Substance regulation in the EU – an update on RoHS and REACH

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April 28th, 2011

Program

- Introductions
- Context
- The RoHS Directive
- The REACH Regulation

Focusing on impacts for US companies
RoHS and REACH Training Seminar

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Introductions

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Engineering Consultancy Services

- Specialist electrical, mechanical and materials consultancy services for products, systems, engineering assets and infrastructures
  - power systems consultancy
  - condition assessment
  - forensic engineering
  - design and materials consultancy
  - electrical device testing
  - EMC design/testing
  - system safety assessment
  - regulatory compliance

Environmental regulatory compliance of engineering products

- We track environment product regulation worldwide
- We advise industry, trade associations, government, regulators and enforcement bodies
- We provide training, conferences etc.
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Supporting you

- Technical consultancy (AccessERA)
  - gap analysis, reasoned opinions, process audit, failure analysis etc.

- RE4view
  - news and analysis covering all electrical product environmental legislation worldwide – RoHS, WEEE, Ecodesign, REACH, Batteries etc.

- Electrical and Electronic Equipment & the Environment Conference
  - 16-17 November 2011, Heathrow, UK
  - www.era.co.uk/conference

Break out 1
- Straw poll

- Are you new to REACH or RoHS?
- In small groups
  - Introduce yourself
  - Share one thing in your personal life which is different or you do differently in last 5 years from an environmental perspective?
  - How has your job changed from an environmental perspective?

- Feedback
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Program

- Introductions
- Context
- The RoHS Directive
- The REACH Regulation

Focusing on impacts for US companies

Context
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Substances

Carbon

Political

http://storyofstuff.org/
Overview of the ecodesign directive

- **Context**

Policy → Requirement → Implementation

The RoHS Directive
Program

- The RoHS Directive - focusing on impacts for US companies
  - Overview
  - The Recast
  - Compliance and enforcement
  - Related global requirements
  - Guidance available

1: The RoHS Directive
- Overview -
RoHS overview
- **Snapshot**

- Restriction of certain **Hazardous Substances** (RoHS) Directive
  - RoHS Directive (2002/95/EC)
    - has applied to most electrical products since 1 July 2006
  - Restricts use in products of
    - Pb, Hg, Cr(VI), PBB and PBDE <= 0.1% by weight
    - Cd <= 0.01%
    - by weight in “homogeneous materials”

RoHS overview
- **Homogeneous materials within IC**

![Diagram showing the components of an IC with labels for various parts such as Silicon chip, Lead-frame coating (Sn), Bond wire (Au), Lead-frame (Cu), Die attach (silver epoxy or high lead solder), Plastic encapsulation, Circuit – transistors, tracks, pads.]
RoHS overview
- **Current scope**

**Applies to**

- Electrical and Electronic Equipment (EEE)
  - Equipment that depends on electric current or electromagnetic fields to function
    - $<1000$ V AC or $<1500$V DC
  
- Electrical and electronic "equipment" within categories 1 – 7 & 10 of WEEE Directive
  
  - Equipment within scope of RoHS need to be made with RoHS compatible components and materials
  
  - WEEE categories in Annex IA

---

RoHS overview
- **Product scope categories**

1. Large household appliances
2. Small household appliances
3. IT, telecom
4. Consumer equipment
5. Lighting equipment
6. Electrical tools (except LSIT)
7. Toys, leisure and sport
8. Medical electronics (not RoHS yet)
9. Monitoring and Control Instruments (not RoHS yet)
  - includes measurement instruments
10. Automatic dispensers
    - and light bulbs and luminaires – **included** in RoHS

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RoHS
- Scope excludes

- Equipment for military and national security purposes only
- Equipment that is part of another type of equipment that is not in scope, e.g.
  - ship
  - plane
  - train

