



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July 13, 2012

MEMORANDUM

SUBJECT: Addendum to the May 21, 2012 Memorandum: Formation of Science Advisory Board Perchlorate Advisory Panel

FROM: Thomas Carpenter /signed/
Designated Federal Officer (DFO)
EPA Science Advisory Board Staff Office (1400R)

THRU: Wanda Bright /signed/
SAB Ethics Officer
EPA Science Advisory Board Staff Office (1400R)

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

On May 21, 2012 The Science Advisory Board (SAB) Staff Office Director signed a memorandum that announced to the public the members of the SAB's Perchlorate Advisory Panel. The memorandum provided a set of determinations that were necessary for forming the SAB Panel, and described all relevant information considered in forming the Panel, including a review of the confidential financial disclosure forms and evaluation of an appearance of a lack of impartiality. Since May 21, 2012, the SAB Staff Office has received additional information regarding membership of the Perchlorate Advisory Panel. Based on review of this additional information, the members of the SAB Perchlorate Advisory Panel are as follows:

Perchlorate Advisory Panel Members

Dr. Steve Roberts, University of Florida, (FL) Chair
Dr. Grant Anderson, University of Minnesota, (MN)
Dr. Hugh Barton, Pfizer Inc. (CT)
Dr. Nancy Carrasco, Yale University (CT)
Dr. Claude Emond, University of Montreal (QC)
Dr. Jeffrey Fisher, U.S. Food and Drug Administration (NC)
Dr. Mary Fox, Johns Hopkins University (MD)
Dr. Wendy Hieger-Bernays, Boston University (MA)
Dr. Julie Herbstman, Columbia University (NY)
Dr. David Hoel, Exponent (SC)
Dr. Judy Lakind, Lakind Associates (MD)
Dr. Paul Lipkin, Johns Hopkins University School of Medicine, (MD)
Dr. Jennifer Peck, University of Oklahoma (OK)
Dr. Joanne Rovet, The Hospital for Sick Children (ON)
Dr. Cheryl Stein, Mount Sinai School of Medicine (NY)

Concurred,

/signed/
Vanessa Vu, Ph.D.

7/13/2012
Date



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May 21, 2012

MEMORANDUM

SUBJECT: Formation of Science Advisory Board Perchlorate Advisory Panel

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Designated Federal Officer (DFO)
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The U.S. Environmental Protection Agency (EPA) Office of Water requested the Science Advisory Board to review the scientific and technical bases for approaches to derive a maximum contaminant level goal (MCLG) for perchlorate. In 2011, EPA announced its decision (76 FR 7762–7767) to regulate perchlorate under the Safe Drinking Water Act (SDWA) and publish a proposal no later than February 2013. SDWA requires EPA to request comments from the SAB prior to proposal of an MCLG and national primary drinking water regulation. Therefore, the Office of Water requested an SAB review of the approaches, supporting data and information to develop an MCLG for perchlorate.

The EPA will charge the SAB with reviewing the available data and information to support an MCLG for perchlorate. The Panel will be asked to consider exposed individuals at different life stages, epidemiologic and biomonitoring data, and physiologically based pharmacokinetic (PBPK) analyses. EPA identified available studies on perchlorate to inform the MCLG published since the National Academy of Sciences 2005 report *Health Implications from Perchlorate Ingestion*. The Agency requests advice on interpretations of the PBPK model results and approaches for applying the PBPK model results to develop an MCLG. The Agency also asks for

advice in considering these multiple lines of information in selecting approaches to develop an MCLG. EPA also seeks additional studies not considered by the Agency for MCLG approaches.

This memorandum addresses the set of determinations that were necessary for forming the SAB Perchlorate Advisory Panel, including:

- (A) The type of review body that will be used to conduct the review, and the nature of the review;
- (B) The list of candidates to be considered for the panel;
- (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 Panel; and
- (E) The selection of Panel members.

DETERMINATIONS:

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

An *ad hoc* panel, composed of subject matter experts, will be formed under the auspices of the Science Advisory Board to provide advice and recommendations through the chartered SAB to EPA on the scientific and technical basis for approaches to develop a maximum contaminant level goal for perchlorate.

