

March 20, 2017

Mr. Jeffery Morris
Director
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
Via direct submission to www.regulations.gov

RE: Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act; Proposed Rule, Docket ID No. EPA-HQ-OPPT-2016-0636 (January 17, 2017)

Dear Mr. Morris:

The National Association of Chemical Distributors (NACD) submits the following comments in response to the proposed rule published by the U.S. Environmental Protection Agency (EPA) regarding docket no. EPA-HQ-OPPT-2016-0636, Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act.

About NACD

NACD is an international association of nearly 440 chemical distributors and their supply-chain partners. NACD members represent more than 85% of the chemical distribution capacity in the nation and generate 93% of the industry's gross revenue. NACD members, operating in all 50 states through nearly 1,800 facilities, are responsible for more than 155,000 direct and indirect jobs in the United States. NACD members are predominantly small regional businesses, many of which are multi-generational and family owned.

NACD members meet the highest standards in safety and performance through mandatory participation in NACD Responsible Distribution®, the association's third-party-verified environmental, health, safety, and security program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations.

EPA Should Provide Further Clarity on the Pre-Prioritization Process

Based on the information provided in the proposed rule by EPA, there is still significant uncertainty as to how the agency will make high or low priority determinations during the prioritization process. As required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the statute), EPA has proposed to select 50 percent of chemical candidates for prioritization from the list "2014 Update to the TSCA Work Plan for Chemical Assessments," but does not describe in further detail how the agency will determine where the other 50 percent of chemical candidates will be identified from, nor how the agency will select candidates from the TSCA Work Plan.

The regulated community will be significantly impacted by the prioritization process and as much information as possible is necessary for manufacturers, importers, and distributors when EPA identifies a chemical for prioritization. EPA has created a pre-prioritization step that will occur before the formal prioritization process is initiated. NACD is concerned EPA has provided limited information about how this pre-prioritization process will work. For example, beyond the reference to the TSCA Work Plan requirement, the agency has not identified clearly how EPA will select chemicals for placement on the pre-prioritization list. Another uncertainty is how long a substance will spend in pre-prioritization. Under the proposed rule, it seems possible chemicals could sit in the pre-prioritization process for long periods of time, which does not help regulated industry to prepare for prioritization. If one chemical is in the pre-prioritization stage for three years and another chemical for six months, it will be difficult for companies to determine what actions need to be taken when and what to expect.

Therefore, NACD also recommends EPA supplement this proposed prioritization process with a notice providing more details on the steps involved in pre-prioritization and provide additional time for public comment. EPA should also outline these steps with proposed date ranges for how long the agency anticipates each step in the pre-prioritization process will take. In other words, the regulated community should be able to reasonably anticipate what chemicals are likely to be published in the *Federal Register* identifying them for prioritization prior to the *Federal Register* notice.

EPA's Proposed Pre-Prioritization Stage Information Gathering Should Be Better Outlined and EPA Should Use Already Available Data When Possible

EPA has proposed to begin collecting data on chemicals during the pre-prioritization stage for ultimate risk evaluation, even though chemicals will not have been identified as high priority at that point. EPA should provide further information about when the agency will gather information during the pre-prioritization process, including how the agency will justify the data it needs to collect and how it will determine whether the information the agency currently possesses is sufficient or not.

NACD recommends that prior to ordering new data, EPA should gather any public, reasonably available information about the chemicals that are in pre-prioritization and request voluntary information to be submitted about a chemical when it enters the pre-prioritization phase. Many sources are available for this such as EPA's Chemical Data Reporting information, data already gathered for the Work Plan chemicals, and data available through other nations' programs, including the Canadian Chemical Management Program and the European Chemical Agency's REACH study summaries. EPA should only use its Section 8 and Section 4 authorities as a last resort. EPA's use of these authorities is much more appropriate for the risk evaluation stage of the process.

EPA Should Not Default Chemicals as High Priority Based on One Condition of Use

Under the proposed rule, EPA states that it can prioritize chemicals as "high priority" based on a single condition of use but that to prioritize chemicals as "low priority," the prioritization must be based on "all conditions of use."

By using this method for prioritization, the agency essentially creates a low bar for prioritizing a chemical as high priority and an extremely high bar for prioritizing a chemical as low priority. With this standard, a chemical is far more likely to become high priority than low priority simply because of this method rather than any scientific basis.

