REACH Workshop

Registration and Notification in practice
14 April 2008

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Aim of Registration

- Responsibility for management of risks of substances is on the manufacturer, importer and those who place the substance on the market or use it for professional activities

- Therefore they
  - Gather and generate data on their substances
  - Use these data to assess the risks
  - Develop & recommend appropriate risk reduction measures
  - Document this information in a **Registration dossier** to be submitted to ECHA

What to register

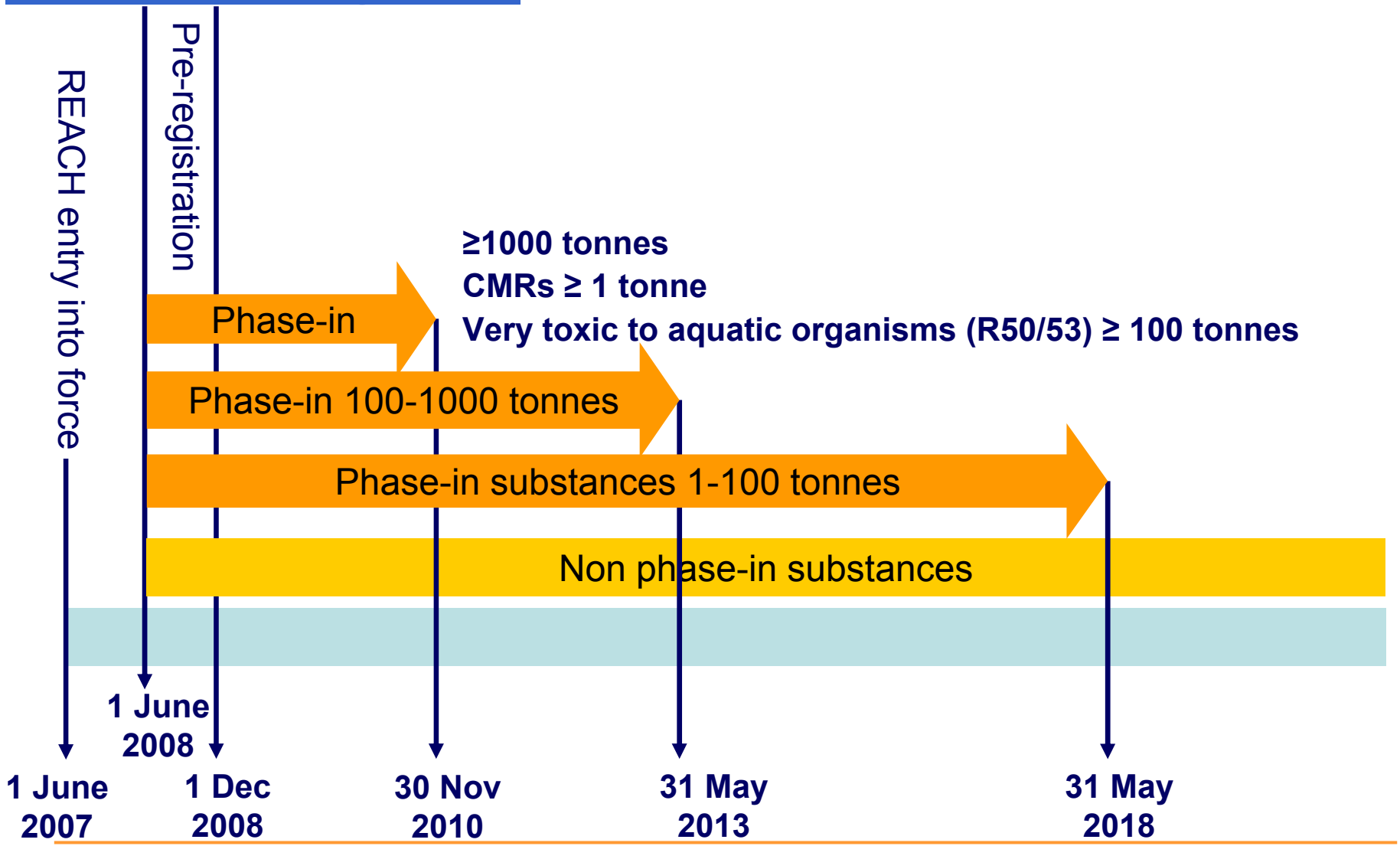
- All substances manufactured o
  ≥ 1 tonne / year per manufactur
  - Substances on their own
  - Substances in preparations
  - Substances in articles intended t
- About 30,000 substances conc
- Exemptions
- Regarded as registered