- (B) The list of candidates considered for the Panel.

The SAB Staff Office announced in a *Federal Register* notice (76 FR 78256-78257) published on December 16, 2011 that it was forming an *ad hoc* SAB panel to review the information available to support approaches to develop an MCLG for perchlorate. To form the panel, the EPA SAB Staff Office sought public nominations of nationally recognized and qualified experts in one or more of the following areas; drinking water, public health, epidemiology, toxicology, endocrinology, requirements and approaches to derive MCLGs, PBPK models, and health implications of perchlorate ingestion. The SAB Staff Office identified 49 candidates based on their relevant expertise, willingness to serve, and response to the *Federal Register* Notice. On March 9, 2011, the SAB Staff Office posted a notice on the SAB Web site inviting public comments on the List of Candidates for the Panel by March 30, 2011. The SAB Staff Office received comments on the candidate list from the following members of the public:

- Mr. Jim Rollins, Perchlorate Study Group
- Ms. Danielle Blacet, Association of California Water Agencies
- Mr. Peter Grevatt, U.S. EPA, Office of Children’s Health Protection
- Dr. Bruce Macler, U.S. EPA, Region 9

(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.

(a) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: The principal interested and potentially affected parties for this topic are: (1) federal, state, and local government agencies, elected officials, industries, and non-government organizations involved in the development of drinking water regulations or remediation of sites including perchlorate, (2) public water systems, (3) business and industries involved in the manufacture or use of perchlorate, and (4) 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 MCLG for perchlorate.

(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 SAB’s Perchlorate Advisory Panel 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)]. 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 Perchlorate Advisory Panel review of information to support the development an MCLG for perchlorate 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 involved with private or public organizations facing regulatory decisions related to the release of or exposure to perchlorate or perchlorate-like compounds.

(ii) Will there be personal and substantial participation on the part of the Panel 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 Panel members will be participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations on the approaches to address exposure and human health assessment of perchlorate, and such advice is expected to directly influence the Agency's guidance on risk assessment and risk management decisions involving perchlorate or perchlorate-like compounds. *Therefore, participation in this review will also be substantial.*

(iii) Will there be a direct and predictable effect on a Panel member's 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)]

Prospective candidates for the Panel were evaluated against the requirements of 5 C.F.R. § 2640.101(a), using each candidate's confidential financial disclosure form (EPA Form 3110-48), to determine whether the work of the Panel will have a direct and predictable effect on his or her financial interests.

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

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."

Prospective candidates for the Panel 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.

Prospective candidates were directed to respond to the questions with respect to perchlorate exposure and health effects of perchlorate from drinking water. The DFO informed candidates that the review would include a white paper describing studies on the health effects of perchlorate ingestion since the NAS publication of *Health Implications of Perchlorate Ingestion* (2005). EPA also identified 11 specific studies for the panel to consider. Candidates were provided a list of the 11 key studies to be reviewed. The studies are listed in Attachment 1. The DFO asked candidates to consider the review document, specific studies, and any involvement in the development of a regulations, standards, or health goals for perchlorate in their responses to the four supplemental questions.

(E) The selection of Panel members

The SAB Staff Office Director makes the final decision about who serves on the Perchlorate Advisory Panel, 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, and application of criteria to ensure a balanced panel. On the basis of a review of all relevant information including: each candidate's confidential financial disclosure form (EPA Form 3110-48); the responses to the four questions above; information independently gathered by the SAB staff; 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 Panel.

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 scientific expertise, and viewpoints.

