

# Exploring the Impact of Regulatory Changes:

## What's on the Agenda for 2011

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# Discussion Topics

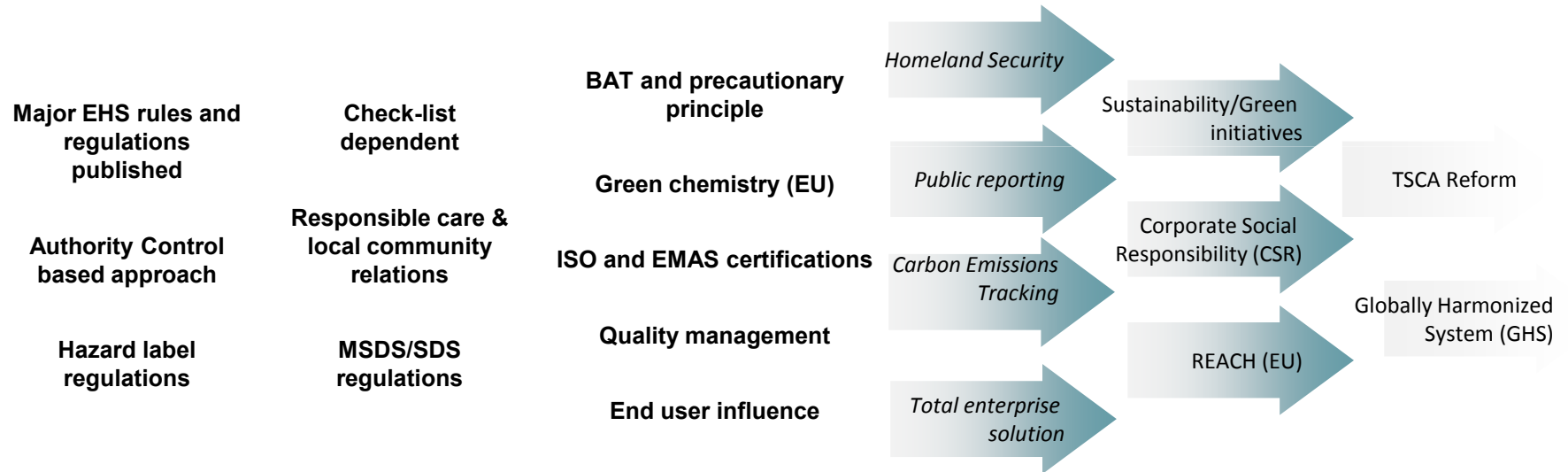


- Regulated Materials Compliance Evolution & Challenges
- TSCA Reform (Legislative and Non-legislative)
- GHS
  - OSHA Proposed Rule
  - Global Implementation
- DOT
  - ORM-D Phase Out / LQ Requirements
  - Lithium Batteries
- Non-Regulatory Compliance
  - CSR and Thinking *GREEN*

# Risks and Costs of Non-Compliance Rising as the Regulatory Environment Becomes Increasingly Onerous



## Current and Future Regulatory Drivers



*EH&S compliance needs are pervasive and persistent across geographies and verticals*

# Environmental Health & Safety Compliance Is Complex And Mission-Critical



## Environmental Health and Safety (EH&S) compliance pertaining to the regulatory enforcement, documentation, and oversight of hazardous material substances

### EH&S Regulatory Complexities

- Material Safety Data Sheets (“MSDS”)
- Hazardous material exposure limits, storage requirements, etc.
- Reporting regulations
- Permits
- Notifications requirements
- Mandated labels
- Recurring regulatory compliance reports
- Transport documentation and compliance
- Regulations differ across markets and geographies

### EH&S Considerations

- What are the reporting requirements?
- How do rules differ across your target markets?
- Are your employees and customers protected?
- What is the impact on the environment?
- Are your upstream suppliers and downstream channels and customers compliant?
- What are the transportation requirements?
  - Packaging/Classification/Labeling
  - Segregation
  - Risk
- Is information localized properly (i.e., language, format)?

