Before the United States
Environmental Protection Agency
Certain Existing Chemicals/ Request to Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act
Docket EPA-HQ-OPPT-2023-0360

Comments of the Chemical Users Coalition

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") recent decision to request additional public comment on the proposed rule, Certain Existing Chemicals; Request to Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 20918 (March 26, 2024) (the "Proposed Rule").

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances. Our members depend on the availability of certain existing substances for which there are not technically feasible substitutes as well as a reliable pipeline for innovative new chemistries to be able to thrive in a competitive, global economy. Consequently, our members encourage EPA to develop regulatory approaches that encourage innovation and permit sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk.

CUC supports EPA's efforts to develop a robust body of information concerning chemical substances and mixtures when such materials are under consideration for regulatory action, including a thorough investigation of the published literature to develop a basic and contemporary understanding of the conditions of use for such substances and articles. CUC believes EPA should use its regulatory authority to develop this body of information in ways that take into account which regulated entities are in the best position to have or to obtain the information. Furthermore, given its limited resources and capacities, CUC believes that the Agency's information collection activities should focus on information that will be of the greatest use to EPA in assessing and managing risks of greatest concern. In other words, the focus of information collection activities should be on addressing meaningful data needs, not filling every information data gap. Requiring reporting on information that is of little potential utility imposes a burden not only on regulated entities that must search for, assemble, and report such information, but also on EPA personnel, who must then sort through the information submitted to ascertain what is truly useful for purposes or risk assessment and (where appropriate) potential regulatory action.

The Proposed Rule Includes Novel Features Unlike Prior 8(d) Rules and Which CUC Does Not Support

In the Proposed Section 8(d) Rule, EPA is announcing its intention to add 16 chemical substances to the list found at 40 CFR 716.120. That list contains chemical substances for which health and safety study data reporting would be required. The chemical substances that are the subject of the Proposed Rule are of particular interest to EPA because they are either candidates for high-priority designations or are expected

to be such candidates in upcoming years. For those found to be of high priority, EPA will be required to immediately conduct a risk evaluation. Consequently, EPA believes that collecting health and safety studies on the subject chemical substances will first assist the Agency in selecting chemicals to designate as high-priority chemicals and then in conducting risk evaluations on such designated chemicals. CUC considers it to be reasonable and appropriate to use Section 8(d) to support EPA's efforts under Section 6 of TSCA to prioritize and evaluate substances that may present unreasonable risks to health or the environment.

Unfortunately, EPA is not only proposing to require submissions from companies manufacturing the identified chemical substances, including when a company is importing the chemical substance as a pure substance and when present in a mixture or formulated product. Rather, and (unlike prior 8(d) rules), EPA is proposing to require submission of data concerning the listed substances when present in an imported article. Moreover, also unlike prior rules, reporting would be required for studies pertaining to material in which the listed chemical substances might be present as an unavoidable impurity. Thus, EPA is proposing that the traditional exemption listed at 40 CFR 716.20(a)(9), for persons manufacturing a listed substance only as an impurity, would not be available for the substances subject to this proposed rule.

CUC Members recommend that EPA should retain the long-standing practice of exempting from the 8(d) requirement reporting of studies conducted on materials in which the listed substance(s) might be present only as impurities or within a manufactured/imported article. EPA has stated in the preamble to the Proposed Rule that in its risk evaluation process, the Agency will consider "conditions of use" associated with circumstances even where the chemical substance is present only as an impurity. EPA therefore asserts that health and safety information associated with the conditions of use, whether a listed chemical is present as a pure chemical, as part of a mixture or formulation, or even if present in an article (or as an impurity in any of the foregoing) would help inform such risk evaluation. It is not clear to CUC Members however, how the effort that will be necessary to meet the additional requirements being imposed by the removal of the exemption for impurities and presence of a chemical in an article, will substantially improve or expand the information EPA will acquire and whether it will be meaningfully related to the conditions of use of any listed chemical. Furthermore, EPA has not provided any examples or analysis demonstrating its assertions that such information would have value (much less that it might exist).

