SUCCESSFUL REGISTRATION WITHIN REACH

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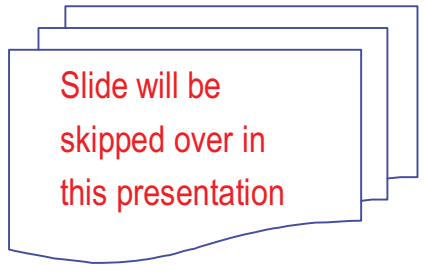
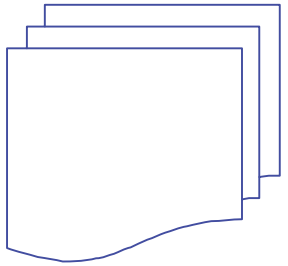


Glossary of Terms (REACH language)

- CMR = Carcinogenic, Mutagenic, Reprotoxic
- CSA / CSR Chemical Safety Assessment / Report
- DU = Downstream User
- ERA/HRA Environmental / Human Risk Assessment
- M/I = Manufacturer / Importer
- OR = Only Representative (SR = Sole Representative)
- PPORD = Product and Process Orientated Research and Development
- QSAR = Quantitative Structure Activity Relationship
- RIP = REACH Implementation Project (Development of Technical Guidance)
- PBT = Persistent Bioaccumulating & Toxic
- SIEF = Substance Information Exchange Forum
- vPvB = very Persistent & very Biaccumulating



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1. Scope of REACH

REACH has a very wide scope. It applies to all chemical substances which are manufactured, imported, placed on the market or used within the European Community, either on their own, in a preparation or in an article.

Some substances are exempted from the overall scope of REACH while others are exempted from certain provisions

2. REACH timetable

2006

- Dec. 31: REACH regulation published in Official Journal L396 as Regulation (EC) No. 1907/2006

2007

- Jun. 1: Entry into force of Regulation
- Publication of final RIP's

2008

- Jun. 1: Entry in to force of REACH Titles for existing (phase-in) substances
- Jun. 1 – Dec 1: Pre-registration period
- Jun. 1: Commencement of registration of new substances (non-phase-in, not pre-registered)

2009

- Jun. 1: First recommendation of priority substances (biennial)

2010 Registration:

- Dec. 1: >1000 t / y per M/I
- Dec. 1: >100 t / y per M/I and R50/53 (dangerous to environment)
- Dec. 1: >1 t / y per M/I and CMR

2013 Registration

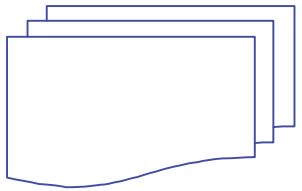
- Jun. 1: >100 t / y per M/I

2018 Registration

- Jun. 1: >1 t / y per M/I

3. Exemptions from registration

- **Substances exempted from REACH** (e.g. radioactive substances, substances under customs control, waste, non-isolated intermediates, substances in the interest of defence)
- **Substances exempted from registration** (food or feeding stuffs, medicinal products, Substances in Annex IV and V, as well as recycled, re-imported and PPORD substances and polymers)
- **Substances regarded as registered** (active substances in biocides, plant protection products, notified substances according to Directive 67/548/EEC)



Further information on exemptions:

Exempt from Registration

- Exclusive human and veterinary medicines
- Food and feedstuff additives and flavorings covered in other directives
- Chemicals listed on
  - -Annex IV (largely fatty acids, vegetable oils and some gasses – this will be revised before end 2007 to exempt some more substances)
  - - Annex V (natural gas, coal, crude oil, radioactive substances)
- Some polymers and monomers as part of a polymer
- Some isolated 'on-site' and isolated 'transported' intermediates

Exempt from Authorization

- Chemicals falling under other Directives i.e. plant protection products (91/414/eec), biocidal products (98/8/EEC) and human & veterinary medicines (2309/93, 2001/82, 2001/83), food (87/101/EEC) and feedstuff additives (70/524/EEC) and flavorings (1999/217/EC)
- Some isolated 'on-site & transported' intermediates

Intermediates

- Non-isolated intermediates (remain in process) are exempted from REACH
- On-site and transported, isolated intermediates (removed from process) need limited registration dossier
  - **On-site**, isolated intermediates under strictly controlled conditions are exempted from Dossier submission and substance evaluation
  - **Transported**, isolated intermediates are exempted from Authorization only

The definition of 'strictly controlled' is still under consideration in the REACH Implementation Programs

Polymers

- A substance …… characterised by the sequence of one or more types of monomer units and comprises the following:
  - (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant (3+1 rule);
  - (b) less than a simple weight majority of molecules of the same molecular weight.
- Polymers are exempted from registration and evaluation for the moment but in the future they may be reassessed.
- Monomers in polymers (> 1t, > 2%) need to be registered under REACH!

