Hazard Material Information Management and Regulatory Compliance

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Introductions

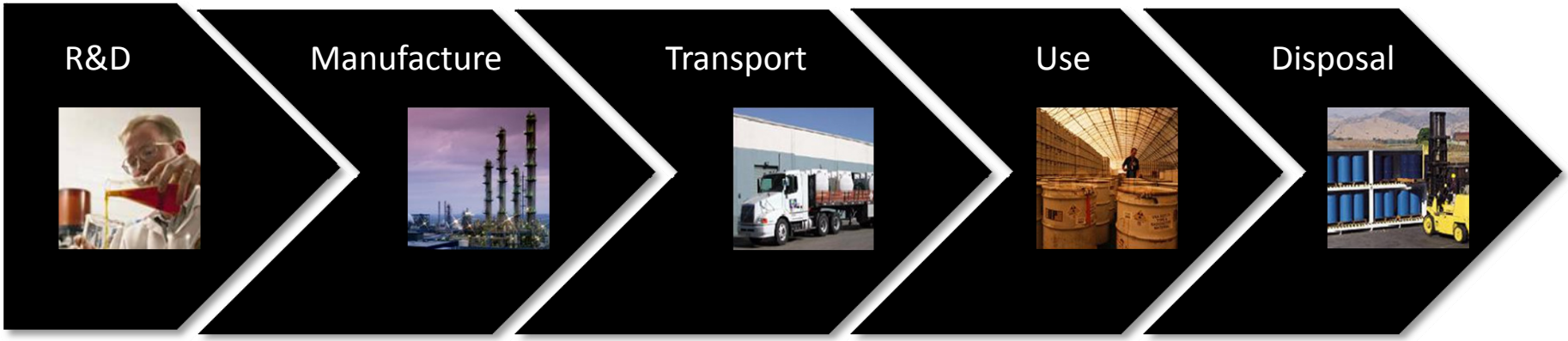
Kami Blake – Discussion Host

- Assess regulatory requirements, information management technology and effectiveness of existing HazMat programs to develop and re-engineer compliance solutions
- Prior to joining 3E in 2002, served in Quality Assurance, Supply Chain Management and Process Engineering roles in the biotech and medical device manufacturing industries
- U.S. Marine
  - Computer Programmer / Systems Analyst
  - Two time Navy Achievement Medal recipient for small systems implementation and training

Discussion Topics

- Evolving Compliance Strategies
- EH&S Information Management Systems
- Data Requirements
- Regulatory Update
  - TSCA Reform (Legislative and Non-legislative)
  - GHS
  - DOT
- Non-Regulatory Compliance
  - CSR and Thinking *GREEN*

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

ECHA

European Chemicals Agency

REACH

Registration, Evaluation, Authorization and Restriction of Chemicals

Workplace

Workplace Hazardous Materials Information System (WHMIS)

OSHA

HSC

Health & Safety Commission: UK

Transportation

DEPARTMENT OF TRANSPORTATION UNITED STATES OF AMERICA

Transport Canada

Environmental

Environment Canada

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Umwelt Bundes Amt
For our Environment

