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Overview of TSCA Reform and Introduction to Key Provisions in New Lautenberg Law

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Our Overview Focuses on Key Changes

- Introduction to new TSCA
- Key definitions
- Science requirements
- Testing (Section 4)
- New chemicals and significant new uses (Section 5)
- Existing chemicals prioritization, risk evaluation, and risk management (Section 6)
- Inventory Reset (Section 8)
Introduction to New TSCA

- Lautenberg fundamentally changes U.S. federal approach to chemicals management
  - Introduces new concepts and approaches
  - Reflects careful balancing of interests
- Centralizing concept is *unreasonable risk*, the evaluation of which:
  - Does not include consideration of cost/benefit factors
  - Focuses on *conditions of use* as determined by the U.S. Environmental Protection Agency (EPA)
  - Includes consideration of *potentially exposed or susceptible subpopulations* identified as relevant by EPA
TSCA Sections 4, 5, 6, & 8

Amended TSCA significantly changes provisions in these core sections of the law

- Section 4 provides additional new testing authority to EPA
- Section 5 on new chemicals retains much of the original approach but makes important changes
- Section 6 significantly revises approach to existing chemical risk assessment and risk management compared to old TSCA
- Section 8 requires EPA to implement an “Inventory Reset”
Key Definitions

- Conditions of Use (COU):
  - “… the circumstances, as determined by [EPA], under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, [etc.]”
  - Role of COU
    - Under Section 5 applies to some but not all provisions
    - Under Section 6 applies generally to prioritizations and risk evaluations, and to some risk management actions
Key Definitions (cont’d)

- Potentially exposed or susceptible subpopulations (PESS):
  
 ➢ “a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical…, such as infants, children, pregnant women, workers, or the elderly.”

- “Protocols and methodologies for the development of information”
Science Requirements

- These apply to all science-based decisions under Sections 4, 5, and 6

  ➢ Scientific Standards (Section 26(h))
    
    • Requires the U.S. Environmental Protection Agency (EPA) science decisions to be done in manner “consistent with the best available science”
      
      - Enumerates several “considerations” regarding scientific information and methods
        
        ◆ Reasonableness for the intended use
        ◆ Relevance
        ◆ Clarity and completeness of documentation of scientific evidence
        ◆ Variability and uncertainty
        ◆ Extent of independent verification or peer review

  ➢ Weight of the Scientific Evidence (Section 26(i))
    
    • EPA decisions must be “based on the weight of the scientific evidence”
Science Requirements (cont’d)

- Consultation with Science Advisory Committee on Chemicals (SACC)
  - Establishes SACC to provide independent advice and expert consultation
  - Composed of representatives from following groups:
    - Science
    - Government
    - Labor
    - Public health
    - Public interest
    - Animal protection
    - Industry
Section 4. Testing of Chemical Substances and Mixtures
Section 4 Process to Require Testing

Additional new authority at Section 4(a)(2) allows EPA to use rules, orders, and consent agreements to obtain needed testing

- EPA required to determine that the information is “necessary” for any of several purposes, including
  - Review Section 5 notice or for Section 6(b) risk evaluation (RE)
  - Establish priority under Section 6(b)

- EPA required to
  - issue “statement of need”
  - use tiered testing

- Explicitly allows testing for exposure and exposure potential

- Section 4(h) requires that EPA:
  - reduce and replace vertebrate testing to extent practicable, scientifically justified, etc.
  - develop and implement strategic plan to promote alternative test methods
    - including list of alternative methods deemed qualified for use, and
  - need to use alternative methods in developing voluntary testing for submission under TSCA
Section 4. Testing of Chemical Substances and Mixtures

- New law appears to solve many of the problems of TSCA Section 4
  - Findings proved difficult to satisfy
  - Rule-based testing was slow and uneven
- Should allow EPA to efficiently meet many, if not most, of its testing/information needs
- Ability to require prioritization testing should ensure informed screening process
Section 4. Testing: Science Aspects

- Tiered testing and Section 6 prioritization
- Ability to go directly to advanced/confirmatory testing
- Exposure and exposure potential testing
- Protocols and methodologies
  - Need to identify and demonstrate vertebrate animal alternatives
  - Develop exposure test guidelines
Section 5. Manufacturing and Processing Notices for New Chemicals and Significant New Uses (NC/SNUs)
Section 5. New Chemicals (NC)

New law retains much of TSCA with important changes

- Requires EPA determination on all NCs
- Three alternative determinations at Section 5(a)(3):
  
  (A) NC/SNU presents an unreasonable risk
  
  (B)(i) Available information is insufficient to permit reasoned evaluation of health and environmental effects or (ii)(I) NC/SNU may present unreasonable risk or (ii)(II) it has substantial production and exposure, or

  (C) NC/SNU not likely to present unreasonable risk
Section 5. New Chemicals (cont’d)

- If EPA determines:
  - (A) or (B), it is required to regulate under Section 5(f) or Section 5(e), respectively
  - (C), it must publish/explain “not likely to present unreasonable risk” finding

- §5 limits ability to regulate articles using SNU rule authority but

- Requires EPA to *also apply* a SNU rule after taking control action or explain its “why not” reasoning
Outline of Section 5(e) Regulatory Process

If EPA makes a (B) determination, it is required to issue a Section 5(e) order

- Control must be to “the extent necessary” to protect against an unreasonable risk

- Manufacture/processing of NC/SNU can commence only in compliance with order
Section 5. Science Implications

