#### Before the United States Environmental Protection Agency

# Toxic Substances Control Act (TSCA) Collaborative Research Program To Support New Chemical Reviews; Notice of Public Meeting and Request for Comments; Dockets EPA-HQ-OPPT-2022-0218/FRL-9593-01-OCSPP

# Comments of the Chemical Users Coalition

#### Introduction

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments in response to the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") recent notice announcing the proposed Toxic Substances Control Act (TSCA) New Chemicals Collaborative Research Program. Specifically, the Agency is seeking comment on the draft document entitled "Modernizing the Process and Bringing Innovative Science to Evaluate New Chemicals Under TSCA." In preparation for this submission, CUC Members have reviewed the written materials for, and key CUC personnel have attended the public meetings concerning, the Office of Chemical Safety and Pollution Prevention (OCSPP) and Office of Research and Development (ORD) proposed multi-year collaborative research program focused on approaches for performing risk assessments on new chemical substances under TSCA.

CUC is an association of companies from diverse industries that typically acquire and use, rather than "manufacture" chemical substances.<sup>1</sup> However, as occasional importers of chemical substances (and articles that may contain substances regulated pursuant to Significant New Use Rules (SNURs) and other TSCA requirement)s, CUC Members have a great interest in the New Chemicals Program. Moreover, to thrive in a competitive global economy, our Members depend on the availability of certain existing substances for which technologically feasible alternatives do not yet exist, as well as access to a steady and reliable stream of innovative new technologies and chemistries. Consequently, our Members encourage EPA, when developing regulatory and scientific approaches, to identify and use methods which will encourage innovation and permit Thus, CUC supports measures that enhance and improve EPA's scientific sustainability. assessments of chemical substances (and the conditions of use of such substances) especially when such enhancements will enable the Agency to make timely and well-informed decisions on chemical substances and mixtures (as well as products that may contain such substances). This should be a critical objective in the context of TSCA Section 5 and the Agency's new chemicals and new uses regulatory policies, and also the focus of EPA's planned OCSPP-ORD collaboration.

CUC has been an active participant in virtually every undertaking of the Agency during the period leading up to, and following, the 2016 amendments to TSCA when public input has been sought. Moreover, CUC has a history of pursuing constructive interactions with EPA, reflecting our Members' practical, solutions-oriented approach. In this spirit, we offer the following comments addressing each of the 5 program areas that are part of the OCSPP-ORD collaboration. Accordingly, our comments are enumerated in sequence, below.

<sup>&</sup>lt;sup>1</sup> CUC's Members include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

# 1. Update and Refine Chemical Categories

CUC Members understand the Agency's historical use of various previously identified "categories" of chemical substance to expedite its decision-making for new chemical substances for which existing data are few. However, the Agency's publicly available list of categories is out of date (last updated in 2010), and the Agency has nevertheless implemented numerous category determinations without notice and without updating the 2010 lists. Moreover, the Agency has not substantially engaged the regulated and scientific community when establishing such categories; nor has EPA solicited public input or potentially available data that might pertain to or better inform the underlying assumptions and determinations. CUC supports using the OCSPP-ORD collaboration as an opportunity to first update the 2010 list to reflect any new data and changes and appropriate refinements in EPA's understanding and the literature. In doing so, CUC recommends EPA and ORD engage in a public process by which the public is given both notice of and an opportunity to comment on the categories and to provide any available data (published or unpublished) that would help bring the categories up-to-date. Further, EPA should engage its own Scientific Advisory Committee for Chemicals (SACC) as part of such refinements.

Furthermore, CUC supports OCSPP's and ORD's commitment to developing a more systematic, transparent, and reproducible approach for the methods used to develop such categories and for making "read-across" and "similarity" determinations. To this end, we recommend making public the current software and internal tools EPA uses for assessing structural (and other) similarities and boundaries; physical-chemical properties; structural alerts for hazard, fate, exposure, and/or functional uses (taking into account the constraints imposed by confidential business information (CBI) considerations). Making such tools publicly available will enable Premanufacture Notice (PMN) and Significant New Use Notice (SNUN) submitters to better anticipate EPA's assumptions and assessments and provide information "up-front" that will be helpful to Agency reviewers.

