

November 23, 2021

Dr. Alison Cullen
Chair
Science Advisory Board
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Dr. Paul Gilman
Chair
Board of Scientific Counselors
Executive Committee
1200 Pennsylvania Ave. NW
Environmental Protection Agency
Washington, DC 20460

Dear Dr. Cullen and Dr. Gilman:

The undersigned organizations urge you to consider additional public input regarding underpinning science and associated approaches for developing possible categories to regulate per- and polyfluoroalkyl substances (PFAS). We support EPA's commitment in the recent [PFAS Roadmap](#) to follow the science and are pleased that the agency indicated that it would not regulate PFAS as a class. This aside, the [National PFAS Testing Strategy](#) was released in October 2021. These test orders were issued far in advance of the Agency's PFAS categorization framework that we view as essential to a logical pursuit of test orders to obtain data critical for informing the Agency about PFAS hazards, exposure, and risk. Furthermore, the strategy and test orders were developed and submitted without feedback from the impacted industries and without the scientific assessment and advice of the SAB and BOSC.

To assist with the SAB and BOSC review, the business community provides the following concepts and factors essential for the soundest scientific and technical groupings of PFAS chemistries into categories. These concepts and factors are intended to provide suggestions that will scientifically support a sound framework that regulators can use in evaluating whether and when to group substances for a variety of regulatory purposes. The list identifies questions regulators should address when examining whether and when grouping may be appropriate, even if different answers are reached for different substances or situations. These grouping principles include considerations identified by multiple sources and are consolidated here to provide a broad view of relevant issues when evaluating grouping substances, not just PFAS for regulatory purposes. Source identification appears at the end of the document in Appendix 1.

Our collective organizations ask that SAB and BOSC technical experts recommend that EPA develop potential categories based on a robust analysis of these principles and that EPA conduct this analysis as the Agency considers issuing test orders under TSCA. Through this recommendation, the public can be confident that EPA is following the best available science and not predetermining answers without appropriate evaluation. We also request that you propose to EPA that additional public deliberation and stakeholder engagement are needed, including with the business community, scientific experts, NGOs, and community leaders.

Concepts and factors:

Identification Considerations

- Can the substances included in a grouping be clearly identified?¹⁷
- Is there a validated method to test for the grouped substances or each individual substance within a group in the relevant media?¹⁷
- How many substances would be included if all criteria are applied?¹⁷

Structural Considerations

- Are the substances structurally similar?^{3, 6, 11, 13, 14} Do the substances have the same or similar functional groups?^{1, 3, 6, 7, 9, 12, 14}
- Do the substances have similar molecular weight?^{3, 6, 10, 13, 14}
- Is the physical state (solid, liquid, gas) of the substance under relevant conditions the same?¹⁷
- Are particles or supermolecular structures relevant? For example: size, shape, density, arrangement of molecules, or 3D-structure.^{4 11}

Toxicological Considerations

- Is the toxicological endpoint the same for an identified category?⁷
 - Are the substances associated with similar adverse effects (i.e., all category members are hepatotoxic and produce identical pathological changes that can be verified with dose-dependency and replication across studies?)
- Are chemistries similarly bioaccumulative?¹⁷
 - What parameters will be used to establish common bioaccumulative properties for a specific PFAS category (e.g., clearance rates, target organ tissue distribution similarities, metabolism similarities)?

Exposure Considerations^{1,2}

- Do the grouped substances have similar exposure frequency and duration?¹⁷
- Do the grouped substances present cumulative risk?¹⁷
- Is the time frame of exposure and potential for adverse effects the same?¹⁷

Ecological Considerations

- Are the fate and transport characteristics the same?^{15, 17}

- Is the level of persistence in the environment similar for the grouped substances?¹⁷
- Are the grouped substances responsive to the same remedial techniques?¹⁷
- Are the ecotoxicological effects similar?¹⁷

Quality of Evidence Considerations

- Are there uncertainties or missing data for one or more substances proposed for inclusion in a group?¹⁷
- Are there objective measures supporting data quality?
 - Have the data used to support the grouping decision been selected through a recognized assessment methodology to evaluate the quality of the literature?⁷
 - If weight of evidence or other expert judgment methods have been used, was the reasoning available for public review and comment?⁷
 - Has there been an independent scientific peer review of the grouping approach for which the public has an opportunity to comment on the proposed panelists, charge questions, and review materials?¹⁶
 - Does the independent peer review panel have the opportunity to hear public comments and ask the opinion of independent scientific experts?¹⁶
- Have data drawn from different evidence streams (e.g., in vitro, in vivo, mechanistic, animal studies) been integrated using quantitative methods?⁷

Legal and Regulatory Considerations

- Can the method of grouping be applied consistently for regulatory purposes?
- Does the grouping include substances with essential/critical uses?¹⁷

Our coalition is committed to working with regulators, Members of Congress, interested stakeholders, and technical experts to establish standards that protect human health and the environment through a risk-based approach that will accelerate clean-ups in communities across our nation. Scientifically sound groupings will help. We welcome the opportunity to discuss these issues with you during your upcoming public meetings and stand ready to assist you.