- **Biocides**: Active substances included in Annex I, IA or IB (98/8/EC) or in the work programme
- **Pesticides**: Active substances included in Annex I (91/414/EEC) or in the work programme for evaluation
- **New substances** notified under 67/548/EEC

Who should register

- EU manufacturers and importers of substances on their own or in preparations
- EU producers and importers of articles
  (meeting criteria of Article 7(1))
- EU-based “only representatives” appointed by a manufacturer, formulator or article producer **outside the EU** to fulfil the registration obligations of importers

When to register



2 routes for registering

- **Non phase-in** ***(or phase-in substance not pre-registered)***

Inquiry

Information to be provided online in REACH-IT

✓Contact details

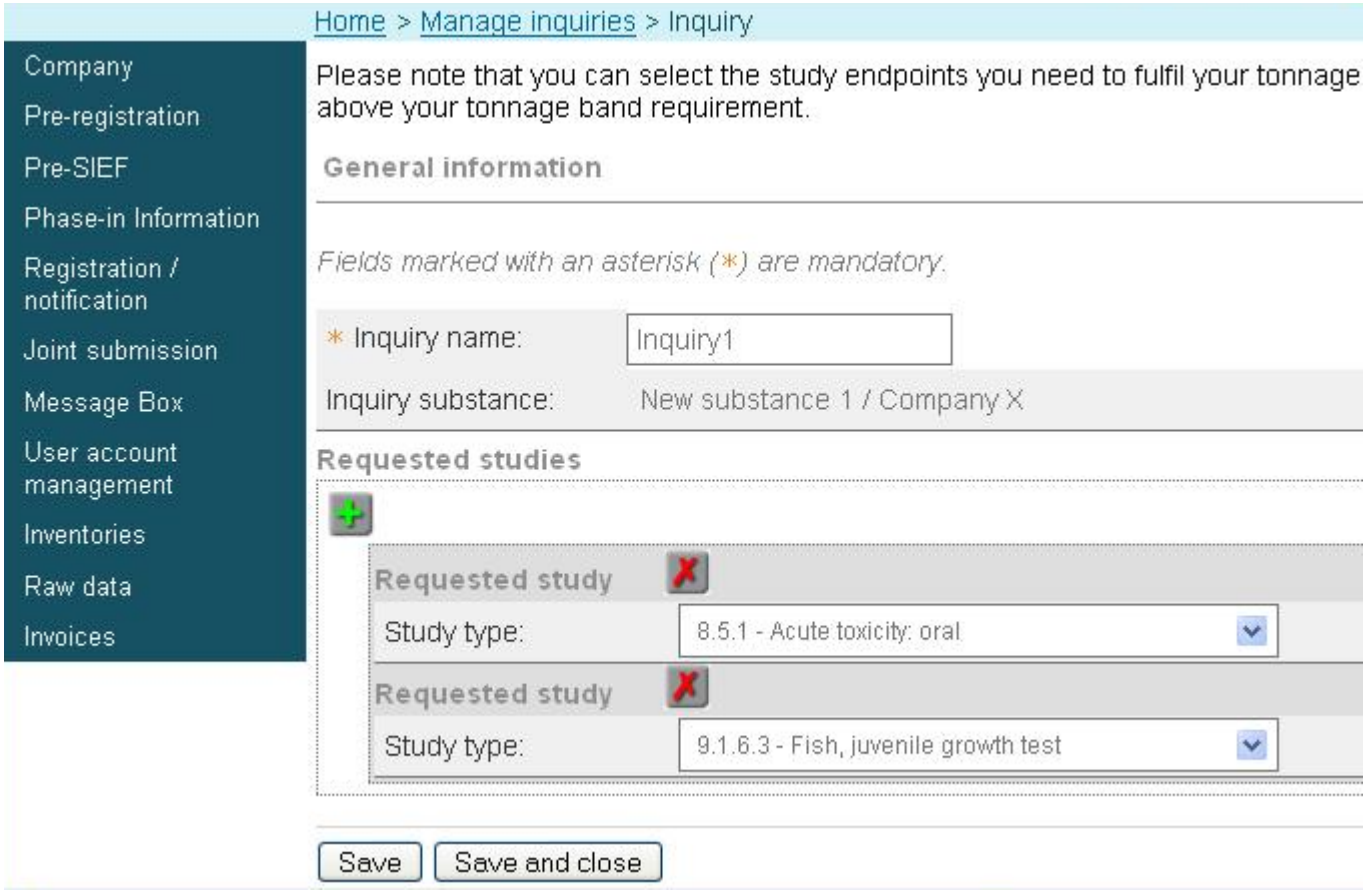
✓ (Detailed) information on substance identity