RoHS
- Present status

- Exemptions under periodic review
- Can I apply for an exemption?
Q&A

2: The RoHS Directive
- The Recast -
### RoHS recast - Comparison

<table>
<thead>
<tr>
<th>RoHS</th>
<th>RoHS recast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Six substances restricted</td>
<td>No change - but review within 3 years (HBCDD, DEHP, BBP, DBP ++). Recital 10</td>
</tr>
<tr>
<td>Restriction on substance use</td>
<td>No change</td>
</tr>
<tr>
<td>Hardware - WEEE categories 1-7, 10</td>
<td>Open scope with exclusions &gt;&gt; Cat 8/9/11(other) included</td>
</tr>
<tr>
<td>Exemptions annex</td>
<td>Exemptions Annex III (existing)</td>
</tr>
<tr>
<td>Self declaration</td>
<td>Exemptions Annex IV (cat 8/9)</td>
</tr>
<tr>
<td>Applied to product placed on EU market from 1 July 2006</td>
<td>Conformity assessment (self)</td>
</tr>
<tr>
<td></td>
<td>Several dates &gt;&gt;</td>
</tr>
<tr>
<td></td>
<td>Formalised market surveillance</td>
</tr>
</tbody>
</table>

### RoHS recast - Open scope with exclusions for

- **Large-scale stationary industrial tools (LSIT)**
  - “a large size assembly of machines, equipment, and/or components, functioning together for a specific application,
  - permanently installed and de-installed by professionals at a given place, and
  - used and maintained by professionals in an industrial manufacturing facility or research and development facility”
RoHS recast
- Open scope with exclusions for

- Large-scale fixed installations
  - “a large size combination of several types of apparatus and, where applicable, other devices, which are
    - assembled, installed by professionals and
    - intended to be used permanently in a pre-defined and dedicated location, and
    - to be de-installed by professionals

- Spare parts
  - for EEE placed on market before 1 July 2006
  - Reuse of spare parts in equipment placed on market before 1 July 2016 where subject to verifiable closed loop audit and customer is notified

- Consumables and accessories (but includes cables<250V)
- Equipment specifically designed solely for R & D (B2B)
- Military equipment
- Means of transport
- Implanted medical devices
- Photovoltaic panels
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RoHS recast
- Timings

- 1.5 years from entry into force (end 2012?)
  - Conformity assessment of products already covered
- 3 years from entry into force (2014?)
  - Medical devices
  - Monitoring and control instruments
- 5 years from entry into force (2016?)
  - In Vitro Diagnostics (IVD)
- 6 years from entry into force (2017?)
  - Industrial monitoring and control instruments*
- 8 years from entry into force (2019?)
  - Other equipment (subject to future review)
* includes both industrial AND professional units but they must be designed exclusively for this use

RoHS recast
- Responsibilities

- Recast makes RoHS a CE mark directive
  - All supply chain is now legally responsible for compliance (Regulation 768/2008)
- Responsible parties not just the “producer”:
  - Manufacturers (within EU)
  - Importers (into EU)
  - All EU based distributors (including retailers)
  - Authorised representatives (agents, consultants, analysis labs, etc.)
3: The RoHS Directive
- Compliance and Enforcement -

Break out 2
- Ensuring RoHS compliance

- Break into groups
- Task
  - What activities should I undertake to ensure that my product is RoHS compliant?
  - What other issues should I take into account when going RoHS compliant?
  - Prepare a short list of suggestions
- Report back
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Producer definition

- Definition
  - Manufactures and sells in EU State
  - Sells under own brand
    - so in this case not manufacturer
  - Imports into EU
  - However all of supply chain is affected

RoHS
- Enforcement

- Active enforcement in many EU States
- Informal RoHS Enforcement Network
  - Guidelines on enforcement strategies published to assist authorities and producers
- Guidance emphasises
  - Authority inspectors will ask producers to see documentation
    - If satisfied, will take no further action
    - Otherwise will ask for more information or may carry out analysis
  - Non-compliant EEE will be taken off the market
    - And fines if due diligence not used
  - Enforcers also buy products for chemical analysis
RoHS
- Enforcement

- If you have put product on market and it is non-compliant you have committed an offence
- Due diligence provides a defence balancing the offence
- Only a few EU States recognise due diligence
  - In some, the size of fine depends on the severity of the offence

