

REACH

a brief overview for

Non - EU Companies

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

REACH



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:
 - **R**egistration by industry of manufactured/imported chemical substances > 1 tonne/year (staggered deadlines over 11 years)
 - Information and communication throughout the supply chain
 - **E**valuation of registered substances (Agency and Member States)
 - **A**uthorisation for uses of substances of very high concern
 - Restriction as “Safety net” (Community wide risk management action)
 - **C**hemicals 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

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

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

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 cumulated:
 - 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

<http://echa.europa.eu>

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)**

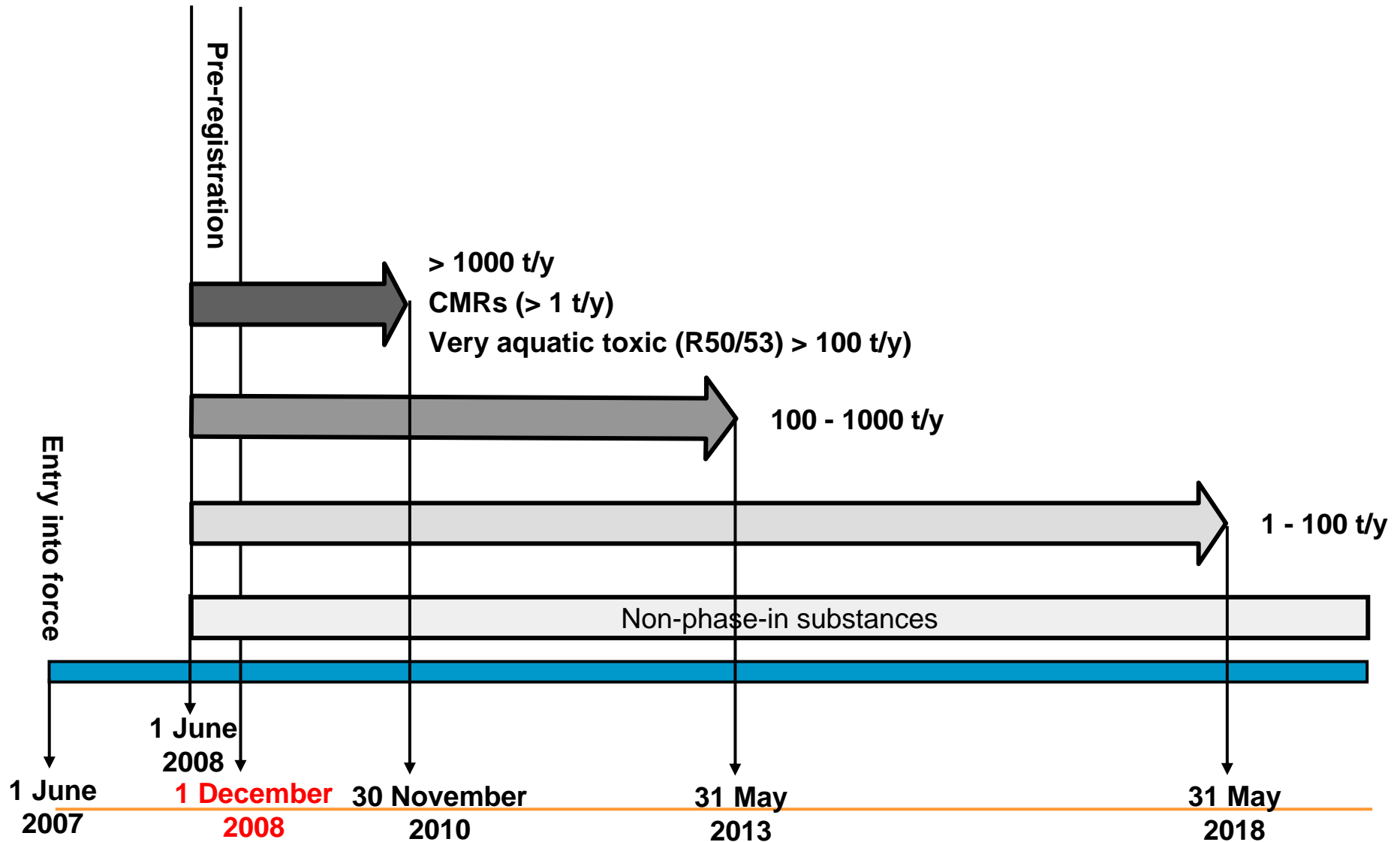
Registration – the concept /2



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 ...

