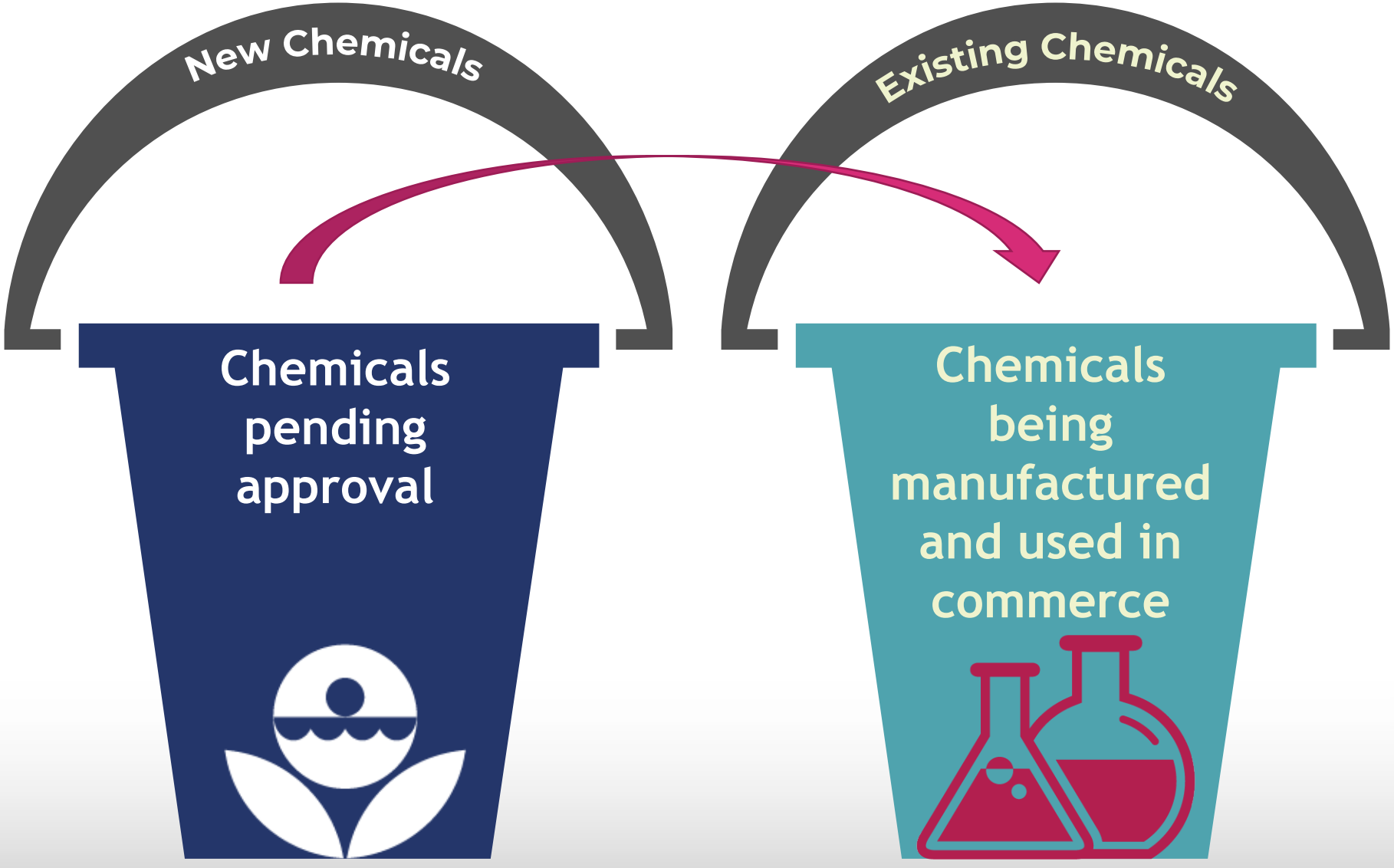
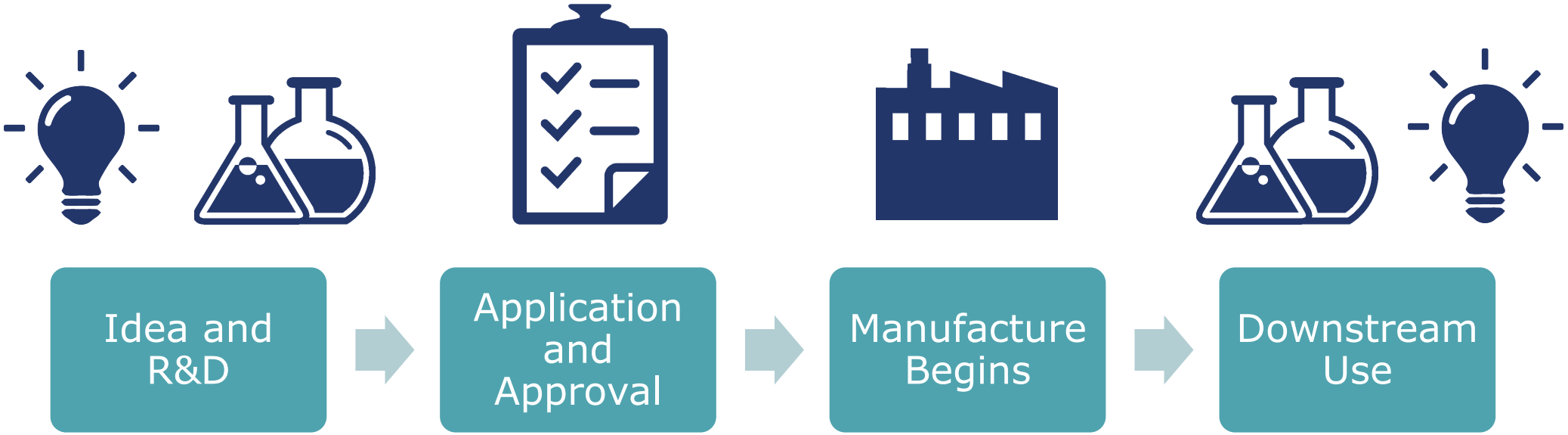
American Chemistry Council

