6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2019-0316; FRL-9995-04-OAR]

Request for Nominations: Scientific Peer Reviewers; Potential Approaches for Characterizing the Estimated Benefits of Reducing $PM_{2.5}$ at Low Concentrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) invites the public to nominate scientific experts to be considered as peer reviewers for the EPA-drafted report titled, "Potential Approaches for Characterizing the Estimated Benefits of Reducing $PM_{2.5}$ at Low Concentrations". A nominee, if selected, will assess the accuracy, content, and interpretation of findings of the report, ensuring that they are factual and scientifically sound. The peer review will provide input to EPA regarding the merits of the technical approaches.

DATES: The nomination period begins on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and ends on **[INSERT DATE 21 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit the nominations, identified by docket ID number EPA-HQ-OAR-2019-0316. In addition, the nomination must include the nominee's full name, address, affiliation, telephone number, email address, and a statement on the nominee's expertise. Use one of the following submission methods:

- Federal eRulemaking Portal: *https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting nominations

- Email: *a-and-r-Docket@epa.gov*. Include the Docket ID No. EPA-HQ-OAR-2019-0316 in the subject line of the message.
- Fax: (202) 566-9744. Include the Docket ID No. EPA-HQ-OAR-2019-0316 in the subject line of the message.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Office of Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Avenue. NW, Washington, DC 20460.
- Hand Delivery/Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. – 4:30 p.m., Monday – Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this Notice. Submissions received may be posted without change to *https://www.regulations.gov*, including any personal information provided. For detailed instructions on sending submissions, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Neal Fann, Health and Environmental Impacts, Office of Air Quality Planning and Standards (C-439-02), Environmental Protection Agency, 109 T.W. Alexander Drive, Durham, NC 27711. Phone: (919) 541-0209, Fax: (919) 541-5315, Email: *Fann.Neal@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

Submit your nomination, identified by Docket ID No. EPA-HQ-OAR-2019-0316, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, submissions cannot be edited or removed from the

docket. The EPA may publish any submission received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written submission. The written submission is considered the official submission and should include discussion of all points you wish to make. The EPA will generally not consider submissions or submission content located outside of the primary submission (i.e., on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. Background

The EPA uses evidence from long-term exposure cohort studies to estimate the number of $PM_{2.5}$-related premature deaths and morbidity effects in its air pollution benefits analyses. Generally, the U.S. EPA quantifies effects for the full distribution of ambient $PM_{2.5}$ concentrations, including at concentrations below the lowest measured levels (LML) of these studies; this reflects the current scientific evidence, which does not find a threshold in the concentration-response relationship. However, because of the absence of data at such low concentrations, there is greater uncertainty about the likelihood of health effects, including premature death. The degree of uncertainty associated with premature deaths estimated at these lower levels has over time taken on greater prominence, due in part to decreasing ambient $PM_{2.5}$ concentrations, the public health importance of $PM_{2.5}$-associated mortality, and the magnitude of the economic value of the effect. As a means of improving its methods for quantifying and characterizing effects estimated at these lower $PM_{2.5}$ levels, the Agency is developing and

evaluating potential alternative approaches for estimating these effects. Potential approaches will be described in a U.S. EPA report. This report will: detail new techniques for deriving information regarding uncertainty at low $PM_{2.5}$ concentrations using data available from the peer-reviewed published epidemiology literature; demonstrate the application of these techniques in an example $PM_{2.5}$ air pollution benefits assessment; discuss the strengths and weaknesses of each technique; and, compare these techniques against alternatives including the use of lowest measured level cut-points or the use of meta-analytic approaches designed to characterize the magnitude of the PM mortality effect across a broader array of concentrations. This report will be subject to an independent, contractor-led peer review.

The EPA identified the "Potential Approaches for Characterizing the Estimated Benefits of Reducing $PM_{2.5}$ at Low Concentrations" as a Highly Influential Scientific Assessment, and according to the Agency's *Science and Technology Policy Council, Peer Review Handbook* (Fourth Edition, EPA/100/B-15/001, 2015) (Agency's *Peer Review Handbook*), is required to conduct an external peer review of that report and supplemental files. The reviewers are asked to assess the accuracy, content, and interpretation of findings ensuring that they are factual and scientifically sound. The review shall generate comments from the individual expert reviewers.

A synopsis of the report may be found on the project website: *https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/PM_Uncertainty*. The Agency will periodically update this website to include the full technical report, public comments on the selected peer reviewers and peer reviewer comments on the technical report.