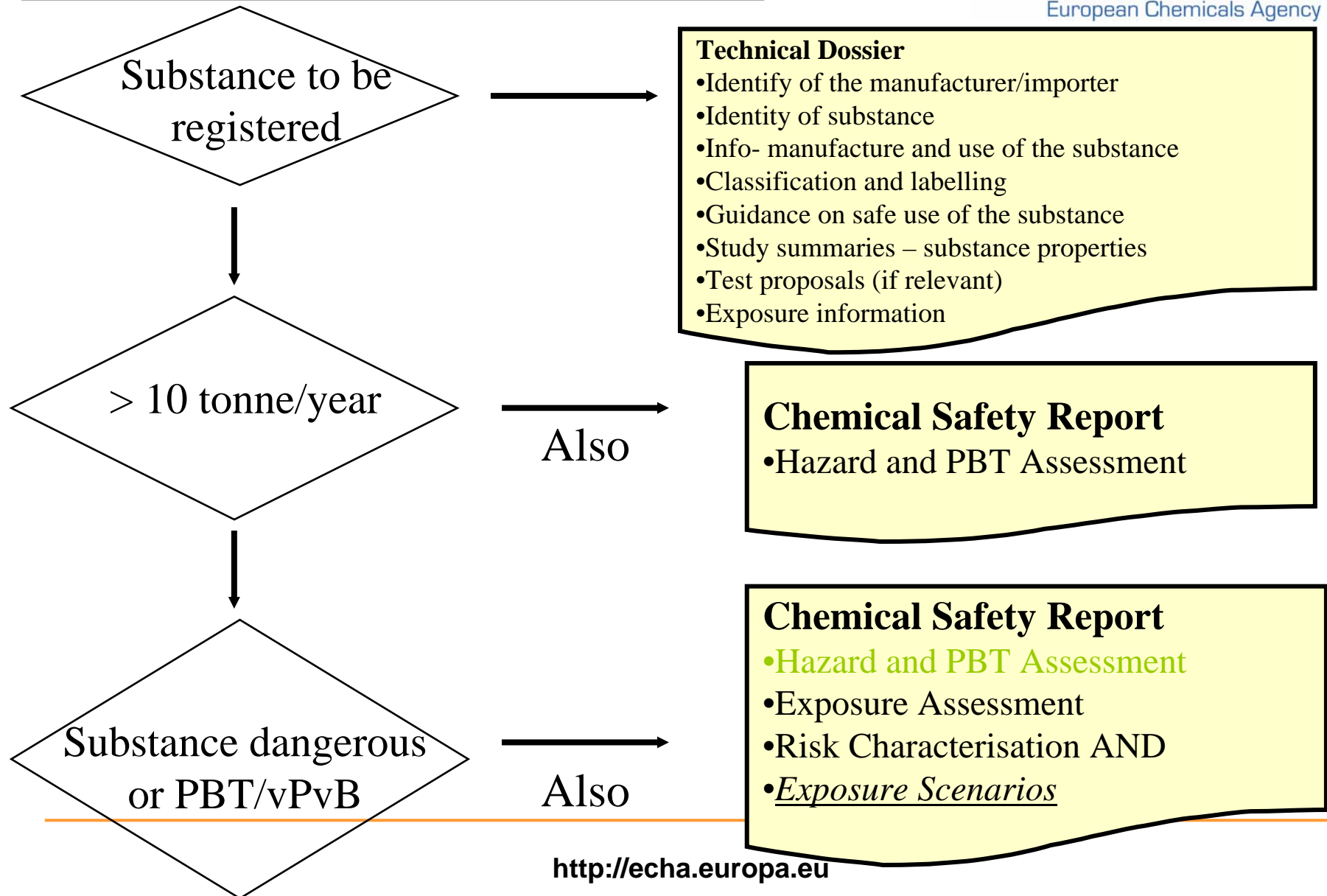
Annexes VII to X of REACH:

