

# Pre-registration and support to industry

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**September 2008**  
**Iceland**

# Pre-registration

State of play

# Basics of pre-registration

Pre-registration is a duty under REACH for **every potential registrant** of phase-in substances, taking place between 1 June – **1 December 2008**, granting them extended deadlines for registration.

# Which substances?

## Phase-in Substances

- Mono-constituent substances
- Multi-constituent substances
- UVCB- substances
  - EINECS #
  - CAS # and CAS name
  - Chemical name

# How to do in practise?

- Potential registrants first need to **sign-up** to **REACH-IT**.
- Each legal entity must sign-up and pre-register separately.
  - an Only Representative must sign-up and pre-register separately for each non-EU manufacturer represented.
- Pre-registration is free of charge.
- 2 ways to pre-register:
  - **on-line**: pre-registrations created one at a time using REACH-IT
  - **bulk pre-registration**: file prepared in a separate system (such as IUCLID) and submitted via REACH-IT

# What data to submit?

- **Substance name + EINECS or NLP or CAS #**
- **Similar substances** (optional): substances which can be used for QSAR, grouping or read-across
- **Envisaged tonnage band + registration deadline**
- **Contact person details** (optional)
- **Third party representative** contact details (optional)
- **Remarks** about the substance (optional)

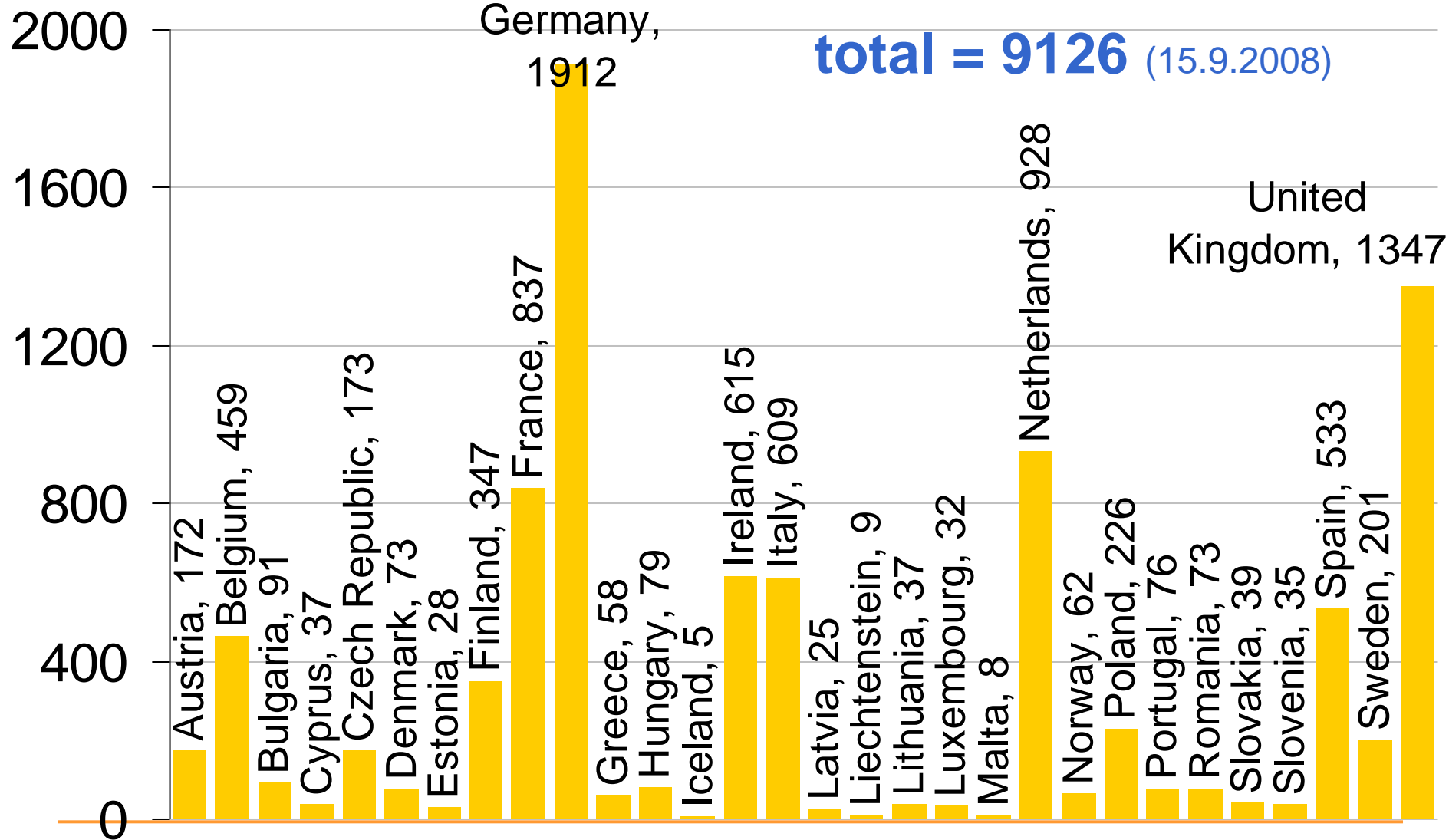
# Let's start...

