

REACH Workshop

Registration and Notification in practice
14 April 2008

Christel Musset

- **Overview of Registration in REACH**
 - What substances should be registered?
 - Who should register?
 - When to register?
 - **How to register?**
- **New substances notified under 67/548/EEC**
- **Notified polymers**
- **PPORD Notifications**

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

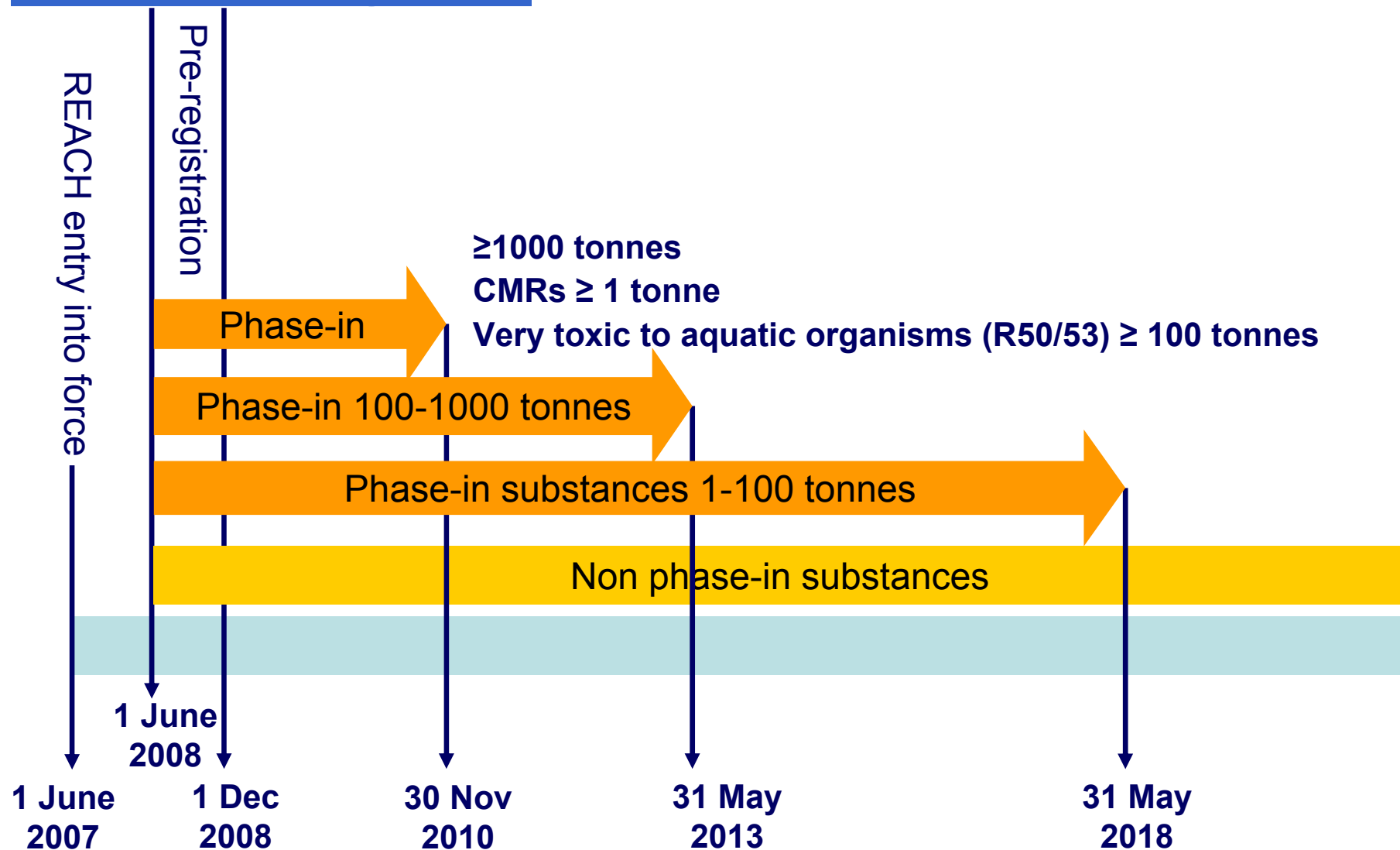
What to register

- All substances manufactured or imported in the EU in quantities ≥ 1 tonne / year per manufacturer
 - Substances on their own
 - Substances in preparations
 - Substances in articles intended to be placed on the market
 - About 30,000 substances concerned
 - 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*)



Home > Manage inquiries > Inquiry

Please note that you can select the study endpoints you need to fulfil your tonnage above your tonnage band requirement.


