

# Enhancing Chemical Management Within the Framework of Existing TSCA Regulations

Kami Blake  
Solutions Engineer  
3E Company  
AHMP Conference 2011

# TSCA Overview



# Toxic Substances Control Act

- Brief History
- Scope and Sections
- Impact on Business
- Recent Activity Impacting Compliance Requirements
  - Federal Chronology
  - State Activity
- Considerations & Recommendations

# BRIEF HISTORY

# TSCA History

- TSCA is a Federal chemical control law promulgated in 1976 by the U. S. Congress
- Administered by the U.S. EPA
- Focused on human health and the environment
- TSCA Objectives:
  - Evaluate risks
  - Prevent human health and environmental effects before a chemical is introduced into commerce

- Authority granted to the EPA under TSCA
  - Gather information about chemical substances
  - Evaluate and prevent risks associated with chemical substances
  - Control exposure by regulating chemical production, distribution and handling
- Activities impacted
  - Manufacture
  - Import
  - Processing
  - Distribution

# SCOPE & SECTIONS

# TSCA Scope

- Industrial chemicals
  - Excludes pesticides, food additives, drugs, cosmetics, etc.
- Regulates manufacturers & processors (imports)
- Distinguishes new from existing substances:
  - “New” refers to any chemical substance not included in the compiled chemical substance (“inventory”) list (TSCA section 8(b))” TSCA
  - “Existing” refers to the the TSCA Inventory List – a list of all chemical substances in commerce prior to 1979 and those that have come on market (about 81K chemicals)
- New chemicals amount to about 1% by volume of chemicals
- Gather data on new and existing substances and mixtures
- Screen, control and require testing of certain chemicals
- Coordinate between Federal and State agencies

# TSCA Compliance

- Section 3 – Definitions
- Section 4 – Test rules/orders
- Section 5 – Pre Manufacture Notification
- Section 6 – Unreasonable Risk Regulation
- Section 8 – Recordkeeping and Reporting
- Section 12 – Exports
- Section 13 – Imports
- Sections 15 and 16 – Penalties (8e = \$16m in fines)

# PMN Requirements (Section 5)

- Any person who manufactures or imports a new chemical substance, or that manufactures, imports, or processes a chemical substance for a significant new use, must notify EPA at least 90 days before manufacturing, importing, or processing the substance.
- EPA has limited or no reporting requirements for new chemical substances in the following cases:
  - Low Volume Exemption (LVE)
  - Research and Development
  - Low Releases and Low Exposures (LoREX)
  - Test Marketing Exemption (TME)
  - Polymer Exemption

# Reporting and Recordkeeping

- Under TSCA Section 8(a), any person who imports, manufactures, or processes chemical substances identified by EPA by rule must report information on production volume, environmental releases, and/or chemical uses – IUR (every 5 years).
- Section 8(b) provides EPA authority to "compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States." TSCA does not include chemical substances subject to other US statutes such as foods and food additives, pesticides, drugs, cosmetics, tobacco, nuclear material, or munitions.

# Reporting 8(c) and 8(e)

- **Records of Significant Adverse Reactions to Health or the Environment (Section 8(c)):**  
Any person who manufactures, imports, or processes chemical substances and mixtures must keep records of significant adverse reactions to health or the environment, as specified in 40 CFR 717.
  - **Notice of Substantial Risk of Injury to Health or the Environment Reporting Requirement (Section 8(e)):**  
Any person who (1) manufactures, imports, processes, or distributes in commerce a chemical substance or mixture, and (2) obtains information that reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment, must promptly\* report the information to EPA, unless the person has actual knowledge that EPA has been adequately informed of the information (see 43 Federal Register 11110 (1978) and 58 Federal Register 37735 (1993)).
- \* *In 2005, violation of 8e requirements resulted in fines of **over \$16 million dollars** against a major US Company for “failing to report to US EPA risk information about a chemical used in the manufacture of...”*

# Importing and Exporting

- **Export Notification (Section 12(b))**

A business that intends to export a chemical substance or mixture for which rules or orders have been issued under certain sections of TSCA (sections 4, 5, 6, or 7) must notify EPA within seven days of exporting or forming the intent to export the chemical, whichever is earlier, for the first time to a particular country in a calendar year (40 CFR 707). For chemicals subject to TSCA section 4, exporters must notify EPA only once for each country, rather than once per calendar year per country.

