TSCA Reform: Update and Overview

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Background

- The Toxic Substances Control Act ("TSCA") became law in 1976
- Since then, the core provisions of TSCA (Title I) have remained unchanged
- Pressure to update TSCA has grown significantly in the past few years
- Sen. Lautenberg introduced the Safe Chemicals Act of 2010 (S. 3209) on April 15, 2010
- Reps. Waxman and Rush introduced the Toxic Chemicals Safety Act of 2010 (H.R. 5820) on July 22, 2010, following stakeholder comments and meetings

Overview of the Proposals

- The bills keep the original structure of TSCA but significantly change or eliminate most Title I provisions
- They shift the burden to demonstrate safety of chemicals from EPA to importers, manufacturers, and processors
- They ban the import, manufacture, processing, and distribution of chemical substances and mixtures for uses not shown to be safe, with limited exemptions
- They also require the submission to EPA of minimum data sets for all chemicals in commerce

Overview of the Proposals

- Once EPA has determined whether a chemical's use is safe, the bills require the Agency to reduce use of or exposure to chemicals of highest concern, and to promote "safer alternatives"
- The bills simplify rulemaking, limit judicial review of some EPA decisions, and allow the Agency to issue orders
- They allow EPA to regulate distinct forms of the same molecular identity (e.g., nanoscale materials), the indoor environment, and risks posed by articles
- They also expand public access to confidential business information and to EPA's decisions

Overview of the Proposals

- The bills reduce the minimal preemption of State laws
- They minimize use of animals in toxicity testing
- They require EPA to conduct a biomonitoring study with HHS to determine whether suspected and potentially harmful chemicals are in pregnant women and infants
- They establish a children's environmental health research program at EPA, research centers to promote the development of "safer alternatives," and grants for green chemistry and engineering
- They also require EPA to develop action plans for "hot spots" disproportionately exposed to toxic chemicals

Major Differences in the Proposals

- Length of time before all chemicals must be tested for toxicity
- Definition of the safety standard that chemicals must meet
- Identification of chemicals of highest concern
- PBT chemicals: Only House bill addresses them directly

Key Changes – Current Definitions (§ 3)

- Chemical substance
  - The bills make different changes, but both allow EPA to define distinct forms of the same molecular identity as "new chemicals"
- Distribution in commerce
  - Both bills add exports, but House bill excludes exports of pesticides and FDA products
- Environment
  - Includes "ambient" and "indoor air"
- Health and safety study
  - Includes <u>any</u> test that relates to a chemical substance, mixture, or specific chemical identity

Key Changes – Current Definitions (§ 3)

- Manufacture
  - House bill excludes manufacture of pesticides and FDA products
- Mixture
  - The bills make different changes
- New chemical substance
  - Any chemical without a declaration on file at EPA to allow a safety determination; House bill has one-year grace period
- Process
  - House bill excludes processing of pesticides and FDA products and relabeling, repackaging, and redistributing of articles

Key Changes – New Definitions (§ 3)

- Adverse effect
- Aggregate exposure
- Bioaccumulative
- Chemical identity
- Cumulative exposure
- End consumer (Senate bill)
- Federal agency
- Importer (House bill)
- Persistent
- Person (Senate bill)
- Reasonable certainty of no harm (Senate bill)
- Special substance characteristics
- Toxic
- Toxicological property
- Use (House bill)
- Vulnerable population

Key Changes – Testing (§ 4)

- Importers, manufacturers, and processors must submit a minimum data set for all chemicals. House bill also requires minimum data sets for mixtures.
- Bills specify different deadlines and contents for minimum data sets.
- EPA must update minimum data sets.
- EPA can require additional data by rule or order.