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

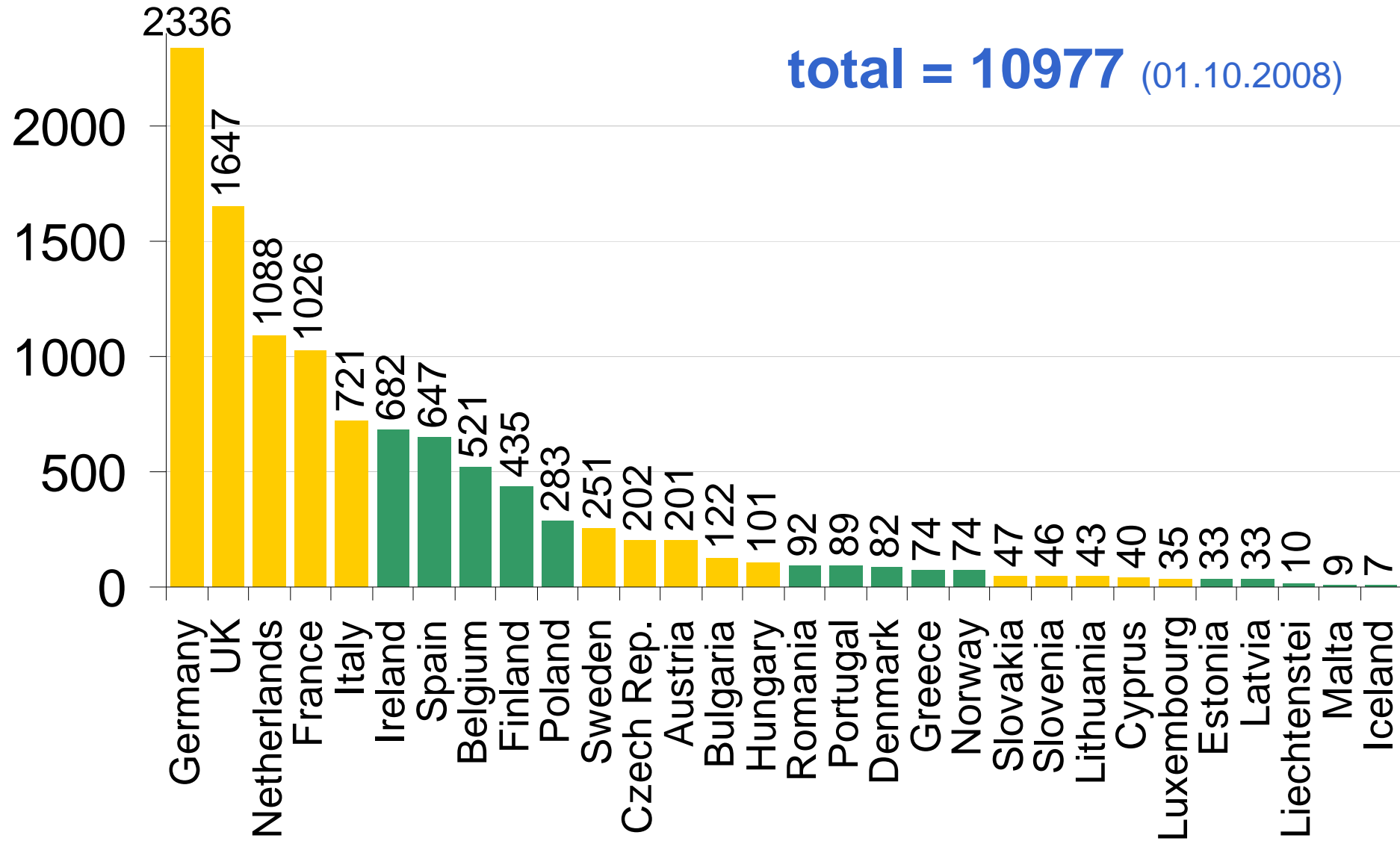
Pre-registration state-of-play



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

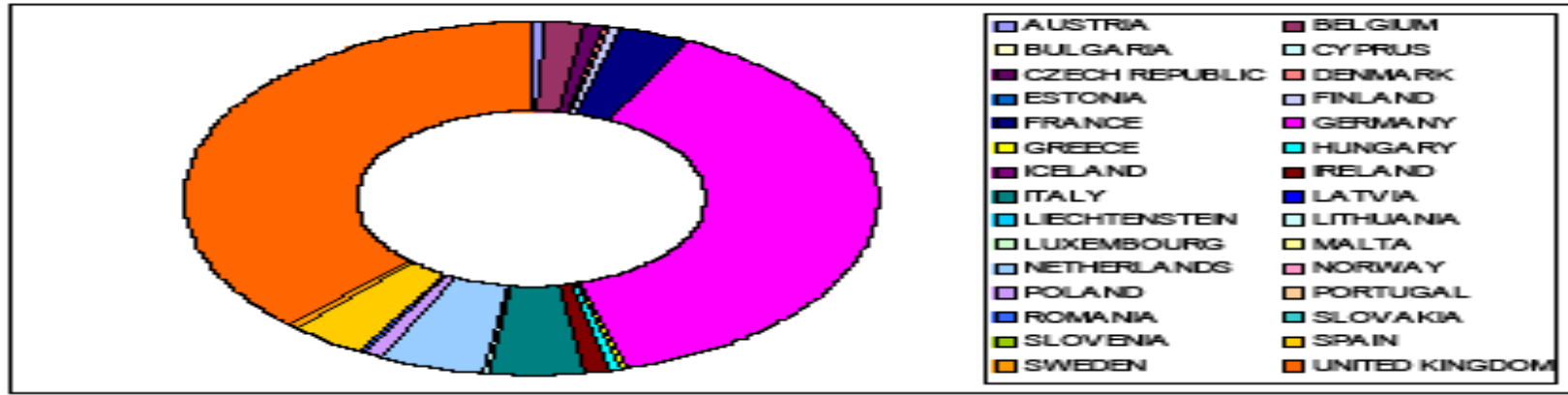
Legal entities signed up



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



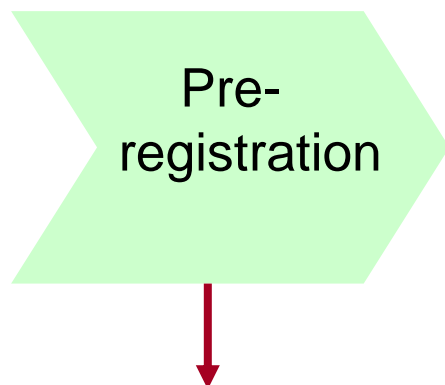
- Article 8
Only Representatives (O.R.) can only be appointed by a person outside the Community who **manufactures** a substance, **formulates** a preparation or **produces** an article that is imported into the Community. (The documents showing this must be available.)
- Pre-registration number is linked 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



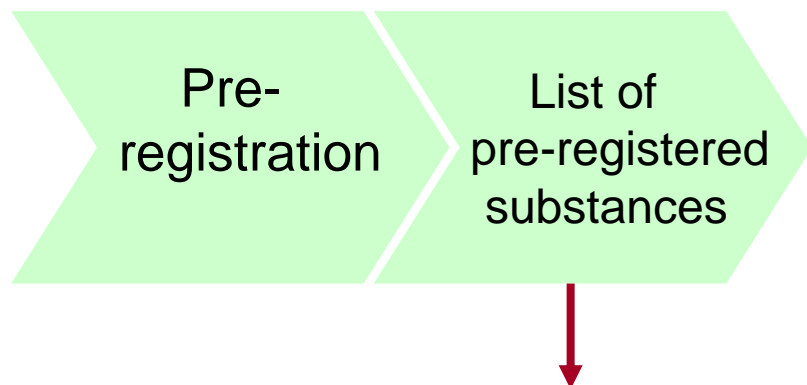
- A pre-registration can at any time be **updated**
 - All fields can be updated, except the substance identity
- If a potential registrant is no longer interested in a substance, he can “**deactivate**” his participation in the pre-SIEF, but he remains visible to the others

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**)

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List of pre-registered substances

Article 28 (4) of the REACH Regulation requires ECHA by 1 January 2009 to publish the list of substances which have been pre-registered within the time period starting on 1 June 2008 and ending 01 December 2008. Here below is an **intermediate** list of all substances which were pre-registered by 1 October 2008, i. e. two months before the deadline.

In certain cases, when ECHA has doubts on the validity of a submitted pre-registration, the company concerned is contacted to clarify its pre-registration. The substances identified in these pre-registrations may not appear on this intermediate list. Companies which were contacted by ECHA are kindly requested to respond to ECHA as soon as possible.

