Balancing Innovation and Risk Management: TSCA's New Chemical Review Process

Trends Across Recent Administrations

Philip A. Moffat
Attorney, Verdant Law

Chemical Watch Regulatory Summit
North America 2025

9/15/2025

VERDANT
VERDANT LAW, PLLC

Philip A. Moffat

Attorney

25 years of experience advising clients on all aspects of TSCA compliance, including PMN/SNUN submissions, exemption eligibility, enforcement defense, and self-audits.

TSCA's Purpose

It is the policy of the United States that…authority over chemical substances and mixtures should be exercised in such a manner as **not to impede unduly or create unnecessary economic barriers to technological innovation** while assuring that such innovation and commerce in such chemical substances and mixtures **do not present an unreasonable risk of injury to health or the environment.**

TSCA Section 2(b)

Lautenberg and New Chemicals

"…old TSCA allows new chemicals to go to market without any real review….[under Lautenberg], the **EPA will be required to determine that all chemicals are safe** before they go to market."

Sen. Tom Udall (D-NM)

"…the amendments to [Section 5] were intended to **conform closely with EPA's current practice and maintain the Agency's timely reviews** that allow substances to market within the statutory deadlines."

Sen. David Vitter (R-LA)

"American innovation relies on new chemicals entering commerce in a timely, predictable manner. **Unfortunately, the new chemical program is broken**."

- Chris Jahn, ACC (2025)

"The EPA's NCD **lacks assurance that the new chemicals review process operates as intended** and achieves its objective to protect human health and the environment."

- 2023 EPA OIG report

"The highly-touted system of chemical risk assessments mandated by [Lautenberg] has been **completely captured by industry, rendering it ineffective**."

- PEER (2021)

"The need for TSCA reform is also evident in EPA's review of new chemical submissions, which **typically take a year or more, far exceeding the 90-day timeframe** anticipated by TSCA."

- David Fischer, Fmr. EPA Dep. Asst. Admin. (2024)

