REACH

a brief overview for

Non - EU Companies

J.Kreysa
ECHA, Oct. 2008

Before REACH /1

4 EU legislative instruments:

- Directive **67**/548: notification of new chemicals, classification & labelling of dangerous chemicals
- Directive **76**/769: Restrictions of marketing & use of certain dangerous substances & preparations
- Directive **88**/379: classification and labelling of dangerous preparations (mixtures)
- Regulation 793/**93**: evaluation and control of risks of existing substances

Before REACH /2

Some successes:

- HPVCs (High Production Volume Chemicals): Large data gathering & summarising process
- Risk Assessment principles agreed
- Priority setting done
- EU harmonised risk assessments for many controversial substances, forming the solid basis for EU wide risk reduction measures

Before REACH /3

Some significant shortcomings:

- **Data gaps:** e.g. for 86% of HPVCs
- **Too slow:** process takes (far) too long
- **Inefficient:** burden of proof on public authorities but data with Industry
- **Info gaps:** Uses of chemicals largely unknown
- **Confusion**: too many directives and regulations
- **Hindering innovation:** notification of new chemicals – too big administrative burden

ECHA
European Chemicals Agency

Solution: a new EU Chemicals Policy

REACH

Registration, Evaluation and Authorisation of CHemicals

REACH

Objective = Sustainable Development

- Protection of human health and the environment
- Maintain/enhance innovation/competitiveness
- Maintain the Internal Market of the EU
- Increase transparency and consumer awareness
- Integrate with international efforts to manage chemicals
- Promote non-animal testing
- Conformity to WTO obligations

REACH

- A Single Coherent System for new (non phase-in) and existing (phase-in, in EINECS) substances
- Key elements:
  - Registration by industry of manufactured/imported chemical substances > 1 tonne/year (staggered deadlines over 11years)
  - Information and communication throughout the supply chain
  - Evaluation of registered substances (Agency and Member States)
  - Authorisation for uses of substances of very high concern
  - Restriction as “Safety net” (Community wide risk management action)
  - Chemicals Agency (ECHA) to efficiently manage the system

Focus on priorities:

- High volume chemicals (greatest likely exposure) register first
- Greatest concern chemicals (CMR and R50/53) register first

REACH

What does it mean for non-EU companies?

REACH for non-EU companies /1

Principle n°1:

non-EU companies are not directly impacted *(i.e. do not have direct legal obligations)*

but imports to the 27 EU-Member States are under the scope of REACH

→ **EU-importers or Only Representatives (OR) must fulfill all REACH obligations for imported substances, preparations, articles; such as:**

- → (pre-)registration, including data exchange (SIEF)
- → notification of SVHC in articles if above 0,1% SVHC in articles:
  - →notification to ECHA (2010)
  - →info. for downstream users (immediate)
  - →info. to consumer (immediate)

REACH for non-EU companies /2

Principle n°2:

EU-importers/O.R. rely on their suppliers in third countries **for** hazard **data** and safe use **information** that is required by REACH

- in practice, non-EU companies have to provide data of sufficient quality (e.g. OECD GLP certified labs) and in time to enable their importers/O.R.
  - to participate in data-sharing and (joint) registration
  - to fulfill their duties with regard to supply-chain information

REACH for non-EU companies /3

In conclusion, if you are an exporter to the EU, for each substance you export, you have first to decide if you want to:

- work with your EU-importers
- or, if you prefer to work with an Only Representative O.R. then you must,
  - find a partner in EU who can act as your O.R.
  - or establish and use your own EU "legal entity" to act as your O.R. or importer

and then find out which data are needed and make them available to your EU-based partner(s)

Focus on Only Representatives /1

REACH text – Article 8 (Title on Registration):

"1. A manufacturer established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers under this requirement.

Focus on Only Representatives /2

REACH text – Article 8 (Title on Registration):

2. **The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 35 (obligation to keep information) shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31."**

Focus on Only Representatives /3

The EU O.R. shall:

- comply with all obligations of an EU-importer, e.g.
  - (pre-)registration including data sharing (SIEF)
  - information in the supply chain
- have a sufficient background in handling substances
- keep available up to date info on imported volumes and customers (importers, treated as down stream users)
- have and distribute the latest version of SDS (to importers)
- notify (2011) SVHC >0.1% to ECHA
- inform DU and consumer (upon request) of presence of >0.1% SVHC in articles

Focus on Only Representatives /4

The non-Community manufacturer shall

- inform the importers within the same supply chain of the appointment
- provide the O.R. with all necessary information
  - Hazard data, incl. test data
  - Information on all importers and their subsequent supply chains (exposure scenarios)
  - Presence of SVHC at >0.1% in articles
  - All information needed for preparing/updating a SDS

Focus on Only Representatives /5

In practice, how to appoint an OR?

- **ECHA cannot help with this**
- Manufacturer can decide but O.R. must be able to meet the requirements, i.e. needs scientific/technical know how
- Once identified,
  - Make a contract identifying the O.R. and defining the rights and obligation of both sides
    - *The O.R. needs this contract to prove his status*
  - Verify which data he needs and when
  - Start collecting the data and making them available to him

Focus on Only Representatives /6

In practice, WHY to appoint an OR?

- **ECHA cannot help with this decision, neither**

- Possible reason: protection of business confidential information
  - One O.R. with clear contractual relation is better to control than a multitude of importers
  - Data need to be supplied only once
  - No need to tailor data supply to different importers – all data to one place
  - All feed-back from ECHA goes to one place only
  - Importers treated as downstream users – less obligations

Focus on Only Representatives /7

Latest news:

- One O.R. can represent one or several “non-Community manufacturers” but substances are not cummulated:
  - If an O.R. acts on behalf of several “non-Community manufacturers” it must submit separate registrations.
  - The tonnage to be registered is the total tonnages covered by the contractual agreements between the OR and the “non-Community manufacturer”.
  - The information requirement for the registration dossier is determined by this tonnage.

Focus on Only Representatives /8

Latest news:

- By making separate submissions,
  - the confidential business information of the “non-Community manufacturer” can be better preserved and
  - equal treatment with EU manufacturers is ensured (EU manufacturers must submit separate registration dossiers for each legal entity)

Focus on Only Representatives /9

For more detailed and/or updated information, please refer to the guidance on registration:

http://reach.jrc.it/docs/guidance_document/registration_en.htm

Questions

REACH

and

(Pre-) Registration

Joachim KREYSA
ECHA
Director for Cooperation

October 2008

Registration - the concept /1

1. **REACH is based on „No Data – No Market“**
2. Registration proofs
   - the existence of the required data
   - that these data are used to ensure responsible and well-informed management of the risks that substances may present (including by downstream users)

Who must register chemical substances?

