With Passage of TSCA Reform, What Happens Next?

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Overview

- Congressional passage
- Key aspects of TSCA reform
  - What has not changed
  - Test orders
  - PMNs and SNURs – and articles
  - Prioritization, risk assessments, risk management
  - Inventory reset
  - Protection of confidential information
  - Preemption
- Industry challenges and opportunities

Congressional Milestones

Multiple bills introduced since 2005

2015

House of Representatives

Narrowly targeted, passed June 23, 2015, *398-1*

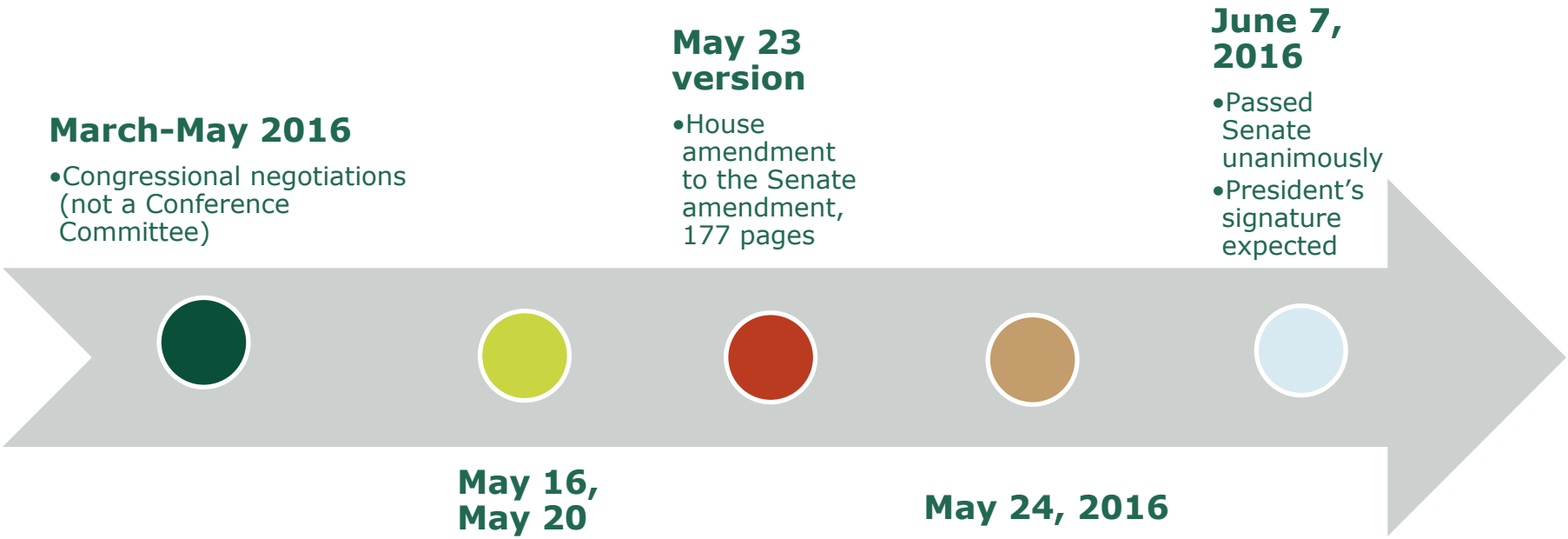
- TSCA Modernization Act of 2015, H.R. 2576
- 46 pages

Senate

Broader overhaul, passed Dec. 17, 2015, *unanimous*

- Frank R. Lautenberg Chemical Safety Act for the 21st Century Act, S. 697 – text substituted into H.R. 2576
- 211 pages

Congressional Milestones



Executive Office of the President

"**The Administration strongly supports** the bipartisan, bicameral efforts to reform the Toxic Substances Control Act (TSCA) embodied in the Senate Amendment to H.R. 2576.

The bill is a **clear improvement** over the current TSCA and represents a **historic advancement** for both chemical safety and environmental law."

"The Administration encourages quick action on this **landmark reform**."

