



REACH

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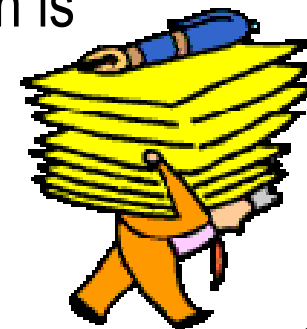
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What is REACH?

- A new EU regulatory framework for chemicals management; intent is to require existing materials to have same EH&S information (hazard/exposure/risk assessment) as new substances
- Under the new system called REACH (Registration, Evaluation and Authorization of CHemicals), manufacturers and importers of chemicals will be required to submit hazard, use, exposure and risk data for substances manufactured or imported in quantities of more than one metric ton per year (type and extent of information is depending upon volume and hazard profile.)



REACH – What does it mean?



REACH:

- R = Registration (> 1 mt/year)
- E = Evaluation (> 100 mt/year)
- A = Authorization (only for substances of high-concern*)
- CH = Chemicals

- A single regulatory system (EU law) for new and existing chemicals that will replace different pieces of the current EU Legislation on chemicals
- Who will be affected?
 - **the manufacturer or importer of substances,**
 - **the importer of hazardous substances in preparations/articles,**
 - **the downstream user, if his substance is not covered by the manufacturer or importer.**

* “High concern” = CMRs (cat. 1 and 2), PBTs, vPvBs

Responsibilities under REACH:

Registration by Manufacturer/Importer:

- Registrant collects and submits hazard, use and risk information to Chemical Agency for each substance subjected to REACH
- Agency releases substance for manufacturing, import and use

Evaluation by Authorities includes:

- Compliance check of registration dossiers (Agency)
- Assessment of need for additional data (Commission)

Authorization provides:

- Identification of substances which are banned for general use
- Authorization of specific uses of such substances (banned for general use) under defined risk management regimes

Scope: Substances, Preparations and Articles

- REACH applies to **substances**. Substances can be on their own, in preparations (intentional mixtures of 2 or more substances), or articles.
- In principle, all substances manufactured in Europe or imported into Europe are subject to the REACH requirements.
- Exemptions are based on use (e.g. food additives, biocides, medicinal/veterinary products), or listed in Annex IV of REACH (e.g. cellulose pulp, glucose, ascorbic acid, etc.), or derived from the criteria listed in Annex V of REACH (e.g. substances occurring in nature if they are not chemically modified and not classified as hazardous)

Substances, Preparations and Articles

- **Preparations**: the different components (substances) need to be considered for the REACH assessment.
- **Articles**: substances contained in articles need to be registered if they are:
 - ✓ **present at >1 t/yr, and**
 - ✓ **intended to be released**
- **Substances in articles** need to be notified to the Agency if they are:
 - ✓ **on the candidate list for authorization,**
 - ✓ **present at >1t/yr and present in article at > 0.1%**

Monomers and Polymers

Polymers are exempted from registration (not authorization!).

However:

- Manufacturers/Importers of polymers have to register monomers as well as any other substances that have been reacted into the polymer backbone if
 - **The polymer consists of 2% or more by weight of such monomers or other substances, and:**
 - **The volume of monomers or other substances in reacted form >1 t/yr**
- Polymer additives need to be registered if they are manufactured or imported in volumes of 1 t/yr.
- No-longer polymers (e.g. small polyols) are considered to be substances under REACH and will require full registration.

* according to the OECD polymer definition



Summary of REACH requirements

REACH -scope	Registration	Authorization
Substance	Full registration, volume dependent	CMRs, PBTs
Intermediates	Reduced requirements	Exempted
Monomers	Full registration, no reduced requirements	Exempted
Polymers	Exempted	Not exempted

