United States Environmental Protection Agency

Reform of the Toxic Substances Control Act

Brian Symmes

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Office of Pollution Prevention and Toxics

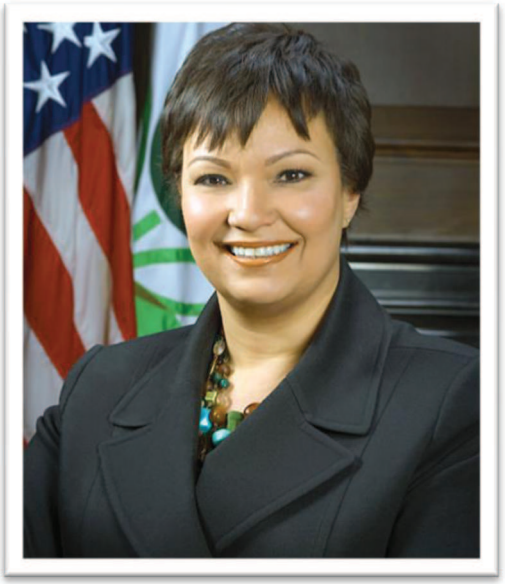
Assuring the Safety of Chemicals

More than 30 years after Congress enacted the Toxic Substances Control Act, it is clear that we are not doing an adequate job of assessing and managing the risks of chemicals in consumer products, the workplace and the environment. It is now time to revise and strengthen EPA's chemicals management and risk assessment programs.

-- EPA Administrator Lisa Jackson, Jan. 23, 2009

TSCA Reform

- On September 29, 2009, Administrator Jackson announced plan to enhance EPA's chemical management program that included the release of a set of Administration principles on TSCA reform.
- On April 15, 2010, Sen. Lautenberg introduced the "Safe Chemicals Act of 2010."
- On July 22, 2010, Congressmen Waxman and Rush introduced the "Toxic Chemicals Safety Act of 2010."



Administrator Lisa Jackson

TSCA Overview

- Enacted in 1976, TSCA set a national program to:
  - Gather information on new and existing chemical substances and mixtures
  - Require testing of chemicals and mixtures
  - Screen and control unreasonable risks of new and existing chemicals and mixtures
  - Coordinate with other Federal agencies
- Only major environmental statute not reauthorized
- TSCA was intended to be the primary means of regulating the production and use of industrial chemicals

Key Elements of TSCA: Inventory

- Lists existing chemicals in commerce -- originally contained 60,000 chemicals.
- Current Inventory contains more than 84,000 chemicals
- EPA collects production level and some exposure and use information every five years
- Information becomes publicly available, unless confidentiality is claimed

Key Elements of TSCA: New Chemicals

- Notifications required in advance of manufacture
- Subject to a 90-day review
- Unless EPA takes action, chemicals enter commerce without further consideration
- To date, EPA has reviewed more than 35,000 new chemical notifications

Key Elements of TSCA: Existing Chemicals

- No comprehensive statutory requirement to test, prioritize or address existing chemicals
- Testing of chemicals must be done through rulemaking process and must make specific findings
- Taking action to limit or ban chemicals is complex and burdensome
  - Only attempted nine ban actions under TSCA, including failed asbestos ban

Utilizing Available Tools in TSCA

- Voluntary phase-out of chemicals

- Formal stewardship/commitment programs like 1998 High Production Volume Challenge
  - After 10 years, still working to fill gaps on sponsored chemicals
  - Still lack data on a significant number of chemicals not sponsored in the Challenge, now using test rules
  - Since the Challenge began, more than 500 additional chemicals have at some point been produced in high volume

Challenges for TSCA Reform

- No mandatory program to determine the safety of existing chemicals.
- Difficult legal and procedural hurdles to limit or ban chemicals
- Significant hurdles to request the generation and submission of health and environmental effects data
- Confidential Business Information claims limit access to information by the public & other governments

Six Principles for TSCA Reform

Principle 1

Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

Current TSCA:

No mandatory review to determine the safety of existing chemicals

Reformed TSCA:

All chemicals on the market reviewed to determine safety

Principle 2

Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Current TSCA:

Only data already available required from manufacturers for new chemicals – no data requirements for existing chemicals – additional information collected only through lengthy rulemaking.

Reformed TSCA:

Manufacturers required to submit vital data on all chemicals in commerce – EPA given clear authority to quickly require submission of any other necessary data

Principle 3

Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations

Current TSCA:

Obstacles to quick and effective regulatory action to limit or ban chemicals found to cause risks

Reformed TSCA:

Clear authority to take risk management actions when chemicals do not meet the safety standard

Principle 4

Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner

Current TSCA:

Review of chemicals are hindered by weak requirements and procedural hurdles. No requirement to review old chemicals

Reformed TSCA:

Clear, enforceable and practicable deadlines set for completion of chemical reviews, in particular those impacting sensitive sub-populations

Principle 5

Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened

Current TSCA:

Green chemistry efforts not mandated—substantial amounts of important information claimed as confidential or not available to the public

Reformed TSCA:

Green chemistry explicitly encouraged and confidentiality claims substantially limited— more and improved information available to the public

Principle 6

EPA Should Be Given a Sustained Source of Funding for Implementation

Current TSCA:

