

# Pre-registration of Substances and Information Exchange Fora

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# This presentation is about



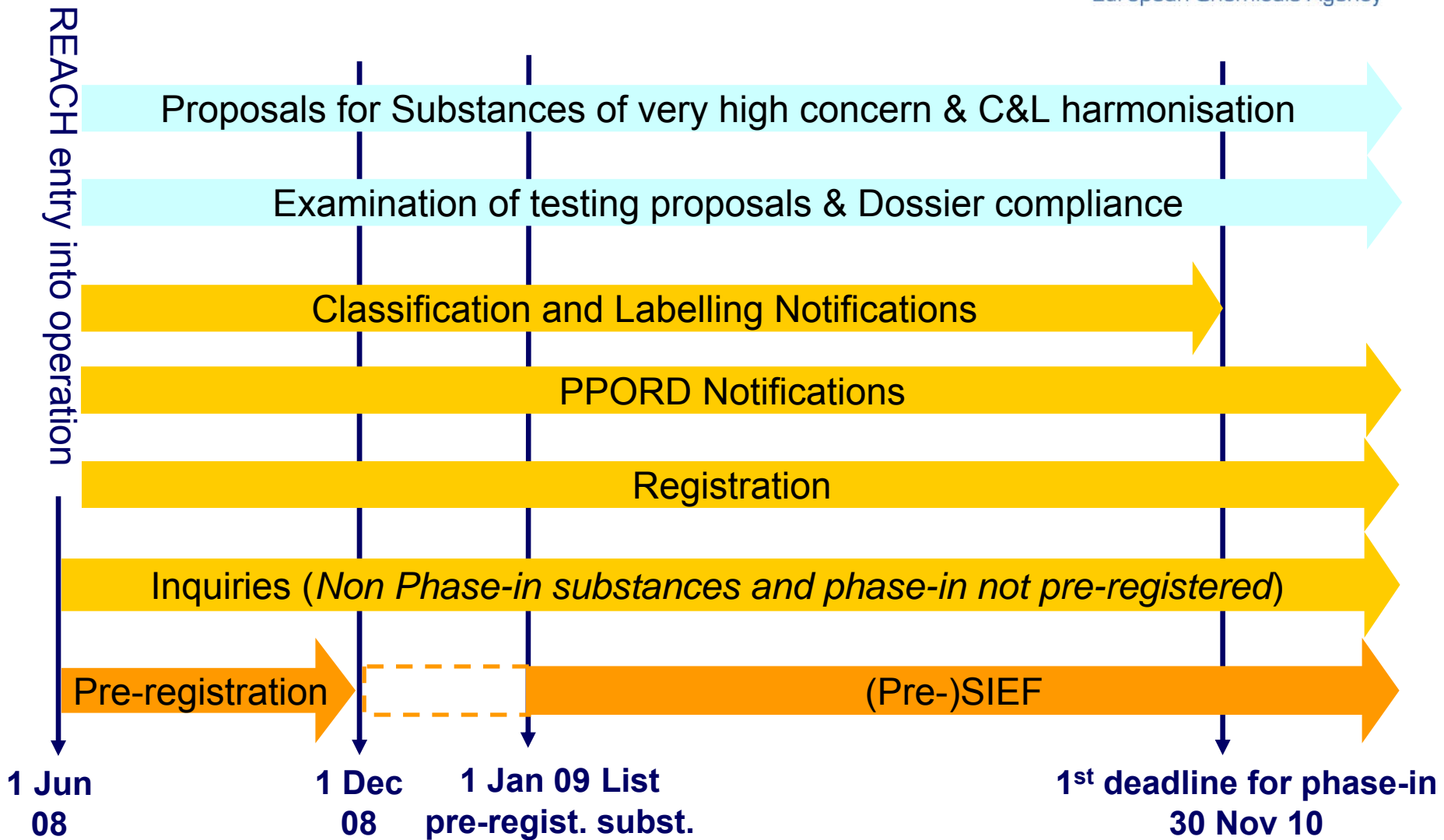
1. brief introduction to ECHA
2. focus on pre-registration and pre-SIEF
  - what / who / why / when
  - what substances / what data
  - next steps
3. with recommendations based on the experiences during the first half of the pre-registration period



- ECHA is
  - established on 1 June 2007
  - to carry out or co-ordinate **the technical, scientific and administrative aspects of REACH** and ensure **consistent implementation** of REACH at Community level
- Staff has moved in over past 15 months
  - 1 September 2008: ~200 staff
- **Helpdesk** and **multilingual website** have been operational since 1 June 2007
- **REACH-IT** portal was launched on 31 May 2008

# What started on 1 June 2008 ECHA

European Chemicals Agency



# What is pre-registration

Pre-registration is a duty under REACH for **every potential registrants** of phase-in substances taking place during the pre-registration period, granting them extended deadlines for registration.