### EH&S Compliance Is Mission-Critical

- Risks of non-compliance include significant fines, potential legal exposure, property and environmental damage, injuries, and death
- Successfully navigating regulatory complexities requires significant resources with domain expertise and vigilance
- Need for product safety and stewardship and workplace chemical safety data, applications, and expertise are especially critical

# Product Lifecycle Compliance



Online Reference Regulatory Data Content Solutions

Transportation Services

Chemical Inventory & MSDS Management

Integrated Regulatory Data Content Solutions (SAP, WERCS, etc.)

Training

Emergency Response

MSDS Authoring & Distribution

Regulatory Reporting (Research, Permits, Disclosures, etc.)

Waste

Green Product Analysis

# Regulatory Landscape

## Chemical



GHS: Global Harmonization System



European Chemicals Agency



Registration, Evaluation, Authorization and Restriction of Chemicals

## Workplace



Health & Safety Commission: UK

## Transportation



Transport Canada



## Environmental



Environment Canada



## Security



## Local



## Criminal



# TSCA Overview



# Toxic Substances Control Act

# 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

# TSCA Scope



- Covers 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)

# TSCA Reform - Legislative



## 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
- CBI Reduction - As a part of its ongoing effort to fulfill a commitment to transparency and increased public access to information on chemicals, the EPA may deny confidentiality claims for the identity of chemicals in health and safety studies

# TSCA Reform – Agency Driven



- EPA is proposing to add twelve chemicals to a list of substances that may present an unreasonable risk of injury to human health or the environment, using the authority under section 5(b)(4) the Toxic Substances Control Act (TSCA).
- Requiring Information Needed to Understand Chemical Risks
- On Feb 25, 2010 EPA announced it would require testing of 29 high production volume chemicals under a proposed rule under a TSCA (4) test rule
- Increasing Public Access to Information About Chemicals
- EPA is making changes to IUR reporting to increase transparency

# TSCA Reform – Impact Areas



- 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. Inventory Update Rule (IUR):** 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.

# IUR UPDATE



EPA issued a Federal Register Notice today amending the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) regulations by **suspending the current June 1, 2011, through September 30, 2011**, submission period for 2011 reports. A revised submission period will be announced when the IUR modifications rule is finalized in the next several weeks. The IUR requires manufacturers (including importers) of certain chemical substances included on the TSCA Chemical Substance Inventory to report current data on the manufacturing, processing and use of the chemical substances. EPA is suspending the current IUR submission period to provide sufficient time for companies to comply with the updated IUR reporting requirements.

The Notice is available at:

<http://www.gpo.gov/fdsys/pkg/FR-2011-05-11/pdf/2011-11562.pdf>

## Globally Harmonized System for Classification and Labeling of Chemicals

- A common and coherent United Nations approach to defining and classifying intrinsic hazards of chemical substances and mixtures, and conveying information about those hazards on labels and Safety Data Sheets (SDS)
- Criteria for hazard classification and hazard communication (Labels and SDS) are harmonized and standardized.



# GHS – OSHA Proposed Rule



**Proposal to modify the HCS to align with the GHS:** OSHA is proposing to modify the current HCS to align with the provisions of GHS for Classification and Labelling of Chemicals.

**Why modify the HCS:** Adoption of GHS will not change the framework and scope of the HCS but will help ensure improved quality and more consistency in the classification and labeling of all chemicals. The harmonized format of the safety data sheets will enable workers to access the information more efficiently.

## **Major proposed changes to the HCS:**

- **Hazard classification:** Provides specific criteria for classification of health and physical hazards, as well as classification of mixtures.
- **Labels:** Chemical manufacturers and importers will be required to provide a label that includes a harmonized signal word, pictogram, and hazard statement for each hazard class and category. Precautionary statements must also be provided.
- **Safety Data Sheets:** Will now have a specified 16-section format.
- **Information and training:** The GHS does not address training, but the proposed HCS will require that workers are trained within **two years** of the publication of the final rule to facilitate recognition and understanding of the new labels and safety data sheets.

# OSHA Proposed Rule Impact



- **Number of workers affected by the proposed HCS:** Over 40 million workers
- **Affected Industries:** Over 5 million workplaces
- **Annualized compliance costs of the proposed standard:** Approximately \$97 million per year, estimates as follows
  - **Re-classifying** chemical hazards (GHS criteria) and revising SDS and labels to meet new format and content requirements = \$11 million a year on an annualized basis for an estimated 90,000 establishments.
  - **Training** for workers to become familiar with new warning symbols and the revised safety data sheet format under GHS would cost \$44 million a year on an annualized basis.
  - \$42 million a year for **general management** to become familiar with the new GHS system and to engage in other management-related activities as may be necessary for industry's adoption of GHS.
- **Date of Implementation:** It was widely expected that OSHA would promulgate the rule some time in Q3 of 2010. However 2010 came and went without action. The UN's target acceptance date was 2008, so OSHA is now 3 years off the proposed pace.