Security

U.S. DEPARTMENT OF HOMELAND SECURITY

Local

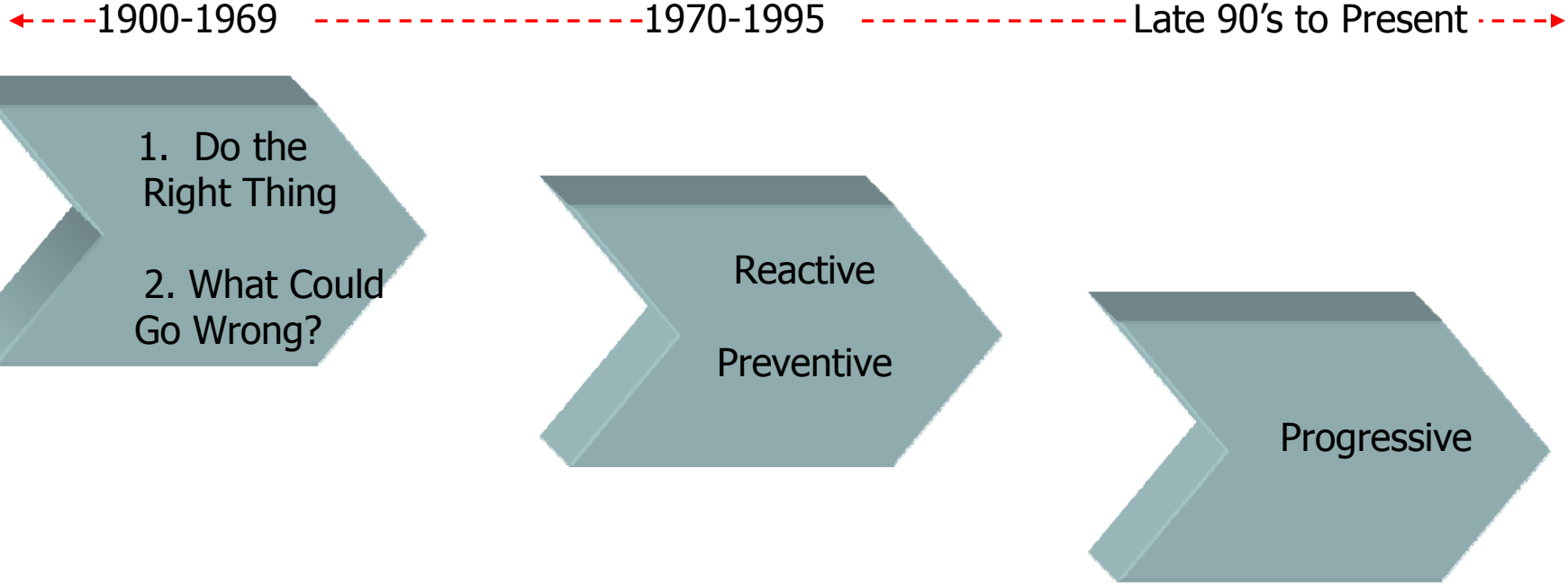
CAL OSHA

Criminal

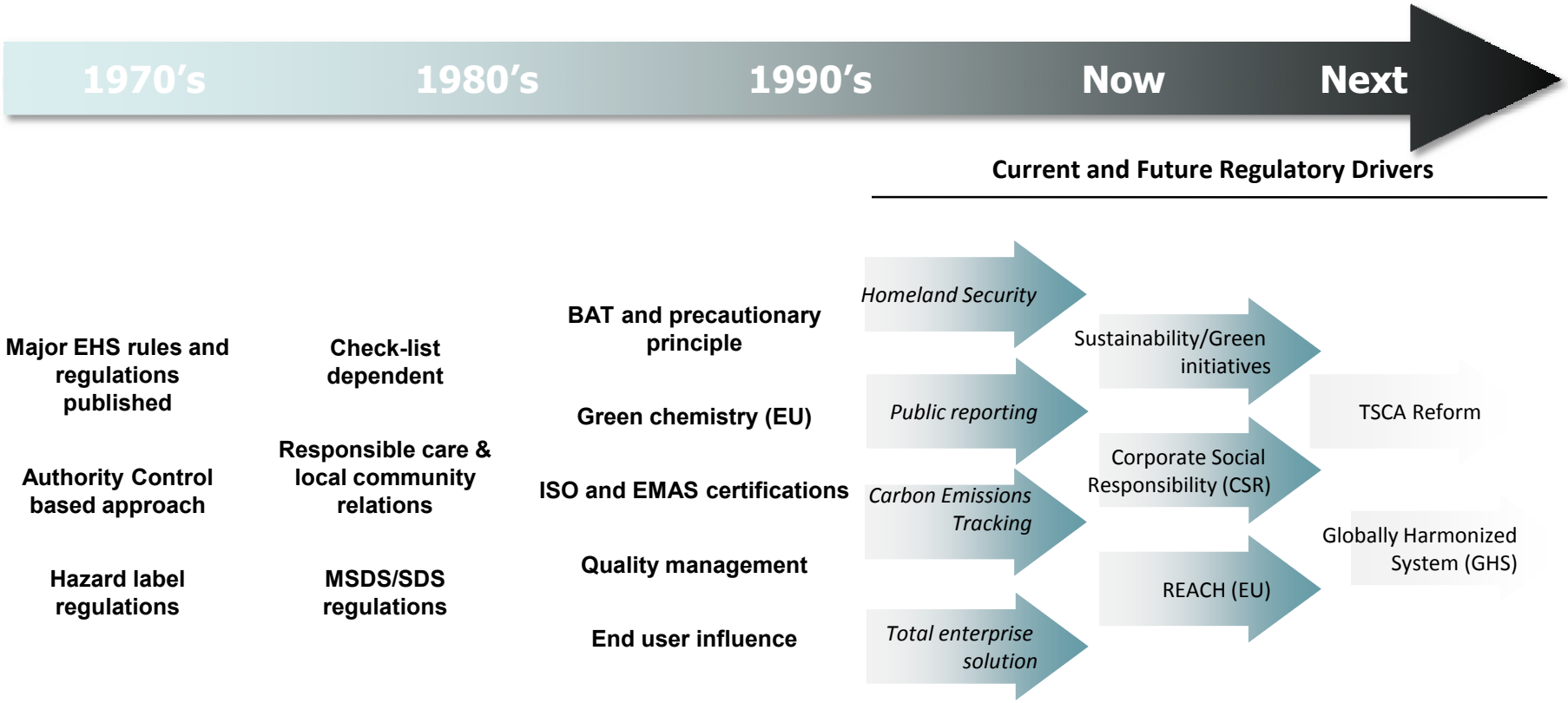
DEPARTMENT OF JUSTICE
QUI PRO DOMINA JUSTITIA SEQUITUR