Key Changes – Testing (§ 4)

- EPA also can order a stop to the import, manufacture, processing, or distribution of a chemical for any failure to submit test data.
- Importers, manufacturers, and processors can "opt out" by ceasing activity with a chemical
- House bill exempts chemicals for which EPA must first make safety determinations under new section 6, PBT chemicals, chemicals that pose no risk of injury due to their intrinsic properties, and "safer substitutes"

Key Changes – Premanufacture Notices (§ 5)

- Required for import, manufacture, and processing of
  - new chemicals and mixtures
  - existing chemicals and mixtures for new uses (bills define "new use" differently)
- Premanufacture notice ("PMN") must include
  - declaration of current manufacturing or processing
  - minimum data set or update thereto, as appropriate
  - statement that the chemical will meet the safety standard (Senate bill) or is "reasonably anticipated" to do so, with justification (House bill)
  - any test data required under a rule or order

Key Changes – Premanufacture Notices (§ 5)

- EPA must make PMNs, minimum data sets and updates, and test data available to the public in various ways
- EPA's response to PMNs
  - Under Senate bill, EPA must determine within 180 days whether chemical or mixture meets safety standard
  - Under House bill, EPA must determine within 90 days whether the use is "critical" or whether a safety determination is required
    - Within a further nine months, EPA must complete any required safety determination
- Bills eliminate EPA's extension of the PMN review period by up to 90 days for "good cause"

Key Changes – Current Exemptions (§ 5)

- EPA loses section 5(h)(4) power to exempt by rule, and House bill requires review of all rule exemptions promulgated under section 5(h)(4)
- Bills add requirements to test marketing exemption
- Revised section 5(h)(2) allows EPA to exempt equivalent chemicals for which PMNs would duplicate previously submitted data
- R&D exemption kept unchanged
- Requirements for EPA to publish exemption requests and act on them with 45 days of receipt also kept unchanged

Key Changes – New Exemptions (§ 5)

- Senate bill: New chemical, metabolite, or degradate is not
  - manufactured/imported in quantity greater than 1,000,000 lbs./year
  - released into environment in quantity greater than 100,000 lbs./year
  - a known, probable, or suspected reproductive, developmental, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor
  - a chemical with other toxicological properties of concern
  - found in human cord blood, fluids, or tissues, unless naturally present at levels commonly found, or
  - found in food, drinking water, ambient or indoor air, residential soil, or house dust, unless naturally present at levels commonly found

Key Changes – New Exemptions (§ 5)

- House bill
  - Use of the new chemical is deemed a "critical use"
  - New chemical approved by EPA as a "safer alternative"
  - EPA finds that "intrinsic properties" render the new chemical "harmless"

Key Changes – Priority List (§ 6)

- Senate bill
  - By order, EPA shall establish a list of 300 chemicals for safety determinations within 18 months of enactment
  - EPA must add chemicals to keep number greater than 300 at all times, until all chemicals in commerce have a safety determination
  - EPA listing decisions and responses to petitions to list specific chemicals cannot be reviewed by any court
- House bill
  - Establishes a priority list of 19 chemicals for immediate safety determinations
  - 12 months after enactment, EPA must update the list to include at least 300 chemicals

Key Changes – Safety Determinations for Existing Chemicals (§ 6)

- Importers, manufacturers, and processors have duty to prove that chemical meets the safety standard
- If data are not submitted, EPA can prohibit import, manufacture, processing, and distribution by order (Senate bill) or determine that chemical does not meet the safety standard (House bill)
- If data are submitted but EPA is late in making a safety determination, importers, manufacturers, and processors have to notify EPA, employees, customers, and the public that EPA's determination is still pending
- Safety determinations last for up to 15 years, but EPA can initiate a new safety determination earlier, upon receipt of any relevant new information

Key Changes – Safety Determinations for Existing Chemicals (§ 6)

- Bills prohibit import, manufacture, processing, and distribution of a chemical, if EPA makes a determination that the chemical does not meet the safety standard
- If EPA makes a favorable safety determination, the permissible uses must be specified, and import, manufacture, processing, and distribution for unapproved uses is prohibited
- EPA can grant exemptions from restrictions on specific uses for up to five years in limited cases
  - Exemption is in "paramount" interest of national security
  - Lack of use would significantly disrupt national economy, or
  - The use is critical/essential, and there is no safer feasible alternative, or the use compared to alternatives benefits health, safety, or environment