- REACH-IT went live on 31 May 2008 at 21:15
    - with company **sign-up** and **on-line** pre-registration
    - the **first** company was signed up after **15 minutes**
    - **1286** pre-registrations were submitted on **01 June**
  - on **04 June**, Norway, Iceland and Liechtenstein were added to the system
  - on **22 July**, the bulk pre-registration functionality became available:
    - up to 500 substances pre-registered with one file
    - limited to substances with EC numbers
    - file must be compliant with the XML format published on the IUCLID website
-

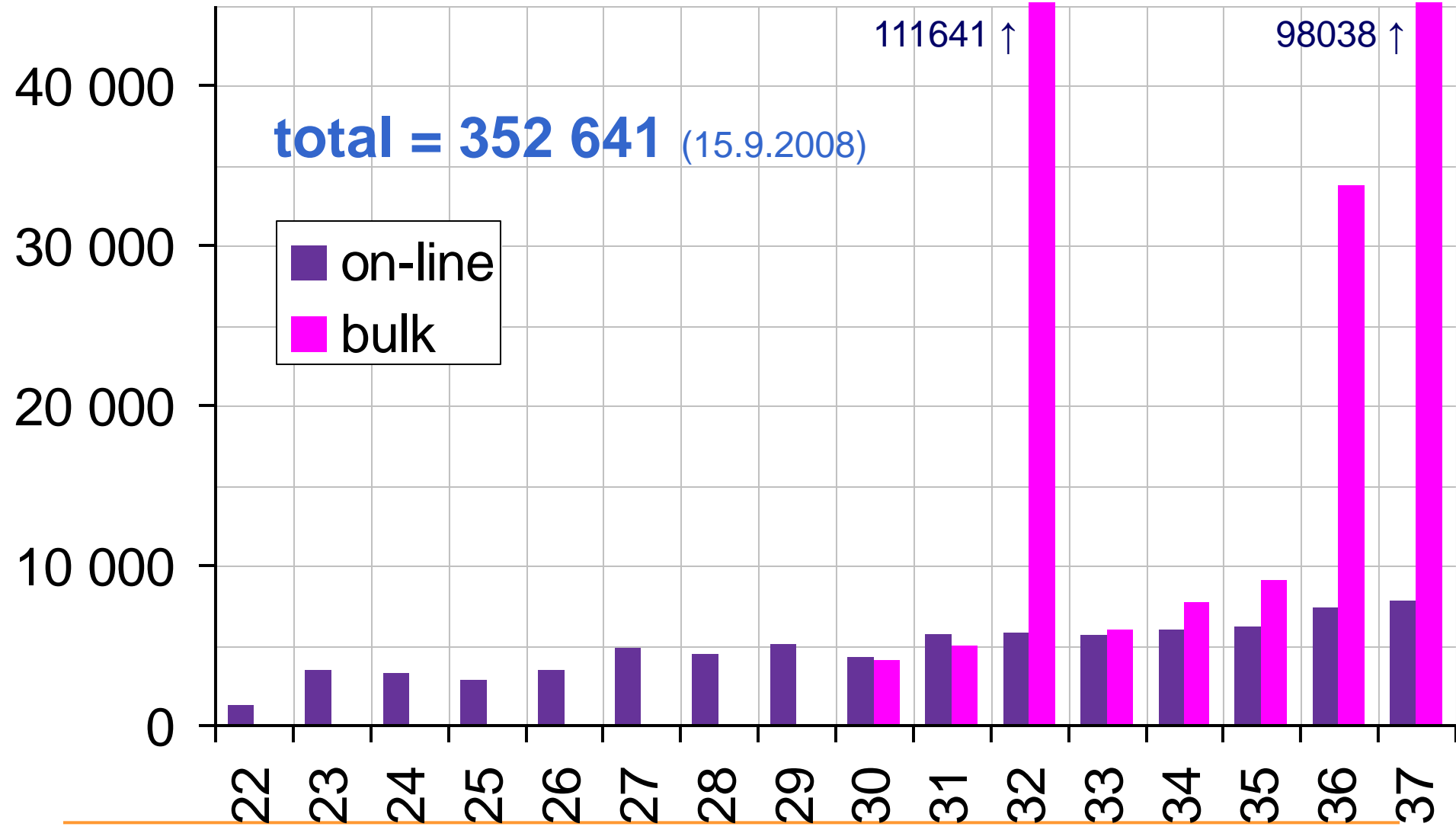
- Number of pre-registrations: 246 794
- Number without EC number: 5931
- Mono-constituent substances: 997
- Mono-constituent by CAS: 3529
- Multi-constituent: 1405



