Alliance of Nurses for Healthy Environments --- Cape Fear River Watch
Center for Environmental Health --- Clean Cape Fear --- Earthjustice
National PFAS Contamination Coalition --- Natural Resources Defense Council
Safer Chemicals Healthy Families --- Science and Environmental Health Network
Toxic Free NC

June 23, 2021

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

Re: **Development and Submission of Analytical Methods under TSCA Sections 4 and 8**

Dear Dr. Freedhoff:

Based on recent discussions, we are concerned that EPA may believe that it lacks authority under section 4 of the Toxic Substances Control Act (TSCA) to require manufacturers to develop analytical methods to identify and quantify the presence of chemical substances in products, workplaces, homes, and environmental media. In our view, such an interpretation of TSCA would be inconsistent with the language and intent of the law and past EPA practice. We ask that you to clarify the Agency's position on this important issue. We hope you will commit to use your TSCA authority both to require industry to develop analytical methods necessary to evaluate and manage risks under the law and to require submission of such methods where they already exist but are not available to the Agency.

Reliable and validated analytical methods are critical for determining exposure to chemicals and thus are fundamental to effective risk evaluation and management under TSCA. Without the ability to compel industry to develop such methods where they are unavailable, EPA would have to invest its limited resources in method development or forego exposure information necessary for sound decisions. Per- and Polyfluoroalkyl Substances (PFAS) are a prime example of high concern chemicals that often cannot be reliably detected in waste streams, drinking water, products and people because of the absence of reliable analytical methods. As EPA devotes more attention to addressing PFAS, it will be unable to deepen its understanding of their potential for exposure and risk if these analytical gaps cannot be filled. EPA must also have access to analytical methods on PFAS developed by industry but not in the public domain.

Requiring Development of Analytical Methods under Section 4

Scope of Section 4 Authority. Section 4(a)(1) of TSCA authorizes EPA to issue rules and orders requiring industry to develop information. To justify these requirements, EPA must find that the chemical either "may present an unreasonable risk of injury to health of the environment" (section 4(a)(1) (A)(i))(I) or "is or will be produced in substantial quantities" and may have substantial environmental release or significant or substantial human exposure (section 4(a)(1)(A)(ii)(I)). EPA must then find that "there is insufficient information and experience upon which the effects [of a substance] on health or the environment can reasonably be determined or predicted." If validated methods are unavailable for accurately detecting and

quantifying human or environmental exposure, EPA will lack "sufficient information" to "determine or predict" the chemical's "effects . . . on health or the environment."

In such cases, section 4(a)(1) directs 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." Plainly, exposure data is "information relevant" to determining unreasonable risk, and EPA's authority to require industry to generate such information would be meaningless if it had no ability to require the development of analytical methods necessary to determine exposure. Moreover, 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, which can be a major source of PFAS exposure and are within the scope of EPA's risk evaluation and management authority under section 6.

Under section 4(b)(1)(B), test rules and orders must prescribe "protocols and methodologies" for developing the required information. Where the rule or order calls for measuring the levels of a chemical in products, workplaces, the environment, or people, these "protocols and methodologies" would necessarily include the development of analytical methods which assure that such measurements are accurate and reliable. Thus, the responsible company or consortium would need to specify procedures for sample collection and storage, duplicate samples, instrumentation, statistical analysis, levels of recovery, limits of detection and quantification, accuracy and precision, and other parameters. It would also be necessary to obtain a "test standard" – a compound of high purity and known concentration to calibrate equipment and assure that the samples to be analyzed are equivalent to the compound of interest. As part of EPA's review of protocols and methodologies for complying with section 4 requirements, the analytical method developed would be submitted to the Agency for approval.

Dioxin Product Testing Rule. EPA followed this process when, in 1987, it used its TSCA section 4 authority to require manufacturers and importers of 12 organic chemicals to test them for the presence of certain chlorinated and brominated dibenzo-p-dioxins and dibenzofurans. 52 Fed. Reg. 21412 (June 5, 1987). The basis for requiring testing was that these contaminants were of public health concern because of their potential for toxic effects at very low levels. Thus, analyzing products to determine their presence at these levels was critical to determine health risks to exposed populations. Because existing analytical techniques were not sufficiently sensitive, the rule required manufacturers to develop analytical methods (including test standards) meeting EPA specifications and criteria and then to use them for product testing. 40 CFR §§ 766.12-766.18. EPA issued a guidance document for developing these methods, required their submission and review by a panel of experts, and then approved them before testing began.