Compliance Today

The Evolution of EH&S Compliance



Risks and Costs are Rising as the Regulatory Environment Expands



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

Compliance Today

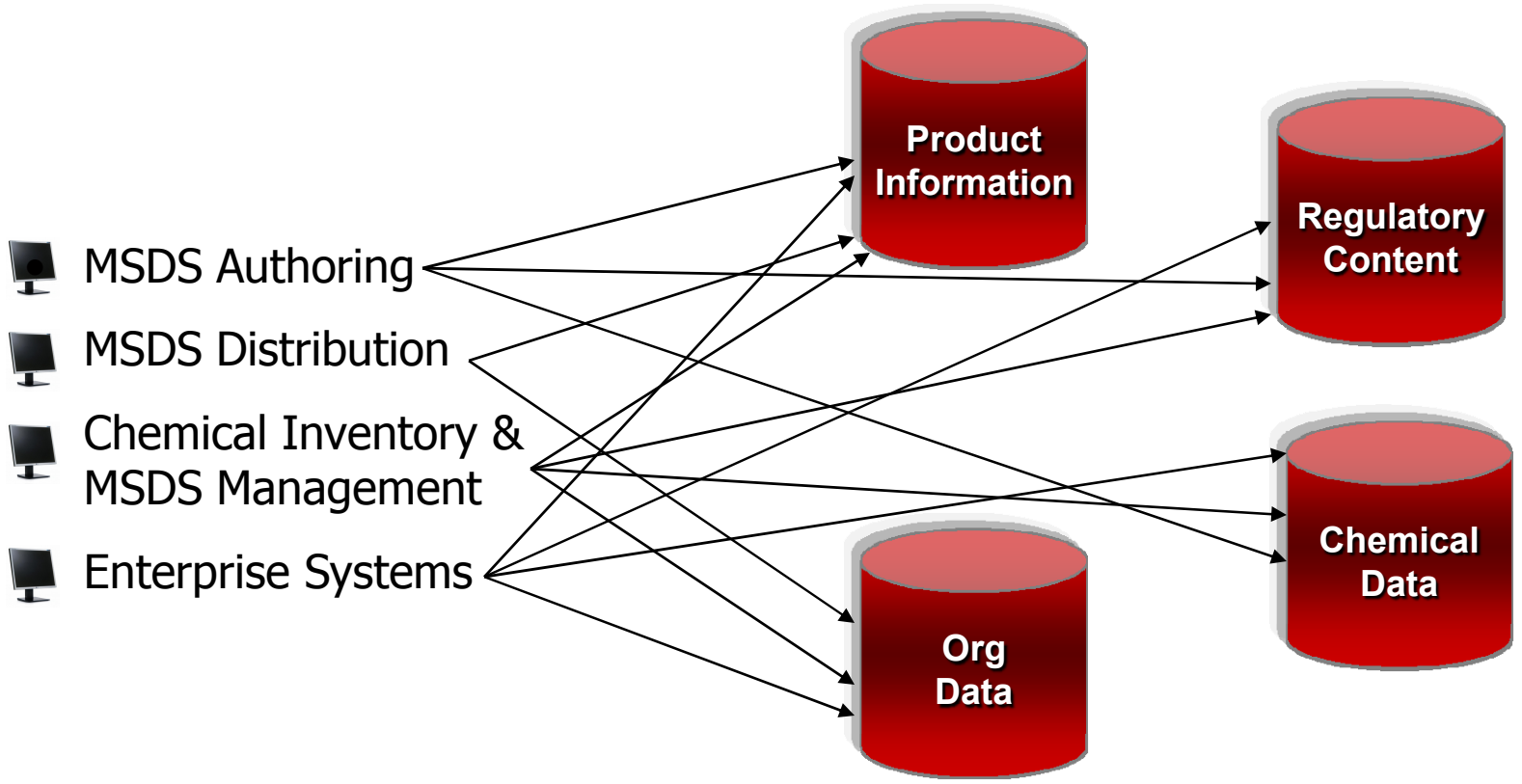
In addition to adhering to International, Federal, State and Local regulations, compliance today includes two progressive approaches that are being broadly accepted and implemented.