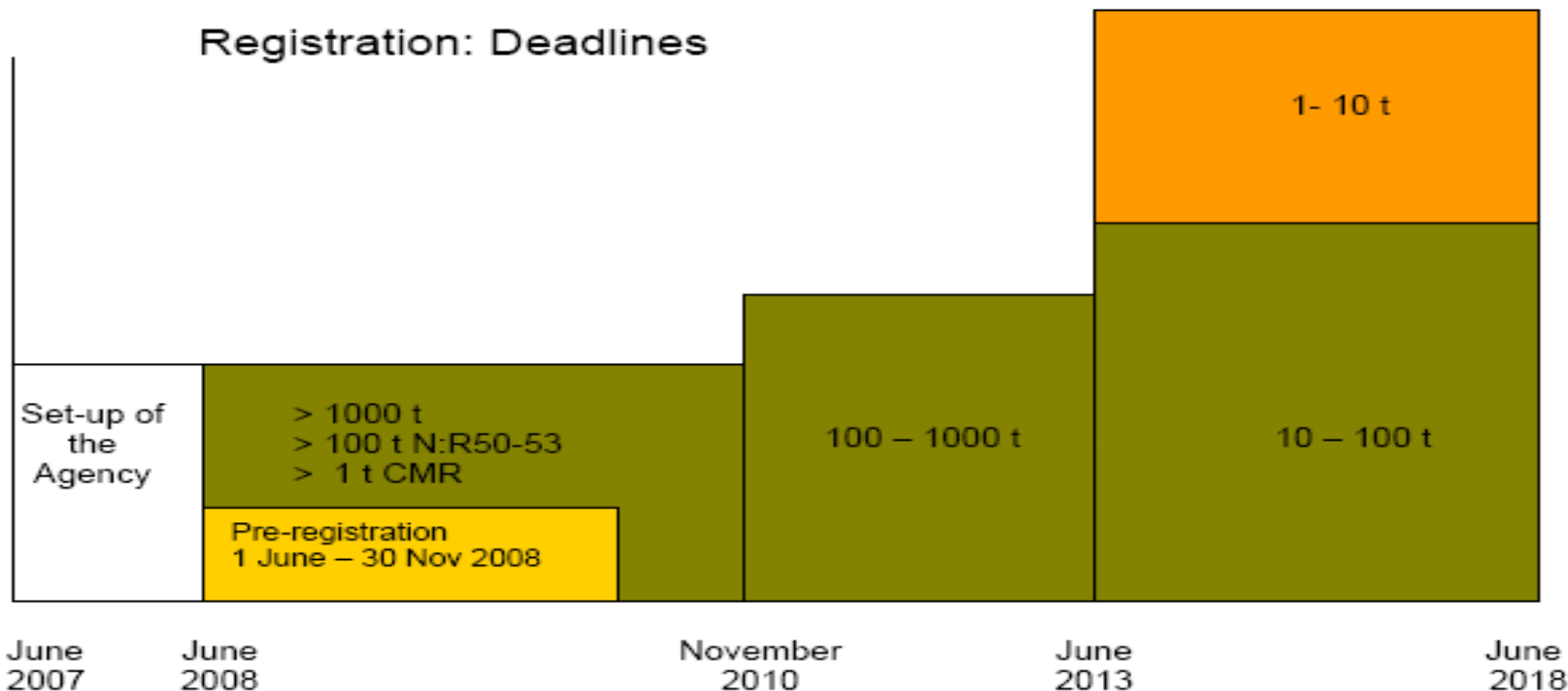
The REACH Registration Process

- Pre-registration in 2008 (July – November)
- Followed by registration by volume band
 - Nov. 2010 - > 1000tpa
 - May 2013 - > 100tpa
 - May 2018 - > 1tpa
- Fixed minimum data set required by volume band by the registration deadline. Note that data may become available from the 'SIEF' – Substance Information Exchange Forum which will drive mandatory data sharing of animal studies.
- Post registration, fixed data set by volume band needs to be addressed in testing and/or waiving proposal. Note that data may become available from the 'SIEF'.

REACH TIMELINE



- Registration required for all substances >1 t/year/legal entity
- 18 months pre-registration for phase-in substances (substances on the European Inventory). Must complete or phase in substances considered immediately in scope.
- Registration starts for high volume substances (>1000 t), for substances very toxic to the aquatic environment (>100 t) and Carcinogen, Mutagens or Toxic to reproduction (>1t)



REACH – Time lines and Requirements

- During Pre-registration phase or immediately thereafter:
 - Formation of SIEF for each pre-registered substance
- **SIEF**: Substance Information Exchange Forum
 - Mandatory sharing of existing animal data between potential registrants of the same substance!
 - We need to know what data we have in our files!
- **Registration** deadlines of phase-in substances:
 - > 1000 t/a, CMRs 1&2, R50-53 at >100 t/a by November 30, 2010
 - > 100 t/a by May 31, 2013
 - > 1 t/a by May 31, 2018

Pre-Registration: Information submitted

- Name and address of the potential registrant (each legal entity)
- Name of the contact person
- Name of the substance:
 - **IUPAC or other international chemical name(s)**
 - **Other names (usual name, trade name, abbreviation)**
 - **EINECS or ELINCS number (if available and appropriate)**
 - **CAS name and CAS number (if available)**
 - **Other identity code (if available)**
- Envisaged deadline for the registration (tonnage band)
- Substance(s) identifiers for which the available information is relevant for the application of (Q)SAR, grouping of substances or a read-across approach)

SIEF = Substance Information Exchange Forum

- Following the pre-registration process, the Commission will publish the list of pre-registered substances and the potential registrants for each substance.
- SIEF designed to facilitate sharing of data/information between potential registrants of a substance and to agree on Classification and Labelling,
- Data-sharing, items to consider:
 - ✓ Data requirements (volume driven, Annex VII to XI & RIP 3.3)
 - ✓ Information retrieval
 - ✓ Data availability and data gaps
 - ✓ Classification & Labelling
 - ✓ Data sharing requirements (source Title III of REACH & RIP 3.4)
- SIEF will be operational until 1 June 2018

