

# Understanding Your Obligations: Registration

## HICCS 2008

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European Chemicals Agency

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  - What substances should be registered?
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  - Which tool to use?
  - New substances & polymers notified under 67/548/EEC
  - Extension of current PORDs
  - Only representatives

# 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 volumes  $\geq 1$  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

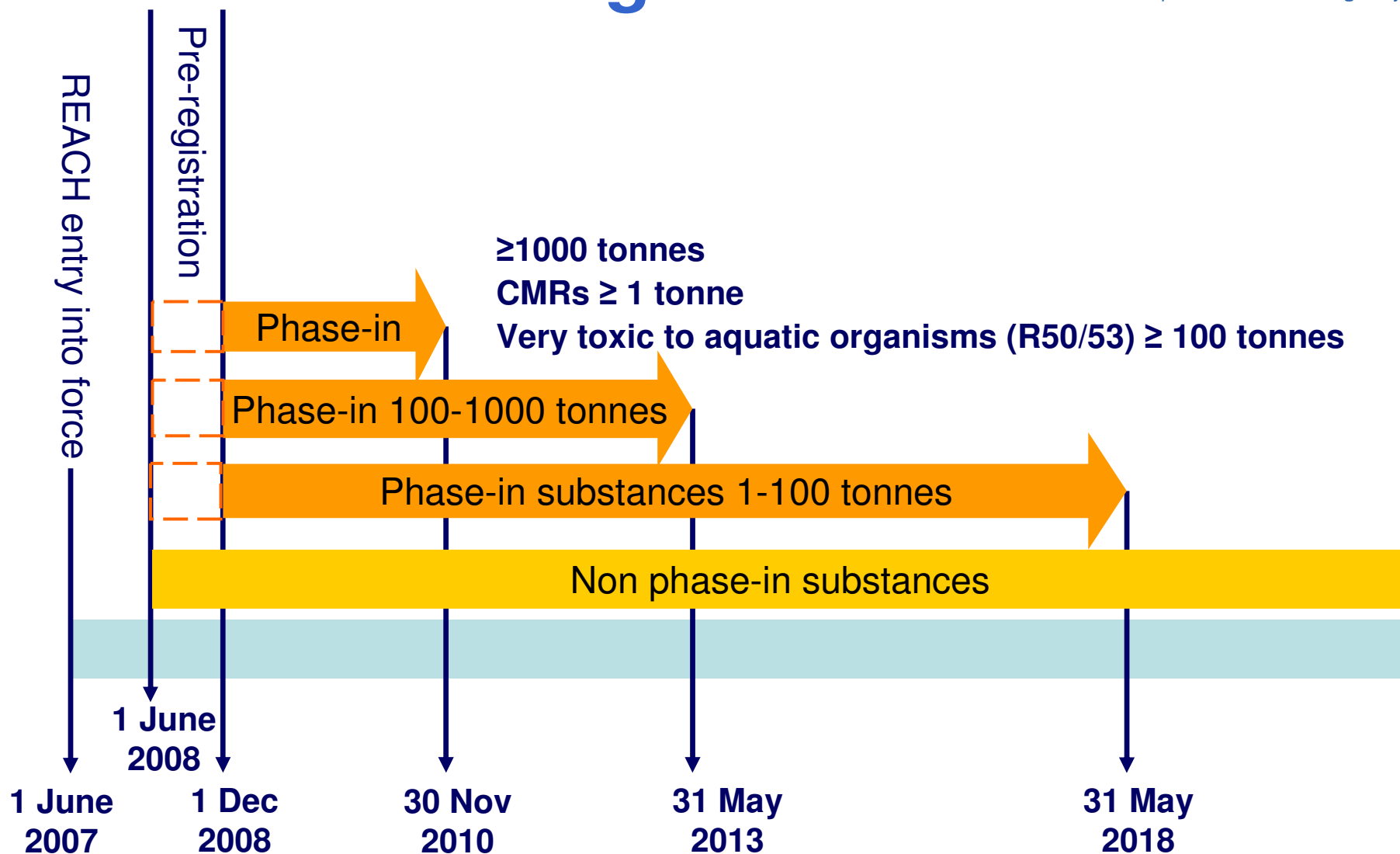
# Who Should Register

- 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

- **Two regimes** depending on the status of the substance:
  - **Non phase-in** substances (“New substances”): obligations start on 1 June 2008
  - **Phase-in** substances: Pre-registration phase: 1 June – 1 December 2008
    - substances listed in EINECS
    - manufactured, but not placed on the market in the EU at least once since 1992
    - no longer polymer

# When to Register



## 2 Routes for Registering

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



Inquiry

Requires to ask ECHA whether the same substance has already been registered - Information to be provided:

- ✓ 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**


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*Fields marked with an asterisk (\*) are mandatory.*

\* Inquiry name:

Inquiry substance:

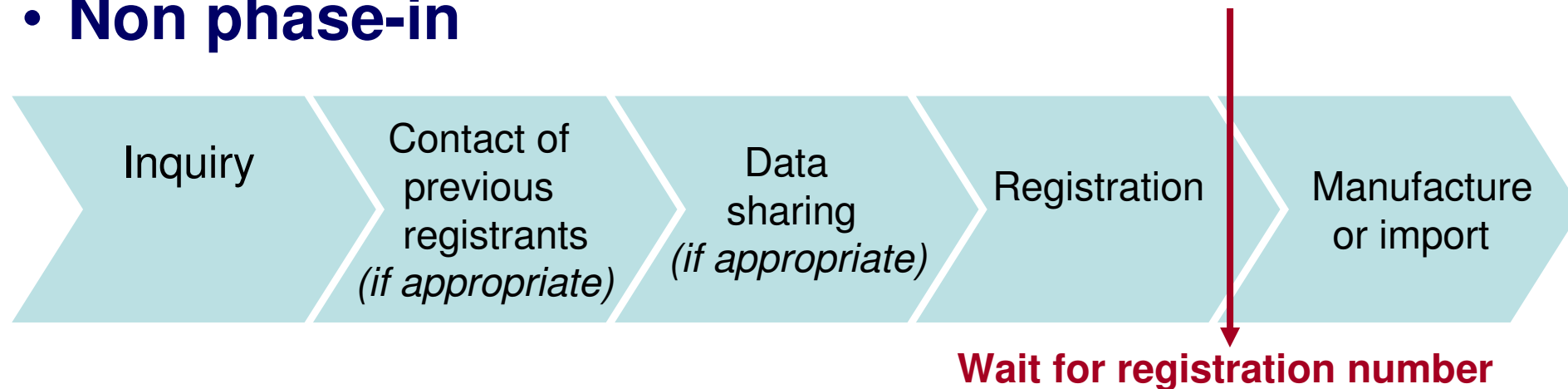
**Requested studies**



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

# 2 Routes for Registering

- **Non phase-in**



- **Phase-in**



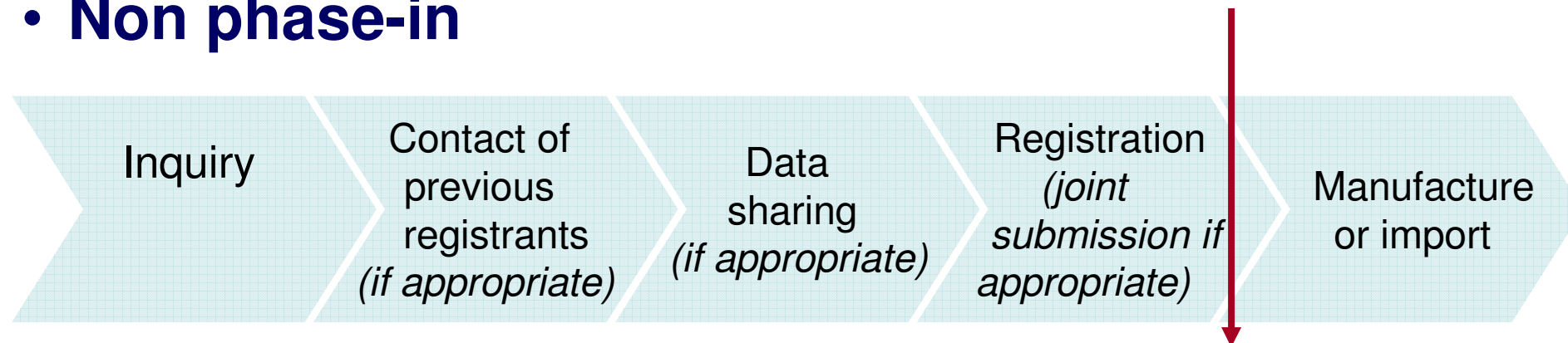
Information to be provided to ECHA

✓ Contact details

✓ Information on substance identity

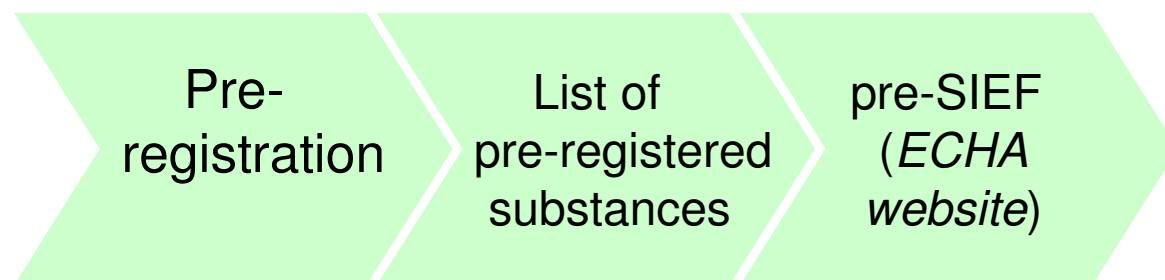
# 2 Routes for Registering

## • Non phase-in



**Wait for registration number**

## • Phase-in

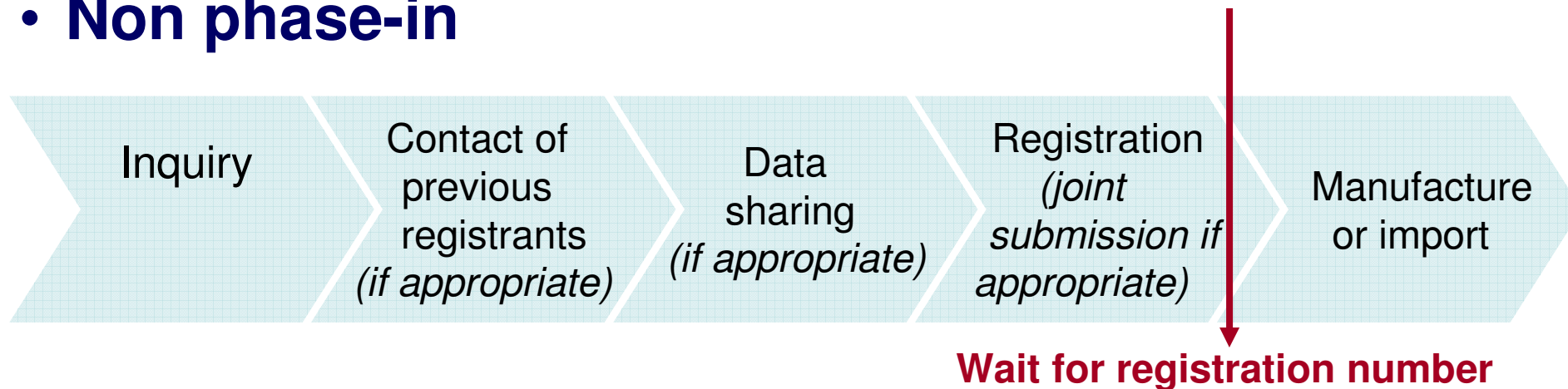


### **Contact details of:**

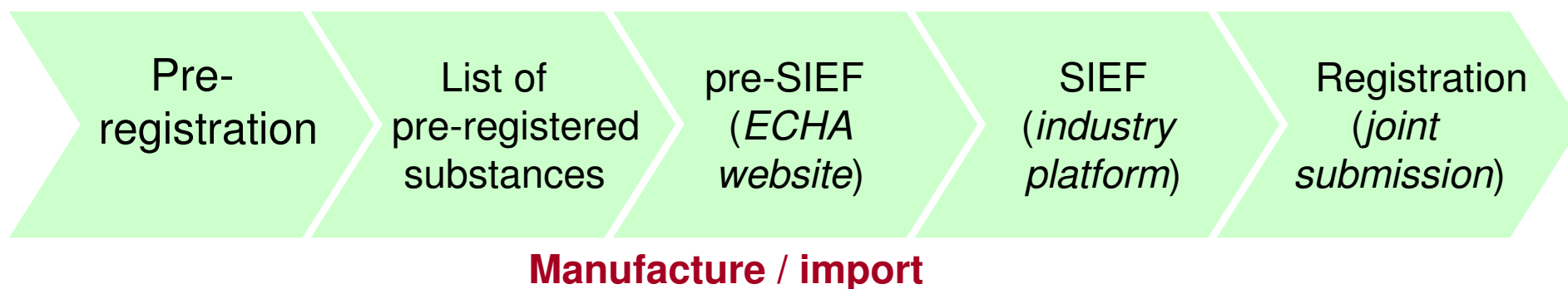
- other pre-registrants
- early registrants
- biocides, pesticides
- Data holders after 1 Jan 09

# 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	<b><i>This part must be submitted by the Lead registrant</i></b>
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**