# Legal entities signed up



# Pre-registrations per week



- 9.126 Legal entities have signed up from all 27 EU Member States + EAA
    - Germany 21% - UK 15% - Netherlands 10% - France 9%
  - 352.641 pre-registrations received
    - Germany 40% - UK 39% - Netherlands 4,9% - Italy 4,0%
    - 110.664 substances pre-registered
    - 104.725 substances pre-registered by one UK company
  - on-line pre-registration remains important:  
>6.000 pre-registrations per week
  - bulk pre-registration: 10% rejections
-

# Typical mistakes... when pre-registering

- Use of ambiguous “chemical names” or trade names or company codes
- Using molecular formula instead of chemical names
- Substance is listed in EINECS but pre-registered with different chemical name
- Pre-registering polymers
- Pre-registering preparations
- CAS number and CA index name do not fit together
- Given name does not refer to the CA index name but to synonym
- Spelling mistakes / typing errors / languages

# 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
-

## Regarding REACH-IT

- Unintentional creation of “reaction mass”
- How can I deactivate?
- How can I modify?
- How can I delete?

## Pre-registration Q&A:

Q1. What happens if I do not pre-register my phase-in substance?

A1. You need to register your substance immediately or lower manufacturing or importing it to quantities lower than 1 tonne/year.

Q2. What happens after pre-registration period?

A2. ECHA will publish list of pre-registered substances.

Downstream users shall inform ECHA if their substance is not listed (Article ) Companies will on the basis of pre-SIEFs create SIEFs (industry responsibility – out of scope of ECHA)

Companies will share data and prepare registration dossiers to be submitted to ECHA.

HOME

PRE-REGISTRATION

What to know

Preparation

Create account

Submission

Pre-SIEF

SIEF

Registration

REACH

REACH-IT

ECHA-CHEM

CLASSIFICATION

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PRESS&EVENTS

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STAKEHOLDERS

LINKS

## What you need to know

### Know your REACH role/s

When you start preparing for REACH you should first know what roles your company may have in relation to its substances. The following roles are relevant for pre-registration:

- Manufacturer / importer of substances
- Producer / importer of articles
- Only representative
- Downstream user
- Distributor
- Data holder

If you are a manufacturer or importer of substances which you need to register them. The registration requirement applies to importers of articles if substances are intentionally released.

Companies that are not established in the EU have no obligation to pre-register and register. However, a non-EU manufacturer or importer of articles whose products are imported into the EU can appoint an Only Representative who will then carry out the REACH obligations on their behalf. An Only Representative will be linked to the imported substances. An Only Representative will be appointed by the event that the importer had already registered the substance.

Downstream users and distributors who buy their substances (or release substances) from EU suppliers or non-EU suppliers who are not Only Representatives do not need to pre-register and register. However, if they are suppliers they will be considered as importers under REACH and will need to register as importers.

If a downstream user or a third party is holding data on substances it can inform ECHA with the intention of participating to exchange of information with the registrants. The REACH IT portal has a separate functionality for these Data holders.



