



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2009-0297; FRL-9942-98-OW]

Request for Nominations for Peer Reviewers for EPA's Biologically Based Dose-Response (BBDR) Model for Perchlorate in Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for nominations for peer reviewers.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites the public to nominate scientific experts to be considered as peer reviewers for the contractor-managed, external peer review of the draft Biologically Based Dose-Response model for perchlorate in drinking water and the draft model support document. The draft model predicts changes in thyroid hormones in sensitive life stages exposed to different dietary iodide and perchlorate levels. EPA has been working with scientists at the Food and Drug Administration to develop the model recommended by EPA's Science Advisory Board for the derivation of a maximum contaminant level goal for perchlorate in drinking water. The model integrates previous perchlorate and iodine models for thyroid hormones in formula-fed and nursing infants, as well as lactating women. The model predicts the effects of perchlorate on serum thyroid hormone concentrations in infants exposed via ingestion of formula mixed with contaminated drinking water or breast milk. EPA anticipates releasing the draft model and draft model support document for peer review and public comment in the near future (the exact date to be determined).

DATES: The nomination period for scientific experts begins on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and ends on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Any interested person or organization may nominate scientific experts to be considered as peer reviewers. Nominations should be submitted in time to arrive no later than **[insert date thirty days after date of publication in the Federal Register]**. Self-nominations will also be accepted. Nominations should be submitted to the EPA contractor, Versar, Inc., using the following email address: perchlorate@versar.com (the subject line should read: BBDR Model Peer Review). Nominations will also be accepted via U.S. Postal Service mail or by an overnight/priority mail service. Mailed nominations should be addressed to Versar, Inc., 6850 Versar Center, Springfield, VA 22151 (Attention: David Bottimore). Nominations should include all nominee information outlined in section II of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Questions concerning the nomination process should be directed to the EPA contractor, Versar, Inc., at 6850 Versar Center, Springfield, VA 22151; by email to perchlorate@versar.com (the subject line should read: BBDR Model Peer Review); or by phone: (703) 642-6815 (ask for David Bottimore). For additional information concerning the draft BBDR model and draft model support document, please contact Russ Perkinson at the U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water, Standards and Risk Management Division, (Mail Code 4607M), 1200 Pennsylvania

Avenue, NW, Washington, DC 20460; telephone: 202-564-4901; or e-mail:

perkinson.russ@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information on the Draft Biologically Based Dose-Response (BBDR) Model and Draft Model Support Document for Perchlorate in Drinking Water

EPA is developing a National Primary Drinking Water Regulation (NPDWR) for Perchlorate in accordance with the requirements under the Safe Drinking Water Act (SDWA). Among these requirements are that the agency must request comment from the EPA's Science Advisory Board (SAB) prior to proposal of a maximum contaminant level goal (MCLG) and a NPDWR (42 U.S.C. 1412(e)).

In 2012, EPA sought guidance from the SAB on how best to consider and interpret life stage information, epidemiologic and biomonitoring data, physiologically based pharmacokinetic (PBPK) analyses and the totality of perchlorate health information to derive an MCLG for perchlorate. The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MCLGs are non-enforceable public health goals.

In 2013, the SAB recommended that, “. . . EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon its mode of action rather than the default MCLG approach using the reference dose and specific chemical exposure parameters” (see Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate, EPA-SAB-13-004). The SAB

found that “. . . this data-driven approach represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages than is possible with the default approach for deriving an MCLG.”

Based on the SAB’s recommendations, EPA and Food and Drug Administration (FDA) scientists developed a BBDR (also known as a PBPK/PD) model to determine under what conditions of iodine nutrition and exposure to perchlorate across sensitive life stages low serum free and total thyroxine would result. EPA is considering deriving a perchlorate MCLG by linking BBDR model output to information from literature to account for adverse health outcomes.

II. How to Submit Nominations for Peer Reviewers

Expertise Sought: EPA is seeking candidates who are nationally and/or internationally recognized scientific experts to serve as external peer reviewers for the draft BBDR model and draft model support document for perchlorate in drinking water. Nominees should possess and demonstrate background knowledge and experience in one or more of the following areas: (1) PBPK, PBPK/PD and/or BBDR modeling, (2) fetal and neonatal thyroid endocrinology (clinical and experimental), (3) iodide homeostasis, and (4) perchlorate toxicology and mode of action or adverse outcome pathway.

Selection Criteria: Selection criteria for individuals nominated to serve as external peer reviewers of the draft BBDR model and draft model support document include the following: (1) demonstrated expertise through relevant peer reviewed publications, (2) professional accomplishments and recognition by professional societies, (3) demonstrated ability to work

constructively and effectively in a committee setting, (4) absence of financial conflicts of interest, (5) no actual conflicts of interest or the appearance of lack of impartiality, (6) willingness to commit adequate time for the thorough review of the draft BBDR model and draft model support document, commencing approximately in June 2016 (exact date to be determined), and (7) availability to participate in-person in a one-day peer review meeting in the Washington, DC metro area, projected to occur in approximately August 2016 (exact date will be published in the **Federal Register** at least 30 days prior to the external peer review meeting). Further logistical information regarding the external peer review meeting will be announced at a later date in the **Federal Register**.

Required Nominee Information: To receive full consideration, the following information should be submitted to Versar (perchlorate@versar.com) (the subject line should read: BBDR Model Peer Review): (1) contact information for the person making the nomination; (2) contact information for the nominee; (3) the disciplinary and specific areas of expertise of the nominee; (4) the nominee's curriculum vitae; and (5) a biographical sketch of the nominee indicating current position, educational background, past and current research activities, recent service on other advisory committees, peer review panels, editorial boards or professional organizations, sources of recent grant and/or contract support and other comments on the relevance of the nominee's expertise to this peer review topic. Compensation for non-federal peer reviewers will be provided by Versar.

Selection Process: EPA's contractor, Versar, will notify candidates of selection or non-selection. Versar may also conduct an independent search for candidates to assemble a balanced

group representing the expertise needed to fully evaluate EPA's draft BBDR model and draft model support document for perchlorate in drinking water. Versar will consider and screen all candidates against the criteria previously listed. Following the screening process, Versar will narrow the list of potential reviewers to approximately 10-15 candidates. Prior to selecting the final peer reviewers, a **Federal Register** notice will be published (exact date to be determined) to solicit comments on the interim list of candidates. In that notice, the public will be requested to provide relevant information or documentation on the nominees within 30 days of the announcement of the interim list of candidates. Once Versar has considered the public comments on the interim list of candidates, Versar will select the final list of peer reviewers, based on who, collectively, will best provide expertise spanning the disciplines previously listed and (to the extent feasible) best provide a balance of perspectives.

Dated: February 21, 2016.

Joel Beauvais,
Deputy Assistant Administrator.
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