RoHS
- Enforcement

- Mitigation considerations are normally
  - somebody else’s fault
  - accident
  - (enshrined in case law)
- Size matters- less will be asked of SMEs than large manufacturer
- Action will target large impact/large risk
RoHS
- Enforcement

• Penalties
  - UK: max fine (Magistrates’ Court): £5,000 (~€7,300)
    unlimited at the High Court
    per offence, per individual product
  - Germany: €50,000 per offence
  - Belgium: up to €20 million plus imprisonment
  - Spain and Estonia: upper fine limits of over €1 million
  - Italy: €500 to €100,000

• The basis for penalties varies (e.g.)
  - UK and Poland accept due diligence defence
  - Germany the authorities need to show that the offence was intentional
  - Intent is a factor in setting penalties in the Netherlands
  - Imprisonment is possible in 8 EU states

RoHS
- Terms and Conditions

• It is not illegal to sell components containing lead, cadmium, etc.

• Component suppliers are less likely to be prosecuted unless they intentionally mislead (and are located in EU)

• So
  - It is important to specify to supplier that components, assemblies, etc. must not contain restricted substances
  - Purchasing department need to understand RoHS requirements
  - Terms and conditions should reflect requirements

• Also
  - Supply of incorrect parts would be a breach of contract – consequential losses?
  - Some suppliers issue disclaimers
4: The RoHS Directive
- Related Global Requirements -

Global RoHS developments

- Other countries tend to follow EU – but with variations
  - Similar definitions
  - RoHS metals + flame retardants
  - Marking + restriction
  - Legislation or voluntary

<table>
<thead>
<tr>
<th>State</th>
<th>Substances</th>
<th>Restriction</th>
<th>Marking</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>PBDE, mercury</td>
<td>Many states</td>
<td>Generally no</td>
</tr>
<tr>
<td>California</td>
<td>RoHS metals</td>
<td>Displays</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>RoHS 6</td>
<td>Printers, phones</td>
<td>All EIPs</td>
</tr>
<tr>
<td>Japan</td>
<td>RoHS 6</td>
<td>No</td>
<td>~Volume/consumer</td>
</tr>
<tr>
<td>Australia</td>
<td>RoHS</td>
<td>Voluntary</td>
<td>No</td>
</tr>
</tbody>
</table>
5: The RoHS Directive
- Guidance -

Guidance

- EC FAQs

- UK government guidance 2011
  - Type “BIS RoHS guidance 2011” in search engine

- NMO
  - www.rohs.gov.uk
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RoHS
- Supporting Standards

- PD IEC/TR 62476:2010
  - A framework for evaluation of products
    - covers all design, manufacturing and other operational functions (e.g., procurement) to evaluate the product for restricted substances

Structured approach to compliance
- Supporting standards

- PD IEC/TR 62476:2010
  - Key elements
    - Identification of restricted/declarable substances requirements (e.g. from legislation, customers)
    - Restricted substance control (RSC)
      - product planning and design (IEC 62430)
      - sources of information
        - supplier information (IEC 62474)
        - analytical testing (IEC/PAS 62596 and IEC 62321)
        - manufacturing assembly process information
      - product evaluation – drawing conclusions
    - Supporting documentation
      - Self declaration
      - Technical Documentation
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6: The RoHS Directive
- Conclusions -

RoHS
- Key pointers 1

- Are you in scope?
  - if not entirely clear perform formal review

- If in scope
  - Do you have a system in place to ensure compliance?
  - Does it work?

- If coming in scope
  - Can you redesign your products in time?

- If out of scope
  - What is the risk of enforced obsolescence?
  - Do you have a substitution plan?
RoHS
- Key pointers 2

- Documentation
  - Formalise in accordance with CE requirements
- Substitution
  - Supply chain may drive obsolescence ahead of legal requirements
  - Understand what potentially restricted substances are used before they are restricted
  - Watch other substance requirements (esp. REACH, Hong Kong Convention)

- So...
  - Consider time for redesign now

Q&A
Session 2: The REACH Regulation
Program

- The REACH Regulation - focusing on impacts for US companies
  - Overview
  - Requirements and key issues for US firms
  - Materials safety data sheets and GHS labelling
  - Related global requirements
  - Guidance available

1: REACH
- Overview -
REACH (1907/2006)  
- What is it?