- → **Manufacturers**
- → **Importers / Only Representatives**
- → **Producers of articles (in the conditions of Article 7)**

Registration – the concept /2

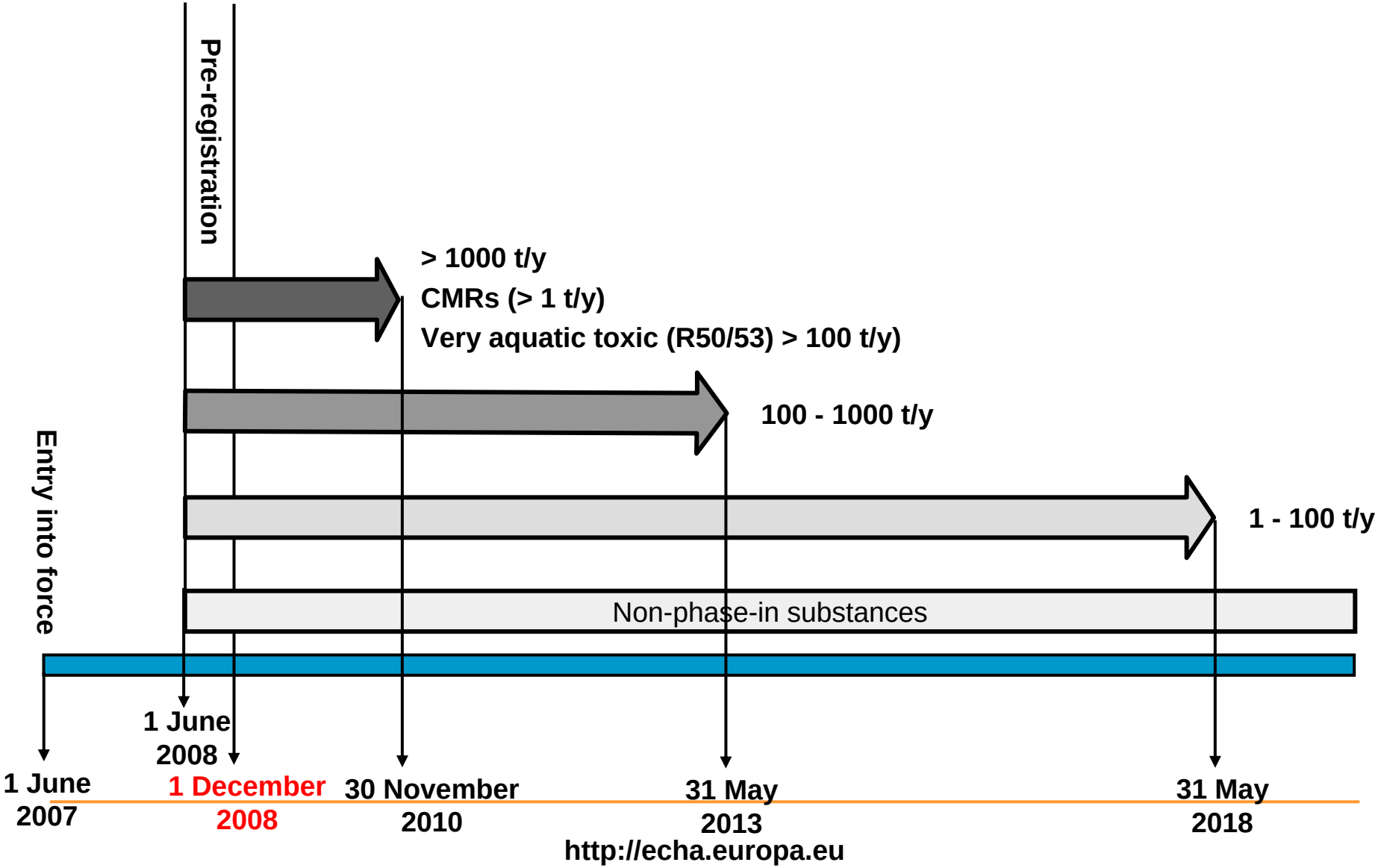
What needs to be registered?

→ Substances (on their own, in preparations, or in articles) if produced/imported ≥ 1 tonne/year per registrant

→ **Specific rules and exemptions** for:

- PPORD
- Intermediates
- Substances in articles
- Polymers
- Biocides, Pesticides, 67/548/EEC notification
- Substances in Annexes IV and V and subject to other laws

Registration - timelines



Registration

DATA NEEDS

Registration – DATA needs /1

1-10 tonnes: **Technical Dossier**

>10 tonnes: **Technical Dossier** **+ Chemical Safety Report**

CSR Tool

Registration – DATA needs /2

Annex VI of REACH:

Identity of registrant, Identity of substance, Information about uses, C&L, Guidance on safe use …