✓Relevant information requirements

2 routes for registering

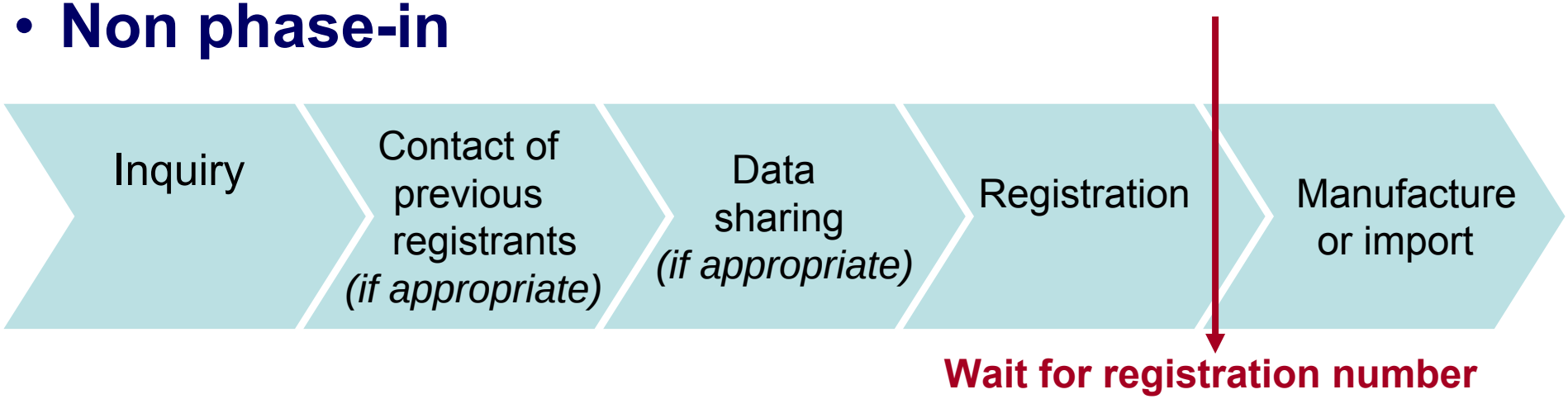
- **Non phase-in** ***(or phase-in not pre-registered)***

Inquiry



2 routes for registering

- **Non phase-in**



- **Phase-in**

pre-registration

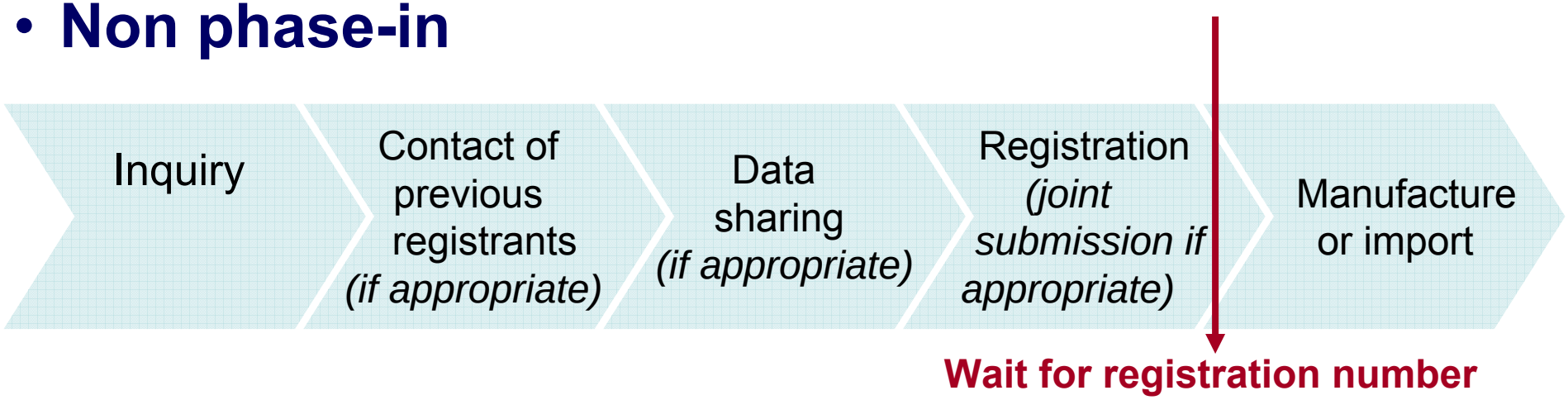
Information to be provided online in REACH-IT