## Launch on 14 April 2008

- 7-step guide from “What to know” to “Registration”
- Is available in 22 EU languages
- <http://echa.europa.eu/pre-registration>



# Available Information on ECHA website (1)

## Pre-registration:

- Pre-registration web pages and material
  - Leaflets on Pre-registration, REACH, REACH for exporters to EU
  - Questions and answers
  - Practical Steps for Pre-registration
- Guidance Documents
  - Registration ( chapters 1.7 and 2.2)
  - Data Sharing (chapters 3.8 and 3.9, Section 4)
  - Identification and Naming of Substances in REACH

# Available Information on ECHA website (2)

## REACH-IT:

- Leaflets
  - How to Submit Data to ECHA
- Training Material
  - Overview
  - Key Concepts
  - Sign-up and User Management
  - Pre-Registration
  - Manuals
  - Data Submission Manual 6: Submission of bulk pre-registrations

## IUCLID 5:

- Pre-registration plugin
  - installation manual
  - user guide
  - Presentation
  - video tutorials 1 and 2
- XML format
  - Toolkit with examples
- IUCLID 5 website
  - End User Manual
  - Installation Manuals
  - Training material
  - Formats
  - Video Tutorials

# Pre-registration Publications

- **2-page leaflet** – to raise your appetite to read more
- **Practical Steps guide** – tells you how it works
- Will be published on ECHA web in **22 EU languages**



 **ECHA**  
<http://echa.europa.eu>

 **European Commission**

## Esirekisteröi käyttämäsi kemikaalit! Näin jatkat liiketoimintaa REACH-vaatimusten mukaisesti

Kemikaalien valmistaja, maahantuojia tai käyttäjiä tai esineiden maahantuojia – Esirekisteröinti 1. kesäkuuta – 1. joulukuuta 2008 on kriittinen vaihe yrityksellesi

**Miksi esirekisteröinti on?**  
REACH-säätöjen mukaan suurin osa kemikaaleista (kaikkiin paitsi esineisiin) on esirekisteröitävä.  
Määrä esirekisteröintiä voi tehdä vain 1. kesäkuuta – 1. joulukuuta 2008.

**Miksi tapahtuu, jos en tee esirekisteröintiä?**  
Jos et ole tehnyt kemikaalin esirekisteröintiä, et voi jatkaa sen valmistusta tai maahantuontia 1. joulukuuta 2008 jälkeen, ennen kuin olet tehnyt sinulta koskevan rekisteröintin Euroopan kemikaalivirastoon (ECHA).

**Kenen pitäisi tehdä esirekisteröintiä?**  
Etässä toimivien yritysten, jotka  
- valmistavat tai maahantovat kemikaaleja  
- valmistavat tai maahantovat esineitä, joita tarkoituksellisesti vapautuu esineistä.  
Ei:n ulkopuolella toimivien valmistajien osalta esirekisteröintiä voi tehdä vain valmistajan EU:ssa toimittava sivustaja.


Kemikaalien käyttäjien (jälkikäyttäjien) ei tarvitse esirekisteröidä, jos he eivät tuo maahan kemikaaleja Euroopan unionin ulkopuolelta.


Jälkikäyttäjät voivat jatkaa esirekisteröintien tai rekisteröintien hankkimista käyttäen. Heidän tulee varmistua, että toimittajilta hankitut kemikaalit on esirekisteröity.



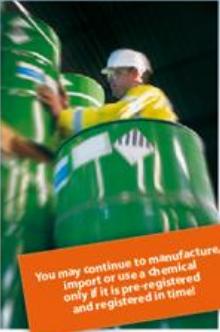
**Voit jatkaa kemikaalien valmistusta, tuontia tai käyttöä vain, jos niiden esirekisteröinti ja rekisteröinti on tehty ajoissa!**

EUROOPAN KEMIKAALIVIRASTO



 **ECHA**  
<http://echa.europa.eu>

## Practical steps for REACH pre-registration



**You may continue to manufacture, import or use a chemical only if it is pre-registered and registered in time!**

EUROPEAN CHEMICALS AGENCY

<b>HOME</b>	
<b>PRE-REGISTRATION</b>	
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<b>REACH-IT</b>	
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<b>ABOUT ECHA</b>	
<b>PUBLICATIONS</b>	
<b>WORKING WITH US</b>	
<b>LINKS</b>	