# Who can pre-register

- Potential registrants =
  - 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

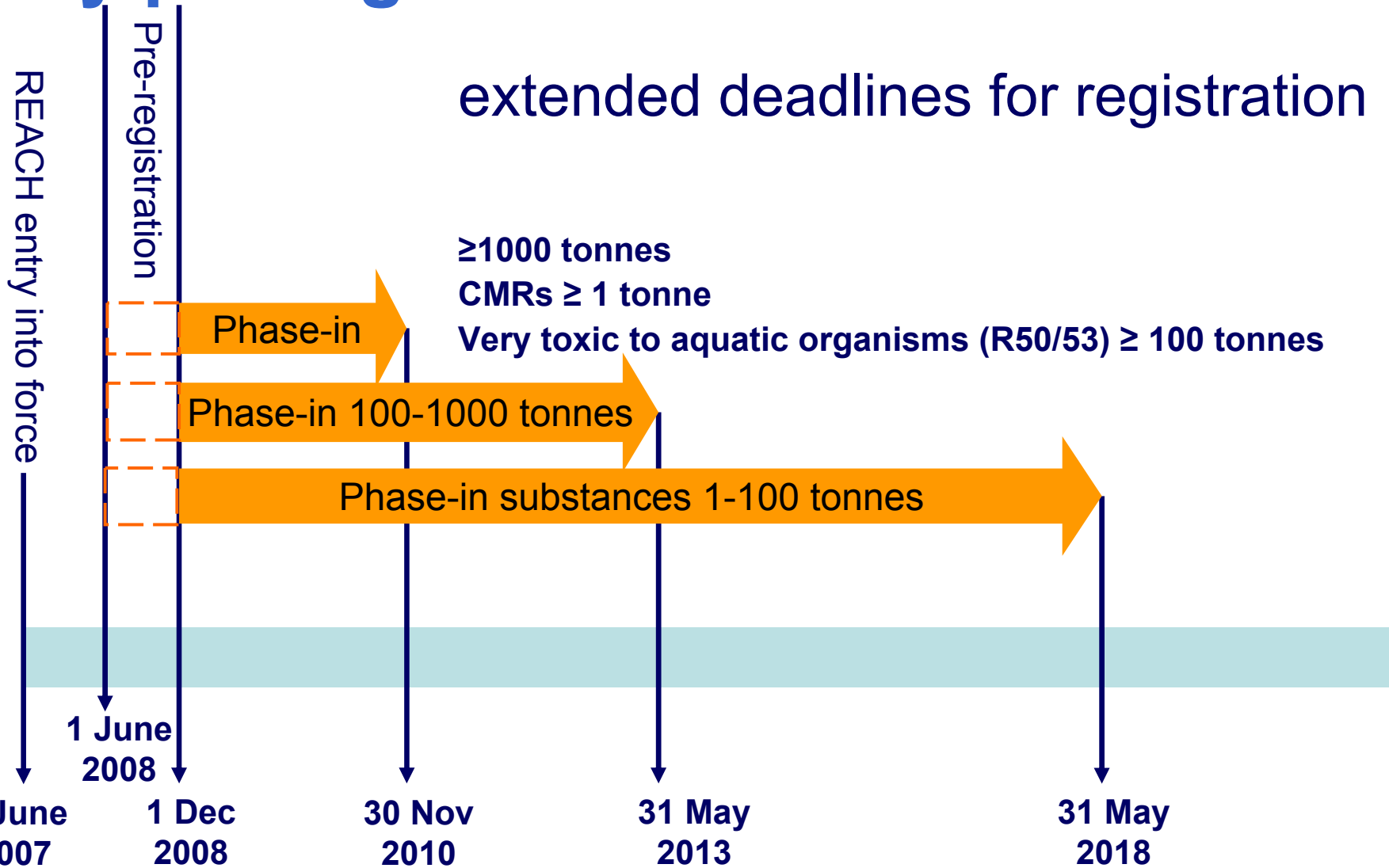
# Why pre-register

- For business continuity reasons and to benefit from the extended deadlines for registration
- Pre-registration brings companies together to share data, thereby reducing duplicate testing and costs
- Pre-registration is free of charge

# Why pre-register

extended deadlines for registration

≥1000 tonnes  
 CMRs ≥ 1 tonne  
 Very toxic to aquatic organisms (R50/53) ≥ 100 tonnes



# What to pre-register

- **Phase-in substances** subject to registration
  - substances, not preparations (= a mixture or solution composed of two or more substances; alloys are considered preparations → pre-register the substances)
  - all types of substances:
    - mono-constituent: one main constituent, present for more than 80% (w/w)
    - multi-constituent: more than one main constituent, all present in a concentration  $\geq 10\%$  (w/w) and  $< 80\%$  (w/w)
    - UVCB: Substances of Unknown or Variable composition, Complex reaction products or Biological materials

