

**Before the United States
Environmental Protection Agency
Updated Working Approach To Making New Chemical Determinations Under the Toxic
Substances Control Act (TSCA)
Docket No.: EPA-HQ-OPPT-2019-0684**

Comments of the Chemical Users Coalition¹

The Chemical Users Coalition (“CUC”) is submitting these comments in response to the U.S. Environmental Protection Agency’s (“EPA’s”) request for input on its document entitled: “TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5” (the “Working Approach”). This document was made available in December 2019 and reflects modifications made to the Agency’s November 2017 document upon which CUC members also commented. CUC has been an active participant in the legislative processes that preceded enactment of the 2016 amendments to the Toxic Substances Control Act (“TSCA”) and CUC continues to engage with EPA on matters related to implementation of the amended statute (including as a participant in the recent public meeting at which the revised Working Approach was discussed). 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 and responding to emerging environmental issues.

CUC is encouraged that the 2019 update to the New Chemicals Working Approach document reiterates the Agency’s commitment to implementing decision making methods that rely on risk-based considerations (considering both hazard and exposure). CUC considers it imperative that EPA focus its limited resources in the New Chemicals review process primarily on analysis of the exposure and release scenarios that could reasonably occur under the known and intended conditions of use as described in the Section 5 Notification for the substance under review. To ensure timely review of Premanufacture Notifications (“PMNs”) and Significant New Use Notices (“SNUNs”), CUC recommends the Agency concentrate its attention during the initial 90-day review on efforts to evaluate only the conditions of use described in the Notification under review. Analysis of more speculative conditions of use which are not within

¹ The members of CUC are Airbus S.A.S., The Boeing Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, and United Technologies Corporation.

the scope of proposed conditions of use of new chemical substances should be addressed differently. CUC agrees with the perspective EPA has set forth in the updated Working Approach document—that the Agency can meet its decision making obligations under Section 5(a)(3) of TSCA by employing its Significant New Use Rulemaking (“SNUR”) authority to address any concerns the Agency might have regarding reasonably foreseen conditions of use that are not within the contours of the conditions of use proposed in a PMN or SNUN. The use of SNURs in this manner can ensure the timely review of Section 5 Notifications, enable market entry where no unreasonable risk has been identified from the proposed conditions of use described in the Notification, and still permit EPA to become aware of and 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 initial (90-day) review on the intended conditions of use described in a PMN (or SNUN), the updated Working Approach enables EPA to either: (a) permit market entry where no unreasonable risks under the intended conditions of use have been identified, or (b) issue a Section 5(e) Order to limit, when appropriate, proposed 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. Moreover, the updated Working Approach also will permit the Agency to avoid issuing unnecessary Section 5(e) Orders when the proposed conditions of use are not likely to 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 updated Working Approach appropriately permits EPA to issue SNURs which might precede “not likely” (to present an unreasonable risk) determinations and SNURs which could follow “not likely” determinations. This approach provides the Agency with much needed flexibility and makes use of the appropriate regulatory mechanisms to ensure EPA has the opportunity to review and reach a case-specific determination on such new uses before they may be commenced.

In closing, CUC reiterates its comments on the initial (2017) Working Document for Section 5 decision making by stating that our members consider it imperative that EPA do all that it can to conduct and complete its initial review and decision making on Section 5 Notifications within the statutory 90-day review period. To expedite the review process, CUC continues to encourage EPA to look for ways it can abbreviate the mechanisms and standard templates for the language it currently uses in preparing Section 5(e) Consent Orders and the time required to propose and promulgate SNURs. The standard language in these documents can and should be abbreviated considerably. CUC also reminds the Agency that when considering the use of a SNUR to regulate the import or processing of an article (or category of articles) that

contain a chemical substance, the 2016 amendments to TSCA require that the Agency must make an affirmative finding that there is a “reasonable potential for exposure to the chemical substance through the article or category of articles” prior to issuing a SNUR pertaining to such an article (or category of articles). (*See* Section 5(a)(5) of TSCA.) CUC members consider this to be a critically important requirement.

CUC appreciates the opportunity to provide comments in support of the updated Working Approach document and recognizes the efforts the Agency is making to provide transparency with respect to the decision making approaches followed in the TSCA New Chemicals Program. CUC’s members would be pleased to meet with appropriate staff from the New Chemicals Program to discuss CUC’s comments, respond to any questions, and to engage in a direct dialogue concerning these important issues if requested.