Environmental Law Update

WEB CONFERENCE SERIES

The New Toxic Substances Control Act: What Industries Need to Know About Changes in Chemical Regulation

July 28, 2016

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Program Speakers

Louis J. Thorson
Associate
Foley & Lardner LLP
414.297.5776
lthorson@foley.com

FOLEY
FOLEY & LARDNER LLP

Program Speakers

Amanda K. Beggs
Associate
Foley & Lardner LLP
414.319.7037
abeggs@foley.com

FOLEY
FOLEY & LARDNER LLP

Program Speakers

Sarah A. Slack
Senior Counsel
Foley & Lardner LLP
608.258.4239
sslack@foley.com

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Overview

- Toxic Substances Control Act (TSCA) Background
- Key Changes to TSCA
- Timeline for Implementation and Implications for Industry

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Toxic Substances Control Act (TSCA) Background

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Background

- History of TSCA (1976)
  - How does TSCA relate to other environmental laws?
  - Who is regulated?
  - What is regulated?
- Which perceived deficiencies spurred the 2016 amendments?

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History of TSCA

- Signed into law in 1976
- While U.S. EPA has issued regulations governing numerous individual toxic substances since its passage (including asbestos, radon, and lead), the main provisions of the 1976 act have not been substantially changed since Congress passed the act

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History of TSCA

- Major provisions of the 1976 act:
  - Environmental Protection Agency (EPA) shall evaluate newly introduced chemicals for safety
  - EPA must prove that a chemical poses a potential risk before it can demand information or testing
  - EPA must conduct a cost/benefit analysis in which it considers health, environmental, and economic effects of potential regulations

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History of TSCA

- Major provisions of the 1976 act (cont.):
  - EPA must choose the "least burdensome" regulations
  - EPA must employ rulemaking to regulate chemicals under TSCA
  - Final federal rules preempt conflicting state law

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TSCA – Relationship to Other Environmental Laws

- TSCA is the United States' primary law for regulating chemicals used in everyday products
- Relationship to other environmental/consumer product laws:
  - EPCRA
  - RCRA
  - CERCLA
  - FIFRA
  - CAA
  - CPSA/FDA

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Application: Regulated Entities

- The 1976 version of TSCA applied to those entities introducing a chemical substance or mixture into active domestic commerce
- However, TSCA required evaluation of only chemicals *newly* introduced into the marketplace
- Those already in use as of 1976 received no review

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Perceived Deficiencies

- Created unwieldy, varied, and conflicting state regulations as a gap-fill for chemicals and circumstances not covered by the Act
- Failed to evolve with science and industry
- Cost/benefit analysis and “least burdensome” requirement resulted in slow, difficult regulation
- Limited EPA to a time-consuming rulemaking process

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Perceived Deficiencies

- Under the Act, the EPA lacked authority to evaluate ~64,000 chemicals in use prior to 1976
- Provided no framework for prioritizing the most dangerous chemicals
- Provided limited access to information on existing chemicals

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Perceived Deficiencies

- Created a backlog of confidential business information (CBI) claims to review
- Did not provide explicit protection for especially vulnerable groups
- Did not give the EPA an explicit duty to review existing chemicals and did not contain enforceable deadlines

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The Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576) (2016)

- Procedural History:
  - TSCA Modernization Act of 2015, H.R. 2576, Passed the House June 23, 2015
  - Frank R. Lautenberg Chemical Safety for the 21st Century Act, S. 697, Passed the Senate December 17, 2015
  - On May 24, 2016, the House voted on and passed a compromise version of H.R. 2576
  - On June 7, 2016, the Senate voted on and passed H.R. 2576
  - On June 22, 2016, President Obama signed the bill into law

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Key Changes to TSCA

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Key Changes to TSCA Under the 2016 Amendments

- Chemical Inventory (Active and Inactive)
- Priority of Chemicals (Low- and High-Priority)
- Risk Evaluations
- EPA Authority
- Confidential Business Information
- Fees
- Preemption
- Mercury

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Chemical Inventory

- EPA must classify the chemicals on the existing TSCA inventory as:
  - Active
    - Refers to chemicals in active domestic commerce
    - EPA to review the safety of chemicals that are in “active commerce”
  - Inactive
  - Only “active” chemicals are prioritized
- The amendments require industry to report on chemicals they have manufactured or processed in the previous 10 years to determine if the chemical is “active”