4. Chemical naming: why is it important?

REACH contains a new naming convention for substances

On the pre-registration list

- Name is used to determine all the interested parties in each substance to facilitate cooperation and data-sharing

The substance identity is vitally important to:

- Establish sameness (of substances in the same Substance Information Exchange Forum - SIEF)
- Assess impurities
- Establish exemptions, data reductions

On the basis of the new naming convention, pre-registrants will have to:

- Establish the SIEF (a virtual organisation in REACH) based on the sameness of the substance
- Find ways to manage all this without REACH providing legal certainty

REACH definition of substance

Substance: means a chemical element and its compounds:

- in the natural state
- obtained by any manufacturing process
- including any additive necessary to preserve its stability
- Including any impurity deriving from the process used
- excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

Substance identity: types of REACH substances

- **Well defined substances**
  - ***Mono-constituent*** – if the main constituent >80%,
    impurities > 1%, or classified as dangerous, to be specified
  - ***Multi-constituent*** – if the main constituents comprise 10 to 80%,
    impurities > 1%, or classified as dangerous, to be specified
- **Well defined substances with additional identifiers** e.g. physical properties
- ***UVCB*****, Unknown of Variable Composition, Complex reaction products or Biological materials** Biological sources - species name
  - Non-biological sources – starting materials
  - Processes – type of chemical reaction, e.g. synthesis or refining (extraction, fractioning, concentration, residues)
- **Preparations**
  - Mixture or solution composed of 2 or more substances (components) which do not (chemically) react

Effects of substance identity

- All materials have to be re-examined to see whether they are still substances, preparations or articles
- Substance indentity needs to be confirmed before exemptions can be decided – in the case of e.g. polymers analytical information may be required
- Determining sameness based on substance identity is the first job of a Task Force or Consortium
- Impurities may form an important barrier to determining sameness - SIEF formation

5. Registration under REACH

Aim: to ensure that industry adequately manages the risk arising from its substances (starting at 1 tonne / y)

Method – EU Manufacturer / Importer / OR:

- Obtains adequate data
- Provides a registration dossier (IUCLID) which includes a chemical safety assessment and chemical safety report for substances above 10 tonnes / y
- Submits dossier to ECHA authorities (enforcement, transparency)
  - Including increased info requirements according to tonnage (testing proposal)
  - Reduced requirements for polymers and intermediates

New & Existing substances

Phase-in substance: are “existing substances”, i.e. substances which were already being manufactured or placed on the market before the entry into force of REACH.

Non-phase in substances: are “new” chemicals, i.e. substances not already being manufactured or placed on the market

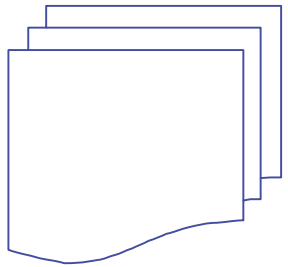
Note: *Such substances are called phase-in substances, because they are being subjected to the registration system in different phases over time*

Phase-in substances are brought in via the following process:

1. Pre-registration (Art. 28)

2. Substance Information Exchange Forum (SIEF) formation (Art. 29, 30) – which carries out the registration work

3. Joint submission of the registration (Art. 11)



Who has to register: actors in the supply chain

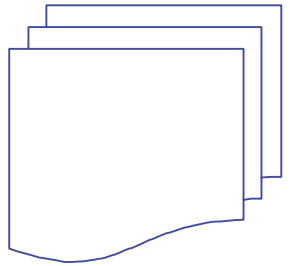
1. EU **manufacturers and importers** of substances on their own or in preparations
2. EU **producers and importers** of articles meeting the criteria explained in the guidance for articles
3. EU-based **"only representatives"** appointed by a manufacturer, formulator or article producer outside the EU to fulfil the registration obligations of importers.

