6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2009-0297; FRL-9947-20-OW]

Request for Nominations for Peer Reviewers for EPA's Draft Biologically Based Dose-Response (BBDR) Model for Perchlorate, Draft Model Support Document and Draft Approach for Deriving a Maximum Contaminant Level Goal (MCLG) for Perchlorate in Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for nominations for peer reviewers.

SUMMARY: The Environmental Protection Agency (EPA) is expanding the scope of the request for nominations announced in the Federal Register on March 1, 2016. Requested nominations are for an external peer review of the draft Biologically Based Dose-Response model and the draft model support document for perchlorate in drinking water. The expanded scope will include the review of the application of the draft Biologically Based Dose-Response Model to develop a perchlorate maximum contaminant level goal. EPA is combining the two panels to achieve efficiency and transparency in evaluating the development and application of key scientific products for analyzing perchlorate in drinking water. EPA invites the public to nominate scientific experts for the peer review. Persons nominated during the previous nomination period requested in the March 1, 2016, Federal Register notice do not need to be renominated under this notice and will be considered for selection for the interim and final list of peer reviewers.

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 and Peer Review of Approach for Deriving a Perchlorate MCLG). Nominations will also be accepted via the 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 and Peer Review of Approach for Deriving a Perchlorate MCLG); or by phone: (703) 642-6815 (ask for David Bottimore). For additional information concerning the draft Biologically Based Dose-Response Model, the draft Model Support Document and the draft approach for deriving a perchlorate MCLG, 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, the Draft Model Support Document for Perchlorate and the Draft Approach for Deriving a Perchlorate Maximum Contaminant Level Goal (MCLG)

EPA has begun the process for 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 EPA's Science Advisory Board (SAB) prior to proposal of an MCLG and a NPDWR. 42 U.S.C. 1412(e). For additional background information, refer to the March 1, 2016, Federal Register notice (81 FR 10617).

Based on the SAB's recommendations, EPA, with contributions from Food and Drug Administration (FDA) scientists, developed a draft BBDR 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. The draft BBDR model integrates physiologically-based pharmacokinetic models for perchlorate with iodine models for thyroid hormones in formula-fed and nursing infants, as well as lactating women. The draft 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 is considering deriving a perchlorate MCLG by linking BBDR model output to alterations in thyroid hormone status that result in alterations in neurodevelopment. The draft approach for deriving a perchlorate MCLG outlines an assessment of the literature linking alterations in thyroid hormone status to alterations in neurodevelopment. Based on the results of this literature review, the report describes potential approaches to set the MCLG based on the availability of the current literature and the output of the BBDR model, predicting the effects of perchlorate on serum thyroid hormone concentrations in infants exposed via ingestion of formula mixed with contaminated drinking water or breast milk (see 81 FR 10617, March 1, 2016). The draft approach will be approximately 100 pages in length with approximately 7-10 figures and 10-15 tables. The draft approach describes application of the BBDR model to the development of a perchlorate MCLG and the appropriateness of the process under SDWA guidelines.

EPA anticipates releasing the draft BBDR model, draft model support document, and draft approach for peer review and public comment in the near future (the exact date to be determined).

II. How to Submit Nominations for Peer Reviewers

Expanded 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, the draft model support document, and the draft approach to derive a perchlorate MCLG. Nominees should possess and demonstrate background knowledge and experience in one or more of the following areas of risk assessment to include: an understanding of thyroid function (preferably in the sensitive life stages of interest), the importance of maternal thyroid

hormone homeostasis in each stage of gestation, hypothyroxinemia, neurodevelopmental assessment indices for young children including the Bayley's Scale, the toxicity of perchlorate, epidemiological assessment techniques, and statistics.

Expanded Selection Criteria: Selection criteria for individuals nominated to serve as external peer reviewers of the draft BBDR model, draft model support document, and draft approach to derive an MCLG for perchlorate 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, the draft model support document and the draft approach for deriving a perchlorate MCLG, commencing approximately during the summer of 2016 (exact date to be determined), and (7) availability to participate in person in a two-day peer review meeting in the Washington, DC metro area, projected to occur during the fall of 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.

Expanded 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 and Peer Review of Approach for Deriving a Perchlorate MCLG): (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.

Expanded 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, draft model support document for perchlorate, and draft approach for deriving a perchlorate MCLG. The contractor will consider and screen all candidates against the criteria previously listed. Following the screening process, the contractor will narrow the list of potential reviewers to approximately 12-18 interim 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 the contractor has considered the public comments on the interim list of candidates, the contractor will select the final list of peer reviewers based on who, collectively, will best provide expertise spanning the disciplines listed above and (to the extent feasible) best provide a balance of perspectives.

Dated: May 23, 2016.

Joel Beauvais,
Deputy Assistant Administrator.
[FR Doc. 2016-12724 Filed: 6/2/2016 8:45 am; Publication Date: 6/3/2016]