General information



Fields marked with an asterisk () are mandatory.*

* Inquiry name:

Inquiry substance:

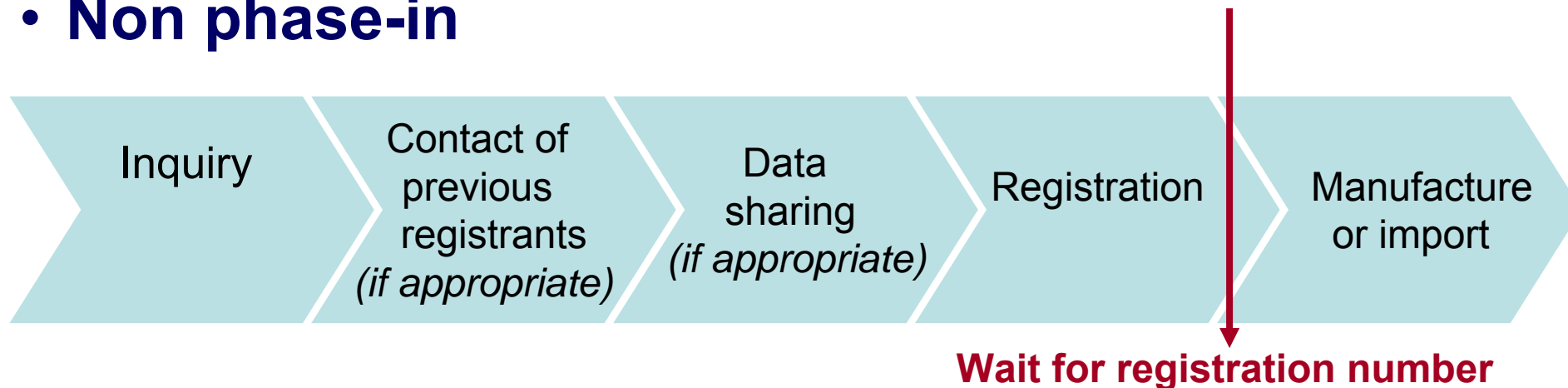
Requested studies



Requested study 
Study type: <input type="text" value="8.5.1 - Acute toxicity: oral"/>
Requested study 
Study type: <input type="text" value="9.1.6.3 - Fish, juvenile growth test"/>

2 routes for registering

• Non phase-in



• Phase-in



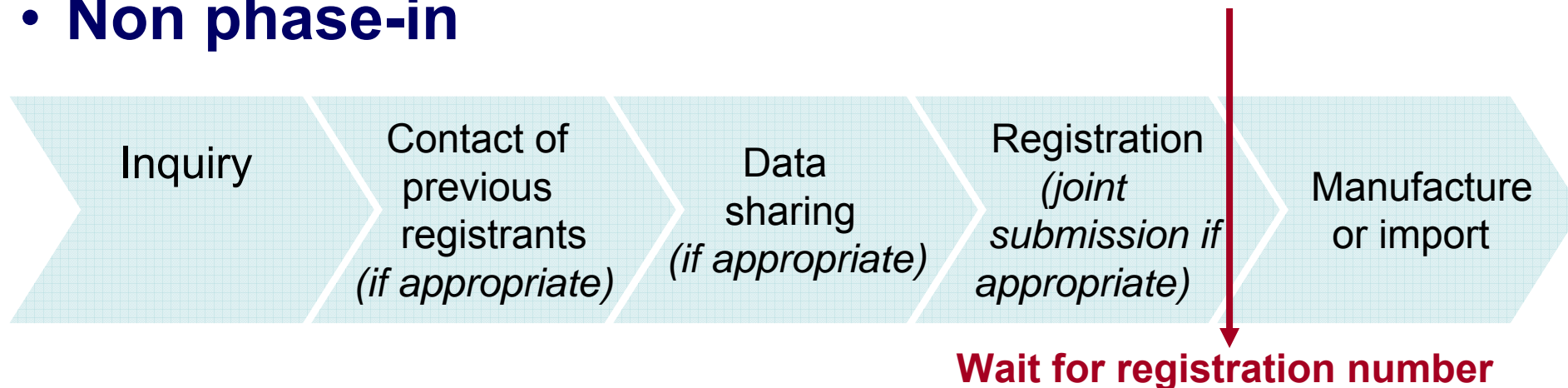
Information to be provided online in REACH-IT