# What to pre-register

- **Phase-in substances** subject to registration
  - substances listed in EINECS (multi-constituent substances are “covered” by EINECS if all main constituents are listed in EINECS)
  - manufactured, but not placed on the market in the EU at least once since 1 June 1992
  - no longer polymer

# When to pre-register

- Pre-registration period: 1 June - **1 December 2008** (inclusive)
- As a first-time manufacturer or importer, you can pre-register after the pre-registration period, but:
  - at the latest 6 months after manufacturing or importing exceeds the 1 tonne threshold; and
  - at least 12 months before the relevant transitional deadline for registration.

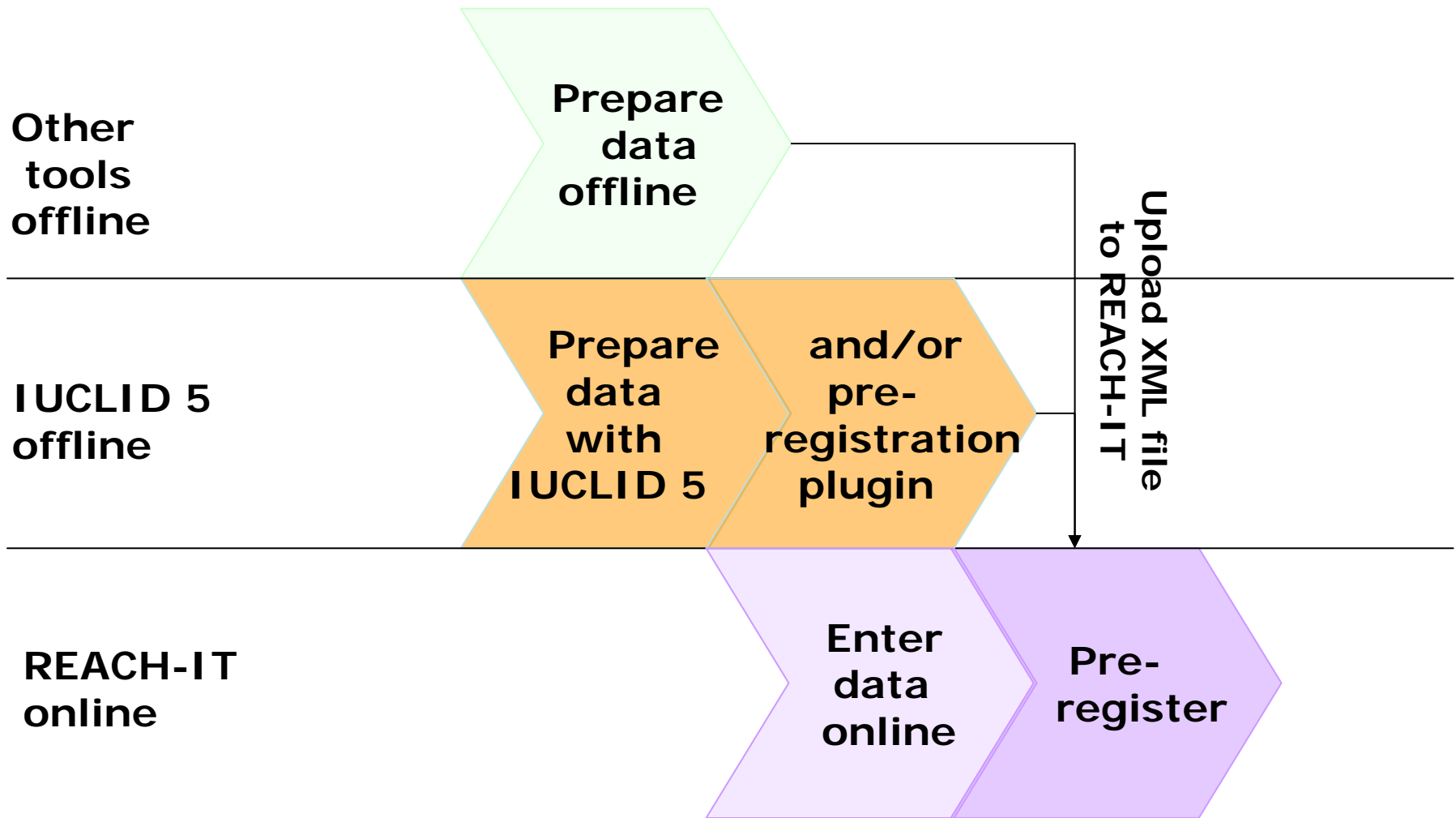
# How to pre-register

- The potential registrant first needs to **sign-up** to **REACH-IT**
- Each legal entity must sign-up and pre-register separately
- Pre-registration is free of charge
- 2 ways to pre-register:
  - **on-line**: pre-registrations created one at a time using REACH-IT
  - **bulk**: file containing information for a large number of substances submitted via REACH-IT