TSCA Background

- TSCA is the primary federal chemicals law
  - Adopted in 1976, not significantly updated since then
    - Perceived as partially ineffective
    - Some parts work well (§ 5)
    - Some don't (§ 4, §6)
  - States have adopted their own restrictions on chemicals in the absence of TSCA restrictions
  - Many stakeholders have called for legislative change
- Congressional passage of TSCA reform will be the first major environmental enactment in 25 years
  - Since the Clean Air Act Amendments of 1990

Key Aspects of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

What Has Not Changed

Basic structure of TSCA

- Exemptions for pesticides, FDA-regulated materials - § 3
- Regulation based on unreasonable risk
- Testing requirements through rulemaking - § 4
- Review and possible regulation of new chemicals and significant new uses + exemptions - § 5
- Existing chemicals regulation - § 6
- Reporting and recordkeeping - § 8
- CBI and public access to information - § 14
- Preemption based on final risk management rule - § 18
- Judicial review under "substantial evidence" test - § 19

What Has Changed

- Fundamental rethinking of how EPA reviews and regulates existing chemicals
- PMNs and SNUNs – affirmative EPA decisions
- Treatment of articles, replacement parts
- Expanded testing authority
- Inventory reset
- CBI claims, confidential Inventory review
- Substantially expanded preemption
- New fee obligations
- New science standards

Unreasonable Risk

1976 TSCA	• EPA must consider a chemical's benefits and economic consequences of rule
1991, *Corrosion Proof Fittings*	• Costs and benefits not adequately considered
H.R. 2576	• Unreasonable risk under the conditions of use, without consideration of cost or other non-risk factors
Original TSCA	• "presents or will present"
New § 6	• "presents"
New § 5	• "presents," "may present," "substantial or significant," "not likely to present"

Section 4: Testing

Testing - § 4

- TSCA § 2(b): "It is the policy of the United States that– (1) **adequate data should be developed** with respect to the effect of chemical substances and mixtures on health and the environment and that the **development of such data should be the responsibility of those who manufacture and those who process** such chemical substances and mixtures."
- Slow pace of testing – 40 years, ~200 chemicals
- "Catch-22" – To require testing, EPA must find that a chemical "may present an unreasonable risk"

Testing

Senate amendment

Would have repealed "may present" test, substituted a showing of need for limited testing

House amendment

Kept "may present" test, added new limited testing authority on a showing of need

- By showing need for §§ 4, 5, or 6, EPA may order testing (or consent agreement)
- Industry should expect more EPA testing requirements

