Implementation of the 2016 Amendments to the Toxic Substances Control Act

Effective and efficient implementation of the 2016 amendments to the Toxic Substances Control Act (TSCA) is paramount. EPA must continue its work to ensure that those amendments are implemented as Congress intended.

Getting Implementation Right:

TSCA Implementation should enable the agency to protect human health and the environment from unreasonable risks, demonstrate the safety and sustainability of existing chemistries for their intended conditions of use, and facilitate the introduction of new, innovative chemistries.

EPA should assess policy positions and technical approaches objectively on their merits. A science-driven, risk-based program across TSCA is required by statute, including the use of the best available science and weight of the evidence. EPA must communicate risks clearly and effectively based on realistic and reasonably foreseen uses of a chemical. Consumers, chemical industry employees, and the public should not be unnecessarily fearful of chemistries that are used safely to deliver benefits to their lives and the economy.

Best Available Science and Weight of the Scientific Evidence:

The foundation of EPA's TSCA implementation is in its chemical evaluation tools and guidance that rely upon the best available science and weight of the scientific evidence as the basis for regulatory decision-making.

- Best available science means information that has been evaluated based on its strengths, limitations, and relevance. Factors that help determine the best available science include: peer review, statistical significance, objectivity, consideration of exposure, and reproducibility.
- To ensure transparency regarding best available science, the agency should describe and document any assumptions and methods used, while addressing any variability, uncertainty, independent verification, and peer review.
- Weight of the scientific evidence means a systematic review method that uses pre-established protocols to comprehensively, objectively, transparently, and consistently identify and evaluate the evidence.
- Peer review by independent scientists and consideration of stakehlolder feedback play a critical role in ensuring EPA's scientific work product is comprehensive, unbiased, objective, scientifically robust, represents the weight of the scientific evidence, and relies on the best available science.

New Chemicals:

U.S. businesses, jobs, innovation, and competitiveness depend on the success of an effective new chemicals program. EPA should adequately consider and seek public comment prior to implementing any potential changes that may reverse years of progress that have been made to properly administer the TSCA new chemicals program, consistent with the statute.

- Delays in the new chemicals process have a significant adverse impact on research and development expenditures, planning product launches, development of new sustainable chemistries, innovation, competitiveness, and prevent the availability of new and innovative chemistries to support infrastructure and climate needs.
- The agency's assessment of reasonably foreseen uses should not be based on speculation or misuse.
- The agency has used non-5(e) significant new use rules (SNURs) for new chemicals since 1995, and it should continue to use them as an efficient exercise of its authority.
- Doing away with non-5(e) SNURs and moving to section 5(e) orders across the board will result in a substantial increase in unnecessary work for EPA, added burdens and delays for pre-manufacture notice submitters, and lost economic benefit.

Risk Evaluation & Conditions of Use:

- It is imperative that risk evaluations are grounded in the best available science and the weight of the scientific evidence as required by TSCA. Clear and accurate understanding of the conditions of use of a chemical is critical to the evaluation of the chemical's risk.
- EPA should clearly identify the conditions of use for each evaluation and be transparent about the agency's rationale and supporting information.
- To ensure that risk evaluations are conducted in an efficient and timely manner, there will be cases where the agency cannot identify and consider all conditions of use of a chemical in certain risk evaluations.
- EPA must ensure that scientific information considered and relied upon from other EPA program offices adhere to the scientific standards required for TSCA risk evaluations.
- EPA should ensure consistency in the application of the TSCA scientific standards and coordination of assessment development when multiple program offices are undertaking an evaluation of the same chemical.
- It is important that EPA continue to take into account the existence of, and compliance with, other federal statutes and regulations in its chemical reviews and regulatory decision making processes (e.g., the Occupational Safety and Health Act).
- EPA should continue to update its systematic review guidance and develop additional guidance on its approaches for occupational exposure assessment.
- The agency should continue to develop New Approach Methods (NAMs) and build scientific confidence in their use in risk-based decision making.
- The overall goals to generate data more efficiently on chemicals and minimize the need for animal testing are consistent with the law.

Confidential Business Information:

EPA must protect confidential business information (CBI) under the law, which includes a process by which claims for CBI protection are substantiated and reviewed by EPA.

- CBI protection is important because it safeguards intellectual property, while ensuring that state officials, medical professionals, and first responders have access to critical information when they need it.
- The law requires companies claiming CBI protection to demonstrate to EPA that the disclosure of the information would cause the company competitive harm.
- While EPA must disclose the health and environmental effects or results of health and safety studies, EPA has discretion under the law to decide the extent to which it will disclose health and safety studies containing CBI, such as underlying data.

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(202) 249-7000 info@americanchemistry.com americanchemistry.com