EXECUTIVE SUMMARY

COMMERCIALIZING INNOVATIVE CHEMICAL PRODUCTS

October 2022

Coalition for Chemical Innovations

Who We Are:

The Coalition for Chemical Innovations (CCI) is a group of diverse stakeholders within the chemical industry, including chemical manufacturers, processors, distributors, and users.

Our Mission:

The U.S. Environmental Protection Agency's (EPA) current interpretation and implementation of the Toxic Substances Control Act (TSCA) in the review of new chemicals under Section 5 is stifling chemical innovation at a considerable cost to sustainability, the economy, and improved human and environmental health.

CCI's mission is to educate decision makers, including Congress, EPA, other federal agencies, and related stakeholders on the true costs of these policies and to outline common-sense policy changes to prevent the further stifling of chemical innovation by EPA's implementation of TSCA Section 5.

The Problems We Seek to Fix

EPA's current practice under TSCA Section 5 is to assume that all chemicals for which it identifies a hazard, other than "low hazard" for health and "ecotoxicity," may be used in a way that leads to an exceedance of the hazard threshold. In other words, EPA assumes that any use is "reasonably foreseen," inevitably leading to the regulation of new chemicals and the application of risk mitigation measures even when submitters provide data disproving EPA's assumptions.

This hazard-based approach is inconsistent with TSCA's risk-based framework and reflects a misapplication of TSCA Section 5. It renders meaningless the TSCA statute's requirement to evaluate chemicals in the context of "reasonably foreseen" conditions of use, as every theorized condition of use then becomes foreseen.

In addition, because existing, incumbent substances, even those that pose *the same or higher* hazard, do not face the same requirements (now or potentially for decades into the future), the requirements on new chemicals pose a significant commercial disadvantage and discourage innovation.

CCI commissioned FTI Consulting, Inc. (FTI) to conduct an analysis of new chemical submissions to EPA, both Premanufacture Notice (PMN) and Low Volume Exemption (LVE) applications from 2011 to the present. FTI assessed the nationwide economic losses associated with implementation of TSCA since it was amended in 2016. The analysis accounts for the "upstream" losses to CCI members and their suppliers from lost sales opportunities and the "downstream" losses to CCI members' customers from lost sales and higher costs, along with indirect costs.

The results of the FTI analysis, obtained in August 2022, confirm:

- **Final EPA determinations on PMNs submitted by CCI members have plummeted since the passage of the Act:**

2011

Seventy (70) chemicals received a final determination from EPA

2019

Six (6) chemicals received a final determination from EPA

- **EPA's average review time for PMNs has increased by 260% since the passage of the Act:**

Prior to 2016

In the five years before TSCA was amended, average PMN review time was 158 days

Since 2016

Since 2016, the average review time of a PMN has increased to 413 days

Under TSCA, PMN reviews are intended to be complete within 90 days.

- **EPA's average LVE review time has increased by 443% since passage of the Act:**

Prior to 2016

In the five years before the 2016 amendments, average LVE review time was 44 days

Since 2016

Since 2016, the average review time has been 87 days. In 2021, the average review time increased to 195 days

Under TSCA, LVE reviews are intended to be complete within 30 days.

More Results of the FTI Analysis

80% Drop in R&D

CCI members have historically spent billions on research and development (R&D) in the United States, providing employment for U.S. workers and helping expand U.S. productivity. Current implementation of TSCA Section 5 has stifled R&D:

- U.S. R&D expenditures by CCI members **peaked at $324 million in 2018**; and
- U.S. R&D expenditures began to decrease in 2019 -- dropping from $324 million in 2018 to $187 million in 2019 and then **falling to just $65 million in 2021** -- an 80 percent drop.

Upstream and Downstream Losses

For CCI members alone -- just a subset of affected industry -- forecasted upstream and downstream losses, both direct and indirect, and associated CCI member losses from 2022 to 2026 include:

- An average of **6,600 job losses** each year across the U.S. workforce;
- **$10 billion in lost economic output** and $4.2 billion in lost gross domestic product (GDP);
- Over **$500 million in reduced federal tax revenue**s and nearly **$300 million in reduced state and local tax revenues**; and
- Extrapolated **GDP loss** to the broader U.S. economy would be **$6.2 billion on average** from 2022 to 2026.

The Solution

EPA frequently reminds the regulated community that it "has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation." 87 Fed. Reg. 39511 at 39512 (July 1, 2022). EPA must use its inherent authority here to make three policy changes to avoid further stifling chemical innovation through its implementation of TSCA Section 5. EPA needs to:

- **Explicitly consider risk reduction in comparison to existing chemicals when assessing new chemicals;**
- **Rely on actual, not modeled, data in making TSCA Section 5 decisions; and**
- **Interpret "reasonably foreseen" as Congress intended in enacting the 2016 TSCA amendment.**

CCI has prepared the attached briefing documents on each of these policy changes.

CCI wishes to work with EPA to effectuate them.

For more information, e-mail info@chemicalinnovations.org

Scan QR code for explainer videos:

TSCA SECTION 5