Presentation Overview

1. Key Issues in New Chemicals
   A. Review backlog
   B. Outcomes/restrictions
   C. Industry and NGO perspectives

2. What the Current Administration (and Congress) Are Doing So Far

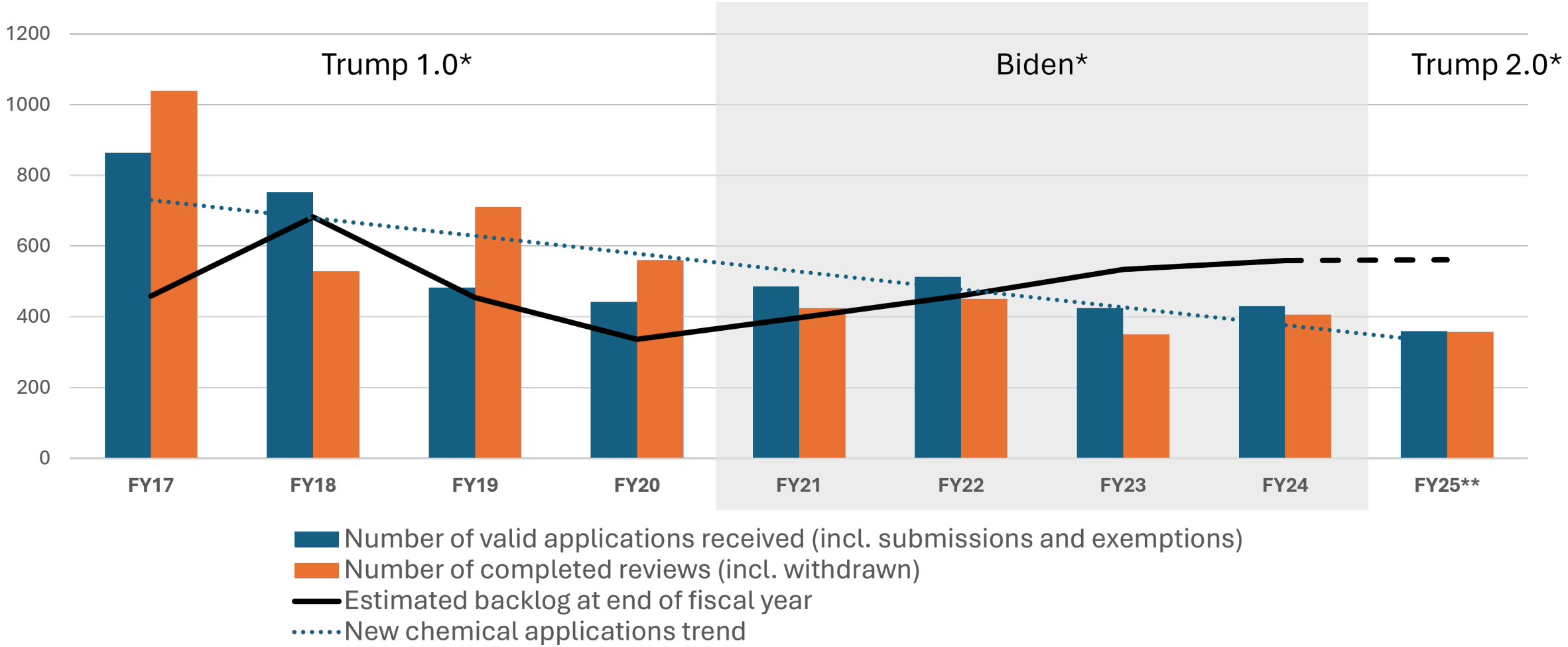
1. Key Issues in New Chemicals

1. Key Issues in New Chemicals

A. New Chemical Backlog

Approximation based on publicly available EPA data.
*Presidential administrations do not align exactly with fiscal years.
**FY25 data is through 9/1/2025.

New Chemicals Backlog



Why Is There a Backlog?

- Lautenberg (2016) requires EPA to make an affirmative determination on all submissions
- **EPA (2023 GAO report):**
  - Resource constraints
  - Risk assessment revisions due to newly provided info
  - Insufficient internal guidance
  - IT challenges
- **Industry (2025 GAO report):**
  - Resource constraints
  - Insufficient EPA reviewer expertise
  - IT challenges
- **EDF**
  - Risk assessment revisions due to newly provided info

Past Strategies to Address Backlog

Trump 1.0

- "Working Approach"
  - "SNUR-only" for concerns re reasonably foreseeable uses
  - Worker PPE usage as intended
- Redeployed staff to TSCA program
- Environmental groups: reviews were less thorough
  - Overly narrowed interpretation of "reasonably foreseen"

Biden

- Outreach campaign to submitters on how to avoid rework
- New Chemicals Procedural Rule (2024)
  - Clarified information requirements for submissions

1. Key Issues in New Chemicals

B. Outcomes/Restrictions

Submission Outcomes: Trump 1.0

- Promulgated SNURs without corresponding Section 5 order
- Assumed PPE usage as part of "intended use"

PMN/MCAN/SNUN Determinations by Fiscal Year*

	FY17	FY18	FY19	FY20
No Section 5 order	16%	16%	66%	55%
Commercialization allowed with restrictions	56%	58%	20%	29%
Commercialization prohibited/ prohibited pending info development	1%	0%	0%	0%
Withdrawn	26%	26%	13%	15%
Total # of determinations (incl. withdrawn)	485	262	402	319

*Adapted from publicly available EPA data. Determinations on valid submissions only. Percentages may not sum to 100% due to rounding. Presidential administrations do not align exactly with fiscal years.

