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TSCA: Three Years Later

Where Are We Now?

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June 24, 2019

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Progress to Date: Statutory Deadlines

The amended Toxic Substances Control Act (TSCA) imposed many challenging deadlines on the U.S. Environmental Protection Agency (EPA), all of which have been met, including:

- Six months after enactment
 - Initiate risk evaluations on the “first 10” chemicals
 - Risk evaluations are underway and first peer review, concerning Pigment Violet 29, was just held
 - Risk evaluations required to be completed by **December 2019**, extendable until **June 2020**

Progress to Date: Statutory Deadlines

- One year after enactment
 - Promulgate procedural rules for prioritization and risk evaluation
 - Rule published in July 2017
 - Prioritization process underway for 20 high- and 20 low-priority candidate chemicals
 - **December 2019** deadline for prioritization decisions
 - High-priority determinations must undergo risk evaluation
 - Low-priority determinations subject to legal challenge

Progress to Date: Statutory Deadlines

- One year after enactment
 - Promulgate Inventory update rule
 - Rule published in August 2017
 - Reporting showed that only 47% of the Inventory-listed chemicals are “active” in commerce
 - Going forward, inactive chemicals will require advance notice to EPA
 - Establish Science Advisory Committee on Chemicals (SACC)
 - SACC established in December 2016
 - First meeting held in June 2019

Progress to Date: Statutory Deadlines

- Two years after enactment
 - Issue strategic plan concerning alternative methods for vertebrate animal testing
 - Strategic plan issued in June 2018 and currently being implemented
- Three years after enactment
 - EPA shall propose Section 6(a) risk management rules for certain persistent, bioaccumulative, and toxic (PBT) chemicals
 - EPA identified seven PBTs in December 2016
 - Five slated for proposed Section 6 action under June 21, 2019, proposed rule
 - Two undergoing manufacturer-requested risk evaluations

Other Progress to Date

- EPA developed new small business standard
- EPA issued in final TSCA fees rule in September 2018 that applies to:
 - Section 4 test rules, orders, and consent agreements
 - Section 5 notifications
 - Section 6 risk evaluations, including those requested by manufacturers

Other Progress to Date

- Section 6(a) risk management based on an existing risk assessment
 - EPA issued final rule in March 2019 banning use of methylene chloride in consumer paint and coating removal products
 - EPA also issued Advance Notice of Proposed Rulemaking (ANPRM) concerning use in commercial paint and coating removal
- Significant New Use Rule (SNUR) on asbestos
 - In April 2019, EPA issued final SNUR locking the door on discontinued uses of asbestos

Area Where Progress Has Proven Difficult: Section 5

Amended TSCA imposed new requirements on EPA in reviewing/taking action on new chemicals

- EPA must:
 - Review and make a determination on all Section 5(a) notifications
 - Take required actions
- Amended law did not include any transition period

Area Where Progress Has Proven Difficult: Section 5

- Determinations and corresponding EPA actions include:
 - Insufficient hazard information
 - May present an unreasonable risk
 - Substantial production and exposure
 - In such cases, EPA must regulate to the extent necessary to protect against unreasonable risk
 - Not likely to present unreasonable risk
 - Notifier can commence manufacture
 - EPA must make its finding public

Area Where Progress Has Proven Difficult: Section 5

- Substantial new requirements proved difficult for EPA to meet
- Absence of a transition period contributed to the problems
 - EPA decision to apply new law to old (suspended) cases added to the difficulties
- Result was an immediate backlog of cases that EPA has been working hard to resolve
- Recent changes in EPA's approach are reducing the backlog
- Challenges remain before EPA, notifiers, and stakeholders in developing an efficient, effective, and predictable new chemicals program

Area Where Progress Has Been Lacking: Section 4

- Amended TSCA gave EPA additional new authority to require testing as long as certain requirements were met
 - Orders
 - Rules
 - Consent agreements
- New authority has yet to be used

Important Areas to Watch in the Future

- EPA staffing and resourcing
- Litigation outcomes
- Confidential Business Information (CBI)
- Preemption
 - As EPA takes certain decisions and regulatory actions under Section 6, preemption is triggered
 - The number and frequency of such preemptive EPA actions will increase over the next few years

Important Areas to Watch in the Future

- Many challenging deadlines, but EPA has met every one; of particular note are the rules needed to establish the framework for implementation (prioritization, risk evaluation, fees, updated Inventory)
- Prioritization has started in earnest and the first tranche of 20 high- and 20 low-priority determinations is expected this year
- Risk evaluations are underway on ten cases and a milestone was reached in holding the peer review of Pigment Violet 29 recently with nine more risk evaluations expected to issue in the next year, setting the stage for significant Section 6 activity in the next several years

Important Areas to Watch in the Future

- EPA has started using its new authorities under Section 6 and its ANPRM asking for comments on training, certification, and limited access programs for commercial paint removal and stripper uses. New Section 6 regulatory actions are expected concerning the five PBT chemicals for which the proposed rule was published on June 21, 2019
- A key long-term component to understanding the potential issues with many of the active chemicals is Section 4 testing with its important new authorities, which have yet to be used by EPA

Important Areas to Watch in the Future

- The new chemicals area has been difficult; progress continues, but challenges remain before EPA, notifiers, and stakeholders in realizing an efficient, effective, and predictable new chemicals program that ensures continued innovation in the new chemicals space

Thank You

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