Toxic Substances Control Act: Regulatory and Legislative Issues and Initiatives

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Chemical Controls and the Toxic Substances Control Act: Legislative Initiatives

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Senate Legislative Action

- S. 847 introduced April, 2011 (Lautenberg)
- Environment and Public Works Committee hearings in November 2011 and July 2012
- Substantial Manager’s amendment considered July 25, 2012
- Ordered reported on party-line vote
- 27 cosponsors as of October 1, 2012
- Floor action not scheduled at this time

Major Legal Issues in S. 847

- Safety standard
- Preemption
- Scope of EPA authority
  - Rule v. order authority
  - New uses of existing chemicals
  - Review of chemicals on basis of special characteristics
  - Management of reimbursement and compensation for data use
- Confidential Business Information
- Judicial review
Safety Standard

- Existing TSCA: “unreasonable risk”
- S. 847: “reasonable certainty of no harm” taking into account aggregate (and where practicable, cumulative) exposures to a substance
  - Precedent in pesticide regulation
  - Suggests zero risk in industrial chemical context
  - Scientifically/technically difficult or impossible
- Better alternative: significant risk of material harm under intended conditions of use

Preemption

- Existing TSCA: Conflict Preemption
  - Limited to direct conflict with EPA rules or orders
  - Limited judicial interpretation
  - Rarely applied as a practical matter
- S. 847: State action preempted only to the extent compliance with both federal and state standard is impossible
- Does not address preemptive effect of an EPA safety decision
Chemical Controls and the Toxic Substances Control Act

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TSCA Debate

• Reenacted in 1976; no amendments to date despite Congressional efforts
• EPA’s current position: TSCA does not provide EPA with a mandatory duty to evaluate safety of existing chemicals (so states are taking independent regulatory actions)
• Manufacturers do not have to generate health and safety data
• Question posed by EPA is: when to use its authority under Section 6 of TSCA
TSCA Debate

• Section 6 of TSCA requires EPA to prove that it has substantial evidence that a chemical poses an unreasonable risk before it can ban, restrict, or take other actions to manage that risk; requires EPA to use the least burdensome means to adequately protect against the unreasonable risk.

• Agency announced it will undertake risk assessments for 83 chemicals (March 5, 2012). EPA will then issue risk management plans (agency has been issuing action plans since December 2009).

Chemical Data Reporting Rule (August 2011)

• Amends the TSCA Inventory Update Reporting Rule; increases the type and amount of information that cos. Are required to report

• Affects chemical substance manufacturers, importers, as well as users and processors who may manufacture a byproduct chemical substance

• Designed to address environmental groups and others’ concerns as to transparency and control over chemicals in the US given the lack of TSCA legislative amendments
• Entities must report if they manufacture (including as a byproduct or import) for commercial purposes chemical substances listed on the TSCA Inventory and produced in volumes of 25,000 pounds or more during the principal reporting year (which is Calendar Year 2011).

• 2012 Submission was scheduled to occur from February 1 to June 30.

• Information includes consumer and commercial product categories to demonstrate uses, commercial workers reasonably likely to be exposed; etc.

• Substantiation must be submitted for processing and use data claimed as “CBI”

• EPA plans to begin work in 2013 to identify chemicals for additional data collection and analysis and to begin the creation of a pipeline of candidate chemicals for future risk assessment and reduction.

• EPA plans to make additional CBI information available; looking for stakeholder input
• TSCA Petition for Rulemaking Concerning Chemical Substances and Mixtures Used in Oil and Gas Exploration or Production (Overview and Status)
Overview

• Green Chemistry
• California Green Chemistry Initiative and Safer Consumer Products Regulations
  – History
  – Current Proposed Regulations
  – Concerns and Potential Impacts
• Chemical Regulation in Other States
  – Washington Children’s Safe Product Act
  – Connecticut Act Concerning Child Product Safety
• Trends

What is Green Chemistry?

• Design Of Chemicals Or Chemical Processes To Reduce Or Eliminate Negative Environmental Impact
• 12 Principles
  – Waste Prevention
  – Design For Degradation
  – Minimize Accident Potential
  – Design Less Hazardous Chemical Synthesis
California Green Chemistry Initiative and Safer Consumer Products Regulations

• Enacted September 29, 2008
  – SB 509 – Toxic Information Clearinghouse
  – AB 1879 – Chemicals In Consumer Products

• Purpose
  – Reduce Or Eliminate Chemical Hazards In Consumer Products And The Environment
  – Provides Mechanism For Review Of Approximately 80,000 Chemicals Sold, Used Or Distributed In California
  – Products Are Benign By Design