- **Import Certification (Section 13)**

Because the definition of "manufacture" under TSCA includes importation, importers of chemical substances must comply with all TSCA requirements applicable to manufacturers. In addition, importers must comply with an import certification requirement established by the United States Customs Service under the authority of TSCA section 13 (40 CFR 707 and 19 CFR 12). The importer must certify for every import shipment that all of the chemical substances in the shipment (1) are subject to TSCA and comply with all applicable rules and orders, or (2) are not subject to TSCA.

# IMPACT ON BUSINESS

- **Regulatory Requirements**

- Most in the chemical industry impacted by TSCA (exceptions: food, drug, cosmetic, nuclear, pesticides)
- TSCA covers raw materials, intermediates and finished goods
- From manufacturing, importing, processing, and disposal activities = **cradle to grave compliance**

- **Regulatory Compliance**

- Access to Expertise (Internal and/or external)
- Access to Data

- **Financial**
  - Compliance fees
  - Fines and penalties
  - Loss of business revenue
- **Legal**
  - Criminal and civil penalties enforced for non-compliance
  - Reputation and brand negatively affected
  - Business Ops suspended or limited

# **RECENT ACTIVITY IMPACTING COMPLIANCE REQUIREMENTS**

## Safe Chemicals Act (2010/2011)

- **"New" prioritization element:** EPA would have to classify chemicals into one of three categories. Slated for immediate risk management would be substances that are or degrade/metabolize into a persistent, bioaccumulative, and toxic substance (PBT) with the potential for widespread exposure to humans or other organisms.
- **Elimination of the article exemption:** This year's bill takes a surprising turn in its attempt to abolish this well-established and globally recognized exemption by making chemical substances in articles subject to its provisions.
- **Virtually unfettered state authority to regulate:** States could be prevented from adopting requirements that are different from or in addition to EPA regulations *only* if it could be shown that it is impossible to comply with both.
- **Safety standard and minimum data set provisions:** Finding that there is "reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the substance" continues to be the proposed as the new U.S. chemical control safety standard, and minimum data regarding physical and chemical characteristics, toxicological properties, exposure, and use would be required for "existing" and "new" chemicals.

# TSCA Reform – Agency Driven



In late 2009, EPA Administrator, Lisa P. Jackson, lead the EPA in initiating a comprehensive approach to enhance the Agency's current chemicals management program within the limits of existing authorities. This effort includes:

- New Regulatory Risk Management Actions
- Development of Chemical Action Plans to target the risk management efforts on chemicals of concern
  - Benzidine Dyes, Bisphenol (BPA), Hexabromocyclododecane (HBCD), Nonylphenol and Nonylphenol Ethoxylates, Phthalates, perfluorinated chemicals (PFCs), polybrominated diphenyl ethers (PBDEs) in products, short-chain chlorinated

# TSCA Reform – Agency Driven



- CBI Reduction - transparency and increased public access to chemical info → EPA rejection of confidentiality claims for the identity of chemicals in health and safety studies
- Proposing to add 12 chemicals to a list of substances that may present an unreasonable risk of injury to human health or the environment (authority under section 5(b)(4))
- Increasing information required to understand chemical risks
- Feb 25, 2010 EPA - required testing of 29 HPVC under a proposed rule under a TSCA (4) test rule
- Increased public access to information about chemicals
- IUR reporting changes to increase transparency ...more later

- January 6, 2010: Federal Register published final rule
- EPA is amending Toxic Substances Control Act (TSCA) section 5 reporting regulations to establish electronic reporting requirements for TSCA section 5 submissions
- Streamlines and reduces the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA
- Establishes standards and requirements for the use of EPA's Central Data Exchange (CDX) to electronically submit premanufacture notices (PMNs) and other TSCA section 5 notices and support documents to the Agency

- Amending TSCA section 5 user fee regulations by adding a new User Fee Payment Identity Number field to the PMN form, to enable the Agency to match more easily a particular user fee with its notice submission.
- Amending the PMN form by removing the Agent signature block field, and thus the requirement for designated agents to sign the form.

