Before the United States Environmental Protection Agency A Long-Term Approach for Organizing the TSCA Chemical Inventory Docket EPA-HQ-OPPT-2018-0659

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments regarding EPA's long-term approach for identifying high- and low-priority chemical substances for risk evaluation under the Toxic Substances Control Act ("TSCA"), as described in EPA's September 27, 2018 document titled, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization" ("Pre-Prioritization Whitepaper").¹

CUC is an association of companies from diverse industries interested in chemical regulatory policy from the perspective of entities that typically acquire and use, rather than manufacture or import, chemical substances.² CUC encourages implementing chemical-regulatory policies in a manner that enables technological innovation and encourages sustainable economic development while protecting human health and the environment. CUC has consistently supported the successful implementation of the 2016 amendments to TSCA in a manner that assures the various TSCA programs are both effective and efficient.

CUC is submitting these comments to specifically encourage EPA's efforts to establish a long-term approach for identifying high- and low-priority chemical substances for risk evaluation under TSCA ("Pre-Prioritization") which leverages the experience gained and information already gathered in the context of ongoing categorization and prioritization efforts in other countries and markets (e.g., Canada, Australia, the European Union). CUC requests EPA to consider how it can make the best use of these credible programs and processes, as well as its own efforts by drawing from the Agency's prior work in identifying low-risk substances in various TSCA and Pollution Prevention programs. CUC also recommends the Agency make clear in its *pre*-prioritization efforts how EPA will consider the statutory criteria in the amended Section 6(b)(1) when evaluating substances and developing bins to prepare for formal prioritization. Finally, CUC recommends that EPA be mindful that the availability of data should not, in and of itself, elevate a substance for prioritization based on the "information availability" portion of the Agency's long-term prioritization approach, as this may unnecessarily focus EPA's limited resources on detailed scrutiny of substances that ultimately may be of low concern, and doing so may ultimately deter manufacturers and processors of chemical substances from voluntarily developing (and sharing with EPA) hazard- and exposure-related data.

¹ A Working Approach for Identifying Potential Candidate Chemicals for Prioritization, EPA Office of Chemical Safety and Pollution Prevention (Sept. 27, 2018), <u>https://www.epa.gov/sites/production/files/2018-</u>09/documents/preprioritization white paper 9272018.pdf ("Pre-Prioritization Whitepaper").

² The members of CUC are Airbus S.A.S., The Boeing Company, General Electric Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, and United Technologies Corporation.

Leveraging Ongoing Categorization Efforts Elsewhere and Prior EPA Work

Data and outcomes derived from the Agency's own efforts to categorize and prioritize chemical substances for "safer" recognition or regulatory exemptions in the U.S. as well as sorting and prioritizing efforts undertaken in other countries and markets (e.g., Canada, the EU, and Australia) should inform EPA's approach to pre-prioritization. This will ensure more efficient use of EPA resources and to provide for greater consistency for regulated entities.

<u>Make Use of EPA-Identified Lower Risk Substances for Binning</u>. EPA should capitalize on its considerable effort and successful experiences in identifying substances that should be considered obvious candidates in any pre-prioritization "binning" process for *low-priority* designations. Accordingly, EPA has established already a foundation for identifying for preprioritization (and binning) any substance on the TSCA Inventory that has a "polymer flag" or that can be determined qualifies for the "Polymer Exemption" from the Section 5 new chemicals notification process.³ Similarly, the Agency could consider for low-priority designation (or place into some "not high" priority "bin") the substances recognized by the Agency as "safer" due to their inclusion on the Safe Chemicals Ingredients List (SCIL).⁴

<u>The Canadian Example</u>. When EPA first presented its possible approaches for identifying potential chemical substances for prioritization in December 2017, EPA noted that Canada was also undertaking an exercise to categorize chemical substances active in Canadian commerce.⁵ CUC supports the Agency in seeking to make use of the outcomes achieved in Canada, and the efficiencies that can be gained by drawing upon those efforts. Between 1999 and 2006, Canada reviewed 23,000 chemical substances.⁶ Of these, Canada identified approximately 4,300 chemical substances as needing further attention based on their "persistence, bioaccumulation and inherent toxicity to the environment," and "potential for exposure and inherent toxicity to humans."⁷ Since 2006, Canada has completed draft and final risk assessments for 3,534 of the 4,300 chemical substances, and has implemented 90 "risk management actions" in connection with these risk assessments.⁸ CUC considers these outcomes to lend themselves to direct application in the "binning" process that is still taking shape at EPA.

https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/domestic/domestic-list.html (last updated June 7, 2018).

