Toxic Substances Control Act

EPA Implementation Update

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The New Law

- "The Frank R. Lautenberg Chemical Safety for the 21st Century Act"
  - Signed by the President on June 22, 2016
  - Effective immediately
- Amends and updates the Toxic Substances Control Act (TSCA)
  - First update to TSCA in 40 years (1976)
  - Most significant update to an environmental law in 20 years
- Passed by large margin in the U.S. House and Senate
  - Bipartisan and diverse stakeholder support

Significance of Passage

"…this is a big deal. This is a good law. It is an important law…"

- **President Obama, June 22, 2016**

"…clear improvement over the current TSCA and represents a historic advancement for both chemical safety and environmental law."

- **WH Statement of Administration Policy, May 23, 2016**

"…the first major update to an environmental statute in 20 years…great news for the environment and for the health of all Americans."

- **Administrator McCarthy, June 22, 2016**

Major Improvements

Pipeline of Existing Chemicals Review and Management

- Mandatory duty on EPA to evaluate risks from existing chemicals
- Clear and enforceable deadlines

Risk-Based Safety Standard

- Chemicals assessed against a purely risk-based safety standard
- Costs and other non-risk factors excluded from consideration
- Unreasonable risks identified in the risk evaluation must be eliminated

Major Improvements

Development of Health and Safety Information

- Expands authorities for EPA to require development of chemical information (e.g., when necessary for prioritization, risk evaluation, etc.)
- Expedites the process through new order authority

Funding Source

- Up to $25 million total in annual user fees, supplemented by appropriations

New Chemicals

- EPA must make affirmative determination before new chemical goes to market

Confidential Business Information

- Requires substantiation of certain CBI claims, ensuring that those claims are merited

First Year Implementation Plan

- "Implementation Plan" published shortly after TSCA signed into law
  - New responsibilities and short deadlines under new law
  - Roadmap of major activities EPA will focus on during the initial year of implementation
  - NOT a comprehensive listing of all requirements in the new law

EPA believes successful implementation will require engaging partners and stakeholders early in the process

New Chemicals

Specific Requirements

- TSCA now requires EPA to make an affirmative finding on new chemicals or significant new uses of existing chemicals
- Requirements effective immediately on June 22, 2016
- Before the chemical can enter the market, EPA must make a determination that the chemical:
  - Presents an unreasonable risk
  - May present an unreasonable risk; and/or Information is insufficient to permit a reasoned evaluation of the risk
  - Is not likely to present an unreasonable risk

New Chemicals

Implementation

- Status of Review Efforts
  - PMNs in process on June 22, 2016 were considered "resubmitted"; restarted 90-day review period
  - EPA continues to receive additional new PMN submissions, resulting in doubling of review efforts
- Additional Challenges
  - Affirmative determination for both "intended" and "reasonably foreseen" uses of new chemicals
  - Developing and implementing a process for implementing the "not likely to present an unreasonable risk" finding, including new documentation and publication requirements
  - Implementing the new finding of "insufficient information to make a reasoned evaluation"
- Upcoming public meeting – December 14, 2016

Existing Chemicals

Implementation

- **First 10 Chemicals for Risk Evaluation**
  - On November 29, 2016, EPA identified and published a list of the first 10 chemicals for risk evaluation as required under new law
    - 1,4-Dioxane
    - 1-Bromopropane
    - Asbestos
    - Carbon Tetrachloride
    - Cyclic Aliphatic Bromide Cluster (HBCD)
    - Methylene Chloride (MC)
    - N-methylpyrrolidone (NMP)
    - Pigment Violet 29
    - Tetrachloroethylene, also known as perchloroethylene (perc)
    - Trichloroethylene (TCE)

Existing Chemicals
Implementation

- **First 10 Chemicals for Risk Evaluation**
  - TSCA required that all of the first 10 chemicals be drawn from the 2014 Update to the TSCA Work Plan
  - Publication triggers statutory deadlines:
    - Scoping of risk evaluation (within 6 months);
    - Completion of risk evaluation (3 to 3.5 years); and
    - Risk management rule for identified "unreasonable risk" (2-4 years following completion of risk evaluation)

Framework Rules

Regulatory Development

- **Prioritizing Chemicals for Assessment**
  - EPA must, by rule, establish a risk-based process to identify "high" and "low" priority substances
    - High priority – the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including risk to "potentially exposed or susceptible subpopulations"
    - Low priority – the chemical does not meet the standard for high-priority
  - Public meeting on development of prioritization rule held on August 10, 2016; opportunity for oral/written comment
  - Statute requires final rule by June 2017
  - Proposed rule with OMB for review; targeting December 2016 publication