California Green Chemistry Initiative and Safer Consumer Products Regulations

• Draft Conceptual Flow Chart – February 23, 2010
• September 13, 2010 – Draft Proposed Safer Consumer Product Alternatives Regulations
• November 16, 2010 – Revised Draft Proposed Regulations
• August 12, 2011 – Notice of Decision Not to Proceed
• October 31, 2011 – Safer Consumer Products Informal Draft Regulations

  – All Consumer Products
  – Containing A Chemical of Concern
  – Four Step Process
California Green Chemistry Initiative and Safer Consumer Products Regulations

• July 23, 2012 - Safer Consumer Products Proposed Regulations
  – Broad, Sweeping and Complex
  – Applies to Any Manufacturer, Importer or Retailer of a Consumer Product Sold in California
  – Four-Step Regulatory Process
    • (1) DTSC Establishes List of “Chemicals of Concern”
    • (2) DTSC Identifies “Priority Products”
    • (3) Responsible Entities Notify DTSC and Prepare Alternatives Analysis
    • (4) DTSC Takes Regulatory Action to Limit or Prevent Public Health and/or Environmental Impacts

California Green Chemistry Initiative and Safer Consumer Products Regulations

• Step 1 – DTSC Establishes List of Chemicals of Concern
  – List of Approximately 1,200 Chemicals of Concern Within 30 Days of Effective Date
  – Including Substances Already Identified as Exhibiting Hazard Trait, Environmental/Toxicological Endpoint, On Lists Developed by Other Agencies/Organizations
  – Exemptions for Certain Types of Products and Products Solely for Use Out-of-State
  – No Exemptions for Individual Chemicals
California Green Chemistry Initiative and Safer Consumer Products Regulations

• **Step 2** - DTSC Identifies “Priority Products”
  – Priority to Products that Contain COCs With Significant Ability to Cause Adverse Public Health/Environmental Impacts and Significant Ability for Exposure
  – DTSC Evaluates Potential Adverse Health and Environmental Impacts Posed by COCs Based on Factors
    • Adverse Impacts from Potential Exposure
    • Extent of Information Available on Adverse Impacts
    • Extent of Regulation Under Other Programs
  – No Exemption for Products Regulated by Other Laws (Considered by DTSC During Product Prioritization)

California Green Chemistry Initiative and Safer Consumer Products Regulations

• **Step 3** - Responsible Entities Notify DTSC and Prepare Alternatives Analysis
  – Manufacturer Notification to DTSC Within 60 Days
  – Alternatives Analysis to Limit Exposures/Impacts
    • Entire Lifecycle of Product
    • Supply Chain Choices
    • Environmental Consequences of Disposal
  – Public Review
California Green Chemistry Initiative and Safer Consumer Products Regulations

• **Step 4 - DTSC Takes Regulatory Action to Limit or Prevent Public Health and/or Environmental Impacts**
  
  – Protection of Public Health and Environment While Maximizing Use of Alternatives of Least Concern That Are Technically and Economically Feasible

  – Potential Regulatory Action
    
    • No Response
    
    • Product Information
    
    • Use Restrictions (COCs and Priority Products)
    
    • Product Sales Prohibition

  – DTSC May Re-Evaluate Selected Response at Any Time

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California Green Chemistry Initiative and Safer Consumer Products Regulations

• **Concerns and Potential Impacts**
  
  – Confidential Business Information/Trade Secrets
  
  – “Failure to Comply List”

  – Product Stewardship (End-of-Life) Plan, Financial Guarantees, Funding of R&D Projects and Grants
  
  – Dispute Resolution

  – Economic Impacts

  • Potential Cost Per Product: $ 785,000 to $ 6,850,000

  • Lawmakers Have Asked Governor to Delay Implementation For More Thorough Analysis of Economic Impact
Chemical Regulation - Other States

- Washington Children’s Safe Product Act
  - Chapter 70.240 RCW (2008)
  - Two Parts
    - Limitations on Amount of Lead, Cadmium and Phthalates in Children’s Products After July 1, 1999 (Preempted by Consumer Product Safety Improvement Act)
    - Dept. of Ecology Develops List of Chemicals that Manufacturers Must Report On
  - Reporting Obligations Phased-In Beginning August 2012
- DOE Guidance On Alternative Assessment but No Authority to Require Submission of Alternative Assessment

Chemical Regulation in Other States

- Connecticut Act Concerning Child Product Safety
  - Overview
    - Children’s Products Containing Lead Banned as Hazardous Substances
    - Certificate of Disposition
    - Commissioners of Public Health and Environment List of Toxic Substances
Internet Resources

• California Department of Toxic Substances Control, Green Chemistry Initiative
  – http://www.dtsc.ca.gov/pollutionprevention/greenchemistryini
  tiative/index.cfm

• U.S. Environmental Protection Agency
  – www.epa.gov/greenchemistry

• Washington Department of Ecology, Children’s Safer Chemical Products Act

• Connecticut Department of Consumer Protection

An Overview of REACH: The EU Chemical Registration Regime

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What is REACH?

