



# TSCA New Chemicals Program

## Background

Section 5 of the Toxic Substances Control Act (TSCA) requires EPA to determine the safety of new chemicals before they can be manufactured in or imported into the United States. The New Chemicals Program, which is part of the EPA's Office of Pollution Prevention and Toxics (OPPT), administers this review and approval process.

Under TSCA, EPA has broad authority to request information and testing to support its decision-making. TSCA requires EPA to have sufficient information to be able to make a safety determination before the chemical can be manufactured or imported. EPA is required to consider known, intended and reasonably foreseen uses.

Delays in the EPA's New Chemicals Program hurt U.S. supply chains, and in particular, delay the uptake of innovative new chemical uses and technologies, many of which are key to achieving sustainability, climate and infrastructure objectives. U.S. businesses, jobs, innovation, and competitiveness rely on a high-functioning, effective, reliable, risk-based and timely New Chemicals Program. Stalled reviews of new chemicals hinder innovations from being manufactured in the United States and limit the availability of new chemistries to support new products and technologies.

## Problem

- Section 5 of TSCA requires EPA to complete a new chemical review within 90 days of a manufacturer or importer submitting a new chemicals application, commonly referred to as a Pre-Manufacture Notification (PMN). EPA routinely misses the statutorily mandated 90-day deadline to review and approve new chemicals. The average new chemical submission and review process can often take twice as long as the statutory deadline. It is reported some chemicals wait for years for review to be completed.
- EPA's program suffers from lack of staff expertise, inconsistencies in evaluation methods, lack of clear guidance on data needs, and slow and inadequate communication with companies requesting reviews of new chemicals.
- Delays in the New Chemicals Program have a significant adverse impact on research and development, innovation, the development of chemistries that support sustainability and onshoring new chemical production.

## Solution

EPA should make significant improvements to the TSCA New Chemicals Program. EPA must implement a comprehensive plan now to improve its processes to ensure the New Chemicals Program meets its obligation to complete new chemical reviews within 90 days. The Agency must be transparent and objective, enhance its communication with submitters of new chemical applications, ensure relevant supporting documents from companies are reviewed and adequately considered in a timely manner, and ensure that relevant information from actual uses and exposures is considered and incorporated based on the best available scientific practices and approaches. These changes can be, and should be made now.