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Chemical Prioritization

- **High-Priority**
  - To start, EPA must review at least 10 chemicals it designates as high-priority
  - TSCA now requires a particular focus on known carcinogens, chemicals stored near drinking water, and those chemicals otherwise known to be dangerous
  - Once EPA determines that a chemical poses an unreasonable risk, it must issue a final rule to manage the chemical and its risks within two years of the final Risk Evaluation performed for the chemical

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Chemical Prioritization

- Low-Priority
  - Eventually, the EPA must review all chemicals in active commerce—including those in commerce prior to the enactment of TSCA
- Within 3.5 years of the amendments, EPA must have identified twenty “high-priority” and twenty “low-priority” chemicals

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Risk Evaluations

- Chemicals that are designated as “high-priority” trigger mandatory EPA Risk Evaluations
- EPA must screen all required chemicals based on the full available hazard, use, and exposure data
  - Risk Evaluations must use up-to-date science
- EPA conducts Risk Evaluations for chemicals designated “high-priority” and those requested by industry
- Chemicals designated as “low-priority” do not require further action, but can be elevated to “high-priority” based on new information

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Risk Evaluations

- Chemical evaluations requested by industry
  - The amendments establish a process for manufacturers to request that EPA evaluate specific chemicals
  - This category requires industry to pay for the evaluation:
    - Manufacturers pay 50% of the costs if the chemical is the on the TSCA Workplan
    - Manufacturers pay 100% of the costs for all other chemicals

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Risk Evaluations

- Chemical evaluations requested by industry
  - Industry requests for evaluations are subject to limitations:
    - Granted at EPA discretion
    - The evaluations do not count toward the 20 risk evaluations that EPA must have ongoing
    - The industry requests must be a minimum of 25% of the ongoing evaluations for high-priority chemicals but not more than 50%
      - For example, if EPA is evaluating 40 high-priority chemicals, there could be an additional 10-20 industry requested evaluations occurring at the same time

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Risk Evaluations

- The standard for screening chemicals is the "unreasonable risk" standard, which replaces the previous cost-benefit and the "least burdensome" standard
- Once EPA determines that a chemical poses an "unreasonable risk" it may then impose restrictions on the chemical
  - Restrictions must protect particularly vulnerable groups—not merely the "average" person
  - When regulating, the focus is now on health and environmental risks rather than economic factors
- EPA still conducts a cost/benefit analysis in tailoring regulations

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Expanded EPA Authority

- Testing Requirements
- Regulation of New Chemicals/New Uses
- Regulation of Existing Chemicals
- Broad Changes

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Expanded EPA Authority

- Testing Requirements
  - The EPA may now require by rule, order or consent agreement that new information for a particular chemical or mixture be developed
    - Testing requirements are based on “need”
    - Tiered testing

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Expanded EPA Authority

- Regulation of New Chemicals/Uses
  - EPA must make an affirmative finding on new chemicals or significant new uses of existing chemicals before the chemical can enter commerce
    - EPA may take a range of actions following the review of the new chemical, including placing a ban on the chemical, placing limitations on the chemical or requiring additional testing of the chemical

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Expanded EPA Authority

- Regulation of Existing Chemicals/Uses
  - Prioritization
  - Risk Evaluations
  - Initial Set of Work Plan Chemical Assessments
    - 10 TSCA Work Plan chemicals identified and Risk Evaluations for those chemicals underway by December 2016
    - Expedited review of TSCA Work Plan chemicals
  - Thousands of existing chemicals were previously unregulated

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Expanded EPA Authority (Broad Changes)

- Authority to compel action through orders instead of rules
  - Increases the efficiency of regulating under TSCA
  - Consent agreements and rulemaking are still available methods for regulating under the Act but are no longer necessary
- General authority to regulate chemicals in TSCA's "articles"
  - EPA previously had this authority, but it rarely exercised this authority
- While, under the amendments, the EPA's burden for requiring information-gathering and testing is generally relaxed, when implementing regulations, the EPA still bears the burden of proof

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Confidential Business Information

- **Previously:**
  - The law prohibited masking the identity of chemicals in health and safety studies
    - But in practice, EPA would often mask chemical identity
  - CBI claims did not have to be substantiated prior to EPA accepting the submittal
  - Backlog of CBI claims to review after the fact