# GHS Global Overview



- GHS legislation or standards have been passed in:

- Asia Pacific:

- New Zealand (2001)
- Japan (2006)
- Korea (2008)
- Taiwan (2008)
- Singapore (2008)
- Vietnam (2008)
- China (2009)
- Indonesia (2009)



- Europe

- EU (2008)
- Russia (2009)

- Africa

- South Africa (2008)

- Americas

- Brazil (2009)

# GHS Global Overview



## Draft regulations on GHS published:

- USA
- Australia
- Malaysia
- Philippines

## Implementation activities

- Canada – GHS compliant SDS accepted with reference to WHMIS
- MERCOSUR countries – SDS standards
- ANDEAN Community – National Plan, capacity building
- UNITAR/ILO Global GHS Capacity Building Programme: Cambodia, Gambia, Laos, Nigeria, Senegal, Zambia
- Serbia, Croatia, Turkey
- Thailand



# Transportation Updates



## ORM-D Phase Out / LQ Requirements

PHMSA issued Final Rule HM-215K – January 19, 2011;

Address 8 primary topics of concern:

A. Limited Quantities and Consumer Commodities

B. Classification of Division 1.4S Explosives

C. Classification of Sour Crude Oil

D. IBC Rebottling

E. Metal Hydride Storage Systems in Conveyance

F. In Vitro Testing for Corrosivity



# ORM-D Today



ORM-D shipments must meet specified packaging, marking and weight requirements

- ORM-D is *Regulated*
  - Multi-Modal Shipments
  - Product Returns
  - Storage/Disposal



# LQs & Consumer Commodities



- US DOT to completely eliminate the use of ORM-D exception for all modes of consumer commodities shipments by January 1, 2014
- Consumer commodity shipments to align with International Limited Quantity requirements
  - Continue to align HMR with international regulations
  - Smoother flow of goods through global commerce
  - Modifies definition of consumer commodity to be consistent with international air requirements
  - Limit need to re-mark packages to US only standards

# Pros



- Elimination of dual marking systems would eliminate confusion and not require carriers and shippers to adjust their training programs to account for a dual system
- Enhance safety by facilitating a single, uniform system of transporting limited quantity materials
- Promote compliance efficiency and consistent training leading to lower post implementation costs
- Some cost savings from shipping paper simplification

# Cons



- The proposed quantity limits for air transport differ from the quantity limits for other modes. This will introduce unnecessary complexity into a fairly simple process.
- Most commenters were opposed to eliminating ORM-D and recommended using a separate rulemaking; not linked to international harmonization
- Question whether costs of eliminating ORM-D have been fully considered
- Question whether there is sufficient safety justification to warrant replacing ORM-D (No major incidents to justify)

# Implementation Timelines



- Final Ruling effective January 19, 2011
- Delayed compliance date beginning January 1, 2012,
- Voluntary Compliance may begin as of January 1, 2011
- New limited quantity marking mandated for use as of January 1 2012 (Conforms to 49CFR and IMDG)
- Use of ORM-D AIR valid through December 31, 2012
- ORM-D valid through December 31, 2013

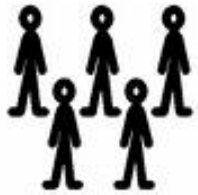
# Lithium Batteries



The DOT published a NPRM on January 11th, 2010 aimed at creating stricter regulations for the air transportation of lithium cells and batteries. PHMSA is the DOT organization responsible for drafting the proposed rule. The proposal comes in reaction to pressure from the Air Line Pilots Association (ALPA) which is concerned with the safety of flights.