Testing

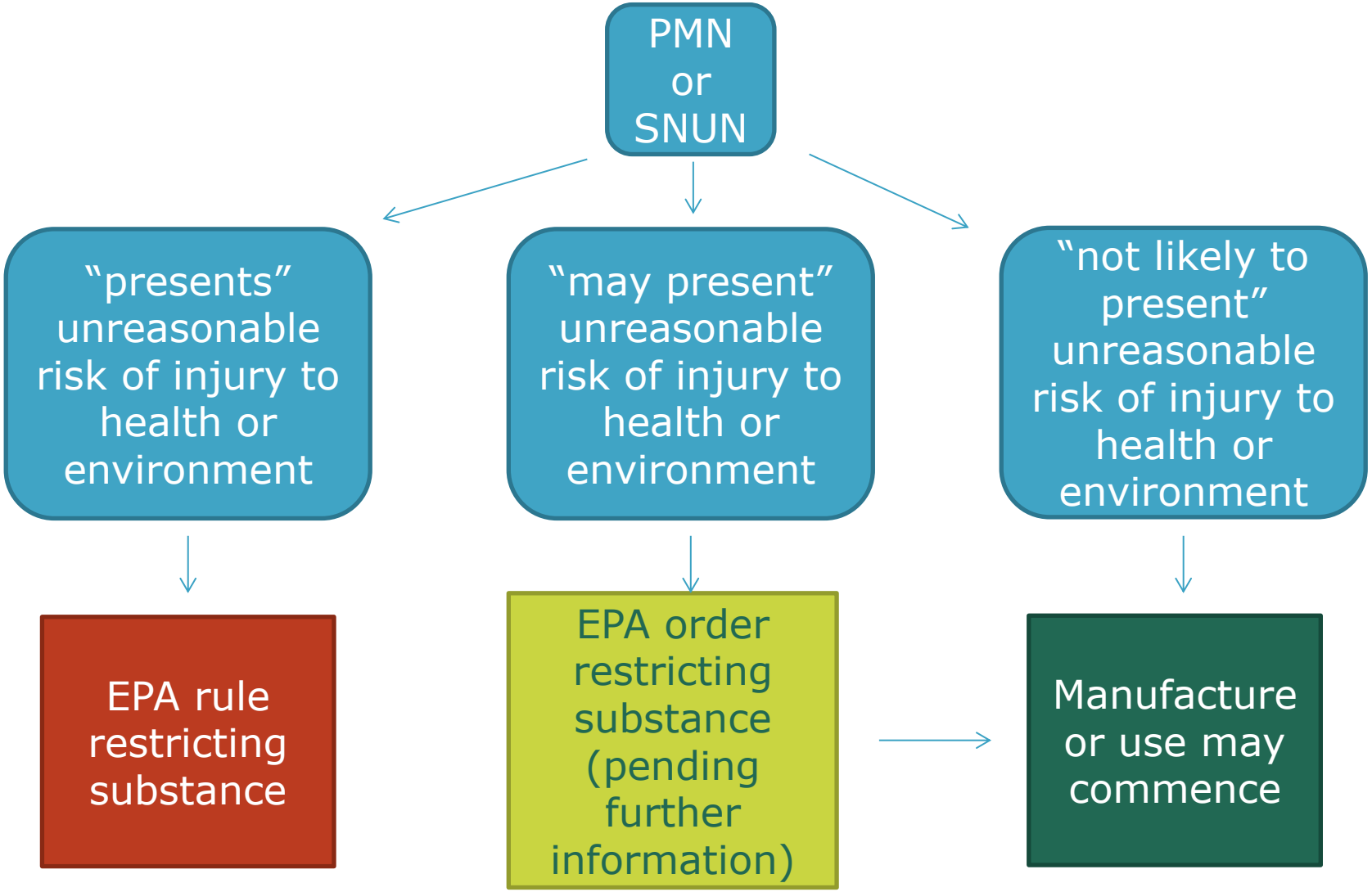
- Tiered testing
  - Screening level tests, then advanced tests
  - Unless requiring only advanced tests is justified
- Reduction of testing on vertebrate animals
- No "base set" testing
- Drop old data compensation standard

Section 5: New Chemicals and Significant New Uses

Timing

- Current
  - Manufacturer of new chemical must submit premanufacture notice (PMN) before beginning non-exempt manufacture
  - Manufacturer or processor of chemical for use determined by EPA in a significant new use rule (SNUR) to be a significant new use must submit significant new use notice (SNUN) before beginning use
  - EPA has up to 90 days to review
- New
  - If EPA not done in 90 days, it must refund submitter's fees, but no commencement
  - If EPA finds chemical or use not likely to present an unreasonable risk, may commence immediately