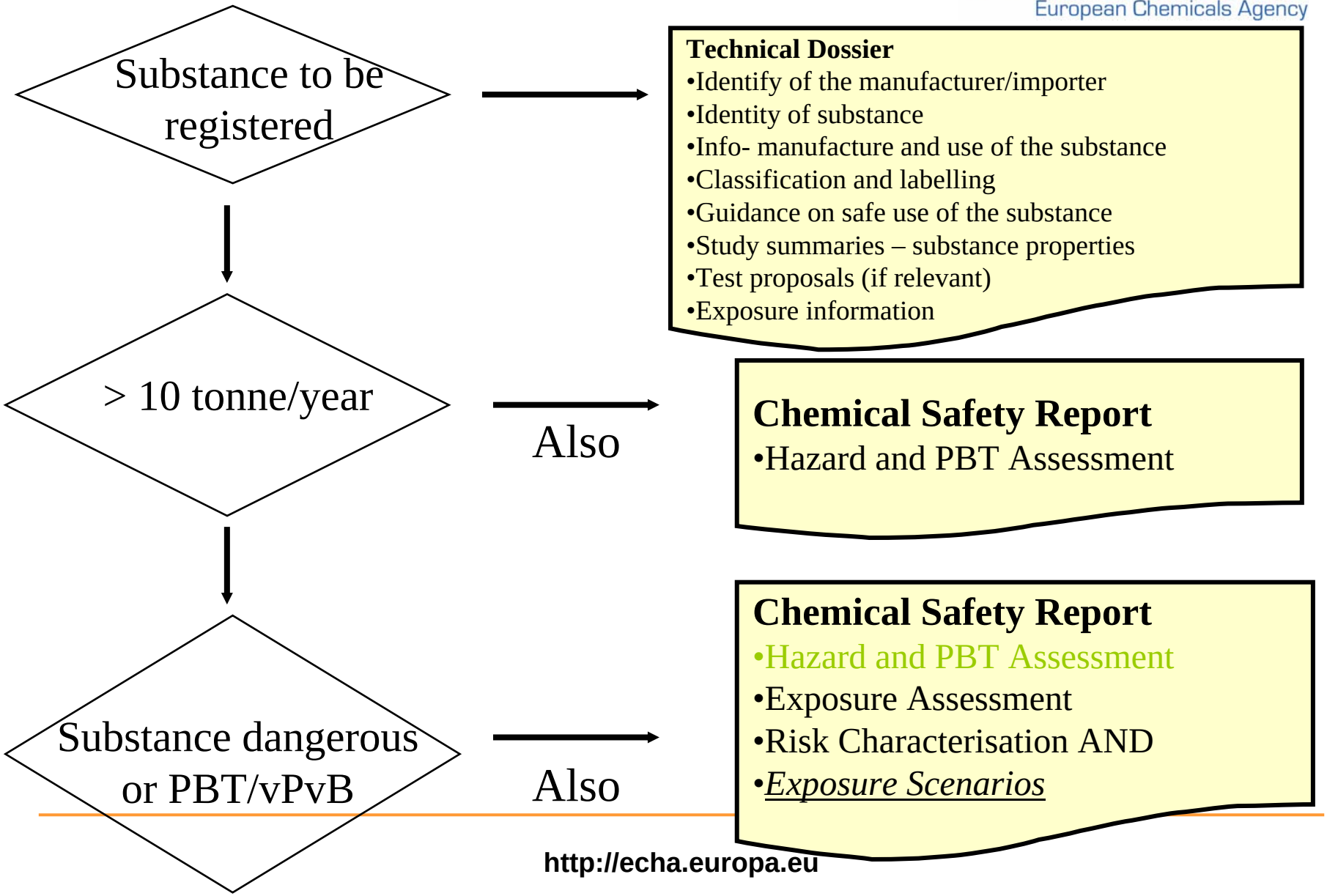
Annexes VII to X of REACH:

Physicochemical, toxicological and ecotoxicological studies requested depends on tonnage :

- 1-10 tons: Annex VII (**technical dossier)**
- 10-100 tons: Annex VII + VIII (**td + CSR)**
- 100-1000 tons: Annex VII + VIII + IX
- >1000 tons: Annex VII + VIII + IX + X

PS: Annex XI of REACH: general rules for adaptation of Annexes VII to X

Registration dossier - content



(pre-) Registration Information source

http://echa.europa.eu/home_en.asp

http://echa.europa.eu/pre-registration_en.asp

http://echa.europa.eu/reach_en.asp

Pre-registration - WHY? /1

1. **Reduce burden for Industry – no fee!**
   - **Pre-registered before 2/12/2008 – staggered registration deadlines give more time to prepare registration dossiers**

   - **After 01.12.08, late pre-registration is possible**
     - **within 6 month after first import/manufacture (i.e. first since 1.6.2008)**
     - **if more than 12 month before registration deadline**

If also the late pre-registration window is missed, substances must be registered BEFORE they can be imported or manufactured!

Pre-registration - WHY? /2

2. Pre-registration enables **data-sharing between pre-registrants of the same substance**
   1. reduced cost for Industry
   2. less animal testing

❖ Data sharing process:
- ➢ pre-SIEF establishes sameness of substances
- ➢ SIEFs (all pre-registrants of the same substances)
  - Mandatory sharing of studies on vertebrate animals
  - Sharing of other tests on request
  - Joint registration (lower registration fee!)

http://reach.jrc.it/docs/guidance_document/data_sharing_en.htm

Pre-registration data /1

The pre-registration file - only basic information

1. Substance identity:
   - identity of the substance to pre-register (EINECS, CAS,..)
2. Similar substances:
   - list of substances considered similar to the one that is pre-registered (QSAR or read-across approach),
3. Tonnage band and deadline:
   - tonnage band & deadline for later registration
4. Contact information:
   - contact information for the substance that is pre-registered
   - Eventually: third party representative
     - represents: the registrant in the SIEF

How to pre-register?

Pre-registration files should be:

- **prepared in IUCLID 5 and then submitted in REACH-IT**
  - Single pre-registration
  - Bulk pre-registration
    - above 10.000 substances - request OK from ECHA

- **or created on-line, directly in REACH-IT**
  - Only single pre-registrations

Pre-registration: IMPORTANT

ECHA advises against pro-actively pre-register substances that are not intended/expected to be registered later

Pre-registration triggers obligations and hence workload in the context of

- Verification of sameness of substances
- SIEF – data exchange

Pre-registration of substances without having/wanting data therefore

- costs money for the pre-registrant
- costs money for the other pre-registrants
- hampers data exchange process