- **TSCA: Polymer Exemption Exclusion**
  - **January 27, 2010:** EPA amended the polymer exemption to exclude certain perfluoroalkyl moieties consisting of a CF<sub>3</sub>- or longer chain length.
  - New manufacturers or importers must be in compliance as of Feb. 26, 2010
  - Existing manufacturers and importers have until Jan. 27, 2012 to come into compliance.

- **March 15, 2010: TSCA Inventory on Web**
  - First time this was free
  - Inventory contains consolidated EPA list of 1,000's of industrial chemicals
  - Part of a series of ongoing steps Agency is taking to empower the public with important information
- Increased public access to potential health and safety risks posed by chemicals

- **May 17, 2010: Facilities Added to Envirofacts db**
  - More than 6,300 chemicals added and 3,800 facilities under TSCA
  - Internet accessible
  - Information about environmental activities that may affect air, water and land
  - Provides tools for analyzing the data
  - Includes facility name and address information, aerial image of the facility and surrounding area and the map location of the facility
  - Links to other EPA information on the facility, such as EPA's inspection and compliance records that are available through the Enforcement Compliance History Online (ECHO)

- **May 27, 2010: Follow-up Action**

- EPA plans to generally deny confidentiality claims for the identity of chemicals in health and safety studies “except in specific circumstances”
- Affected chemicals are those submitted to EPA with studies that show a substantial risk to people’s health and the environment that have been previously disclosed on the TSCA Inventory
- Under Section 8(e), companies must immediately provide notice if they learn that a chemical presents substantial risk of injury to health or environment. These reports are made available on the EPA website. Until this agency-driven reform, companies would routinely claim CBI.
- New reforms increase information availability by granting public access to the chemical identification information submitted, along with other health and safety data under Section 8(e)

- **December 22, 2010: Chemical Data Access Tool** to locate health and safety data that submitted to the Agency under authorities in sections 4, 5 and 8 of TSCA
  - eDoc – broad range of H & S info reported by industry under Sections 4, 5, 8(d) and 8(e)
  - TSCATS - online index to unpublished, non-confidential studies covering testing results and adverse effects of chemicals on health and ecological systems
  - HPVIS – High Production Volume Information System that provides access to health and environmental effects information obtained through the HPV Challenge

- **More on Confidential Business Information.....**

- March 24, 2011 EPA released identities of chemicals in 42 health and safety studies previously claimed as CBI by companies (declassified). The American Chemistry Council and its members worked cooperatively with EPA.
- CAS Nos. 93-65-2; 57-55-6; 111-76-2; 677-21-4 named in the 42 studies
- EPA will regularly post additional chemical information as it is declassified

## New IUR Reporting – Name Change to CDR (Chemical Data Reporting)

- **August 13, 2010** -- EPA published a proposed IUR Modifications Rule
- **August 2011** -- EPA published the CDR Final Rule proposed in the Federal Register as the IUR Modifications Rule.
- The final rule delineates a number of improvements for 2012
  - Reporting (requiring electronic submission), via the e-CDRweb
  - Making reporting easier and more accessible to all potential reporters
  - Modifies the reporting of manufacturing, processing and use data for most chemicals and makes changes to specific data elements, including the submission of production volume for calendar year 2010.
  - Manufacturers (including importers) provide a greater amount of substantiation for confidential business information claims

# IUR to CDR



- Next submission period will occur from February 1, 2012 to June 30, 2012
- Electronic reporting for the 2012 CDR is not yet available. EPA will make the CDR electronic reporting tool, e-CDRweb, available through the Agency's CDX. e-CDRweb is a free, web-based reporting tool for completion of Form U for the 2012 CDR.
- On September 23, 2011, EPA will be hosting a webinar to demonstrate e-CDRweb. Those interested will be able to test the tool during the following week. The test version will not be usable for 2012 submissions.
- Expect more changes

# State Chemical Laws



- California
- Connecticut
- Illinois
- Maine
- Massachusetts
- Michigan
- Minnesota
- New York
- Oregon
- Vermont
- Washington

# State Chemical Laws: California

- April 2010: California lawmakers released proposed draft regulations for the implementation of the State's foundational Green Chemistry legislation.
- Viewed by many as a potential national model for chemical reform, California's legislation, which aims to control potential hazards in consumer products, is considered to be one of the nation's first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals, a core principle of Green Chemistry.
- The impact of the legislation and similar laws emerging throughout the states is potentially far-reaching for manufacturers and industry, which may face a number of new obligations, such as the full disclosure of product ingredients, and new restrictions, such as outright chemical bans.

