To cover…

• Introduction to chemicals regulation
• Key duties in REACH/CLP
  – Authorisation
  – Restriction
  – Use
• Impact on other EH&S legislation
• Keeping up to date
  – Use of the ECHA website
• Brexit
REACH and CLP

REACH = Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

The CLP Regulation = Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures

Introduction to chemicals regulation
How are chemicals regulated in the UK?

In addition to more general legislation on:
- Worker protection (HSWA, COSHH, DSEAR, COMAH etc)
- Consumer protection (e.g. GPSR, toys)
- Environmental protection (e.g. EPR, waste)
- Transporting chemicals (ADR etc)
- Exporting chemicals (PIC)

Chemicals Regulation Division (CRD)

- York, Bootle & London
- UK Competent Authority for
  - REACH
  - CLP
  - Biocides
  - Pesticides (plant protection products)
  - Prior Informed Consent (PIC)
  - Detergents
- Enforcement of REACH, CLP, PIC, biocides and pesticides
Introduction to REACH and CLP

sodium lauryl sulphate

Is it dangerous?

sodium lauryl sulphate
“… known to cause skin irritation, serious eye damage, diarrhea, breathing difficulty – even death – in laboratory animals”

“… can cause malformation in the eyes of children”

“… can damage the immune system, potentially leaving the body open to damage, disorders and disease, including cancer”

“…a known cancer-causing ingredient”

“… also causes liver damage, skin rashes, depression, diarrhea and eye damage”
So, is it dangerous?

In short, yes!

**Labelling**

| Signal word: | Danger |

**Hazard pictogram**

- GHS01: flame
- GHS05: corrosion
- GHS07: exclamation mark

**Hazard statements**

- H228: Flammable solid.
- H302: Harmful if swallowed.
- H322: Harmful if inhaled.
- H315: Causes skin irritation.
- H318: Causes serious eye damage.
- H335: May cause respiratory irritation.
- H412: Harmful to aquatic life with long lasting effects.
Introduction to REACH and CLP

Precautionary statements

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
P304: Rinse mouth.
P302+P352: IF ON SKIN: Wash with plenty of water/....
P305+P335+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER/doctor/....
P321: Specific treatment (see ... on this label).
P332+P313: If skin irritation occurs: Get medical advice/attention.
P362: Take off contaminated clothing.
P372: Avoid release to the environment.
P501: Dispose of contents/container to ... in accordance with local/regional/national/international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both.

Introduction to REACH and CLP

So, is it dangerous?

In short, yes!

But should we be concerned?

Well … perhaps?
This is how REACH and CLP work:

- They provide us with information on chemicals
  - their hazards
  - their risks (including risks arising from different uses)
  - how to manage those risks
- Which enables us to decide what we need to do
  - whether you’re an employer
  - a consumer
  - or a regulatory authority

**Introduction to REACH and CLP**

**REACH and CLP:**

**Key duties**
How do I know what I have to do?

- REACH and CLP requirements are based on a simple model of a chemical supply chain
- Your role in the chemical supply chain determines what duties you have
  - Chemicals regulation does not take the ‘traditional’ H&S approach of duties on employers, self-employed, employees etc

The regulatory view of the chemical supply chain
The actual chemical supply chain …

REACH / CLP Key duties

• Those **manufacturing** or **importing** a substance must:
  - register it (REACH)

• Those **supplying** a substance / mixture must:
  - classify it (CLP)
  - and if it is classified as hazardous:
    - provide safety, health and environmental information via the safety data sheet (REACH)
    - label it correctly (CLP)
    - package it correctly (CLP)
    - notify the classification (CLP)
Key duties (contd.)

• Those using a substance / mixture must:
  ➞ use it safely (REACH, COSHH, DSEAR etc)

• Everyone must:
  ➞ observe authorisation and restriction requirements for substances, mixtures and articles (REACH)

REACH: Authorisation

• Authorisation is the mechanism through which REACH will phase out use of the most hazardous chemicals
  – List of authorisable substances keeps growing

• Businesses must justify the continued use of substances that are subject to authorisation

• Uses that are not authorised must cease
  – There are some exemptions, e.g. substances used in scientific research and development (SR&D)