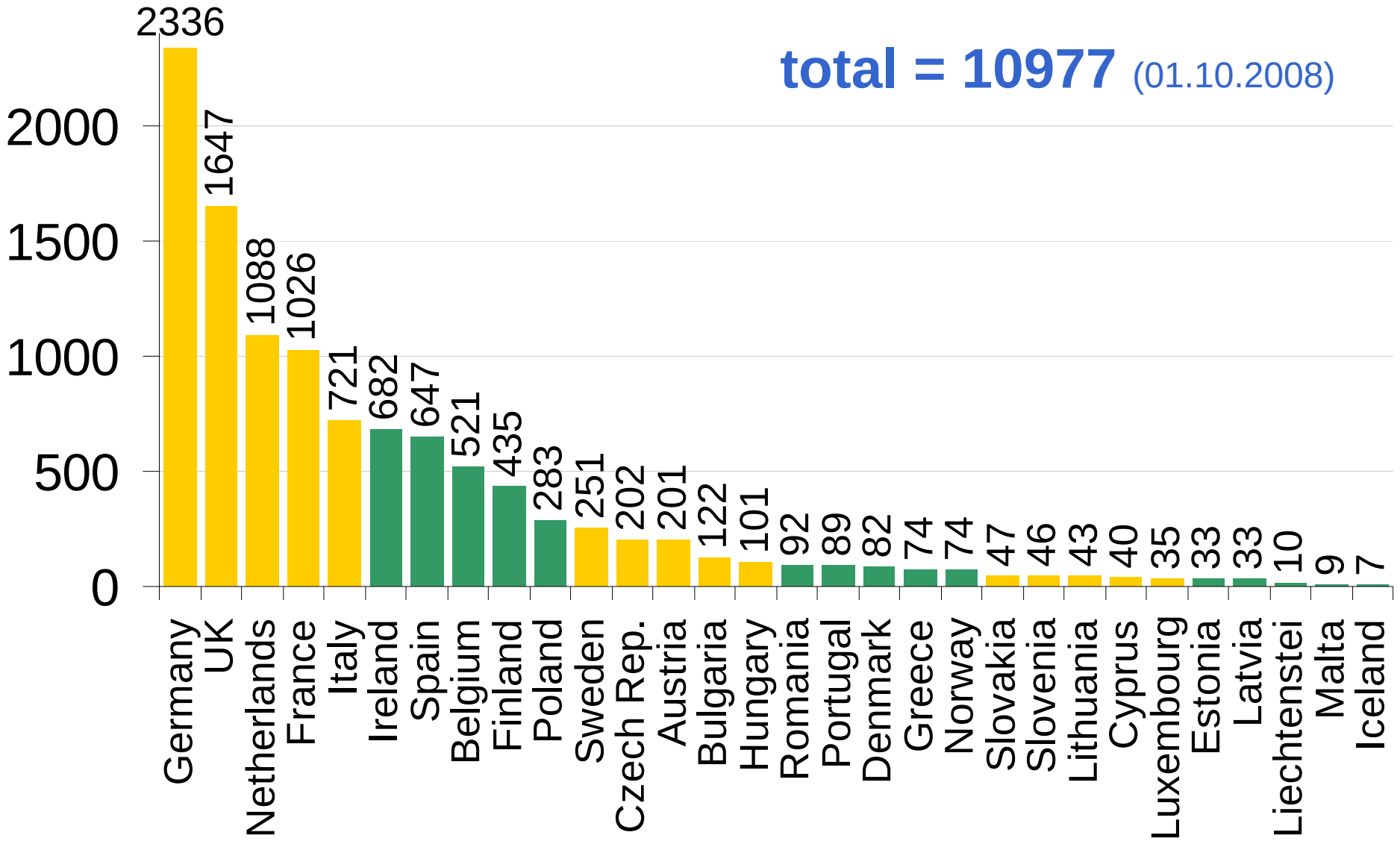
Pre-registration state-of-play

4 months into the pre-registration period:

- more than 10,000 Companies from all 27 MS + EEA
- number of sign-ups is increasing
  - 600 per week in August
  - 800 per week in September
- more than 400,000 pre-registrations received
  - More than 150,000 “valid” pre-registrations
  - 40,000 different substances pre-registered
- some companies have / want to pre-register the complete EC list

Legal entities signed up

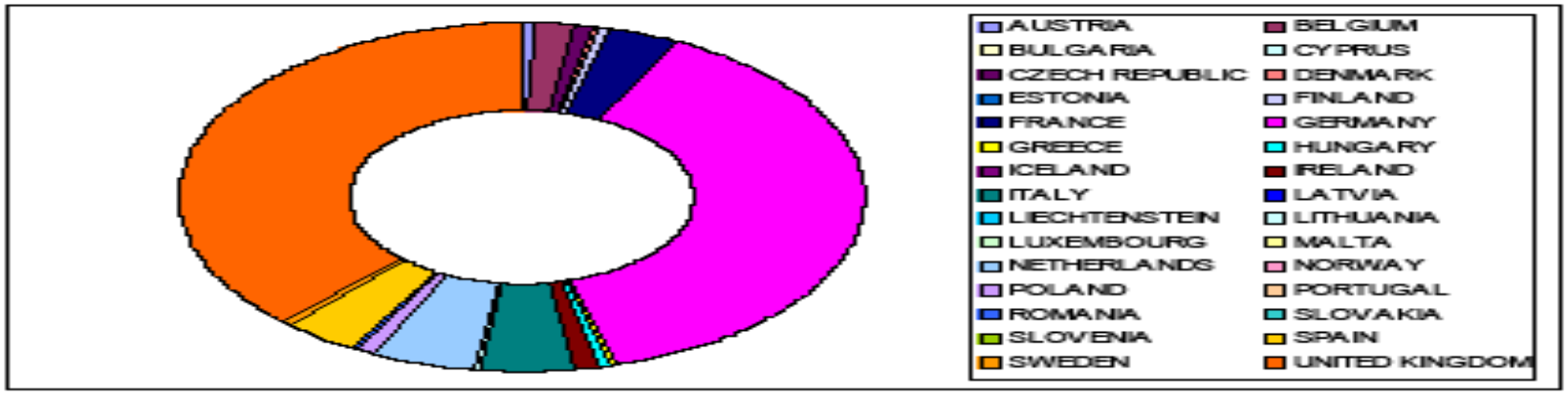
total = 10977 (01.10.2008)



2008-06-10

Pre-registrations

06/10/2008 03:45:30



AUSTRIA	2 447
BELGIUM	7 772
BULGARIA	773
CYPRUS	104
CZECH REPUBLIC	2 945
DENMARK	1 232
ESTONIA	249
FINLAND	1 840
FRANCE	14 894
GERMANY	163 595
GREECE	551
HUNGARY	2 522
ICELAND	28
IRELAND	4 363
ITALY	19 345
LATVIA	325
LIECHTENSTEIN	292
LITHUANIA	123
LUXEMBOURG	329
MALTA	14
NETHERLANDS	21 354
NORWAY	380
POLAND	2 894
PORTUGAL	763
ROMANIA	840
SLOVAKIA	451
SLOVENIA	250
SPAIN	14 860
SWEDEN	2 427
UNITED KINGDOM	160 864
TOTAL	**428 826**

Two companies registered the EINECS (>100.000)