Framework Rules

Regulatory Development

- **Process for Chemical Risk Evaluations**
  - EPA must, by rule, establish a process to conduct risk evaluations, including the form, manner, and criteria for manufacturer-requested risk evaluations
    - Need for both transparency in process and flexibility to adapt with rapid advances in science that will inform risk evaluations
  - Public meeting on development of risk evaluation rule held on August 9, 2016; opportunity for oral/written comment
  - Statute requires final rule by June 2017
  - Targeting proposed rule for December 2016

Framework Rules

Regulatory Development

- **Industry Fees**
  - EPA may, by rule, require payment of fees from manufacturers and processors who:
    - Are required to submit test data;
    - Submit notification of intent to manufacture a new chemical or new use of a chemical;
    - Manufacture or process a chemical substance that is subject to a risk evaluation; or
    - Request EPA to conduct risk evaluation on an existing chemical
  - EPA can set fees amounts to defray 25% of program implementation costs; subject to initial annual cap of $25 million
  - Industry consultations held on August 11 and September 13, 2016
  - No statutory deadline, but targeting proposed rule by January 2017, and final rule June 2017

Framework Rules

Regulatory Development

- **Inventory of Active/Inactive Chemicals**
  - EPA must promulgate a rule to require manufacturers to notify the Administrator of each chemical substance manufactured in last 10 years.
    - Depending on whether a notice is received, chemicals on the TSCA inventory will then be designated either "active" or "inactive"
    - EPA has discretion to apply the rule requirements to processors, in addition to manufacturers
    - Chemicals' status as listed on the TSCA Inventory will not change
  - Statute requires final rule by June 2017
  - Targeting proposed rule for December 2016

Existing Chemicals
Implementation

- **Ongoing Section 6 Rulemakings**
  - For chemical uses with completed risk assessments showing unreasonable risk before June 22, 2016, Section 26 allows EPA to propose and issue final Section 6 rules consistent with those assessments
  - EPA anticipates issuing the following rules:
    - TCE use in spot cleaning and aerosol degreasing
    - TCE use in vapor degreasing
    - Methylene chloride (MC) and N-methylpyrrolidone (NMP) in paint removers
  - Assessments for TCE, MC, and NMP all demonstrate significant risks to workers

Existing Chemicals

Implementation

- **Persistent, Bioaccumulative and Toxic (PBT) Chemicals**
  - Section 6(h) requires EPA to take expedited risk management action on certain PBT chemicals listed on the TSCA Work Plan
    - EPA must propose rules to reduce exposure to the extent practicable within 3 years (June 22, 2019) and finalized 18 months later
    - No risk evaluation; only a use and exposure assessment
  - Manufacturers could request full risk evaluation by Sept. 19, 2016, in lieu of expedited action
    - EPA received a request for risk evaluation on 2 of the 7 PBT chemicals - both used in fragrance mixtures
      - Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) and
      - Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)

Existing Chemicals

Implementation

- **Persistent, Bioaccumulative and Toxic (PBT) Chemicals**
  - **5 PBTs subject to expedited action under section 6(h)**
    - Decabromodiphenyl ethers (DecaBDE)
      - Flame retardant in textiles, plastics, wiring insulation, and building and construction materials;
    - Hexachlorobutadiene (HCBD)
      - Solvent in the manufacture of rubber compounds and as hydraulic, heat transfer or transformer fluid;
    - Pentachlorothiophenol (PCTP)
      - Mercaptan (sulfur) cross-linking agent to make rubber more pliable in industrial uses;
    - Tris(4-isopropylphenyl) phosphate
      - Flame retardant in consumer products and as lubricant, hydraulic fluid, and other industrial uses; and
    - 2,4,6-Tris(tert-butyl) phenol
      - Antioxidant that can be used as a fuel, oil, gasoline or lubricant additive.
  - EPA currently refining assessment of exposure and uses for these chemicals

Other New Requirements

Implementation

- **Scientific Advisory Committee on Chemicals (SACC)**
  - EPA must establish an advisory committee to provide independent advice and expert consultation with respect to the scientific and technical aspects of implementation
    - Representatives from science, government, labor, public health, public interest, animal protection, industry and other groups as the Administrator determines to be advisable
  - Statutory deadline of June 22, 2017
  - EPA issued a Federal Register Notice soliciting membership nominations in August 26, 2016; comment period closed October 11, 2016

For additional information on TSCA, visit EPA's website at:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act