# How to pre-register for OR

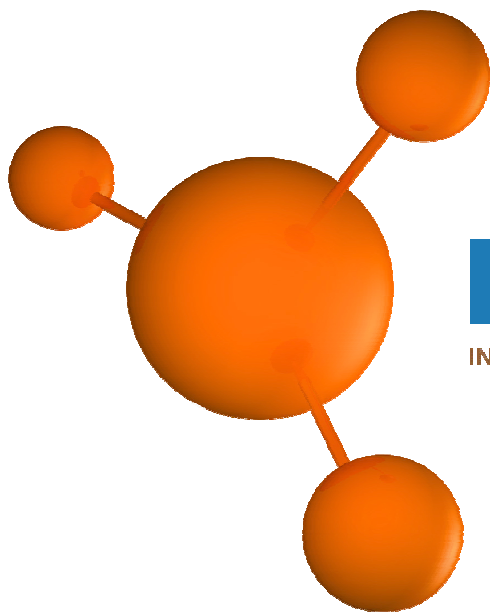
- Only Representative must sign-up to REACH-IT for each non-EU manufacturer represented
  - multiple legal entities with same name and same VAT/DUNS number are allowed in REACH-IT
  - company size = size of non-EU manufacturer represented
- 1 individual pre-registration per substance and per non-EU manufacturer represented, with the tonnage band and the envisaged deadline for registration

# What tools to use



# What tools to use: IUCLID 5

- for preparing bulk pre-registration files using the plug-in
- used **locally** in company IT installations
- also for dossier preparation: registration, PPORD,...



**IUCLID 5**  
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

available for download free of charge on IUCLID website:  
<http://echa.europa.eu/iuclid>

# What tools to use: REACH-IT

available on ECHA website: [echa.europa.eu/reachit/portal\\_en.asp](http://echa.europa.eu/reachit/portal_en.asp)

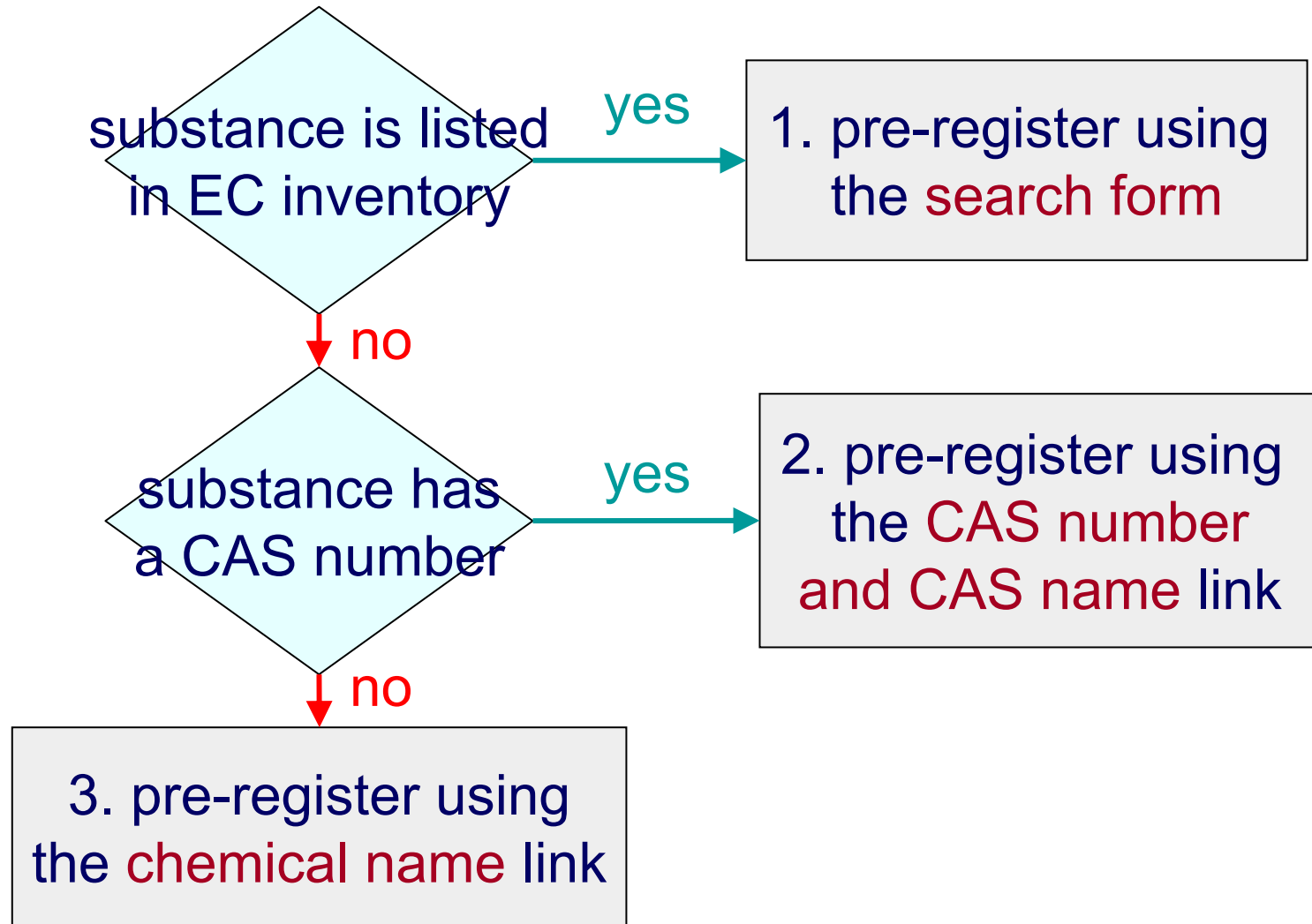
- company sign-up + third party representative sign-up
- on-line and bulk pre-registration:
  - creating a pre-registration on-line
  - submitting a pre-registration (on-line and bulk) (mandatory)
  - viewing and downloading submission reports
  - updating a pre-registration (except substance identity)
  - overview of all your pre-registrations
  - accessing the pre-SIEF
  - pre-SIEF functionalities

