REACH: Science Base and Integrated Testing Strategies

SETAC ESSS ITS

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Contents

- REACH
- What's Old?
- What's New?
- Conclusions

REACH: Aim of Registration

- Responsibility for management of risks of substances is on the manufacturer, importer and those who place on the market.

- Therefore, they:
  - Gather and generate data on their substances
  - Use those data to assess the risks
  - Develop and recommend appropriate RMM
  - Document and submit in a Registration dossier

REACH: Who should register

- Manufacturers, who manufacture the substance in the EU.
- Importers, who import the substance on its own, in preparations or in articles.
- Producers of articles.

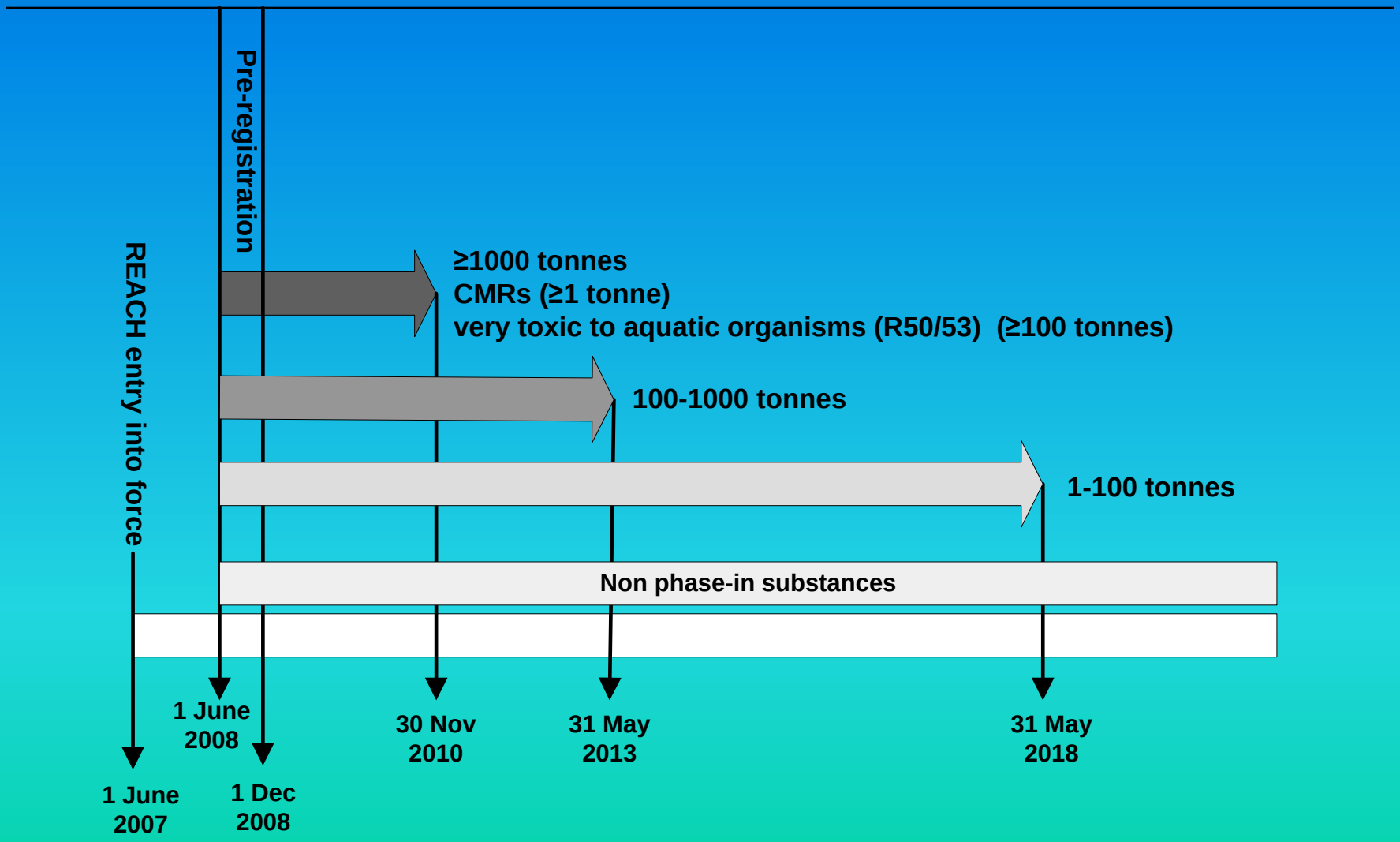
- Manufacturing: production or extraction of substances in the natural state.
- Import: physical introduction into customs territory of the Community.

