

**Before the United States
Environmental Protection Agency**

Docket numbers: **EPA-HQ-OPPT-2017-0585 (New Chemicals Review
EPA-HQ-OPPT-2017-0586 (candidates for prioritization)**

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") is submitting these comments in response to the US Environmental Protection Agency's ("EPA's") request for input from the public concerning information presented during recent public meetings addressing implementation of the 2016 amendments to the Toxic Substances Control Act (TSCA). CUC was a participant in the recent public meetings due to the interests shared by CUC member companies. CUC's members are a diverse group of industries that generally use, rather than manufacture or import, chemical substances that might be subject to regulation under TSCA.¹ CUC members are committed to encouraging responsible chemical regulatory policies that protect human health and the environment while enabling the regulated community's ability to develop and timely pursue technological innovation. CUC members consider such goals to be completely compatible with environmentally sustainable economic development in the U.S. Such policies are especially important in the area of new and existing chemicals management policy affecting high-technology sectors, which are addressing new and innovative technologies while frequently adapting to meet commercial demands while responding to emerging environmental issues.

During December 2017, the Agency held public meetings to discuss implementation activities under the 2016 amendments to the Toxic Substances Control Act (TSCA). Specifically, the December 6, 2017 meeting addressed EPA's progress in implementing changes to the TSCA Section 5 New Chemicals Review Program; the December 11 meeting focused on possible approaches for identifying potential candidate chemical substances for prioritization under Section 6 of TSCA. CUC is providing these comments for inclusion in the dockets for both meetings as the considerations being raised by CUC are pertinent to EPA's regulatory efforts affecting both new chemical review and when identifying existing chemical substances for prioritization. Specifically, CUC encourages in both the new and existing chemicals programs efforts to establish processes that enhance EPA reliance on risk-based analyses to consider reasonably likely exposure and release scenarios that could occur under the intended conditions of use for substances under review and to treat as a lower priority efforts to evaluate speculative conditions of uses which are not within the scope of proposed or ongoing uses of chemical substances.

I. New Chemicals Review

CUC members support EPA efforts to ensure its review process for new chemical notifications submitted under Section 5 of TSCA is risk-based. CUC members consider EPA's New Chemicals Decision-Making Framework (November 2017) presented during the December 6, 2017 public meeting to

¹ 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.

represent a reasonable and appropriate approach to performing new chemical reviews. Specifically, the document describes a process that reflects the requirements of the amended statute and fulfills EPA's obligations to: (a) focus on an evaluation of the conditions of use which are intended to be undertaken by the new chemical pre-manufacture notification (PMN) submitter, while (b) considering whether any reasonably foreseeable conditions of use (which are outside of the scope of those intended to be undertaken by the PMN submitter) might present potential changes in human exposures or environmental releases sufficient to merit review prior to commencement of such use. In such cases, the Agency's Decision-Making Framework appropriately encourages EPA to consider issuing a significant new use regulation (SNUR) to permit EPA to review a significant new use when and if it is reasonably likely to be undertaken. This approach is consistent with the requirements of the amendments to Sections 5(a)(3) and 5(e) of TSCA (concerning the review and regulation of new chemicals and new uses) as well as the terms of Section 5(a)(2) (the authority to promulgate SNURs).

By focusing the Agency's review on the intended conditions of use described in a PMN, the approach set out in the Decision-Making Framework will enable EPA to issue a Section 5(e) Order to limit, when appropriate, manufacturing and processing activities to sufficiently mitigate exposures or releases of potential concern and provide an opportunity for additional data to be generated if necessary to enable a more reasoned evaluation. Alternatively, the Decision-Making Framework also will permit the Agency to avoid issuing unnecessary Section 5(e) Orders when the proposed conditions of use *will not* present an unreasonable risk (even though there might be new uses which are conceivable but which are not among those proposed). In such instances, to address potential "new" uses which could increase exposures or releases, but are not among those proposed in the PMN, the Framework appropriately permits EPA to issue a "follow-up" SNUR to ensure EPA has the opportunity to review and reach a determination on such new uses before they may be commenced. When this occurs, CUC recommends: (a) EPA issue such follow-up SNURs expeditiously, and (b) resume its practice of issuing a "drop letter" to the PMN submitter prior to the end of the review period which specifically advises the submitter of any concerns EPA might have related to the PMN substance and of the Agency's intent to issue a rule to require reporting of any new uses before they may be undertaken. Such correspondence also should request the PMN submitter provide a copy of the letter to any of the PMN submitter's customers or processors who receive the PMN substance to ensure the Agency's concerns are communicated and enhance awareness in the processor and user communities that a SNUR will be issued.