✓ Contact details

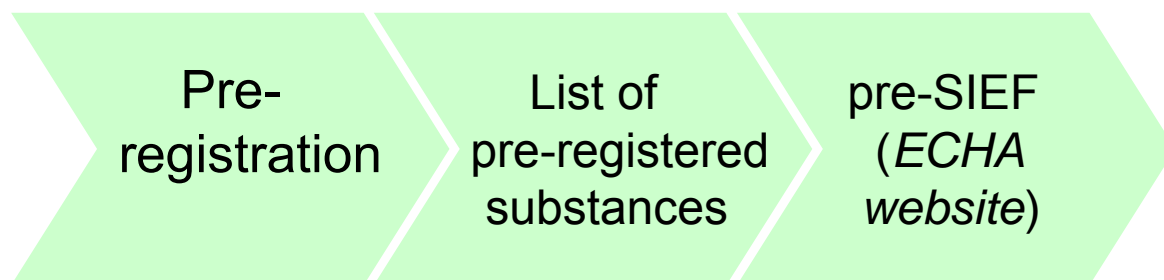
✓ Information on substance identity

2 routes for registering

• Non phase-in



• Phase-in

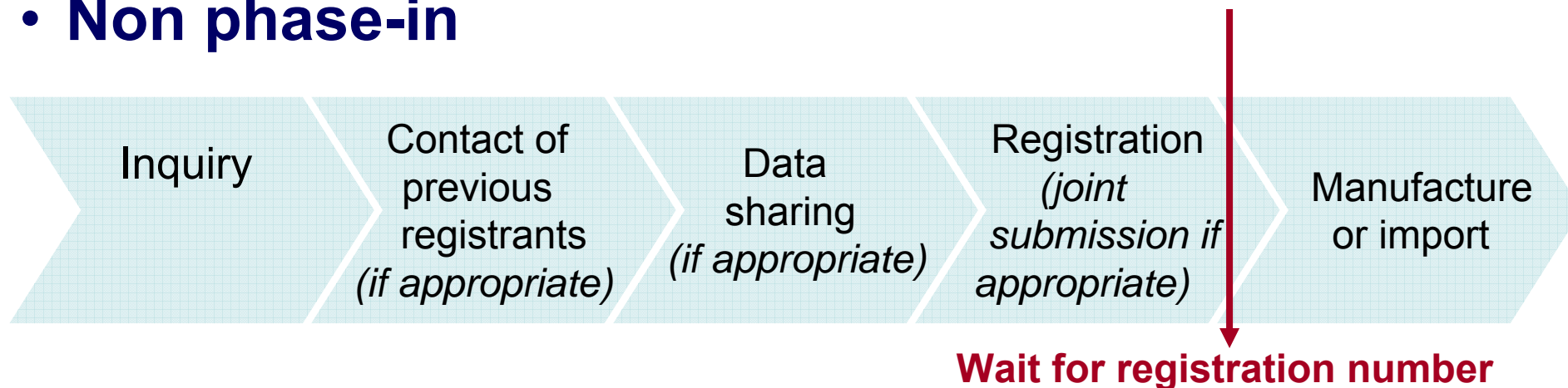


Contact details of:

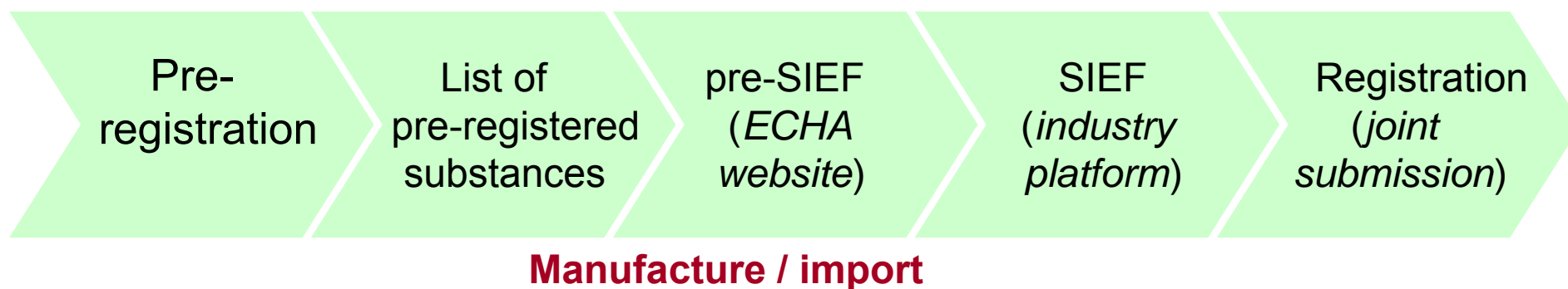
- other pre-registrants
- early registrants
- biocides, pesticides
- Data holders after 1 Jan 09