Real pre-registrations, with intention to register: ~ 200.000

Pre-registration state-of-play

- Bulk pre-registration:
  - since 22 July 2008, now most used method
  - 10% failure after submission → format, structure and content must be compliant
  - limit of 10,000 that can be submitted per company without prior approval
- online pre-registration:
  - remains important with >7,000 pre-registrations per week

Pre-registration experiences

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

Pre-registration experiences

- 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 comments field)
  - use of non-English chemical names

Main recommendations

1. Know your substances

- Pre-register the phase-in substance you intend to register, and for certain types of substances, if in doubt that the substances will be registered by 01/12/2008
- Follow the Guidance on substance identification for naming your substances
- Respect the preferred order for substance identifiers to use:
  - 1. EC number
  - 2. CAS number and CAS name
  - 3. IUPAC name

Main recommendations

2. Pre-register in time

- Due to the 6 hours quarantine period, pre-registration numbers for bulk submissions can come up to 24-48 hours later

3. Fill in your company's and contact person's details correctly

- data sharing is an obligation
- ECHA and/or MSCA might want to contact you

Pre-registration reminders

- Pre-registration period: 1 June - **1 December 2008, 24:00 EU time**

- Article 26.8
  First-time (since 2008-06-01) manufacturer or importer can pre-register “late”, i.e. **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.

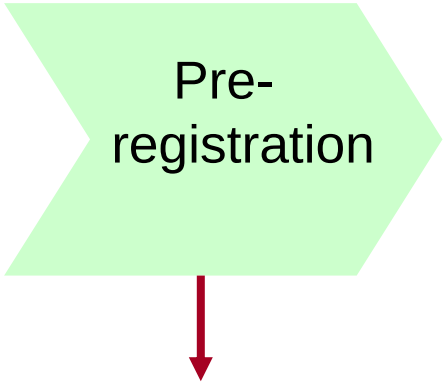
Pre-registration reminders

- Article 8
  Only Representatives (O.R.) can only be appointed by a person outside the Community who manufactures a substance, formulates a preparation or produces an article that is imported into the Community. (The documents showing this must be available.)
- Pre-registration number is linked to the legal entity which has pre-registered
  - it cannot be transferred/sold to another Legal Entity without a justification (merge/split/divest, etc…)

Pre-registration reminders

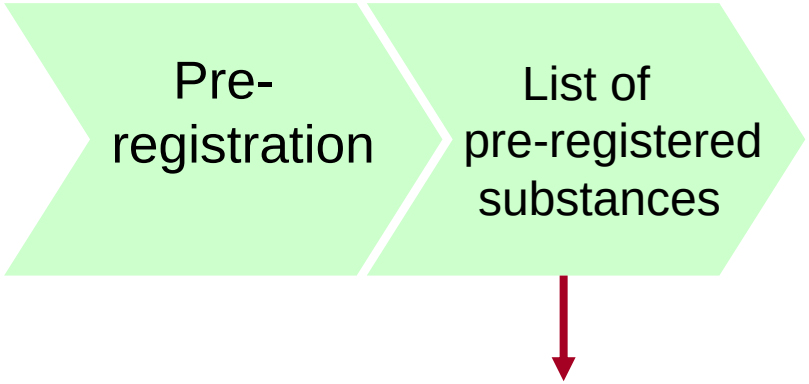
- A pre-registration can at any time be updated
  - All fields can be updated, except the substance identity
- If a potential registrant is no longer interested in a substance, he can "deactivate" his participation in the pre-SIEF, but he remains visible to the others

Next steps



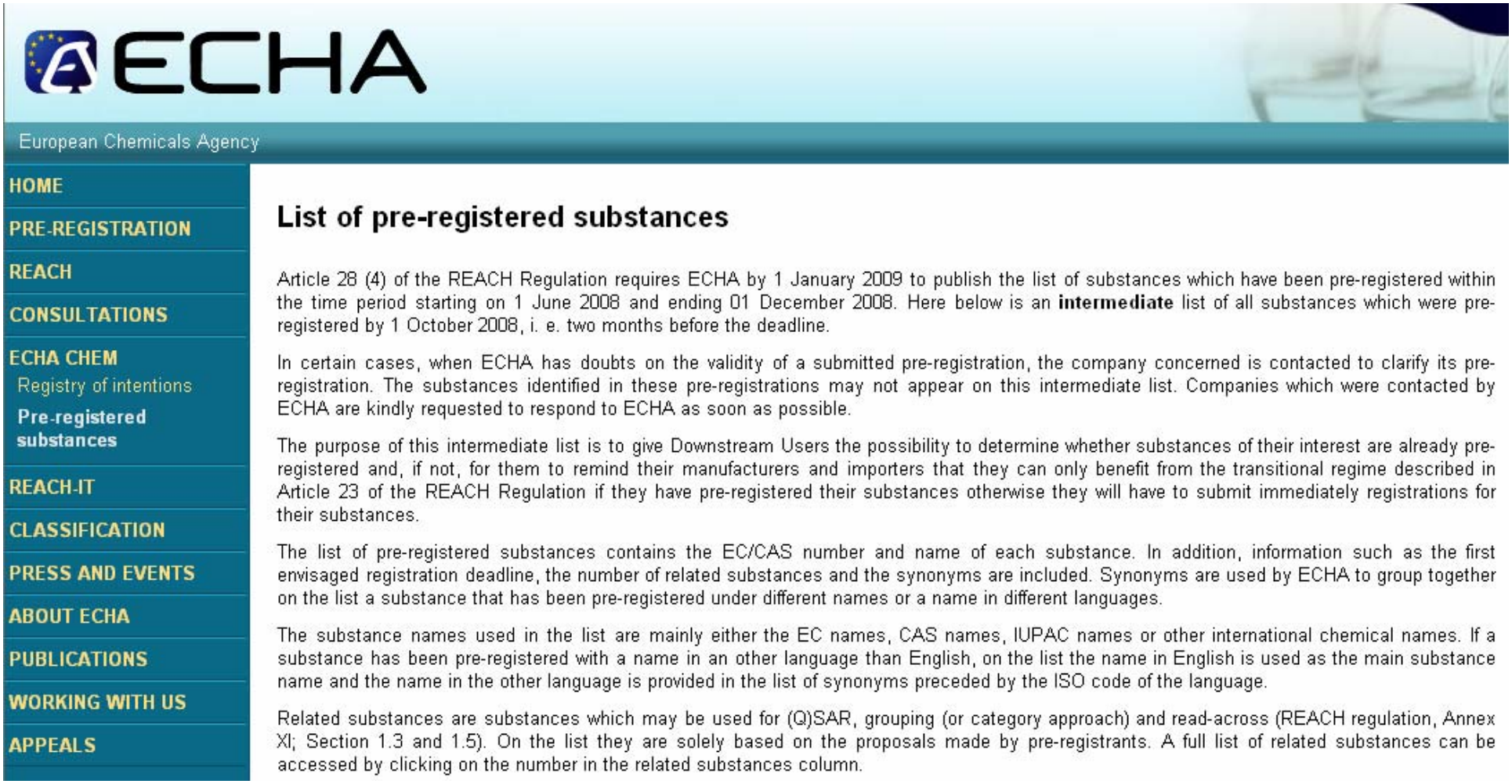
- Pre-registration is still open until 1 December 2008
- **Remind your EU-partners to pre-register**

