



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD
STAFF OFFICE

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MEMORANDIUM

SUBJECT: Formation of the per- and polyfluoroalkyl substances (PFAS) Review Panel under the Science Advisory Board (SAB)

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EPA has made final determinations to regulate two contaminants, perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA). EPA is currently moving forward to implement the national primary drinking water regulation development process for PFAS. The Regulatory Determinations outline avenues that the agency is considering to further evaluate additional PFAS chemicals and provide flexibility for the agency to consider groups of PFAS as supported by the best available science.

EPA documents are being developed to support EPA's National Primary Drinking Water Rulemaking for per- and polyfluoroalkyl substances (PFAS). These draft documents will describe EPA's prepared analyses of health effects data that will inform the derivation of proposed Maximum Contaminant Level Goals for PFOS and PFOA. Additionally, the documents will include elements from EPA's assessment of the health risk reduction benefits of potential reductions in drinking water concentrations of PFOA and PFOS for targeted health endpoints. The documents will also include a framework for estimating health risks associated with PFAS mixtures.

This memorandum addresses the set of determinations that were used in forming the per- and polyfluoroalkyl substances (PFAS) Review Panel under the Science Advisory Board.

1. The type of review body that will be used to conduct the review, and the nature of the review;
2. The types of expertise needed to address the general charge;
3. Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
4. How regulations concerning “appearance of a loss of impartiality” pursuant to 5 C.F.R. § 2635.502 apply to members of the augmented committee;
5. Other considerations that might affect the objectivity of members of the augmented committee; and
6. How individuals were selected for the augmented committee.

DETERMINATIONS:

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

The per- and polyfluoroalkyl substances (PFAS) Review Panel consists of members of the SAB Chemical Assessment Advisory Committee (CAAC) and the SAB Economic Analysis Committee (EAC) augmented with subject matter experts to provide advice through the chartered SAB. The chair of the Panel will be a member of the chartered SAB and the Panel’s report(s) will be reviewed by the chartered SAB before they are transmitted to the EPA Administrator.

2. The types of expertise needed to address the general charge.

The EPA SAB Staff Office formed the per- and polyfluoroalkyl substances (PFAS) Review Panel. The SAB Staff Office identified current members of the SAB Chemical Assessment Advisory Committee (CAAC) and the SAB Economic Analysis Committee (EAC) augmented with subject matter experts with expertise in one or more of the following areas; *Toxicology, specifically: Reproductive/ developmental, hepatic, immunology and neurotoxicology; epidemiology with expertise in: Immunology, endocrinology, reproductive/ developmental and cardiology; physiologically-based pharmacokinetic (PBPK) modeling; physician/clinician with a focus on cardiology; risk assessment; toxicity of chemical mixtures; economist with expertise in health related benefit cost analysis and valuing avoided adverse health outcomes; dose response relationships in economic models.*

3. Financial conflict of interest consideration, including identification of parties who are potentially interested in or may be affected by the topic reviewed.

- a) Identification of parties (or class of parties) whose financial interests may be affected by the matter to be reviewed:

The principal interested and affected parties as a class for this topic are: organizations involved in processes that could be considered part of the life-cycle of the chemicals (i.e., per- and polyfluoroalkyl substances (PFAS)) to be considered by the Panel (including, but not limited to, manufacture, use, distribution, treatment and disposal).

This review will focus on environmental policies regarding PFAS. *Thus, this Panel's deliberations will be focused on the interests of a discrete and identifiable class of parties.*

- 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 financial conflict of interest; however, the general provisions in the appearance of impartiality guidelines still apply and need to be considered.
- i. Does the general charge to the 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 specific party means a particular matter that is focused on the interests of a specific party [5 C.F.R. § 2640.102(m)].

The activity of the Review Panel and SAB Committee members for the purpose of addressing the charge for peer review of the EPA documents that are being developed to support EPA’s National Primary Drinking Water Rulemaking for per- and polyfluoroalkyl substances (PFAS) *will qualify as a particular matter of general applicability because the resulting advice will be part of a deliberation and under certain circumstances that 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 in processes that could be considered part of the life-cycle of the chemicals (i.e., per- and polyfluoroalkyl substances (PFAS)) to be considered by the Panel (including, but not limited to, manufacture, use, distribution, treatment and disposal).*

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 Review Panel and SAB members will be participating personally in the matter. Panel members will be providing the Agency with independent advice and recommendations on the EPA documents being developed to support EPA’s National Primary Drinking Water

Rulemaking for per- and polyfluoroalkyl substances (PFAS), and such advice is expected to directly influence the Agency's use and enhancement of these documents. Therefore, participation in this review will be substantial.