Corporate Social Responsibility: Assumption of responsibility for the impact of all corporate activities upon its employees, customers, community and the environment. Often carried out in the context of voluntary improvement commitments and performance reporting.

Industry Best Practices: Technique or methodology that, through experience and research, has proven to reliably lead to a desired result. A commitment to using the best practices is a commitment to using all the knowledge and technology at one's disposal to ensure safety and compliance.

EH&S Information Management

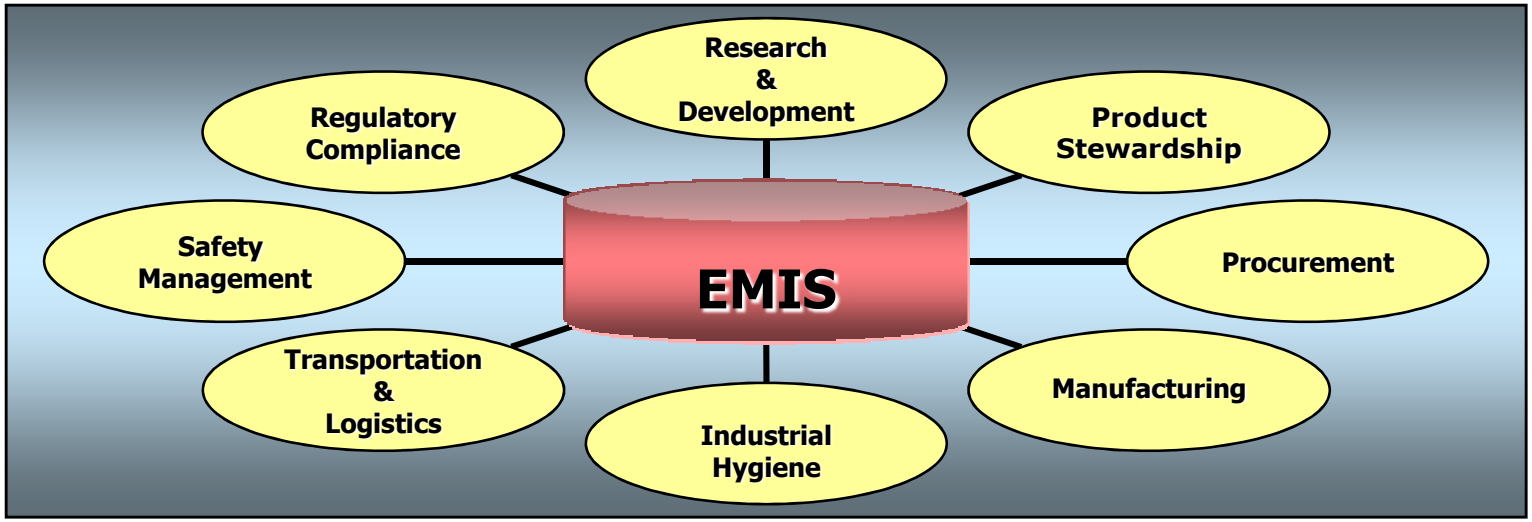
Systems and data are dependent on Operations



