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# **BARBOUR CPD SEMINAR**

# **UNDERSTANDING REACH**

# REACH

EC Regulation 1907/2006 concerning the *Registration, Evaluation, Authorisation and restriction of Chemicals* and establishment of the *European Chemicals Agency*

## WHY REACH ?

- REACH is intended to address previous shortcomings in management of chemicals within the EU, namely:
  - new and existing chemicals were treated differently
  - risk assessment of identified SVHC was very slow
  - a 10kg threshold for registration of new chemicals was damaging innovation
  - Users of chemicals were not included in the substance control regime

# OBJECTIVES OF REACH

- **Ensure the protection of human health and the environment.**
- Maintenance and enhancement of the competitiveness of the EU chemical industry.
- Prevention of fragmentation of the internal market.
- Increased transparency.
- Integration with international efforts including conformity with EU obligations to WTO.
- Promotion of non-animal testing.

# REACH PRINCIPLES

- Both *existing* and *new* chemicals will be treated in the same way.
- The onus for assessing the impact of substances on human health and the environment is transferred from public authorities to the manufacturers and importers of those substances.
- Downstream users are included and are given specific responsibilities.
- The Regulation will be managed by a newly formed European Chemicals Agency (ECHA) which will be based in Helsinki.
- There will be a single hazard assessment pack for each substance (OSOR) and testing involving animals will be subject to approval by the ECHA.

# REACH - TERMINOLOGY

- **Substances**, preparations and articles
- Manufacturers (*registration obligations*)
- Importers (*registration obligations*)
- Only representative (*registers for non-EU businesses*)
- Downstream Users – not consumers (*follow use directions, identify uses, pass information up and down supply chain*)
- Distributors – are not downstream users (*pass information up and down the supply chain*)

# REACH - KEY ELEMENTS

- Registration (of substances M/I in 1tpa or more)
- Evaluation (dossier and substance)
- Authorisation (limits use of SVHCs)
- Restriction (imposes limits on how substances are manufactured/used)
- One substance one registration (OSOR)
- Substance information exchange forum (SIEF)
- Downstream users (DSU's) and supply chain

# REACH REGULATORS

- ***The European Chemicals Agency*** (ECHA) – based in Helsinki
- ***Defra*** – The UK government department with policy lead on REACH
- ***The UK Competent Authority*** (UKCA) – Located within the Health & Safety Executive, responsible for the day to day running of REACH in the UK

# EXCLUSIONS AND LIMITATIONS

- Radio-active materials
- Waste
- Carriage of dangerous substances
- Substances under customs supervision
- Non-isolated intermediates
- Polymers (but not monomers used in them)
- Certain named substances (Annex IV)
- Certain groups of substances (Annex V)
- Certain uses (medicinal, veterinary, food and foodstuffs)
- R & D and PPORD
- Recovered materials
- Re-imports

## EXCLUSIONS AND LIMITATIONS (2)

- Certain substances will be assumed to be registered under REACH:
  - ELINCS registered (UK NONS regulation)
  - Biocidal products as covered by the BPD
  - Plant Protection Products
- The need to register under REACH does not apply to certain **uses** of substances covered by other legislation:
  - medicinal/veterinary products
  - food and food ingredients both for human and animal

# REGISTRATION

- REACH requires that all *importers* into the EU and *manufacturers* in the EU of substances either on their own or in preparations (and in certain cases in articles) in a quantity of 1 tonne per year or more must register those substances with the European Chemical Agency based in Helsinki
- Registration of 'new' substances will have to be completed by 1<sup>st</sup> June 2008 or thereafter, before a substance is imported or manufactured in the EU in quantities >1 tpa.
- 'Existing' substances need to be **pre-registered** with the ECHA between **1<sup>st</sup> June – 30<sup>th</sup> Nov. 2008** for them to be treated as 'phase-in' substances
- Registration of 'phase-in' substances is in 3 tranches dependant upon annual tonnage and substance classification.
- **Non EU manufacturers** cannot register under REACH but can appoint an '**Only Representative**' who can register on their behalf

# REGISTRATION

- The 3 registration deadlines for '*phase-in*' substances depend on the tonnage being manufactured/imported and the hazard classification of the substance
- Programme for registration of '*phase-in*' substances:

CMR's cat. 1&2(> 1tpa)	before 1 <sup>st</sup> Dec. 2010
R50/53 > 100tpa	before 1 <sup>st</sup> Dec. 2010
>1000tpa	before 1 <sup>st</sup> Dec. 2010
> 100tpa	before 1 <sup>st</sup> June 2013
> 1tpa	before 1 <sup>st</sup> June 2018

# PRE-REGISTRATION

- Pre-registration takes place between 1<sup>st</sup> June 2008 and 30<sup>th</sup> Nov. 2008
- Submission is made electronically to ECHA
- No Fee is levied
- Information required:
  - Registrants name, address & contact person details
  - Substance name(s)
  - CAS, ELINCS, EINECS number of substance
  - Envisaged deadline for registration/tonnage band
  - Name & No. of any substances expected to be used for grouping or read-across in the registration technical dossier (optional)
  - 3<sup>rd</sup> party representative (optional)
- Pre-registration does **not** have to lead to full registration