# State Chemical Laws: Connecticut



- In 2008, Connecticut passed the Act Concerning Child Product Safety, which requires the state to create a list of toxic substances, recommend the maximum amount of these substances that may exist in children's products, and develop a corresponding list of safer alternatives to the toxic substances identified.
- The law also allows Connecticut to participate in a multi-state clearinghouse on toxic chemicals that would prioritize chemicals of concern used in commercial goods, as well as organize and manage available data on chemicals.
- Through the clearinghouse, the state would also be able to produce and inventory information on safer alternatives to specific uses of chemicals and model policies and programs related to these safer alternatives.
- In addition, this law also phases out lead and asbestos from children's products.

# State Chemical Laws: Illinois



- **Two versions of a Child-Safe Chemicals Act are under consideration:**
  - Under House Bill 3792, an advisory panel would be created to form a pilot program to address chemicals that pose a threat to children’s health. Panel would be responsible for identifying such chemicals, establishing limits for these chemicals, identifying safer alternatives and incentivizing the development of these alternatives, and providing notice to consumers about these chemicals and their impacts.
  - House Bill 2485 would authorize Illinois’ participation in a multi-state clearinghouse to manage and organize available data on chemicals in order to promote safer chemicals in consumer products.
- **Both bills have been referred to committee**

# State Chemical Laws:

## Maine

- In February 2006, the Governor of Maine signed an Executive Order to promote safer chemicals in consumer products sold in the state.
- The order established a task force to identify and promote the use of safer alternatives to hazardous chemicals in consumers goods and services. In April 2008, Maine enacted its Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products.
- Maine's law follows a similar structure to California's regulatory proposals but is limited to priority chemicals in children's products. Pursuant to the law, Maine published a list of chemicals of high concern in summer 2009.
- In February 2010, Maine adopted final regulations which establish the process by which priority chemicals are designated and which detail the factors that will be taken into account when reviewing alternatives assessments and in determining whether safer alternatives are available.
- By 2011, at least two of these chemicals of high concern must be identified as "priority chemicals" subject to regulatory requirements, and every three years, additional priority chemicals may be designated.
- Manufacturers or distributors of children's products containing a priority chemical are required to notify the state if any of its children's products sold in Maine contains a priority chemical.
- They will also need to provide supplemental information on exposure, harm, and alternatives, if requested.
- Rules regarding the fee structure to administer the state's Green Chemistry program have also been adopted.

# State Chemical Laws: Massachusetts

- The Act for a Competitive Economy Through Safer Alternatives to Toxic Chemicals was proposed in Massachusetts in 2009.
- Under this bill, chemicals commonly used in the state's industry or used in products sold in the state would be categorized and prioritized.
- Annually, two to five chemicals prioritized as high concern chemicals would be subject to a safer alternatives assessment performed by the Toxics Use Reduction Institute, and the state would create a chemical action plan that would be used in promulgating regulations that restrict use of the priority chemical.
- Manufacturers using priority chemicals for which feasible safer alternatives exist would be obligated to substitute any priority chemicals with the safer alternatives.
- Further, additional efforts would be made to interface with business to promote these safer alternatives.
- A similar bill was previously proposed that would permit the annual designation of one to five high hazard substances to be evaluated for safer alternatives.

# State Chemical Laws: Michigan

- In 2009, Michigan's House of Representatives passed three bills aimed at promoting the state's Green Chemistry efforts through amendments to various economic development statutes.
- House Bills 4817, 4818, and 4819 would make companies engaged in the development of Green Chemistry initiatives eligible for grants, tax credits, and other benefits.
- All three bills have been sent to Michigan's Senate.