CUC also recommends that EPA limit its use of a "categories" approach strictly to hazardrelated features of the new chemicals review. Presumptions that structural similarities might be predictive of commercially and technically feasible (much less reasonably "foreseeable") uses is not a reliable approach and unfairly disadvantages PMN submitters and the customers who rely on PMN substances.

It is imperative to CUC Members that OCSPP and ORD prioritize their limited resources to efforts intended to develop tools and measures that will increase the efficiency of new chemical reviews while simultaneously promoting use of the best available science and information available.

# 2. Develop and Expand Databases Containing TSCA Chemical Information

CUC Members support efforts to digitize existing information and resources and to enhance search and retrieval tools that will improve EPA access to existing information (including published literature and studies) concerning chemical substances, their physical-chemical properties, and potential health or environmental effects. CUC recommends that EPA's efforts should include: (a) training of existing staff on research and literature search methods, and (b) the recruitment and hiring of personnel with backgrounds in the commercial sectors as well as those with experience with scientific information and research who understand where such information may reside and how to locate and interpret such information. We encourage EPA's efforts to further develop and make publicly available (as they are developed) refined QSAR models and read-across interpretations and tools, and to curate and embellish tools for cataloguing and predicting physical-chemical properties, environmental fate characteristics, functional use information, monitoring data, ecological and human hazard information, and toxicokinetics information. Storing such information in a common format, such as EPA proposes (i.e., IUCLID) should be considered if it means all EPA reviewers will have access to the same information and a shared understanding of the information. We encourage EPA to ensure CBI data and information are protected while enabling EPA reviewers who have the necessary clearances to have ready access to such information on secure platforms.

We recommend that among the technical tools and models being developed, that the Agency assess whether it has up-to-date standard exposure assessments for certain common chemical-use combinations and ensure that these models and their assumptions are routinely refreshed to reflect the current practices in the industry. As part of this effort, EPA should engage in an interactive process with the regulated industry to make available to experts in those sectors information on EPA's common assumptions about uses, exposures, and releases under these standard scenarios. Input concerning the current standard practices in those industries should be solicited and incorporated in the EPA's standard models. Too many EPA "use models" and "exposure" or "release assumptions" are based on outdated, or incorrect information and do not reflect the current standards and methods used in US industries and workplaces. If the OCSPP-ORD collaboration occurs only within EPA (and academia), the effort will likely continue to replicate these assumptions. EPA should invest the time and effort needed to solicit input, and to accept as correct the information it receives, from companies that are actively engaged in these common uses.

# 3. Develop and Refine QSAR and Predictive Models for Physical-Chemical Properties, Environmental Fate/Transport, Hazard, Exposure, and Toxicokinetics

As noted in our comments on item 2, above, CUC encourages EPA's efforts to improve and update its various predictive models and tools that are used to estimate physical-chemical properties, exposure, environmental fate/transport, and hazard. It is critical that such efforts involve professionals beyond EPA personnel and the Agency's standard group of consulting firms and academics. EPA should challenge itself in this effort to work with stakeholders in the practical, commercial, and industrial sectors engaged in the operations EPA seeks to assess and to estimate. The amended statute requires the Agency's decisions to be based on the "best available science" as well as the "information available" to EPA. The Agency cannot assume it has all the "information available" if it does not create and encourage collaboration with the private sector to critically assess and validate its modeling tools and standard assessment scenarios. Interacting with experts in the field only on a PMN-by-PMN basis is inefficient and counterproductive. EPA's commitment to improving its scientific capacity and expertise on new chemicals and new uses will continue to stagnate if the Agency is not committed to enhancing, rather than inhibiting, innovation in the US. Confidentiality concerns do not prevent a more expansive and inclusive approach to making improvements with practical benefits to both EPA and the entities it regulates.