- Registration, Evaluation, Authorisation and Restriction of Chemicals
  - Reduction in negative impact on health/environmental through exposure to chemicals
  - Restrict use of most hazardous substances > encourage use of safer alternatives
  - Better data on substance properties
  - Better information to users
  - A level playing field

REACH - So what?

Chemical manufacturers will deal with it – REACH has nothing to do with us

No data – no market
REACH - Comparison with EU RoHS

<table>
<thead>
<tr>
<th>Current EU RoHS</th>
<th>REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Six substances</td>
<td>- 30,000 + substances</td>
</tr>
<tr>
<td>- Restriction on all substances covered</td>
<td>- Registration, restriction,</td>
</tr>
<tr>
<td></td>
<td>authorisation, notification,</td>
</tr>
<tr>
<td></td>
<td>information, etc.</td>
</tr>
<tr>
<td>- Sector specific finished products (electrical)</td>
<td>- Virtually all products and</td>
</tr>
<tr>
<td></td>
<td>materials</td>
</tr>
<tr>
<td>- Applies to products sold in EU</td>
<td>- Applies to exports too</td>
</tr>
<tr>
<td>- Applies to “producer”</td>
<td>- Applies to many actors</td>
</tr>
<tr>
<td>- Self declaration</td>
<td>- Complex &gt; evidence and formal approval</td>
</tr>
<tr>
<td>- Single date of entry into force</td>
<td>- Rolling out over ~10+ years</td>
</tr>
<tr>
<td>- Excludes military</td>
<td>- No military exclusion…</td>
</tr>
</tbody>
</table>

REACH impact and obligations depends on your role

**Role -1 -** “Importer/mfr” of substances/preparations

**Role -2 -** “Downstream user” of substances/preparations

**Role -3 -** “Importer/manufacturer” of articles

**Role -4 -** “Distributor” of substances/preparations
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Importer/producer of articles
- What is an article?

- “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition"

REACH
- main requirements

Role -1-
"Importer/mfr" of substances/preparations
registration, define and ensure safe use, notification

Role -2-
"Downstream user" of substances/preparations
ensure safe use

Role -3-
"Importer/producer" of articles
communicate safe use, notification

Role -4-
"Distributor" of substances/preparations
communicate up / down supply chain
Timeline for registration
- Phase-in (existing) substances

<table>
<thead>
<tr>
<th></th>
<th>1 June 2010</th>
<th>1 June 2013</th>
<th>1 June 2015</th>
<th>1 June 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-registration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substances</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 100 tpa*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMRs†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 1 tpa*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R50/53‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* substances produced/ imported per manufacturer or importer in volumes of
† carcinogen, mutagenic, toxic for reproduction, cat 1 or 2 according to Directive 67/548/EEC
‡ very toxic to aquatic organisms according to Directive 67/548/EEC

Breakout 3
- REACH Brainstorm

- Break into small groups
  - Write down key reasons why your organisation can or can’t ignore REACH
    1. ......................................................................................
    2. ......................................................................................
    3. ......................................................................................
    4. ......................................................................................

- Feedback
I operate in the US. Why can’t I ignore REACH?

- If you do not supply to the EU
  - Maybe your customers do
  - Maybe your suppliers do
  - What if a substance is phased out?
- If you do supply to the EU
  - Can you still do so legally?
  - What information do your customers need to operate legally?
  - Can you make this easier for your customers than your competitors?

Q&A
2: REACH
- Requirements in brief -

Role

Importer/manufacturer of substances/preparations

- Treated as the manufacturer unless non EU manufacturer appoints “only representative”
- Obligations
  - registration – see timeline – requires data submission
  - develop exposure scenarios
  - pass and accept data up and down supply chain
- Key issues for US firms
  - providing data
  - resources for registration
  - continuity of business
Downstream user
- summary of obligations

- Communicate up/down supply chain
- Use chemical substances/ preparations safely
  - How do they do this now?
    - Refer to supplier’s Safety Data Sheet
    - Carry out workplace safety assessment (COSHH in the UK)
  - This remains essentially the same but >>> see later
- Key issues for US firms
  - Is data you provide up to date and in the right format?