# State Chemical Laws: Minnesota

- Minnesota enacted the Toxic-Free Kids Act in 2009.
- Under the law, the state will generate a list of chemicals of high concern by July 2010 as well as a list of priority chemicals by February 2011.
- Notably, several categories of chemicals are excluded from these lists, including priority chemicals used in the manufacturing process but which are not present in the final product, and certain categories of products, such as consumer electronic products, are also exempt.
- Further, the law authorizes Minnesota's participation in a multi-state clearinghouse on toxic chemicals.
- In January 2010, the state legislature received a progress report on the statute's implementation, as well as an overview on Green Chemistry initiatives taking place in other states and countries.
- In December 2010, a follow-up report will be released that identifies ways to reduce and phase out the use of priority chemicals in children's products and promote the use of safer alternatives.
- This report is also expected to discuss ways to fund efforts to phase out or substitute priority chemicals and ways to promote and provide incentives for products that are designed using Green Chemistry concepts.

# State Chemical Laws: New York

- In March 2010, the New York Senate referred An Act to Amend the Environmental Conservation Law, In Relation to Regulation of Toxic Chemicals in Children's Products to committee.
- The New York bill is modeled after Washington's Children's Safe Products Act, and would require the Department of Environmental Conservation to publish a list of chemicals of high concern, to determine priority chemicals from that list based on likelihood of exposure, and allow the Department to ban the sale, manufacture, import, or distribution of products containing priority chemicals in the state if a safer alternative exists.
- The bill would require the development of a list of chemicals of high concern within six months of its effective date.

# State Chemical Laws: Oregon

- Oregon's Children's Safe Products Legislation involves two bills that are currently in committee.
- First, HB 2367 would ban the use of phthalates and bisphenol A in children's products sold or manufactured in Oregon.
- Also, HB 2792 would require the Department of Human Services ("DHS") to identify chemicals in consumer products that are of high concern for children's health.
- It would also require manufacturers to notify DHS when their products contain those chemicals, and allow DHS to require safer alternatives to toxic chemicals when practical.
- The bill would also help provide consumers with information regarding toxic chemicals in children's products and allow participation in a multi-state clearinghouse.

# State Chemical Laws: Vermont

- An Act Relating to the Regulation of Toxic Substances was proposed in Vermont in 2010.
- This bill would establish a toxic chemical identification and reduction program in the state.
- Chemicals of high concern would be identified, and some of them would be designated priority chemicals.
- Manufacturers of children's products sold in Vermont that contain priority chemicals would be subject to reporting requirements, which include the likelihood of a release from the children's product and alternatives to the priority chemical.
- The bill would allow the state to prohibit the manufacture, sale, or distribution of a children's product containing a priority chemical if there is risk of direct or indirect exposure of the chemical to children, and if safer alternatives are available at a similar cost.
- Further, the bill would create an advisory counsel in the state on toxic substances and would also allow the state to participate in a multi-state clearinghouse on toxic chemicals.

# State Chemical Laws: Washington



- Enacted in 2008, Washington's Children's Safe Products Act consists of two basic parts.
- First, it limits the amount of phthalates, lead, and cadmium in children's products.
- Second, the law requires the state to address chemicals that may pose exposure risks to a child or developing fetus.
- The state must identify high priority chemicals that carry such risks, and in January 2010, the state released a draft of an initial list containing 66 chemicals which it describes as a "starting point" in implementing the law.
- The state will also have to identify children's products or product categories that may contain these chemicals.
- The manufacturers of any products containing a high priority chemical must report to the state.
- In addition, the state is also authorized to establish a children's product safety education campaign.
- In July 2009, the state released a report highlighting various policy options for addressing children's products containing chemicals of high concern, including ways to inform customers about toxic chemicals in products.
- Currently, the rulemaking process is underway, and a pilot rule is now being voluntarily tested by a group of children's products manufacturers through April 2010.
- Afterwards, the state intends to assess the pilot project to determine if the draft rules need to be adjusted before proceeding with the formal rule adoption process.

## Does TSCA effect my company?

- What types of products does your company manufacture/import, process, dispose or export?
- What end use applications do your products provide?
- Are your blends mixtures or new substances?
- Are the materials you are using, manufacturing or exporting listed on the TSCA 8b Inventory?