# CONTENTS OF REGISTRATION DOSSIER

- Identity of M/I
- Identity of Substance
- Tonnage band
- Description of manufacturing process
- Split between own and downstream uses
- ***Identified uses***
- Uses advised against
- Classification and labelling
- Guidance on safe use
- ***Information associated with Annexes VII-X***
- For < 10 tpa band information on exposure
- ***For > 10 tpa bands a CSR based on a CSA***
- Requests for information confidentiality

# TEST DATA REQUIREMENTS FOR REGISTRATION

- Non-phase-in 1 – 10 tpa Annex VII
- Phase-in subs 1- 10 tpa (class 1&2  
CMRs or PBTs or vPvB) Annex VII
- Phase-in subs 1-10tpa Annex VII phys-chem data +  
available human health &  
environmental data
- All subs >10 - <100tpa Annex VII + Annex VIII
- All subs > 100 - <1000tpa Annex VII + VIII + proposals for  
Annex IX
- All subs >1000 tpa Annex VII + VIII + proposals  
for Annex IX & X
- On-site & transported  
intermediates All available phys-chem, human  
health & environmental data
- Transported intermediates >1000tpa Annex VII

# REGISTRATION FEES

Tonnage band (tpa)	Individual registration (euros)	Joint registration (euros)	Medium enterprise Individual (euros)	Small enterprise individual (euros)	Micro enterprise individual (euros)
1 -10	1600	1200	1120	640	160
10 -100	4300	3225	3010	1720	430
100 – 1000	11500	8625	8050	4600	1150
>1000	31000	23250	21700	12400	3100

# EVALUATION

- Initial completeness check is not evaluation.
- **Dossier Evaluation:**
  - CMRs etc. and >100 tpa testing proposals will be assessed and approved.
  - At least 5% of all registration dossiers to be evaluated.
- **Substance Evaluation:**

A 3 year rolling programme driven by ECHA & MS on substances of most concern. Likely to result in authorisation or restriction.

# AUTHORISATION

- Authorisation is the mechanism for identifying and controlling the use of **substances of very high concern** (SVHC) with the longer term aim of finding alternatives.
- The ECHA & MS will generate a **candidate list** of SVHC. Commission will decide to include in Annex XIV with a '**sunset date**'
- M/I/DSU will need to apply for authorisation to use 18 months before the 'sunset date' or apply for a specific use if substance is already an Authorised Substance (listed in Annex XIV).
- Applicant will need to demonstrate adequate control (may not be possible) and/or justify use on socio-economic grounds.
- Considerations of alternatives and plans for substitution will need to be submitted.
- Authorisations will be subject to review .

# SUBSTANCES OF VERY HIGH CONCERN (SVHC)

- SVHC will be those substances that are placed in the candidate list for authorisation
- Types of substances considered as SVHC
  - Class 1&2 carcinogens
  - Class 1&2 mutagens
  - Class 1&2 toxic to reproductive systems
  - PBT's (persistent, bio-accumulative and toxic)
  - vPvB (very persistent and very toxic)
- Initial candidate list will have only 12-16 substances
- Final list will have around 150 substances
- SVHC may require to be notified by article producers/importers

# RESTRICTIONS

- The restriction aspect of REACH allows the Commission to impose limitations on the marketing and application of certain chemical substances
- Proposals for restrictions on certain substances will be made by MS Competent Authorities or by the ECHA. They will need to be approved by the EU Commission.
- Existing Restrictions set out in the Marketing & Uses Directive (76/769/EEC) will be carried over into REACH and are listed in Annex XVII.

# DATA SHARING

- REACH requires registrants to share data relating to the properties and behaviour of substances in order to generate a joint hazard data set based on Annexes VII – X of the Regulation
- This data sharing principle applies to both new and existing (phase-in) substances
- Although introduced to reduce costs and minimise testing involving animals it adds a complexity to the entire registration process
- **Data sharing does not mean one substance one registration**

# DATA SHARING

- For new substances all M/I will register but one will be lead registrant and will submit the hazard data set in their Technical Dossier. Other registrants then reference this dossier.
- All pre-registrants of a phase-in substance are formed into a *Substance Information Exchange Forum (SIEF)* which lasts 10 years.
- SIEF members share data and testing costs to generate the hazard data set which is used in the Technical Dossier.
- Guidance on cost sharing is available but is not prescriptive.
- How the SIEF organises itself is down to the SIEF members!!
- In both cases it is possible to opt out but only if this can be justified based on cost, confidentiality and/or dispute over interpretation of data.

## DOWNSTREAM USERS (DSUs)

- Downstream users are those companies other than M/I who use substances on their own or in preparations. This includes:
  - Formulators
  - End users
  - Industrial users
  - Article producers
  - Craftsmen
  - Re-fillers
  - *Importer where there is an Only Representative*
- The responsibilities will vary depending upon the DSUs role but the main obligations are.....

## DOWNSTREAM USERS (DSUs) - COMPLIANCE

- DSUs need to notify suppliers of '*identified uses*' and **abide by any conditions of use specified by the supplier for that 'identified use'**.
- **Or** register their own use with ECHA and carry out an exposure scenario and/or Chemical Safety Assessment (CSA) for their use and customers uses.
- Supply sufficient information on an 'identified use' to allow the registrant to generate an exposure scenario
- Pass up the supply chain uses identified by their DSUs or carry out exposure assessment and determine control conditions for those DSU's.
- DSUs must notify the ECHA/supplier of any changes that may effect the risk assessment of a substance.
- Abide by any restriction/authorisations set under REACH.
- **Distributors** are not DSUs but have a role in passing information up and down the supply chain