The approach described in the Framework will permit more timely review of PMNs and the market entry of new and innovative chemical substances which, under the conditions of the intended uses proposed, will not present an unreasonable risk. This also allows EPA to target its limited resources to the review of more speculative uses when needed in the context of Significant New Use Notifications (SNUNs) when they are submitted at least 90 days prior to a new condition of use being undertaken.

CUC recommends EPA implement the Decision-Making Framework at once, as doing so will enable EPA to more effectively keep pace with the timelines imposed by the amended law, and appropriately allocate its resources where they are needed most.

II. Identifying Candidate Chemicals for Prioritization

During the December 11, 2017 meeting, EPA staff presented numerous possible approaches that could guide the Agency in the identification of potential candidate chemicals for prioritization. CUC appreciates EPA's efforts to solicit public comment on the approaches under consideration. CUC recommends the Agency carefully consider the comments it receives and prepare a revised approach which incorporates the elements of the various approaches considered which are intended to include as prioritization factors contemporary and reliable indicators of both hazard and exposure when prioritizing candidate chemicals on the basis of risk. Approaches which are less resource intensive and which employ recognized methods for screening level-sorting tools that are risk-based should be considered. For example, CUC encourages EPA to further its consideration of ways to update and build upon the work that has already been performed by EPA staff in the context of the Work Plan efforts. This provides a sensible starting point given the statutory requirement that substances identified for Risk Evaluation chemicals must consist to a large extent of Work Plan chemicals until all substances on the 2014 edition of that list have undergone such evaluations. As a further resource savings, CUC also encourages EPA's apparent efforts to consider ways the Agency might incorporate in its efforts to update the Work Plan lists by overlaying the methods used by Canada for its Chemical Management Plan.

Prioritization tools that might consider speculative uses for chemicals which are not on-going and approaches for sorting that are strictly "hazard-driven" should not be seriously investigated by EPA given its current time and resource constraints. With this in mind, initial candidates for prioritization should include those substances that not only present potential risk concerns, but also those substances for which there are sufficient data (including exposure and use information) already in EPA's possession to permit prioritization decisions to be made on the basis of risk, rather than hazard alone. Finally, given EPA's limited resources and the many tasks it must complete under the amended statute, CUC encourages EPA to seriously consider taking bold steps to narrow the field of candidate chemicals for prioritization by eliminating from consideration all substances that are well recognized as comparatively safer substances. CUC encourages EPA to continue to consider making preliminary or tentative low-priority designations whenever appropriate, with the understanding that as new information on hazards or exposures is identified, such tentative designations can be updated or removed. Chemicals which could readily be classified tentatively as lower priority substances should include substances that meet the chemistry criteria for the Polymers Exemption from the new chemicals notification rules as well as substances appearing on other EPA-recognized lists of lower risk substances such as those on the Agency's Safer Chemical Ingredients List (SCIL) and all substances considered by EPA to be "low risk" inert ingredients which qualify for EPA's exemption from the pesticide registration requirements.

When EPA has narrowed the field and refined the approaches it intends to consider as pre-prioritization tools, the Agency should release for public comment the approach or approaches under the most serious consideration. At that time, EPA should ensure that the tools which remain under consideration will permit EPA to clearly and reliably communicate to the general public and the regulated community the substances which are identified for prioritization. To be effective, such communications should include not only the accepted chemical names and or categories for the substances, but also a full list of corresponding CAS Registry Numbers if they appear on the public Inventory (or an alternative identifier if there are CBI claims that pertain). This will make it possible for interested members of the

public and the regulated community to offer accurate input, which could include important data and use information which might not be located or made available to EPA if the CAS numbers for the substances under consideration are not made known.

Conclusion

We appreciate the Agency's interest in soliciting public input on the New Chemicals Review Process and approaches for identifying candidates for prioritization. CUC members encourage a continuing public dialogue on the subject of how to effectively identify substances for both high and low-priority designations; our members would be pleased to meet with EPA personnel to discuss these comments and related issues.