- ii. Will there be a direct and predictable effect on panel members' financial interests? 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 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)(ii)]. The ethics regulations include an exemption allowing special government employees (SGEs) serving on federal advisory committees to participate in any particular matter of general applicability where the disqualifying financial interest arises from their non-Federal employment or non-Federal prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class [5 C.F.R. § 2640.203(g)]. (This exemption does not include the interests of an SGE arising from the ownership of stock in his employer or prospective employer.)

For this review, the SAB staff office has determined that the work conducted by the Panel will not have a direct and predictable financial effect on any members financial interests.

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 financial conflict of interest; thus no COI has been identified by the SAB staff office.

4. How regulations concerning "appearance of a loss 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."

5. Other considerations that might affect the objectivity of members of the Panel.

Members of SAB panels must be scientific and technical experts who are objective and open-minded, able to engage in deliberative discussions with scientists who may have disparate perspectives. To evaluate candidates, the SAB Staff Office considers information provided by candidates (including on the EPA Form 3110-48), and information independently gathered by SAB staff.

As part of a determination that committee members are objective and open-minded on the topic of the review, and consistent with the agency's Peer Review Policy, the SAB Staff Office considers previous involvement in the matter before the augmented committee. This evaluation includes responses provided by candidates to the following supplemental questions:

- (a) 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?
- (b) Have you had any current or 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.
- (c) Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- (d) 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.

The SAB Staff Office has determined that there is no reason to believe that the members selected for the Panel would not be objective and open-minded and able to engage in deliberative discussions with scientists who may have disparate points of view on the matter before the augmented committee.

6. How individuals were selected for the panel.

The SAB Staff Office Director makes the final decision about who serves on the augmented committee based on all of the relevant information, including a review of each candidate's confidential financial disclosure form (EPA Form 3110-48), the responses to the questions above, and information independently gathered by SAB Staff.

For the SAB Staff Office, a balanced committee or panel is characterized by candidates who possess the necessary domains of scientific knowledge, relevant 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 panel member include: (a) scientific and/or technical expertise, knowledge, and experience; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality pursuant to 5 C.F.R. § 2635.502; (e) skills working on advisory committees and panels (including objectivity and open-mindedness); and (f) for the committee as a whole, diversity of scientific expertise and viewpoints.

per- and polyfluoroalkyl substances (PFAS) Review Panel members

On the basis of the above-specified criteria, the members of the PFAS Review Panel are as follows:

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|-----|----------------------------|-------------------------------------------------|
| 1. | Dr. Weihsueh Chiu, CHAIR | Texas A&M University |
| 2. | Dr. Kevin Boyle | Virginia Tech |
| 3. | Dr. Sandeep Burman | Minnesota Department of Health |
| 4. | Dr. Aimin Chen | University of Pennsylvania |
| 5. | Dr. Deborah Cory-Slechta | University of Rochester |
| 6. | Dr. Jamie C DeWitt | East Carolina University |
| 7. | Dr. Jeffrey Fisher | ScitoVation |
| 8. | Dr. James K. Hammitt | Harvard University |
| 9. | Dr. Lisa Kamendulis | University of Indiana |
| 10. | Dr. David Keiser | University of Massachusetts |
| 11. | Dr. Lala Ma | University of Kentucky |
| 12. | Dr. Sheila Olmstead | University of Texas at Austin |
| 13. | Dr. Gloria Post | New Jersey Department of Environment Protection |
| 14. | Dr. Kristi Pullen-Fedinick | Natural Resources Defense Council |
| 15. | Dr. Loren Lipworth | Vanderbilt University Medical Center |
| 16. | Dr. David Savitz | Brown University |
| 17. | Dr. Angela L Slitt | University of Rhode Island |

Concurred,

Thomas Brennan
Director and Deputy Ethics Official
EPA Science Advisory Board Staff Office (1400R)

October 7, 2021

Date