Importer/producer of articles
- Providing information (Article 33)

- Required if SVHC present in article at > 0.1% by wt
  - Provide information to recipients on which SVHCs are present and safe use of article
    - B2B – automatically
    - B2C – within 45 days of request
- No tonnage limit!
- Key issue for US firms
  - Getting information from your supply chain
- NB Other obligations also apply
  - Notification
  - Registration where intentional release of an SVHC
3: REACH
- Key Issues -

REACH key issues
- 1. Continuity of supply in EU

- Case study: potassium dichromate
  - Uses in engineering
  - Registered only as an intermediate - 30 Nov 2010
    - ✓ Continue selling/using existing stocks
    - ✗ Import/manufacture/place new stocks on the market
  - Suppliers forced to carry out full registration at last minute
  - Some users anticipated the problem and stockpiled
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REACH key issues
- 2. Substance obsolescence

• Don’t get your fingers burnt!

SVHCs and where they occur
- The Process and implications

Legal Requirements

None but increasing pressure on supply chain, from customers, NGOs and investors

Provide data (+notification)

Only allowed in authorised "uses"
REACH
- Projected growth of SVHCs

SVHCs

- Latest developments
  - Registry of intentions
  - Candidate list
  - Authorisation
### SVHCs - Registry of intentions-added 2011

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Main uses in engineering products (present in final product)</th>
<th>Main uses in manufacturing of engineering products (not present in final product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3-trichloropropane</td>
<td>solvent, cleaner (possible alternative to other chlorinated solvents)</td>
<td></td>
</tr>
<tr>
<td>1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; Di-n-heptyl phthalate (DNHP or DNP)</td>
<td>phthalate plasticiser used in PVC, rubber, adhesives, etc. Could be used to replace DEHP</td>
<td></td>
</tr>
<tr>
<td>1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DNHUP)</td>
<td>phthalate plasticiser used in PVC, rubber, adhesives, etc. Could possibly be used to replace DEHP</td>
<td></td>
</tr>
<tr>
<td>ethylene glycol acetate; 2-ethoxyetyl acetate; ethanol, 2-ethoxy-, acetate; (2-EEA)</td>
<td>general purpose solvent (e.g. paint, coating or cleaning) widely used including in semiconductor production</td>
<td></td>
</tr>
<tr>
<td>pyrazine</td>
<td>air bag precursor and in rocket thruster fuel (e.g. satellite launch)</td>
<td></td>
</tr>
<tr>
<td>N-methyl pyrrolidone; N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone</td>
<td>solvent in paints, for PVC and in other applications</td>
<td></td>
</tr>
</tbody>
</table>

### SVHCs - Candidate list - added Dec 2010

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Main uses in engineering products (present in final product)</th>
<th>Main uses in manufacturing of engineering products (not present in final product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-methoxyethanol; ethylene glycol monomethyl ether (EGME)</td>
<td>none known. Anti-icing additive in aviation fuels</td>
<td>solvent, e.g. varnishes, dyes, and resins. In photoreists, and in manufacturing copper-laminate circuit boards</td>
</tr>
<tr>
<td>Acids generated from chromium trioxide and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid</td>
<td>none known.</td>
<td>ingredient of chrome passivation treatment solutions and hard chrome plating solutions</td>
</tr>
<tr>
<td>chromic oxide; chromium (VI) trioxide; brooeadium</td>
<td>none known.</td>
<td>ingredient of chrome passivation treatment solutions and hard chrome plating solutions</td>
</tr>
<tr>
<td>cobalt acetate; cobalt dicarbonate</td>
<td>none known.</td>
<td>wooding consolidating, hard metal treatment. Rubber adhesion to steel, dyes. Dryer in paints. Invisible inks</td>
</tr>
<tr>
<td>cobalt carbonate; cobalt (II) carbonate</td>
<td>none known.</td>
<td>colorant in glasses. Frit as adhesion promoter for industrial enamels</td>
</tr>
<tr>
<td>cobalt nitrate; cobalt nitrate</td>
<td>batteries?</td>
<td>metal surface treatment. To make pigments, dyes and inks (invisible). To make industrial NiMH and NiCd batteries.</td>
</tr>
<tr>
<td>cobalt sulphate; cobalt (II) sulphate; sulfuric acid, cobalt(II) sulphate (1:1)</td>
<td>batteries?</td>
<td>to make superalloys, carbides (for hard cutting surfaces etc.), steel, magnetic alloys, wear resistant alloys etc. Pigments, glass decolorisers, dyes and inks, Li-ion batteries.</td>
</tr>
<tr>
<td>ethoxy ethanol; 2-ethylhexanol; ethylene glycol monooxyethyl ether (EGEE)</td>
<td>none known. Anti-icing additive in aviation fuels.</td>
<td>was used for surface cleaners, solvent for paints, inks, semiconductors and photoreists. Solvent for marker pens. Used in semiconductor manufacture</td>
</tr>
</tbody>
</table>
SVHCs
- Authorisation proposed – sunset 2014/2015