✓Contact details

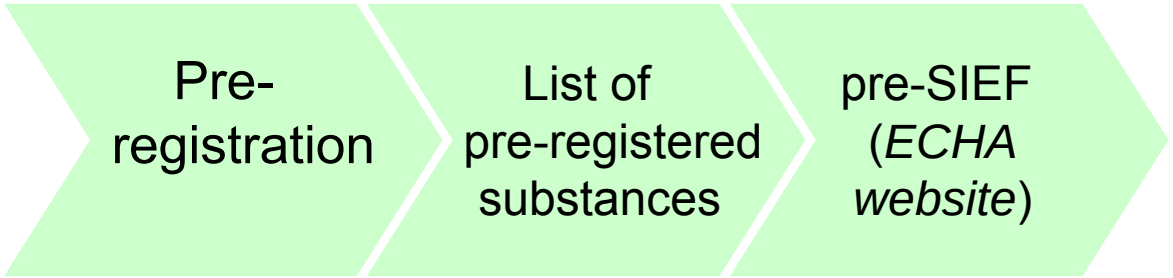
✓Information on substance identity

2 routes for registering

- **Non phase-in**



- **Phase-in**

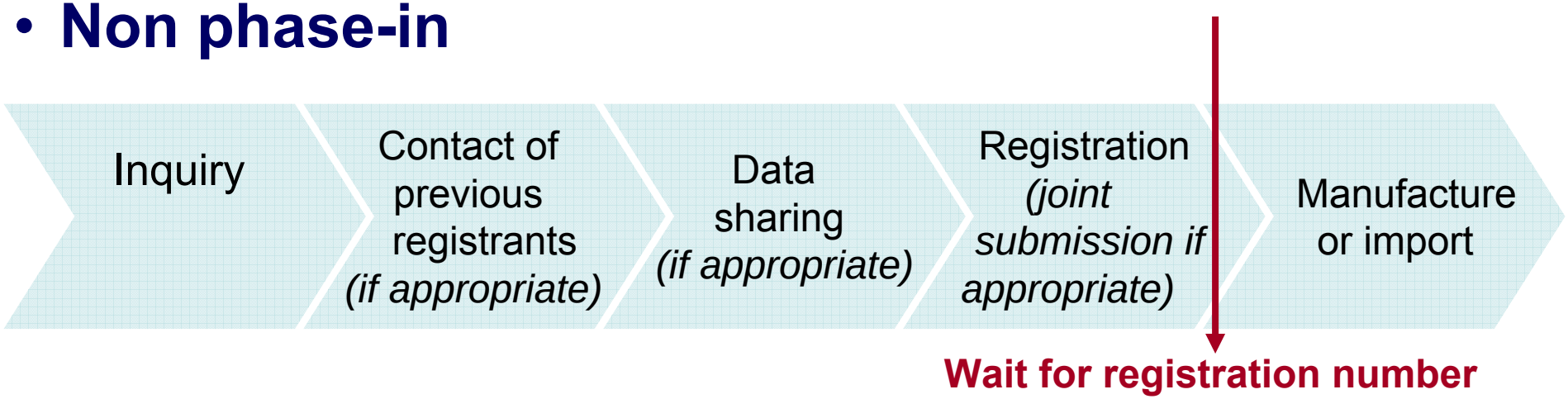


Contact details of:

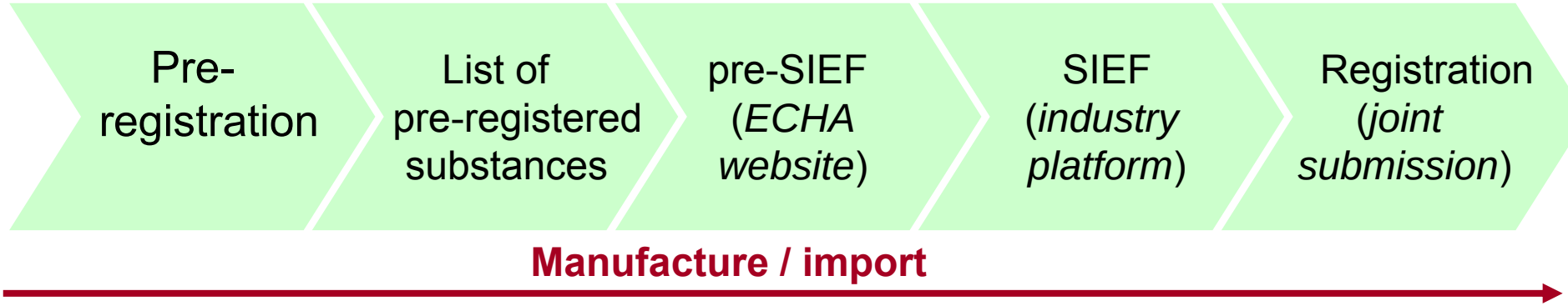
- other pre-registrants
- early registrants
- biocides, pesticides
- Data holders after 1 Jan 09

2 routes for registering

- **Non phase-in**



- **Phase-in**



Joint submission

Joint information	Hazard information & testing proposals Classification and labelling
Choice	Chemical Safety Report Guidance on safe use Quality assessed
Company specific	Company and substance identity Manufacture and uses Exposure information

Joint submission

Joint information	***This part must be submitted by the Lead registrant***
Choice	Chemical Safety Report Guidance on safe use Quality assessed
Company specific	Company and substance identity Manufacture and uses Exposure information

Separate submission

- **A registrant may submit information separately (opt-out) if:**
  - Joint information would be disproportionally costly for him
  - Information is commercially sensitive
  - Disagreement with the lead on selection of this information

- **Justification of the above must be provided along with the dossier**

How to prepare the registration dossier

- The **only tool** for preparing the dossier: IUCLID 5

Available free of charge on ECHA website

How to prepare the registration dossier

- Technical dossier: **IUCLID 5 format**
  - company identity & substance identity
  - manufacture & uses – guidance on safe use
    C&L - exposure information
  - (robust) study summaries - testing proposals

- Chemical Safety report (*above 10 tonnes per year*):
  - document created outside IUCLID but later is attached to it