## REACH-IT

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### Portal

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### Registration

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## Launch in mid May 2008

- Up-to-date info in 22 languages about
  - Pre-registration
  - PPORD, Inquiry & Registration
  - <http://echa.europa.eu/reachit>

# Data- sharing and SIEF

# 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.

# What Happens after Pre-registration?

Pre-  
registration

List of  
pre-registered  
substances

pre-SIEF  
(*ECHA  
website*)

SIEF  
(*industry  
platform*)

- 
- 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 or not.
- If agreement on the sameness: SIEF is ‘born’ (Article 29)

- 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

- In many cases EINECS = SIEF, but:
  - substances within one EINECS number may, after detailed examination, turn out to be so different in terms of composition that data from one substance may not be relevant to describe the profile of the other substance: several SIEFs may be formed.
  - different EINECS numbers may reflect the same substance: one SIEF may be formed.
- Data sharing obligations must be respected!  
(it is not allowed to form 2 SIEFs for the same substance)

## 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
-

# Support to industry

# Info - ECHA website



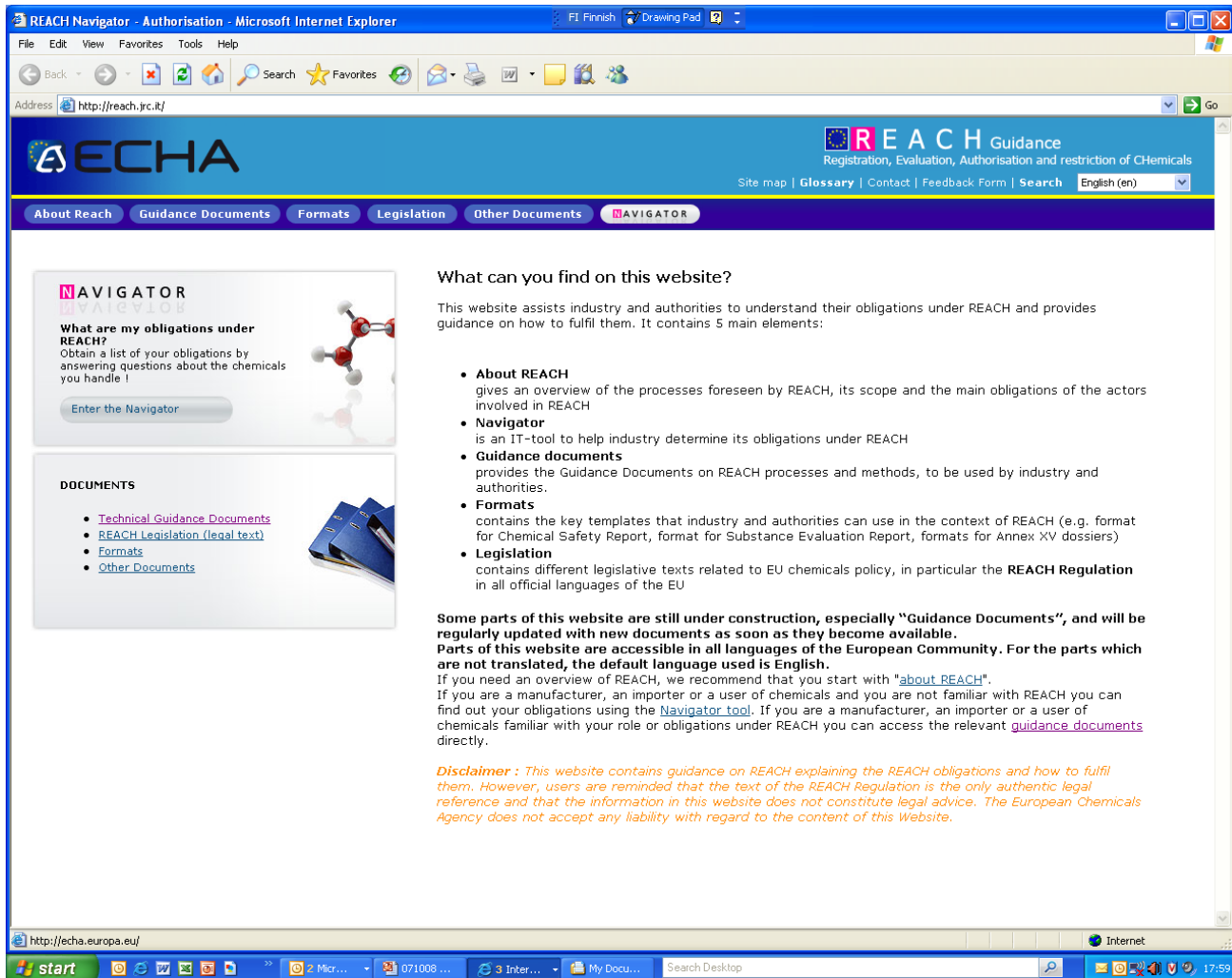
- CV** Evropská agentura pro chemické látky
- DA** Det Europæiske Kemikalieagentur
- DE** Europäisches Amt für chemische Stoffe
- ET** Euroopa Kemikaalide Amet
- EL** Ευρωπαϊκός Οργανισμός Χημικών Προϊόντων
- EN** European Chemicals Agency
- ES** Agencia Europea de Sustancias y Preparados Químicos
- FI** Euroopan kemikaalivirasto
- FR** Agence européenne des produits chimiques
- IT** Agenzia europea delle sostanze chimiche
- LT** Europos cheminių medžiagų agentūra
- LV** Eiropas ķīmisko vielu aģentūra
- HU** Vegyi Anyagokkal Foglalkozó Európai Ügynökség
- MT** L-Aġenzija Ewropea tal-Kimika
- NL** Europees Chemicaliënagentschap
- PL** Europejska Agencja ds. Substancji Chemicznych
- PT** Agência Europeia dos Produtos Químicos
- SK** Európska agentúra pre chemické látky
- SL** Evropska agencija za kemikalije

