TN)
- Dr. Andrew Sharpley, University of Arkansas (AR)

Concurred,

/Signed/	August 12, 2009
Vanessa Vu, Ph.D.	Date
Staff Director	
EPA Science Advisory Board (1400F)	