New Chemicals and New Uses



Articles

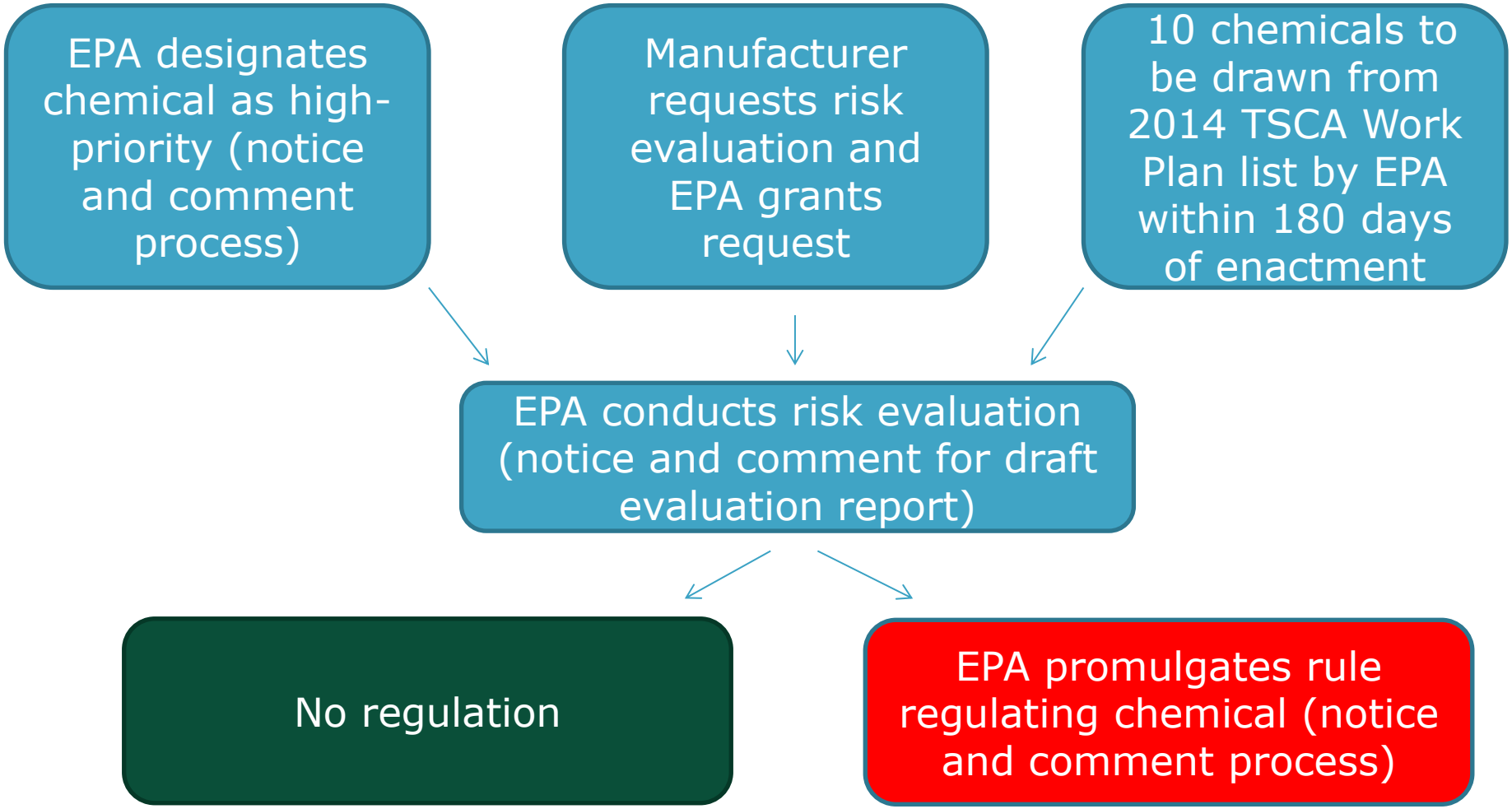
- Limited restriction on EPA's current authority to promulgate SNUR for a chemical in articles
  - Affirmative finding required
- EPA may promulgate SNUR for importing or processing chemical as part of an article or only if EPA finds that there is "reasonable potential for exposure to the chemical substance through the article … justifies notification"

Section 6: Prioritization, Risk Evaluation, Risk Management

Existing Substances

- EPA regards § 6, TSCA's principal control provision for regulating existing substances, as unworkable
  - EPA has not proposed rulemaking under § 6 for 25 years
- Current standard: EPA must restrict existing chemicals using "least burdensome" requirements
- Legislation removes "least burdensome" standard
  - Much easier for EPA to regulate existing substances

Process for Regulating Existing Substances (Except Certain PBT Substances)



Designation of High-Priority and Low-Priority Substances

- High-priority substance: EPA determines, without consideration of cost, that chemical "may present an unreasonable risk"
  - Designation as high-priority substance triggers requirement for EPA to conduct risk evaluation
- Low-priority substance: EPA determines, without consideration of cost, that chemical does not meet standard for high-priority
- Preferences for prioritization

Designation of High-Priority and Low-Priority Substances

- EPA must publish rule within one year of enactment mandating process for designation
- Process of designation to include:
  - EPA requests interested parties to submit information
  - EPA publishes proposed designation, provides 90-day comment period
  - EPA publishes final designation
- Timing for entire designation process: between 9 months and 1 year

