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Changes in U.S. Chemical Laws: Impacts of TSCA Modernization

September 4, 2013

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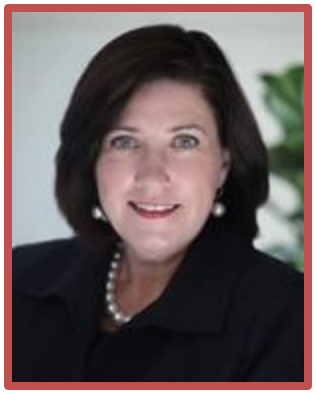
Changes in U.S. Chemical Laws: Impacts of TSCA Modernization

September 4, 2013

Agenda

- Background on Toxic Substances Control Act (TSCA) Reform
- The Current Law: TSCA
- Chemical Safety Improvement Act (CSIA)
- Science Policy Implications of CSIA
- Political Prospects
- Q&A

Today's Presenters



Cheryl A. Falvey
Crowell & Moring
Partner | Washington, D.C.

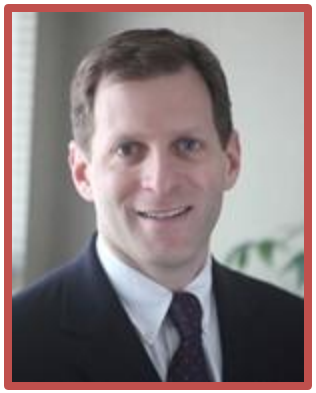
- Concentrates on the defense of consumer class action, toxic tort, mass tort, and other tort claims arising out of consumer, occupational, and environmental exposures
- Formerly served as the General Counsel of the Consumer Products Safety Commission

Warren Lehrenbaum
Crowell & Moring
Partner | Washington, D.C.

- Focuses on chemical regulation and biotechnology issues arising under TSCA, FIFRA, FFDCA and related federal and state laws
- Assists companies in obtaining product approvals, achieving regulatory goals, assuring ongoing compliance, and defending against enforcement actions

John Phillips
Exponent
Principal Scientist | Alexandria, VA

- Specializes in the areas of global product stewardship, regulatory affairs, and regulatory toxicology
- Extensive experience with the design and implementation of industry and corporate-wide programs that support sustainability initiatives, enable growth, and improve reputation
- 30 years of experience at Dow Chemical: Director of Global Product Stewardship, Regulatory Affairs and Chemical Policy
- 4 years consulting for major multi-national companies



Josh Tzuker
Crowell & Moring
Counsel | Washington, D.C.

- Focuses on providing strategic counsel, technical advice, and advocacy for clients who have policy challenges before the Congress and Administration
- Previously served as legislative director and counsel for Congressman Jim Matheson (D-Utah) and former Energy and Commerce Chairman John Dingell

The Current Law: Toxic Substances Control Act (TSCA)

How it works . . . and how it doesn't work

The Current Law: TSCA

- Main features of TSCA
  - Chemical substances inventory
    - Existing vs. new chemicals
  - Information gathering tools
    - Testing; reporting; imports; exports
  - Risk management tools
    - Section 6; Significant New Use Rules (SNURs); Section 5(e)
  - Definitions
    - Exemptions; quirks

Common Complaints About TSCA

- "Grandfathered" chemicals not reviewed
- Inadequate/cumbersome risk management tools
- Insufficient data on chemicals
- No showing of "safety" required
- Excessive confidential business information claims

The Chemical Safety Improvement Act (CSIA)

Chemical Safety Improvement Act (CSIA)

- Bipartisan bill – introduced May 22, 2013
- Broad industry support
- Division among non-governmental organizations (NGOs)

CSIA Key Features

- Establishes an "active" and "inactive" inventory
  - ~80K substances currently on inventory
  - Requires reporting by manufacturers and processors
  - Important for processors to be engaged

Who is a Processor?