• It is difficult (and costly) to get authorisation
Which substances are in scope?
• Substances of Very High Concern (SVHCs):
  - carcinogens, mutagens and repro-toxic substances (CMR) category 1A or 1B
  - persistent, bio accumulative and toxic (PBT) or very persistent and very bio accumulative (vPvB)
  - substances of similar concern (e.g. endocrine disruptors)
• Listed in Annex XIV of REACH
  https://echa.europa.eu/authorisation-list

REACH: Authorisation (contd.)
There are currently 43 substances on Annex XIV, including:
• Lead compounds
  – lead chromate, lead sulfochromate yellow & lead chromate molybdate sulphate red
• Various chromates / dichromates:
  – sodium, potassium & ammonium dichromate
  – sodium, strontium & potassium chromate
• Various phthalates:
  – bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP)
49 substances currently recommended for inclusion in the list of authorisable substances
Using trichloroethylene as an example:

- Trichloroethylene has various uses, e.g. as a process chemical (e.g. in purification), a lab chemical, an industrial degreaser etc
- According to registration information about 50,000 – 100,000 tonnes per year of trichloroethylene are manufactured or imported in the EU
- Trichloroethylene meets the criteria for an SVHC (cat 1B carcinogen)

REACH: Authorisation (contd.)

Using trichloroethylene as an example:

- Trichloroethylene was included on the candidate list in June 2010
  - triggering the duties for SVHCs in articles
- Prioritised and recommended for inclusion on Annex XIV by ECHA in December 2011
- Included on Annex XIV in April 2013 by amending REACH
  - applications for authorisation to be submitted by 21/10/2014
  - ‘sunset date’ was 21/04/2016
  - REACH requirements for authorisation now fully in force for this substance
**REACH: Authorisation (contd.)**

*Using trichloroethylene as an example:*

- There have been 20 applications for authorisation, e.g.
  - For continued use as a process solvent, in the manufacture of batteries, for industrial degreasing, to extract resin from dyed cotton cloth etc
- 1 application still ‘in process’
- Decisions reached on 19 applications
  - Most have been successful and authorisations granted
  - Conditions imposed, e.g. exposure monitoring
  - Review periods set

**REACH: Restriction**

- Annex XVII contains list of restricted substances
- Illegal to manufacture, market or use a substance outside of the conditions of restriction
  - List of restricted substances keeps growing
- Restrictions take many forms, not necessarily outright bans
  - SR&D again exempted
  - Some restrictions contain further derogations from their application
Examples of restrictions include:

- Asbestos prohibitions
- Lead carbonates & sulphates in paint
- Benzene (on its own or in mixtures)
- Chromium VI compounds in cement
- Phthalates in toys and childcare articles
- Nickel and lead in jewellery
- Methanol in screenwash

REACH: Restriction (contd.)

- Azocolourants and azodyes in clothes and other materials which may come into contact with the skin
- Category 1 or 2 CMRs in substances or preparations for sale to the general public
- Dichloromethane in paint strippers (with some exemptions)
- Toluene in adhesives or spray paints intended for supply to the general public
REACH: Use-related duties

Users of chemicals have duties under REACH to:
• identify and apply appropriate risk management measures from information from their suppliers
  – including ‘exposure scenarios’
• take action if their use is ‘outside the norm’
• pass certain information up the supply chain
• use chemicals registered as intermediates only under ‘strictly controlled conditions’

These duties complement those under ‘conventional’ H&S legislation (such as COSHH) but can sometimes conflict

Impact of chemicals regulation on EH&S legislation
Provision of information on hazards, risks and control measures

<table>
<thead>
<tr>
<th>SAFETY DATA SHEETS (REACH)</th>
<th>SUPPLY LABELS (CLP)</th>
<th>TRANSPORT LABELS (ADR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• EU regulation</td>
<td>• EU regulation</td>
<td>• International (UN) regulations</td>
</tr>
<tr>
<td>• REACH (Regulation 1907/2006)</td>
<td>but follows UN scheme</td>
<td>• Less comprehensive</td>
</tr>
<tr>
<td>• Annex II contains detailed requirements</td>
<td>• CLP (Regulation 1272/2008)</td>
<td>• Implemented by CDG Regulations</td>
</tr>
<tr>
<td>• Main source of detailed information</td>
<td>• Implements GHS into the EU</td>
<td>• Source of some hazard information</td>
</tr>
<tr>
<td></td>
<td>• Source of quick hazard information</td>
<td></td>
</tr>
</tbody>
</table>