Manufacturer Requests for Risk Evaluations

- Manufacturer of a chemical may request EPA to conduct a risk evaluation of that chemical
  - Not a request for "low-priority" designation"
  - Not a "high-priority" substance
  - Manufacturer must pay 100% of cost of evaluation (50% if a TSCA Work Plan chemical)
  - 25-50% of risk evaluations must be for manufacturer-requested chemicals (if sufficient requests are made)
  - Not subject to "high-priority pause" preemption

Risk Evaluations

- EPA must publish rule within 1 year of enactment mandating process for risk evaluations
  - EPA publishes scope of risk evaluation within 6 months of initiation
    - 3 months of initiation for TSCA Work Plan chemicals
    - "High-priority pause" begins with scope publication
  - EPA may not consider costs or other non-risk factors in risk evaluations
  - EPA publishes draft risk evaluation, provides 30-day comment period
  - EPA publishes final risk evaluation
- Timing for entire risk evaluation process:
  - 3 years (may extend for an additional 6 months)

Initial Risk Evaluations and Subsequent Workflow

- Within 180 days of enactment, EPA must ensure that risk evaluations are being conducted on 10 substances on 2014 TSCA Work Plan list
- EPA must ensure that within 3.5 years of enactment:
  - Risk evaluations are being conducted on at least 20 high-priority substances
  - At least 20 substances have been designated as low-priority substances
- Upon completion of each risk assessment (other than those requested by manufacturers), EPA must designate at least 1 high-priority substance

Risk Evaluation Outcomes

Chemical presents an unreasonable risk under conditions of use

- Proceed to risk management rulemaking
- End of "high-priority pause"
- No new preemption until final rule
- Tort implications?

Chemical does not present an unreasonable risk

- Preemption of new and existing state restrictions for scope of evaluation

Timing for Risk Management

- EPA must publish proposed rule within 1 year of publication of risk evaluation that contains an "unreasonable risk" finding
- Final rule must be published within 2 years of publication of risk evaluation
- In certain cases, timing may be extended for up to 2 years total for above deadlines
- Prohibitions in rule to take effect within 5 years of publication of final rule

Factors to Consider

In selecting restrictions, EPA must factor in, to the extent practicable:

- Exposure of humans and the environment to the substance
- Effects on health and the environment
- Benefits of the substance for various uses
- Reasonably ascertainable economic consequences of the restriction, including costs and benefits and overall cost effectiveness of the restriction
- Whether technically and economically feasible alternatives (that are preferable from a health and environmental standpoint) will be reasonably available when the prohibition takes effect

Articles

- Limited restriction on EPA's current authority to restrict a chemical in articles
- EPA may promulgate restriction for chemical as part of an article only "to the extent necessary to address the identified risk from exposure to the chemical … from the article" so that the chemical does not present an unreasonable risk

Replacement Parts

- EPA must exempt replacement parts for complex durable goods and complex consumer goods designed prior to publication date of rule
  - Unless EPA finds that replacement parts contribute significantly to the identified risk

PBT Substances

Within 3 years of enactment, EPA must propose § 6 rules restricting certain 2014 TSCA Work Plan chemicals having persistence, bioaccumulation, and toxicity characteristics

No requirement for EPA to conduct a risk evaluation for these substances

EPA must conduct exposure and use assessment before deciding to regulate

Final rule must be published within 18 months of publication of proposed rule

Final rule must restrict exposure to extent practicable

Section 8: Reporting

Inventory Reset – Active Substances

- "84,000 chemicals on the TSCA Inventory"
- Inventory reset – keeps chemicals listed
  - Final rule 1 year from enactment
  - 6 months to report
  - Chemicals manufactured in 10 years before enactment
  - CDR as Candidate List (7,690 substances; no polymers or naturally occurring)
  - Processors may report chemicals for last 10 years
  - (EPA then prioritizes active substances)
  - Later, must notify EPA before manufacture or process an inactive substance