CSIA Key Features *cont'd*

- Creates a new safety standard
  - No unreasonable risk of harm to human health or the environment
    - More workable than proposed standard in prior bills?
    - Comparable to current TSCA standard for Environmental Protection Agency (EPA) action?
  - Applied to both "new" and existing substances

CSIA Key Features *cont'd*

- Requires EPA review of "active" chemicals
  - EPA to prioritize for safety assessment
  - "High priority" → safety assessment → safety determination
  - "Low priority" → likely to meet safety standard → no safety assessment or determination required

Prioritization (§4)

- EPA to develop a risk-based screening process <u>within 1 year</u>
- Prioritization criteria include:
  - Hazard and exposure potential
  - Volume of substance manufactured or processed
  - Recommendation of states
  - Availability of hazard and exposure information
  - Extent of existing federal or state regulation

Prioritization (§4) *cont'd*

- EPA must make "every effort" to complete prioritization screening "in a timely manner"
- Prioritization decisions are subject to notice and comment

but

they are **not** subject to judicial review

CSIA Key Features *cont'd*

- Expanded testing authority (§4)
  - EPA can require manufacturers and processors to generate test data if EPA determines data are needed to perform a safety assessment or determination, or to meet testing needs under another statute
  - Can be imposed by promulgating a regulation or issuing an administrative order, or by consent agreement
  - Shall incorporate tiered testing and, to the extent deemed reliable, in-silica, high-throughput screening, and non-animal testing

CSIA Key Features *cont'd*

- Safety assessment and determination (§6)
  - EPA must review existing data (including data submitted by "interested persons"); can require development/submission of new data
    - *Safety assessment*: **solely** risk-based; to be conducted according to EPA-developed methodology that uses best-available science and considers weight of the evidence. Is **not** subject to judicial review
    - *Safety determination*: evaluates whether safety standard will be met under intended conditions of use; no fixed timeline for completion. Determination **is** subject to judicial review

CSIA Key Features *cont'd*

- Outcomes from safety determination
  1) Substance meets safety standard under intended conditions of use
  2) Substance does not meet safety standard
     - EPA will impose appropriate restrictions by rulemaking
  3) Additional information needed
- Similar outcomes for new chemical review under Section 5

CSIA Key Features *cont'd*

- Preemption (§18)
  - Current state requirements that are preempted:
    - Duplicative testing requirements
    - State restrictions on substances with completed safety determination
  - New state restrictions that are preempted:
    - Prohibitions or restrictions on high priority substances
    - Prohibitions or restrictions on low priority substances
  - States may seek waiver upon showing:
    - Compelling local conditions, no undue burden on interstate or foreign commerce, state requirement based on best available science

CSIA Key Features *cont'd*

- Effect on private causes of action (§18)
  - Completed safety determinations by EPA for a high priority substance are admissible in any proceeding for relief relating to harm from exposure to the substance
  - EPA's safety determination "shall be determinative" of whether the substance meets the safety standard under the conditions of use addressed in the safety determination

CSIA Key Features *cont'd*

- Confidential business information (CBI)
  - Establishes categories of information presumed to be entitled to CBI protection
  - Requires up-front substantiation for chemical identity information
  - CBI protection lasts for whatever period EPA deems "reasonable"
  - Certain types of information are not entitled to CBI protection (*e.g.*, health and safety data; safety assessments and determinations)

CSIA Additional Features

- Importer requirements: a mixed bag
  - Importer must certify TSCA compliance "to the best of knowledge and belief"
  - Importer must notify the U.S. Customs and Border Protection if imported substance has been found not to meet the safety standard
  - "Chemical substance" for purposes of these provisions is expressly defined to cover ***articles*** containing a chemical substance
- Narrower export notification requirements
- Various provisions requiring EPA to develop guidance on data quality, data evaluation criteria, and weight of the evidence

Science Policy Implications

Science Policy Implications of CSIA

- Overview
  - Highlight implications of CSIA on science policy
    - Focus on Sections 2, 4, and 6
  - Proactive steps for companies to consider

Key Science Policy Implications of CSIA

- Section 2 – Findings, policy, and intent
  - Essentially, a total rewrite of TSCA Section 2
  - Two purposes:
    - "Improve the safety of consumers in the U.S."
    - "Ensure that risks from chemicals are adequately understood and managed"
  - This is a significant change from the "unreasonable risk of injury to health or the environment" standard in TSCA

