International Environmental Regulations Update

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Change
Benefits

• Design for the Environment.
• More proactive approach than reactive.
• Focus is on preventing long-term issues.
• Address global issues verses domestic.
• Accountability is at all levels instead of just EH&S organization.
RoHS Regulations

- **RoHS**: Restriction of Hazardous Substances
- On July 1, 2006 EU RoHS became effective.
- On March 1, 2007 China RoHS became effective.
- China RoHS modeled after EU RoHS, but has major differences.
RoHS

• **Six substances are targeted by both EU & China RoHS.**
  - Lead
  - Mercury
  - Cadmium
  - Hexavalent Chromium
  - Polybrominated Bi-Phenols (PBB)
  - Polybrominated Diphenyl Ethers (PBDE)
RoHS

- **Maximum Concentration of Restricted Substances allowed are:**
  - 0.1% by weight in homogenous material for all.
  - 0.01% by weight in homogenous material for cadmium.
  - Numerous exemptions available by EU RoHS.
  - Hardly any exemptions offered by China RoHS.
• RoHS Directive applies to:
  
  - **EU RoHS:** Electrical and Electronic Equipment
  
  - **China RoHS:** Electronic Information Products List
Additional Requirements of China RoHS

**Phase I: Information Disclosure**
- Labeling
- Packaging Material Disclosure Requirements

**Phase II: Material Restrictions**
- EIP listed in the catalog must comply with hazardous substance ban.
- EIP listed in the catalog are subject to China’s Compulsory Certification and labeling requirements.
- Requires testing using government-approved Chinese labs affiliated with China National Certification and Accreditation Administration (CNCA).
China RoHS Labeling Requirements

- **Green Logo**
  - Arrow means the product should be recycled.
  - “e” means that the product is “environmentally friendly”.
  - Hazardous substance not present or below maximum concentration value.
China RoHS Labeling Requirements - Continued

• Orange Logo
  - One or more of the six substances present above maximum concentration value.
  - Numeral indicates “Environmental Protection Use Period (EPUP)”.
  - EPUP is the period during which hazardous substance in EIP will not leak out or mutate.
  - Additional disclosure in consumer manual.
### Toxic or Hazardous Substances and Elements

<table>
<thead>
<tr>
<th></th>
<th>有毒或有害物质及元素</th>
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</thead>
<tbody>
<tr>
<td>Lead</td>
<td>铅 (Pb)</td>
</tr>
<tr>
<td>Mercury</td>
<td>汞 (Hg)</td>
</tr>
<tr>
<td>Cadmium</td>
<td>镉 (Cd)</td>
</tr>
<tr>
<td>Hexavalent Chromium</td>
<td>六价铬 (Cr₆)</td>
</tr>
<tr>
<td>Polybrominated Biphenyls</td>
<td>多溴化联苯 (PBB)</td>
</tr>
<tr>
<td>Polybrominated Diphenyl Ethers</td>
<td>多溴化二苯醚 (PBDE)</td>
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○: Indicates that this toxic or hazardous substance contained in all the homogeneous materials for the products contained in this package, according to EIP-A is below the limit requirements in SJ/T11363-2006 and complies with EU directive 2002/95/EC.

EIPs Subject to China RoHS

- EIPs Manufactured on or after March 1, 2007.
- EIPs for sale in People’s Republic of China (Hong Kong, Taiwan are not PRC).
- EIPs to be exported outside of China are NOT subject to China RoHS.
- Self declaration of compliance with EU RoHS to PRC customs.
Compliance Strategy
Supply Chain

Tracking materials declaration

Materials and Components

Sub-assemblies

Products

Plus - Selected Analysis

Technical File
RoHS

- **Sanctions for Non-Compliance**
  - Fines & Penalties
  - Product Recall (Sony Playstation Cost $150M)
  - Prohibition of Future Sales
  - Withdrawal of Operating Licenses
  - Criminal Liabilities in Serious Cases
• Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)
  - In Effect June 1, 2007
  - Replaced 40 Existing Laws
  - European Chemical Agency Created
Purpose of this regulation is:

- Improve protection of human health and the environment.
- Enhance competitiveness and innovation in the EU.
- Place responsibility for risk management on the chemical producers or downstream users.
- Application of the precautionary principle.
• REACH is a regulation versus a directive.

• Does not require transposition into national laws of 27 member states.

• Member states may set up a system of controls and penalties for non-compliance.

• 1000 pages of legal text and 10 guidance documents known as RIPs.
REACH legal requirements apply to:

• **EU importer** = established within EU and responsible for import = manufacturers.