Registration, Evaluation, and Authorization of Chemicals

REACH At-A-Glance

- **The Law**
  - Purpose is to manage risks to health and the environment from chemical substances → burden is on industry
  - Sets out procedures for collecting and assessing information about chemicals
  - Administered by the European Chemicals Agency (ECHA)
  - What’s required?
    - Registration by manufacturers and importers
    - Data Sharing
    - Evaluation by ECHA
    - Authorization for certain hazardous materials
Basic REACH Terminology

- **Substances**: Chemical elements or chemical compounds
- **Substances of Very High Concern (SVHC)**: CMR, PBT, vPvB
- **Mixtures**: Solutions composed of 2+ substances (e.g. paint, varnish, ink)
- **Articles**: Products where shape or design determines function to a greater degree than does chemical composition (e.g. toys, textiles, furniture)
- **Manufacturer**: produces or extracts substances in the natural state
- **Formulator**: makes or produces a mixture
- **Producer**: makes or assembles an article

Registration Overview

- **What Must Be Registered?**
  - Substances only; 1 metric ton threshold
  - Some limited exemptions
- **Who Must Register?**
  - EU manufacturers and importers of substances
  - EU producers and importers of articles
  - Non-EU manufacturers, formulators, and producers **MAY** register through “Only Representative”
- **What Does Registration Require?**
  - Information requirements – collect all available existing information from supply chain
  - Submit registration dossier – technical dossier and chemical safety report
Registration Regime

• “Phase-in” v. “Non Phase-in”
  – Phase-in substances were already being manufactured or placed on EU market

• Transitional Regime for Phase-in Substances
  – If pre-registered by December 2008, benefit from extended deadlines
  – Late Pre-Registration permissible for first time producers/importers
  – Non phase-in must submit “Inquiry” before registration

• Registration Deadlines
  – All non-phase-in substances and phase-in substances not pre-registered by 2008 MUST be registered before they can be manufactured, imported, or placed on the market in the EU
  – Phase-in substances MUST be registered by deadlines based on tonnage

Registration Regime (cont’d)
Data Sharing & Downstream Users

• **Required Data Sharing**
  – Purposes: streamline registration, reduce testing on animals
  – Substance Information Exchange Forums (SIEF)
  – Consortia

• **Downstream Users**
  – Entities within a registrant’s Supply Chain
  – Must provide usage information to suppliers and communicate safety information to customers (e.g. safety data sheets)

Evaluation, Authorization, Restriction

• **ECHA Evaluation**
  – Examination of registration dossier and testing
  – Further information could be required

• **Authorization**
  – Additional procedures apply to SVHC
  – “Authorization List” → limited, specific uses; other uses banned

• **Restrictions**
  – ECHA may restrict substance if it poses an unreasonable risk to health and environment
Additional Duties of Registrants

- **Provide Information to Customers**
  - Safety Data Sheets if CMR, PBT, vPvB, or otherwise classified as hazardous
  - Information about authorization, any restrictions
  - REACH registration information

- **Update Registration**
  - Legal entity change
  - Changes to status based on ECHA determination
  - Changes to chemical composition, different use

Related Regulations

- **Export Restrictions on Hazardous Chemicals**
  - Recent revisions to law restricting exports of 110 substances/groups of substances (EC No. 649/2012)
  - EU law requires (1) notify authority in country of export and (2) obtain consent from authority in country of import
    - Does not apply to exports for research or analysis if small quantities
    - Some exceptions (e.g. proof that import was permitted in previous 5 years)

- **Product Labeling Requirements (CLP)**
  - Classification into categories specified in EU directive
  - Labeling is required when substance is hazardous or mixture contains one or more hazardous substances above certain thresholds
  - Packaging rules specify where label must be placed and when pictograms are required to indicate hazards
What’s Next?

• Determine REACH’s impact on your business
  – 2013 deadline is approaching
    • Do you need an Only Representative or would it improve your EU business by streamlining your supply chain?
    • Do you or will you have a subsidiary that will need to register or late pre-register?
  – Situations to consider:
    • Asset acquisition or transfer
    • Merger
    • “Spin-off”

Questions?