Key Science Policy Implications of CSIA *cont'd*

- Section 2 – Findings, policy, and intent
  - CSIA changes the focus from "unreasonable risk" to "safety"
  - Under TSCA Section 2(b)(2):
    - Congress sets the policy to "regulate chemical substances and mixtures that present an unreasonable risk of harm"
  - Under CSIA Section 2, Congress:
    - (a)(1) finds that "chemicals should be safe for the intended use"
    - (b)(1) sets the policy that the Act "should protect the health of people and the environment from unmanaged risks of chemical substances"

Key Science Policy Implications of CSIA *cont'd*

- Section 2 – Findings, policy, and intent
  - The change in focus from "unreasonable risk" to "safety" has a significant impact on Congressional intent from…
    - 2 (c) EPA is to "carry out this [Act] in a reasonable and prudent manner … that …shall consider the environmental, economic, and social impact" 2(c)

  To

    - 2(c)(1) EPA shall "rely on robust scientific evidence" and
    - 2 (c)(2) "protect the health of people … and …the environment"

Key Science Policy Implications of CSIA *cont'd*

- Section 2 – Findings, policy, and intent
  - There is limited controversy that the Act should protect human health and the environment
    - In general, NGOs and industry agree with this intent
  - There is continued controversy on the definition of safety
    - Currently, means "no unreasonable risk of harm" - Section 3(16)
    - Suggestions include "reasonable certainty of no harm"
      - Which goes beyond "safe for intended use" to "proving safety"

Key Science Policy Implications of CSIA *cont'd*

- Toxicology 101
  - A Margin of Safety (MOS) is established when:
    - The potential exposure (*e.g.*, 10 ppm) is lower than
    - The potential for the hazard to be realized (*e.g.*, 100 ppm)
  - Base-line information needed for a safety assessment:
    - Potential exposure defined per use
    - No Observed Effect Level established per end-point
  - Safe Use Conditions are defined by a:
    - $\text{MOS} = \dfrac{\text{No Observed Effect Level (}e.g.\text{, 100 ppm)}}{\text{Level of Exposure (Ingredient Concentration) (}e.g.\text{, 10 ppm)}}$
    - In this case, a 10 fold MOS

Key Science Policy Implications of CSIA *cont'd*

- Section 4 – Chemical assessment framework, prioritization screening, and testing
  - In CSIA in Section 4 (and 6), there are major changes to safety assessments and determinations
  - These changes reflect a move to treat "existing chemicals" similar to the way "new chemicals" are treated under TSCA (and more)
  - The changes will require more information, evaluation, and decision making, and more manufacturer/processor involvement

Key Science Policy Implications of CSIA *cont'd*

- Section 4 – Chemical assessment framework, prioritization screening, and testing
  - Under Section 4 of CSIA, EPA would be authorized to:
    - Develop a "Chemical Assessment Framework" that uses "best available science and risk assessment principles" 4(a)
    - "Establish[ed] … scientifically sound criteria" 4(b)(1)
    - A "Prioritization Screening Process" 4(e) of "active" 8(b) chemicals
    - A "structured evaluative process" with a "two tiered" process with "Tier 1 screening" and "Tier 2" … to determine if additional testing is needed 4(h)

Key Science Policy Implications of CSIA *cont'd*

- Section 6 – Safety assessments and determinations
  - Requires EPA to:
    - "Conduct safety assessments on high priority chemicals" 6(a)
    - Use a "science-based methodology" 6(b)(4)
    - "Determine, based solely on consideration of risk to human health and the environment," that the safety standard has been met 6(c)(2)
    - If not, "promulgate … necessary restrictions … based on weight of evidence" 6(c)(9)(b)

Key Science Policy Implications of CSIA *cont'd*

- Sections 4 and 6 – Potential areas of debate
  - There is limited controversy that the Act should protect people and the environment or use sound scientific methods, a tiered approach, and weight of evidence
  - However, the devil is in the details and there are many details:
    - What will be the criteria for defining safety?
    - How will hazards be defined and to what level of detail?
    - How will threshold effects be determined?
    - What defines a safer alternative?
    - How will exposure be determined for the intended use(s)?
    - How will chemical safety assessments be conducted?
  - There will opportunity for public comment at many stages