Next steps



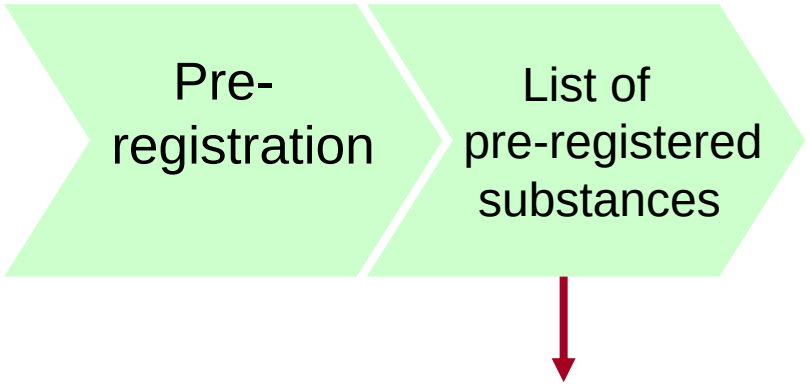
- ECHA has published the list of substances pre-registered by 1 October 2008 (intermediate list)

ECHA
European Chemicals Agency



http://echa.europa.eu

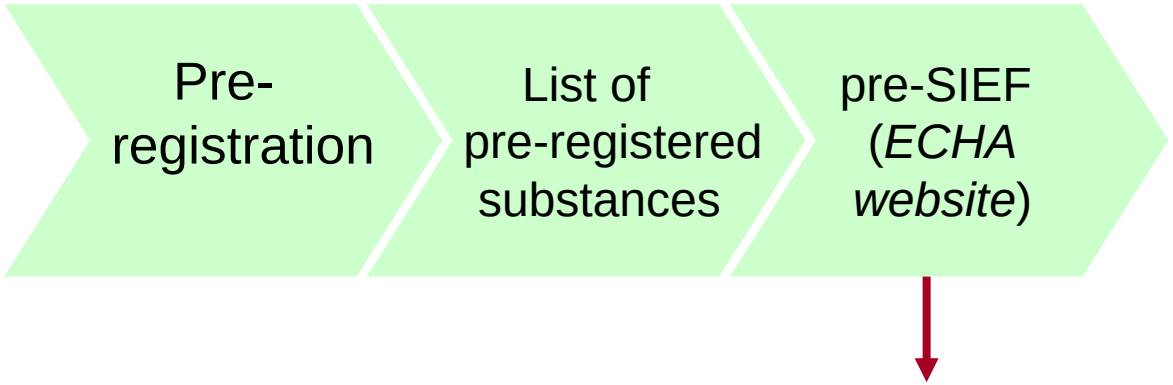
Next steps



- ECHA will publish the final list of pre-registered substances by 1 January 2009
- After 1 January 2009, DU can notify ECHA of their interest in a substance not on the list
- After 1 January 2009, data holders may indicate that they have data on pre-registered substances, using REACH-IT

Could be from Non-EU!

Next steps



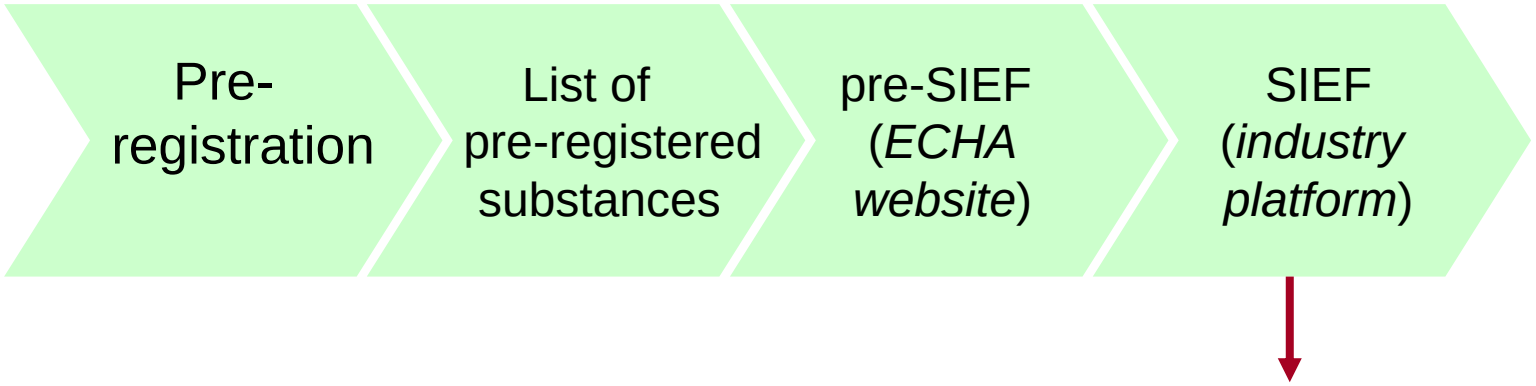
- REACH-IT brings submitters of the same identifier together in a “pre-SIEF” webpage
- Can see contact details of:
  - other pre-registrants
  - early registrants, substances regarded as registered
  - data holders after 1 January 2009

SIEF formation facilitator

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

- Only potential registrants can volunteer to become SIEF formation facilitator, on a first-come first-serve basis (also O.R.!)
- 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