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

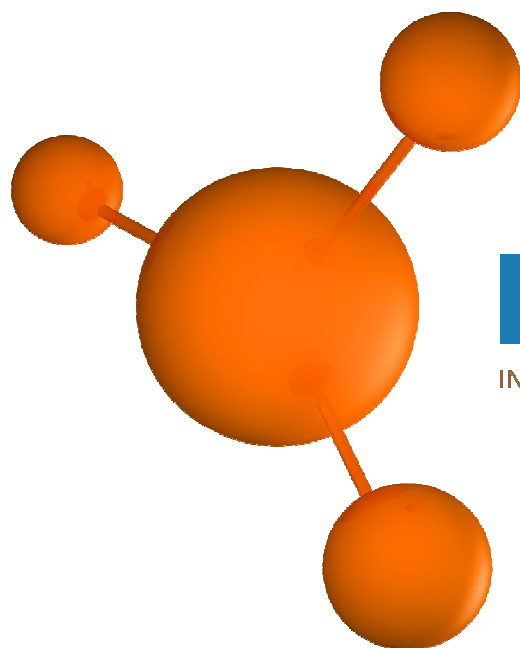
Joint information	<i>This part must be submitted by the Lead registrant</i>
Choice	Chemical Safety Report Guidance on safe use Quality assessed
Company specific	Company and substance identity Manufacture and uses Exposure information

Separate submission

- **A registrant may submit information separately (opt-out) if:**
 - Joint information would be disproportionately 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



IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

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

- + 1 General Information
- + 2 Classification and Labelling
- + 3 Manufacture, use and exposure
- + 4 Physical and chemical properties
- + 5 Environmental fate and pathways
- + 6 Ecotoxicological Information
- + 7 Toxicological information
- + 8 Analytical methods
- + 9 Residues in food and feedingstuffs
- + 10 Effectiveness against target organisms
- + 11 Guidance on safe use
- + 12 Literature search
- + 13 Assessment Reports

**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








The screenshot shows the ECHA REACH-IT submission interface. At the top left is the ECHA logo. Below it, a navigation menu lists various options: Company, Pre-registration, Pre-SIEF, Phase-in Information, Registration / notification (highlighted), Joint submission, Message Box, User account management, Inventories, Raw data, and Invoices. The main content area is titled 'Home > Submit Dossier Intro' and 'Registration / notification submission'. It contains a text block explaining the submission process, followed by three dropdown menus: '[Select dossier type]' with 'Registration' selected, '[Select a tonnage band]' with 'Between 1 to 10 tonnes/year' selected, and '[Purchase Order]'. Below these is a checkbox labeled 'I acknowledge that the substance for which I want to submit a dossier is not subject to any restrictions in existing legislations or any exemptions under REACH'. A 'Proceed' button is located at the bottom left of the form area.

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

Use the sign * as wildcard for your search criteria.

Dossier type	Registration	
Substance Name:	<input type="text"/>	
Dossier name:	<input type="text"/>	
Submission Number:	<input type="text"/>	
Submission Date:	From: <input type="text"/>  [dd/mm/yyyy]	To: <input type="text"/>  [dd/mm/yyyy]
Reference Number:	<input type="text" value="0*"/>	
Is it an Update?	<input type="checkbox"/> 	
Is it a Joint Submission?	<input type="checkbox"/> 	
Status of the Dossier:	<input type="checkbox"/> 	
Advanced Search...		

In case you want to display the whole list of dossiers submitted by your organisation, click search without entering any search criterion above.

Search results

Submission number	Substance name	Type	Submission date	Reference number	Update?	Joint submission?	Dossier status
XK120434-33	Testene_TCC	Registration	10/04/2008	01-2114301-83-0000	No	No	Complete
WG120503-45	Testene	Registration	10/04/2008	01-2114370-70-0000	No	No	Complete

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