June 2024

New Chemicals under the Toxic Substances Control Act

TSCA Regulates Production and Use of Chemicals in Commerce





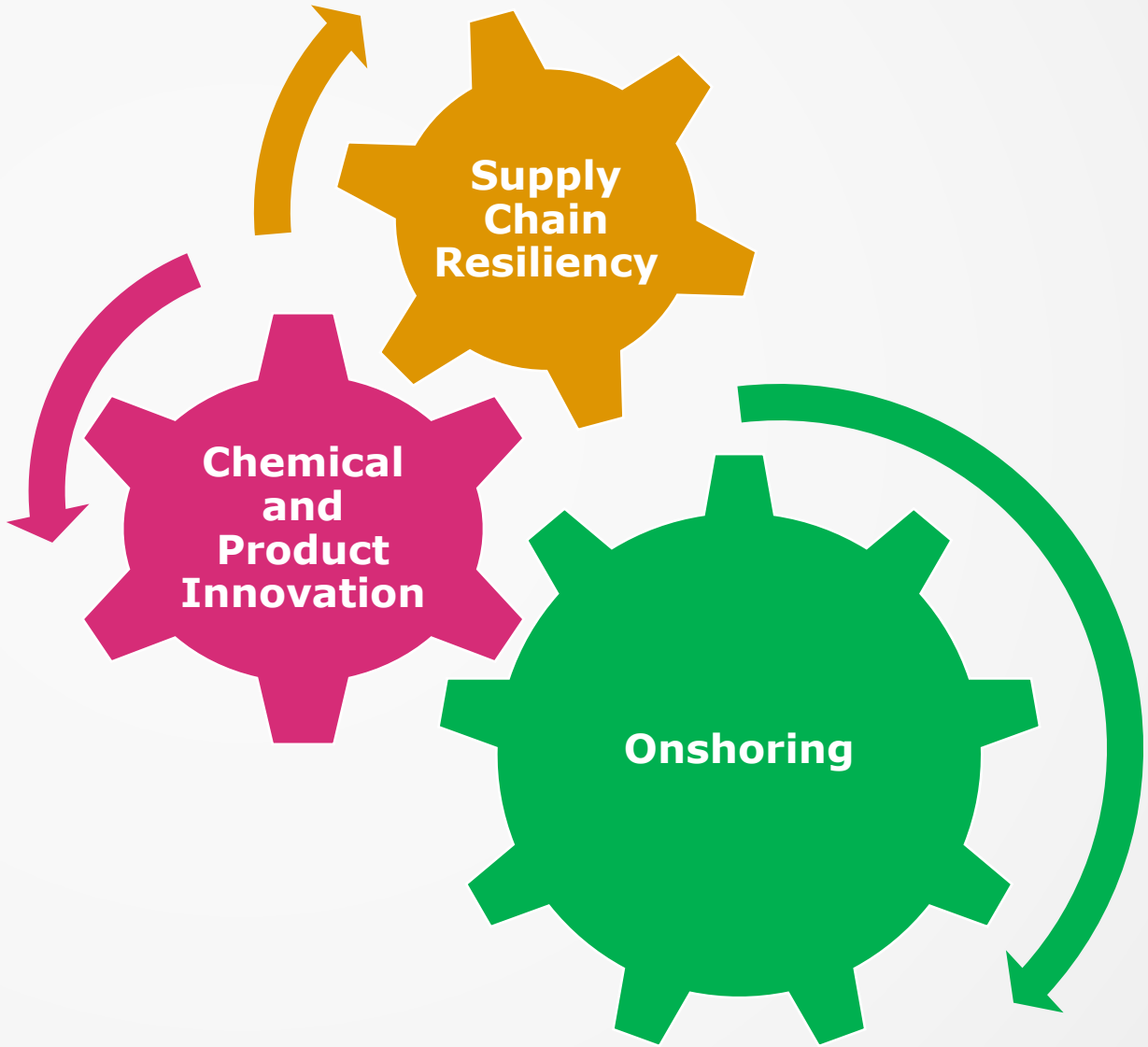
New chemicals have statutory 90-day review