# 4. Explore Ways to Integrate and Apply NAMs in New Chemical Assessments

The use of non-animal testing and other "new-approach" methods (NAMs) can be a valuable means of obtaining preliminary data on new chemicals and assessing potential hazards while

minimizing the use of animals in testing where possible. CUC encourages EPA's efforts in this regard and recommends the Agency make clear to the regulated community which NAMs EPA considers to be acceptable for purposes of new chemicals reviews and when it would be appropriate for PMN submitters to conduct such studies in lieu of animal studies. If members of the regulated community have confidence that the Agency considers specific *in vitro* NAMs to be reliable and that such NAMs would be accepted for specific endpoints to address data gaps in the context of new chemicals reviews, this would further advance the Agency's efforts to implement the 2016 amendments to Section 4 of TSCA that relate to discouraging animal testing where feasible.

#### 5. Develop a TSCA New Chemicals Decision Support Tool to Modernize the Process

CUC Members depend heavily on innovation and the ability to adapt to new challenges in the market and production of their products. Accordingly, our Members benefit from a reliable and predictable new chemicals "pipeline" to remain on the cutting edge of business and technology advances. The current program is fraught with undependable timelines and regulatory outcomes. The Agency has advised the regulated community that some of the inefficiencies and chronic delays in the New Chemicals Review process are attributed to searching, collating, and integrating data on new chemicals. Furthermore, the Agency quite reasonably notes that many delays are attributable to PMN submitters failing to submit the most complete and accurate information on their PMN substances and intended conditions at the time of submission. However, increasingly, OCSPP leadership and managers attribute the delays to critical staff shortages and backlogs due to the shortage of technical reviews. It remains unclear how, if at all, the OCSPP-ORD collaboration is addressing the apparent budgeting and personnel issues.

The published description of the OCSPP-ORD collaboration advises an effort will be made to move the Program to using a standard format (IUCLID) which is used by the international regulatory community to capture, store, and maintain data on intrinsic and hazard properties of chemical substances and exposure-related data for chemicals. CUC supports EPA's objectives of promoting data interoperability between OPPT, ORD, and other stakeholders. CUC Members also are pleased to learn EPA plans to digitize data for TSCA chemicals as part of an effort to construct a decision support tool that integrates information streams specifically for evaluation of chemical risks to human health and the environment in a more timely and transparent manner. EPA expects the new decision support tool will efficiently integrate data streams (e.g., chemistry, fate, exposures, hazards) into risk assessment documents which will add transparency to Agency decisions and assumptions. CUC Members believe the New Chemicals Program must be improved and favor a decision support tool if it will improve speed and consistency in the Program. CUC also hopes the Agency will simultaneously take steps to critically examine the current process and look for near-term ways to expedite PMN and SNUN reviews.

#### **Additional Areas for Consideration**

CUC Members recommend EPA initiate improvements and expand outreach efforts such as the one it has undertaken for bio-based fuels. EPA should actively solicit suggestions from the regulated community to identify other categories of new chemical substances which contribute to the Agency's climate goals as well as those chemical substances and new uses that provide for beneficial, risk-reducing substitutions. For too long, the Agency has been unable to implement a capacity in the Section 5 program to consider comparative risks and enable beneficial innovations (including exposure-reducing engineering controls and release minimization tools that are optimized by new chemicals). The continued adherence to the current tools and methods without a commitment to objectively considering overall and comparative risks does not reward innovation, represent sound public policy, or serve the Agency's environmental mission. EPA should engage with the regulated community to explore how to accomplish this mission.

#### Conclusion

As discussed above, CUC encourages the OCSPP-ORD collaboration to focus on both long- and near-term efforts that emphasize the use of the best available science, while concentrating on practical approaches to improving the New Chemicals Program's efficiency and dependability. Further, as chemical users and importers of products and articles, CUC Members encourage EPA to offer more transparent processes generally and to affirmatively reach out to entities that are not routine PMN submitters (specifically chemical users and importers of products and articles) to seek input concerning the difficulties and concerns they are facing competing in the global economy in light of the delays and impediments to innovation which are affecting their competitiveness. By doing so, EPA can better identify areas for improvement to the New Chemical Program that will enable and encourage R&D and the development and production of innovative chemistries and products in the US.

CUC Members would be pleased to meet with EPA personnel to discuss these comments.