# What data is needed

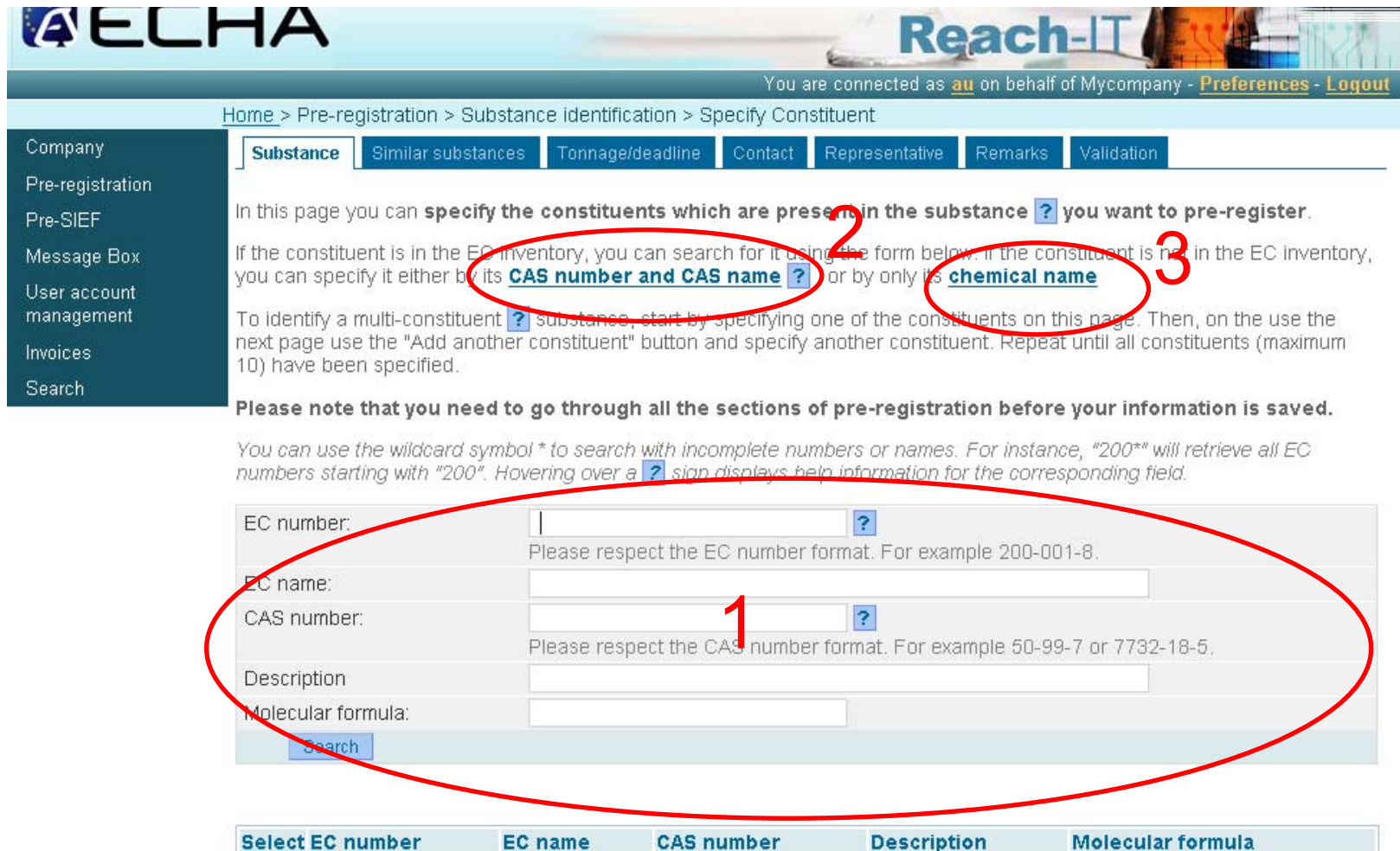
- Substance name
- Similar substances (optional): substances which can be used for QSAR, grouping or read-across
- Envisaged tonnage band + registration deadline (pick-list)
- Contact person details (optional)
- Third party representative contact details (optional): if you have concerns about confidentiality, you can appoint a third party representative to deal with data-sharing on your behalf
- Remarks about the substance (optional)

