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Re: Enhancing Use of EPA's Testing Authority Under TSCA Section 4

Dear Dr. Freedhoff:

Welcome to EPA! Thank you so much for your tremendous efforts in Congress to pass the amended Toxic Substances Control Act (TSCA). We are sure that you are working closely with career staff to take a hard look at what can be done to both repair the agency from the damage done during the Trump administration and address longer term issues at EPA. The Environmental Protection Network (EPN) is an organization comprised of over 550 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health and the environment.

As you determine next steps, we recommend that EPA more effectively utilize the expanded authority under Section 4 of the amended Toxic Substances Control Act (TSCA) to improve the science base for risk evaluations and other assessments under the law. We express concern that the Trump EPA failed to use this authority to obtain health effects and ecological data necessary for prioritization and sound and protective risk evaluations and recommend a pre-prioritization process to identify and fill data gaps before EPA is locked into the prescriptive timelines of the new law. A similar process was included in the Obama EPA's proposed prioritization framework rule but never finalized. Now is the time to revive and operationalize this concept.

Expanded TSCA Section 4 Authority

The 2016 Lautenberg Amendments to TSCA now give EPA authority to issue test orders as well as rules to require manufacturers and processors to generate information on the risks of chemical substances and mixtures. The amended law continues to allow EPA to justify testing using the long-standing risk-and exposure-based criteria in section 4(a)(1)(A). In addition, section 4(a)(2) provides authority to require testing by rule or order for a broad range of other purposes under TSCA. These include "where information is necessary to perform a risk evaluation under section 6(b)"; "for the purpose of prioritizing a chemical substance under section 6(b)"; and "at the request of another Federal implementing authority under another federal law," either administered by EPA (e.g., Clean Water Act, Safe Drinking Water Act, Clean Air Act, or Comprehensive Environmental Response, Compensation, and Liability Act) or other Federal agency (e.g.,

Occupational Safety and Health Administration or Consumer Product Safety Commission) in order "to meet the regulatory testing needs of that authority with regard to toxicity and exposure." Test rules or orders justified on these grounds can be issued without making the findings required under section 4(a)(1).

This expanded authority is a far-reaching departure from the original 1976 law, which allowed EPA to require testing only through an arduous notice and comment rulemaking process and after first making a set of three findings related to toxicity and exposure, insufficiency of available data, and the necessity of testing to generate information to determine chemical risks. Because of the constraints imposed by the law, EPA struggled to require testing under TSCA, and the amount of data generated was disappointing. Congress (and others) clearly expected that EPA's expanded authority would open the door to substantially more testing.

Implementation of the New Law

However, during the Trump administration, use of the streamlined testing authorities was minimal. To date EPA has issued test orders for only 10 chemicals in support of its risk evaluation activities. These orders have been narrow in scope, requiring only ecotoxicity studies, chemical solubility studies, and short-term occupational exposure studies. No test orders have yet been issued that require human health toxicity information even though these data are critical for informed and health-protective risk evaluations, and several of the first 10 evaluation chemicals lacked sufficient information on critical health endpoints.

We believe EPA needs to more proactively utilize Section 4 to require necessary health and safety information on chemicals. To accomplish this, the agency must establish a process that allows for early identification of data gaps on chemicals of concern, as well as for sufficient time to complete longer-duration health effects studies when needed, so that the resulting data can inform prioritization and risk evaluations under TSCA.

Importance of High-Quality and Comprehensive Health Effects Data

A robust database on human health effects is a necessary foundation for high-quality determinations of chemical risks under TSCA. For most chemicals, key human health-related information deemed necessary for a high-quality risk evaluation typically includes data on acute and subchronic effects, mutagenicity, toxicokinetics, reproductive and developmental effects, neurotoxicity, and chronic effects/cancer. Often, additional information may be needed on focused endpoints like developmental neurotoxicity and immunotoxicity. Lack of data for critical effects adds uncertainty to risk determinations and can lead to overlooking harmful health impacts. Availability of data reduces the need for database uncertainty factors used in deriving reference values such as Reference Doses (RfDs), Reference Concentrations (RfCs), or Benchmark Margin(s) of Exposure (MOEs) that serve as hazard benchmarks in agency risk assessments and TSCA existing chemical risk evaluations. There is also a need to gather information on the impact of exposure to ecological species found in aquatic and terrestrial settings.