Inventory Reset - CBI

- Any manufacturer or processor of chemical on confidential Inventory must give notice of claim
- EPA will move any unnoticed active substance to public Inventory
- Within 1 year of compiling active substances list, EPA must adopt a rule establishing plan to review all CBI claims for noticed chemicals on confidential Inventory
- Claimants must substantiate CBI claims
- EPA must evaluate claims within 5 years (+2)
- If manufacture or process inactive substance, must notify EPA and substantiate claim if on confidential Inventory

Mercury and Mercury Compounds

- EPA must publish an inventory of mercury and mercury compounds every 3 years
- Persons who manufacture mercury or mercury compound, or use it in a process, must notify EPA within 2 years of enactment
- Mercury-containing waste is excluded
- Export of certain mercury compounds prohibited by 2020
- Allows export for to OECD country for environmentally sound disposal
- Federal storage facilities for mercury

Section 14: CBI and Public Access to Information

Confidential Business Information

§ 14(a) prohibits disclosure of CBI

§ 14(b) exceptions

Health and safety studies submitted under TSCA for existing chemicals; § 4 testing; § 5 notification

Except for information that discloses process information or portion of mixture information

General information about chemicals

Identity of banned or phased-out chemicals

Except for critical use, export, specific conditions of use

Requirements for CBI Protection

- Must assert CBI claim when submitting information to EPA
- Must substantiate confidentiality
  - Including not readily discoverable by reverse engineering
- Must provide structurally-descriptive generic name
- Must renew CBI claims after 10 years
- EPA will assign a unique identifier

Exceptions to CBI Protection

- EPA may disclose CBI :
  - If necessary to protect health or the environment against an unreasonable risk of injury
  - To a state to administer or enforce a law (subject to limitations)
  - To a physician, nurse, poison control center, public official, or first responder in the event of an emergency
  - To government officials or medical professionals in a non-emergency based on a written statement of need
  - If required to be made public under another federal law
  - Pursuant to a judicial process under federal or state law

Section 18: Preemption

Preemption of State Actions

Requiring development of information

- "Reasonably likely" to produce the same information

Chemical substances restricted by EPA

- The hazards, exposures, risks, and uses or conditions of use of such chemical substances

Chemicals found not to present an unreasonable risk

- The hazards, exposures, risks, and uses or conditions of use of such chemical substances

Requiring new use notification

"High-Priority Pause"

New state restrictions are preempted for a high-priority chemical

- Once EPA publishes the scope of the risk evaluation

Duration:

- Until EPA publishes the risk evaluation or the risk evaluation deadline expires

Limited to the hazards, exposures, risks, and uses of conditions of use of such chemical substances included in the scope of the risk evaluation

Existing Laws & Exceptions

- State restrictions excluded from preemption:
  - Those imposed prior to April 22, 2016 (Earth Day)
  - Proposition 65, including future actions
  - Those imposed under other federal laws
  - Those implementing a reporting, monitoring, or other information obligation for the chemical
    - Includes most state green chemistry laws
  - Those related to water quality, air quality, or waste treatment or disposal (unless affecting manufacture, processing, use, etc.)
  - Those identical to TSCA restrictions

State Waivers

- States *and* political subdivisions of a state may apply for a waiver
- Discretionary vs. required waivers
- Waiver application is subject to notice and comment
- EPA determinations regarding waivers are subject to judicial review

Industry Challenges & Opportunities

Industry Challenges

- EPA can more easily regulate existing chemicals
- EPA can quickly require testing
- EPA focus on use of chemicals in articles likely to continue
- Inventory reset will impose reporting obligation and requirement to renew CBI claims for chemicals on confidential Inventory (or risk losing existing CBI protections)
- Potential tort implications for EPA findings that substances "present" unreasonable risks

Industry Opportunities

Provide comments on upcoming EPA rulemakings, including:

- Establishment of EPA process to designate high-priority and low-priority substances
- Establishment of EPA risk evaluation process
- Inventory reset rule

Provide input on EPA guidance documents to be issued under reformed TSCA

EPA proposed designations, draft risk evaluations, and proposed rules for individual chemicals

Questions?

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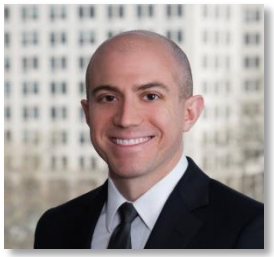

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