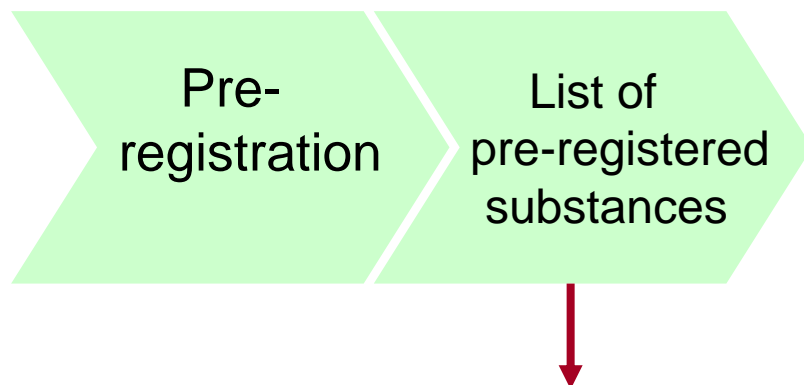
The purpose of this intermediate list is to give Downstream Users the possibility to determine whether substances of their interest are already pre-registered and, if not, for them to remind their manufacturers and importers that they can only benefit from the transitional regime described in Article 23 of the REACH Regulation if they have pre-registered their substances otherwise they will have to submit immediately registrations for their substances.

The list of pre-registered substances contains the EC/CAS number and name of each substance. In addition, information such as the first envisaged registration deadline, the number of related substances and the synonyms are included. Synonyms are used by ECHA to group together on the list a substance that has been pre-registered under different names or a name in different languages.

The substance names used in the list are mainly either the EC names, CAS names, IUPAC names or other international chemical names. If a substance has been pre-registered with a name in an other language than English, on the list the name in English is used as the main substance name and the name in the other language is provided in the list of synonyms preceded by the ISO code of the language.

Related substances are substances which may be used for (Q)SAR, grouping (or category approach) and read-across (REACH regulation, Annex XI; Section 1.3 and 1.5). On the list they are solely based on the proposals made by pre-registrants. A full list of related substances can be accessed by clicking on the number in the related substances column.