Submission Outcomes: Biden

- Stopped SNUR-only approach
- Stopped assuming PPE usage; absence of usage viewed as "reasonably foreseen"

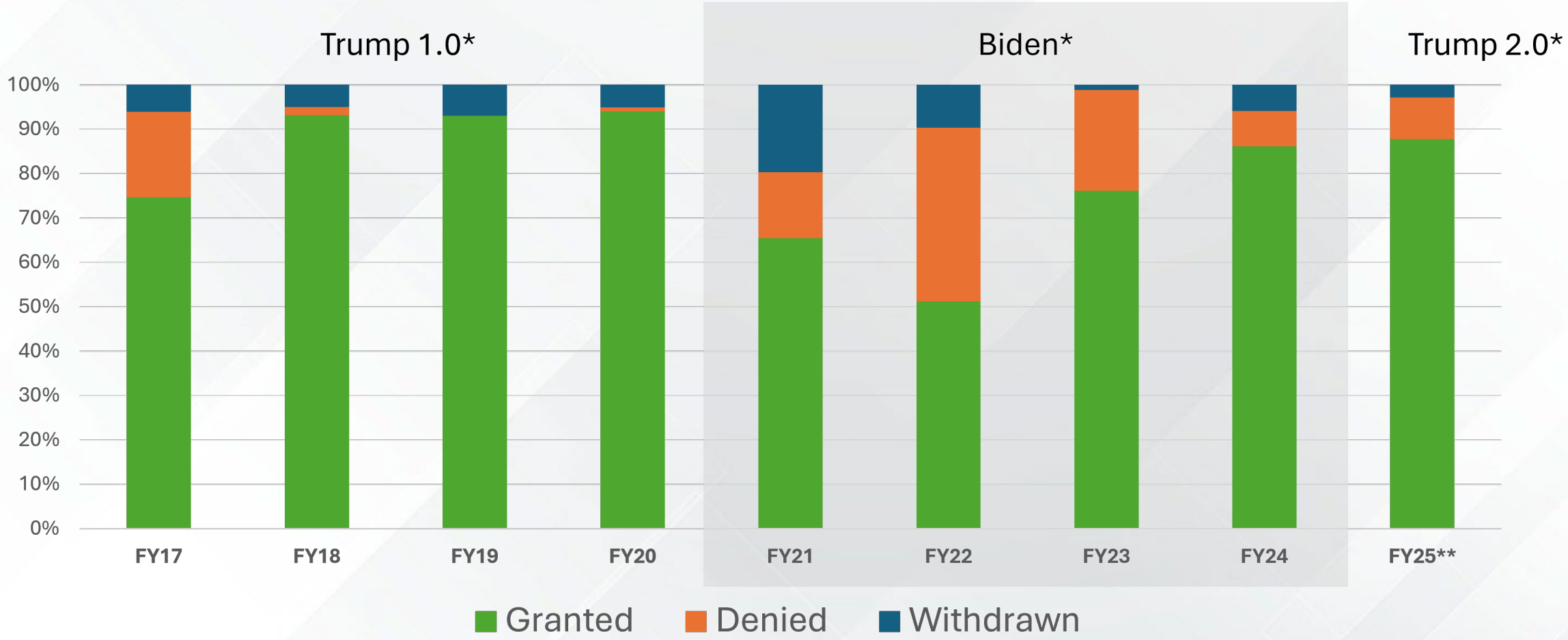
PMN/MCAN/SNUN Determinations by Fiscal Year*

	FY21	FY22	FY23	FY24
No Section 5 order	43%	23%	14%	19%
Commercialization allowed with restrictions	29%	56%	59%	61%
Commercialization prohibited/ prohibited pending info development	2%	0%	0%	5%
Withdrawn	26%	20%	27%	16%
Total # of determinations (incl. withdrawn)	184	147	145	216

*Adapted from publicly available EPA data. Determinations on valid submissions only. Percentages may not sum to 100% due to rounding. Presidential administrations do not align exactly with fiscal years.

Approximation based on publicly available EPA data.
Only valid exemption applications are included.
*Presidential administrations do not align exactly with fiscal years.
**FY25 data is through 9/1/2025.