## Is my TSCA Compliance Program adequate?

- Does your company have a written TSCA Compliance program?
- Does your company have a TSCA Team or Coordinator or Specialist?
- Has your company ever been audited by EPA for TSCA Compliance?
- Has your company ever been cited for non-compliance with TSCA?
- Does your company make new materials or synthesize polymers?
- Does your Operating system [SAP, for example] have flags for TSCA Compliance?
- Does a broker handle your imports / exports or are they handled by in house specialists – have they been TSCA trained?
- Are **your** Customers asking you about TSCA Status for the materials they purchase from you?

- To ensure compliance with TSCA, develop and maintain a comprehensive and detailed plan, which should include the following:
  - **TSCA Inventory** - Checking the TSCA inventory for substances imported or manufactured, including the ingredients in finished products
  - **TSCA R&D Exemption** - Reviewing R&D exemption requirements and setting up procedures to govern related activities
  - **Import Certification** – Obtaining import certification once the status of the substance or product to be imported has been checked against the TSCA inventory.
  - **Export Notification** - Establishing processes for tracking 12(b) exports and assisting with export notification
  - **Adverse Effects** - Establishing processes for compliance with adverse effects reporting and recordkeeping
  - **Regulatory Tracking** - Monitoring and tracking regulatory changes which are likely to impact business
  - **Recordkeeping** - Maintaining required records and auditing against various recordkeeping requirements

- Change is in the air: new EPA initiatives have and **will continue** dramatically change scope of TSCA
- Increasing transparency and access in information
  - This effort includes:
    - New Regulatory Risk Management Actions
    - Development of Chemical Action Plans which will target the Agency's risk management efforts on chemicals of concern
    - Quick action by EPA on chemicals demonstrating high risk. Chemical safety to be proven to keep it on the market.
    - Further restrictions on the data claimed by industry to be confidential
    - Automating submissions and access
- Growing list of states implementing control laws
- Non-compliance could result in severe repercussions

# Recommendations

- 1. Willful Violations:** No longer limited to those who purposefully and covertly intend to subvert applicable regulations, and the EPA is far from the only watchdog. Consumer groups and eco/environmental activism have elevated awareness and increased the number of groups that monitor, scrutinize and report on a broad base of industry-specific chemical related activities. As the focus shifts from compliance to CSR this issue requires corporate governance, procedural review and an enterprise-wide program that includes on-going employee education and awareness training.
- 2. CBI:** Organizations should be selective in the types of molecules that are deployed and look for common alternatives. In preparation for current and future changes that may make it very difficult not to disclose formulation ingredients, manufacturers may want to consider avoiding the design of complex molecules for the trade secret purposes. It is and will become even more difficult to protect.
- 3. IUR / CDR.** This list is detailed and includes mandatory electronic filing, the addition of previously exempted chemicals (when meeting/exceeding the 25,000 lb. threshold), elimination of the 25,000 lb. threshold for certain chemical substances as well as require manufacturers (including importers) of such chemicals to report under the IUR rule, regardless of the production volume, and increased data requirements, as the form has expanded and calls for more information about chemicals in commerce.
- 4. Greener and Safer Alternatives:** CAPs have been (and will continue to be) developed that will further restrict the manufacture and use of substances and compounds. Though there is no accepted rating system in place to uniformly evaluate substances, mixtures and finished goods, there is a wealth of hazard data, and global regulatory content that identifies environmental impact and other informational resources that can assist with decision making. The EPA has emphatically put its weight behind Green Chemistry initiatives.

# TSCA Jargon

- **TSCA** Toxic Substances Control Act
- **PMN** Premanufacture Notification
- **E-PMN** Electronic Premanufacture Notification
- **NOC** Notice of Commencement
- **R&D** Research and Development
- **LVE** Low Volume Exemption
- **TME** Test Market Exemption
- **LoRex** Low Releases and Low Exposures
- **SNUR** Significant New Use Rule
- **SNUN** Significant New Use Notice
- **IUR** Inventory Update Rule
- **HPVC** High Production Volume Chemicals
- **CDX** Central Data Exchange

[www.epa.gov](http://www.epa.gov)

[www.gpoaccess.gov](http://www.gpoaccess.gov) (easier to navigate)

Navigate to 40 Code of Federal Regulations Parts 700 to 789 “Protection of Environment”

Thank you!