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Confidential Business Information

- **Now:**
  - Chemical and mixture identity are explicitly eligible for masking where justified to the satisfaction of EPA
  - Regulated entities must provide up-front justification for all CBI claims, including those for chemical identity
  - All CBI claims expire after 10 years, unless they are adequately reasserted
  - Under certain conditions, EPA may share CBI with state governments, health providers, and emergency responders if the information is deemed critical

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Fees

- To defray the cost of information-gathering and testing, EPA may now levy up to $25 million in annual user fees from regulated entities

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Fees

- EPA has authority to collect fees from manufacturers and processors who:
  - Are required to submit test data
  - Submit notice of an intent to manufacture a new chemical or new use of a chemical
  - Manufacture or process a chemical substance that is subject to Risk Evaluation
  - Request EPA to conduct a Risk Evaluation on an existing chemical
- EPA can set fees to defray 25% of the implementation costs
- Supplemented by Congressional appropriations

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Preemption

- Under TSCA (1976), only final federal rules preempted conflicting state law
  - With a dearth of final rules—since 1976, the EPA has tested only 200 chemicals and issued regulations for only five—preemption was nearly non-existent
- **Under the 2016 amendments:**
  - States may act on chemical risks that are not specifically addressed by the EPA
  - Preemption applies only to the scope contemplated by the EPA (e.g. if the EPA issues a rule regulating industrial but not home use, states are only preempted from regulating industrial use)
  - The states and EPA have co-authority over identical state and federal requirements and penalties not exceeding the federal maximum
  - Some state laws are “grandfathered” and therefore are not preempted

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Preemption

- State laws are preempted:
  - If EPA's assessment demonstrates that the chemical is safe
  - If EPA takes final action to address a chemical's risks
  - New rules may not be more stringent than existing EPA rules that address the same issue

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Preemption Pause

- State regulation is "paused" while EPA conducts a Risk Evaluation of a high-priority chemical
- If EPA finds that the chemical is safe, then preemption continues
- States may regulate a chemical if the federal Risk Evaluation takes longer than 3.5 years

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Preemption Waivers

- States may apply to the EPA for a waiver of general preemption or the preemption pause
  - EPA must grant a waiver of the preemption pause if:
    - The state has enacted a statute, or proposed or finalized an administrative action to prohibit or restrict a chemical
  - EPA may grant a waiver of general preemption if:
    - There are compelling conditions requiring the waiver
    - The waiver will not place an undue burden on interstate commerce
    - EPA supports the state's decision on the risk, based on the best available science and evidence

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Mercury

- The amendments to TSCA also place greater restrictions on mercury:
  - Effective January 1, 2020, the amendments add certain mercury compounds to the export ban on elemental mercury
  - The amendments require that EPA publish an inventory of mercury compounds use and trade in the U.S.
  - The amendments require that the EPA report to Congress related to mercury

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Timeline for Implementation and Implications for Industry

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Short-term Outlook

- Immediately – new PMN review requirements
- New CBI requirements
- Within 90 Days – List of mercury compounds that will be prohibited from export as of January 1, 2020
- Continued work on ongoing Section 6 Rulemakings (TCE, MC, and NMP)

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Six-Month Outlook (December 2016)

- Within six months/180 days, EPA must:
  - Initiate Risk Evaluations for 10 TSCA Work Plan chemicals
  - Publish list
  - Report to Congress on its ability to implement new mandates
  - Review small business reporting recordkeeping requirements
    - Subsequent reviews at least every ten years

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One-Year Outlook

- April 1, 2017 – Establish inventory of mercury supply, trade and use in the United States
- Publish a final rule for the active TSCA inventory
- Issue guidance for industry-requested Risk Evaluations
- Establish the Science Advisory Committee on Chemicals

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One-Year Outlook

- Publish scope of assessment of initial 10 Chemicals
- The EPA must promulgate a rule for risk-based screening to designate chemicals as either high- or low-priority
- The EPA must issue a rule for the Risk Evaluation process
- Fee Rule (?)

