REACH – Key measures in detail
Overview of REACH requirements

- Registration (pre-registration)
- Supply chain
- End use

- Evaluation
- Authorisation
- Restriction
REACH roles

- Manufacturer / importer / ‘only representative’ (registration)
- Supplier / distributor (supply chain)
- ‘Downstream user’ (use)

...though a single person may have several roles
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 an ‘only representative’
**REACH terminology**

REACH is concerned about *substances*, either on their own, or in preparations or articles.

<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>Brass</td>
</tr>
<tr>
<td></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>Ylang-ylang extract</td>
<td>Fragrance concentrate</td>
</tr>
<tr>
<td></td>
<td>(ylang-ylang extract + …)</td>
</tr>
</tbody>
</table>
Articles
Exemptions

Substances not covered by REACH:

Radioactive
Dangerous goods in transit
In customs
*Non-isolated* intermediates
Waste

Also a defence exemption
Tailored provisions:

- Human and veterinary medicines
- Food and foodstuff additives
- Plant protection products and biocides
- Isolated intermediates
- Substances used for R&D
- Polymers
- Substances in Annexes IV and V
- Recovered and re-imported substances
Registration

Does your company introduce to the EU 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

ECHA
Helsinki

REACH
UK Competent Authority
Key features of registration:

• ‘No data, no market’

• Separate registration required for each manufacturer / importer

• Must submit a technical dossier of information to ECHA

• Information requirements increase with increasing tonnage supplied

• It will cost to register (though the cost will vary)
<table>
<thead>
<tr>
<th>Tonnage Range (tonnes/year)</th>
<th>Standard Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>€1,600</td>
</tr>
<tr>
<td></td>
<td>(Free if full data package submitted)</td>
</tr>
<tr>
<td>10-100</td>
<td>€4,300</td>
</tr>
<tr>
<td>100-1000</td>
<td>€11,500</td>
</tr>
<tr>
<td>&gt;1000</td>
<td>€31,000</td>
</tr>
</tbody>
</table>

**Costs to register under REACH**

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

All: 25% reduction for joint submissions
Chemical safety assessments are required for +10 tpa registrations:

- essentially a risk assessment, undertaken by the manufacturer / importer
- derived no-effect levels (DNELs)
- ‘exposure scenarios’ – a description of operational conditions and risk management measures
- exposure scenarios to be annexed to SDSs
Pre-registration

• **Not** a requirement (though is free)
• Between 1 June and 1 December 2008 only (*first time* manufacturers / importers can pre-register ‘late’)
• Dutyholders can then take advantage of registration phases between 2010 and 2018
• Substances not pre-registered must be registered by 1 December 2008 or cannot be manufactured, imported or placed on the market (legally!)
• Those that pre-register join with others wanting to register the same substance in a Substance Information Exchange Forum (SIEF)
Registration phases:

<table>
<thead>
<tr>
<th>Date</th>
<th>Deadline for registration of substances supplied at:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Dec 2010</td>
<td>≥ 1000 tonnes per annum (tpa) or;</td>
</tr>
<tr>
<td><strong>PHASE 1</strong></td>
<td>≥ 100 tpa and classified under CHIP as very toxic to aquatic organisms or;</td>
</tr>
<tr>
<td></td>
<td>≥ 1 tpa and classified under CHIP as Cat 1 or 2 carcinogens, mutagens or reproductive toxicants</td>
</tr>
<tr>
<td>1 June 2013</td>
<td>≥ 100 tpa</td>
</tr>
<tr>
<td><strong>PHASE 2</strong></td>
<td></td>
</tr>
<tr>
<td>1 June 2018</td>
<td>≥ 1 tpa</td>
</tr>
<tr>
<td><strong>PHASE 3</strong></td>
<td></td>
</tr>
</tbody>
</table>
UK pre-registration activity

By 1 December 2008:

• Around 21,000 companies pre-registered one or more substances

• Highest number of any Member State (second highest Germany with around 8,500)

• Around 450,000 substances were pre-registered

• Second highest (Germany higher with around 670,000)
Supply

Supply information up and down the supply chain:
• Contact your suppliers:
  - with any new information on hazards
  - if risk management measures not appropriate
• Provide your customers with information:
  - formulators: if substance is ‘dangerous’ (SDSs)
  - producers of articles: if article contains substances of very high concern (‘SVHCs’)

REACH
UK Competent Authority
REACH repeals and replaces CHIP requirements as regards safety data sheets

Through registration, safety data sheets will contain more and better information about risk management measures (‘exposure scenarios’)
Use

Requirements regarding use:

• Identify and apply risk management measures from supply information

• Take action if use is ‘outside’ registration

• Observe duties on suppliers (last slides) if relevant
All dutyholders

General requirements:
• Obtain authorisation where required (or notify ECHA of use)
• Observe restrictions
• Provide workers access to information
• Keep information
Registration (pre-registration)

Supply chain

End use

Evaluation
Authorisation
Restriction
Evaluation

- Completeness check
- Compliance check
- Dossier evaluation
- Substance evaluation

May require further information to be submitted
Authorisation

Applies to ‘substances of very high concern’ (SVHCs) included in Annex XIV. They may be:

- category 1 or 2 carcinogens, mutagens or reproductive toxicants
- persistent, bioaccumulative and toxic (PBT)
- very persistent or very bioaccumulative (vPvB)
- substances giving rise to an equivalent level of concern (e.g. endocrine disruptors)
By June 2009 ECHA will produce a list of substances for authorisation (Annex XIV of REACH).

Dutyholders will then need to submit an application for authorisation to either market or use.

There will be a cost to apply for an authorisation.

Designed to encourage substitution.
Restriction

• Enters into force 1 June 2009
• Annex XVII contains list of restricted substances
• Restrictions take many forms, not necessarily outright bans
• Illegal to manufacture, market or use a substance outside of the conditions of restriction
• Replaces ‘Marketing and Use Directive’
Timeline

1 June 2007  REACH came into force (though only supply chain related duties apply)

1 June 2008  All other duties (apart from restrictions) apply

1 June 2008  Registration for new substances starts

1 June to 30 Nov 2008  Pre-registration for existing substances

1 Dec 2008  Registration for existing substances (that have not been pre-registered) starts

1 Dec 2008  REACH Enforcement Regulations 2008 come into force
1 June 2009  Restrictions provisions apply
1 June 2009  Annex XIV published
1 Dec 2010  Deadline for Phase 1 registrations
1 June 2013  Deadline for Phase 2 registrations
1 June 2018  Deadline for Phase 3 registrations
The role of the UK REACH Competent Authority (CA)

- Delegated to HSE; operating on behalf of UK government(s)

- HSE & Environment Agency will have significant roles; with valuable assistance from other government bodies

- Based in Redgrave Court, Bootle
  - Chemical Assessment Schemes Unit (CASU)
  - Corporate Specialist Division (CSD)
  - Science and Technology Group (STG)
CA responsibilities

Enforcement (registration compliance)

Substance evaluation

EU influence

Help

UK enforcers liaison

Propose substances for authorisation / restriction

Awareness raising
Educational events (4 national conferences, 30+ regional roadshows etc)

Supporting events run by others (+150)

Publicity → e-bulletin
HELP

→ Helpdesk: enquiries

→ Website: guidance; info, case studies

→ Signposting to other sources
The contact details for the UK CA Helpdesk are:

- **Telephone:** 0845 408 9575
- **E-mail:** UKREACHCA@hse.gsi.gov.uk
- **Post:** UK REACH CA Helpdesk
  2.3 Redgrave Court, Bootle
  Merseyside, L20 7HS

www.hse.gov.uk/reach