



REACH REGULATION

Registration, Evaluation,
Authorisation and Restriction of
Chemicals



Background

- Reach became law throughout Europe in 2007 and requires that all chemicals used within the EU should be registered with the European Chemicals agency in Finland.
- The requirement applies to all chemicals manufactured in or imported into the EU
- If the chemicals you are using are not registered you will not be allowed to market your products.





Main Reasons for Introduction

- Protection of human health
- To safeguard and improve the competitiveness of EU chemical industry
- To allow an open market within the EU



Definitions in REACH

- Substances
- Preparations
- Articles
- Manufacturer
- Producer
- Importer
- Downstream user
- Only representative
- Distributor
- Registrant



Materials

- Substances
 - These are chemicals or reactive compounds
- Preparations
 - These are things made from substances which can still be reacted or which can still release substances during further processing or use (mixture or solution of two or more substances)
- Articles
 - These are parts or items made from either preparations or substances which are no longer reactive or which are not intended to release any substances under normal use



Substances

- Chemical elements or their compounds
- Substances (chemical compounds) obtained by manufacturing processes
- Substances in their natural state (e.g. vegetable oils, mica)
- Additives and impurities in the above



Legal entities

- Manufacturer
 - A company or person who manufactures substances
- Producer
 - A company or person who produces preparations for onward sale or use within a process or a company who produces articles from either substances or from preparations
- Importer
 - A company or person who imports substances or preparations from outside the EU



Legal entities

- Downstream user
 - A company or person who uses substances or preparations made by another or imported by another in his processes
- Only Representative
 - A legal entity established within the EU acting as the only representative of a company residing outside the EU who manufactures a substance on its own, formulates preparations or produces articles which are imported into the EU



Only Representative

- Must have experience with the substance
- Must have knowledge and keep records on customers and volumes sold
- Must be announced by non EU manufacturer to importing EU customers who are then regarded as downstream users



Legal entities

- Distributor
 - Person or company who only stores and forwards (but does not himself use) substances or preparations
- Registrant
 - Person or company who pre-registers and / or registers a substance with the European Chemical Agency. Normally the manufacturer or importer but can be the only representative or a downstream user.



Article

- An object which has been given specific shape surface or design which defines its function to a greater degree than does its chemical composition.
- Any substances of very high concern (SVHC) included in the article of greater than 1% w/w need to be registered
- Any substances released from an article under normal use need to be registered (e.g. spray paint or varnish from a can, ink from a pen etc.)



Restriction of use

- The use of a substance or preparation in the EU will only be permitted if the following 3 criteria are met
 - The substances are registered under Reach
 - Risk management criteria are followed
 - The substance registration file covers the intended application.



Other considerations

- Registration is based on substances only – not on preparations or articles
- Registration is normally carried out by the manufacturer or the importer
- Data required for submission will depend on the substance and the volume manufactured or imported (3 bands)
- Each substance will only have 1 registration number- Manufacturers will need to work together and share data.



Other considerations

- Polymers will not be registered but monomers will have to be
- Risk management measures identified at registration must be passed down the supply chain so the MSDS (for substances) will play a more important role than at present



Implementation

- The organisation overseeing implementation is the European Chemicals agency (ECHA) in Finland
- As the process progresses, black lists of prohibited or restricted use items will be issued



What should you be doing

- Most EIA members will be downstream users
- You need to ensure that substances used by your company (as substances or within preparations) are pre-registered



What should you be doing

- To do this make an inventory of all the substances or preparations you use and all the articles you buy and use
- Contact your suppliers and ask them to confirm that the substances used will be pre-registered and / or Registered
- Keep records of their responses



What should you be doing

- If you find there are any SVHC's or restricted use substances within your products, consider if you can find a substitute

- USE THE STANDARD QUESTIONNAIRES PROVIDED FOR THIS PURPOSE





Information sources

- <http://app.reach.gov.sg/reach/default.aspx>
 - UK REACH PORTAL – VERY GOOD SOURCE OF INFORMATION AND HELP DESK
- http://echa.europa.eu/home_en.html
 - ECHA Website details on registration
- [**http://reach.jrc.it/guidance_en.htm#GUID_PROCC_I**](http://reach.jrc.it/guidance_en.htm#GUID_PROCC_I)
 - Guidance documents available here – there are already in excess of 8,000 pages of guidance and more to come