<table>
<thead>
<tr>
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<th>Main uses in engineering products (present in final product)</th>
<th>Main uses in manufacturing of engineering products (not present in final product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl butyl phthalate (BBP)</td>
<td>Vinyl polymer plasticiser (PVC cable etc.). Flooring (main use), adhesives, potting, lacquers, sealants, paints, coatings and inks.</td>
<td>None to our knowledge</td>
</tr>
<tr>
<td>Di (2-ethylhexyl) phthalate (or bis(2-ethylhexyl) phthalate) (DEHP)</td>
<td>Plasticiser, mainly in PVC (cables, electronics, medical, tubing etc.), adhesives, lacquers, inks, etc. As dielectric in capacitors and in hydraulic fluids.</td>
<td>None to our knowledge</td>
</tr>
<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>Plasticiser in plastics (e.g. nitrocellulose and polyeutrocellulose but not in PVC), varnishes, nitrocellulose paints and film, &quot;sizing&quot; glass fibre before impregnation &amp; in paper coatings.</td>
<td>None to our knowledge</td>
</tr>
<tr>
<td>Hexabromocyclododecan (HBCDD) and all major diastereoisomers identified (α-HBCDD, β-HBCDD, γ-HBCDD)</td>
<td>Flame retardant in extruded and expanded polystyrene and flexible PU foam (main use). Textile coatings, additive to HIPS. There are alternative flame-retardants suitable for HIPS but all are brominated compounds.</td>
<td>None to our knowledge</td>
</tr>
<tr>
<td>Methylene diamine (4,4'-diaminodiphenylmethane; 4,4'-methylenedianiline); DMA, MDA</td>
<td>None to our knowledge</td>
<td>98% used as intermediate for PU foam and resins, some epoxy resins, adhesives and specialist polymers as a hardener</td>
</tr>
<tr>
<td>Musk xylene; 3,5-tetra-tert-butyl-2,4,6-trinitro-m-xylene</td>
<td>Very unlikely (fragrance)</td>
<td>None to our knowledge</td>
</tr>
</tbody>
</table>

Breakout 4
- Analysing one of your products

- Split into small groups
- Task
  1. Choose a product of relevance to you.
  2. What SVHCs might be present, where, and how likely is this?
     - Make a table
- Report back
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for TURI

April 2011

Breakout 4
- Analysing one of your products

<table>
<thead>
<tr>
<th>Substance</th>
<th>Location(s)</th>
<th>H/M/L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product selected ________________

How is REACH impacting now?

- Big increase in supply chain communications
  - can I meet my customers’ requirements?
  - can I get the data I need from my suppliers?