EPA's authority to require analytical testing under section 4 was challenged by industry but EPA rejected this challenge:

> The potential for a chemical to be contaminated with dangerous Impurities, such as [dioxins], falls within the "effects" or "characteristics" of that chemical which would be relevant to whether the chemical may present an unreasonable risk. Requiring analytical testing of the type discussed in the proposed rule- the levels at which a particular toxic contaminant, such as HDDs, is present In a chemical substance-is an important factor In any determination of unreasonable risk because it provides EPA with information from which human and environmental exposure to the contaminant can be assessed. Moreover, information on the amount of the contaminant in a chemical substance allows the Agency to better assess the hazard of that particular chemical substance. Finally, requiring chemical manufacturers to conduct such analytical chemistry testing is consistent with the well-defined Congressional intent in enacting TSCA that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the

development of such data should be the responsibility of those who manufacture and those who process such chemical substance and mixtures(.)" TSCA section 2(b)(1).

52 Fed. Reg. 21416.

Section 5(e) Analytical Requirements. EPA has also required submitters of premanufacture notices (PMNs) to develop analytical standards and methods in order to determine compliance with exposure limits in section 5(e) orders. Appendix 9 to EPA's boilerplate section 5(e) order requires the submitter to provide EPA with a validated sampling and analytical method for the new chemical substance which satisfies detailed criteria specified by the Agency. Section 5(e) orders, like section 4 testing requirements, are based on findings that "information available to the Administrator is insufficient to conduct a reasoned evaluation of the health and environmental effects of a chemical substance." Thus, if a determination of "insufficient information" can be based on the absence of reliable analytical procedures and EPA can require their development under section 5, it has equivalent authority under the parallel provisions of section 4.

Expansion of Section 4 Authority. The 2016 amendments to TSCA underscore the breadth of EPA's authority under section 4 to require development of analytical tools necessary to measure the presence of chemicals in the environment, people and products. Throughout section 4, Congress substituted the broader term "information" for "data" in describing the scope of test rules and orders. It also revised section 4(b)(2)(A) to make clear 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." Plainly, a requirement to develop analytical methods for assessing exposure would fall within this grant of authority.

Congress also inserted a new section 4(a)(2)(A) providing EPA with 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, EPA may "require the development of new information relating to a substance or mixture if the Administrator determines that the information is necessary . . . to perform a risk evaluation under section 6(b)." EPA may also require such information to be developed at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure."

The phrase "new information relating to a substance or mixture" is expansive and encompasses not only toxicity and exposure data but information necessary to its development, such as sound analytical methods. Thus, EPA could compel industry to develop such methods in anticipation of conducting a TSCA risk evaluation. Alternatively, analytic method development could be required where EPA's air, waste and water programs determine that such methods are necessary to set and implement regulatory limits for environmental releases and discharges. For example, as EPA strengthens environmental release controls and cleanup standards for PFAS, it will need significant new analytical capabilities to assure compliance and, working with EPA's media programs, OCSPP could use section 4(a)(2)(B) to direct industry to undertake their development.

Requiring Submission of Existing Analytical Methods under Section 8

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 section is plainly broad enough to require the submission of analytical methods for determining the presence of a chemical in the environment or other exposure mediums because the resulting information would "concern[] the environmental and health effects" of the subject chemical. . In the National Defense Authorization Act for Fiscal Year 2020, Congress directed EPA to issue a Section 8 data call-in rule for PFAS chemicals. EPA's

proposed data call-in, while covering many important sources of information, does not require the submission of analytical methods (including test standards) that are needed to ensure that state regulators, academic researchers, impacted communities, and others are able to identify those chemicals in products and the environment. EPA has solicited comment on whether to require the submission of analytical methods, and we urge EPA to include that requirement in its final rule.

In sum, we believe EPA has ample authority to require industry to develop and/or submit analytical methods (including standards) under TSCA sections 4 and 8, and this authority is essential in effectively evaluating and managing risks of PFAS and other chemicals under the law. We look forward to learning EPA's position on this important issue.

Please contact Safer Chemicals Healthy Families counsel Bob Sussman with any questions at bobsussman1@comcast.net.

Respectfully submitted,

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