- Eliminates exception for smaller lithium ion and lithium metal cells and batteries and nearly all equipment packed with or containing them when shipped by air.
- Applies new packaging requirements on shipments of equipment that contain lithium ion or lithium metal cells or batteries, as well as on batteries.
- Requires employees who ship lithium ion and lithium metal cells and batteries and equipment packed with or containing them, including excepted batteries and equipment, to receive hazardous materials training.
- Places restrictions on where shipments of lithium ion and lithium metal cells and batteries and equipment can be stowed on aircraft.
- Imposes testing and battery design criteria inconsistent with the UN Manual of Tests and Criteria, ICAO Technical Instructions and IMDG Code.
- Prohibits shipping by air and vessel lithium ion and lithium metal cells or batteries that have been damaged, identified as defective or are otherwise being returned to the manufacturer for safety reasons.
- Prohibits passengers from placing spare “dry cell” batteries in checked baggage.

# Thinking “Green”



## People

- Industrial Hygiene
- Human Resources



## Property

- Logistics
- Facilities Management
- Insurance Carriers



## Environment

- Environmental Managers
- Marketing



## Profit

- Procurement
- Stakeholders

# Green Product Analysis



## Green Score – Potential Criteria

People (Health)	Property (Storage)	Environment
<ul style="list-style-type: none"><li>• Known Carcinogens</li><li>• Probable Carcinogens</li><li>• Mutagens &amp; Reproductive Toxins</li><li>• Endocrine Disruptors</li><li>• Target Organ Effects</li><li>• Health Effects</li></ul>	<ul style="list-style-type: none"><li>• EHS</li><li>• Corrosive</li><li>• Explosive</li><li>• Flammable</li><li>• Oxidizer</li><li>• Reactive</li><li>• Water Reactive</li></ul>	<ul style="list-style-type: none"><li>• Air Pollutants</li><li>• Marine Pollutants</li><li>• Release Hazards</li><li>• Hazardous Waste</li><li>• PBTs</li></ul>

# Market Environment for EH&S Compliance



## “The Brain Drain Spurs Interest in Commercial EH&S Solutions”

- After years of passive compliance and minimal spending, companies are finally waking up to the risks and opportunities
- 40% of companies will address EH&S as a data-driven solution this year!
- Brain Drain issue is looming larger than ever before
  - Aging EH&S workforce is retiring, taking knowledge with them
- EH&S processes, which were isolated niche afterthoughts,...
  - Now are becoming front and center boardroom global issues
  - EH&S risks are being assessed and repaired throughout the supply network
  - Smart data and service providers are being sought to support

*Source: AMR Research*

# Market Environment for EH&S Compliance



## “Factors to Consider in EH&S Compliance Initiatives, Prioritization, and Budgets”

- Regulatory costs of noncompliance now make it a necessity
- Brand opportunity of active EH&S compliance has become significant
- Peer pressure as Vendors, Customers, and Competitors also invest in EH&S solutions

*Source: AMR Research*

# Market Environment for EH&S Compliance



## “The Brand opportunity of Active Compliance”

- Companies are linking EH&S initiatives to Corporate Social initiatives:
  - Dow Chemical, Rohm & Haas, Kimberly-Clark, H-P, Home Depot
- Seen as a corporate issue for shareholders, brand, employees, and customers
- Downstream channels and customers are demanding proper stewardship
- Brand is the greatest asset; stakeholders care
  - Negative publicity is hard to overcome
  - Compliance is a cornerstone
- Financial pressure
  - Dow Jones Sustainability Index now factors in EH&S compliance

*Source: AMR Research*

# Market Environment for EH&S Compliance



## “Incorporating EH&S Compliance into the Business”

- Transition from Passive EH&S compliance to making it part of strategy
- Global Implementations will be challenging
  - Varied local regulations, policies, processes, and assets
  - EH&S Solutions need to flexibly accommodate these diverse requirements
  - Harvesting IT support for EH&S continues to be difficult

*Source: AMR Research*

# Market Environment for EH&S Compliance



## “EH&S to Finally Get a Share of the Data Management Pie”

- Product Level EH&S Data an Arduous Task
  - Chemical compositions
  - Calculations
  - Raw material
  - Testing
  - Equipment
- Now across different databases and applications
  - Harmonization is critical
- Recognized need for Simple, consistent, Globally visual, accurate EH&S data
- Needed: Tools, Data, Metrics

*Source: AMR Research*

# Market Environment for EH&S Compliance



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# Questions & Contact Information



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