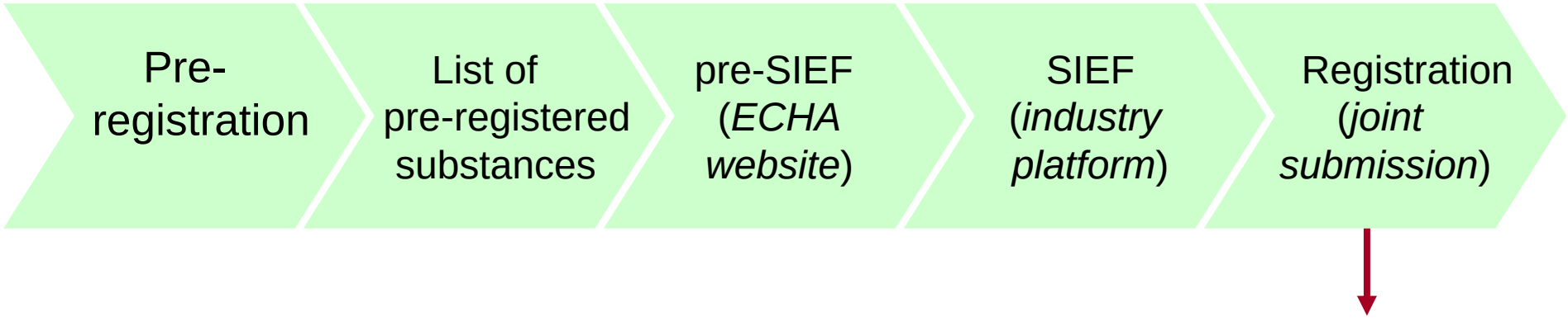


- Pre-registrants needs to agree on SIEF formation (same substance!) and share data and costs within the SIEF

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)
- No ECHA intervention on agreement on sameness of a substance, cost sharing for studies or consortium formation

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
  - 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

Questions

REACH

and

the European Chemicals Agency

Joachim KREYSA
Director for Cooperation

October 2008

Part I

The European Chemicals Agency:

general overview

ECHA - Overview

http://echa.europa.eu

Mission of ECHA

We work to ensure safe use of chemicals across the EU

Mission of ECHA

Make REACH reachable

- Manage and carry out technical, scientific and administrative aspects of REACH
- Ensure consistency at Community level
- Provide the best possible scientific/technical advice on questions relating to REACH
- Provide guidance and advice for stakeholders
  - Publish guidance & explanatory documents
  - Run a helpdesk on REACH, IUCLID, and REACH-IT
- Make information on chemicals accessible

Core values of ECHA

Efficient in operations, transparent in procedures!

- **Transparent** *(public docs & data, observer, …)*
- **Science-driven** *(in-house expertise, Committees)*
- **Independent**
- **Balanced** *(equal treatment of all interests)*
- **Trustworthy** *(data security, respect of BCI)*
- **Respecting deadlines** *(many are very short!)*
- **Helpful** *(timely delivered, clear & relevant advice)*

What is ECHA?

- **ECHA comprises (Art. 76)**
  - The **Management Board**
  - The **Committees:**
    - Risk Assessment **(RAC)** and Socio-economic Analysis Committees **(SEAC)**
    - The Member State Committee **(MSC)**
    - The **Forum** for Exchange of Info on Enforcement
  - The **Executive Director** heading the **Secretariat** (now ± 220)
  - The Board of Appeal (**BOA**, independent)

Status of ECHA

- ECHA **started** in Helsinki on **1 June 2007;**
- Staff has moved in over past 15 months;
  - 1 October 2008: around 220 staff
- **Helpdesks** operate since the start;
- A **multilingual website** becomes a single point of info;
- **REACH-IT** is the portal
  - to send registration dossiers, applications to ECHA
  - to securely communicate about dossiers/applications

ORGANISATION CHART OF ECHA – October 2008

ECHA
European Chemicals Agency

MANAGEMENT BOARD

EXECUTIVE DIRECTOR
Geert Dancet
Kirsi Larjava – ext. 8220

EXECUTIVE OFFICE
Head of Unit
Nadine Nassen – ext. 8201

SCIENTIFIC ADVICE : Derek Knight

INTERNAL AUDIT : Regis Durand

BOARD OF APPEAL
Registrar: Sari Haukka
Gabrielle Rieder – ext. 8226

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Nathalie Alt-Antskog – ext. 8205

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- **A2 - COMMITTEES & INTERNATIONAL RELATIONS** — Leena Ylä-Mononen
- **A3 - COMMUNICATION & REACH TRAINING** — Juhani Sormunen

B - ASSESSMENT
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Minna Juusela - ext 8411

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C – REGISTRATION & IT TOOLS
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- **C1 – SCIENTIFIC IT TOOLS** — Head of Unit
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Alice Lutunu Osako – ext. 8335

- **R1 – FINANCE** — Tuula Hakala
- **R2 - HUMAN RESOURCES & FACILITIES** — Alastair MacPhail
- **R3 - ICT** — Peter van den Hul

Directorate
Unit

Achievements so far

1. **ECHA helpdesks** – answered thousands of questions
2. **Helpdesk network** - harmonising advice, FAQs
3. **Guidance** is on ECHA's website **– a one stop shop**
4. **Committees & Forum** – operational, MSC – SVHC-list
5. **Recruiting** and **training** staff - at schedule
6. **Procedures (SOP)** for key processes - ready
7. **IT tools** (IUCLID, REACH-IT, NAVIGATOR) - available
8. **Stakeholder** partner organisations - identified
9. **National trainers – trained, continues**
10. **Chemical "*acquis*"** - taken over from the EC
11. **Pre-registration** - half way through