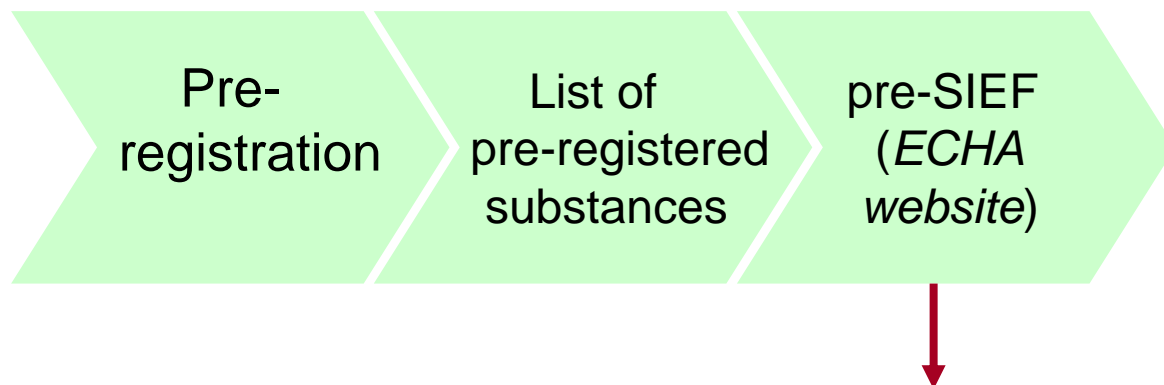
Next steps



- 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

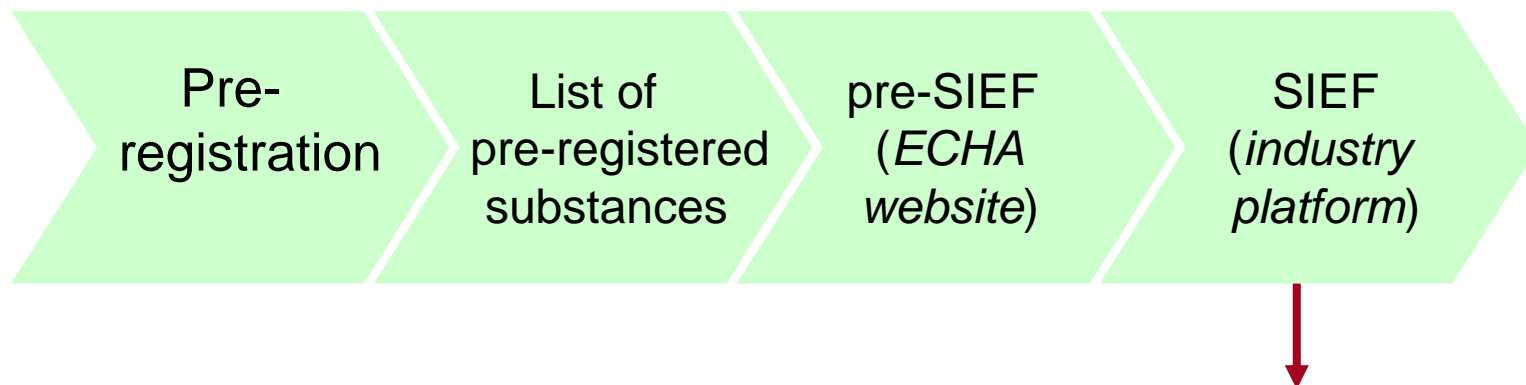
SIEF formation facilitator



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

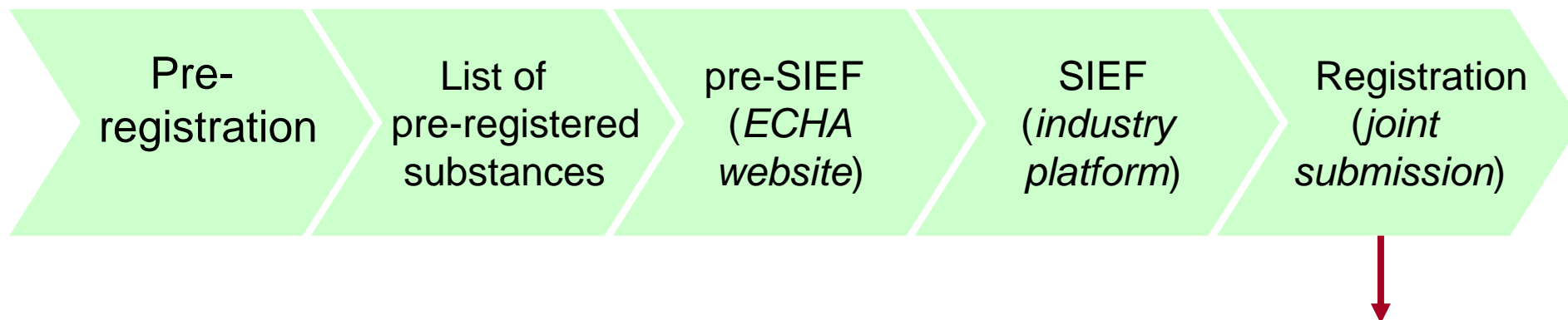


- Pre-registrants needs to agree on SIEF formation (same substance!) and share data and costs within the SIEF

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

<http://echa.europa.eu>

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**

<http://echa.europa.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?