Value of safety data sheets

• Contain vital information to assist you with
  – Health (COSHH assessment / control)
  – Safety (DSEAR assessment / control)
  – Other EH&S law, e.g. COMAH, waste etc

• REACH and CLP have driven significant improvements
  – Amount of information on chemical hazards, risks and risk management
  – Quality / reliability of that information

• Substances registered under REACH at >10tpa will have ‘exposure scenarios’
Format of a safety data sheet

Under REACH, a SDS must have 16 headings:

- identity of product and supplier
- hazards identification
- composition/information on ingredients
- first aid measures
- fire-fighting measures
- accidental release measures
- handling & storage measures
- exposure controls and personal protection
- physical and chemical properties
- stability and reactivity
- toxicology
- ecological information
- disposal
- transport
- regulatory information
- other information

With ‘exposure scenarios’ appearing as an Annex

Use of a safety data sheet

<table>
<thead>
<tr>
<th>CHEMICAL DATA</th>
<th>MANAGEMENT</th>
<th>EMERGENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECTION 2</td>
<td>SECTION 7</td>
<td>SECTION 1</td>
</tr>
<tr>
<td>- Hazards identification</td>
<td>- Handling &amp; storage</td>
<td>- Supplier details</td>
</tr>
<tr>
<td>SECTION 3</td>
<td>SECTION 8</td>
<td>SECTION 4</td>
</tr>
<tr>
<td>- Composition</td>
<td>- Exposure control and PPE</td>
<td>- First aid measures</td>
</tr>
<tr>
<td>SECTION 9</td>
<td>SECTION 10</td>
<td>SECTION 5</td>
</tr>
<tr>
<td>- Physical / chemical properties</td>
<td>- Stability &amp; reactivity</td>
<td>- Fire fighting</td>
</tr>
<tr>
<td>SECTIONS 11 &amp; 12</td>
<td>SECTION 13</td>
<td>SECTION 6</td>
</tr>
<tr>
<td>- Tox &amp; ecotox data</td>
<td>- Disposal considerations</td>
<td>- Accidental release</td>
</tr>
<tr>
<td>SECTION 14</td>
<td>SECTION 15</td>
<td>SECTION 16</td>
</tr>
<tr>
<td>- Transport information</td>
<td>- Regulatory information</td>
<td>- “Other information”</td>
</tr>
</tbody>
</table>
Issues with safety data sheets

- Won’t cover all hazardous substances you use
- Too much information…?
  - Length
  - Complexity
  - ‘Extended’ SDS
- Not often compiled properly (or missing information)
- Often computer-generated (can be too ‘generic’)
- Information can vary from supply chain to supply chain
- No substitute for a COSHH assessment!

Changes to labelling under CLP

- **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...
An example (solvent)

‘Toxic’
Flammable.
Irritation to the respiratory system.
May cause harm to the unborn child.
2 Safety Phrases

‘Danger’
Flammable liquid and vapour.
May damage the unborn child.
May cause respiratory irritation.
21 Precautionary Phrases

Consequences of changes to hazard classification due to CLP or REACH

Hazard classification
Labelling
Packaging
Waste
Worker protection
Major accidents (COMAH)
Environmental protection
Consumer protection / marketing restrictions

More than 20 H&S Regulations affected by the switch to CLP (let alone other areas of regulation)
For example (human health, oral exposure route)

<table>
<thead>
<tr>
<th></th>
<th>Very toxic</th>
<th>Toxic</th>
<th>Harmful</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHIP LD₅₀</td>
<td>&lt; 25 mg/kg</td>
<td>&gt; 25 - 200</td>
<td>&gt; 200 - 2000</td>
</tr>
</tbody>
</table>

Sodium selenite (oral LD₅₀ is 7 mg/kg)

For example (physical hazards, flammable liquids)

<table>
<thead>
<tr>
<th></th>
<th>Extremely flammable</th>
<th>Highly flammable</th>
<th>Flammable</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHIP</td>
<td>Flash point &lt; 0°C</td>
<td>Boiling point ≤ 35°C</td>
<td>&gt; 21°C but &lt; 55°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLP</td>
<td>Flash point &lt; 23°C</td>
<td>Boiling point ≤ 35°C</td>
<td>&gt; 23°C but &lt; 60°C</td>
</tr>
</tbody>
</table>