- Obsolescence threat – now becoming a reality
  - What components may be phased out?
  - What chemicals/materials will be phased out or not usable?
  - What are the alternatives?
REACH
- Article 33 declaration

• Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

REACH
– Managing Article 33 declaration

• Process
  – Be intelligent in asking for information
  – Prioritise

• Automotive sector
  – pushing for declaration based on information available at time of production (not placing on the market)

• Other approaches
  – e.g. information made available at time of supply
• Document the rationale for your approach!
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What you do not need to do

- Register articles
  - not even possible
- Provide total substance declarations
  - .... but customer requirements may differ
- Provide an SDS for articles
  - again not usually possible
- Provide SVHC concentrations at <0.1%
  - .... but customers and some States may differ
- Provide SVHC information on articles not available to you
  - but you need to be diligent in gathering what is possible

What you do not need to do

- Notify ECHA of SVHCs (>1 tonne) in articles
  - if supplier has done this
- Register “released” substances from articles
  - if supplier has done this
- Analyse articles for SVHCs
  - this is a last resort, do only if no information can be obtained from supplier and you suspect they may be present
4: REACH
- MSDS and SDS -

Materials Safety Data Sheets (MSDS)
- State of play

- EU requires SDS # US MSDS
  - Many do not comply with older EU requirements
- Are likely to come under close scrutiny by Member State Authorities
- Under pressure to change owing to SVHC information provision etc.
Safety Data Sheets
- When do I need to provide an SDS?

You don’t but your EU importer does if

1. They supply a
   a) substance or a mixture classified as
      - dangerous under Dangerous Substances Directive, 67/548/EEC or
      - dangerous under the Dangerous Preparations Directive, 1999/45/EC; or
      - hazardous under the Classification Labelling and Packaging (CLP) Regulation 1272/2008 (as amended by 790/2009); or
   b) substance that is PBT, or vPvB
      - as defined in Annex XIII of REACH; or
   c) SVHC

2. Their customer requests a SDS for a mixture that is not classified as dangerous under DPD but contains either:
   a) a substance posing human health or environmental hazards at ≥ 1 % by weight for solid or liquid mixtures, or ≥ 0.2 % by volume for gaseous mixtures; or
   b) a substance that is PBT, or vPvB at ≥ 0.1 % by weight for solid or liquid mixtures (i.e. non-gaseous mixtures); or
   c) SVHC (for reasons other than those listed above), at ≥ 0.1 % by weight for non-gaseous mixtures; or
   d) a substance for which there are Europe-wide or national workplace exposure limits even if not classified as dangerous.
Safety Data Sheets

- When do I need to provide an SDS?

3. They are a supplier of a product listed as a ‘special case’ in paragraph 1.3 of Annex 1 of the CLP Regulation for which there are labelling derogations
   - e.g. gas containers intended for propane, butane or liquefied petroleum gas.

You don’t, nor does your EU importer, if

1. The substances/mixtures are supplied in the UK and not classified as hazardous or considered PBT, vPvB or of equivalent concern (e.g. endocrine disruptors)

2. For certain products intended for the final user
   - e.g. medicinal products or cosmetics

3. If you offer or sell dangerous substances or mixtures to the general public and you provide sufficient information to enable users to take the necessary measures as regards safety and the protection of human health and the environment
   - However, a downstream user or distributor can ask you to provide one
     • Suggest calling it “Product Information Sheet” or similar
Substance restrictions & safety
- CLP Labelling

Substances

<table>
<thead>
<tr>
<th>1 Dec 2008</th>
<th>1 Dec 2009</th>
<th>1 Dec 2010</th>
<th>1 Dec 2012</th>
<th>1 Jun 2015</th>
<th>1 Jun 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old label</td>
<td>Old label ok</td>
<td>or</td>
<td>New label ok</td>
<td>New label mandatory</td>
<td></td>
</tr>
</tbody>
</table>

Mixtures/Preparations

<table>
<thead>
<tr>
<th>1 Dec 2008</th>
<th>1 Dec 2009</th>
<th>1 Dec 2010</th>
<th>1 Jun 2015</th>
</tr>
</thead>
<tbody>
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<td>Old label ok</td>
<td>or</td>
<td>New label ok</td>
</tr>
</tbody>
</table>
Safety Data Sheets
- May be required when an MSDS is not

- In case of SVHCs which have environmental impact only
  - MSDS only required in case of physical or health hazard

- Low concentrations in mixtures <0.1%
  - US only requires reporting of substances in mixtures in MSDS >1%
    - except for carcinogens where a lower limit of 0.1% applies
  - EU requires reporting of SVHCs > 0.1%
  - Therefore US MSDS may not contain sufficient information on SVHCs to compile EU SDS
    - unless the SVHC is a carcinogen category 1 or 2 (at least 10 are not)

- Low concentrations of restricted substances
  - Again MSDS may miss this (e.g. PAH restricted at <1ppm)

Safety Data Sheets
- How do they differ from MSDS?