European Chemicals Agency

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# Info - REACH Guidance



REACH Navigator - Authorisation - Microsoft Internet Explorer

FI Finnish Drawing Pad

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address <http://reach.jrc.it/> Go

**ECHA** REACH Guidance  
Registration, Evaluation, Authorisation and restriction of Chemicals

Site map | Glossary | Contact | Feedback Form | Search English (en)

About Reach Guidance Documents Formats Legislation Other Documents NAVIGATOR

### NAVIGATOR

**What are my obligations under REACH?**  
Obtain a list of your obligations by answering questions about the chemicals you handle !

Enter the Navigator

### DOCUMENTS

- Technical Guidance Documents
- REACH Legislation (legal text)
- Formats
- Other Documents

### What can you find on this website?

This website assists industry and authorities to understand their obligations under REACH and provides guidance on how to fulfil them. It contains 5 main elements:

- About REACH**  
gives an overview of the processes foreseen by REACH, its scope and the main obligations of the actors involved in REACH
- Navigator**  
is an IT-tool to help industry determine its obligations under REACH
- Guidance documents**  
provides the Guidance Documents on REACH processes and methods, to be used by industry and authorities.
- Formats**  
contains the key templates that industry and authorities can use in the context of REACH (e.g. format for Chemical Safety Report, format for Substance Evaluation Report, formats for Annex XV dossiers)
- Legislation**  
contains different legislative texts related to EU chemicals policy, in particular the **REACH Regulation** in all official languages of the EU

**Some parts of this website are still under construction, especially "Guidance Documents", and will be regularly updated with new documents as soon as they become available. Parts of this website are accessible in all languages of the European Community. For the parts which are not translated, the default language used is English.**

If you need an overview of REACH, we recommend that you start with "[about REACH](#)".

If you are a manufacturer, an importer or a user of chemicals and you are not familiar with REACH you can find out your obligations using the [Navigator tool](#). If you are a manufacturer, an importer or a user of chemicals familiar with your role or obligations under REACH you can access the relevant [guidance documents](#) directly.

*Disclaimer : This website contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this website does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the content of this Website.*

<http://echa.europa.eu/> Internet

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# Info - REACH Brochures

## How can I prepare?

Identify within your company who will be **responsible** for REACH compliance.

Create an **inventory** of all substances or substances in preparations/articles that you import/distribute/handle. Check if the **substances or uses** in your inventory are exempted from one or all aspects of REACH.