NACD is concerned about this approach and believes EPA should be able to make high priority designations and low priority designations based on one condition of use, some conditions of use, or all conditions of use. Not every chemical should be treated identically as each has different properties and different conditions of use. NACD sees the need to sometimes prioritize a chemical as high priority based on a single condition of use, but it is unreasonable to set this as a default standard for the treatment of all chemicals. NACD recommends EPA modify its thinking on conditions of use to represent the wide variety of chemicals that exist in commerce today and not create a system where chemicals, which compose every product, are automatically designated high priority.

On a related note, EPA is required to designate at least twenty chemical substances as low-priority within three and one half years after enactment but there is no requirement to continue to designate chemicals as low-priority after this time period, exacerbating the issue described in the paragraph above. However, it is in EPA's interest to continue to designate a certain minimum number of chemicals as low priority each year. By doing so, EPA will be able to use its time and resources appropriately to focus on the risk evaluations for chemicals that have been determined as high priority.

Furthermore, if EPA doesn't have enough information to designate a chemical as a low priority, the agency is required by the statute to designate the chemical automatically as high priority. This statutory requirement and the statute's limitations on the time a chemical may spend in the prioritization process will result in a system that is significantly weighted to prioritize chemicals as high priority.

EPA Should Use Section 26 Science Standards In the Development of the Prioritization Process

NACD strongly believes EPA should use science-based standards for decisions; however, EPA does not indicate it will use the required standards within the proposed rule, in fact, EPA states:

“Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA use certain scientific standards and base those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the prioritization of chemical substances, EPA is not obliged to include them in this proposed rule. By their express terms, these statutory requirements apply to EPA's decisions under TSCA section 6, without the need for regulatory action.” p. 4828, col. 1

EPA is correct that the scientific standards are relevant to the prioritization of chemical substances. One might argue that scientific standards are essential to the prioritization of chemical substances given that EPA may need to collect significant amounts of data that must

meet certain scientific standards during the pre-prioritization and prioritization process. We disagree that EPA is not obliged to include scientific standards in the proposed rule and recommend EPA include these standards in the final rule.

NACD furthermore recommends EPA provide definitions for “best available science” and “weight of the evidence” as these terms will hold EPA accountable to the science that may be used in prioritization and risk evaluations. Clear definitions of these terms will also provide needed consistency and transparency for all parties involved.

EPA Should Not Waive Issues After Final Designation of Low-Priority Substance

In the proposed rule, EPA states its intention to require that all comments that could be raised on the issues in a proposed low priority designation must be presented during the comment period and that any issue not raised will be considered to be waived. EPA then states that these issues “may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.” For the agency to automatically not consider new information about any chemical is inappropriate, and NACD recommends EPA modify its approach to state that it will consider new information that is relevant to a chemical’s designation at any time.

EPA Should Provide Further Clarity on How the Agency Will Consider Small Businesses During the Prioritization Process

EPA does not provide any information in the proposed rule as to how the agency will consider small businesses that may be involved in the prioritization process, such as through test orders. The agency did not conduct a Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) panel prior to proposing the prioritization proposed rule. Given the rapid timetable mandated by the statute, it is understandable that EPA may not have had enough time to conduct a SBREFA panel. Instead, the Small Business Administration (SBA) Office of Advocacy held a small business roundtable workshop on the prioritization and risk evaluation proposed rules for a half-day with EPA’s participation on February 17, 2017.

During this meeting, EPA presented on the prioritization and risk evaluation proposed rules; however, the presentations did not outline the impacts on small businesses. Largely, the questions after the presentations focused on various provisions within the proposed rules and did not focus on the challenges that small businesses might experience working and complying with the proposed rules. Given this, we strongly believe EPA should provide further information about how the agency will reach out to small businesses to educate them about the rule and how EPA will involve small businesses that may be affected at each stage in the prioritization process. For example, in the prioritization phase, EPA should solicit additional input from small businesses and collaborate with SBA and/or Office of Advocacy to provide opportunities for small business input including, but not limited to, SBREFA panels, the Environmental Roundtables held at SBA Office of Advocacy, etc.

NACD notes that EPA has not designated a chemical in decades and the supply chain, the business models, and the number of involved entities have significantly changed since then. Although EPA may be accustomed to working with manufacturers, the ripple effect of this proposed rule on prioritization and the subsequent proposed designations of various chemicals

will be felt down the supply chain. EPA should recognize that it will likely encounter many newly regulated entities and prepare accordingly. NACD also recommends the agency outline a plan for how EPA will involve all downstream entities when prioritizing a chemical.

Conclusion

NACD appreciates EPA's consideration of our comments on the prioritization of chemicals proposed rule. If you have questions or need additional information about the comments, please do not hesitate to contact me.

Sincerely,



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