Annex VII (1-10 t/y) requirements

- State of the substance at 20° C
- Physical-chemical data (13 endpoints)
- *In vitro* skin irritation
- *In vitro* eye irritation
- Skin sensitisation (local lymph node assay)
- Mutagenicity: *in vitro* gene mutation assay in bacteria (Ames test)
- Acute toxicity (oral route)
- Acute toxicity to invertebrates (Daphnia)
- Growth inhibition study on aquatic plants (algae)
- Degradation: ready biodegradation test

Annex VIII (10-100 t/y) requirements

Annex VII requirements, plus:

- *In vivo* skin irritation
- *In vivo* eye irritation
- *In vitro* cytogenetic test in mammalian cells
- *In vitro* gene mutation test in mammalian cells (if the results of other *in vitro* tests are negative)
- Acute toxicity (inhalation or dermal route)
- Short-term repeated dose toxicity study (28-day), oral route
- Screening for reproduction/developmental toxicity (OECD 421 or 422)
- Assessment of toxicokinetic behaviour
- Short-term toxicity testing on fish
- Activated sludge respiration inhibition test
- Abiotic degradation: hydrolysis as function of pH
- Adsorption/desorption screening

For 1-100 t/y substances

- Data/Information needs to be available, but:
 - Read-across or QSARs possible to fill data gaps
 - Adaptations to the requirements possible, if criteria listed in column 2 of Annexes VII and VIII are met.
 - Example: an *in vivo* eye irritation study does not need to be conducted if the substance is classified as a severe eye irritant or corrosive to skin, if the substance is a strong acid or base, if the substance is flammable in air at room temperature.
 - Exposure-based waiving only possible for the 28-day study and screening reprotox study, and only if relevant human exposure can be excluded in accordance with Annex XI (section 3) of REACH.
 - Based on exposure scenarios developed in the CSR
 - Justification and documentation shall be provided

Annex IX (100 -1000 t/y) requirements



- Stability in organic solvents and identity of relevant degradation products, dissociation constant, viscosity
- Other *in vivo* mutagenicity test: micronucleus test (OECD 474) or UDS assay (OECD 486)
- Sub-chronic toxicity study (90-day) in rats (oral gavage, dermal or inhalation)
- Developmental toxicity study, rats, oral gavage
- One or two-generation reproduction toxicity study, oral gavage
- Long-term toxicity testing on Daphnia, 21-days
- Fish early-life stage (FELS) toxicity test or Fish short-term toxicity test on embryo and sac-fry stages Fish, juvenile growth test
- Simulation testing on ultimate degradation in surface water
- Soil simulation testing (for substances adsorbing to soil)
- Sediment simulation testing (for substances adsorbing to sediment)
- Identification of degradation products
- Bioconcentration in (one) aquatic species, preferably fish
- Further studies on adsorption/desorption
- Further environmental fate and behaviour studies
- Short-term toxicity to earthworms
- Effects on soil micro-organisms
- Short-term toxicity to plants

1. Test plan or proposal for waiving of testing needs to be submitted
2. Testing can not started before test plan has been approved by the Agency

Annex X (> 1000 t/y) requirements

- Long-term repeated toxicity study (longer than 12 months)
- Carcinogenicity study/combined chronic toxicity, rats, dietary route
- Long-term toxicity testing on earthworms
- Long-term toxicity testing on soil invertebrates other than earthworms
- Long-term toxicity testing on higher plants
- Long-term toxicity to sediment organisms
- Long-term or reproductive toxicity to birds

1. Test plan or proposal for waiving of testing needs to be submitted
2. Testing can not started before test plan has been approved by the Agency

REACH – General Conclusions

”No data no market”

- All substances ≥ 1 ton/year need to be registered
- Data requirements by tonnage band
- EU manufactures and importers have same registration obligations
- Downstream users have also obligations
- REACH gives greater responsibility to industry
 - to manage the risks from chemicals,
 - to generate safety info, and
 - to pass safety info down the supply chain
- Mandatory data sharing (animal studies)

Impact to Biocides Businesses



Active substances manufactured or imported for use in biocidal products **only** and included either in Annexes I, IA or IB to **Directive 98/8/EC** of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market or in Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, **shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product** and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title

REACH and BPD

Which means:

- That non-biocidal uses (including cosmetics/personal care, as not covered under the BPD) require registrations under REACH. So, uses not covered in the 23 Product Types from are in-scope for REACH.
- Note that for plant protection products, the active ingredient and co-formulants shall be considered as registered under REACH if registered under the Plant Protection Directive (PPPD) and for PP use only.



QUESTIONS??