• **EU producer** = makes or assembles an article within the EU = user of chemicals.

• **US companies exporting into EU** have no direct legal liability but may have customer requirements.
Scope:

- Applies to all substances whether manufactured, imported, used as intermediates, or placed on the EU market either on their own or in preparations or in articles.

- **REACH** gives priority to **Substances of Very High Concern (SVHC)** and large volume substances.
**Substances**: A chemical substance and its compounds in the natural state or obtained by any manufacturing process. For example: chemicals, metals, etc.

**Preparations**: A mixture of solution composed of two or more substances. The function is more determined by the chemical composition than by its shape, surface or the design. For example: Paints, Resins, Alloys, etc.

**Article**: An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
• If you import >1 ton or more of any substance either on itself or in preparation per year, registration is required.

• If you import articles that are intended to release substances >1ton/year, registration is required.

• We also need to evaluate articles that contain substances of very high concern >0.1% by weight and totaling >1 ton/year.

• Down-stream user of substances must ensure their “Use” in Europe is registered.
Substances of Very High Concern (SVHCs)

- Substances classified as carcinogenic, mutagenic, reproductive toxin (CMR category 1 & 2).
- Substances which are persistent, bioaccumulative, and toxic (PBT, vP and vB).
- Endocrine disrupters or have similar concern.
- Candidate list to be published in 2009.
**REACH Obligations:**

- **Pre-Registration:** June 1 – Dec. 1, 2008
- **Registration:**
  - >1000 Metric Tons (and Dangerous Substances Dec. 1, 2010)
  - >100 Metric Tons June 1, 2013
  - >1 Metric Ton June 1, 2018
- **Notification:** June 1, 2011
- **Authorization:** June 1, 2009 .....
- **Restrictions:** TBD
“Registration” of substances, substances in preparations, substances in articles. “Registration” on basis of "tonnages", "SVHC or not", "phase-in or not". “Registration” after 3 1/2 year (> 1000 t/j), 6 year (100-1000 t/j), 11 year (1-100 t/j). “Notification” of Substances of Very High Concern (SVCH) in articles.
REACH Exemptions

- Waste substances.
- Radioactive substances.
- Substances used in medical cures, food stuff, interest of defense.
- Substances in transportation
- Non-isolated intermediates and by-products that don’t enter the market.
- Substances for R&D under certain conditions.
- Return substances when identical to exported substances.
- Polymers (monomers must be registered).
• **Vendor of Critical Products:**
  - May not register or not register for our intended “use”.
    - Some specialty chemicals may be phased out due to high registration cost.
  - Withdrawal from market (business continuity).
    - User may have to reformulate their products and re-qualify with the customers.
    - User or importer may have to register themselves.
    - User has to do the chemical safety assessment.
    - Cost
  - May increase their prices due to registration costs.
  - Substances of very high concern may be subject to use restrictions.
  - May pre-register, but not register ... =>😊

• Intellectual Properties.
• **First priority now:**

  - Prepare a list of all substances, preparations, articles that are intended to release substances or with SVHC over one ton per year.
  - Identify whether you are manufacturer, importer *(think global)* or downstream user.
  - Ask your suppliers (if importer or downstream user) if they can reassure that they will take the necessary steps to register.
REACH Implementation

• **Based on these answers:**

  ▪ Negotiate with the suppliers to integrate your “use” in their chemical safety assessment.

  ▪ Negotiate with non-EU-suppliers to get them organized as importer/distributor in EU or retain only representative. It has to be an EU based legal entity.

  ▪ Find alternative suppliers/products/processes.

• **If all else fails:**

  ▪ Prepare to pre-register and register yourself.
• Challenges we know about already:
  
  **Inter-company deliveries:**
  - Virtually **all raw materials** can be shipped from one division to the other.

  **Difficulty in classification of preparations, articles, and polymers:**
  - Coating on a carrier material: preparation or an article? Foams: Polymer or an article?
  - REACH Implementation Plans (RIPS) are not available for all scenarios.

  **New product lines:**
  - What are the new products we will use? Will they be registered?
REACH Compliance Strategy

- Plan for chemicals in-use at European Operations.
- Plan for chemicals imported into Europe.
- Plan for Articles imported into Europe.
- Response to customer inquiries.
- May have to revise MSDSs to comply with EU requirements.
- Plan for phased-out chemicals.
- Communication within and outside your company.
What is Needed

• **A sustainable approach is needed:**
  - To maintain global market access.
  - At lowest cost.
  - To minimize business disruptions.
  - To minimize legal liabilities.
  - On-time product development.

“Capture as a Business Opportunity instead of Liability”
Questions and Comments