Identify for each substance in which roles you need to act under REACH:

- ▶ **Manufacturer/Importer:** you manufacture or import a substance on its own or in a preparation of  $\geq 1$  tonne/year.
- ▶ **Producer/Importer or Supplier of articles:** you manufacture/import articles or place them on the market.
- ▶ **Distributor** (including retailers): you store and place on the market a substance, on its own or in a preparation.
- ▶ **Downstream user:** you use a substance, either on its own or in a preparation, in the course of industrial or professional activities, (for example: formulation, dilution, repackaging, spraying, painting).

Carry out first preparatory actions (for example establish a dialogue through the supply chain, compile information on uses and use conditions) according to your role. Identify and plan for future responsibilities you will have, keeping in mind the different timelines linked to the three tonnage levels ( $\geq 1$  tonne,  $\geq 100$  tonnes,  $\geq 1000$  tonnes).



## Where can I find further information?

The best way is to consult the website of the European Chemicals Agency:

<http://echa.europa.eu>

This website contains:

- ▶ A **Navigator tool** which will assist you to find out your REACH obligations and how to fulfil them
- ▶ **"About REACH"** which gives an overview of the legislation
- ▶ **Guidance documents**
- ▶ **IT tools** for REACH
- ▶ **FAQ** - Frequently asked Questions In English

Your **industry association** is a good source of information for sector specific issues and your **supplier/s** can answer chemical specific questions.

The **REACH helpdesk** in your country provides advice about your responsibilities and roles. Their contact details can be found on the **ECHA website**.



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KH-77-07-234-EN-C

# REACH

The new EU chemicals legislation

## Does REACH affect me?

Do you know what REACH means for your products and your company? You should find out your duties under REACH if:

- ▶ You **manufacture or import chemical substances or mixtures** of chemical substances (preparations).
- ▶ You **produce or import articles** (for example construction materials, electronic components, toys or vehicles) which contain substances included in a list of 'substances of very high concern' or which are released during their use.
- ▶ You **process chemicals** or you **formulate preparations** for end use (for example cleaning products, paints or motor oils) or you **use** these **formulated products** professionally. In this case you are a 'downstream user'.

# REACH ME?



European Commission



European Chemicals Agency

# REACH

THE NEW EUROPEAN  
CHEMICALS LEGISLATION

## Information for exporters to the European Union

## What should your company know?

### What is REACH?

REACH is a new European Community Regulation on chemicals and their safe use. It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. The new Regulation entered into force on 1 June 2007.



