

CHEMISTRY CREATES AMERICA COMPETES™



Improving TSCA Existing Chemical Reviews

In 2016, Section 6 of the Toxic Substances Control Act (TSCA) was amended with overwhelming bipartisan support to strengthen the U.S. Environmental Protection Agency's (EPA) authority to regulate existing chemicals in commerce that may present an "unreasonable risk" to human health or the environment. EPA received greater authority to require testing and impose restrictions, or ban, a chemical substance already in the marketplace to the extent necessary to address unreasonable risk.

Every chemical has some hazardous properties but the level of exposure to the chemical is a critical component of the actual risk. When Congress amended TSCA Section 6, the statute required EPA to assess risk, calling on the agency to consider both the hazards of and the exposures to a chemical substance.

Congress Aimed to Modernize Existing Chemical Reviews

The 2016 TSCA amendments required EPA to implement Section 6:

- **Using a risk-based approach consistent with the best available science** and based on the weight-of-the-scientific evidence, considering both hazards and exposure.
- **Establishing a Prioritization Framework** for EPA to select and prioritize chemicals to evaluate and assess the chemicals' specific conditions of use.
- **Requiring EPA to consider real-world, relevant exposure information** and not default to inefficient, overly conservative data models.
- **Ensuring EPA focuses its resources on the chemicals' actual use** in the marketplace and not on conditions regulated by other statutes like the Clean Air Act or agencies like the Occupational Safety and Health Administration (OSHA).

Congress intended for TSCA reforms to ensure a substance does not pose unreasonable risks to human health or the environment, all while supporting innovation and protecting American jobs. Congress envisioned reforming TSCA would make it the model for sound, risk-based chemical management across the globe.



Current State of TSCA's Existing Chemicals Program

EPA is not using a risk-based approach to implementing TSCA Section 6, instead wasting agency resources by assuming that chemicals are used in commerce without any exposure controls, which is known to be a dangerous practice. This results in EPA making overly conservative assumptions about exposures to a chemical,

leading to unnecessary regulations impacting manufacturers and downstream users.

To better protect human health and the environment, it is imperative EPA take a risk-based approach to correct significant challenges facing TSCA existing chemicals reviews.

1 Problem: EPA's review of every conceivable use of a chemical is not an efficient use of agency resources and expertise, sidetracking the risk evaluation focus from actual current uses of the substance.

Why it Matters: EPA is mandated to complete a risk evaluation within 3.5 years. When EPA evaluates every conceivable condition of use, meeting this timeline is nearly impossible and additional resources are required. In addition, this approach creates regulatory uncertainty for industry and downstream users and diverts resources from addressing actual risks.

Solution: EPA must revise the TSCA Risk Evaluation Framework Rule and scope the risk evaluation to focus on current uses with the highest potential for risk.

2 Problem: EPA disregards existing workplace protection regulations and makes incorrect assumptions about worker protection guidelines. For example, EPA does not assume workers are using personal protective equipment (PPE), even when mandated by OSHA. Furthermore, EPA is establishing occupational exposure limits (OEL) using an approach that is inconsistent with current best practices resulting in values that are significantly lower than those that have been adopted by other international authoritative bodies.

Why it Matters: Industry and downstream users are subjected to conflicting regulations and increased uncertainty. This jeopardizes domestic manufacturing and could lead to unnecessary measures on already protected workers.

Solution: EPA should defer to OSHA expertise on occupational regulations.

3 Problem: EPA does not institute a tiered testing approach for data collection or restrict the need for animal testing when non-animal alternatives exist.

Why it Matters: EPA discounts TSCA's mandate to conduct tiered testing and does not consider the most recent and relevant data. This approach is an inefficient use of EPA resources, delays the regulatory process, and may hinder domestic innovation and manufacturing.

Solution: EPA must implement a tiered testing approach as TSCA mandates, prioritize non-animal testing alternatives, and focus on data and information needs based on real-world use and risk.

4 Problem: EPA fails to establish *de minimis* levels for chemicals entering risk management.

Why it Matters: If EPA determined *de minimis* levels, it would provide a practical threshold to better determine whether a chemical substance or product should be regulated and focus resources on areas of greatest concern.

Solution: EPA should avoid increased regulatory uncertainty and establish *de minimis* thresholds levels for all chemicals in risk management.