III. Expertise Sought

Any interested person or organization may nominate him or herself or any qualified individual in the areas of expertise described below. Peer reviewers should have: (1) published 5

or more manuscripts in one more relevant manuscripts in journals with an impact factor of 5 or greater; and (2) demonstrated expertise in one or more of the following areas:

A. *Air pollution epidemiology*. Author or co-author of multiple studies that examined the relationship between long-term air pollution exposure and mortality or morbidity in a large cohort.

B. *Air pollution biostatistics*. Intricate knowledge of the development of new and innovative statistical methods to examine the relationship between air pollution and human health. This knowledge is reflected in the individual's publication record, and by leading or co-leading the development of statistical models used in epidemiologic studies examining the health effects of either short- or long-term air pollution exposure.

C. *Risk assessment and benefits analysis*. Expertise in the best practices for expressing the probability of population-level adverse outcomes expected to occur due to changes in environmental stressors. This knowledge will have been reflected by the individual having led studies interpreting and applying novel approaches in the epidemiology literature to characterize population risks. Expertise in the best practices for estimating the economic value of uncertain air pollution-related effects, including the risk of premature death. Expertise in characterizing uncertainty in the value of reducing the risk of adverse effects.

D. *Decision sciences and uncertainty analysis*. Expertise in using quantitative techniques to inform decision-making in a public health, public policy or regulatory context. Expertise in both frequentist and Bayesian techniques of uncertainty analysis.

E. *Economics*. Expertise in econometrics, particularly in using these techniques to analyze time series data and panel data. Expertise in running survival models and in performing large-scale quantitative meta-analyses. Expertise in welfare economics.

IV. Peer-Review Panel Selection Criteria

Selection criteria for individuals nominated to serve as external peer reviewers include the following:

A. Demonstrated expertise through relevant peer reviewed publications.

B. Professional accomplishments and recognition by professional societies.

C. Demonstrated ability to work constructively and effectively in an advisory panel setting.

D. Absence of financial conflicts of interest.

E. No actual conflicts of interest or the appearance of lack of impartiality.

F. Background and experiences that would contribute to the diversity of viewpoints on the panel, e.g., workforce sector; geographical location; social, cultural, and educational backgrounds; and professional affiliations.

G. Willingness to commit adequate time for the thorough review of the draft external peer review document in July–August 2019 (exact date to be determined).

H. Availability to participate in-person in a 1-day peer review meeting in Research Triangle Park, NC in August or September 2019 (exact date will be published in the *Federal Register* at least 30 days prior to the external peer review meeting).

Further information regarding the external peer review meeting will be announced at a later date on the project website here*: https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/PM_Uncertainty*.

V. Peer-Review Panel Selection Process

The EPA contractor will follow the Agency's Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA Highly Influential Scientific Assessment (HISA) and Influential Scientific Information (ISI) documents (*https://www.epa.gov/sites/production/files/2015-01/documents/epa-process-for-contractor_0.pdf*) and *Peer Review Handbook* (*https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015*) to select the peer-review panel. After candidates are nominated subsequent to this *Federal Register* notice, the EPA contractor will follow-up with nominees and request additional information such as:

A. The disciplinary and specific areas of expertise of the nominee.

B. The nominee's curriculum vitae.

C. 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.

The EPA contractor may also conduct an independent search for candidates to assemble a balanced group representing the expertise needed to fully evaluate EPA's draft report and supplemental materials. The EPA contractor will consider and screen all candidates against the criteria listed in Unit III and the Agency's Conflict of Interest (COI) and appearance of bias guidance with the Agency's *Peer Review Handbook*, available online at: *https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015*. Following the screening

process, the EPA contractor will narrow the list of potential reviewers. Prior to selecting the final peer reviewers, a second *Federal Register* notice will be published to solicit comments on the interim list of 7-10 candidates. The public will be requested to provide relevant information or documentation on the nominees that the EPA contractor should consider in evaluating the candidates within 21 days following the announcement of the interim candidates. Once the public comments on the interim list of candidates have been reviewed, the EPA contractor will select the final peer reviewers who, collectively, best provide expertise spanning the multiple areas listed in Unit III and, to the extent feasible, best provide a balance of perspectives. The EPA contractor will ultimately notify candidates of selection or non-selection. Compensation of non-Federal peer reviewers will be provided by the EPA contractor.

Dated: June 7, 2019.

Panagiotis Tsirigotis,

Director,

Office of Air Quality Planning and Standards.

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