³ Safer Chemicals Ingredients List, EPA, <u>https://www.epa.gov/saferchoice/safer-ingredients</u> (last updated Sept. 27, 2018).

⁴ *Id*.

⁵ Agenda: Possible Approaches for Identifying Potential Candidates for Prioritization, EPA (Dec. 11, 2017), <u>https://www.epa.gov/sites/production/files/2017-11/documents/final_agenda_for_12.11.17_pre-</u> prioritization_meeting_v2.pdf.

⁶ Canada's Chemicals Management Plan, Approaches to Prioritization and to Streamlined Assessments, Health Canada & Environmental and Climate Change Canada (Dec. 11, 2017),

https://www.epa.gov/sites/production/files/2017-12/documents/us_epa_cmp_deck__december_2017_v4.pdf. ⁷ Categorizing Substances on the Domestic Substances List, Government of Canada,

⁸ Chemicals Management Plan: Progress Report, Government of Canada (Summer 2018), <u>https://www.canada.ca/content/dam/eccc/documents/pdf/pded/chemicals-management-plan-(cmp)-progress-report/cmp-progress-report-summer-2018.pdf</u>.

Designations in the EU. In the European Union, the REACH regime permits member states and the European Chemicals Agency can propose additions to the Candidate List of Substances of Very High Concern for Authorisation ("Candidate List"). Chemical substances may be proposed for addition to the Candidate List if they meet criteria which are inclusive of the TSCA Section 6(b)(1)(A) factors: carcinogenic, mutagenic, toxic for reproduction, or persistent, bioaccumulative, and toxic, among other criteria.⁹ At least every other year, the European Chemicals Agency must submit recommendations to the European Commission regarding the prioritization of chemical substances for regulation to reduce the risk to human health and the environment from the chemical substances.¹⁰ Factors in prioritization for risk reduction measures include the persistence, bioaccumulation and toxicity of a chemical substance.¹¹ Similarly, CUC advocates that EPA should consider these outcomes for use in identifying higher-priority substances in the pre-prioritization "binning" process being defined at the Agency.

Australian Experience. The Australian Inventory Multi-Tiered Assessment and Prioritisation ("IMAP") framework was developed to assess industrial chemicals registered on the Australian Inventory of Chemical Substances.¹² The IMAP framework has three tiers of risk assessments. The first tier of risk assessment ("Tier I assessment") involves a "high throughput" assessment of risk and exposure to human health and the environment.¹³ Chemical substances may be excluded from further assessment if they are not expected to pose a concern to human health and the environment based on the Tier I assessment.¹⁴ The second tier of risk assessment ("Tier II assessment") involves a chemical-by-chemical assessment of risk and exposure to human health and the environment. If, following a Tier II assessment, a chemical may pose a concern to human health or the environment, Australia's National Industrial Chemicals Notification and Assessment Scheme ("NICNAS") may recommend risk management measures, or may choose to conduct an in-depth assessment of the chemical ("Tier III assessment"). Following the completion of a Tier III assessment, NICNAS must determine that a chemical substance does not pose a concern to human health and the environment, or recommend risk management measures. As with the EU approach noted above, the relevant factors in Australia for determining whether a chemical substance presents a concern to human health or the environment under IMAP include numerous factors harmonized with the TSCA criteria: carcinogenicity, neurotoxicity, and persistence, bioaccumulation, and toxicity of a chemical substance.

The categorization and prioritization approaches in Canada, the EU, and Australia apply many of the same criteria EPA has stated it will consider when refining its long-term approach to pre-prioritization, including persistence, bioaccumulation and toxicity of a chemical substance,

⁹ Commission Regulation 1907/2006 of 18 Dec. 2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Article 57, 2006 O.J. (L 396).

¹⁰ *Id.* at Article 58.

¹¹ Id.

¹² National Industrial Chemicals Notification and Assessment Scheme, Australian Government Department of Health (Aug. 27, 2013), <u>https://www.nicnas.gov.au/__data/assets/word_doc/0019/37036/IMAP-Framework.docx</u> ("IMAP Framework").

