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Risk & Policy Analysts

Understanding REACH: Registration

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Presentation Overview

1. Registration: Overview
2. Information Sharing
3. Chemical Safety Assessment
4. Submitting a Registration
5. Supply Chain Issues
6. Guidance

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Registration: Overview

- **Disclaimer:** REACH is a very complicated piece of legislation. Everything included here should be correct but has been simplified compared to 'real-life'. Caution is required because there is an exception to almost every obligation under REACH!
- **Who needs to register?** – Manufacturers & Importers
- **What needs registering?** – All substances that a registrant manufactures or imports in quantities greater than 1 tonne/ annum
- **Who is affected?** – Anyone who uses the substance: Manufacturers and Users (Industrial, Professional & Consumer)
- **Please Note:** Each Registration applies to the supply of **one substance** by **one company**
  Some substances are exempt from Registration

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Information Sharing – Joint Registration

Registrants of same substance jointly submit information on:

- Hazardous properties (compulsory);
- Classification and labelling (compulsory);
- Testing proposals (if any) (compulsory);
- Chemical safety report (voluntary); and
- Guidance on safe use (voluntary).

But must also submit individual registrations that refer to the joint registration (know as lead registration)

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Information Sharing – Joint Registration cont.

Why joint registration?

- to save money by co-operating on the preparation of the dossier via SIEF; and
- to reduce the need for testing, in particular on vertebrate animals

But can opt out – Individual Registration

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Information Sharing - SIEFs

- **What is a SIEF?** – Substance Information Exchange Forum to share information and costs of registration (especially for Chemical Safety Assessment)
- **How is a SIEF organised?** – SIEF for every substance but up to industry to organise with some support and guidance (e.g. ECHA support for Lead Registrants and guidance documents)
- **What does a SIEF do?** – Co-operation, Data sharing, Data gathering (filling gaps inc. additional testing), Joint Registration
- **Issues** – Competitors have to agree a legal framework for working together and sharing valuable data – often against short time-frames – with different time-frames for different registrants
- **Number of Lead Registrants** – 2072 (02/12/2009)

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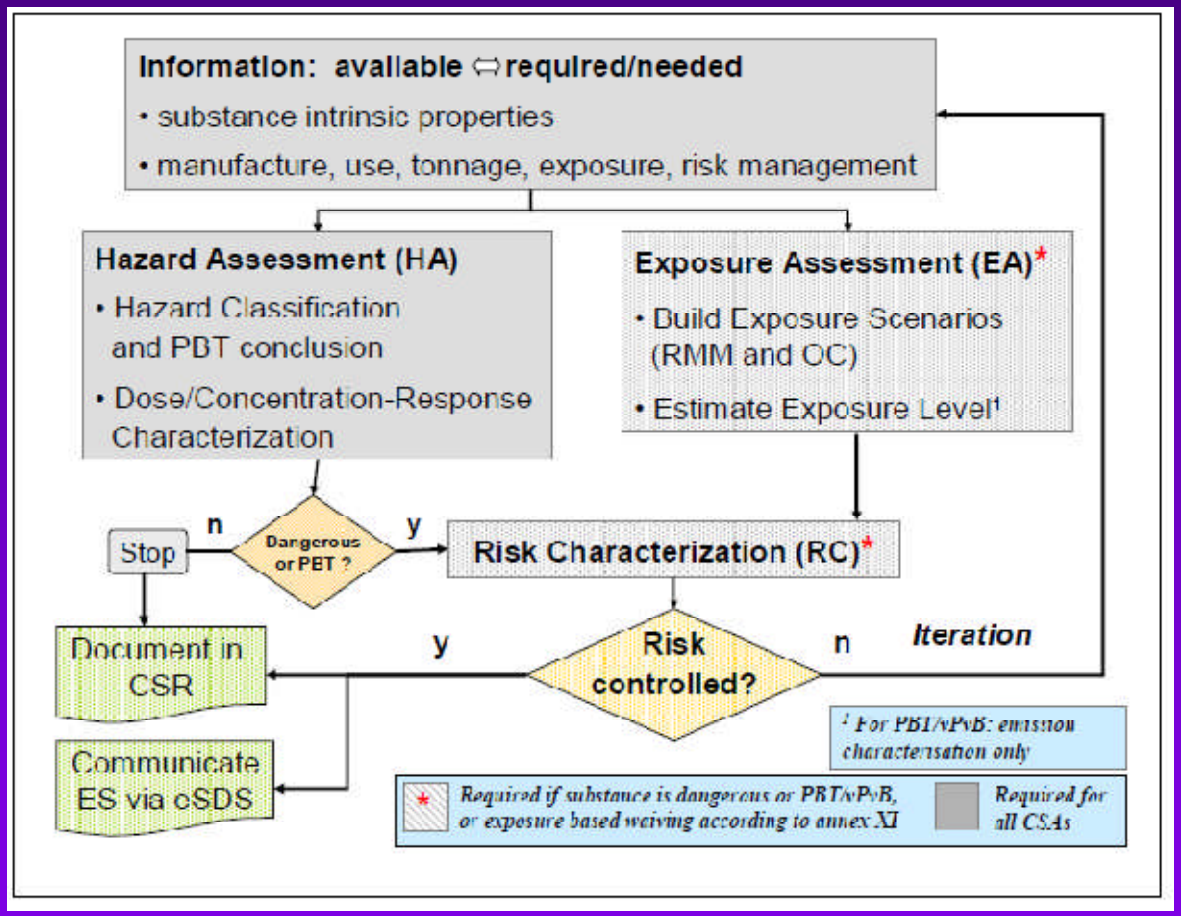
Chemical Safety Assessment - Process