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  - Extension of current PORDs
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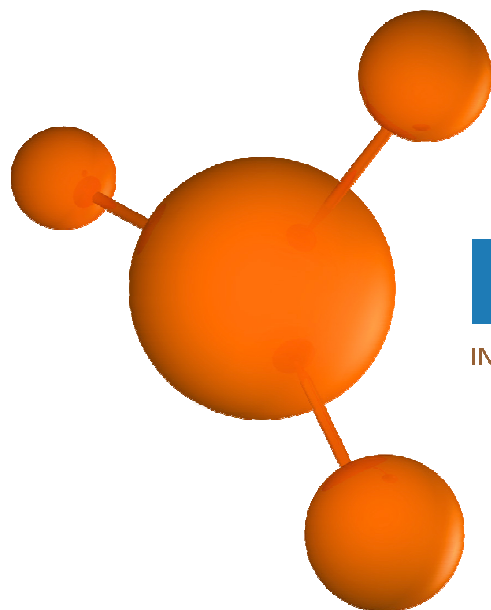
# What Starts on 1 June 2008



- Pre-registration of phase-in substances
- Registration of non phase-in substances
  - 1<sup>st</sup> step: Inquiry!
- Exemptions from registration for Product and Process Oriented Research & Development (**PPORD notifications**)
- Classification & Labelling for substances subject to registration or within the scope of Art. 1 of Dir. 67/548/EEC (**C&L notifications**)

# Which Tool to Use

- **Dossier preparation:** registration, PPORD, C&L,...
- Also used for preparing pre-registration files
- Used **locally** in company IT installations



**IUCLID 5**  
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

*Available for download  
free of charge  
on IUCLID website*

# Which Tool to Use

- **Dossier submission: REACH-IT**
  - only available on ECHA web site (no local use)
- **Also used for**
  - pre-registering
  - doing an inquiry
  - preparing “small” dossiers: PPORD, C&L,...
  - follow the status of submitted dossiers or notifications
  - communicating with Authorities
  - consult information on substances (REACH-IT dissemination)

# Which Tool to Use

- **REACH-IT**

- will be made available in steps
- 1 June 2008: sign-up and pre-registration
- Later:
  - dossier submission
  - preparation of dossiers online: PPORD, C&L, inquiries
  - joint submission
  - consultation ...