 $^{13^{13}}$ Id. at 11-12.

¹⁴ *Id.* at 12.

and exposure potential.¹⁵ Thus, the methods and outcomes of the categorization and prioritization efforts in these jurisdictions lend themselves to use during EPA's pre-prioritization approach, especially when binning substances in higher priority bins to potentially enter more formal prioritization. CUC urges EPA to consider whether other countries have found a chemical substance to be likely to pose a risk to human health and the environment, and to incorporate previously developed data that have been relied upon by these other countries when "binning" chemical substances for TSCA purposes.

This approach will allow EPA to undertake pre-prioritization of chemical substances with a reduced burden on Agency resources. Additionally, many manufacturers and users of chemical substances, like CUC's members, operate in multiple jurisdictions outside of the United States, and their products are subject to regulatory requirements in numerous countries. Competing regulatory requirements put a burden on manufacturers and users of chemical substances, and can hinder innovation in this sector. CUC believes that by leveraging categorization and prioritization efforts already underway in Australia, Canada, and the EU, EPA can comply with the chemical substance prioritization requirements of TSCA while minimizing the burden on manufacturers and users of chemical substances.

Incorporating the Section 6(b)(1)(A) Factors More Explicitly

EPA should make every effort to be transparent about its intention to consider and apply as early as during its *pre-prioritization* efforts the specific factors Congress specified EPA ultimately must consider during the formal prioritization phase. At a minimum, these include consideration of the hazard and exposure potential of a chemical substance (or a category of substances); persistence and bioaccumulation; potentially exposed or susceptible subpopulations; storage of a substance or category of substances near significant sources of drinking water; the conditions of use (including significant changes in the conditions of use of the substance); and the production volume (including significant changes in the volume of the chemical substance manufactured or processed). CUC encourages EPA to apply these factors even during the near term exercises in which the Agency will scrutinize its 2014 Work Plan Chemicals for purposes of pre-prioritization.

Information Availability Score

CUC commends EPA for focusing on human hazard-to-exposure, genotoxicity, ecological hazard, susceptible populations, and persistence and bioaccumulation when binning chemical substances during the pre-prioritization process ("binning score").¹⁶ Based on the Pre-Prioritization Whitepaper, CUC understands that EPA is considering categorizing substances into a bin first based on the substance's binning score, and second based on the substance's "information availability score." CUC believes this approach reflects properly the importance of focusing during the pre-prioritization process on the potential risks posed by a chemical substance. However, CUC is concerned that EPA's proposal for an "information availability score" puts too much emphasis on the importance of information availability in EPA's preprioritization decisions. The approach appears to emphasize an inclination to identify for

¹⁵ Pre-Prioritization Whitepaper at 6.

¹⁶ Pre-Prioritization Whitepaper at 18.

consideration and potentially prioritization a substance for which there is an abundance of data, but perhaps without proper emphasis on whether those data indicate any need for concern. This emphasis on the availability of data may unintentionally deter manufacturers and users of chemical substances from developing data if these data could eventually cause chemical substances of commercial importance to these manufacturers and users to be considered to be of higher priority for scrutiny by EPA.

CUC therefore encourages EPA to consider creating one bin for chemical substances with the highest binning score based solely on the factors affecting risk (e.g., a combination of toxicity and exposure)—without regard to an information availability score. EPA's creation of one bin for chemical substances most likely to present a risk to human health or the environment without consideration of information availability will demonstrate that EPA's primary focus during the pre-prioritization process will be on factors influencing risk. Additionally, for lower tiers of chemical substances, CUC encourages EPA to use the information availability score only as a "tie-breaker," *i.e.* to classify or refine sorting of substances within the same bin. Using information availability scores in this manner will reassure the public and the regulated community that EPA will concentrate its limited resources on chemical substances of greatest concern. This also will further encourage the voluntary generation of toxicity and exposure data that could be of use to EPA if requested during a published request for such data (e.g., public comment periods on problem formulation statements, etc.) or through data call-in exercises, such as those authorized under Sections 8(a) and (d) of TSCA.

Conclusion

CUC appreciates the Agency's interest in soliciting public input on the Pre-Prioritization Whitepaper and would be pleased to meet with EPA personnel to discuss these comments and related issues if doing so would assist in the development of the pre-prioritization process.