ECHA website - one stop shop

http://echa.europa.eu

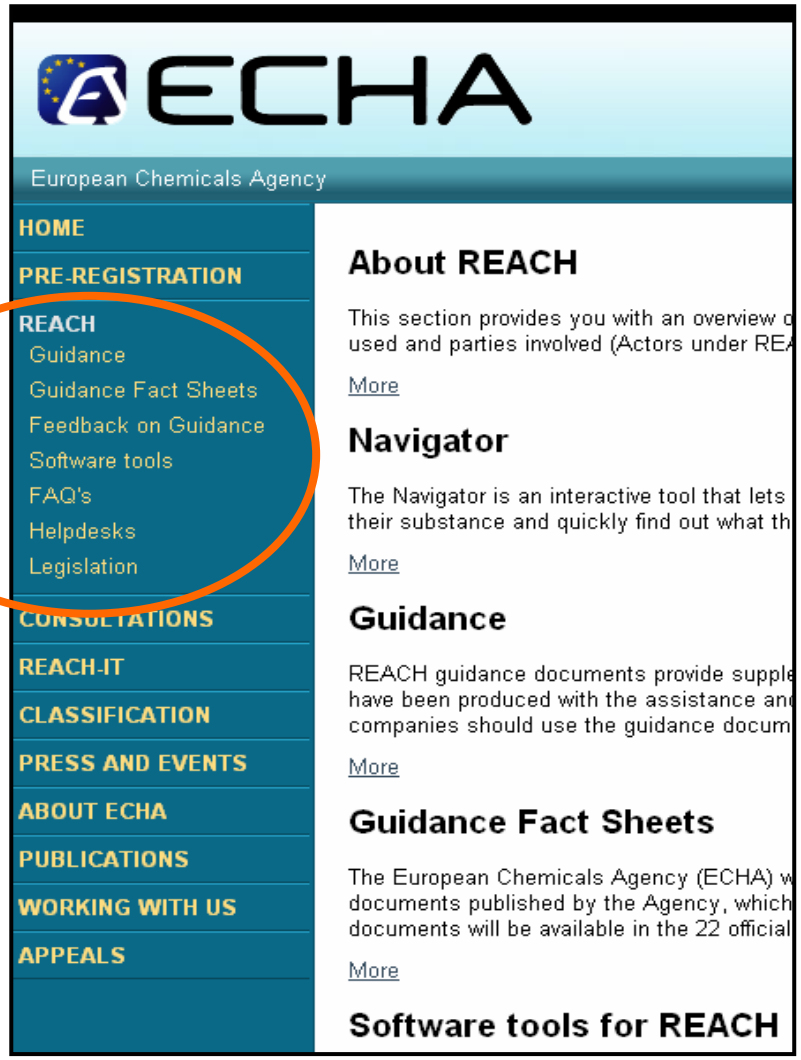
Follow the news on our home page

ECHA – web-content

- **Documents:** Guidance, Fact sheets, Leaflets, Brochures, … on REACH, GHS/CLP coming
- **Dedicated sections**, e.g. pre-registration
- **Tools:** Navigator, CSR-tool (near future), Guidance pathfinder, Guidance feedback form, Web Tutorials, Glossary, etc.
- **Spreading the news:** News Alert, Press Service
- **Requesting info via web forms:** REACH Advice, IUCLID, REACH IT, ECHA-info; ECHA-press

REACH information

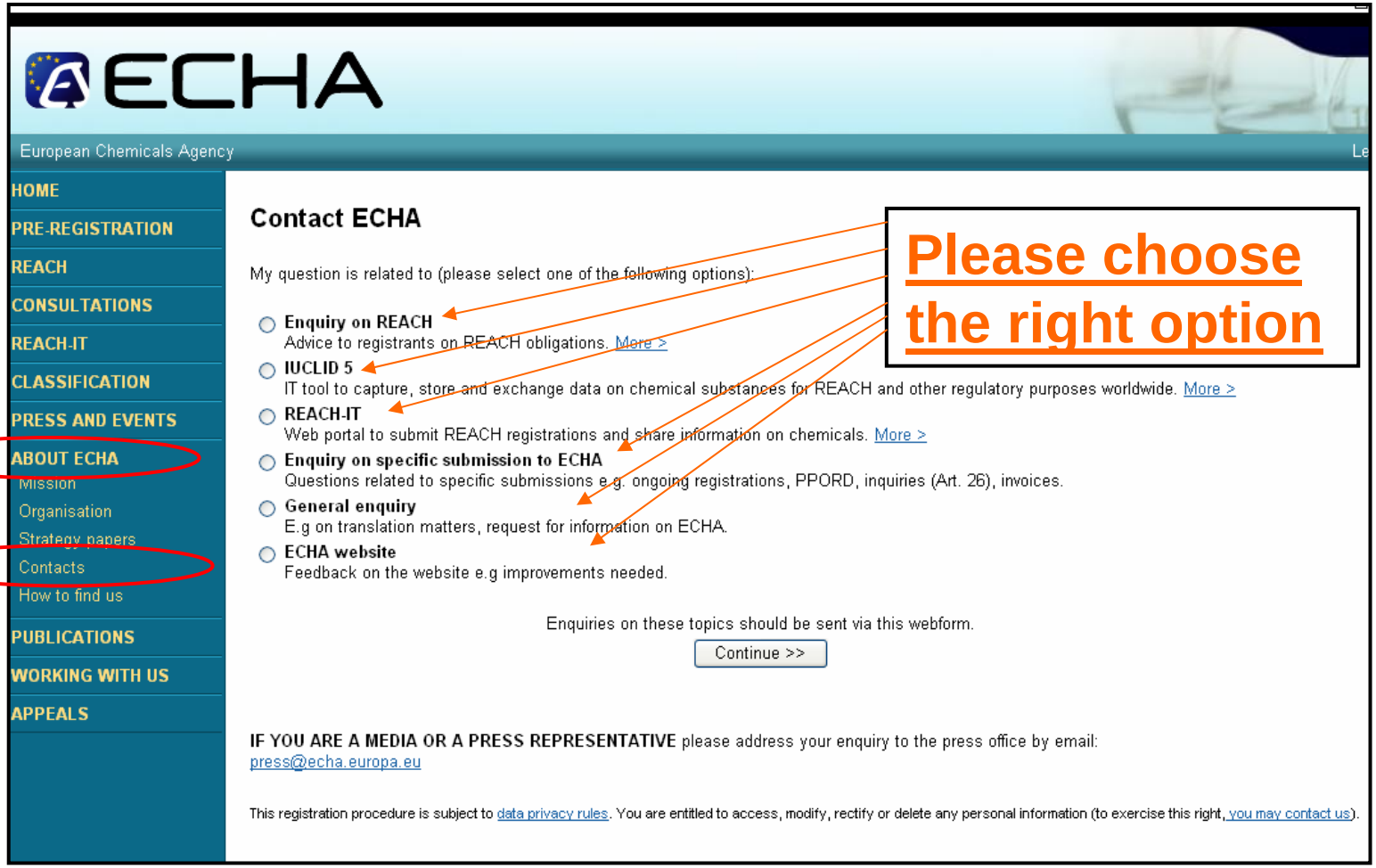
Different web pages/sections with useful information for better understanding of REACH



http://echa.europa.eu

ECHA contact

For additional information



Questions