While most risk evaluations require studies on critical health effects, the exact testing needed must be based on application of knowledge about the chemical and the human and environmental pathways that determine the nature and magnitude of release and exposure. Under such a paradigm, both the selection of studies that would be required as well as the design of the tests themselves would be influenced by other substantive and reliable information about the chemical and the category it belongs to; this includes the toxicity of chemicals

with similar activity and structure, insights into the mode of action and pharmacokinetics of the chemical, the chemical's physical and chemical properties, and fate and transport.

The Challenge of Using TSCA Section 4 to Support Prioritization and Risk Evaluations and the Consequences of Not Doing So

Section 4 authorities should be used strategically to provide timely information for prioritization and risk evaluations under TSCA. Unfortunately, this has not happened over the last four years because there has been no workable process for aligning testing under Section 4 with the TSCA requirements and deadlines for priority listings and risk evaluations.

To ensure that the chemical risk evaluation and risk management process is implemented without undue delay, the Lautenberg Amendments provide EPA with a clear mandate to review the safety of chemicals in commerce through a three-part process. The first step is prioritization; then, chemicals deemed high-priority must undergo full risk evaluations to determine whether or not the substance presents an unreasonable risk; and finally, risk management is required if EPA finds that the chemical presents an unreasonable risk for one or more conditions of use. Each of these steps comes with mandated deadlines. Prioritization must be completed in 9-12 months; risk evaluations must be completed in 3-3.5 years; and risk management rules must be promulgated in two years, or longer if limited extensions are needed.

These deadlines are incompatible with the minimum timeframes for conducting most types of health effects testing and reporting data under Section 4. These time frames vary from the shortest tests (3-6 months) to more complex human health studies (90-day subchronic human health study—15 months; 2-generation reproductive effects and fertility study—29 months; developmental neurotoxicity study—18 months; oncogenicity study—53 months). While there is a major effort ongoing in the scientific community to develop and validate new assessment methodologies that are designed to eventually replace these longer-term whole animal studies, this transition will take some years to accomplish. Animal studies have traditionally played an essential role in chemical risk assessments, and this will continue for the foreseeable future. Furthermore, one must be mindful that even the replacement assays will take time to conduct, albeit with timelines of weeks or months rather than years.

Formal prioritization begins when EPA publishes a notice in the *Federal Register* identifying a chemical substance for consideration as low or high priority. This triggers the 9-to-12-month statutory time frame for priority listing. TSCA permits only two outcomes from the priority setting process: 1) *high-priority* designation for those chemicals that may present an unreasonable risk of injury to health or the environment due to potential hazard and a route of exposure, including to vulnerable subpopulations, or 2) *low-priority* designation based on information sufficient to establish that the substance does not meet the standard for designation as high priority. Once the priority setting process has been formally initiated, EPA cannot withdraw chemicals lacking adequate data without jeopardizing its ability to list the minimum number of high-priority chemicals required under the law. This is problematic for the following reasons.

1. After a chemical enters the prioritization process, the TSCA amendments provide that if data are inadequate to determine that the chemical is low priority, the chemical must be deemed high priority by default. Since high-priority chemicals must proceed expeditiously into risk evaluation, chemicals that are assigned high priority by default have a high probability of lacking the critical data needed

for a thorough and accurate risk evaluation, potentially leading to an underestimation of risk and erroneous conclusions regarding unreasonable risk. This would, of course, run the risk of EPA deciding that one or more conditions of use do not present an unreasonable risk or taking a risk management action that is not adequately protective of human health and the environment.

2. Even where available information provides a basis to conclude that the chemical meets the TSCA high-priority criterion, this does not necessarily mean that data on the chemical's health effects are sufficient for a high-quality, comprehensive risk evaluation. If there are critical data gaps, the risk evaluation may have major uncertainties and could be under-protective or over-protective. Although the statute contemplates that EPA may require testing during the prioritization process to inform listing decisions, as a practical matter, the 9-12-month time frame precludes all but the shortest health effects studies. The result may be that EPA proceeds to the risk evaluation stage without either a full determination of data gaps or the ability to require testing to fill these gaps so that the evaluation is based on the best available science. Again, chemicals that lack data on critical endpoints may erroneously undergo risk evaluations even though a better path would be to delay prioritization until the necessary data has been generated to support a robust risk evaluation.