Based on the above-specified criteria, the members of the Perchlorate Advisory Review Panel are as follows:

Perchlorate Advisory Panel Members

Dr. Steve Roberts, University of Florida, (FL) Chair
Dr. Grant Anderson, University of Minnesota, (MN)
Dr. Hugh Barton, Pfizer Inc. (CT)
Dr. Nancy Carrasco, Yale University (CT)
Dr. Claude Emond, University of Montreal (QC)
Dr. Jeffrey Fisher, U.S. Food and Drug Administration (NC)
Dr. Mary Fox, Johns Hopkins University (MD)
Dr. Sean Hays, Summit Toxicology (CO)
Dr. Wendy Hieger-Bernays, Boston University (MA)
Dr. Julie Herbstman, Columbia University (NY)
Dr. David Hoel, Exponent (SC)
Dr. Judy Lakind, Lakind Associates (MD)
Dr. Paul Lipkin, Johns Hopkins University School of Medicine, (MD)
Dr. Jennifer Peck, University of Oklahoma (OK)
Dr. Joanne Rovet, The Hospital for Sick Children (ON)
Dr. Cheryl Stein, Mount Sinai School of Medicine (NY)

Concurred,

/signed/

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

5/25/12

Date

Attachment 1
Specific Studies Identified by the Office of Water
For the Perchlorate Advisory Panel to Consider

- Amitai, Y., G. Winston, J. Sack, J. Wasser, M. Lewis, B.C. Blount, L. Valenti-Blasini, N. Fisher, A. Israeli, and A. Leventhal. 2007. Gestational exposure to high perchlorate concentrations in drinking water and neonatal thyroxine levels. *Thyroid* .17(9):843-850.
- Blount, B.C., J.L. Pirkle, J.D. Osterloh, L. Valentín-Blasini, and K.L. Caldwell. 2006. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. *Environ. Health Perspect.* 114(12):1865-1871.
- Huber, D.R., B.C. Blount, D.T. Mage, F.J. Letkiewicz, A. Kumar, and R.H. Allen. 2011. Estimating perchlorate exposure from food and tap water based on U.S. biomonitoring and occurrence data. *J. Expo. Sci. Environ. Epidemiol.* 21(4):395-407.
- Dasgupta, P.K., A.B. Kirk, J.V. Dyke, and S. Ohira. 2008. Intake of iodine and perchlorate and excretion in human milk. *Environ Sci. Technol.* 42:8115-8121.
- Kirk, A.B., P.K. Martinelango, K. Tian, A. Dutta, E.E. Smith, and P.K. Dasgupta. 2005. Perchlorate and iodide in dairy and breast milk. *Environ. Sci. Technol.* 39(7):2011-2017.
- Mendez, W., E. Dederick, and J. Cohen. 2010. Drinking water contribution to aggregate perchlorate intake of reproductive-age women in the United States estimated by dietary intake simulation and analysis of urinary excretion data. *J. Expo. Sci. Environ. Epidemiol.* 20(3):288-297.
- Pearce, E.N, J.H. Lazarus, P.P.A. Smyth, X. He, D. Dall’Amico, A.B. Parkes, R. Burns, D.F. Smith, A. Maina, J.P. Bestwick, M. Jooman, A. M. Leung, and L.E. Braverman. 2010. Perchlorate and thiocyanate exposure and thyroid function in first-trimester pregnant women. *J. Clin. Endocrinol. Metab.* 95(7):3207-3215.
- Pearce, E.N., C.A. Spencer, J.H. Mestman, R.H. Lee, L.M. Bergoglio, P. Mereshian, X. He, A.M. Leung, and L.E. Braverman. 2011. Effect of environmental perchlorate on thyroid function in pregnant women from Cordoba, Argentina, and Los Angeles, California. *Endocr. Pract.* 17(3):412-417.
- Steinmaus, C., M.D. Miller, and A.H. Smith. 2010. Perchlorate in drinking water during pregnancy and neonatal thyroid hormone levels in California. *J. Occup. Environ. Med.* 52(12):1217-1524.

Tellez, R.T., P. Michaud, C. Reyes, B.C. Blount, C.B. Van Landingham, K.S. Crump, and J.P. Gibbs. 2005. Chronic environmental exposure to perchlorate through drinking water and thyroid function during pregnancy and the neonatal period. *Thyroid*. 15(9):963-975.

Valentin-Blasini, L., B.C. Blount, S. Otero-Santos, Y. Cao, J.C. Bernbaum, and W.J. Rogan. 2011. Perchlorate exposure and dose estimates in infants. *Environ. Sci. Technol.* 45(9):4127-4132.