- **Information on availability**

- will be announced on ECHA web site

# Temporary Procedure



- Until REACH-IT is available!
- All dossiers prepared in IUCLID 5
  - “Ad-hoc” guidance will be published on ECHA web site
- All dossiers submitted via e-mail (functional mailbox) or CD-ROM (courier)
- Addresses will be communicated on ECHA web site
- Communication to the registrant will be done via e-mail + letter
  - Submission number & date
  - Invoice
  - Registration and notification numbers

# What Happens after Submission



- 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
- Registration number is sent when dossier is complete & fee is paid

# 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 Substances



- Current sole representative:
  - should establish contractual arrangements with the non EU manufacturer to be appointed only representative under REACH
  - should provide this contractual arrangement in REACH-IT before claiming the registration number
  - the document will be communicated to the MS CA concerned for further verification

# Notified Polymers

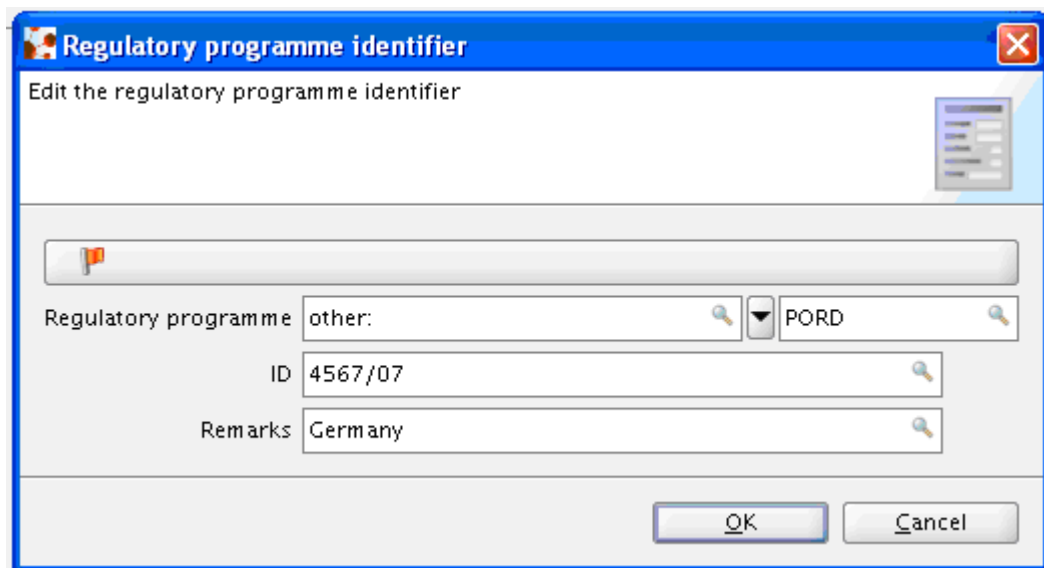


- Considered as registered
- Registration number assigned by ECHA (same as notified substances)
- When the notified polymer passes the next tonnage threshold,
  - a registration is required for the monomer(s)

***Updated guidance  
available on ECHA website***

# Extension of Current PORDs

- Must be submitted as PPORD by **2 June 2008**
- Use IUCLID 5 to prepare the PPORD notification
- Indicate the **current PORD number** and the **MS** concerned:



Regulatory programme identifier

Edit the regulatory programme identifier

Regulatory programme other: PORD

ID 4567/07

Remarks Germany

OK Cancel

**Contact your  
Competent Authority:  
for further information!**

# Only Representatives



- One **individual** pre-registration per substance and per non EU manufacturer represented, with the tonnage band and the envisaged deadline for registration
- One **individual** registration dossier per substance and per non EU manufacturer represented
  - even if the OR needs to register the same substance for several non EU manufacturers

Thank you for your attention