The roles and duties of the main stakeholders of REACH are specified in Appendix 1 of "Guidance on registration" (ECHA, 2007) and Van Leeuwen, Hansen and de Bruijn (2007).

Different roles and responsibilities for industry

A REACH navigator tool has been developed by the Commission to help the users identifying their obligations under REACH. It can be found on:

http://echa.europa.leu/reach_en.htm



Features:

- Interactive tool on the Agency website
- Sequence of questions (supported by guidance) to be answered by the user
- The outcome is a list of obligations for the user
- Each of the obligations will be linked to guidance (RIP projects) describing how to fulfil the users' obligations

What is pre-registration and how does it work?

What: pre-registration is a one time process that has to take place in the period from 1 June 2008 to 1 December 2008.

Aim:

- to take advantage of the transitional registration deadlines. This will allow companies to continue manufacturing and importing their phase-in substances for several years until the registration deadline is reached.
- it will allow manufacturers and importers of the same substance(s) to initiate the data sharing processes.

How: submit a pre-registration dossier during this period.

The pre-registration dossier

Contents

- Company and contact information to the Agency
- Name of the substance including EINECS and CAS number
- The envisaged deadline for the registration and tonnage band
- Specification of possible “read-across” substances

Advice

- Pre-registration creates no legal or other obligation to proceed to a registration
- If in doubt about a substance – you should pre-register
- Read-across information might potentially be sensitive

6. Preparing an inventory before pre-registration

- Confirm tonnages (raw materials, intermediates, products)
- Confirm substance definitions
- Identify exemptions and limited registrations
- Assess data availability
- Map downstream use
- Identify Pre-consortia (other companies preparing for REACH)
- Prepare initial proposal for Grouping & Read-across
- Pre-register

Determine regulatory category of each substance (TNO system for assessing substance status)

Regulatory landscape

- Category 1: Existing substances priority lists 1-4, RAR status
- Category 2: All other existing substances
  - » a) classified in the EU (risk assessment required)
  - » b) not classified
- Category 3:monomer registration for polymers
- Category 4: transported intermediates
- Category 5: on-site intermediates
- Category 6: articles for intended release or candidate authorization substances
- Category 7: exemptions from registration
- Category 8: misc. undefined products, re-usable waste streams
- Category 9: New substances!

Inventory check-list leading to pre-registration and registration: TNO procedure

- Substance inventory, identity & composition
- Determine regulatory category of each substance
- Identify existing consortia
- Quality check of existing Company data
- Economic value of existing Company studies (helps determine consortium position)
- Gather publicly available data (hot spots, gaps, trends)
- Carry out a preliminary PBT(CMR) vPvB check
- Establish Company data gap table
- Proposal for grouping & read across (internal to portfolio & external)
- Use and exposure data (quick-scan)
- Preliminary risk assessment

7. SIEFs, Task Forces & Cooperation

- There is only one dossier per substance – data sharing is obligatory – cooperation with competitors in the best (only) way forward
- A SIEF is a total list of companies who have pre-registered a given substance – it has no structure or entity in its own right
- A Consortium or Task Force is formed by industry to carry out the real REACH work (IUCLID Dossier, CSA, CSR)

Registration: company options & opting out

- One Substance, One Dossier = OSOD – intended to reduce the burden of animal testing and increase efficiency
- Some aspects of registration may be approached by individual M/I on their own without opting out:
  - Guidance on safe use
  - Chemical Safety Report
  - Indications regarding review by a 3rd party assessor
- Opting out (refusing joint registration)
  - Joint submission would be disproportionately costly
  - Would lead to disclosure of commercially sensitive information
  - Disagreement with lead registrant on selection fo information
  - May lead to evaluation of dossier

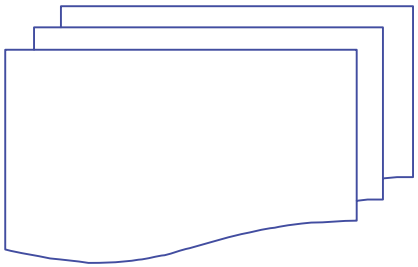
Task Forces/ Consortia

- Task Forces need lean and efficient management – 3-4 market leaders (avoid big committees)
- Task Forces need legal, administrative and scientific expertise (clear contracts, strong administration, good science)
- There are three levels:
  - Lead registrant (market leader or their nominee)
  - Active participant (management/scientific team member)
  - Corrsponding member/passive participant – can be data contributer/sharer
- Where possible use existing industry cooperative structures

8. Only representative and importer responsibilities

A natural or legal person established outside the Community who manufactures and imports into the Community:

- a substance on its own
- in preparations
- in articles
- formulates a preparation (of substances)
- produces an article (containing substances)



May by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers

Obligations of an OR

The only representative shall also comply with all other obligations of importers under this Regulation:

- Sufficient background in the practical handling of substances and the information related to them
- Maintain up-to-date information on quantities imported and customers sold to
- Information on the supply of the latest update of the safety data sheet referred to in Article 31.