If you have any questions, please contact Chuck Chaitovitz, Vice President, Environmental Affairs and Sustainability at the U.S. Chamber of Commerce at cchaitovitz@uschamber.com.

Sincerely,

American Apparel & Footwear Association
American Coatings Association

American Forest & Paper Association
American Fuel and Petrochemical Manufacturers
American Petroleum Institute
National Association of Chemical Distributors
National Association of Printing Ink Manufacturers
National Council of Textile Organizations
National Farm Bureau Federation
National Milk Producers Federation
National Mining Association
Plastics Industry Association
PRINTING United Alliance
U.S. Chamber of Commerce

cc: Radhika Fox, Assistant Administrator, Office of Water
Dr. Michal Freedhoff, Office of Chemical Safety and Pollution Prevention
Deb Szaro, Acting Administrator, Region 1

APPENDIX 1: CITATIONS

1. European Chemicals Agency (ECHA). Grouping of Substances and Read-Across. <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across> (ECHA cites REACH Annex XI, Section 1.5 for identifying conditions for grouping).
2. European Chemicals Agency (ECHA). Work on Groups—Getting to Safer Use of Chemicals Faster. https://echa.europa.eu/documents/10162/10543934/work_on_groups_kuster_20211006_en.pdf/bfe99239-f814-b1f2-e50b-79c27380aa1a?t=1633513173424
3. European Commission. Technical Assistance Related to the Review of REACH with Regard to the Registration Requirements on Polymer Final Report (2015). <https://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf>
4. Hartmann et. al. Are We Speaking the Same Language? Recommendations for a Definition and Categorization Framework for Plastic Debris, Environmental Science & Technology, 2019, 53, 1039–1047. <https://pubs.acs.org/doi/10.1021/acs.est.8b05297>
5. National Research Council 2014. Review of EPA’s IRIS Process. Washington, D.C.: The National Academies Press. <https://doi.org/10.17226/18764>. See Box 8-1, the NRC’s list of high-priority reforms.
6. OECD (2009). Data Analysis of the Identification of Correlations between Polymer Characteristics and Potential for Health or Ecotoxicological Concern, OECD Task Force on New Chemicals Notification and Assessment, Expert Group Meeting on Polymers; 2007 Mar; Tokyo, Japan. Paris (FR). <https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf>
7. OECD (2017). Guidance on Grouping of Chemicals, Second Edition, Series on Testing & Assessment. No. 194. <https://www.oecd-ilibrary.org/docserver/9789264274679-en.pdf?expires=1635227239&id=id&accname=guest&checksum=A7791CDC142A12E13A6E6AC6820C5427>
8. OECD (2018). Considerations for Assessing the Risk of Combined Exposure to Multiple Chemicals, Series on Testing and Assessment. No. 296, Environment, Health and Safety Division, Environment Directorate.
9. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex XI, Section 1.5. https://reachonline.eu/REACH/EN/REACH_EN/articleXI.html

10. TR 133-1 – The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers). <https://www.ecetoc.org/wp-content/uploads/2019/06/ECETOC-TR133-1CF4Polymers.pdf> TR 133-2 – The Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment. <https://www.ecetoc.org/wp-content/uploads/2020/03/ECETOC-TR133-2.Polymers-Risk-Assessment.pdf> TR 133-3 – A Selection of Case Studies Addressing Different Components of Polymer Grouping and RA to Put the CF4Polymers into Practice. <https://www.ecetoc.org/wp-content/uploads/2021/10/ECETOC-TR-133-3-CF4Polymers-Case-Studies.pdf>
11. U.S. Environmental Protection Agency. National PFAS Testing Strategy. <https://www.epa.gov/system/files/documents/2021-10/pfas-natl-test-strategy.pdf>
12. U.S. Environmental Protection Agency. Office of Pollution Prevention and Toxics, Chemical Categories. https://www.epa.gov/sites/default/files/2017-12/documents/presentation_4_and_5_-_categories_sustainable_futures_december_6th_pub.pdf
13. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, TSCA New Chemicals Program (NCP): Chemical Categories. https://www.epa.gov/sites/default/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf
14. U.S. Environmental Protection Agency, Polymer Exemption Guidance Manual (1997). <https://www.epa.gov/sites/default/files/2015-03/documents/polyguid.pdf>
15. U.S. Environmental Protection Agency, Risk Assessment Forum, Framework for Cumulative Risk Assessment (2003). https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf
16. U.S. Office of Management and Budget. Final Information Quality Bulletin for Peer Review, Peer Review Bulletin 70 FR 2671-2672.
17. These principles are based on an overall review of the literature and general scientific principles that can be found in numerous supporting sources.