- Defined by Regulation 453/2010 (superseding REACH, Annex II)
  - Not OSHA!

- New requirements include
  - Revised format (e.g. Sections 2/3 swapped)
  - REACH registration number, exposure scenarios with use descriptors
  - Hazard pictograms
  - Information on hazardous decomposition products
  - More detail on first aid and accidental release measures, toxicological properties etc.
  - Reporting at lower concentrations of hazardous substances in mixtures >>

- Must be supported by a Chemical Safety Report
  - unless substance < 10 tpa or below certain concentration in mixtures
Safety Data Sheets
- When do they need changing?

- When substance already classified according to DSD/DPD is classified under CLP
- When new information on hazards arises
  - Substance newly classified as hazardous
  - When REACH registration number provided
  - When substance contained is authorised or restricted

Substance restrictions and safety
- Classification and labelling – other changes

- New and different classifications
- Signal words
  - DANGER, WARNING
- Statements
  - Hazard ('H' codes)
  - Precautionary ('P' codes)
    - Prevention
    - Response
    - Storage
    - Disposal
- Supplemental ('EUH' codes)
  - Physical
    - Explosive when dry
  - Health
    - Contact with acids...
4: REACH
- Global requirements -

Global requirements

- Similar elements to EU REACH
  - Under pressure for reform and to align with EU REACH
    - Senator Lautenberg - Safe Chemicals Act (2011)
  - California - Green chemistry initiative
  - Legislation proposed by DTSC late 2010
  - Prioritised, evidence-based process > alternatives assessment
  - Consumer products only
  - Chemicals of concern > Toolbox of sanctions
    - e.g. Providing information to consumers and labelling
Global requirements

Canada Challenge
- 197 "high priority for action" substances being considered in batches
  - > Schedule 1, Canada Environmental Protection Act (1999)
    - > action
- South Korea “REACH”
  - Draft regulation published 25 Feb 2011 by Environment Ministry
  - Plan to adopt Q3 2011 (covers both existing and new substances)
  - Entry into force 2 years later
- Japan
  - Chemical Substances Control Law (CSCL) - amended
  - Apr 2011: New requirement to report import/production quantity (when > 1 tpa) and end use application for existing substances

Global requirements

China REACH
- Measures on the Environmental Management of New Chemical Substances, Order No. 7, Oct 2010
  - Guidance published Sept 2010
  - Applies mainly to chemicals and mixtures not to "articles"
    - but includes new chemicals released from articles during normal use
  - Main obligations on manufacturers/importers of substances in China
  - References (Globally Harmonised System) system. Classifications proposed:
    - general new, hazardous new, priority hazardous chemicals
  - Annual reporting by manufacturers/importers of hazardous and priority new hazardous substances
  - Phase out hazardous substances
    - promoting safer alternatives, six-month reporting requirement
  - Risk management of new chemicals
    - based on hazardous properties and risk of exposure to workers / consumers
  - Notification requirements for chemicals based on tonnage bands
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5: REACH
- Guidance -

REACH
- Guidance

• http://echa.europa.eu

• http://www.hse.gov.uk
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My key points for today

- Learning points
  1. .................................................................
  2. .................................................................
  3. .................................................................
  4. .................................................................
- Actions
  1. .................................................................
  2. .................................................................
  3. .................................................................
  4. .................................................................

Conclusions

- These are world issues
- Obsolescence has always been an issue – know your materials
- Sound processes, properly implemented and resourced give the best assurance
- Changing market conditions provide opportunities for the best to shine
Thank you!

Dr Chris Robertson
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ERA Technology Limited

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