AMERICAN CHEMISTRY COUNCIL

Enhancing Supply Chain Resiliency & Onshoring of Manufacturing Through TSCA Implementation

Sound chemical management policies are critical not only to American innovation and competitiveness, but also to meeting supply chain, climate, sustainability, energy efficiency, national security, and infrastructure needs.

Many crucial factors and issues are involved in robust chemical management in the U.S., and effective and efficient risk-based implementation of the Toxic Substances Control Act (TSCA) is critical. EPA's approach has a **direct impact on the U.S. economy**, and America's ability to lead in the creation of products and technologies needed to accomplish a wide range of societal goals. Notably, chemistries the EPA reviews and manages under TSCA—both new chemicals and existing chemicals—are used to make **essential products from building and construction materials to computers, electronics, healthcare, and clean energy solutions including EVs, wind turbines, solar panels, and replacements for ozone-depleting substances.**

Working to strengthen the timeliness and scientific basis of reviews will be imperative to securing the Nation's future as a leading innovator, enabling the continued availability of products and materials, and protecting human health and the environment.

Strengthening the New Chemicals Program to Support Innovation

New chemistries have faced regulatory barriers under TSCA that impact the timing of reviews and availability of products, creating uncertainty in the supply chain and stifling the ability of companies to bring new products to market. Such barriers and delays have **discouraged new U.S. innovations and resulted in offshoring of both new chemical R&D and manufacturing.**

To support American innovation, EPA must improve its pre-notice and interim communications processes, providing TSCA submitters a clear understanding of timelines, submission requirements and data expectations. Manufacturing cannot start until reviews are completed – so it's essential that EPA meet its statutory mandate to complete reviews within 90 days.

EPA and industry can work together to advance efforts to promote the use of **alternative energy, reduce greenhouse gas emissions, and support the availability of semiconductors and other critical goods** by improving the new chemicals program.

Applying Science-Based, Well-tailored, Smart Risk Management Approaches

EPA is required, under TSCA, to reduce any unreasonable risk presented by a condition of use of a chemical to a safe level – in other words, to a reasonable risk level. To decide whether additional regulation is needed, EPA needs first to look at how a chemical is currently used in commerce, including standard industrial hygiene practices such as use of engineering controls, administrative controls and personal protective equipment, and other regulatory requirements already in place. EPA's current "whole chemical"

approach is flawed as it does not consider real world conditions first, resulting in serious **overregulation problems** at the risk management step, and applies hypothetical assumptions.

EPA needs to clearly identify the conditions of use that do, and that *do not*, present unreasonable risk at the end of the risk evaluation. Risk determinations need to be based on information regarding how the chemical is actually being used, not guesswork and assumptions.

In the risk management step itself, EPA has a suite of tools available to reduce any unreasonable risk to a reasonable risk level. All these tools—from labels, instructions, and warnings; to recordkeeping and reporting and others—should be considered, and the tools best able to reduce unreasonable risk to reasonable should be selected. Bans and phaseouts are the most severe options, and when selected, they should be well-tailored and well-justified - particularly when the use category is broad, because **sweeping category bans can impact important, socially valuable uses.**

It is also important to consider supply chain effects from aggressive bans and phaseouts. If, for example, EPA proposes eliminating a substantial percentage of uses or amount of chemical manufacturing volume, this could result in manufacturers exiting the entire market or in supply or price shocks. Non-TSCA uses that would otherwise be exempted from TSCA regulation could be affected and markets **like medical devices, pharmaceuticals, and food packaging**, for example, could find their U.S. domestic supply of a critical chemical has disappeared.

In the rare cases where EPA proposes a blanket ban of a chemistry in a use category that includes formulated and manufactured products, it is critical that EPA establish de minimis concentration limits so that industrial, commercial, and consumer products with trace amounts of a chemistry subject to risk management are not inadvertently banned or regulated.

Removing Uncertainty in Chemicals Management by Meeting Statutory Obligations

Chemicals management relies on strong policy, procedures, and guidance to support science-based reviews that can be conducted in a transparent, consistent, objective, and timely manner. Delays in chemical reviews or risk management activities, missing Congressionally mandated deadlines, can squeeze U.S. supply chains, impede the uptake of innovative new chemical uses and technologies, or limit access to important existing chemistries which have crucial uses. U.S. businesses, jobs, innovation, and competitiveness rely on a high-functioning, effective, reliable, risk-based, and timely TSCA program. We encourage EPA to develop a transparent and comprehensive path forward with quantitative metrics and goals to achieve TSCA's statutory requirements.

Charging Fair and Equitable Fees that Don't Disadvantage U.S. Manufacturing

TSCA allows EPA to require payment "of a fee that is sufficient and not more than reasonably necessary to defray the cost related to" administering certain sections of TSCA. However, to date EPA has not provided adequate information to justify its program costs, and therefore the associated fees. A recent Office of the Inspector General report notes that EPA "did not have an adequate methodology to accurately report the expenses incurred," resulting in a recommendation for EPA to correct its accounting methodology.

This report makes clear that EPA has been unable to accurately estimate its program costs. EPA's inability to estimate program costs and justify fees

has a real impact on the chemical manufacturing sector, particularly when it comes to the manufacture of new, innovative chemicals. The high fee that manufacturers must pay for a premanufacture notice, along with the delayed and inconsistent review timelines, has led to a dramatic decrease in the number of new chemicals brought to market in the United States. EPA must provide clear substantiation of, and accountability for, any fee increases for the TSCA program and modernize the process for collecting fee payments. As mandated by TSCA Section 26, EPA should submit a report on the fiscal accountability of the TSCA program to the Senate Committee on Environment and Public Works (EPW) and the House Energy and Commerce Committee by the end of Q3 2023.

Justifying Sensible Section 4 Test Orders

Test orders should be a component of a tiered and iterative risk evaluation process. EPA should clearly articulate its process for risk-based decision-making considering currently available data. EPA should provide guidance regarding criteria for the generation of new data and when alternative approaches such as read-across or computational approaches are inadequate. Additionally, before EPA develops a Section 4 test order, the process should include an effective and productive pre-consultation with industry and request for data.

Strengthening Intra- and Inter-Agency Coordination

EPA should develop a document that explains to stakeholders its coordination, consultation, engagement, and referral processes, throughout all its TSCA programs. This includes engagement with other EPA program offices, federal agencies, including OSHA, SBA, DOD, DOE, and NASA, and experts to better inform TSCA prioritization, risk evaluation and risk management, as well as other TSCA regulatory processes. EPA should also explain its process to identify other federal agencies, particularly smaller agencies, which should be engaged in interagency consultation, such as NIST, GSA, NIOSH, ATSDR, DOT, USGS, USDA, FDA, USFWS, the Army Corps of Engineers, and Homeland Security.

Improving Transparency, Objectivity and Peer Review

TSCA requires that EPA use the best available science and a weight-of-the-evidence approach. EPA must ensure that all peer review panels are fully independent, and members do not have disqualifying conflicts of interests or inordinate bias. Peer review panels must be assembled in accordance with appropriate policies to ensure the range of technical expertise required is achieved, perspectives are balanced, and potential conflicts of interest are rigorously, transparently, and fairly evaluated.

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