REACH: When to register

- Registration of non-phase in substances
  - Submit inquiry dossier before registration
  - Registration before manufacture or import (3 wks)
- Registration of phase-in substances
  - Requires pre-registration (**1 June – 1 December 2008**)
  - Deadlines depending on tonnage and properties

- Phase-in substances:
  - Substances on EINECS (existing substances)
  - Manufactured but not placed on the market (1 June 1992 – 1 June 2007)
  - 'No longer polymers'

REACH: Registration timelines



What's Old (for Industry)?

- Data Collection using IUCLID, *but now*:
  - Implements OECD Harmonised Templates (BNEP)
  - Linked directly to OECD Global Portal (world wide access)
  - Enables "one stop shop" from test house to registration
- Hazard Assessment (OECD Existing Chemicals Programme), including formats for SIAR
- Classification and Labelling
- SDS Preparations

What's Old (for Authorities)?

- Classification and Labelling Harmonised, *but now*:
  - Use IULCID
  - Use format of CSR (built on SIAR)
  - Justify Action at EU Level
- Authorities Risk Assessment as a basis for Restrictions, *but now*:
  - Use IULCID
  - Use format of CSR (built on SIAR)
- Authorities Risk Reduction Recommendation as a basis for Restrictions, *but now*:
  - Structured SEA added
- Authorities Identification of PBTs and vPvBs, *but now*:
  - Use IULCID
  - Use format of CSR (built on SIAR)

What's New (for Industry)?

- The Chemicals Safety Report, *in particular*:
  - Exposure Scenarios
  - DNEL derivation
- Annex XI, *in particular*:
  - Systematic documentation of Grouping, Categories, QSAR, Weight of Evidence, Exposure based Waiving
  - ITS (substance tailored information gap moulded approaches and end-point covering hazard assessment)
  - OECD QSAR Toolbox
- Authorisation (SEA and documentation)

What's New (for Authorities)?

- Compliance Check by a New Agency, *in particular*:
  - For the HPVCs (effectively all hazard data)
  - Checking derogation statements (justifications for Annex XI application)
- Substance Evaluation left for Authorities, *in particular*:
  - Addressing information needs due to concern from multiple registrations
- (Authorisation)

What's New (ITS)?

- The legislative frame is there
  - Testing as last resort means pressure on using Annex XI methods
  - Weight of Evidence (in its broadest sense and in its narrow sense)
  - Read across, grouping, categories, QSAR, in-vitro, ….

What's New (ITS)?

- The Legislative "Approach"
  - OECD (or Test Method Regulation) defines "gold standard" for information requirement
  - E.g., criteria for CLaP can be directly applied to results of "gold standard" tests
  - An information "package" which in sum total equals the information content of the "gold standard" is acceptable for Annex XI application provided:
    - Adequate for Classification and Labelling
    - Adequate for Risk Assessment
    - Adequate and reliable documentation
    - …

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Who?

Adequate for Classification and Labelling
Adequate for Risk Assessment
Adequate and reliable documentation
…

What's New (ITS)?

- Adequacy for Classification and Labelling and Risk Assessment is determined ultimately by the **Commission** and it's **Comitology Committee**
- Adequacy for Classification and Labelling and Risk Assessment is determined initially by the **Risk Assessment Committee**
- Ad interim, adequacy of arguments for derogating from the standard information requirements is determined by the **Member State Committee**
- Initially, adequacy of arguments for derogating from the standard information requirements is evaluated by the **ECHA Secretariat**
- To start with, **Industry** decides what they think will be acceptable as adequate

Conclusions

- Theory: REACH creates a legal frame for ITS
- Theory and past practice: The scientific basis has been developed in the RIPs
- New Practice: Industry to upfront decide for their purposes what is an appropriate scientific basis
- New Practice: EC and ECHA (RAC, MSC and Secretariat) who are the “judges”

Thank you!

http://europa.eu.int/comm/environment/chemicals/index.htm

http://echa.europa.eu/home_en.asp/

http://europa.eu.int/comm/enterprise/chemicals/index.htm