On this basis, and in the interest of focusing limited resources on efforts likely to result in the identification and submission of existing information and data most pertinent to the effects of the listed chemicals, CUC's Members recommend EPA should continue its practice of providing an exemption for those entities that have manufactured and/or imported a listed chemical as an impurity or when the substance is present as a component in an article. The requirement to include all unpublished studies and data on impurities that may have been present in another substance for which an existing test report might exist, will significantly increase the burden on companies for search for, and reporting of studies. This burden will also be imposed as well on EPA staff who are responsible for reviewing and determining the value of the submissions. As currently stands, there does not appear in the preamble to the Proposed Rule (or in the docket itself) to be sufficient justification to waive this exemption. It may be the case that in certain circumstances, impurities or presence of a listed chemical in an article may warrant a thorough evaluation. If EPA believes that is the case with any of the subject substances, EPA should propose specific requirements (and its analysis in this regard) for those substances. The chemicals on this list are significantly different from one other. Reporting requirements tailored to specific substances would allow for proper justifications to be given on a chemical-by-chemical basis for removing the impurity exemption and help the Agency receive only the most relevant information.

EPA Has Provided No Basis or Need for Changing its Prior Practices Regarding Exemptions.

The Proposed Rule is not the first TSCA §8(d) Rule intended to inform the risk evaluation process. The Rule issued in 2021 did not require submission of studies on materials in which the listed chemicals were present as impurities or in articles. EPA has not argued that the failure to require such in that rule prevented EPA from conducting the required risk evaluations on the substances in that rule. EPA has provided no evidence to demonstrate that submission on impurities is truly needed for EPA to fulfill its risk evaluation obligations. There is likely a good reason for that.

When studying a substance or formulation, including impurities contained therein, It can be difficult to ascertain what may be driving an observed adverse effect attributable to a tested mixture, particularly if a substance is present (e.g., unintentionally as an impurity) at a very low concentration. It also is difficult to segregate effects of the specific components in a given mixture and it is infrequent that a study report will describe, report or make any conclusion concerning how an impurity or other minor component may contribute to the test results. Therefore, requirements to identify, much less to submit, information that might be present in a Company's files on a test materials in which a listed substance might have been present only as an impurity will only serve to increase the burden on both the regulated community and EPA and be likely to provide little (if any) benefit to the risk evaluation process. Should EPA reasonably conclude that information in a study will have value even when a listed chemical is present only as an impurity, then the Agency should provide clear boundaries including establishing a minimum concentration level at which a listed substance must be present to trigger the Section 8(d) reporting obligation and a reasonableness standard for the degree of inquiry required.

Section §8(d) Does Not Specify Collecting Data on Substances in Articles

Section 8(d) states, in part:

> *The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any c**hemical substance or mixture** (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—*
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> *(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this chapter; …*

This section, the statutory basis for the proposed rule, while mentioning mixtures, does not reference substances in articles. Thus, Section 8(d) is unlike Sections 5 and 6 of the amended statute, which do make specific reference to substances when present in "articles". Such an omission in Section 8 of TSCA implies that when amending the Act in 2016, Congress did not intend to grant EPA authority to require the generation, or submission, of data on the presence of a chemical in articles (especially where, as here, EPA has made no showing that exposure to the listed substances in an article is reasonably likely to occur).

For these reasons, CUC believes that reporting on substances in articles should continue to be excluded from the requirements in the Proposed Rule. The entities that import and use articles that might contain the subject chemical substances are not (in the traditional sense) "chemical manufacturers" or even "formulators" of traditional commercial use chemical-based mixtures. Consequently, they are unlikely to have health or safety studies germane to the prioritization or risk evaluation of the subject substances. Many

article importers may not even know if the imported articles contain the subject substances, and therefore they will not know if they have any obligation to provide the required information.

Similar to reports on testing of formulations and mixtures that might have included a listed substance as an unintentional impurity, the likelihood of the existence of the type of information EPA is requesting for the substances in articles is even smaller. However, the compliance burden imposed on articles importers is significant. CUC therefore requests that EPA remove the reporting obligation from article importers. If EPA has a reasonable basis that the presence of any of the subject substances in an article truly requires the provision on additional information for risk evaluation purposes, EPA should address that need on a substance-by-substance basis.

Conclusion

In closing, CUC members appreciate the opportunity to provide comments on the Proposed Rule. CUC members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to evaluate existing chemicals under TSCA Section 6.