- Effect of “insufficient information” determination could be significant
- Requirement to explain drops will increase transparency
- Appears to maintain EPA’s ability to rely on its prior assessment approaches, including Structure-Activity Relationships (SAR), exposure models
- Requirement on EPA to review and take required actions as needed will likely lead to more frequent controls
- No specific or additional requirements for nanomaterials and genetically modified microorganisms likely means that EPA will continue to apply prior approaches although “insufficient information” could have important effect
Section 6.
Prioritization, Risk Evaluation (RE), and Risk Management (RM) of Existing Chemicals
Section 6(b). Existing Chemicals Prioritization and Risk Evaluation (RE)

- Within 1 year, EPA require to establish by rule:
  - Risk-based prioritization process, including
    - Criteria for high- vs. low-priority
    - Describe process and how EPA will consider hazard and exposure potential, including
      - persistence and bioaccumulation,
      - PESS,
      - storage near sources of drinking water,
      - conditions of use,
      - Volume manufactured
  - Process to conduct REs
- EPA plans to get proposal out this year
Section 6(b)(1). Existing Chemicals Prioritization

Prioritization applies risk-based screening process to designate high- versus low-priorities based on following standards:

- **High-priority**: without consideration of costs/non-risk factors, chemical *may present* an unreasonable risk, because of a potential hazard and a potential route of exposure under the COU, including to a PESS identified as relevant by EPA

  - High-priorities must undergo risk evaluation (RE)
Section 6(b)(1). Existing Chemicals Prioritization (cont’d)

- **Low-priority**: EPA concludes it has “sufficient information to establish” that chemical does not meet the high-priority standard.
  - Low-priority determinations are subject to judicial review
- Where information is insufficient to support low-priority, default decision is high-priority
- Prioritization timeline = 9-12 months
Section 6(b)(2). Existing Chemicals RE

Risk evaluation standard:

to determine whether chemical, under its conditions of use, presents an unreasonable risk,

➤ without consideration of costs/nonrisk factors, but

➤ including unreasonable risks to PESS identified as relevant by EPA

All chemicals meeting this standard must proceed to RM
Section 6(b)(4). Existing Chemicals RE (cont’d)

Conclusions that a RE chemical does not meet this standard, *i.e.*, *that it does not present unreasonable risk*, are issued by order and subject to legal challenge.
Section 6(b). Existing Chemicals

- Various requirements must be met in conducting RE:
  - Integrate and assess available information on hazards and exposures for COU, including PESS aspects
  - Describe whether aggregate or sentinel exposures under COU were considered
  - Not consider costs or nonrisk factors
  - Take into account duration, intensity, frequency, under COU
  - Describe weight of the scientific evidence

- RE timeline = 3 years + 6 month extension
  - Scope of RE published 6 months after initiation
Minimum Goals for Section 6 Prioritizations and REs

- 6 months after enactment, REs underway on 10 chemicals
- 3 years later, REs underway on 20 high-priority cases and at least 20 chemicals designated as low-priority
- EPA also required to designate one high-priority chemical upon completion of each RE
- Manufacturers can request and pay for EPA RE and “interested persons” can submit draft REs
Section 6(b). Science Aspects

- Science requirements and relationship to EPA RAGs, EAGs, work plan process, data quality requirements
- Assessment of metals and metal compounds
Sections 6. Existing Chemicals RM

- For chemicals meeting RE standard, EPA required to take RM action within 2 years, extendable for 2 additional years

- Regulatory standard: action must be taken to the “extent necessary so that the chemical no longer presents an unreasonable risk “

- New law:
  - Deletes TSCA’s “least burdensome” language
  - Simplifies procedural requirements for Section 6 action
  - Requires EPA to “factor in” and publish statements on:
    - Health and environmental effects/magnitude of exposures
    - Benefits of the chemical for various uses
    - Reasonably ascertainable economic consequences of the rule
Section 6. Existing Chemicals RM (cont’d)

- When EPA effectively bans one or more uses
  - it must also consider availability of “technically and economically feasible alternatives that benefit health or the environment”
- RM action “shall be as soon as practicable”
- EPA has some flexibility in imposing compliance dates
Section 6. RM Exemptions/Limitations

- Law includes various limitations/exemptions if requirements can be met:
  - Limitation on regulating articles
  - Exemptions:
    - For certain replacement parts for complex durable and consumer goods
    - From a ban or phase-out requirement can be granted by EPA if, e.g.,
      - “Critical or essential use”
      - Compliance would significantly disrupt national economy, national security, etc.
Section 8(b)(4) -- Inventory Reset

- TSCA Inventory first established in 1979 and currently contains over 80,000 “existing chemicals”

- Reset process:
  - By June 2017, EPA must promulgate rule to “reset” the Inventory to distinguish actives vs inactives
  - Manufacturers required to notify; processors can be included in rule

- Reporting:
  - Inventory substances manufactured or processed in the ten years prior to enactment
  - Six month reporting period
Section 8(b)(4) -- Inventory Reset (cont’d)

- Reset process (cont’d):
  - If a notice is received, substance is designated as “active”
  - If no notice is received, substance is designated as “inactive”
    - Inactive substances stay on the Inventory
  - Inactive chemicals can be returned to active status via advance notice to EPA
Other Provisions of Note

- Confidential Business Information (CBI)
- Preemption
- Judicial review
- Fees
- Administration of the law
Questions/Discussion?
Thank You

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