Manufacturers pay nominal fees for review of new chemicals but fees do not directly support EPA's work

Reformed TSCA:

Fees assessed to cover the costs of reviewing chemicals—directly supporting the work necessary to ensure the safety of chemicals

Proposed Legislation

- House and Senate bills share many elements
- House bill introduced following stakeholder discussions
- Burden placed on manufacturers and processors

  to prove chemical substances and mixtures meet safety standard
- Significantly expands EPA authority to collect data and regulate use of chemicals
- New and existing chemicals subject to same safety standard
- New concepts include safety determination and mandatory minimum data set

Highlights from House Bill: Data Requirements

- Declaration of current manufacturing or processing within 1 year
- Rulemaking by EPA to establish minimum data set for all chemical substances and mixtures within 1 year
- Minimum Data Set submission required for:
  - priority list chemicals within 18 months of listing
  - high volume chemicals within 3 years of enactment
  - moderate volume chemicals within 4 years
  - low volume chemicals within 5 years
  - new chemicals at submission of pre-manufacture notice
- Order authority to compel testing

Highlights: Prioritization

- Establishes priority list, starting with 19 substances
- Within 1 year, EPA must expand list to no fewer than 300 existing chemical substances
  - list must always have a minimum of 300 existing chemicals
  - listed at EPA's discretion, based on various factors
  - mixtures may also be added
- Requires identification and expedited exposure reduction for persistent, bioaccumulative and toxic substances

Highlights: Safety Standard

- EPA must:
  - Apply a safety standard which "takes into account aggregate exposure to a chemical substance or mixture and ensures that, for all intended uses with regard to public health, there is a reasonable certainty that no harm will result, including to vulnerable populations; and the public welfare is protected."
  - Determine whether the substance or mixture meets the standard "taking into account any existing conditions or controls already in effect, or can be made to meet the safety standard through the imposition of additional conditions," or whether intended uses that don't meet the standard are critical

Highlights: Risk Management

- Substances or mixtures which do not meet the safety standard are effectively banned 1 year after the determination
  - EPA can extend this period up to 3 years
- EPA may set conditions on use including:
  - prohibitions or limits on manufacturing, processing, distribution in commerce and uses
  - may require marking with warnings and instructions on use
- Critical use exemptions allowed

Highlights: New Chemicals and Uses

- Requires safety determinations in the pre-manufacture stage for:
  - new chemical substances
  - new uses of existing chemical substances
- Minimum data set submitted with new chemical pre-manufacture notices
- EPA determines within 90 days if new substance or use is a critical use or requires a safety determination
- Safety determination must be completed within 9 months

Highlights: Managing and Disclosing Data

- Publicly accessible database with all significant information, including significant decisions
- Ingredient disclosure throughout supply chain
- Limits on confidentiality claims:
  - chemical identification and health and safety studies cannot be claimed
  - requires substantiation and EPA review of a sample of claims while allowing data sharing with other governments
  - approvals limited to no more than 5 years

Highlights: Other Key Provisions

- Preemption
  - no preemption unless simultaneous compliance with State and Federal requirements is impossible
- Hot Spots
  - establish criteria to define disproportionate exposure
  - identify localities disproportionately exposed
  - develop action plans
- Safer Alternatives and Green Chemistry
  - must create market incentives for the development of safer alternatives, including an approval process and exemptions from certain requirements
  - establish a green chemistry research network
- Minimize use of animal testing

Selected Statements from Key Legislators & Stakeholders

The new legislation goes a long way toward ameliorating the major structural flaws of TSCA.

Richard Denison, Environmental Defense Fund,
July 22, 2010

We must strike the right balance and our assessment of [the House bill] as currently drafted promotes unworkable approaches to chemicals management. It creates additional burdens that do not contribute to and, in fact, detract from making advances in safety, while coming up short with respect to promoting innovation and protecting American jobs.

Cal Dooley, American Chemistry Council, July 29, 2010

Selected Statements from Key Legislators & Stakeholders

. . . we have serious concerns with this bill. And many of us genuinely believe that if this legislation is passed as written and as amended then instead of helping us create more jobs in America, it will help us lose more jobs in America.

Rep. Ed Whitfield, Ranking Member, House Subcommittee on Commerce, Trade and Consumer Protection, July 29, 2010

We clearly need to protect the public, but we need to do so in a way that does not stifle innovation and that protects American manufacturing and industry, something that we have been hearing quite a bit about lately. The United States has at this time a very fragile economy and we cannot afford to lose any more jobs in this country than we have already lost.

Rep. John Dingell, Chairman Emeritus, House Energy & Commerce Committee, July 29, 2010

Selected Statements from Key Legislators & Stakeholders

I've talked to [Senator] Lautenberg a lot on this subject. I can't really tell you the specifics or the ingredients that would come into a good TSCA bill. I think we need to have one and he thinks so, too, and we might surprise everyone and come together on something.

Sen. James Inhofe, Ranking Member, Senate Environment & Public Works Committee, Nov. 19, 2010 (as quoted in *Inside EPA*)

Resources

- TSCA and EPA's Enhanced Chemical Management Program: http://www.epa.gov/opptintr/
- Legislative information from the Library of Congress: http://thomas.loc.gov/