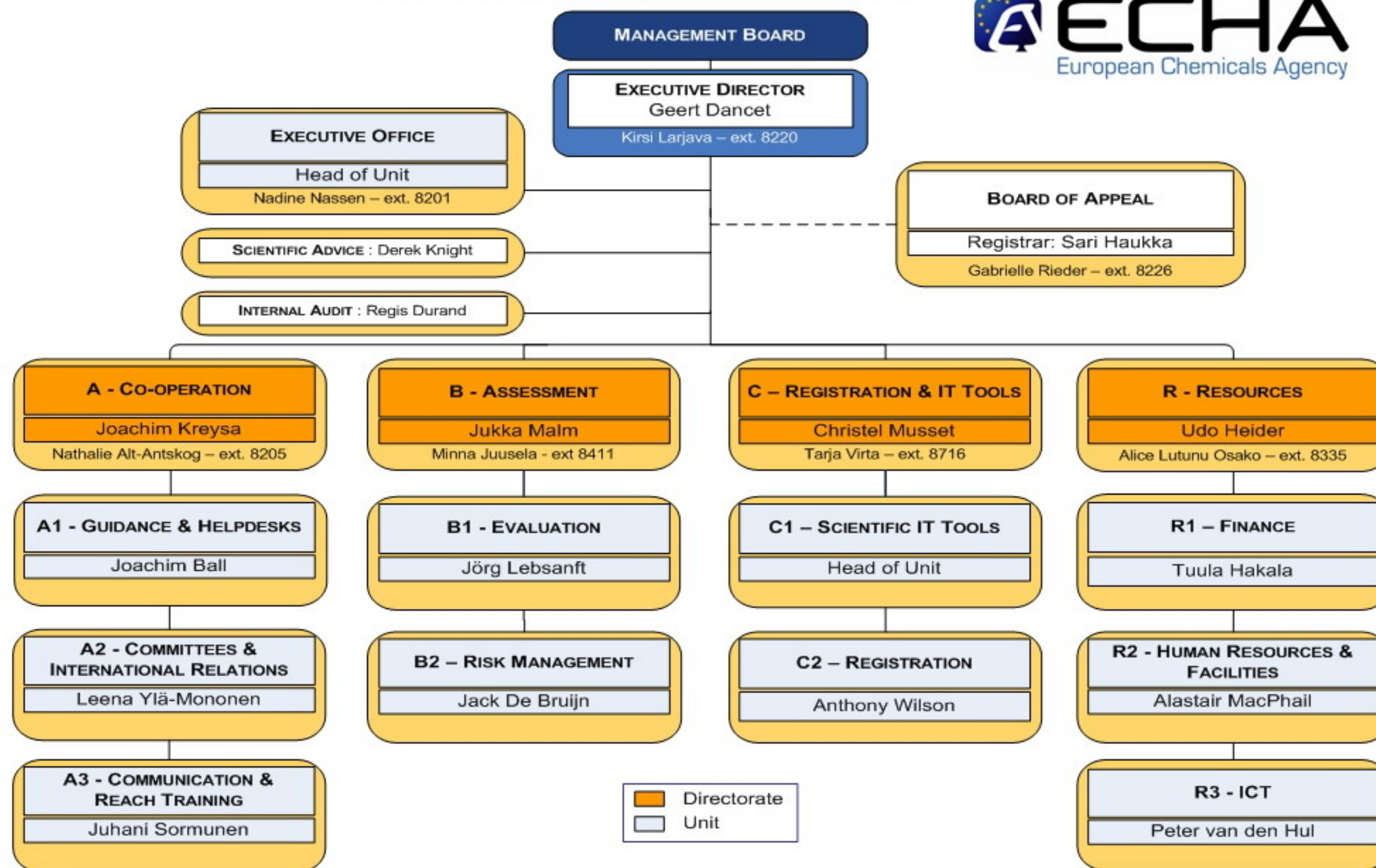
- **ECHA comprises (Art. 76)**
 - The **Management Board**
 - The **Committees:**
 - Risk Assessment (**RAC**) and Socio-economic Analysis Committees (**SEAC**)
 - The Member State Committee (**MSC**)
 - The **Forum** for Exchange of Info on Enforcement
 - The **Executive Director** heading the **Secretariat**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



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)



<http://echa.europa.eu>

The banner features the ECHA logo at the top right. Below it is a list of the agency's names in various European languages, each preceded by a small yellow square containing the language code. The background of the banner includes images of a hand holding a test tube, a grid of data points, and laboratory glassware.

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-Agenzja Ewropea tal-Kimika
NL Europees Chemicalagentschap
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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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



