REACH and needs for screening data

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Content

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- Use/needs for monitoring data
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  - Substances of Very High Concern (SVHCs) (authorities)
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  - Restrictions (authorities)
- Conclusions

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REACH-regulation (EC No 1907/2006)

- Came into force 1st June 2007
- REACH provisions will be implemented step by step
- All provisions in force by 11 years from entry into force
- Objectives:
  1) Improved protection of human health and the environment
     - More information on exposure and effects to ensure safe use of chemicals
     - Increased industry responsibility on risk management
  2) Efficient functioning of the internal market
     - Free movement of substances
     - Enhance innovation/competitiveness

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REACH – main elements

1.Registration
- manufacturer of importer of a substance compiles a registration dossier and submits it to ECHA
- collect information about substances and ensures their safe use

2.Evaluation
-ECHA and Member States Authorities evaluate dossiers and substances
-ensure compliance with registration requirements and fill in information needs to verify suspected risks

3. Authorisation
- manufacturer, importer or downstream user applies for authorisation for using a substance of very high concern
- promote substitution by safer alternatives and ensure adequate control of risks

Main goal is to ensure safe use of substances

Safety net: Restrictions on marketing and use

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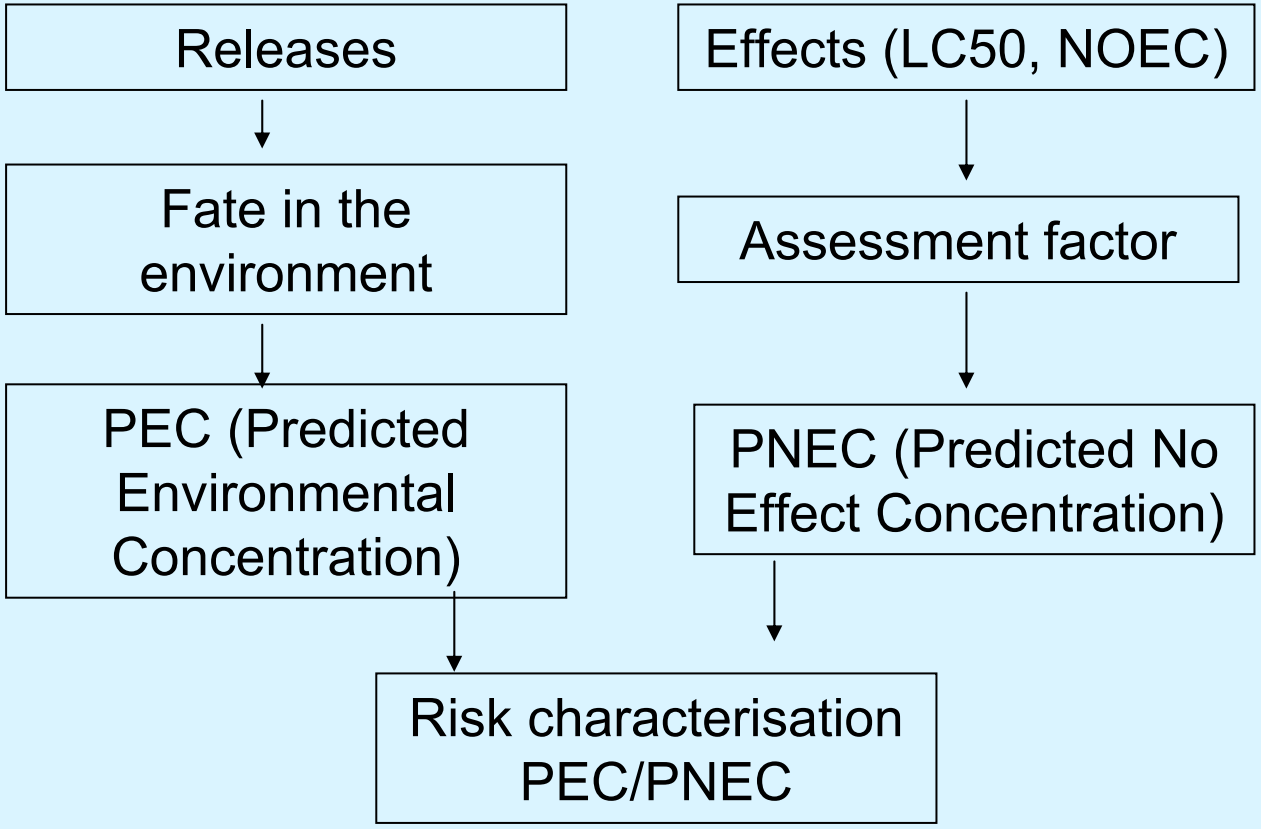
Chemical Safety Report for the environment