Source: ECHA Guidance on Information Requirements

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CSA - Hazard Assessment

The information requirements for the Hazard Assessment are set out in Annexes VII to X to REACH, where the level of information required increases depending upon the quantity manufactured or imported each year:

- 1 tonne or more (Annex VII)*;
- 10 tonnes or more (Annex VIII)*;
- 100 tonnes or more (Annex IX)*; and
- 1,000 tonnes or more (Annex X)*.

* Tonnages manufactured/imported by each company not total for EU

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Hazard Assessment Information - 1

Physicochemical Properties	Tonnage Threshold/s	Annex/es
State of substance	1	VII
Melting/freezing point	1	VII
Boiling point	1	VII
Relative density	1	VII
Vapour pressure	1	VII
Surface tension	1	VII
Water solubility	1	VII
Partition coefficient	1	VII
Flash-point	1	VII
Flammability	1	VII
Explosive properties	1	VII
Self-ignition temperature	1	VII
Oxidising properties	1	VII
Granulometry (solids only)	1	VII
Stability in organic solvents and identity of relevant degradation products	100	IX
Dissociation constant	100	IX
Viscosity	100	IX

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Hazard Assessment Information - 2

Toxicological Information	**Tonnage Threshold/s**	**Annex/es**
Skin irritation or skin corrosion (VIII)	1 & 10	VII & VIII
Eye irritation (VIII)	1 & 10	VII & VIII
Skin sensitisation	1	VII
Mutagenicity (VIII & X)	1 & 1,000	VII & X
Acute toxicity (VIII)	1 & 10	VII & VIII
Repeated dose toxicity (IX & X)	10, 100 & 1,000	VIII, IX & X
Reproductive toxicity (IX & X)	10, 100 & 1,000	VIII, IX & X
Toxicokinetics	10	VIII
Carcinogenicity study	1,000	X
Ecotoxicological Information		
Aquatic toxicity (VIII & IX)	1, 10 & 100	VII, VIII & IX
Degradation (VIII, IX & X)	1, 10, 100 & 1,000	VII, VIII, IX & X
Fate and behaviour in the environment (IX & X)	10, 100 & 1,000	VIII, IX & X
Effects on terrestrial organisms (X)	100 & 1000	IX & X
Long-term toxicity to sediment organisms	1,000	X
Long-term or reproductive toxicity to birds	1,000	X
Other		
Description of analytical methods supplied on request	100	IX

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Hazard Assessment Output

"Safe" thresholds for exposure:

- Human Health – Derived No Effect Level (DNEL)
- Environment – Predicted No Effect Concentration (PNEC)

But not all hazards have a threshold!

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Hazard Assessment PBT/vPvB

- **PBT** = **P**ersistent, **B**ioaccumulative and **T**oxic
- **vPvB** = very **P**ersistent and very **B**ioaccumulative

as set out in Annex XIII to REACH (1 page)

Plus…….

Guidance from ECHA on Information Requirements:

- Part C (16 pages); and
- Chapter R11 (97 pages).

Please note: CMR properties considered in main hazard assessment

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Exposure Assessment

Identify use conditions and risk management measures throughout the lifecycle in the EU including:

- manufacture;
- formulation;
- industrial use;
- professional use;
- consumer use (DIY), if relevant; and
- waste (collecting, treating, recycling and disposal).

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Exposure Assessment cont.

ECHA guidance documents set out standard use descriptors:

- Sector of Use (SU);
- Chemical product Category (PC);
- PROcess Category (PROC);
- Article Category (AC); and
- Environmental Release Categories (ERCs).

Together these describe Exposure Scenarios for a Substance

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Exposure Assessment cont.

Software tools including:

- EUSES 2.1 (developed before REACH);
- ECETOC TRA (developed by industry); and
- ECHA Tool (not yet available).

Produce estimates of the exposure

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Risk Characterisation

To produce a Risk Characterisation Ratio (RCR):

$$RCR = \frac{PEC}{PNEC} \text{ or } \frac{Exposure}{DNEL}$$

Hazards with thresholds only ie. not PBT/vPvB or all CMRs

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Risk Characterisation cont.