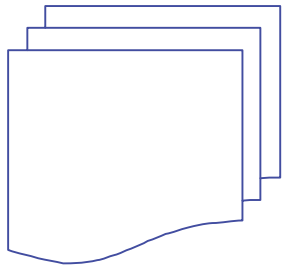
Manufacturers in the EU have the same obligations as importers of substances and an OR takes over the responsibilities of an importer: all three have equal responsibility (liability and contractual relationships are a problem for independent OR's) – an OR is not the same as an SR under the old legislation

9. Authorisation – some advice

- Authorisation is the licencing process whereby substances of high concern are selected for further examination and possible restriction
- Its underlying intention is sooner or later to remove such substances from the market
- PBT(CMR) classification is the start of the authorisation mechanism
- Substitution of authorised substances is also a goal of the legislation – room for innovation?
- Identifying potentially PBT(CMR) substances at an early stage is an important part of preparing a REACH inventory of your chemicals portfolio

PBT Requires a separate strategy in REACH!

1. Persistent, Bioaccumulating, & Toxic		2. Very Persistent & very Bioaccumulating	
1.1.	***Persistent***	***2.1***	***Very Persistent***
	half-life • **marine water > 60d, or** • **fresh- or estuarine water > 40d, or** • **marine sediment > 180d, or** • **fresh/estuarine water sediment > 120d, or** • **soil > 120d**		***half-life*** • **marine, fresh or estuarine water > 60d, or** • **marine, fresh- or estuarine water sediment > 180d, or** • **soil > 180d**
1.2	***Bioaccumulating***	***2.2***	***Very Bioaccumulating***
	• **BCF >2000.**		• **BCF > 5000.**
1.3	***Toxic***		
	• **long-term NOEC to marine or freshwater organisms < 0.01 mg/l, or** • **carcinogenic (category 1 or 2), or** • **mutagenic (category 1 or 2), or** • **toxic for reproduction (category 1 or 2), or** • **other evidence of chronic toxicity, i.e. R48, T, [toxic] or Xn, [harmful]**		



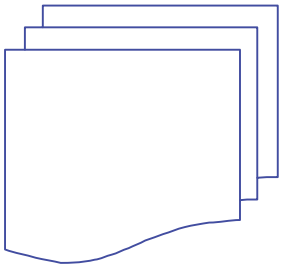
Defending a candidate PBT substance

- PBT is a hazard based and not a risk based classification mechanism
- Finding residues in the environment (soil, sediment, biota) gives a strong political argument in favour of PBT classification and authorisation
- P and B are expensive to defend with experimental data (watch out for vP and vB)
- T is multifunctional (aquatic environment and human health) – animal testing to avoid classification will not be allowed
- A carefully thought out strategy is required
- Defense on socio-economic grounds (no substitutes available) may be important

10. Summary: What can help to reduce the burden

- General exemptions from registration (Annex IV & V), Non-isolated intermediate exemptions
- Polymer exemptions (3+1 rule),
- On-site & Transported isolated intermediates
- Data sharing (One Substance One Dossier)
- Grouping & read-across, QSAR, data waivers
- PPORD Product and Process Orientated Research and Development
- Join forces with a reliable and knowledgable REACH specialist such as TNO

Relevant websites



- Website of the European Chemicals Bureau: http://ecb.jrc.it/reach/
- Website of the European Chemicals Agency: http://ec.europa.eu/echa/home_en.html
- Websites of the European Commission
  http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
  http://ec.europa.eu/enterprise/reach/index_en.htm
- http://ecb.jrc.it/DOCUMENTS/REACH/REACH_in_brief_0207.pdf
- Helpdesks of the EU member states, i.e.:
  http://www.reachright.ie
  http://www.senternovem.nl/reach