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1. Registration: Exposure assessment

- Exposure assessment not requirement for all substances:
  - Production or import of a substance > 10 tons/year/producer or importer and
  - Classified as dangerous for human health or the environment or assessed to be PBT or vPvB
- Obligation of the Registrant, but needs exposure data (monitoring) from users
- Registrant to provide Exposure scenarios for all identified uses as part of Chemical Safety Report
- For each exposure scenario:

  (1) emission estimation;

  (2) assessment of chemical fate and pathways;

  (3) estimation of exposure levels (fresh water/marine water, wastewater treatment plant, sediment, soil, air, accumulation via food-chain)

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ECHA Guidance on information requirements and chemical safety assessment - Chapter R16 - Guidance on Environmental Exposure Estimation

- Measurements/monitoring can be used as:
  - part of carrying out release and exposure estimation by the M/I
  - part of the user → M/I communication. This could happen if the user has relevant measured data, e.g. on measured release factors of a substance
- Adequately measured and representative data
  - Quality of sampling and analytical techniques
  - Temporal and spatial variations
- Table R.16-2: Quality criteria for use of existing measured data (based on OECD, 2000)
- Measured data should be compared to calculated PEC. For naturally occuring substances background concentration have to taken into account. High quality data shall overwrite calculated values

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2. Registration: PBT/vPvB - assessment

- Obligation of a registrant as part of Chemical Safety Report
- Aims to determine if substance fullfills the criteria in Annex XIII and if so, to characterise the emissions
- Annex XIII on PBT/vPvB criteria revised – will include more flexibility in fullfilling the criteria
- If the available information is not sufficient to decide whether the substance fulfils the criteria in Annex XIII, then other evidence like monitoring data available for the registrant and giving rise to an equivalent level of concern shall be considered on a case-by-case basis

PBT = Persistent, Bioaccumulative and Toxic

vPvB = very Persistent, very Bioaccumulative

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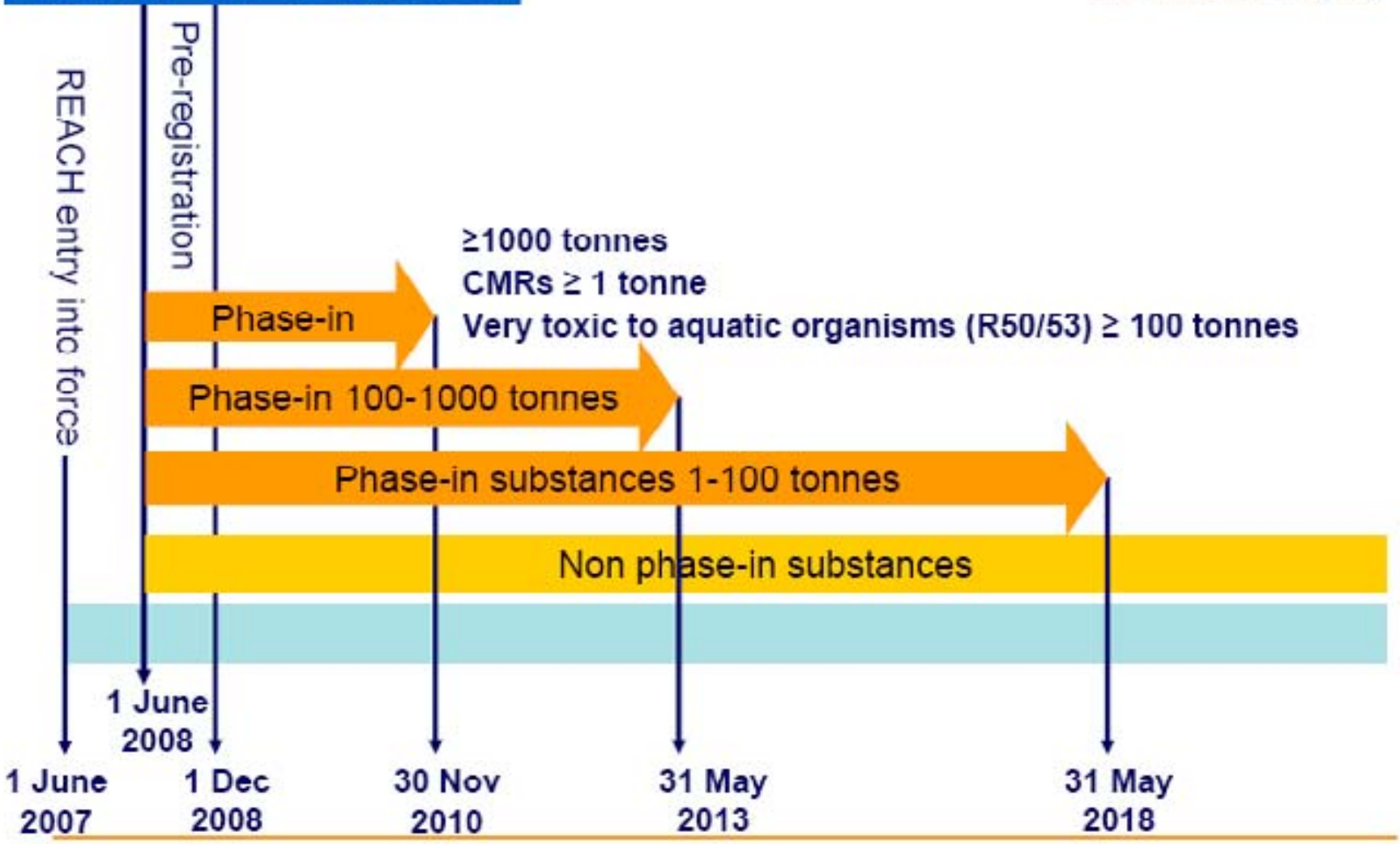
When to register