EH&S Information Management

Organizational Considerations

- Stakeholders – VP of Risk Management, Compliance & Ethics Officer, VP of Sales
- Power Users



- Beneficiaries – Employees, Consumers, Clients, Community

Data Requirements

- Substance level data
  - Phys/chem properties
  - Tox/Ecotox
- Product level MSDS data
  - Composition information
  - Phys/chem characteristics
  - Hazards
  - PPE
  - First Aid
  - GHS Classification and Labeling
- Product data – site level
  - Internal codes, numbers
  - Annual quantity and usage
  - Volume tracking

Data Requirements

- Product level classification data
  - Chemical (Fire Code, HMIS, NFPA, SARA Hazards)
  - Transportation
  - Waste
- Location specific information
  - Applicable local, state and federal compliance requirements
  - Permits, disclosures and storage of other critical documents
  - HazCom Plan
  - ER Plan
- Integrated regulatory data
  - Ingredient/CAS # specific lists
  - Searchable full text
  - Alerts and notifications

Regulatory Updates

- TSCA Reform
- GHS
- DOT

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:

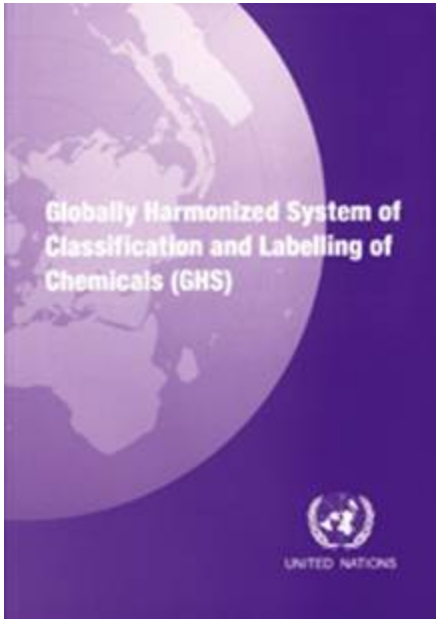
- New Regulatory Risk Management Actions
- Development of Chemical Action Plans to target the risk management efforts on chemicals of concern
  - Benzidine Dyes, Bisphenol (BPA), Hexabromocyclodoecane (HBCD), Nonylphenol and Nonylphenol Ethoxylates, Phthalates, perfluorinated chemicals (PFCs), polybrominated 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

GHS

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.

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

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

Implementation Timelines

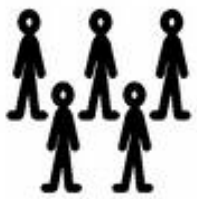
- Final Ruling effective January 19, 2011
- Delayed compliance date beginning January 1, 2012,
- Voluntary Compliance may begin as of January 1, 2011
- New limited quantity marking mandated for use as of January 1 2012 (Conforms to 49CFR and IMDG)
- Use of ORM-D AIR valid through December 31, 2012
- 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**
• Known Carcinogens • Probable Carcinogens • Mutagens & Reproductive Toxins • Endocrine Disruptors • Target Organ Effects • Health Effects	• EHS • Corrosive • Explosive • Flammable • Oxidizer • Reactive • Water Reactive	• Air Pollutants • Marine Pollutants • Release Hazards • Hazardous Waste • PBTs

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

Questions?

Thank you!