An introduction to REACH

UK Competent Authority

Verson 2 - Jan 2008
Aim of this today is to:

- Ensure each of you goes away knowing what REACH means for your business.
An Introduction to REACH

What is REACH?

Registration, Evaluation Authorisation and Restriction of Chemicals

- New EU Regulation that became law in the UK on 1 June 2007
- It’s big and broad in scope
  AND
- It’s not just for the chemical sector
## An Introduction to REACH

**REACH Terminology**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper</td>
<td>Brass</td>
</tr>
<tr>
<td>Zinc</td>
<td>Alloy of copper + zinc</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>White Paint</td>
</tr>
<tr>
<td></td>
<td>[titanium dioxide + …]</td>
</tr>
<tr>
<td>Ethylene glycol</td>
<td>Antifreeze</td>
</tr>
<tr>
<td></td>
<td>[ethylene glycol + …]</td>
</tr>
<tr>
<td>Sodium dodecyl sulphate</td>
<td>Washing detergent</td>
</tr>
<tr>
<td></td>
<td>(sodium dodecyl sulphate + …)</td>
</tr>
<tr>
<td>Ylang-ylang extract</td>
<td>Fragrance concentrate</td>
</tr>
<tr>
<td></td>
<td>(ylang-ylang extract + …)</td>
</tr>
</tbody>
</table>
REACH Terminology: Articles
REACH terminology: Roles

- Manufacturers (registration)
- Importers (registration)
- Only Representative (registers for non-EU business)
- Downstream Users – not consumers (follow use directions; supply information up and down the supply chain)
- Distributors - including retailers (information conduit – both ways)
Downstream Users:

- Formulator
- End-User
- Industrial User
- Article Producer
- Craftsmen, micro enterprise, professional service providers
- Re-fillers
- Re-importers

(Importers with non-EU supplier using Only Representative)
Key players in REACH:

• The European Chemicals Agency (ECHA) – Based in Helsinki.
• Defra – The government Department with policy lead on REACH
• The UK Competent Authority (CA) – located within the Health and Safety Executive (HSE), responsible for the day to day running of REACH in the UK.
Key features of REACH

• Introduces new Registration requirement covering almost all substances manufactured or imported into the EU market above 1 tonne per year – no data, no market!

• Information requirements increase with increasing tonnage supplied

• Will introduce system for “Authorising” the use of some chemicals
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REACH elements and your business

- Registration (Pre-registration)
- Evaluation
- Authorisation
- Restriction
Note – REACH applies to substances

Two types of substance:

“Phase-in” – largely those already around (existing)
  The following slides refer to these substances.

“Non-phase in” – new to the EU
Scope

• All substances manufactured or imported into the EU at 1 tonne per year or more per manufacturer/importer

• Includes substances supplied in preparations (e.g. mixtures, formulations) to the extent where they are not covered by other more specific legislation

• Includes substances supplied at over 1 tonne per year in articles (per producer or importer) if substance is intended to be released during normal and reasonably foreseeable conditions of use
Substances not covered

- Radioactive
- Dangerous goods in transit
- In customs
- *Non-isolated* intermediates
- Waste (as defined in 2006/12/EC)
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Tailored provisions:

• Human and veterinary medicines
• Food and foodstuff additives
• Plant protection products and biocides
• Isolated intermediates
• Substances used for R&D
• Polymers
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Does your company introduce the EU to a substance by manufacture or importation at ≥1 tonne per year?
- as the substance itself
- within a preparation
- within an article, with intended release

If so,

PRE-REGISTRATION
then
REGISTRATION (via SIEF?)
Registration

- Registration involves submission of a dossier of technical information to the ECHA – through an electronic format
- Includes information on: name of registrant, identity of substance, uses, physico-chemical, toxicology and ecotoxicological properties (and possibly assessments of risk and risk management measures)
- It will cost to register
- The cost to register will vary (e.g. tonnage, data submitted, SME)
## Cost to register under REACH

<table>
<thead>
<tr>
<th>Tonnage Range (tonnes/year)</th>
<th>Standard Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>€1,600 (£1,195) (Free if full data package submitted)</td>
</tr>
<tr>
<td>10-100</td>
<td>€4,300 (£3,210)</td>
</tr>
<tr>
<td>100-1000</td>
<td>€11,500 (£8,580)</td>
</tr>
<tr>
<td>&gt;1000</td>
<td>€31,000 (£23,135)</td>
</tr>
</tbody>
</table>

Reduced fees for SMEs:
- Medium: 30% reduction
- Small: 60% reduction
- Micro: 90% reduction

All: 25% reduction for joint submissions
Registration (Pre-registration) of substances

• There is a period of pre-registration 1 June 2008 – 30 November 2008
• Substances are registered in tonnage-related phases between 2008 and 2018
• Substances not pre-registered must be registered in December 2008 or cannot be manufactured/imported (legally!)
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Pre-registration

- Pre-registration is **free of charge**
- It flags up an intention to register
- It allows the use of the phase-in periods
- Simple - done via ECHA electronically
- It means you join with others wanting to register this substance in a Substance Information Exchange Forum (SIEF)
Registration - Downstream Users

• You do **NOT** need to Register or Pre-register.
• Think about the chemicals you use
  – Standard chemicals in standard ways – nothing to worry about
  – Niche chemicals or chemicals in a novel way – think about talking to suppliers about registration intentions, are your uses covered?
Downstream Users - other aspects

• More information will become available in the supply chain, up and down.

• Follow risk management advice
Authorisation of Substances (Manufacturer/Importers and Downstream Users)

• By June ’09 ECHA will produce a list of substances for authorisation – this will be reviewed periodically and will appear in Annex XIV of REACH.

• The list will be drawn off a bigger “candidate list”

• Industry will then need to submit an application for authorisation to use.

• There will be a cost to apply for an authorisation
### Fees for application for an Authorisation

<table>
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<tr>
<th></th>
<th>€50,000 (£37,315)</th>
<th>€10,000 (£7,460)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Fee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Fee per Substance</td>
<td>€10,000 (£7,460)</td>
<td></td>
</tr>
<tr>
<td>Additional Fee per Use</td>
<td>€10,000 (£7,460)</td>
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</tr>
</tbody>
</table>

**Reductions for SMEs:**
- Medium: 20% reduction
- Small: 50% reduction
- Micro: 85% reduction
Key Messages

- There is time to prepare but you need to start now.
- Identify your status under REACH – Your duties will depend on this.
- What substances are involved in your business?
- If you have a registration duty (Manufacturers and Importers) - Pre registration is vital.
- Downstream users do not have to register.
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Summary

• REACH is here

• It could impact on your business – it’s not just for the chemical sector
Support for business

- Trade Associations
- Commercial helpdesks/consultants
- EU guidance
- CA Helpdesk
  - [www.hse.gov.uk/reach](http://www.hse.gov.uk/reach)
    - Telephone: 0845 408 9575
    - e-mail: UKREACHCA@hse.gsi.gov.uk
      - Just launched UK REACH CA e-bulletin