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Two-Year Outlook

- EPA must develop a strategic plan to promote development and implementation of alternative testing methods and to reduce animal testing
- Develop policies, procedures, and guidance
- Mercury use and reporting rules

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Three-Year Outlook

- Expedited action on chemical substances on the 2014 TSCA Work plan for certain chemicals
- Within 3.5 years of the amendments, EPA must have identified twenty “high-priority” and twenty “low-priority” chemicals

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Long-Term Outlook

- Approximately 4 to 5 years – completion of first risk evaluations
- Every 5 years – report to Congress on capacity and resources to conduct risk evaluations and issue rules to address unreasonable risks
- Every 10 years – re-evaulate CBI requests

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Implications to Industry

- Near-term Impacts
  - Submit information on “active” chemicals
  - PMN and SNUN submissions
  - CBI – need to submit supporting information

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Implications for Industry

- EPA Order Authority Expansion
  - Likely to increase enforcement and information requests
    - Burden for requiring data generation is less
    - “Need” standard for information-gathering
  - Relaxed cost/benefit analysis
    - Risk-based standard makes it more likely for a chemical to be subject to regulation
  - Rulemaking not required
    - Easier to issue an order

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Implications for Industry

- Prioritization Process for Active Chemicals
  - Impacts related to “high-priority” chemicals
  - The entire regulatory process may still be slow as EPA will begin with 20 high-priority and 20 low-priority chemicals
  - Industry petitions for Risk Evaluations of chemicals
    - Pros: regulatory uncertainty until evaluated, and request could provide certainty quicker
    - Cons: fees and compliance costs

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Implications for Industry

- EPA Authority to Regulate Chemicals in “Articles”
  - This regulatory authority is not new, but the EPA has rarely used it
  - New EPA authority and regulatory framework may change this practice
    - Restrictions on chemicals contained in articles could impact certain products that were previously unaffected by the law
    - Industry will have to be thoughtful of the previously unaddressed chemicals in their articles

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Implications for Industry

- EPA Ability to Collect Fees
  - Which companies will be required to pay fees?
    - Those that submit test data
    - Those that submit a notice of an intent to manufacture a new chemical or new use of a chemical
    - Those that manufacture or process a chemical substance that is subject to a Risk Evaluation
    - Those that have requested EPA to conduct a Risk Evaluation on an existing chemical
  - Fees could impact development costs

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Implications for Industry

- Upfront CBI Justification Required
  - Requestor must assert that:
    - Took reasonable measures to protect the confidentiality
    - Determined that the information is not required to be disclosed
    - Reasonable basis that disclosure is likely to cause substantial harm to the competitive position
    - Reasonable basis to believe the information is not readily discoverable through reverse engineering
  - Chemical Identity CBI:
    - Must include a structurally descriptive generic that the EPA may disclose to the public when requesting that a chemical name be treated as confidential

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Implications to Industry

- Overall EPA will not assume that the information claimed as confidential is in fact CBI, and CBI claims expire after 10 years
  - Upfront justification for CBI will make submittals more time-intensive and subject to greater scrutiny
  - Industry will need to be cognizant of the expiration date on their CBI claims and enlist resources to re-substantiate any CBI claims

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Implications for Industry

- CBI- Information Generally NOT subject to substantiation requirements
  - Process-specific information
  - Marketing and sales information
  - Information identifying a supplier or customer
  - Details of the full composition and percentages for a mixture
  - Specific information regarding the use, function or application of a chemical substance\
  - Specific production or import volumes

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Implications for Industry

- Import/Export Requirements:
  - While the import and export requirements remain unchanged under the amendments, because more chemicals will be subject to regulation, more chemicals will be subject to import and/or export notifications or controls.

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Implications for Industry

- State Laws- many state laws will be preempted by the EPA federal rules as previously discussed
- However, state limitations passed prior to April 22, 2016 (Earth Day) are “grandfathered” and enforceable, as are new actions taken under state laws passed prior to August 31, 2003
  - Notably, California Proposition 65 is grandfathered under the amendments

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Implications for Industry

- Best practices
  - Know how this impacts your business
  - Consider being proactive
  - Consider opportunities for cooperation/coordination

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Questions & Answers

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Contact Information

Amanda K. Beggs
Associate
414.319.7037
abeggs@foley.com

Sarah A. Slack
Senior Counsel
608.258.4239
sslack@foley.com

Louis Thorson
Associate
414.297.5776
lthorson@foley.com

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