Key Changes – Declarations (§ 8)

- Importers, manufacturers, and processors must submit "declarations" of current manufacturing or processing containing information to help EPA make safety determinations and otherwise administer TSCA
- Declarations will require IUR report-like information (chemical identity, quantities, sites, uses, exposures, etc.) and include both lists and copies of "reasonably ascertainable" health and safety studies
- Declarations must be updated at least every three years or when there is relevant new information
- By order, EPA many prohibit import, manufacture, or processing of a chemical for any failure to submit or update declarations

Key Changes – Records and Reporting (§ 8)

- EPA can require any person who imports, manufactures, processes, distributes, uses, or disposes of chemicals, mixtures, or articles to keep records or make reports, to help EPA administer TSCA
- EPA must publish a list of all chemicals distributed in commerce and categorize the chemicals, using available information, by known health or environmental effects, exposure, insufficient data, or other category that the Agency considers appropriate

Key Changes – Records and Reporting (§ 8)

- EPA must establish an electronic database of information about toxicity and uses of and exposures to chemicals and include "all significant decisions" by EPA and "significant information" submitted under Title I
- Section 8(c) records also must be reported to EPA
- Section 8(e) reporting is not changed
- New certifications (of accuracy, reliability, and completeness) required for all submissions under rules and orders

Key Changes – Confidential Business Information

- EPA can give confidential business information ("CBI") to States and municipal governments who agree to protect it
- EPA must release CBI to protect health or environment against "imminent and substantial endangerment" (Senate bill) or "substantial risk of injury" (House bill)
- CBI claims require justification and a certification that the CBI is not public
- EPA must develop CBI substantiation standards and forms
- EPA must review CBI claims within 90 days
- CBI claims will be limited to five years
- Chemical identities, safety standard determinations, and information indicating chemicals in consumer articles intended for or reasonably expected to be used by children cannot be CBI

Key Changes – Other Notable Provisions

- Bills eliminate export-only exemption (§ 12(a))
- Maximum civil penalties increased to $37,500
- Bills preempt only State law that is “less stringent” than Federal law
- Bills direct EPA to minimize the use of animals in testing
- Bills establish a program to encourage the development of safer alternatives to existing chemicals, expedite their review, and recognize them as safer alternatives
- Bills require EPA to identify “hot spots” that are “disproportionately exposed” to toxic chemicals, publish and update a list, develop actions plans to reduce exposure, and report annually to Congress
- Bills subject all Federal agencies to TSCA and authorize EPA to implement international agreements related to chemicals

Some Issues with the Proposals

- Overreaction to an exaggerated threat
- Vastly increased scope and complexity
- Limited resources of EPA and industry
- Use of regulatory paradigm for food-use pesticides
- No preemption of duplicative State laws
- Questionable science
- Effect on introduction of new chemicals

Legislative Outlook

- The bills are still in committee, and Congress has run out of time to act on them
- The bills will need to be reintroduced in the next Congress (2011)
- Democrats are expected to lose House and Senate seats in the coming election and also may lose control of the House
- Chemical management legislation may not be a legislative priority of the next Congress
- Accordingly, passage of the current bills in the next Congress is uncertain

Until TSCA Reform

- EPA is using its existing TSCA authority to enhance its current Chemical Management Program

  http://www.epa.gov/opptintr/existingchemicals/pubs/enhanchems.html

- EPA's ongoing efforts including the following
  - Taking new regulatory risk management actions
  - Developing Chemical Action Plans that target EPA's risk management efforts on chemicals of concern

    http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html
  - Requiring information needed to understand chemical risks
  - Increasing public access to information about chemicals
  - Engaging stakeholders in prioritizing chemicals for future risk management action