2. Substance evaluation

- Aims to clarify a concern that a given substance constitutes a risk to human health or the environment
- Competent authorities (CAs) have a suspicion, propose substance, make the evaluation and propose further actions
- First list of substances (CoRAP) by 1.12.2011, list will be updated annually
- If monitoring data available can be used by authority to show that the substance may pose a risk
- May lead to:
  - Request for further information
  - Classification proposal
  - Restriction proposal
  - Proposal to be included in the Candidate list

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3. Substances of Very High Concern (SVHCs)

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR) classified in category 1 or 2,
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to criteria in Annex XIII of REACH,
- Substances of equivalent level of concern
- Identifications (proposals) by authorities
- Monitoring data can be used to show that substance persistent in the environment
- SVCHs constitute a Candidate list, which is regularly updated (38 substances)
  http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp
- SVCHs will be gradually included in authorisation

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4. Authorisation

- Apply only to SVHC substances
- Aim:
  - Risks of SVHCs are properly controlled during use
  - Substances are progressively replaced by suitable alternatives where economically and technically viable
- Producers, EU importers or users of SVHCs apply authorisation from ECHA for their use
- 6 substances agreed at the REACH committee to be included to the authorisation process
- Still subject to Parliament formal approval
- Publication at OJ probably early next year

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Draft Commission Regulation on amending Annex XIV on REACH

	Transitional arrangements		
Substance	Application	Sunset	Intrincic property
5-tert -butyl -2,4,6-trinitro-m-xylene (musk xylene)	24 months	42 months	vPvP
4,4'-Diaminodiphenylmethane (MDA)	24 months	42 months	Carcinogenic
Hexabromocyclododecane (HBCDD)	36 months	54 months	PBT
Bis(2-ethylhexyl)phtalate (DEHP)	30 months	48 months	Toxic for reproduction
Benzyl butyl phtalate (BBP)	30 months	48 months	Toxic for reproduction
Dibuthyl phtalate (DBP)	30 months	48 months	Toxic for reproduction

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Applications and granting of authorisations

Applications (by industry)

- **Chemical Safety Report (incl. monitoring)**
- **Analysis of possible alternative substances or technologies**
- **If suitable alternative, need to provide substitution plan**

Granting authorisation (by Commission)

- **Applicant demonstrate that the risk from use of substance adequately controlled.**
- **Possibility for monitoring obligation to industry**
- **The "adequate control route" does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.**
- **Socio-economic reasons may result in granting authorisation**

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5. Restrictions

- If monitoring data available which show that a substance may pose a risk to the human health or the environment, a Member State may prepare a restriction proposal
- MS need to provide Chemical Safety Report, data on alternatives and socio-economic assessment
- Community-wide restriction
- Annex XVII of REACH will be amended

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Conclusions

Possibilities for authorities to use monitoring data in REACH processes

- **Registration: no**
- **Substance evaluation: yes**
- **SVHC-identification: yes**
- **Authorisation: not known yet**
- **Restrictions: yes**

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Thank you for your attention!

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