

August 3, 2021

Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Re: Analytical Methods Under Toxic Substances Control Act Sections 4 and 8

Dear Assistant Administrator Freedhoff:

As you know, the Environmental Protection Network (EPN) is an organization of over 550 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health, and the environment. We are writing to you to urge EPA to consider requiring industry submission of existing analytical methods not in the public domain under the Toxic Substances Control Act (TSCA) Section 8, and industry development of analytical methods to identify and quantify the presence of chemicals in products, workplaces, homes, and environmental media under TSCA Section 4. This letter builds on EPN's [PFAS Action Plan Recommendations](#) sent to Administrator Regan in April 2021.

Reliable and validated analytical methods are critical for determining exposures to chemicals and are essential for EPA's chemical risk evaluation and management under TSCA. We feel that more and improved analytical methods will also help the agency identify how to categorize Per- and Polyfluoroalkyl Substances (PFAS) for TSCA risk evaluations, recognizing that a category approach will be the most efficient and expeditious way to take action on these chemicals. EPA has the authority to require industry to routinely provide analytical methods in order to sell their product. If EPA does not require industry to provide these methods, we are concerned that EPA will have to invest its limited resources in method development, delaying risk evaluation and management of toxic chemicals for years. EPA's experience with PFAS demonstrates how the lack of analytical methods has slowed the regulation of these chemicals for decades. Since the 1990s, EPA has been aware that a number of PFAS chemicals raise concern for human health and the environment, but today EPA has final analytical methods for only 29 PFAS chemicals in drinking water and none yet finalized for these chemicals in air, surface/ground water, wastewater, soil, sediment, biosolids, and fish tissue. EPN recommends that EPA require industry to provide these methods to accelerate public health and environmental protection.

Section 8 Submission of Existing Analytical Methods

TSCA Section 8 grants EPA the authority to compel the submission of information that is "known" or "reasonably ascertainable" by chemical manufacturers and processors, including "all existing information concerning the environmental and health effects of such substance or mixture." This broad language covers submission of analytical methods, which are key to determining the presence of a chemical in products and in air, water, and soil and are therefore key to evaluating routes of exposures and potential human health and environmental impacts. EPN recommends that EPA begin using its TSCA Section 8 authority to require industry to submit test standards for their chemicals and existing analytical methods that are not in the public domain. EPN has [submitted comments](#) on EPA's proposed rule, "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances," recommending that chemical standards and existing analytical methods be added to the required submissions, but our letter

today recommends that this be required in Section 8 data call-in rules for all chemicals lacking these standards and methods.

Section 4 Development of Analytical Methods

If validated analytical methods are not available for detecting and quantifying human or environmental exposure, EPN would be supportive of EPA making a finding under Section 4 that “there is insufficient information and experience upon which the effects ... on health or the environment can reasonably be determined or predicted.” If this finding is made, Section 4(a)(1) would then direct EPA to issue a rule or order “to develop information... relevant to a determination that the manufacture, distribution in commerce, processing, use or disposal of such substance ... does or does not present an unreasonable risk of injury to health or the environment.” The authority to require the development of analytical methods applies not only to chemicals on the TSCA inventory, but also to their byproducts and transformation products—major sources of exposure that we believe would be covered by EPA’s risk evaluation and management process under Section 6.

EPN recommends that under Section 4(b)(1)(B), EPA’s test rules and orders prescribing “protocols and methodologies” for measuring the levels of a chemical in products, workplaces, the environment, or people specify the development of analytical methods to assure such measurements are accurate and reliable. Based upon our experience, we suggest that the industry-developed analytical methods include chemical standards, limits of detection and quantification, accuracy and precision, and other relevant parameters and that they be submitted to EPA for approval.

We believe the 2016 amendments to TSCA expanded EPA’s Section 4 authority to require the development of analytical methods. Throughout Section 4, Congress substituted the broader term “information” for “data” in describing the scope of test rules and orders. Congress revised Section 4(b)(2)(A) to clarify that “protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment.” In addition, Congress inserted a new Section 4(a)(2)(A) granting EPA authority to impose obligations on industry to develop information under rules and orders without making the findings required under Section 4(a)(1). Under this provision, it would be possible for EPA to require the development of new information if the Administrator determines it is needed to perform a risk evaluation under Section 6(b). The new provision also allows EPA to require such information be developed at the request of a federal implementing authority under another federal law, thus giving EPA the ability to require analytical methods needed for EPA’s water, waste, and air programs to set regulatory limits for environmental releases and discharges.

In conclusion, EPN urges EPA to routinely use TSCA Sections 4 and 8 authorities to require industry to provide chemical standards and analytical methods needed to conduct TSCA risk evaluations and prevent air, water, and waste contamination. Please contact Betsy Southerland if you have any questions regarding our recommendations.

Respectfully submitted on behalf of the EPA alumnivolunteers on the EPN TSCA team,

Michelle Roos
Executive Director
Environmental Protection Network