Iterations of CSA until:

- RCR < 1 for all uses;
- RCR < 1 for all environments and people; and
- Rigorous control of all non-threshold hazards.

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Submitting Registration to ECHA

- Technical Dossier (CSA and Details of Registrant)
- Chemical Safety Report (CSR)
- Format (IUCLID 5 and plug-ins)
- Fees and Fee Structure

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Chemical Safety Report

CSR:

- Summarises the CSA and its findings;
- Is the source of information to be communicated further down the supply chain (extended Safety Data Sheet);
- Should be readily understandable as a stand-alone document;
- Standard template provided by ECHA;
- Accompanies the Technical Dossier; and
- Submitted to ECHA.

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IUCLID 5

- Software provided free of charge
- All CSA data must be included
- MUST be used to submit registration to ECHA via REACH-IT
- REACH-IT = ECHA Portal for registration before and after submission

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Fees and Fee Structure

Fees for submitting and updating registration.

Fees lower for:

- Joint registrations;
- Lower tonnages (1,000, 100, 10 and 1); and
- Medium, small and micro enterprises (SMEs).

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After Submitting Registration

- Virus and administration check {ECHA automated};
- Technical and financial completeness check {ECHA};
- Dossier evaluation (at least 5%) {ECHA}:

  a. Testing proposals; and

  b. Compliance check;
- Substance evaluation {Competent Authorities}; and
- Registration dossier must be kept up-to-date by registrant.

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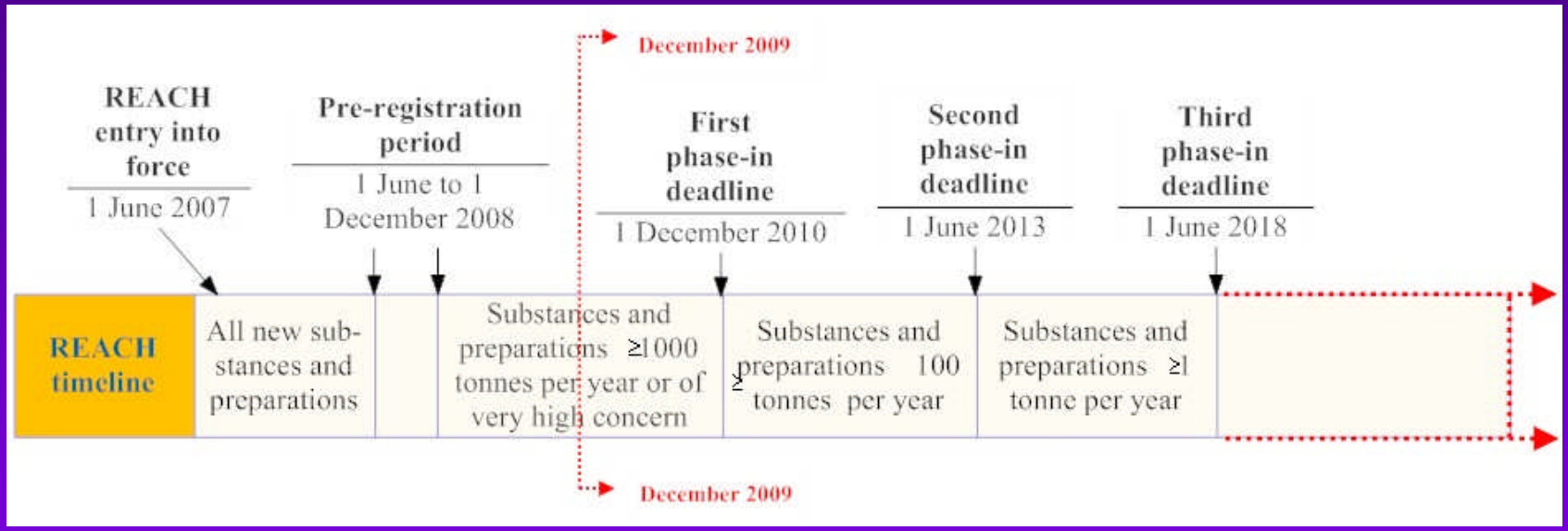
Registration - Timescale



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Supply Chain Issues

- Communication of Uses (Manufacturers/ Importers and Downstream Users)
- Problems (Uses not communicated to registrants, uses not included in registration, shock to companies not part of the 'Chemical Industry' e.g. importers and supermarkets)
- Extended Safety Data Sheets (eSDS) (plus communication where SDS not required)

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Registration Guidance

- ECHA (e.g. Registration, Information Requirements, CSA, CSR, Information Sharing, IUCLID 5, newsletter and helpdesk)
- Competent Authority – Clarification on interpretation (e.g. Accessible guidance documents, newsletter, helpdesk)
- Industry – Practical application often focused on specific industry (e.g. Generic Exposure Scenarios, imports, isolated intermediates)
- Private companies

Please Note: Only the text of REACH is legally binding

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Thank You

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