- Substance name / Similar substances / Remark
- Contact details:
  - if a company specifies a third party representative (TPR), the contact details of the TPR will be made available in the pre-SIEF to others pre-registering this substance
  - if a company specifies a contact person, his/her contact details will be made available in the pre-SIEF, unless a TPR is specified
  - if no contact person is selected, and no TPR is specified, the company's general contact details will be made available in the pre-SIEF

# How to pre-register on-line



# How to pre-register on-line



**ECHA** **Reach-IT**

You are connected as **au** on behalf of Mycompany - [Preferences](#) - [Logout](#)

[Home](#) > [Pre-registration](#) > [Substance identification](#) > [Specify Constituent](#)

**Substance** Similar substances Tonnage/deadline Contact Representative Remarks Validation

In this page you can **specify the constituents which are present in the substance** ? you want to pre-register.

If the constituent is in the EC inventory, you can search for it using the form below. If the constituent is not in the EC inventory, you can specify it either by its **CAS number and CAS name** ? or by only its **chemical name** ?

To identify a multi-constituent ? substance, start by specifying one of the constituents on this page. Then, on the next page use the "Add another constituent" button and specify another constituent. Repeat until all constituents (maximum 10) have been specified.

**Please note that you need to go through all the sections of pre-registration before your information is saved.**

You can use the wildcard symbol \* to search with incomplete numbers or names. For instance, "200\*" will retrieve all EC numbers starting with "200". Hovering over a ? sign displays help information for the corresponding field.

EC number:  ?  
Please respect the EC number format. For example 200-001-8.

EC name:

CAS number:  ?  
Please respect the CAS number format. For example 50-99-7 or 7732-18-5.

Description:

Molecular formula:

[Select EC number](#) [EC name](#) [CAS number](#) [Description](#) [Molecular formula](#)

# How to pre-register in bulk

- Bulk pre-registrations are prepared locally in IUCLID 5 or any other company IT system
- Only for substances (incl. similar substances) and constituents **with EC numbers**
- Up to **500 substances** per bulk pre-registration file
- Bulk file must be compliant with the XML format published on the IUCLID website
- Files are submitted via REACH-IT. Limit of **10000 substances** per company without prior ECHA approval

# What happens next

- You will receive a **submission number**
- For “bulk” pre-registration files: REACH-IT will verify the file format, structure and content of the file, and will reject it if it is not conform
- You will receive a message in your REACH-IT message box, containing:
  - a link to the submission report (pdf format) and
  - the **pre-registration number**
- You will have access to the pre-SIEF webpage
- You can view / update your pre-registrations

# How to update

- A pre-registration can at any time be updated in REACH-IT, independently from the way it was submitted (on-line or bulk pre-registration).
- All fields can be updated, except the substance identity, and the information in the pre-SIEF will be updated accordingly
- If a potential registrant is no longer interested in a substance, he can “deactivate” his participation in the pre-SIEF, but he remains visible

# How to delete

- to have a pre-registration deleted
  - send the request by registered mail to:  
ECHA, Directorate C / Pre-registration Team  
Annankatu 18, 00121 Helsinki, Finland
  - include a print-out of the submission report
- ECHA will exclude it from the list of pre-registered substances and – in a later phase – delete the pre-registration

- more than 10.000 Legal entities have signed up from all 27 EU Member States + EAA
  - Germany 21% - UK 15% - Netherlands 10% - France 9%
- more than 400.000 pre-registrations received
  - Germany 39% - UK 38% - Netherlands 4,8% - Italy 4,2%
  - more than 40.000 substances pre-registered
- on-line pre-registration remains important:  
>6.000 pre-registrations per week
- bulk pre-registration: 10% failure after submission

