Executive Forum

Global Regulatory Requirements from a Product and Operating Perspective

Chuck McCormick, Practice Director
Global SAP Enterprise Compliance & Sustainability

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How would you rate the ability of your organization to achieve and maintain compliance with company-wide product stewardship requirements?

- Fully-compliant today -- business processes and technology systems adequate to keep pace with future requirements
- Fully-compliant today -- anticipate the need for enhanced business processes and technology systems adequate to keep pace with future requirements
- Partially-compliant today -- anticipate the need for enhanced business processes and technology systems adequate to keep pace with future requirements
- Partially-compliant today -- reliant on manual business processes; need to invest in technology systems to keep pace with future requirements
- Significantly non-compliant today -- need to enhance business processes and invest in technology systems to keep pace with future requirements

Source: Preliminary results from 3rd Annual CSC/Chemical Week Survey
Panelists

• **Julia Tsvetkova** - Senior Product Management 3E

• **Frank Kochendoerfer** - SAP Chemical Industry Director

• **Tamie Webber** — Director, Product Management 3E
Global EH&S Regulatory Landscape

- Increase in frequency and volume of regulatory changes
- Burden of assessing and complying with changes is increasing
- Fewer EH&S resources

- **Restricted Substances**
  - RoHS
  - Phthalates
  - BPA

- **Authorization/Registration**
  - EU REACH
  - Japan CSCL (PAC)
  - Korea MOE

- **Classification Labeling**
  - Classification
  - Labeling
  - Packaging

- **Environment**
  - Carbon Reporting
  - Emissions
  - GHGs
  - Waste – ELV, WEEE
Restriction of Use of Certain Hazardous Substances in Electric and Electronic Equipment (RoHS)

- **EU Directive 2011/65/EU (RoHS Recast)**
  - Replaces original RoHS as of 2013
  - Expands the original categories of EEE
  - Exemptions and exclusions remain, with some new in place
  - EU Declaration of Conformity
  - Documentation retention (technical and declaration of conformity) for 10 years

- **Scope**
  - Same list of substances and thresholds but the new directive opens room for expansion in line with REACH and regulations related to nanomaterials

- **RoHS in Asia and the Americas**
  - Japan, Korea, India (January 1, 2012), Australia (Draft)
  - US States (California, New Jersey)
Restricted Substance Bans and Regulations

• **BPA**
  – EU Directive banning BPA in baby bottles
  – Other existing or proposed regulatory bans – Canada, Belgium, Denmark, France, South Africa, Turkey

• **Phthalates**
  – California Phthalates Law
EU REACH

• Regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (1907/2006/EC)
  – First deadline was 30 November 2010:
    • Phase-in substances > 1,000 t/y
    • CMRs > 1 t/y
    • Substances very toxic to aquatic environment (R50/53) > 100 t/y
  – Second deadline is 30 May 2013
    • Phase-in substances > 100 t/y
  – Third deadline is 31 May 2018
    • Phase-in substances ≥ 1 t/y
EU REACH (cont’d)

• **Substances of Very High Concern (SVHCs)**
  – Authorization required for substances of very high concern (SVHC) (i.e., CMRs, PBTs, vPvBs) included in Annex XIV (Authorization List)
  – SVHCs identified in Candidate List – 53 SVHCs as of June 2011
  – Currently, 6 substances in Annex XIV

• **REACH notification obligation for manufacturers and importers of articles**
  – M/I must notify ECHA if any SVHC included in the Candidate List is present above 0.1% w/w and if over 1 ton per producer/importer per year
  – Deadline for notification June 1, 2011 (six-month deadline from Dec. 1, 2010 after substance identified as SVHC) if 1 ton reached
  – 76 page guidance on requirements for substances in articles
REACH-like regulations in Asia Pacific

• **Japan CSCL**
  – Japan Chemical Substance Control Law (CSCL) – ‘Kashin-ho’, effective April 1, 2011
    • Establishes mandatory reporting of all chemicals manufactured/imported over 1 ton in the previous year
    • Priority Assessment Chemical Substances (PACS) – currently 88 – specific notification requirements
    • Evaluation, Authorization/Restriction

• **Korea AREC Draft**
    • TCCL – handles already tested, proven hazardous chemicals
    • AREC – handles semi-tested, suspected hazardous chemicals
    • New chemicals notification under TCCL will be repealed and integrated into AREC
    • Establishes mandatory reporting on all chemicals manufactured/imported
    • No tonnage or other exemptions specified
    • Priority Evaluation Chemicals (PEC) – list of chemicals posing risk to human life and the environment – pre-registration period proposed
## Global Harmonized System (GHS) on Classification and Labeling

### GHS Regulation Passed

- **Asia Pacific**
  - New Zealand (2001)
  - Japan (2006)
  - Korea (2008)
  - Vietnam (2008)
  - China (2009)
  - Indonesia (2009)

- **Europe**
  - EU (2008)
  - Serbia (2009)
  - Russia (2009)
  - Switzerland (2009)

- **Americas**
  - Brazil (2009)
  - Uruguay (2009)
  - Mexico (2011)

- **Middle East/Africa**
  - South Africa (2008)
  - Abu Dhabi (2009)

### GHS Draft Regulations

- **Asia Pacific**
  - Australia
  - Malaysia
  - Philippines
  - India

- **Americas**
  - US

### GHS Preparation Activities

- **Americas**
  - Canada
  - Mercosur – Argentina, Paraguay
  - Andean Community – Bolivia, Columbia, Ecuador and Peru