Proactive Steps for Companies to Consider

- What can companies do in the meantime?
  - Monitor CSIA progress and engage in public commenting
  - Evaluate company stewardship and compliance programs
    - Define current processes (the "is")
    - Compare to applicable established processes (the "should')
    - Identify opportunities for continual improvement (*i.e.*, gaps)
    - Establish plans to implement improvements (*i.e.*, fill gaps)
    - Implement plans
  - Evaluate raw materials and product ingredients for:
    - Global chemical inventory status (including TSCA) and other requirements
    - Inclusion on lists of chemicals of concern
    - Hazards and exposure scenarios
  - Develop a strategy for defining safe use conditions or alternatives

Proactive Steps for Companies to Consider *cont'd*

- What can companies do in the meantime?
  - Evaluate new product development and commercialization processes
    - Include compliance considerations at each development stage
    - Conduct "stage-gate" reviews
    - Ensure requirements are met for "go, no-go decisions"
  - Apply new product development considerations to existing products
  - Establish a "business risk review" process
    - For new products and new applications for existing products
    - Define business and functional roles
    - Define corporate and business levels of authority for decision making
    - Define "elevation criteria" for moving decisions from business level to corporate level
    - Establish a records retention schedule for documentation

Political Prospects

The Path to a Bipartisan Bill has Taken Years

- Hearings in 2007, 2009, and 2011 in the Senate
- Amendments impacting TSCA were added to the 2007 Energy Act and the 2008 Mercury Export Ban Act
- Sen. Frank Lautenberg introduced legislation in each of the past three Congresses

The Legislative Outlook on TSCA

- S. 1009 introduced by Lautenberg just before his death
  - Bipartisan introduction, written with Sen. David Vitter (R-La.)
  - Surprised many watchers of Congress, the previous Congress ended with Lautenberg and Vitter ending their negotiations, and the U.S. Senate Committee on Environment and Public Works passing a Democratic reform bill along party lines

What has Happened Since Introduction?

Senate

- Sen. Lautenberg has died and Sen. Udall (D-NM) has emerged as leader on issue
- 25 co-sponsors (12 Democrats, 13 Republicans) have signed on in support
- First hearing held in July, gave a preview of where the debates will occur

House

- Have had a series of hearings designed to educate members
- Most members have no history with TSCA, and hearings have focused on CBI and how TSCA works
- So far, hearings seemed less rancorous than the Senate; indications of bipartisanship

The Fall Will be Crucial for Prospects

- Are concerns expressed in the July hearing addressed?
  - Preemption: Chairwoman Boxer and allied groups are concerned about California's regulatory regime
  - CBI protections
  - Establishment of enforceable timelines
- Is there a signal for house support?
  - Currently, there are some signs that the left and the right edges of the House have concerns

Areas of Concern Expressed at Hearing

- Preemption and its effect on state chemical programs, particularly California
- CBI provision
- Timelines for EPA action
- Discussion of the safety standard: “no unreasonable risk” vs. “reasonable certainty of no harm”

So What Happens?

- Despite widespread support on the Committee, Chairwoman Boxer opposes the current bill
  - If she doesn't come around, or feel a sense of authorship, unlikely she'd acquiesce to moving it
  - Substantial "progress" must be made on preemption
  - If it reaches the Senate floor, likely a 70+ vote for approval
- A large, bipartisan vote in the senate makes things easier in the House; look for consideration by early next year
- There are concerns that budget chaos might endanger other items on the agenda, like TSCA reform

Proactive Steps for Companies to Consider

- What can companies do in the meantime?
  - Continue to monitor progress on CSIA
  - Understand industry positions that are active in the debate
    - American Chemistry Council (ACC)
    - Synthetic Organic Chemical Manufacturers Associations (SOCMA)
    - Chemical Specialty Producers Association (CSPA)
    - American Cleaning Institute (ACI)
  - Monitor the EPA Chemical Work Plan webpage
    - http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html
    - Includes chemicals under evaluation and the assessment process
    - May provide early indications on priority chemicals and how CSIA will function

Q&A

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