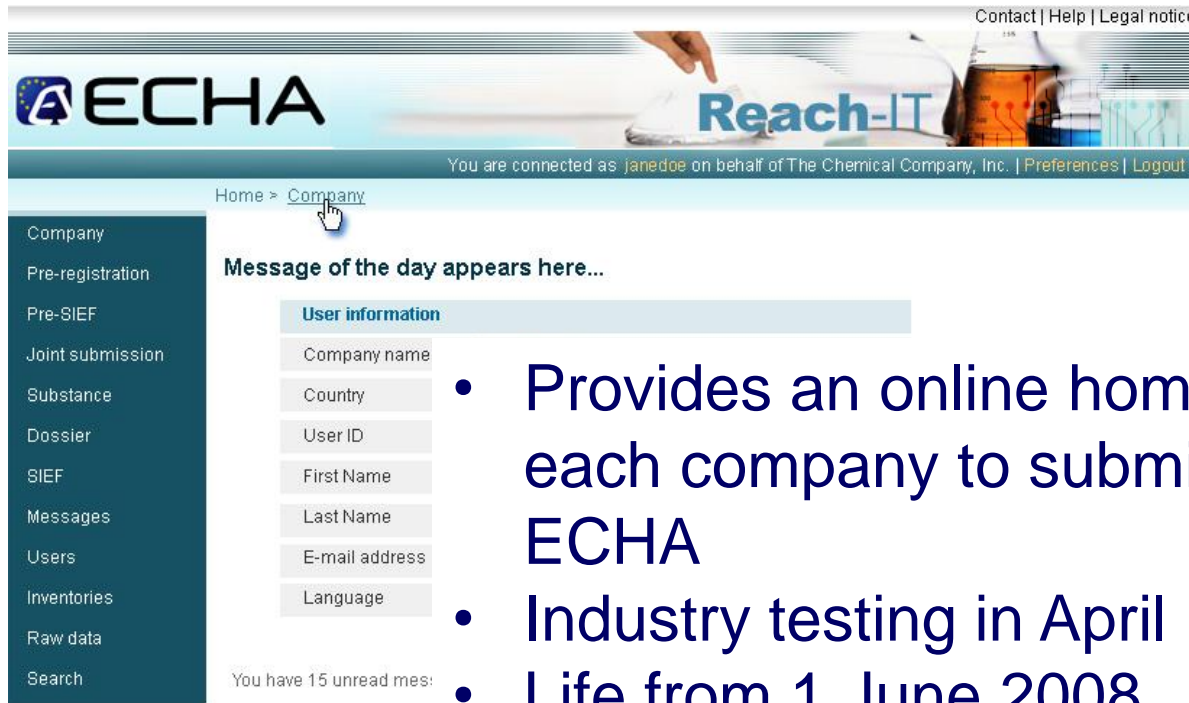
European Commission



European Chemicals Agency



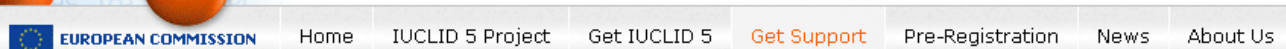
- IT portal for data submission to ECHA



The screenshot shows the REACH-IT portal interface. At the top right, there are links for 'Contact | Help | Legal notice'. The main header features the ECHA logo and the 'Reach-IT' title. Below the header, a navigation bar shows 'Home > Company' with a mouse cursor over 'Company'. A sidebar on the left contains a menu with items: Company, Pre-registration, Pre-SIEF, Joint submission, Substance, Dossier, SIEF, Messages, Users, Inventories, Raw data, and Search. The main content area displays 'Message of the day appears here...' followed by a 'User information' section with fields for Company name, Country, User ID, First Name, Last Name, E-mail address, and Language. At the bottom left of the main content, it says 'You have 15 unread mes:'. To the right of the screenshot, there are three bullet points.

- Provides an online homepage to each company to submit data to ECHA
- Industry testing in April
- Life from 1 June 2008

# IT Tools – IUCLID 5



Documentation | Training | Links | Get Reference substances | IUCLID format | FAQ | Service Desk Contact | Get



## Documentation

Find anything you want to improve or enhance your knowledge in many areas related to our project.

[Read more...](#)



## Training

Here you will find all information and resources available to master IUCLID. Video Tutorials, guidelines, manuals.

[Read more...](#)



## Links

Do you want to get information from the Internet? What other people learn from you will find a selection of useful links.

[Read more...](#)



## Get Reference substances

Reference substances provide identification information (e.g. IUPAC names, structural information) for more than 68.000 substances listed on the IUCLID database.

[Read more...](#)

## ➤ REACH

### ➤ Software Tools

#### ➤ IUCLID 5

Or <http://iuclid.eu>

– Pre-registration page

- Plug-in

- XML format specs

– Get Support section

- User guide, training material, FAQs etc.

- Software for companies to store data and prepare for their registration
- Launched in June 2007

# Helpdesks – National

- Established in 27 EU Member States in 2007
  - In most cases operated by national REACH Authorities
- Provide
  - Advice to companies and other stakeholders on their REACH obligations
  - Wide ranging information on the provisions of REACH
- National helpdesks the first point of contact for enquiries
- List of national REACH helpdesks available on ECHA website

[http://echa.europa.eu/reach/helpdesk/nationalhelp\\_contact\\_en.asp](http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.asp)

## Support to registrants on REACH, REACH IT and IUCLID 5 [http://echa.europa.eu/about/contact-form\\_en.asp?topic=reach](http://echa.europa.eu/about/contact-form_en.asp?topic=reach)

ECHA Helpdesk

### Contact ECHA

My question is related to (please select one of the following options):

- Enquiry on REACH**  
Advice to registrants on REACH obligations. [More >](#)
- IUCLID 5**  
IT tool to capture, store and exchange data on chemical substances for REACH and other regulatory purposes worldwide. [More >](#)
- REACH-IT**  
Web portal to submit REACH registrations and share information on chemicals. [More >](#)
- Enquiry on specific submission to ECHA**  
Questions related to specific submissions e.g. ongoing registrations, PPORD, inquiries (Art. 26), invoices.
- General enquiry**  
E.g on translation matters, request for information on ECHA.
- ECHA website**  
Feedback on the website e.g improvements needed.

→ ECHA Communications

→ Webmaster

Enquiries on these topics should be sent via this webform.

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# Questions?



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