- **Other**
  - Turkey
  - Thailand
  - UNITAR/ILO Global GHS Capacity Building Programme: Cambodia, Gambia, Laos, Nigeria, Senegal, Zambia
New and Emerging Regulations and Regulatory Trends

• Following Europe
  – REACH-like
  – RoHS/WEEE-like
  – Regulating nanomaterials

• More disclosure requirements on companies

• Green initiatives and eco-labeling programs
  – DfE
  – EU Ecolabel

• Taking non-governmental lists into consideration
  – EU SIN List
New and Emerging Regulations and Regulatory Trends

• Dodd-Frank Act – final rule was expected in April 2011
  – Section 1502 ‘Conflict Minerals Provision’
  – Applies to tungsten ( wolframite), tantalum, tin ( cassiterite), gold from the DRC and adjoining countries
  – Applies to products for which conflict minerals are necessary to their functionality or production
  – Establishes a new reporting requirement on publicly traded companies. A report to the SEC to include:
    • a description of the measures taken by the person to exercise due diligence on the source and chain of custody of such minerals, which measures shall include an independent private sector audit
    • a description of the products manufactured or contracted to be manufactured that are not DRC conflict free

• Impacted Industries
  – Electronics, Medical Devices, Aerospace, Automotive, Jewelry, Industrial Machinery
CONNECT FOR SUSTAINABILITY

THANK YOU
Business Response to Expanding Regulatory Challenges

Frank Kochendoerfer, Ph.D.
Director Industry Business Unit Chemicals SAP

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Executive Forum

September 18-20, 2011
Gaylord Opryland Nashville, Tennessee
New and Upcoming Regulations

- EU REACH / CLP
- US TSCA
- JAPAN CSCL / KASHINHO
- CHINA CSCL
- CA GREEN CHEM
- MAINE GREEN CHEM
- WASHINGTON GREEN CHEM
- ... GREEN CHEM
Regulations will affect Businesses Everywhere

- Targeting substances and products...
- Affecting the entire supply chain...
- Affecting product/substance substitutions
- To secure your business

Core Business Processes:
- Suppliers
- Purchasing
- Materials Management
- Production
- R&D
- Sales

Data Exchange and Collaboration

SAIC, MICCA

Ever more complex regulations...
Commonality of Requirements – an Business Process Perspective

Past:
- Provision of product and substance data
- Monitoring of compliance status – ‘need for action’?

New:
- Registration or notification based on risk assessment
- Uses and exposures have to be described and assessed
- Determination and tracking of substance volumes
- Upstream and downstream communication
- Monitoring of compliance status – ‘need for action’?
Embedded Product Compliance

Legal Product Compliance Requirements
How do you manage relevant product compliance related regulations (Definition, Monitoring, Extraction of requirements, inclusion into product development, etc.)?

Information / Data
How to collect data related to your supply chain?
How do deal with missing data

Product Development

Information / Data
How do you integrate product compliance aspects into the business processes (marketing, controlling, procurement, sales, logistic)?

Supplier
Procurement
Manufacturing
Sales
Customer

Controlling

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THANK YOU
Challenges & Best Practices - Supply Chain Collaboration & Data Exchange

Tamie Webber
Director, Product Management
3E Company
Supply Chain Collaboration & Data Exchange

• Securing Raw Material Information
  – Content
  – Source

• Distributing Product Information
  – Distributors
  – Customers

Capture BOMs
Collect compositions, product data and process information
Determine regulatory impact
Analyze for compliance
Mitigate risk
### Key Components to Supply Chain Data Flow

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<tr>
<th>Component</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Collection</strong></td>
<td>• Collecting information from suppliers to ensure compliance throughout the supply chain</td>
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<tr>
<td><strong>Analysis</strong></td>
<td>• Verification of supplier provided information and analysis tools for compliance</td>
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<tr>
<td><strong>Maintenance</strong></td>
<td>• Maintaining this information via a central repository</td>
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<tr>
<td><strong>Dissemination</strong></td>
<td>• Central repository for internal access and data delivery to customers and other supply chain participants</td>
</tr>
<tr>
<td><strong>Integration</strong></td>
<td>• Integration of data/documents into ERP and other tools</td>
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Supply Chain Collaboration

- Challenges
  - Engaging all relevant supply chain participants is difficult
  - Supplier participation key to fulfilling data requirements
  - Critical data needed to satisfy all internal stakeholders must be validated
  - Data maintenance is critical to support complex dynamic regulatory landscape
  - Global regulatory knowledge
  - Change Management: Ensuring suppliers are staying current with newly revised global regulations and proposed legislation
Supply Chain Collaboration

Confidential Business Information

Confidentiality  Transparency
Emerging Trends

• Supply chain processes are adapting to new regulatory requirements
• New methods for protecting CBI - 3rd party validation
• In absence of standards (IPC, JIG, GADSL), industries looking for alternative methods for collecting data
• Required information beyond product and ingredients
Best Practices

• Work with all internal stakeholders to ensure streamlined approach
• Develop supply chain collaboration processes with participation goals in mind
• Data maintenance is critical to reducing supply chain risk
Roundtable

• Organized by topic area:

  • Julia Tsvetkova (discussion leader), Elliot Blatt (scribe)

  • Frank Kochendoerfer (discussion leader), Scott Feldman (scribe)

  • Tamie Webber (discussion leader), Jane Howell (scribe)

• Instructions:

  – Join roundtable based on topics of interest associated with the panelist and generate ideas where industry collaboration would be beneficial (e.g., best practices, benchmarks, specific issues approach) and how (e.g., formal teams vs. peer to peer portal) for 30 minutes

  – Each roundtable should select a spokesperson to speak about recommendations (10 minutes each)