## for metals



- Substance name: no major problem so far
  - >98% of pre-registered substances are on EINECS
  - Remaining substances: most identified by CAS number
  - some substances identified only by chemical name
    - sometimes unrightfully, even with the EINECS or CAS number mentioned in comments field
- Polymers
  - Monomers should be pre-registered
- Multi-constituent substances
  - preparations should NOT be pre-registered as multi-constituent substances

- Substance name: screened by ECHA
  - for substances without an EINECS number
  - multi-constituent substances
- Use of functional mailbox to communicate with the pre-registrant in case of issues → facilitate SIEF formation by industry after pre-registration
  - mainly omission of an existing EINECS number (should be used, not merely mentioned in remarks field)
  - use of non-English chemical names.

# Main recommendations

- Follow the Guidance on substance identification for naming your **phase-in substance**
- Respect the preferred order for substance identifiers to use:
  - 1. EC number
  - 2. CAS number and CAS name
  - 3. IUPAC name
- Specify the chemical name carefully:
  - use the IUPAC name in **English**,
  - add all other available numerical identifiers
  - if regarded necessary, add synonyms and/or chemical names in other languages
- Fill in your company's and contact person's details

# Next steps



Pre-  
registration



- Pre-registration is now open until 1 December 2008

# Next steps

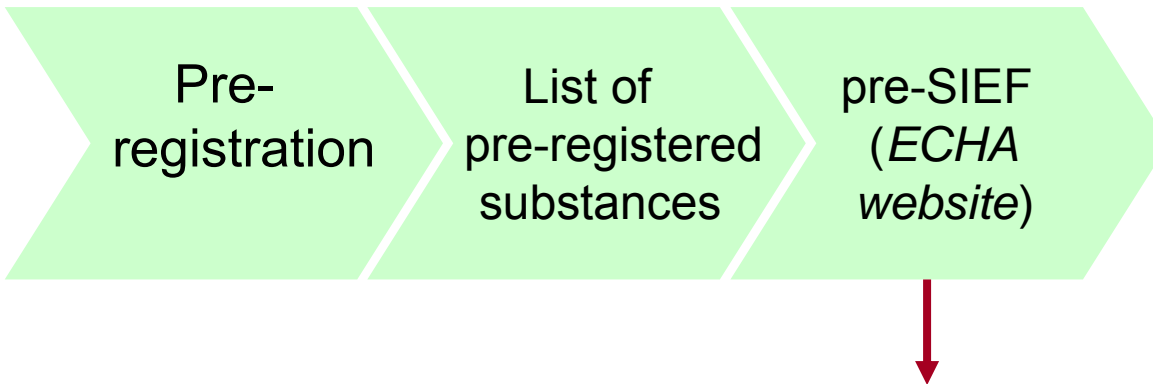


Pre-  
registration

List of  
pre-registered  
substances

- ECHA publishes an **intermediate** list of pre-registered substances in October 2008
- ECHA publishes the list of pre-registered substances by 1 January 2009
- Data holders may indicate that they have relevant data on pre-registered substances, using REACH-IT

# Next steps



- REACH-IT brings submitters of the same identifier together in a “pre-SIEF” webpage
- Can see contact details of:
  - other pre-registrants
  - early registrants, substances regarded as registered
  - data holders after 1 January 2009