Chloroacetonitrile (flash point 56°C)
Examples of the impact of chemicals regulation

CLP classification example:

- Nitric acid
  - Currently classified as an oxidising liquid (if conc. >65%) and corrosive
  - Germany proposed it be re-classified as Acute Tox 1 (inhalation) in 2011
  - HSE estimated this would lead to a 10% increase in COMAH sites – proposal ultimately did not go ahead
  - Germany submitted a new proposal in 2016 for Acute Tox 3 (inhalation) based on REACH registration data
  - Concentrations >26% = COMAH substance

Examples of the impact of chemicals regulation

REACH authorisation example:

- Polymers manufacturer
  - Use cobalt compound as a catalyst – no alternatives identified
  - ECHA recommended a number of cobalt compounds should become authorisable substances
    - Application for authorisation is very costly and difficult
    - No guarantee of success when applying for authorisation
    - Even if authorised, only authorised for 5 years
  - The Commission ultimately postponed that decision but asked ECHA to investigate restriction instead
Examples of the impact of chemicals regulation

REACH restrictions example:

• Fireworks supplier
  – Through REACH registration, a substance present in a fireworks product range is discovered to be carcinogenic
  – Results in firework being classified as carcinogenic
  – Can no longer be sold to the general public due to the REACH restriction on supply of CMR substances to the public

Examples of the impact of chemicals regulation

REACH ‘downstream use’ example:

• Pharmaceutical manufacturer
  – Use a substance bought from an Austrian supplier as an intermediate in the production of antibiotics
  – Were compliant with COSHH and using a range of appropriate control measures
  – Had to purchase additional quantities from an Italian supplier who has only registered the substance as an intermediate
  – Site now has to observe ‘strictly controlled conditions’ and must make fundamental changes to how material is handled
Finding out more about chemicals

How to stay up to date

Keep aware of developments by using the ECHA website.

**Authorisation:**

- The Registry of Intentions
  - substances intended to become SVHCs
- The Candidate List
  - substances that are SVHCs and may be added to Annex XIV
  - https://echa.europa.eu/candidate-list-table
- Annex XIV recommendations
  - substances on the Candidate list that have been recommended for authorization
  - https://echa.europa.eu/previous-recommendations
How to stay up to date

Keep aware of developments by using the ECHA website.

Restriction:
- The Registry of Restriction Intentions
  - a list of current restriction proposals

Hazard classification:
- Registry of CLH intentions
  - Lists intentions for new or revised harmonized classifications and labelling for substances

ECHA and HSE e-bulletins provide useful (free) updates

Some examples

- Titanium dioxide
  - White, inorganic compound widely used in paints, plastics, paper, pharmaceuticals, suntan lotion and food
  - Current proposal is for a harmonised classification as carcinogenic cat 1B
Some examples

• Microplastics
  – Small plastic particles typically less than 5mm in length
  – Proposal to restrict the use of intentionally added microplastic particles to consumer or professional use products of any kind

• Diisocyanates
  – Used to make polyurethane products such as rigid and flexible foams, coatings, adhesives, sealants and elastomers
  – Classified as respiratory sensitisers
  – Proposal for restriction which seeks to ban the use of diisocyanates unless they are present at <0.1wt% or specified training and control measures are put in place
Some examples

• Bisphenol A
  – In widespread use for the manufacturing of polycarbonate plastics and epoxy resins
  – Classified as toxic to reproduction and an endocrine disruptor
  – Already some restrictions on use, e.g. in thermal paper, infant feeding bottles, toys for young children etc
  – Proposal for it to become subject to authorisation under REACH

https://echa.europa.eu
Brexit

- Duties under health and safety law will not change
- European legislation will become a new type of UK law known as ‘retained EU law’
- In the event of ‘no-deal’, some changes will be made to retained EU law to ensure it continues to operate effectively – for instance, to refer to UK institutions rather than EU ones
- Implications of ‘no-deal’ for chemicals regulations are significant – find out how you might be affected!
- HSE website contains lots of guidance:
  https://www.hse.gov.uk/brexit
Thank you!

IF YOU’RE NOT PART OF THE SOLUTION...
YOU’RE PART OF THE PRECIPITATE!