One single file to be sent to ECHA

How to prepare the registration dossier

- Information is entered in the company IUCLID 5 database

Data required in REACH Annexes VI-X *(depending on tonnage)*

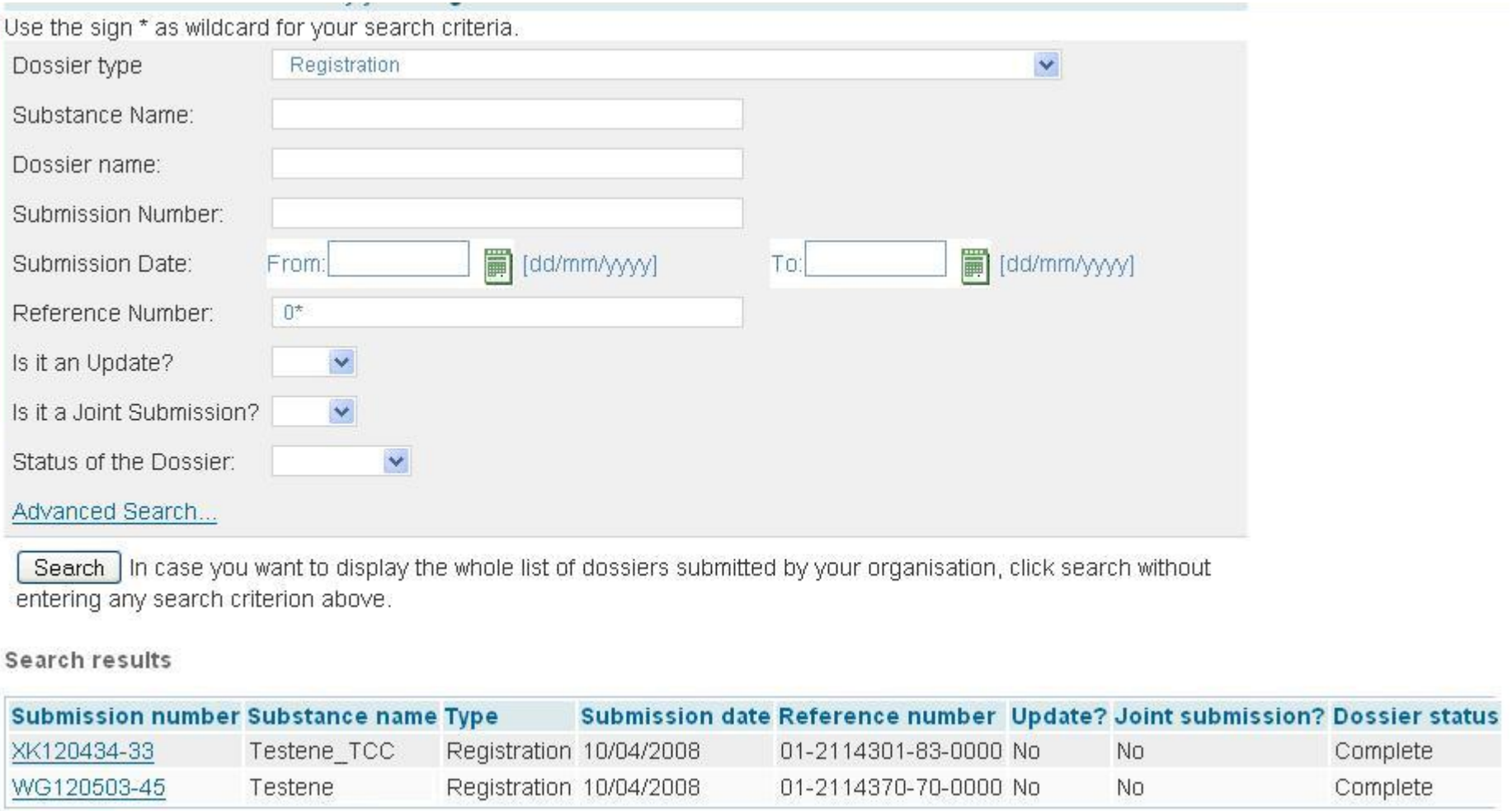
- When the dossier is final, it is **exported** & **sent** to ECHA *(via REACH-IT)*

Submission in REACH-IT

What happens next

- Completeness check
- Invoice is generated based on a number of parameters:
  - Size of the company *(reduced fees for SMEs)*
  - Tonnage band
  - Joint or individual submission
  - Request to confidentiality according to Art. 10(a)(xi)
  - Initial submission or update
- Invoice is sent to the registrant *(via REACH-IT and mail)*
- Submission report is available for download in REACH-IT
- Registration number is sent when dossier is complete & fee is paid

Tracking system for industry



Notified substances

- Considered as registered
- ECHA must assign a registration number by 1 December 2008. To receive this number:
  - Notifiers must identify themselves in REACH-IT
  - Claim their registration number
  - If no issue with notifier identity, registration number is sent
  - In case of problem, the Competent Authority is informed for verification

Contact your Competent Authority:
your current notifications must be up-to-date,
in particular the identity of the notifier!

Notified polymers

- Considered as registered
- Registration number assigned by ECHA (same as notified substances)

- When the notified polymer passes the next tonnage threshold,
  - a registration is required for the monomer(s)

Updated guidance available on ECHA website

PPORD notifications

- 2 routes to prepare the notification
  - Offline in your IUCLID installation, starting now!
  - Online in REACH-IT, starting 1 June 08
  - Submission process: same as for the registration dossier, incl. fee payment

- Manufacture or import may start 2 weeks after notification if no indication of the contrary by ECHA

PPORD notifications

- Extension of current PORDs
  - Must be submitted as PPORD by **2 June 2008** at latest
  - with an indication of the current PORD number
  - Contact your Competent Authority for further information

Thank you for your attention