Short on ECHA registration

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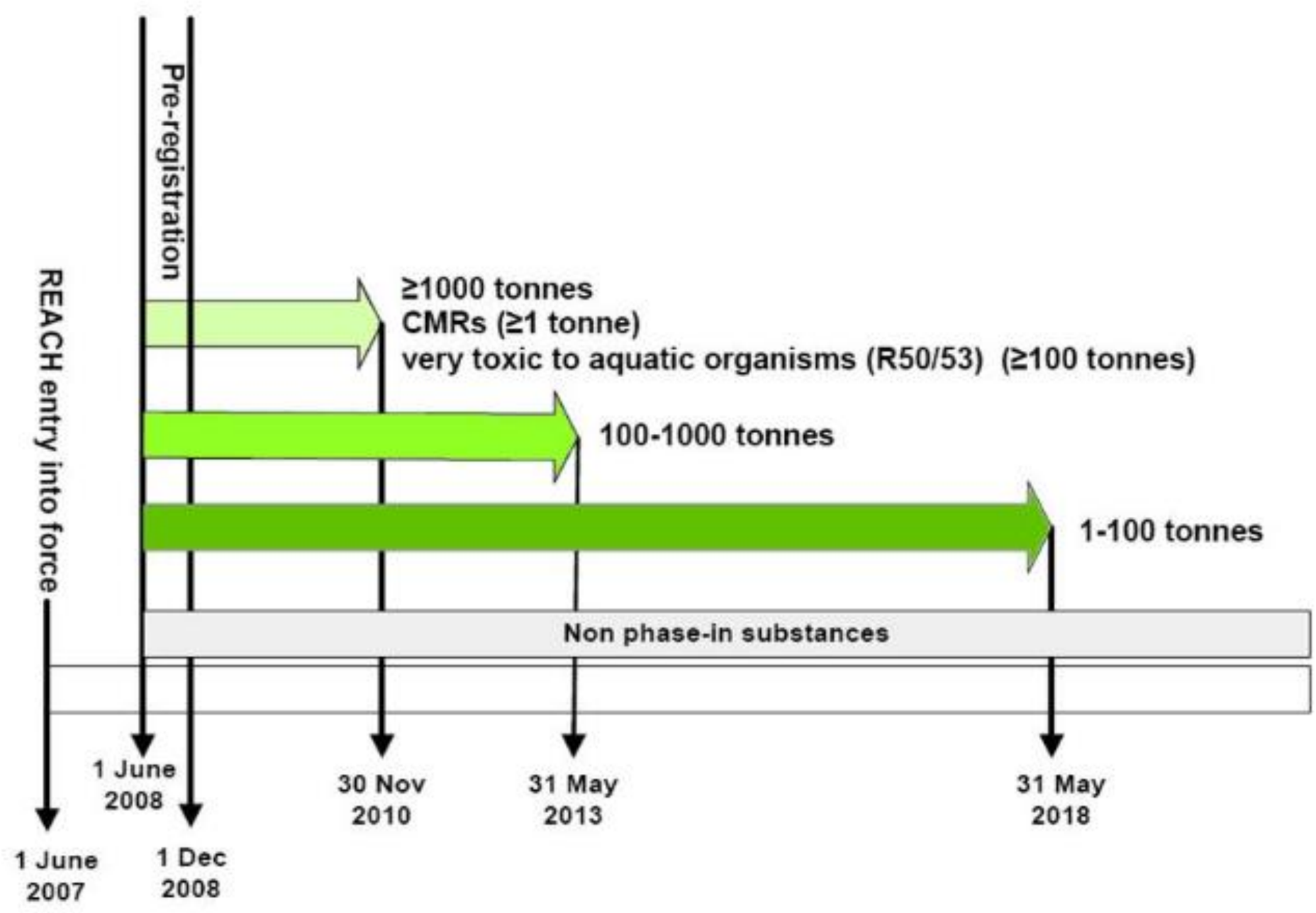
Place responsibility on industry!

- Producers and importers shall
  - Register hazard data – more data the larger volumes
  - Make chemical assessments
  - Giver recommendations for safe use

- Downstream users shall
  - communicate their uses to the suppliers
  - follow recommendations for safe use

Registration



CMRs: carcinogenic, mutagenic or toxic to reproduction

Registration cont.

- Technical Dossier
  - Identity of manufacturer/importer;
  - Identity, volume and identified uses of substance;
  - Classification and labeling ;
  - Study report and robust study summaries according to Annex VII to X (physiochemical, toxicological, eco-toxicological properties, etc);
  - Testing proposal;
  - Statement whether tests have been carried out on vertebrate animals

Registration cont.

- Chemical Safety Report (> 10 ton per year)
  - Human hazard assessment, physicochemical properties assessment, environmental hazard assessment and PBT/vPvB assessment;
  - Exposure Scenario is required if classified as dangerous or PBT/vPvB;
    - operational conditions and risk management measures for each use;
  - Exposure estimation

Authorities (ECHA and MS agencies)

- Authorities are to
  - control industry action
  - take part in EU decision making procedures
- Authorities may
  - **use** the database of registrations
  - identify and propose priority substances which may later be used after **authorization** only
  - identify unacceptable risks and propose measures to reduce them − **restrictions**

Authorisation

- Substances of Very High Concern

- List of substances subject to authorisation, Annex XIV:
  - Substances on Annex XIV can not be used, or placed on the market, without an authorisation

- Application for authorisation shall be made to the ECHA by manufacturers / importers / users, for one or several specific uses

- Decision by the European Commission

Restrictions

- Hazardous substances on its own, in mixtures or in articles
  - with unacceptable risk for human health or the environment
- List of substances subject to restrictions Annex XVII:
  - Restrictions on the manufacture / placing on the market / uses
- Proposals from a Member State or EU commission to address risks on an EU basis

- Decision by the European Commission

Fees (€)

Fees for registrations submitted under Article 6, 7 or 11 of Regulation (EC) No 1907/2006

Table 1

Standard fees

	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	EUR 1 739	EUR 1 304
Fee for substances in the range 10 to 100 tonnes	EUR 4 674	EUR 3 506
Fee for substances in the range 100 to 1 000 tonnes	EUR 12 501	EUR 9 376
Fee for substances above 1 000 tonnes	EUR 33 699	EUR 25 274