3. EPA's ability to fill data gaps on high-priority substances is even more constrained once the risk evaluation is initiated, when the pressure of statutory deadlines and the need for lead time for data review and analysis make it all but impossible to require health effects studies of any duration. Thus, while EPA used the Section 4 order authority for PV29 (one of the first 10 risk evaluation chemicals) and is now using it for several ongoing risk evaluations, the scope of testing is narrow and the studies required are of very short duration. To the extent that there are major human health effects data gaps, it will be impossible to fill them once the risk evaluation is underway.

4. Once EPA designates a substance as high priority and defines the scope of the risk evaluation, section 18(b)(1) of TSCA(15 U.S.C. §2617) preempts states from imposing new restrictions on the chemical while the evaluation is underway. Therefore, if EPA initiates a risk evaluation without adequate data, the agency jeopardizes the ability of states and local jurisdictions to protect the health of their citizens and their environment.

The Solution and Our Recommendation

The only approach to ensure that data are adequate for priority setting and risk evaluation is to conduct a comprehensive data needs analysis *before* initiating priority setting. The focus of this analysis would be to examine the body of literature on the chemical from the perspective of making the second finding under TSCA Section 4(a)(1): the goal would be to ascertain whether "there is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted."

Such a pre-priority process to identify data needs was actually proposed by EPA on January 17, 2017: *Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substance Control Act* (82 FR 4825). The preamble to the proposed rule recognized all of the issues and concerns that we have expressed above and states as follows:

> Another key consideration in the pre-prioritization phase is the existence and availability of risk-related information on a candidate or potential candidate chemical substance. Because EPA must complete its prioritization process within 12 months once prioritization has been initiated for a chemical substance, immediately initiate a risk evaluation for High-Priority Substance, and complete the risk evaluation within three years of initiation, EPA cannot assume that it will be able to require the generation of critical information during these time frames. Furthermore, the statute does not grant EPA the discretion to significantly delay either of these processes, pending development of information. Consequently, prior to initiating the prioritization process for a chemical substance, EPA will generally review the available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete both prioritization and risk evaluation processes. (82 FR 4831).

But regrettably, this aspect of the proposal was not included in the final procedural rule.

The benefits of the pre-prioritization process proposed by EPA in 2017 have been amply demonstrated by EPA's experience with priority setting and risk evaluations in the intervening four years. Thus, we call upon EPA to move ahead to fully describe and implement this process as soon as possible. We do not believe rulemaking is necessary to put pre-prioritization in place since it would not impose direct obligations on industry. Thus, after consultation with stakeholders, the process could be announced in the *Federal Register* and/or on EPA's TSCA website.

We recommend that EPA structure the pre-prioritization process around a list of 100-150 chemicals that are "candidates" for high-priority listing and risk evaluations. Chemicals on the 2014 TSCA Work Plan list that have not yet been selected for risk evaluations should be included because they have already been screened for hazard and exposure and determined to raise significant concerns. EPA has been working on other screening approaches for prioritization, and as they are introduced, they can also provide a source of candidate chemicals. Other EPA offices and other agencies should also propose chemicals for inclusion on the list based on their data requirements and priorities. Because of the serious concerns they present across all EPA programs, PFAS should certainly be on this list as well.

When placing chemicals on the list, EPA should trigger TSCA Section 8(d) reporting on listed chemicals so it has access to all unpublished health and safety studies. EPA would then systematically review all published and unpublished data on candidate chemicals to determine whether they should proceed to prioritization directly or require additional testing to fill data gaps. In the latter case, EPA would issue testing orders under Section 4. These orders could be based on the traditional findings in Section 4(a)(1) or, alternatively, on Section 4(a)(2)'s new authority to require testing to perform a risk evaluation, for the purposes of prioritizing a chemical, or to meet data needs under other federal laws implemented by EPA or other agencies. As chemicals advance to priority setting or become subject to testing orders, they would be removed from the list and replaced by other candidate chemicals.

In conclusion, we strongly recommend that EPA modify its existing process under TSCA to include a systematic mechanism for data adequacy analysis on candidate chemicals before they advance to prioritization and risk evaluations. This mechanism is necessary to assure that assessment of chemical safety

under the law is informed by necessary health and environment effects studies, avoiding the pitfalls that have plagued TSCA implementation in the last four years and that EPA itself anticipated and tried to address in the 2017 notice of proposed rulemaking for the prioritization process.

Respectfully submitted,

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Environmental Protection Network