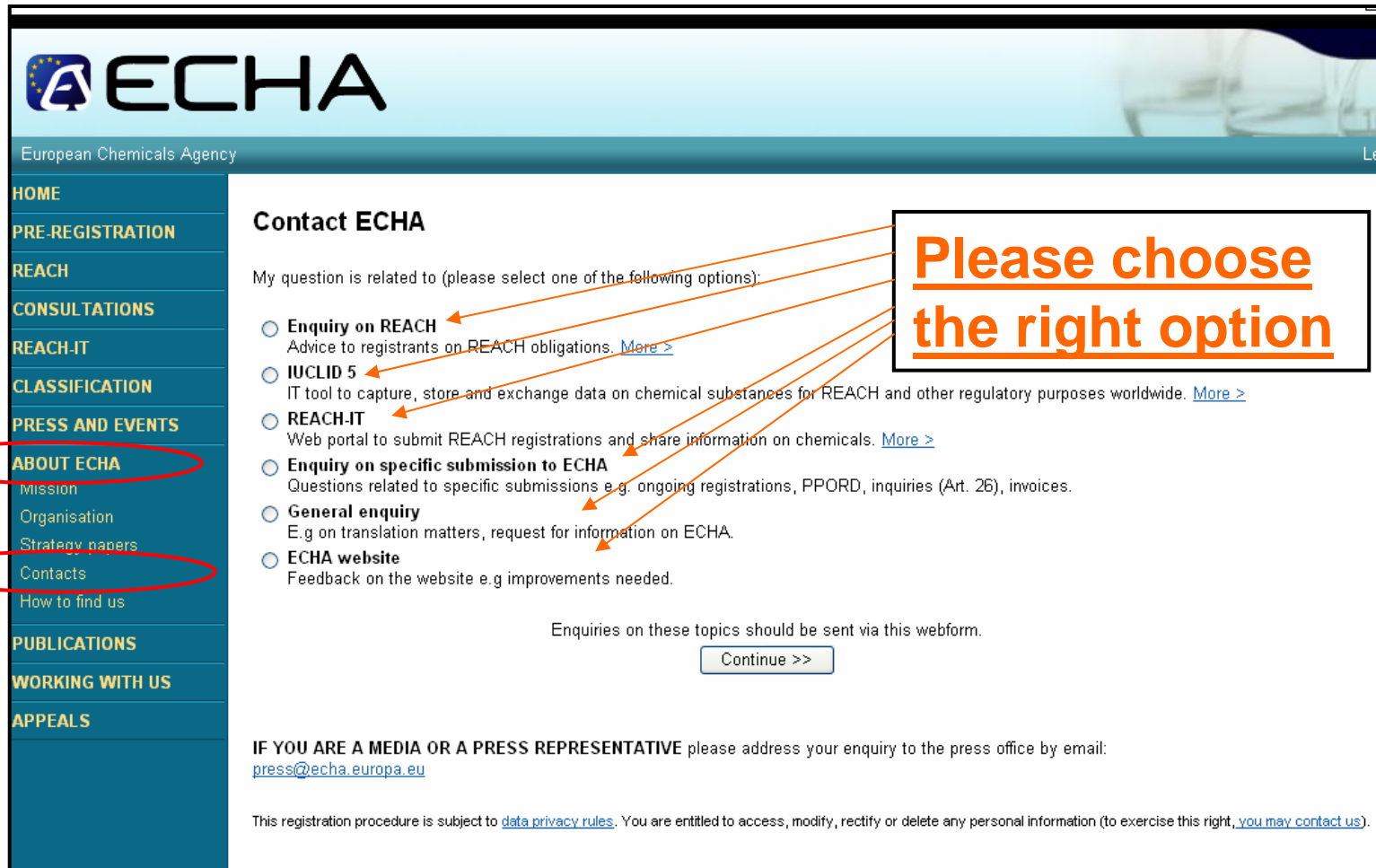
Different web pages/sections with useful information for better understanding of REACH

The screenshot shows the ECHA website interface. The top navigation bar includes the ECHA logo and the text 'European Chemicals Agency'. Below this is a vertical menu with the following items: HOME, PRE-REGISTRATION, REACH (highlighted with an orange circle), CONSULTATIONS, REACH-IT, CLASSIFICATION, PRESS AND EVENTS, ABOUT ECHA, PUBLICATIONS, WORKING WITH US, and APPEALS. The 'REACH' section is expanded, showing a list of sub-items: Guidance, Guidance Fact Sheets, Feedback on Guidance, Software tools, FAQ's, Helpdesks, and Legislation. The main content area on the right contains sections for 'About REACH', 'Navigator', 'Guidance', 'Guidance Fact Sheets', and 'Software tools for REACH'. Each section includes a brief description and a 'More' link.

<http://echa.europa.eu>

ECHA contact

For additional information



ECHA
European Chemicals Agency

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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.

Enquiries on these topics should be sent via this webform.

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Questions