Exemption Outcomes



1. Key Issues in New Chemicals

C. Industry and NGO Perspectives

Industry's Perspective

Causes Competitive Disadvantages	Creates Uncertainty	Discourages Innovation
• ACC survey (2022): 70% of companies introduce chemicals outside US instead	• GAO 2025 report: reviews overrun marketing windows, contracting deadlines	• SNURs (and associated delays) discourage innovation, investment in safer substitutes for legacy chemicals

Environmental Groups' Perspective

Prioritize Health and Safety	Regulatory Integrity Is at Risk	Transparency is Insufficient
• EPA's success should be measured by thoroughness, not speed	• EPA scientists are pressured to approve risky chemicals	• Limited disclosure of review data inhibits public oversight

2. What the Current Administration (and Congress) are Doing So Far

Trump 2.0: Aggressive Focus on LVEs

- Categorization of LVEs based on features like uses and characteristics
- Staff with expertise on different issues review simultaneously
- EPA touts improved communication with submitters and within agency
- Dr. Dekleva: EPA intends to apply new LVE strategies to other types of reviews

*Approximation based on publicly available EPA data. Excludes rework assessments completed.

Trump 2.0: Staffing and Funding

- Administration is attempting to add more staff to OCSPP to speed reviews
- $17 million appropriation for IT modernization
- White House's proposed FY26 budget would reportedly cut funding for TSCA risk and reduction activities by 24%
  - Senate bill (S.2431, Murkowski): 17% increase
  - House bill (H.R.4754, Simpson): 16% decrease

Trump 2.0: Artificial Intelligence

- Zeldin: EPA will use AI to speed reviews
- AI tools purportedly under development:
  - "AI Chemist Assistant" – would identify chemical and analog information from repositories
  - "EcoVault" – would provide summaries of studies
- Existing Open AI-powered tool available for staff, including OCSPP
- EPA policy requires that AI responses are thoroughly checked for accuracy

Trump 2.0: Possible Section 5 Reform

- Trade press reports that the House is close to releasing draft reform bill
- Likely includes changes to TSCA Section 5
- Potential targets for reform:
  - Hard deadlines for completing reviews
  - Revised statutory criteria for Section 5 orders / SNURs
  - Tightened timeframe between Section 5 order and SNUR
- A partisan reform bill is unlikely to advance in the Senate

Trump 2.0: Possible Section 5 Reform

Sept 8 letter from American Alliance for Innovation:

Our organizations have challenges with TSCA and have identified some additional statutory improvements and clarifications, including:

- Ensuring timely and predictable reviews of new chemicals;
- Avoiding unnecessary regulation, including overuse of Consent Orders (COs) and Significant New Use Rules (SNURs) that discourage adoption of innovative and sustainable chemicals;
- Following a risk-based approach to regulating a chemical's intended use in commerce that is rooted in actual uses and real-world scenarios;
- Strengthening the scientific standards included in TSCA for what constitutes "the weight of the scientific evidence;" and
- Providing additional clarity to other sections of TSCA that govern testing, regulatory petitions, and data sharing.

Trump 2.0: TSCA Reform Timeline

Jan 22, 2025:
House Environment Subcommittee hearing to assess Lautenberg's impact, with particular focus on new chemicals

June 25, 2025:
ELI/B&C/GWU conference on TSCA reform

Aug 27, 2025:
Inside EPA reports that the House is "poised to release a draft TSCA reform bill soon after…summer recess"

October 2025:
Possible Senate EPW hearing

Sept 30, 2026:
TSCA fee authorization expires

Conclusions

1. TSCA has two primary objectives: preventing unreasonable risk and avoiding undue burdens on innovation. Different administrations have weighed these goals differently.

2. No stakeholder is entirely satisfied with Section 5 implementation. EPA, NGOs, and industry maintain competing perspectives.

3. Significant changes are underway—including policy alterations, resource reallocations, and potential reforms—with the potential to greatly impact the program.

Questions?

Philip A. Moffat

pmoffat@verdantlaw.com

202-828-1233

VERDANT

VERDANT LAW, PLLC