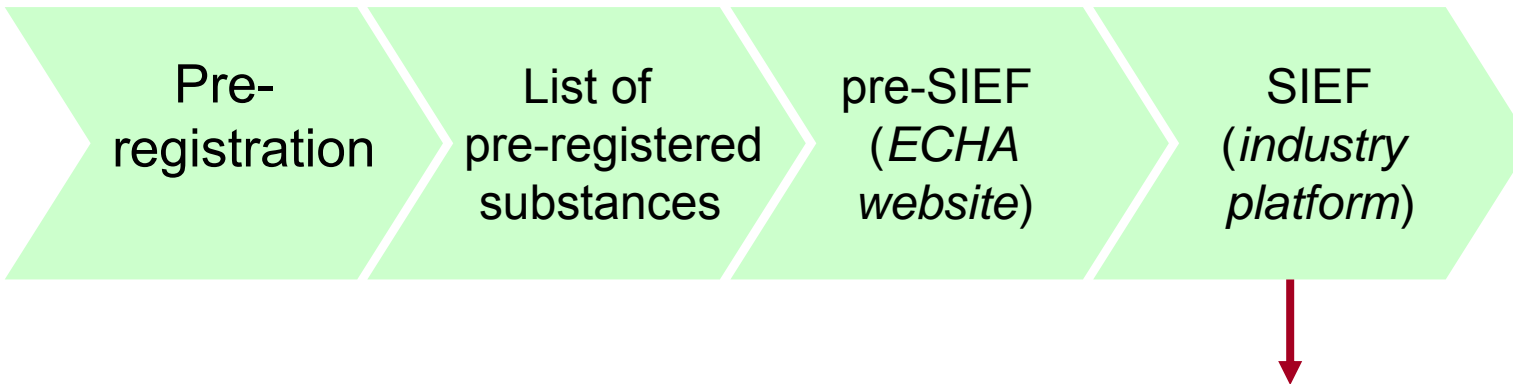
# What is a pre-SIEF

- After pre-registration, a substance pre-SIEF webpage will be formed for each EINECS n°/ CAS n°/ other identity code
- All potential registrants will be able to see:
  - each others contact details + contact details from data holders
  - identified read-across possibilities
  - remarks about the substance
- It is possible to navigate to the pre-SIEF webpages of the substances identified for read-across (to and from)
- If you have concerns on confidentiality, use a third party representative during pre-registration

To initiate discussions after pre-registration a “SIEF formation facilitator” can be identified on the pre-SIEF webpage:

- Only potential registrants can volunteer to become SIEF formation facilitator, on a first-come first-serve basis.
- Not legally binding, no additional obligations.
- Can post information to the other participants in a separate text box on the pre-SIEF webpage, e.g. on further communication tools to be used.

# Next steps



- Industry needs to agree on SIEF formation and share data and costs within the SIEF

# What is a SIEF

- Obligatory platform to:
  - share data among potential registrants of the same phase-in substances and data holders + avoid unnecessary testing
  - agree on classification and labelling
- Suitable platform to organise the mandatory joint submission of data
- Potential registrants within a pre-SIEF must discuss whether their substances are the same
- If agreement on the sameness: SIEF is ‘born’ (Article 29)

# SIEF formation – key issues

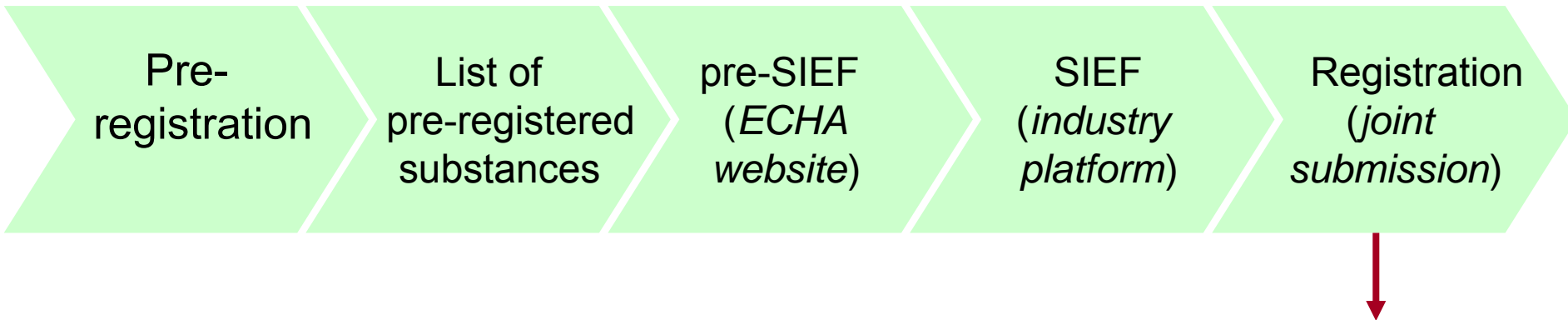
- Industry must assess the sameness (see guidance on substance identity)  
No confirmation by ECHA!
- SIEF participants are free to organize themselves as they see fit
  - Consortium is one possible form of co-operation
  - Co-operation and collective approaches highly encouraged

# SIEF formation – key issues

## Cost sharing (see guidance on data sharing)

- Costs must only be shared for information:
  - that a registrant is required to submit
  - at the time when a registrant is required to submit the information
- Costs must be shared in a fair, transparent and non-discriminatory way
- If SIEF participants cannot reach an agreement, costs shall be shared equally

# Next steps



- Industry needs to jointly submit data to ECHA via REACH-IT

# For more information...

- Detailed information on ECHA website
  - Pre-registration section in 22 languages
  - user guides for sign-up and pre-registration
  - Manuals for all (temporary) submission procedures
  - Guidance documents, e.g. on substance identification
  - Downloadable answers to FAQ in all languages
- Regular communication with stakeholders
  - News Alerts on ECHA website
  - Leaflet distributed to trade associations and Member States Competent Authorities
  - bimonthly ECHA newsletter

Thank you for your attention