Uses are varied - industrial, commercial, consumer

- Regulatory process must be **speedy**, **predictable**, and provide for **protection of intellectual property**
- Once on the TSCA Inventory, other regulatory tools are available for data gathering, prioritization, risk evaluation, and risk management of chemicals under the **conditions of use**

Why it matters

Broad impact - the ability to get building block materials, green new and sustainable breakthroughs, specialty chemicals, cutting-edge discoveries and developments are at risk.



New Chemical Program Background

TSCA Section 5 Mandates

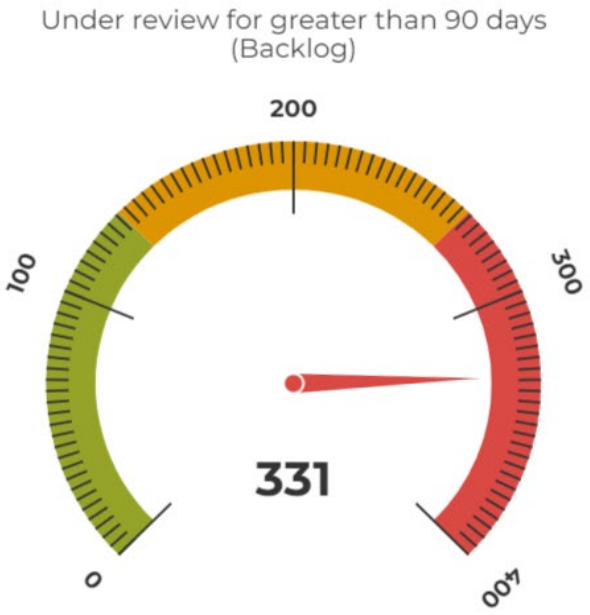
- Under the 2016 amendments to TSCA Section 5, the EPA is required to assess whether a new chemical substance poses an unreasonable risk before it can be manufactured or imported into the United States. The EPA must make this determination within 90 days, with the option to extend the review period if necessary.

Challenges

- EPA’s inability to meet the statutorily mandated 90-day deadline has created a significant backlog, impacting manufacturer's ability to innovate and manufacture in America.

- In a 2022 survey of ACC member companies, 70% of respondents reported that they have decided to introduce new chemicals outside of the U.S. due to uncertainties and challenges with the EPA’s New Chemicals Program.

New Chemical Program Statistics



407 TSCA new chemical substances under review

- 76 chemicals under review for < 90 days.
- 331 new chemicals under review for > 90 days
- 81% of new chemicals under EPA review for > 90 days.

Backlog Details

- 13% backlog reduction in April
- Due to # of new submissions, the # of new chemicals under review > 90 days, remained nearly the same.

Data provided on this slide was last updated May 16, 2024.

New Chemical Program Statistics

EPA Completed Reviews

- EPA completed 23 PMN submissions in April from the TSCA new chemical review backlog. The average number of PMN submissions per month in 2023 was approximately 11.6; this number increased in the first 3 months of 2024 to an average of 20.

Review Duration

- 244 PMNs (74%) of the backlog have been under EPA review for greater than or equal to one year.

Data Sources: ACC developed the visualizations to help interpret and track EPA's performance of the TSCA New Chemicals Program. The data and information compiled in the slides above are from the following EPA sources: 1) the New Chemicals case tracker and, 2) the Premanufacture Notices (PMNs) and Significant New Use Notices Table.

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Thank You!