

## **PUBLIC COMMENTS ON EPA'S 2017 "NEW CHEMICALS DECISION MAKING FRAMEWORK": *Summary and Response***

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EPA received public comments on the "New Chemicals Decision Making Framework: Working Approach to Making Determinations under section 5 of TSCA" released in 2017. Commenters included approximately 40 entities and individuals, including trade associations, coalitions of chemical industry stakeholders, public health and environmental groups, other non-governmental organizations, academic institutions, scientists, health and environmental professionals. All comments, including a transcript of the December 2017 public meeting, are available in the docket at <https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2017-0585>. EPA appreciates the time and efforts of these stakeholders to help EPA improve its new chemicals program and has incorporated feedback where possible into the updated working approach.

Public comments can be grouped into three main categories: (1) general or specific comments on the document itself and EPA's expected implementation, (2) the Agency's identification of reasonably foreseen conditions of use, and (3) the role of section 5(e) orders and significant new use rules in managing risks.

EPA received comments that prompted some important clarifications. For example, commenters requested additional discussion on topics such as "information sufficiency," "reasoned evaluation," "unreasonable risk," and testing requirements that may be associated with new chemical reviews. Others sought assurance that the Agency would make decisions consistent with the scientific standards in TSCA section 26. In response, EPA added additional content to clarify the general principals and key concepts associated with the working approach.

Several commenters raised questions or concerns regarding EPA's expected implementation efforts. Some commenters opposed the approach in the document and urged EPA to delay implementation and/or change course while others strongly supported the approach. Commenters raised questions or made comments regarding application of the approach that EPA believes may have stemmed from a misunderstanding of the Agency's intent. In addition to providing the clarifications and additional content on principals and key concepts, EPA added new sections to describe the document's purpose and the Agency's approach to threshold questions that have significant bearing on the section 5(a)(3) determination. EPA reorganized the entire document to increase readability. EPA believes the updated working approach will help clear up some of these misunderstandings and underscore EPA's commitment to continue to implement new chemical determinations in a manner consistent with TSCA section 5, as amended.

EPA also received comments regarding reasonably foreseen conditions of use. Generally, commenters provided suggestions and/or requests for an expanded discussion of this concept. Given the significant impact of identifying the conditions of use when making determinations on

new chemicals, EPA has expanded its description of intended, known and reasonably foreseen conditions of use, and added a new section on how the Agency approaches the identification of conditions of use.

Commenters suggested that EPA should limit its review to only those uses identified by a new chemical submitter. EPA disagrees, as this approach would be inconsistent with the mandate in TSCA to review new chemical substances under their conditions of use. Conditions of use include not just those that are intended by a submitter, but also those other circumstances that are known and reasonably foreseen. EPA believes its working approach is consistent with this mandate.

Finally, commenters expressed concern that EPA's working approach would lead to fewer section 5(e) orders and much higher numbers of SNURs. Some suggested that SNURs are ineffective tools for managing risks and were never intended to be a primary regulatory tool for new chemicals under TSCA. Others indicated concern that SNURs may be burdensome for industry in terms of compliance tracking. Several commenters indicated concern with delays associated with an approach that relied on SNURs. In response to these comments, EPA added new content to the document to clarify what a SNUR is, what it requires of certain manufacturers and processors, and the different ways that EPA applies this tool to ensure the safety of chemicals in the marketplace. EPA is not forgoing 5(e) orders; in fact, TSCA mandates issuance of an order for a number of determinations under section 5(a)(3). EPA is continuously working to streamline its processes for reviewing and managing new chemicals, including the development of SNURs, and has made significant progress to these ends.